The EORTC 1962–2012:
Celebrating 50 years of Research and Treatment of Cancer in Europe
The EORTC: Developing practice-changing academic research for personalized patient care in oncology

Through the dedication and vision of all EORTC members, the EORTC has consolidated its position at the forefront of academic clinical and translational research in Europe and Worldwide.

We still need to further develop the EORTC within the rapidly changing landscape of oncology characterized by a better understanding of the biology of tumors, the development of molecular diagnostics, evolving paradigms for drug development and collaborations with pharmaceutical industry, the growing need to develop links with other clinical research networks in other continents, and the challenges of medical demography.

In 2011, the cancer patient should be more than ever at the center of the networks of care and research. To establish future state of the art treatments, we not only need to be a top level global academic clinical research organization, but we also need to further reinforce innovative and efficient collaboration processes with pharmaceutical industry partners.

Building upon past initiatives, the EORTC Network now benefits from a very efficient Headquarters organizational structure which has enabled the implementation of innovative approaches that strengthen its research partnerships.

Developing the new generation of academic clinical trials and partnerships with pharmaceutical industry for establishing new standards of care

Molecular characterization of the tumor will drive future clinical trials, and the EORTC will further reinforce its strategy, be engaged in innovative research programs, and conduct pivotal multidisciplinary large-scale clinical trials to address relevant medical scientific questions with a strong translational research component.

An EORTC tumor bio-bank facility for the storage and management of sample bio-specimens linked to an electronic patient treatment outcome database has been established.

The Network of Core Institutions, NOCI, represents an extraordinary potential and guarantees the future of independent academic clinico-genomic cancer research in Europe. NOCI, dedicated to high quality innovative translational research and multi-tumor type trials, is already providing an innovative translational and clinical platform enabling efficient collaboration with partners in the pharmaceutical industry.
The EORTC Network as a platform for European and worldwide intergroup collaborations

The increasing complexity of innovative clinical trials will require the EORTC to liaise with other partner academic research networks. Frequent tumor types are becoming increasingly fragmented in more homogenous molecular subcategories and now pose challenges previously encountered only in “rare” tumor types. For large clinical trials in the frequent tumor types, as well as for small focused clinical trials in well characterized models, we will need international collaborations beyond the EORTC Network. This has already been initiated in established collaborations with national and international research groups. Further expanding these collaborations will be important.

Promoting young researchers and innovative research programs with all partners

Most countries in Europe are facing a medical demography problem as they are experiencing a shortage of doctors in key specialties, e.g. pathology, medical oncology, surgical oncology, and radiation oncology. Research in oncology has been demonstrated to be an extremely attractive field of research in the last 10 years, and the EORTC is an international leader in academic clinical and translational cancer research. The EORTC is therefore in a very good position to enable young committed researchers to develop their careers in oncology. The scientific strategy, and dedicated initiatives by large partner institutions, should inspire young scientists and clinicians to become the next generation of active EORTC members.

European and national governments, healthcare policymakers, and cancer funding organizations will also need to be further associated with the EORTC research strategy in order to delineate the oncology research and care of the future. The role of patient advocacy groups is becoming more and more important, and they, too, should be associated further into our research activities.

Finally, as the EORTC will be celebrating its 50th anniversary in 2012, I appreciate more than ever the major importance and responsibility that the EORTC has for the development of clinical and translational research. I would like to express my sincere gratitude to Françoise Meunier and Denis Lacombe as well as the EORTC Headquarters staff, the EORTC Executive Committee, the Board, the General Assembly, and all the EORTC investigators and scientists for their support, commitment, and belief in the EORTC mission.

This is our mission for cancer patients.

Jean-Yves Blay
EORTC President
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Administrative Editor: Ms Suzanne Peedell (ejcancer@elsevier.com)
1. Structure and Organization

The EORTC Headquarters (located in Brussels) deals with all scientific, legal, and administrative issues related to the EORTC.

Arrangements have been made for the NCI Liaison Office to be located adjacent to the EORTC Headquarters. Moreover, the European CanCer Organisation (ECCO) formerly the “Federation of European Cancer Societies” (FECS), the European Society for Therapeutic Radiology and Oncology (ESTRO) the European Oncology Nursing Society (EONS) la Société Internationale d’Oncologie Pédriatique Europe (SIOP Europe), and the European Society of Surgical Oncology (ESSO) are also located in the same building as the EORTC.
The aims of the European Organisation for Research and Treatment of Cancer (EORTC) are to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patient quality of life. Extensive and comprehensive research in this wide field is often beyond the means of individual European hospitals and can be best accomplished through the multidisciplinary multinational efforts of basic scientists and clinicians.

The ultimate goal of the EORTC is to improve the standard of cancer treatment through the testing of more effective therapeutic strategies based on drugs, surgery and/or radiotherapy that are already in use and also through the development of new drugs and other innovative approaches. This is accomplished mainly by conducting large, multicenter, prospective, randomized, phase III clinical trials. In this way, the EORTC facilitates the passage of experimental discoveries into state of the art treatments.

Through translational and clinical research, the EORTC offers an integrated approach to drug development, drug evaluation programs and medical practices.

EORTC Headquarters, a unique pan European clinical research infrastructure, is based in Brussels, Belgium, from where its various activities are coordinated and run. The EORTC is both multinational and multidisciplinary, and the EORTC Network comprises over 300 hospitals and cancer centers in over 30 countries which include some 2,500 collaborators from all disciplines involved in cancer treatment and research.

The 180 members of the EORTC Headquarters staff handle some 6,500 new patients enrolled each year in cancer clinical trials, approximately 30 protocols that are permanently open to patient entry, over 50,000 patients who are in follow-up, and a database of more than 180,000 patients.

Intergroup collaboration is also promoted to face current challenges of clinical trials aiming at targeted therapies.

**History**

The EORTC was founded as an international organization under Belgian law in 1962 by eminent oncologists working in the main cancer research institutes of the EU countries and Switzerland. It was named the Groupe Européen de Chimiothérapie Anticancéreuse (GECA) and became the EORTC in 1968.
EORTC Presidents

Georges Mathé
Vilaplana, France
(1962-1965)

Silvio Garattini
Milan, Italy
(1965-1968)

Dirk Willem Van Bekkum
Rijswijk, The Netherlands
(1969-1975)

Henri Tagnon
Brussels, Belgium
(1975-1978)

Lazlo George Latja
Manchester, UK
(1979-1981)

Carl Gottfried Schmidt
Essen, Germany
(1981-1986)

Umberto Veronesi
Milan, Italy
(1985-1988)

Louis Deva
Antwerp, Belgium

Emmanuel van der Schueren
Leuven, Belgium,

Gordon McVie
London, UK
(1994-1997)

Jean-Claude Horiot
Dijon, France
(1997-2000)

Allan T. van Oosterom
Leuven, Belgium

Alexander M.M. Eggermont
Rotterdam, NL
(2003-2006)

Martine Piccart
Brussels, Belgium
(2006-2009)

Jean-Yves Blay
Lyon, France
(2009 – 2012)
EORTC Structure

The EORTC is comprised of the General Assembly, the Board, several committees, a network of scientists and clinical investigators, and the Headquarters staff.

The General Assembly is the legislative body of the EORTC. Policies, proposals, and strategies are discussed and approved by the General Assembly. The General Assembly delegates specific functions to the Board, Committees, or appointed persons.

The EORTC Network is organized into groups of scientists and/or clinicians, each with a specific area of interest in cancer research. These groups conduct translational research and/or clinical trials on all types of cancers using a multidisciplinary approach. The effective voting members of the General assembly are the President, the past three Presidents, each Group Chair, the Task Force Chairs, each of the Committee Chairs, and a representative from each of the top 15 accruing institutions. The General Assembly meets at least once a year and elects a new EORTC Board once every three years.

The Board is the steering and executive body which advises the General Assembly on new activities and formulates proposals to be ratified by the General Assembly. The Board meets at least twice a year. The Board consists of 21 elected (voting) members and several ex officio members. The Board members select among themselves the President, Vice-President, Treasurer, and Secretary General.

The Executive Committee provides support to the President in the decision making and strategy planning process. The Executive Committee consists of several voting members of the Board plus the Director General and the Director who are ex officio (non-voting) members of the Executive Committee. The Executive Committee meets as often as needed (once every six weeks on average), and communicates via phone and e-mail on a weekly basis. The Executive Committee reports to the Board.

The Director General coordinates all administrative, legal and financial management activities of the organization; and implements the strategies and policies as defined by the Board. Additional responsibilities include EU projects coordination, information dissemination and logistic support for EORTC courses and conferences.

The Director is appointed by the Board and is in charge of daily management and scientific activities of EORTC Headquarters.
Structure of the EORTC

EORTC General Assembly

EORTC Board

Executive Committee - Director General

Control Mechanisms

MC ↔ IRB ↔ SAC ↔ QAC

Action Mechanisms

EORTC Headquarters

PRC

NDAC ↔ TRAC ↔ IDMC

EORTC Groups, Network of Scientists & Clinical Investigators

Laboratory Research Groups

Translation Research

Clinical Research Groups

EORTC Committees

MC: Membership Committee
IRB: EORTC Headquarters Institutional Review Board
SAC: Scientific Advisory Committee
QAC: Quality Assurance Committee
PRC: Protocol Review Committee
NDAC: New Drug Advisory Committee
TRAC: Translational Research Advisory Committee
IDMC: Independent Data Monitoring Committee
The EORTC Network

All EORTC scientific activities are conducted within multidisciplinary groups divided into the Translational Research and Clinical Research Divisions. Emphasis is placed on translational research and cooperation between EORTC Groups and Task Forces.

This forms the basis of a network of oncology specialists including clinical experienced investigators and study coordinators as well as experienced translational research and laboratory scientists.

More recently a Network of Core Institutions (NOCI) has been created with access to:
• high patient accrual;
• rare cancer subpopulations;
• multi-tumor studies.

EORTC research offers an integrated approach to the evaluation of innovative agents, a comprehensive broad clinical trial program, multimodality therapeutic strategic evaluation, and research projects including the study of quality of life and patient reported outcomes.

In cooperation with the clinical groups, the EORTC Translational Research Division, which includes the Pharmacology and Molecular Mechanisms, Pathobiology, and Imaging Groups, focuses on pre-clinical testing of new anticancer agents, receptors, and tumor markers. It also provides support for translational research projects conducted within the EORTC on pharmacology and molecular mechanisms, pathology, and imaging.

The EORTC Clinical Research Division is mainly involved in the conduct of clinical trials through either tumor-specific groups (Brain Tumor, Breast Cancer, Melanoma, Leukemia, etc.) or modality-oriented cooperative groups such as the Radiation Oncology Group.

Groups are created and dissolved by decision of the EORTC Board. The EORTC Board may set up task forces which may possibly be converted into groups after a probationary period and SAC review.

Individuals interested in forming a Group should contact EORTC Headquarters to obtain guidance as to where they would best fit into the EORTC structure.
EORTC Membership

Effective Membership

All members of the General Assembly are effective members of the EORTC. In addition, members of the EORTC Groups and EORTC Committees are associate members of the organization.

Associate Membership

Investigators who recruit patients into EORTC clinical trials and contribute to laboratory research conducted for these clinical studies or to other EORTC activities approved by the Board are admitted as associate members. They must be natural persons.

Applications of candidate associate members are submitted for assessment by the Membership Committee. They may be submitted by the candidate directly or by a Group Chair. The Membership Committee delivers its recommendation to the Board. A Group Chair may appeal to the General Assembly against the refusal of an application he or she had submitted.

Associate membership is granted for an initial probationary period ending immediately prior to the date of the third ordinary General Assembly held after the admission of the associate member. Associate membership can then be renewed for successive periods of three years. The Board decides on the renewals at its last meeting before each ordinary General Assembly. A Group Chair may appeal to the General Assembly against the refusal to renew the associate membership of a member of his or her group.

The Board may withdraw the associate membership from members who no longer meet the admissibility criteria applied by the Board (a minimum of 15 patients recruited over the last three years across all EORTC Groups).

In some circumstances, other types of membership may be considered for scientists who bring a substantial contribution to the activities of a group without recruiting patients into clinical trials (basic scientists, pathologists, and radiologists, etc.). Foreign membership may be considered for “temporary” affiliation of an institution with an EORTC Group in the context of a specific clinical trial provided that EORTC rules allowing foreign membership have been followed.

For any further information regarding membership, please contact the EORTC Membership Committee at the following address:
Avenue Mounier 83/11, B-1200 Brussels
E-mail: membership@eortc.be
Additional information is also available in the ‘Membership Committee’ section.
# EORTC Board 2009 - 2012: Members

## Full Members (Voting)

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>President</td>
<td>J.-Y. Blay</td>
<td>Lyon (FR)</td>
</tr>
<tr>
<td>Past President</td>
<td>M. Piccart</td>
<td>Brussels (BE)</td>
</tr>
<tr>
<td>Vice-President</td>
<td>R. Stupp</td>
<td>Lausanne (CH)</td>
</tr>
<tr>
<td>Secretary General</td>
<td>E. Rutgers</td>
<td>Amsterdam (NL)</td>
</tr>
<tr>
<td>Treasurer</td>
<td>J. Jassem</td>
<td>Gdansk (PL)</td>
</tr>
</tbody>
</table>

### Chairs:

- Clinical Research Division (CRD): P. Schöffski, Leuven (BE)
- Translational Research Division (TRD): N. Harbeck, Cologne (DE)
- Independent Data Monitoring Committee (IDMC): R. Kaplan, Leeds (UK)
- Membership Committee (MC): A.M.M. Eggermont, Villejuif (FR)
- New Drug Advisory Committee (NDAC): J.-C. Soria, Villejuif (FR)
- Protocol Review Committee (PRC): F. Shepherd, Toronto (CA)
- Quality Assurance Committee (QAC): K. Haustermans, Leuven (BE)
- Scientific Audit Committee (SAC): I. Tannock, Toronto (CA)
- Translational Research Advisory Committee (TRAC): S. Sleijfer, Rotterdam (NL)

### Member:

- D. Fennell, Belfast (UK)
- H. Gelderblom, Leiden (NL)
- L. Licitra, Milano (IT)
- C. Sternberg, Roma (IT)
- F. Sweep, Nijmegen (NL)
- E. Van Cutsem, Leuven (BE)
- C. van Herpen, Nijmegen (NL)

## Ex Officio Members (Non Voting)

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director General, EORTC</td>
<td>F. Meunier</td>
<td>Brussels (BE)</td>
</tr>
<tr>
<td>Director, EORTC</td>
<td>D. Lacombe</td>
<td>Brussels (BE)</td>
</tr>
<tr>
<td>Chair, EORTC Charitable Trust</td>
<td>Sir Christopher Mallaby, London (UK)</td>
<td></td>
</tr>
<tr>
<td>Editor-in-Chief, European Journal of Cancer</td>
<td>A.M.M. Eggermont</td>
<td>Villejuif (FR)</td>
</tr>
<tr>
<td>European Journal of Cancer Liaison Officer</td>
<td>J.-C. Horiot</td>
<td>Genolier (CH)</td>
</tr>
<tr>
<td>Executive Secretary, EORTC Charitable Trust</td>
<td>V. Agnew</td>
<td>London (UK)</td>
</tr>
<tr>
<td>European Programs Manager US-NCI Liaison Office</td>
<td>S. Radske</td>
<td>Brussels (BE)</td>
</tr>
<tr>
<td>Former President</td>
<td>A.T. van Oosterom</td>
<td>Leuven (BE)</td>
</tr>
</tbody>
</table>
EORTC General Assembly
2009 - 2012: Members

**EFFECTIVE VOTING MEMBERS**

Acting President: J.-Y. Blay, Lyon (FR)
Past Presidents (last three):
- M. Piccart, Brussels (BE)
- A.M.M. Eggermont, Villejuif (FR)
- A.T. van Oosterom, Leuven (BE)

**EORTC Groups Chairs**

<table>
<thead>
<tr>
<th>Group</th>
<th>Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Tumor</td>
<td>W. Wick, Heidelberg (DE)</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>T. Cufer, Golnik (SI)</td>
</tr>
<tr>
<td>Children’s Leukemia</td>
<td>Y. Benoit, Gent (BE)</td>
</tr>
<tr>
<td>Gastrointestinal Tract Cancer</td>
<td>A. Roth, Geneva (CH)</td>
</tr>
<tr>
<td>Genito-Urinary Cancers</td>
<td></td>
</tr>
<tr>
<td>Gynecological Cancer</td>
<td>A. Casado-Herraez, Madrid (ES)</td>
</tr>
<tr>
<td>Head and Neck Cancer</td>
<td>J.A. Langendijk, Groningen (NL)</td>
</tr>
<tr>
<td>Imaging</td>
<td>S. Stroobants, Edegem (BE)</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>P. Donnelly, Nijmegen (NL)</td>
</tr>
<tr>
<td>Leukemia</td>
<td>J.-P. Marie, Paris (FR)</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>M. O’Brien, Sutton (UK)</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>R. van der Maazen, Nijmegen (NL)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>P. Patel, Nottingham (UK)</td>
</tr>
<tr>
<td>PathoBiology</td>
<td>M.G. Daidone, Milano (IT)</td>
</tr>
<tr>
<td>Pharmacology and Molecular Mechanisms Group</td>
<td>G.J. Peters, Amsterdam (NL)</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>G. Velikova, Leeds (UK)</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>V. Grégoire, Brussels (BE)</td>
</tr>
<tr>
<td>Soft Tissue and Bone Sarcoma</td>
<td>P. Hohenberger, Mannheim (DE)</td>
</tr>
</tbody>
</table>

**EORTC Task Forces Chairs**

<table>
<thead>
<tr>
<th>Task Force</th>
<th>Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer in the Elderly</td>
<td>H. Wildiers, Leuven (BE)</td>
</tr>
<tr>
<td>Cutaneous Lymphoma</td>
<td>M. Bagot, Paris (FR)</td>
</tr>
<tr>
<td>Endocrine Tumors</td>
<td>M. Schlumberger, Villejuif (FR)</td>
</tr>
</tbody>
</table>

* A team comprised of Dr A. Bex, Dr N. Clarke, Dr C. Sternberg and Dr B. Tombal is leading the Group *ad interim* until elections take place.
## EORTC Committees / Divisions Chairs

<table>
<thead>
<tr>
<th>Committee</th>
<th>Chair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Division</td>
<td>P. Schöffski, Leuven (BE)</td>
</tr>
<tr>
<td>Translational Research Division</td>
<td>N. Harbeck, Cologne (DE)</td>
</tr>
<tr>
<td>Independent Data Monitoring Committee</td>
<td>R. Kaplan, Leeds (UK)</td>
</tr>
<tr>
<td>Membership Committee</td>
<td>A.M.M. Eggermont, Villejuif (FR)</td>
</tr>
<tr>
<td>New Drug Advisory Committee</td>
<td>J.-C. Soria, Villejuif (FR)</td>
</tr>
<tr>
<td>Protocol Review Committee</td>
<td>F. Shepherd, Toronto (CA)</td>
</tr>
<tr>
<td>Translational Research Advisory Committee</td>
<td>S. Sleijfer, Rotterdam (NL)</td>
</tr>
<tr>
<td>Quality Assurance Committee</td>
<td>K. Haustermans, Leuven (BE)</td>
</tr>
<tr>
<td>Scientific Audit Committee</td>
<td>I. Tannock, Toronto (CA)</td>
</tr>
</tbody>
</table>

## Representatives from the 15 top Academic Recruiting Institutions

<table>
<thead>
<tr>
<th>Institution</th>
<th>Representative</th>
</tr>
</thead>
<tbody>
<tr>
<td>NKI - Antoni Van Leeuwenhoekziekenhuis, Amsterdam (NL)</td>
<td>E. Rutgers</td>
</tr>
<tr>
<td>Hopitaux Universitaires Bordet-Erasme, Brussels (BE)</td>
<td>A. Awada</td>
</tr>
<tr>
<td>Arnhem's Radiotherapeutisch Instituut, Arnhem &amp; Harderwijk (NL)</td>
<td>R. Keus</td>
</tr>
<tr>
<td>Institut Gustave Roussy, Villejuif (FR)</td>
<td>G. Vassal</td>
</tr>
<tr>
<td>UZ Leuven, Leuven (BE)</td>
<td>I. Vergote</td>
</tr>
<tr>
<td>Radboud University Nijmegen Medical Centre, Nijmegen (NL)</td>
<td>T. de Witte</td>
</tr>
<tr>
<td>Centre Léon Bérard, Lyon (FR)</td>
<td>O. Tredan</td>
</tr>
<tr>
<td>UZ Rotterdam, Rotterdam (NL)</td>
<td>R. de Wit</td>
</tr>
<tr>
<td>Leiden University Medical Centre, Leiden (NL)</td>
<td>C. van de Velde</td>
</tr>
<tr>
<td>Institut Curie, Paris (FR)</td>
<td>V. Diéras</td>
</tr>
<tr>
<td>Institut Bergonie, Bordeaux (FR)</td>
<td>H. Bonnefoi</td>
</tr>
<tr>
<td>Centre Hospitalier Universitaire Vaudois, Lausanne (CH)</td>
<td>R. Mirimanoff</td>
</tr>
<tr>
<td>Cliniques Universitaires St. Luc, Brussels (BE)</td>
<td>M. Hamoir</td>
</tr>
<tr>
<td>Academisch Medisch Centrum, Amsterdam (NL)</td>
<td>G. van Tienhoven</td>
</tr>
<tr>
<td>Centre Georges-Francois-Leclerc, Dijon (FR)</td>
<td>P. Fumoleau</td>
</tr>
</tbody>
</table>
**GENERAL ASSEMBLY EFFECTIVE NON-VOTING MEMBERS**

**Board Members**

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vice-President</td>
<td>R. Stupp, Lausanne (CH)</td>
</tr>
<tr>
<td>Secretary General</td>
<td>E. Rutgers, Amsterdam (NL)</td>
</tr>
<tr>
<td>Treasurer</td>
<td>J. Jassem, Gdansk (PL)</td>
</tr>
<tr>
<td>Member</td>
<td>D. Fennell, Belfast (UK)</td>
</tr>
<tr>
<td>Member</td>
<td>H. Gelderblom, Leiden (NL)</td>
</tr>
<tr>
<td>Member</td>
<td>L. Licitra, Milano (IT)</td>
</tr>
<tr>
<td>Member</td>
<td>C. Sternberg, Roma (IT)</td>
</tr>
<tr>
<td>Member</td>
<td>F. Sweep, Nijmegen (NL)</td>
</tr>
<tr>
<td>Member</td>
<td>E. Van Cutsem, Leuven (BE)</td>
</tr>
<tr>
<td>Member</td>
<td>C. van Herpen, Nijmegen (NL)</td>
</tr>
</tbody>
</table>

**Other Effective Members**

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director General, EORTC</td>
<td>F. Meunier, Brussels (BE)</td>
</tr>
<tr>
<td>Director, EORTC</td>
<td>D. Lacombe, Brussels (BE)</td>
</tr>
<tr>
<td>Chair, EORTC Charitable Trust</td>
<td>Sir Christopher Mallaby, London (UK)</td>
</tr>
<tr>
<td>Editor-in-Chief, European Journal of Cancer</td>
<td>A.M.M. Eggermont, Villejuif (FR)</td>
</tr>
<tr>
<td>EJC Liaison Officer</td>
<td>J.C. Horiot, Genolier (CH)</td>
</tr>
<tr>
<td>Executive Secretary, EORTC Charitable Trust</td>
<td>V. Agnew, London (UK)</td>
</tr>
<tr>
<td>European Programs Manager, US-NCI Liaison Office</td>
<td>S. Radtke, Brussels (BE)</td>
</tr>
<tr>
<td>Former President</td>
<td>A.T. van Oosterom, Leuven (BE)</td>
</tr>
</tbody>
</table>

**Past Presidents (other than the last 3)**

<table>
<thead>
<tr>
<th>Name</th>
</tr>
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<tbody>
<tr>
<td>J.-C. Horiot (FR)</td>
</tr>
<tr>
<td>J.G. Mc Vie (UK)</td>
</tr>
<tr>
<td>L. Denis (BE)</td>
</tr>
<tr>
<td>U. Veronesi (IT)</td>
</tr>
<tr>
<td>D. van Bekkum (NL)</td>
</tr>
<tr>
<td>S. Garattini (IT)</td>
</tr>
</tbody>
</table>
Funding of the EORTC

The EORTC is funded through several sources including the EORTC Charitable Trust providing a core grant which is mainly supported by numerous national cancer leagues.

Since 1972, the US National Cancer Institute (NCI) has provided core support to EORTC Headquarters, and with this support a close scientific collaboration has been maintained to promote transatlantic research projects.

A core grant from the Fonds Cancer, FOCA (BE), provides support for the EORTC Headquarters staff.

EORTC Headquarters receives annual grants allocated by BELSPO (the Belgian Federal Science Policy Office) and by the Belgian National Lottery.

Funding for the Fellowship Program is provided by the EORTC Charitable Trust, Fonds Cancer, FOCA (BE), the Koningin Wilhelmina Fund, KWF (NL), and several leagues including La Ligue Nationale contre le Cancer (FR) and the Vlaamse Liga tegen Kanker, VLK (BE).

In addition, grants for EORTC research projects are received from the European Commission under the 6th and the 7th Framework Programme and the Innovative Medicines Initiative (IMI).

The EORTC has received support for bio-banking in a prostate cancer clinical trial from the Institute for the encouragement of Scientific Research and Innovation of Brussels, ISRIB.

Clinical studies evaluating new drugs for potential registration or testing innovative therapeutic agents, including some educational projects, are conducted in cooperation with pharmaceutical industry partners. Pharmaceutical industry sponsorship is also provided in the form of “unrestricted grants” for EORTC conferences.

The finances of the EORTC include all accounts from the EORTC Headquarters as well as all EORTC Groups and Task Forces. These accounts are consolidated as required under Belgian Law. The EORTC accounts are audited by Ernst & Young.

The Academic Research Fund

The EORTC Board initiated an Academic Research Fund to support academic clinical trials or research projects submitted to the Board. Selected trials are academic in nature with inadequate or no funding from other sources. A final decision at the Board level is required based on the strategic/added value the proposed clinical trial brings to the overall EORTC strategy.
The EORTC Charitable Trust
Honorary President: H.R.H. Princess Astrid of Belgium

Honorary Vice-President: Sir Ronald Grierson
Chair: Sir Christopher Mallaby GCMG, GCVO

Members of the General Assembly

Chair
Sir Christopher Mallaby GCMG, GCVO (UK)

Vice-Chair
Sir David Tang KBE (HK)

Executive Secretary
Mrs. Victoria Agnew (UK)

Professor Jean-Yves Blay Lyon (FR)
Mr. Christian Boel Hellerup (DK)
Monsieur Alain Camu Brussels (BE)
Dr. Gérard Depadt Lille (FR)
Professor Alexander M.M. Eggermont Villejuif (FR)
H.E. Ambassador Evelyne Genta Monaco (MC)
Dr. Jean de Gunzburg London (UK)
Mr. Luc van Haute Brussels (BE)
Mrs. Elizabeth Hjorth Copenhagen (DK)
Mrs. Cora Honing Amsterdam (NL)
Professor Jean-Claude Horiot Genolier (CH)
Comte Aymar de Lastours Paris (FR)
Ms. Kate Law London (UK)
Mr. Marc Leland Washington (US)
Mr. Oscar M. Lewisohn London (UK)
Mrs. Sally Lo MBE Hong Kong (HK)
H.R.H. Prince Guillaume of Luxembourg Contern (LU)
Baroness Suzanne von Maltzahn London (UK)
Dr. Rolf Marti Bern (CH)
Professor J. Gordon McVie Milan (IT)
Professor Françoise Meunier Brussels (BE)
Mr. Hans Neefs Brussels (BE)
Professor Allan T. van Oosterom Antwerp (BE)
Mr. Ole Alexander Opdalshei Oslo (NO)
Professor Martine Piccart Brussels (BE)
H.E. Ambassador Marie-Thérèse Pictet-Althann Geneva (CH)
Professor Dr. Martin Roth Dresden (DE)
Dr. Piero Serra Milan (IT)
Professor John Smyth Edinburgh (UK)
Lady Solti London (UK)
Professor Bengt Westermark Stockholm (SV)
Dr. Carlos Oliveira Coimbra (PT)
The EORTC Charitable Trust

In 1976, the EORTC Foundation was established by Royal Decree under the laws of the Kingdom of Belgium as an international association under Belgian Law with the specific aim of obtaining funds for the support of the activities of the EORTC, to support the structure of the organization and to support independent academic research projects. It receives the majority of its funds from National Cancer Charities. All the major European National Cancer Charities which support the work of the EORTC are represented in the General Assembly, as well as the Hong Kong Cancer Fund and distinguished lay members.

In March 2006, the EORTC Foundation changed its name to The EORTC Charitable Trust to take account of recent changes in Belgian Law. The aims of The EORTC Charitable Trust remain exactly the same.

The Charitable Trust records with sadness the death in December 2010 of Mrs. Marianne Boel from Denmark. She was a most dedicated and active member of our Council for many years until she died. We remember her with gratitude and affection.

The Honorary President is H.R.H. Princess Astrid of Belgium, and the Chair is Sir Christopher Mallaby. Sir Ronald Grierson, Past-Chair, is now the Honorary Vice-President of The EORTC Charitable Trust.

During 2009, the EORTC Charitable Trust received core support for the year for the EORTC of 1,270,038 Euros from several European National Cancer Charities and the Hong Kong Cancer Fund: additionally 198,945 Euros were received in relation to core support for 2008. The EORTC Charitable Trust awarded a core grant of 1,450,000 Euros to the EORTC for the year. During 2009, the Charitable Trust provided funding for fellowships of 175,000 Euros. During 2009 the Charitable Trust received a 73,421 Euros donation from the Oak Foundation. The generous donation received from the Schroder Family Foundation in 2008 continued to support a Fellowship during 2009, the Schroder Foundation Fellowship, for research in an important EORTC Children’s Leukemia study.

During 2010, the EORTC Charitable trust received core support for the year for the EORTC of 1,577,369 Euros from several European National Cancer Charities and the Hong Kong Cancer Fund: additionally 265,192 Euros were received in relation to core support for 2009. The EORTC Charitable Trust made a core grant of 1,450,000 Euros to the EORTC for the year. During 2010, the EORTC Charitable Trust provided funding for fellowships of 173,682 Euros. During 2010 the Charitable Trust received a 19,539 Euro/25,000US$ donation from Mr and Mrs M. Seiden. The Schroder Foundation Fellowship will continue to be supported for a second year from the generous donation received from the Schroder Family Foundation in 2008. The new Schroder Fellow is Dr Francisco Bautista.

The Charitable Trust held an important fundraising event in Monaco in 2009, under the High Patronage of H.S.H. Prince Albert II of Monaco, who attended the evening. The Honorary President of the Charitable Trust, H.R.H. Princess Astrid of Belgium and her husband, H.R.H. Prince Lorenz, both supported the event by participating. The dinner took place on the stage of the Opera Garnier in Monte Carlo in October. Plans are well advanced for a major fundraising event in Dresden in May 2011.

The Charitable Trust applied to the Belgian authorities in autumn 2007 for renewal of its Charitable Status for the period 2008-2013, which has been received.

The annual audit for 2009 of the EORTC Charitable Trust asbl was carried out by its new auditors, Buzzacott LLP. Tax and legal advice continue to be provided by PricewaterhouseCoopers Tax Consultants cvba/scrl.
EORTC Headquarters

EORTC Staff
# EORTC Headquarters Staff

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Director General</strong></td>
<td>Françoise Meunier, MD, PhD, FRCP</td>
</tr>
<tr>
<td><strong>Director General’s Office</strong></td>
<td></td>
</tr>
<tr>
<td>Coordinator</td>
<td>Lily Geyoro, MA</td>
</tr>
<tr>
<td>Personal Assistant</td>
<td>Saida Jinah, BA</td>
</tr>
<tr>
<td>Assistant</td>
<td>Alvine Sike, BA</td>
</tr>
<tr>
<td>Secretaries / Receptionists</td>
<td>Sophie Hons</td>
</tr>
<tr>
<td></td>
<td>Alexia Yannopoulos</td>
</tr>
<tr>
<td><strong>EU Programme Officer</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stéphane Lejeune, MPH</td>
</tr>
<tr>
<td><strong>Education Office Coordinator</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Danielle Zimmermann</td>
</tr>
<tr>
<td><strong>Communications Office</strong></td>
<td></td>
</tr>
<tr>
<td>Medical Science Writer</td>
<td>John Bean, PhD</td>
</tr>
<tr>
<td>Assistant</td>
<td>Stéphanie Vandergooten</td>
</tr>
<tr>
<td>Administrative Assistant</td>
<td>Jennifer Crespo, B Econ</td>
</tr>
<tr>
<td><strong>Human Resources Department</strong></td>
<td></td>
</tr>
<tr>
<td>Manager</td>
<td>Bernard Kamp, B Econ</td>
</tr>
<tr>
<td>Assistants</td>
<td>Delphine Cnockaert, B Econ</td>
</tr>
<tr>
<td></td>
<td>Nelly Gonay, M Econ</td>
</tr>
<tr>
<td>Office Manager</td>
<td>Frédéric Hubinon</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Farha Derbal</td>
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<tr>
<td></td>
<td>Donatella Locci</td>
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<tr>
<td><strong>Contract, Accounting and Finances Reporting Office</strong></td>
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<tr>
<td>Accounting – Finances Reporting Manager</td>
<td>Ariane Jablonka, M Econ</td>
</tr>
<tr>
<td>Contract Manager</td>
<td>Frédéric Hénot, PhD</td>
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<tr>
<td>Accountants</td>
<td>Christophe Bellem, B Econ</td>
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<tr>
<td></td>
<td>Mauaik Nadia Luboya, B Econ</td>
</tr>
<tr>
<td>Accounting Assistant</td>
<td>Sandrine Cazeils</td>
</tr>
<tr>
<td>Assistant</td>
<td>Vicky Konstantakopoulou</td>
</tr>
<tr>
<td><strong>Quality Systems &amp; Compliance Unit</strong></td>
<td></td>
</tr>
<tr>
<td>Head of Quality Systems &amp; Compliance Unit</td>
<td>Cindy Wyns, MSc</td>
</tr>
<tr>
<td>Quality and Process Manager</td>
<td>Marie-Laure Couvreur, BSc</td>
</tr>
<tr>
<td>Quality Assurance Auditor</td>
<td>Michel Lapaige, MSc, VET</td>
</tr>
<tr>
<td><strong>Clinical Trial Insurance Office</strong></td>
<td></td>
</tr>
<tr>
<td>Coordinator</td>
<td>Vicky Minas</td>
</tr>
<tr>
<td>Officer</td>
<td>Michèle Lidarssi</td>
</tr>
</tbody>
</table>
#### Director, EORTC Headquarters

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Secretary</td>
<td>Vicky Minas</td>
</tr>
</tbody>
</table>

#### Assistant Directors

- Richard Sylvester, ScD
- Martine Van Glabbeke, Ir, PhD
- Ann Marinus, RN
- Pascal Ruyskart, MSc
- Andrew Bottomley, PhD

#### Headquarters Coordinating Committee

- Jan Bogaerts, ScD
- Andrew Bottomley, PhD
- Laurence Collette, MSc, PhD
- Jocelyne Flament, MD
- Caroline Gilotay, MSc
- Denis Lacombe, MD, MSc
- Ann Marinus, RN
- Sandrine Marréaud, MSc, MD
- Françoise Meunier, MD, PhD, FRCP
- Pascal Ruyskart, MSc
- Richard Sylvester, ScD
- Martine Van Glabbeke, Ir, PhD

#### Early Project Optimization Department (EPOD)

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head of Department</td>
<td>Denis Lacombe, MD, MSc</td>
</tr>
<tr>
<td>Strategic Development Officer</td>
<td>Anne-Sophie Govaerts, PhD</td>
</tr>
<tr>
<td>Secretary</td>
<td>Sonia Pazos, M Econ</td>
</tr>
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</table>

#### Protocol Development Unit

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Strategic Development Officer</td>
<td>Jillian Harrison, PhD</td>
</tr>
<tr>
<td>Protocol Help Desk Officer</td>
<td>Françoise Peeters</td>
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<tr>
<td>Protocol review Committee Secretariat Officer</td>
<td>Gabriel Solbu, MSc</td>
</tr>
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#### Fellowship Program Department

<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Scientific Coordinator</td>
<td>Denis Lacombe, MD, MSc</td>
</tr>
<tr>
<td>Executive Secretary</td>
<td>Vicky Minas</td>
</tr>
<tr>
<td>Fellows</td>
<td>Francisco Bautista Sirvent, MD</td>
</tr>
<tr>
<td></td>
<td>Alysa Fairchild, MD</td>
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<tr>
<td></td>
<td>Diego Gomes Candido Reis, MD</td>
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<tr>
<td></td>
<td>Julie Lorent, Ir</td>
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<td></td>
<td>Camilo Moulin, MD</td>
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<td>Zouheir Snouber, MD</td>
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<tr>
<td></td>
<td>Erik Tanis, MD</td>
</tr>
<tr>
<td></td>
<td>Gloria Tridello, MSc</td>
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<td></td>
<td>Gustavo Werutsky, MD</td>
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</tbody>
</table>
Quality Control Unit
Head of Unit Christine de Balincourt, Pharm
Quality Control Coordinator Christine Waterkeyn, MSc
Clinical Research Associates Julien De foiche, PhD
Steve Douterlungne, MSc

Translational Research & Imaging Department
Head of Department Jocelyne Flament, MD

Translational Research Unit
Head of Translational Research Unit Jacqueline Hall, PhD
Tumor Bank Administrator Nawal Bekka, MSc

Imaging
Imaging Officer Ivalina Hristova, BSc, AAS

Quality Assurance in Radiotherapy (QART) Unit
Officer Coreen Corning, BSc
Manager To be appointed

Medical Department
Head of Department Sandrine Marréaud, MSc, MD
Assistant Michèle Lidarssi

Clinical Research Physicians
Senior Clinical Research Physicians Sabine Margerit De Bedout, MBA, MD, MPH
Lisa Pylkkänen, PhD
Jocelyne Flament, MD
Matthias Karrasch, MD
Denis Lacombe, MD, MSc
Sandrine Marréaud, MSc, MD
Björn Penninckx, MD

Junior Clinical Research Physician
Ravi Karra, MD

Medical Affairs
Head of Unit Björn Penninckx, MD

International Regulatory Affairs / Intergroup
Head of Int'l Regulatory & Intergroup Strategy Anastassia Negrouk, MSc, DEA

Regulatory Affairs Unit
Associate Head of Unit Claire Van Den Bogaert, MSc
Senior Regulatory Affairs Manager Marta Marques, MSc
Regulatory Affairs Managers Magali Castremanne, DESS
Julie Engel, MSc
Carine Pontegnies, Ir

Assistant Nadia El Medassi
1. Structure and Organization

**Pharmacovigilance Unit**
Head of Unit: Nathalie Dubois, MSc
Associate Head of Unit: Marie-Pierre Gauthier, PhD
Managers: Nathalie Crokart, MSc, PhD
Izabella Jagiello, MSc, PhD
Sara Meloen, MSc
Thomas Valkaert, MSc
Secretary: Angela Geithman

**Statistics Department**
Head of Department: Jan Bogaerts, ScD
Senior Statistical Scientist: Richard Sylvester, ScD
Senior Biostatistician: Martine Van Glabbeke, Ir, PhD
Associate Head of Department: Laurence Collette, MSc, PhD
Senior Biostatistians: Catherine Fortpied, MSc
Jan Schuller, PhD
Stefan Suciu, PhD
Biostatisticians: Sandra Collette, MSc
Baktiar Hasan, PhD
Saskia Litiere, PhD
Murielle Mauer, PhD
Monia Ouali, MSc
Statisticians: Corneel Coens, MSc
Thierry Gorlia, MSc
Statistical Programmer: Jérôme Rapion, MSc, DESS
Secretary: Zeina Tayah

**Independent Data Monitoring Committee**
Assistant Director Biostatistics: Martine Van Glabbeke, Ir, PhD
Assistant Head of Department: Laurence Collette, MSc, PhD
Officer: Gabriel Solbu, MSc
Secretary: Françoise Peeters

**Project and Budget Development Department**
Head of Department: Ann Marinus, RN
Membership Coordinator: Teodora Kirova, BSc
Assistant: Cristel Grimonpont

**Project Management / Clinical Trial Assistants Unit**
Senior Clinical Operation Manager: Anouk Allgeier, PhD
Clinical Operation Managers: Gaetan de Schaezzen, PhD
Kristel Engelen, P.T.
Senior Projects Managers: An Demeester, MSc
Anne Kirkpatrick, MSc
Project Managers: Anita Akrapovic, BSc
Hilde Breyssens, PhD
Nicolas Dif, PhD
Nadège Gosselin, PhD
Aurore Jacques, MSc
<table>
<thead>
<tr>
<th>Role</th>
<th>Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Clinical Trials Assistants</td>
<td>Delphine Van Gorp, Vinciane Vinckx</td>
</tr>
<tr>
<td>Clinical Trials Assistants</td>
<td>Gladiddy Arias, Katrien Baus, Rachel Ho, Beata Piskor, Aurelia Siraut</td>
</tr>
<tr>
<td>Data Management Department</td>
<td></td>
</tr>
<tr>
<td>Head of Department</td>
<td>Caroline Gilotay, MSc</td>
</tr>
<tr>
<td>Associate Head of Department</td>
<td>Bart Meulemans, MSc</td>
</tr>
<tr>
<td>Senior Data Managers</td>
<td>Linda De Prijck, BSc, Nicole Duez, MSc, RN, Livia Giurgea, PhD, Catherine Hermans, Marie-Ange Lentz MSc</td>
</tr>
<tr>
<td>Lead Data Managers</td>
<td>Edith Bastiaens, MSc, Valérie Dewaste, PhD, Liv Meert, MSc, Bart Meulemans, MSc, Larissa Polders, MSc</td>
</tr>
<tr>
<td>Data Managers</td>
<td>Isabelle Blangenois, PhD, Peter De Burghgraeve, MSc, Maarten De Rouck, MSc, Marlies Dictus, MSc, Niels Goossens, MSc, Nils Helsen, MSc, Sven Janssen, MSc, Tuân Le, MSc, Niels Lema, Pharm, Lies Meirlaen, MSc, Isabelle Meulders, BSc, Gloria Montanes, MSc, Sarah Morren, VET, Edwin Nys, MSc, Axelle Nzokirantevye, MSc, Christine Olungu, Ir, Nicolas Othmezouri, MSc, Tiana Raveloarivahy, BSc, Françoise Rigaux, BSc, Seraphine Rossi, MSc, Virginie Soete, MSc</td>
</tr>
</tbody>
</table>
## IT Department

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head of Department</td>
<td>Pascal Ruyskart, MSc</td>
</tr>
<tr>
<td>Associate Head of Department</td>
<td>Eric Decossaux, MSc</td>
</tr>
<tr>
<td>Analyst Programmers</td>
<td>Yves Dohogne, MSc</td>
</tr>
<tr>
<td>Computer Application Specialist</td>
<td>Michel Kirschen, BSc</td>
</tr>
<tr>
<td>IT Support Analyst</td>
<td>Edouard Klopfer, BSc</td>
</tr>
<tr>
<td>System Analyst</td>
<td>Jonathan O’Sullivan</td>
</tr>
<tr>
<td>System Manager</td>
<td>Gilles De Vrye, MSc</td>
</tr>
<tr>
<td>Quality of Life Department</td>
<td>Guillaume Migaszewski</td>
</tr>
</tbody>
</table>

## Quality of Life Department

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head of Department</td>
<td>Andrew Bottomley, PhD</td>
</tr>
<tr>
<td>Translation Team Leader</td>
<td>Dagmara Kulis, MA</td>
</tr>
<tr>
<td>Officers</td>
<td>Maria Arnott, M Econ</td>
</tr>
<tr>
<td>Researchers</td>
<td>Petra Jeglikova, MA</td>
</tr>
<tr>
<td>Research Administrator</td>
<td>To be appointed</td>
</tr>
<tr>
<td>Secretary</td>
<td>Rossella Guzzo</td>
</tr>
<tr>
<td>Clinical Trial Assistant</td>
<td>Sheila Scott-Sanderson</td>
</tr>
</tbody>
</table>
Several EORTC committees have been created to oversee the independence of the EORTC, as well as the relevance and scientific value of all research efforts, thereby ensuring the highest quality of scientific work possible. Each Committee Chairman serves a three years elected term.

Committees

- EORTC New Drug Advisory Committee (NDAC)
- EORTC Translational Research Advisory Committee (TRAC)
- EORTC Protocol Review Committee (PRC)
- EORTC Scientific Advisory Committee (SAC)
- EORTC Quality Assurance Committee (QAC)
- EORTC Independent Data Monitoring Committee (IDMC)
- EORTC Membership Committee (MC)
- EORTC Headquarters Institutional Review Board (IRB)
EORTC New Drug Advisory Committee (NDAC)

The aim of the New Drug Advisory Committee (NDAC) is to expedite the introduction of new drugs into clinical trials within the EORTC. It works closely with EPOD, the Early Project Optimization Department within EORTC Headquarters, and to a lesser extent with the Translational Research Advisory Committee (TRAC). In order to ensure a consistent approach towards the pharmaceutical industry, the NDAC acts a reference body for all EORTC Groups and makes recommendations to them in all aspects of drug development, including the selection of the most promising compounds. This includes the strategic approach and setting priorities regarding drug development within the entire EORTC Network as well as being a recipient of information from disease oriented groups at the earliest stages of their discussions about trials involving new agents. It encourages early contact with investigators and disease oriented groups.

The remit of the NDAC are those agents that have not been registered and/or not yet with a role in oncology, or possibly agents which come to the EORTC for the first time in a specific setting. Working very closely with EPOD, NDAC’s continued mission is to stimulate, organize and prioritize access to new drugs. It has responsibility for benchmarking the choice of target/agent and/or company, taking advice from both the disease oriented groups and EPOD. The expectation is that the earlier the involvement of NDAC (and of course EPOD) in the development of a project, the higher the chance of such projects being approved by the Executive Committee as they will already be aligned with EORTC priorities.

The NDAC coordinates Advisory Boards performed with the pharmaceutical industry, and in 2009-2010 oversaw, along with EPOD, successful interactions with large pharmaceutical companies which have led to a number of new projects being actively discussed between the EORTC and the company. The NDAC also supports EPOD regarding methodological issues inherent to innovative agents with new mechanisms of action in the approach of early studies design.

Along with TRAC, NDAC continues to comment on projects being reviewed by the Protocol Review Committee, and this past year there were 19 such projects, indicating a healthy activity in the generation of new projects within the EORTC.

Members

Chair
J.-C. Soria, Villejuif (FR)

Members
A. Awada, Brussels (BE) K. Dhingra, Sparta (US)
U. Banerji, Sutton (UK) H. Gelderblom, Leiden (NL)
A. Burger, Baltimore (US) M. Scurr, London (UK)
J. Dancey, Kingston (CA) J. Tabernero, Barcelona (ES)
M. de Jonge, Rotterdam (NL) M. van den Bent, Rotterdam (NL)

Ex Officio members
N. Harbeck, Cologne (DE) D. Lacombe, Brussels (BE)
S. Sleijfer, Rotterdam (NL)
The Translational Research Advisory Committee (TRAC) was created to support and provide expert advice from a scientific and practical perspective on translational research projects conducted within the EORTC. The aims of TRAC are to ensure the independence of the EORTC, the relevance of translational research efforts, and to guarantee scientifically sound results so as to increase the scientific visibility of the EORTC. As a pre-clinical scientists advisory committee, TRAC also acts as a permanent EORTC forum between the Clinical and Translational Research Divisions by fostering interest in translational research within Clinical Research Division Groups and promoting clinical development ideas/concepts emerging from Translational Research Division Groups.

**Missions of TRAC are to:**
- Lead Strategic translational research developments within the EORTC;
- Assist EORTC Clinical Groups in optimizing translational research studies and integrating translational research approaches into their scientific strategy;
- Stimulate EORTC translational research projects either as side studies of new EORTC clinical trial protocols or on the use of existing sets of clinically annotated bio-samples;
- Provide expert advice on any translational research project conducted within the EORTC both from scientific and practical perspectives;
- Ensure optimal flow of information between EORTC Translational Research and Clinical Research Divisions and contribute to the reinforcement of the EORTC platform of pathologists and laboratory scientists;
- Support the Early Project Optimization Department (EPOD).

TRAC comprises permanent members and ex officio members. All the main disciplines of translational research in oncology are represented in the review panel.

Each member of TRAC is elected for a renewable three-year term.

**Members**

**Chair**
S. Sleijfer, Rotterdam (NL)

**Vice-Chair**
S. Tejpar, Leuven (BE)

Fatima Cardoso, Lisbon (PT)
M.G. Daidone, Milano (IT)
M. Debiec-Rychter, Leuven (BE)
T. De Witte, Nijmegen (NL)
J.A. Foekens, Rotterdam (NL)
O.S. Hoekstra, Amsterdam (NL)
R. Iggo, Fife (UK)
K.M. Kerr, Aberdeen (UK)
P. Lambin, Maastricht (NL)
G. Peters, Amsterdam (NL)
M. Schmitt, Munich (DE)
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S. Stroobants, Edegem (BE)
F. Sweep, Nijmegen (NL)
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N. Zaffaroni, Milano (IT)
S. Michiels, Brussels (BE)
J.-A. Chapman, Kingston (CA)

**Ex Officio Members**
J. Hall, Brussels (BE)
N. Harbeck, Cologne (DE)
J.-C. Soria, Villejuif (FR)
EORTC Protocol Review Committee (PRC)

Members & Ex Officio Members

Chair  F. A. Shepherd, Toronto (CA)
Vice-Chair  M. Eriksson, Lund (SE)

J.-P. Armand, Toulouse (FR)
J. Bernier, Genolier (CH)
L. Blomqvist, Stockholm (SE)
S. Bodis, Aarau (CH)
F. Brunotte, Dijon (FR)
A. Chiti, Rozzano (IT)
K. Conlon, Dublin (IE)
A. Craft, Newcastle (UK)
T. de Witte, Nijmegen (NL)
V. Diéras, Paris (FR)
C. Dittrich, Vienna (AT)
P. Goodwin, Toronto (CA)
F. Guillemin, Vandoeuvre-Les-Nancy (FR)
C. Hill, Paris (FR)
N. Isembert, Dijon (FR)
A. Jimeno, Aurora (US)
O. S. Nielsen, Aarhus (DK)
J. Oliveira, Lisboa (PT)
M. Parmar, London (UK)
R. Rosell, Badalona (ES)
A. Sobrero, Genova (IT)
B. van Beers, Clichy (FR)
G. Velikova, Leeds (UK)
C. Weltens, Leuven (BE)

Phase I-II PRC Experts:
J. Cassidy, Glasgow (UK)
M. De Jonge, Rotterdam (NL)
H. Dumez, Leuven (BE)
A. Elias, Aurora (US)
H.W. Hirte, Hamilton (CA)
I.R. Judson, London (UK)
P.J. O’Dwyer, Philadelphia (US)
W. Parulekar, Kingston (CA)
A. Ravaud, Bordeaux (FR)
D. Ross Camidge, Denver (US)
L. Seymour, Kingston (CA)
L. Siu, Toronto (CA)

Ex Officio:
D. Lacombe, Brussels (BE)
F. Meunier, Brussels (BE)
R. Sylvester, Brussels (BE)
M. Van Glabbeke, Brussels (BE)

All protocols conducted by EORTC need to be approved by an independent panel of experts. This independent peer review process has been implemented by EORTC as early as 1983: the Protocol Review Committee (PRC) appointed by the EORTC Board reviews all projects proposed by EORTC Groups.

For a study to be conducted under the EORTC label, EORTC experts have to have an impact on the study design and the project has to be approved by the PRC. In addition, the database should be handled by the Headquarters (HQ) staff and the final analysis should be performed by an EORTC statistician unless conducted by another independent research group in the context of a so-called intergroup clinical trial.
The PRC comprises experts in the field of cancer clinical research. All disciplines of oncology are represented in the review panel. About 50% of the PRC members are non-EORTC, which also includes a representation of the US National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP). Additionally, the PRC makes systematic use of external reviewers – a minimum of three international experts are consulted for each outline, thereby providing independent review.

Globally, from 1 January 2009 until 31 December 2010, the PRC reviewed outlines for 32 studies, this involved reviewers from 111 members of the PRC or Phase I/II experts and from 180 external reviewers.

The function of the EORTC PRC is to assess the compliance of studies proposed by EORTC Groups with the EORTC scientific strategy, and to assess their scientific value in terms of originality, interest, methodology and scientific feasibility. The PRC assists the groups whenever necessary concerning any aspect of the design and implementation of their studies from the first outline proposal to the full protocol.

Protocol outlines are submitted to the PRC Secretariat via the Internet using a supplementation and maturation of the information provided in the Early Project Optimization Department (EPOD) form. The outline submission questionnaire is available from the EORTC website: www.eortc.be. Once final, an outline is submitted to the PRC, this can only be done after an initial feasibility go-ahead.

About 30% of the current submitted projects are joint protocols with non-EORTC Groups (e.g. Trans-Tasman Radiation Oncology Group, International Breast Cancer Study Group, Dutch-Belgian Cooperative Trial Group for Hematology Oncology, Gynecologic Oncology Group, RTOG) and of these approximately 30% are coordinated by the EORTC. The review of intergroup studies depends on whether the EORTC is the coordinating group or joins a protocol which will be run by another Group’s data centre.

Outlines may be approved at the time of review or more often only approved after revision, and others are rejected. Most protocol outlines are resubmitted after detailed comments from the PRC, and could still at that time be reviewed by external experts of the particular field involved.

Outlines approved by the PRC may be subsequently developed as full protocols once feasibility has been confirmed and if the budget needed to manage the study is fully covered. If this budget is not fully covered, they are subsequently submitted to a competitive selection process carried out by the EORTC Board. The Board will decide to allocate EORTC funding (from the EORTC Academic Fund) on the basis of the scientific evaluation provided by the PRC. Selected projects will be subsequently developed as full protocols. The “EORTC protocol submission, selection and development procedures” are described in the EORTC Policy 16, also practical information is provided in the PRC submission procedures section both of which are available on the EORTC website.

In order to simplify the writing of the full protocol, but also to guarantee homogeneity of protocols and compliance to EORTC policies, the PRC in conjunction with the EORTC Protocol Help Desk have developed a set of core documents and templates available to the EORTC HQ teams and Groups. The PRC approved documents include guidelines to improve the content/clarity of all protocols; guidelines
developed for the writing of each of the chapters and appendices of a protocol and standard versions for various administrative chapters (for example insurance, ethical consideration, reporting serious adverse event and randomisation).

The Protocol Development Unit (PDU) follows the overall protocol development and approval process. Full protocols must be a faithful development of approved outlines. Significant modifications of the study outline after its approval will need to be approved again by the PRC. If the modifications have an impact on the resources to be allocated by the EORTC, the decision of the EORTC Board to have the study supported by the EORTC may be reconsidered. After a protocol is approved and released any change is deemed an amendment. The PRC approves scientific amendments to EORTC protocols and the PDU coordinates their implementation into protocols.

All efforts are made to speed up the review process to meet the wishes of groups to get protocols activated quickly but there is an absolute necessity for the PRC to make sure that all studies with the EORTC label are carried out according to the highest possible standards (scientific, administrative and regulatory) of clinical scientific investigation. The New Drug Advisory Committee (NDAC), the Translational Research Advisory Committee (TRAC) including imaging and the Elderly Task Force (TFE) provide additional scientific expertise when needed.

Summary of the Protocol Review Committee activities in 2009 & 2010

In the period ranging from 1 January 2009 to 31 December 2010 (refer to table), a total of 27 new outlines were submitted and decisions were made for 32 outlines by the PRC (3 Phase I-II, 10 Phase II, 2 Phase II/III, 15 Phase III, one imaging validation and one prognostic factor studies). Of these, 27 were accepted and 54 remained pending for resubmission and one was cancelled before being resubmitted.

Outlines reviewed in 2009 & 2010

<table>
<thead>
<tr>
<th>Study number</th>
<th>Group(s)</th>
<th>Phase</th>
<th>EORTC strategic classification</th>
<th>1st outline submission date</th>
<th>Latest decision date for the outline</th>
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<td>07/07/2008</td>
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<td>21081</td>
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<td>1A+</td>
<td>09/10/2008</td>
<td>03/02/2009 Accepted</td>
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<tr>
<td>30081</td>
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<td>08/10/2008</td>
<td>09/02/2009 Accepted</td>
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<td>III</td>
<td>1B+</td>
<td>09/10/2008</td>
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<tr>
<td>22085-10083</td>
<td>Radiation Oncology + Breast Cancer</td>
<td>III</td>
<td>2A+</td>
<td>02/12/2008</td>
<td>19/02/2009 Accepted</td>
</tr>
</tbody>
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1. Structure and Organization
<table>
<thead>
<tr>
<th>Study number</th>
<th>Group(s)</th>
<th>Phase</th>
<th>EORTC strategic classification</th>
<th>1st outline submission date</th>
<th>Latest decision date for the outline</th>
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<tbody>
<tr>
<td>90091-10093</td>
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<td>II</td>
<td>2B+</td>
<td>14/01/2009</td>
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<tr>
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<td>58081</td>
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<td>2</td>
<td>17/11/2009</td>
<td>26/05/2010 Accepted</td>
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**2010**

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<th>Study number</th>
<th>Group(s)</th>
<th>Phase</th>
<th>EORTC strategic classification</th>
<th>1st outline submission date</th>
<th>Latest decision date for the outline</th>
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<tr>
<td>Study number</td>
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<td>Phase</td>
<td>EORTC strategic classification</td>
<td>1st outline submission date</td>
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<tr>
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<td>Melanoma Group</td>
<td>I/II</td>
<td>3B</td>
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</tr>
</tbody>
</table>

(1) Intergroup study coordinated by EORTC
(2) Intergroup study to which EORTC is collaborating

From the 1 January 2009 until 31 December 2010, a total of 21 Full Protocols / Group Specific Appendices (GSAs) have submitted for review. Nine submitted and seven approved in 2009 and twelve submitted and ten approved in 2010. Of those, 17 were approved, three were in review at the end of 2010, and one was cancelled after starting review.

During the same period, 74 protocol amendments were approved (2009: 37 amendments: 11 substantial, 5 scientific, 10 non-substantial and 11 administrative amendments; 2010: 37 amendments: 22 scientific and 15 administrative).

**Submission of outlines and protocols to the EORTC Protocol Review Committee**

For each study proposed by an EORTC Group, an outline should be submitted to the EORTC PRC via the Internet. The outline should briefly describe and justify the principal parameters of the trial (objectives, principal eligibility criteria, therapeutic interventions, end-points, statistical design, companion studies and translational research projects) in such a way that the PRC will be able to assess the scientific value of the proposed study. The outline should also identify a Study Coordinator appointed by the EORTC Group(s), and eventual non-EORTC partners. All submitted outlines must be approved by the EORTC Group Chairman.

Prior to PRC submission, the study proposal should have been approved by the EORTC Executive Committee. EPOD will be in charge of the submission process. Groups are encouraged to discuss their projects with EPOD prior to submitting to the EORTC Executive Committee. EPOD was established to support the groups in streamlining their projects and strategies along the EORTC strategy defined by the EORTC Board.

For studies that might contribute to a new drug development project, the Groups are advised to consult the NDAC. For studies including a Translational Research project, the Groups are advised to...
consult the TRAC (including imaging). Eventual support of the NDAC or of the TRAC should be
notified at the time of outline submission.

An outline can only be submitted to the PRC once it has an initial budget and feasibility go-ahead from
the Project and Budget Development Department.

The first PRC decision will be notified to the EORTC Study Coordinator(s), the EORTC Group
Chairman and the EORTC HQ team within one month of receipt of the outline (approval, 
resubmission or rejection).

**Full Protocol Submission**

Full protocols are developed in a modular way with the logistical support of the HQ Protocol Help
Desk (PHD) and of the HQ team. Appropriate instructions, guidelines and templates will be addressed
to the Study Coordinator by the PHD shortly after outline approval.

When the final version of the full protocol is available, the Study Coordinator in collaboration with the
HQ team should send a submission letter (or e-mail) to the PRC secretariat, which includes the
description of eventual differences between the accepted outline and the full protocol.

The final protocol version will be submitted to an internal revision process within the HQ, to check
adherence with the PRC approved outline, compliance with EORTC Policies and with EORTC
Standard Operating Procedures, and to detect eventual discrepancies or inconsistencies that might
affect the conduct and/or the management of the study. In case of major discrepancies with the original
outline and/or irresolvable disagreement with the internal reviewers, the protocol will be resubmitted
to the PRC.

All Study Coordinators need to complete a conflict of interest form, according to the EORTC Conflict
of Interest and Confidentiality Policy, and sign the document entitled “Tasks & responsibilities of Study
Coordinators”. Both documents are sent to the Study Coordinator at the time of outline approval and
must be signed before submission of the full protocol.

**Intergroup Studies**

Intergroup studies should follow the EORTC Intergroup Policy. If the trial is coordinated by an EORTC
Group or the EORTC HQ, the EORTC approval will be obtained through the usual submission
procedure (see above). If EORTC is neither the Coordinating Group, nor the Coordinating data
center, the EORTC Group(s) should appoint an “EORTC Coordinator” who will complete an outline
questionnaire (even if the full protocol is already available) and send to the PRC secretariat a copy of all
available documentation of prior peer reviews of the project (preferable as electronic documents). If
the study is already active in another group, the reasons why the EORTC will join the trial at a late
stage should be explained in the comment section of the outline questionnaire. If the full protocol is
already finalized, it should be sent to the PRC secretariat at the time of outline submission. If the
“EORTC Group Specific Appendix” (GSA) is already finalized and approved by the EORTC
International Regulatory Affairs / Intergroup Unit, the PRC Secretariat should be informed.
Development of the full protocol is normally the responsibility of the Coordinating Group. The EORTC HQ will develop an “EORTC GSA”. The further review process will be decided by the PRC on the basis of the information provided at the time of outline submission.

**Amendments**

After PRC approval, any modifications to the protocol, PIS/IC or GSA must be discussed and subsequently submitted or notified to the PRC, as appropriate. The changes will be reviewed, approved and implemented in the protocol, and a new version issued. The HQ will make new versions available on the web site, circulate the amendment and the new version of the protocol to all investigators, and will inform health authorities and ethics committees when needed.

All documents and correspondence should be addressed to the EORTC PRC Secretariat, e-mail: prc.sec@eortc.be
EORTC Scientific Audit Committee (SAC)

The EORTC Scientific Audit Committee (SAC) gives independent advice to the EORTC Board regarding the activities and scientific output as well as overall priorities and strategies of the Divisions, Groups, and Task Forces of the EORTC. Recommendations also include criteria such as conformity with EORTC structure, policies, and interaction with other EORTC Groups.

The SAC evaluates the effectiveness of the research programs conducted by the Groups. The SAC provides suggestions intended to strengthen the Groups and overall functioning of the EORTC. Each research group bearing the EORTC name is reviewed every three to four years. Approximately 50% of SAC members have no EORTC involvement. Its members represent a cross-section of international opinion and expertise. The choice of EORTC members or non-EORTC members is approved by the EORTC Board and is revised as appropriate.

Members are committed to a three-year renewable term. The SAC chair reviews the composition of SAC after his/her appointment and makes a proposal for new members to the EORTC Board. A replacement of only two to three members at a time is recommended to avoid a lack of continuity in SAC reviews.

Members
- Chair: I. Tannock, Toronto (CA)
- Secretary: F. Cardoso, Lisbon (PT)
- D. Bron, Brussels (BE)
- L. Cataliotti, Florence (IT)
- C. Dittrich, Vienna (AT)
- E. Eisenhauer, Ontario (CA)
- D. Kian Ang, Houston (US)
- D. Lacombe, Brussels (BE)
- T. Le Chevalier, Villejuif (FR)
- F. Meunier, Brussels (BE)
- J.-Y. Pierga, Paris (FR)
- M. Tempero, San Francisco (US)

Scientific Audit Committee Report 2010

In April 2010, eight Groups were reviewed at the SAC meeting: Genito-Urinary Tract Cancer Group, Soft Tissue and Bone Sarcoma Group, Breast Cancer Group, Quality of Life Group, Head & Neck Cancer Group, Gastrointestinal Tract Cancer Group, Lung Cancer Group, and Children’s Leukemia Group (written report only).

Dr. Tannock presented an executive summary of the SAC committee deliberations and recommendations to the EORTC Board at its meeting in June 2010.
EORTC Quality Assurance Committee (QAC)

The primary objective of the QAC is to work closely with all quality assurance partners from the EORTC disease oriented groups and the EORTC Headquarters Quality Systems & Compliance Unit (QS&C) to ensure continuous improvement and development of forward thinking in relation to transversal quality strategies. It also stimulates transversal EORTC quality assurance initiatives such as for radiotherapy and surgery. The QAC assesses serious non-compliance issues and recommends actions, as appropriate, to comply with Good Clinical Practice and new directives/guidelines from Regulatory Authorities. For issues in which an allegation of scientific misconduct has been raised, the issues are directed to the QAC, and the follow up is coordinated by the QS&C and the QAC. The QAC reports these issues to the EORTC Board.

Members

Chair  K. Haustermans, Leuven (BE)
Secretary  C. Wyns, Brussels (BE)
L. Collette, Brussels (BE)
M. den Dulk, Leiden (NL)
L. Greillier, Marseille (FR)
D. Lacombe, Brussels (BE)
M. Leahy, Manchester (UK)
F. Meunier, Brussels (BE)
P. Poortmans, Tilburg (NL)
H. van Krieken, Nijmegen (NL)
C. Schuhmacher, Munich (DE)
L. Verleye, Utrecht (NL)
A permanent Independent Data Monitoring Committee (IDMC) was established in 2001 to review the status of EORTC clinical trials and make recommendations to the Groups concerning trial continuation, modification, and/or publication.

**Members**

**Chair**
R. Kaplan, Leeds (UK)

A. Awada, Brussels (BE)
M. Gnant, Vienna (A)
G. Griffiths, Cardiff (UK)
A. Horwich, Sutton (UK)
K. Pritchard, Toronto (CA)
P. Scalliet, Brussels (BE)
R. Sylvester, Brussels (BE) (*Ex officio* member)

In accordance with EORTC POL 004, external study specific experts provide advice to the committee on a confidential basis.

The committee meets on a quarterly basis or according to need. In 2009, seven different trials were reviewed.

IDMC review is mandatory for phase III trials where formal interim analyses and early stopping rules are foreseen and is recommended in the following situations:

- Intergroup trials coordinated by the EORTC;
- All trials requiring the randomization of more than 1000 patients or more than four years of patient accrual;
- Trials with highly toxic regimens or particular safety concerns;
- Trials encountering major strategic dilemmas (for instance, problematic issues arising from similar studies elsewhere);
- Pivotal phase III trials which will be used for drug registration;
- Randomized phase II trials that may be continued as a phase III trial without clear rules in the protocol.

The IDMC also reviews requests for the early release of data prior to trial maturity.

The Committee’s recommendations are forwarded to the trial management group and to the EORTC Executive Committee when further action is required.

In 2010, the EORTC Data and Safety Monitoring Board (DSMB) was formed as a subcommittee of the EORTC IDMC. Chaired by C. Twelves (Leeds, UK), the DSMB has early trials/drug development expertise and provides a separate review process, having no access to outcome data. It reviews safety problems identified by the EORTC HQ for which advice is sought, primarily for phase I and non-randomized phase II studies, but also as an initial step in phase III trials to advise if the study should then go to the full IDMC.

The EORTC policy for IDMCs and interim analyses is available on the EORTC website:
The Membership Committee (MC) was created and approved by the Board in November 2004. Since then, EORTC membership has been subject to a ‘location criterion’ restricting membership to ‘geographical Europe’ due to administrative and logistical complexity. This restriction was re-confirmed by the Board in 2009. However, centers from Mediterranean countries (e.g. Turkey, Israel, and Egypt) which had been members of the EORTC before the ‘location criterion’ was introduced may continue to be members of the EORTC under condition that they perform and provide support for any administrative, regulatory and logistical organization to EORTC Headquarters. However, new institutions located outside ‘geographical Europe’ which are not members of the EORTC are invited to collaborate in so-called ‘EORTC Intergroup studies’ (See EORTC POL 005). Intergroup studies are decided on a case by case basis according to the capabilities of the potentially collaborating groups, i.e., whether these groups contribute sufficiently to the studies by engaging a large number of centers with a significant number of patients.

Members

Chair
A.M.M. Eggermont, Villejuif (FR)

Secretary
A. Marinus, Brussels (BE)

T. Conroy, Vandoeuvre-Les-Nancy (FR)
T. de Witte, Nijmegen (NL)
J.W. Leer, Nijmegen (NL)
F. Meunier, Brussels (BE)
R. Mirimanoff, Lausanne (CH)
J. Vermorken, Edegem (BE)

New membership in the EORTC is organized in a centralized procedure:

Any new applicant (institution / member) must submit a membership application to the Membership Committee. The Membership Committee assesses the application in question according to the following criteria:

• track record of research of the institution / member;
• status of available medical facilities of the institution / member;
• availability of qualified personnel for clinical trial management of the institution / member;
• potential benefit for other EORTC institutions / members that the applying institution / member might provide.

Lastly, the Board confirms membership once yearly on the basis of a report issued by the Membership Committee in collaboration with the EORTC Chairs of the relevant EORTC Groups.

For any further information regarding membership, please contact the EORTC Membership Committee at the following address: Avenue Mounier 83/11, B-1200 Brussels
E-mail: membership@eortc.be
The Institutional Review Board (IRB) of the EORTC Headquarters is responsible for safeguarding the rights and welfare of subjects participating in clinical trials supported by the Headquarters. In particular, the IRB is responsible for protecting the privacy and confidentiality of the individuals’ data. The IRB is responsible for the validation of the document templates for informed consent and patient information sheets. All institutions and investigators submitting data to the Headquarters agree to abide by the decisions of the IRB regarding data collection, transfer, storage, release, retention, and disposition, as these pertain to individual patient privacy and confidentiality. The IRB also reviews potential conflicts of interest reported to the Headquarters. All electronic and computer programs/software and procedures are evaluated annually in order to comply with the international requirements for patient data protection.

In addition, the EORTC IRB oversees the clinical trials performed with the US cooperative groups / national cancer institutes under the Federal Wide Agreement (FWA).

**Members**

**Chair**  
A. Negrouk, Brussels (BE)

J. Geissler, Riemerling (DE)  
F. Crawley, Leuven (BE)  
F. Wells, Ipswich (UK)  
J. Otten, Brussels (BE)  
P. Ruyskart, Brussels (BE)  
C. Fortpied, Brussels (BE)  
C. Wyns, Brussels (BE)
EORTC Policies

The full text of all EORTC Policies is available on the EORTC website, www.eortc.be, in the policies section.

• Conflict of Interest - Confidentiality
  Define areas of conflict of interest and identifies when disclosure should be provided (to eventually place limitations on investigators’ participation in EORTC activities).

• Protection of Human Subjects Participating in Medical Research
  Ensures the respect of the rights and the integrity of human subjects participating in EORTC trials.

• Trial Misconduct and Fraud
  Minimize the effects of clinical trial fraud and misconduct and if possible prevent them from occurring.

• Independent Data Monitoring Committee and Interim Analyses
  Describes the EORTC policy for the use of IDMC in randomized phase II and randomized phase III clinical trials.

• Intergroup Trials Involving Non-EORTC Group
  Outlines the EORTC policy on intergroup trials in order to facilitate intergroup collaboration.

• Criteria and Guidelines for Giving the EORTC Label to Scientific Meetings
  The EORTC name may be used only with the approval of the EORTC Executive Committee via the Director General. The document describes the applications, the EORTC support, and the contractual obligations of the applicant / organizer.

• Scientific Audit Committee
  It describes the responsibilities of the Scientific Audit Committee (SAC) and the process of EORTC group review.

• Release of Data from EORTC Studies for Use in External Research Projects
  It defines the terms and conditions under which individual data from all or a subset of the patients treated within EORTC protocols may be released to academic institutions for the purpose of scientific research projects.

• Disclosure of Results and Publication Policy
  It describes the EORTC policy regarding the primary trial publication with respect to the timing of the release of results and publication in a peer-reviewed journal, the authorship rules, the rules for acknowledging contributors to the study and sources of funding, and the review process within EORTC Headquarters.

• Accrual Accounting in Intergroup Trials
  Describes how patient accrual within Intergroup trials involving an EORTC clinical group will be counted for EORTC membership.
• **EORTC Support to Intergroup Trials**
  Concerns only trials that are not conducted by industry and describes the framework of the EORTC support to Intergroup trials.

• **New Drug Advisory Committee (NDAC)**
  Committee which supports and gives recommendations to the clinical research groups in new drug development within the EORTC Network.

• **Translational Research Advisory Committee (TRAC)**
  Describes the role and missions of the TRAC.

• **EORTC Protocol Submission, Selection and Development Procedures**
  Describes the procedure implemented by the EORTC Board to select studies that will be supported by EORTC.

• **EORTC Principles for Investigational Sites Activation**
  Describes the principles for investigational site participation to EORTC studies.

• **EORTC Guidelines on Cancer Care**
  EORTC Policy for Producing EORTC Guidelines/Expert Opinions/Promotional Material on Cancer Care.

• **EORTC Policy on the Collection, Storage and Use of Biological Materials**
  Outlines the general principles of biological material collection, storage and use as part of EORTC clinical studies.
The EORTC is an international association under Belgian law. The registered office of the EORTC is 83 Av. E. Mounier, B-1200 Brussels, Belgium.

EORTC is the legal sponsor for the majority of the trials run under its auspices, except in US, Canada, and Australia where trials are performed in collaboration with other partners.

The EORTC insurance program, established in 1993, covers all patients entered into EORTC studies and for which the EORTC is the sponsor/promoter.

For Intergroup trials lead by non-EORTC groups, sponsorship issue is discussed on a case by case basis taking into account applicable legislation. For fully industry supported trials, usually industry is the sponsor.

In order to fulfill the sponsor’s legal obligations and to guarantee compliance with applicable national laws, the Regulatory Affairs Unit at the EORTC Headquarters keeps its legal expertise up to date in more than 30 countries in Europe and other countries.

The EORTC also plays a major role both at the European and national levels to alert regulators to the need for independent clinical research conducted without commercial aims.

**Ethical Aspects and Informed Consent/Insurance**

All EORTC protocols are written and conducted in accordance with international standards for ethics: the Declaration of Helsinki, Good Clinical Practice guidelines approved by the International Conference on Harmonization. A standard chapter on Ethical Considerations is included in all EORTC protocols.

In accordance with local, regional, and national requirements, written approval from competent ethics committees must be obtained before an institution is given the authorization to register or randomize a patient into a study. Standard guidelines for obtaining informed consent from patients entered in EORTC protocols have been developed. Investigators must obtain a dated and signed consent form from each patient.

All internal and external people involved in clinical activities need to comply with EORTC policies and procedures. More specifically, investigators and Board members must sign a conflict of interest statement.
Although development of new and innovative therapies is critical for improving cancer care, the primary interests of the EORTC remain with clinical trials that investigate strategic therapeutic questions that will influence medical practice or will fundamentally improve the understanding of a disease.

The EORTC has built an important part of its success on the multidisciplinary approach to cancer treatment, and this remains the principal strength of the EORTC. However, the present-day multidisciplinary approach to research into cancers and their treatment in the clinic also encompasses pathologists, imaging specialists, and laboratory scientists through translational research programs that must be integrated into clinical trials. Hence translational research is an essential component of the EORTC Scientific Strategy, and it contributes to the ability to distinguish between a ‘simple’ trial and high quality academically driven studies.

Clinical Trials

The EORTC Scientific Strategy is defined by the EORTC Board and encompasses the following types of clinical trials:

- Large phase III academic trials aimed at changing the standard of care;
- Clinical trials with a strong and methodologically sound translational research component;
- Clinical trials addressing rare tumor types;
- Clinical trials optimizing integration of new agents in therapeutic strategies.

For the EORTC Executive Committee to determine the level of importance of each new trial proposal within the global strategy of the EORTC, for the EORTC Board to assign priorities when there is a competitive process for resources and/or funding, and for the EORTC Scientific Audit Committee (SAC) to review the global performance of each EORTC Group, three main trial categories have been defined within the priorities of the EORTC. Category 1A represents the highest priority for EORTC involvement and category 3C the lowest. The categories are defined as follows:

- 1A: Randomized Phase III (new standard of care)
- 1B: Randomized Phase III or II/III (strong targeted translational research)
- 1C: Intergroup type 1A or 1B (EORTC not leading)
- 2: Phase I and Phase II (novel mechanism of action plus vertical development with EORTC)
- 3A: Randomized Phase III or II/III (not type 1 or 2)
- 3B: Phase I and Phase II (novel mechanism of action but no development plan with EORTC)
- 3C: Phase I and Phase II (not type 2 or 3B)
The EORTC Board launched the Network of Core Institutions (NOCI) to promote and support high quality translational research-driven clinical trials and to promote cooperation between the Translational Research and the Clinical Research Divisions as well as among the various EORTC disease oriented Groups.

The principal goal of NOCI is to conduct the most challenging clinico-genomic studies and transfer discoveries of molecular markers and genomic signatures to new medicines and tailored therapies.

NOCI is a concept that optimizes and builds on the strengths and expertise of the traditional disease oriented Groups as well as of the EORTC laboratory networks. NOCI allows optimization of the scientific contribution of EORTC Groups while enhancing the knowledge and the know-how to build sophisticated clinical trial platforms. With this approach, the individual visibility and activities of the EORTC disease oriented Groups are maintained.

The expected benefits of the NOCI concept are multifold:

- The challenges of tailored treatment require new trial design and methodology to optimize testing of treatments that may only benefit small molecularly defined subsets of the global population while also mandating rigorous biomarker validation and uniform testing. The NOCI network was created to meet these challenges in the rapidly evolving environment of cancer clinical trials. NOCI offers a unique and single EORTC platform to address specific pathways and targets across tumor types. It ensures a comprehensive approach to a certain target with multiple therapeutic applications.

- NOCI facilitates prospective tissue collection with the final objective being the establishment of bio-banks and the uniform collection of high quality samples on a routine basis. NOCI is therefore a key feature to retrospectively address emerging challenges with access to comprehensive clinical databases and related biological data.

NOCI consists of a network of institutions brought together for their potential to provide the EORTC with a pan-European comprehensive laboratory / imaging infrastructure as well as high accrual of patients. It will fulfill this purpose for any initiative requiring such expertise while remaining an open network. NOCI as a concept is applicable throughout the EORTC Group networks which actually constitute and benefit from the expertise of NOCI.

The NOCI institutions have been invited to sign a specific consortium agreement which regulates storage and access of biological material collected within the scope of EORTC NOCI trials. This is justified by the current regulatory environment and is put in place to facilitate and promote access to such biological materials for future scientific projects.

The NOCI Steering Committee is led by Martine Piccart, EORTC past President.
EORTC Fellowship Program

EORTC Fellows
(from left to right)
Erik Tanis, Alysa Fairchild, Zouheir Snouber, Francisco Bautista, Gloria Tridello,
Gustavo Werutsky, Julie Lorent, Camilo Moulin
An EORTC Fellowship Program was established in 1991 to promote European clinical research by encouraging physicians and scientists from all over the world to stay for up to three years as research fellows at EORTC Headquarters in Brussels. Medical doctors, bio-statisticians, and other scientists are entitled to this fellowship program which is specifically linked to the EORTC Groups, research program, or specific research projects undertaken by EORTC Headquarters.

At EORTC Headquarters, research fellowships have been awarded to 116 fellows from various countries within the European Union as well as from Argentina, Australia, Brazil, Canada, Morocco, Japan, the Republic of South Korea, Zimbabwe, as well as from Central and Eastern Europe.

The purpose of the fellowship program is to provide training in the methodology of clinical research for physicians and other professionals interested in cancer clinical research to complete a research project and/or PhD thesis based on data available in the EORTC databases. All research work undertaken is performed internationally. This approach also promotes the rapid diffusion of results of clinical trials.

Scientific support is provided by EORTC Headquarters staff, and supervision is provided by both EORTC Headquarters as well as members of the EORTC disease/specialty-oriented groups.

Support for this Fellowship Program was obtained from several sources including the Vlaamse Liga tegen Kanker, the TRANSBIG Traineeship, the Dutch Konijin Wilhelmina Fonds, the Pfizer Foundation, and EORTC Headquarters. This funding program is coordinated by the EORTC Charitable Trust.

In addition to support from the EORTC, fellowships for medical doctors are also provided by the Fonds Cancer / FOCA (Belgium).

The Emmanuel van der Schueren Fellowship was created in 1999 in memory of Professor Emmanuel van der Schueren. This fellowship aims to promote research on quality assurance in radiotherapy. The first Emmanuel van der Schueren Fellowship was awarded in 2001 and was jointly supported for one year by the ‘Vlaamse Liga tegen Kanker’, FECS (ECCO), ESTRO and EORTC. Currently, this program is supported by the Vlaamse Liga tegen Kanker and the EORTC.

Further information on the Fellowship Program can be found on the EORTC website:

www.eortc.be/jobs/documents/FellowshipProgram.hrm
# The EORTC Headquarters Fellowship Program

## 1991 – 2011

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<th>Name</th>
<th>Country</th>
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<td>Pascal Piedbois, MD</td>
<td>France</td>
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<td>Ann Marie Ptaszynski, MD</td>
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<td>Sabrina Pocceschi, JD</td>
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<td>Patrick Therasse, MD</td>
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<td>Magdalena Bielska-Lasota, MD</td>
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<td>Said Serbouti, MS</td>
<td>France</td>
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<td>Ivana Teodorovic, MD</td>
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<td>Adam Pawinski, MD</td>
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<td>Cristina Oliva, MD</td>
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<td>Anne Magotteaux, MD</td>
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<td>Koen Torfs, MS</td>
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<td>Elke Bahner, MD</td>
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<td>Desmond Curran, MS</td>
<td>Ireland</td>
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<td>Channa Debruyne, MD</td>
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<td>Petra J. Timmers, MD</td>
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<td>Jan Bussels, MS</td>
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<td>Michèle van der Heyden, MS</td>
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<td>Sandra Kalman, MS</td>
<td>Australia</td>
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<td>Fatma Ataman, MD</td>
<td>Turkey</td>
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<td>Koen Peeters, MD</td>
<td>The Netherlands</td>
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<tr>
<td>Jeremie Lebrec, MS</td>
<td>France</td>
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<td>Elçin Ozalp, MD</td>
<td>Turkey</td>
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<td>Iske Florien Van Luijk, MD</td>
<td>The Netherlands</td>
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<td>Fabio Efficace, PhD</td>
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<td>Saidi Abdessamad, PhD</td>
<td>Morocco</td>
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<td>Takuhiro Yamaguchi, PhD</td>
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<td>Julie Francart, MS</td>
<td>Belgium</td>
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<td>Hwan-Jung Yun, MD</td>
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<td>Maria Karina, MD</td>
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<td>Murielle Mauer, PhD</td>
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<td>Brazil</td>
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<td>Diane Van Vyve JD</td>
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<td>Tom Budiharto, MD</td>
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<td>Carolina Claassens, MSc</td>
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<td>Monia Ouali, MSc</td>
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<td>Leen Verleye, MD</td>
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<td>Oscar Matzinger, MD</td>
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<td>Francesca Martinelli, MSc</td>
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<td>Athanasios Pallis, MD</td>
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<td>John Maringwa, MSc</td>
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<td>Paul Fenton, MD</td>
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<td>Jurgen Vercauteren, MSc</td>
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<td>Alysa Fairchild, MD</td>
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<tr>
<td>Erik Tanis, MD</td>
<td>The Netherlands</td>
<td>2010 -</td>
</tr>
<tr>
<td>Diego Gomes Candido Reis, MD</td>
<td>Brazil</td>
<td>2011 -</td>
</tr>
<tr>
<td>Francesco Bautista Sirvent, MD</td>
<td>Spain</td>
<td>2011 -</td>
</tr>
</tbody>
</table>
The EORTC Lady Grierson Research Fellowship Program

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingvar Rosendahl, BA</td>
<td>Sweden</td>
<td>1996 - 1997</td>
</tr>
<tr>
<td>Jocelyn Kramer, MD</td>
<td>United Kingdom</td>
<td>1999 - 2000</td>
</tr>
<tr>
<td>Fabio Efficace, PHD</td>
<td>Italy</td>
<td>2001 - 2002</td>
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The Emmanuel Van Der Schueren Fellowship Program

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
<th>Years</th>
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<tbody>
<tr>
<td>Vassilios Kouloulias, MD, PhD</td>
<td>Greece</td>
<td>2001 - 2002</td>
</tr>
<tr>
<td>Fatma Ataman, MD</td>
<td>Turkey</td>
<td>2002 - 2004</td>
</tr>
<tr>
<td>Elena Musat, MD</td>
<td>Romania</td>
<td>2004 - 2005</td>
</tr>
<tr>
<td>Tom Budiharto, MD</td>
<td>Belgium</td>
<td>2006 - 2007</td>
</tr>
<tr>
<td>Oscar Matzinger, MD</td>
<td>Switzerland</td>
<td>2008 - 2009</td>
</tr>
<tr>
<td>Paul Fenton, MD</td>
<td>United Kingdom</td>
<td>2009 - 2010</td>
</tr>
<tr>
<td>Alysa Fairchild, MD</td>
<td>Canada</td>
<td>2010 -</td>
</tr>
</tbody>
</table>

EORTC Fellowship in 2009 - 2010

Nine medical fellows worked on their programs at the EORTC Headquarters in the following fields: quality assurance in radiotherapy (granted by the Vlaamse Liga tegen Kanker / Emmanuel van der Schueren Fellowship) and general methodology of cancer clinical trials (brain, breast, children’s leukemia, gastro-intestinal, gynecological, leukemia, lung, and sarcoma).

Five statisticians (from Belgium, France, Italy and Zimbabwe) also came to EORTC Headquarters to specialize in the field of cancer clinical trials statistics (brain, breast, gastro-intestinal, and head and neck) and to work within the EORTC Quality of Life Department on the PROBE (Patient Reported Outcomes and Behavioral Evidence) research project.

Two health scientists (from Canada and Hungary) worked on research projects on quality of life in cancer patients.
EORTC Involvement with the European Commission and the European Medicines Agency

Core support is crucial in the field of clinical research in oncology to pursue a strong European-wide effort with a view towards establishing state-of-the-art treatment strategies on an independent basis so as to rapidly improve cancer care in Europe. Significant progress will only result from international cooperation. The coordinating structure of the EORTC can be regarded as vital to harmonizing and conducting high-quality clinical and translational cancer research in Europe. As such, the EORTC deserves recognition and support at a European level as a true and established research infrastructure contributing both to EU research efforts to build a European Research Area and to the improvement of cancer management.

The EORTC does not receive any core support from the European Union.

The EORTC has a long-standing history of participation in European Commission (EC) funded projects in the framework of the European Union (EU) research activities. Since 1985, the EORTC has participated in more than 30 research projects funded by the European Commission in various cancer related fields including quality of life assessment, leukemia research, supportive care, telematics, biological response modifiers, pharmacokinetics, treatment costs evaluation, meta-analyses of cancer clinical studies, biomarkers, genomics, tissues banking, fellowships, and research infrastructures.

The EORTC created the EU Program Office (EUPO) for supporting and optimizing the EORTC participation in European institutional activities as well as to raise the visibility of the EORTC within the European arena. The EUPO mission is mainly to support the preparation of proposals for EU projects and to coordinate and support EORTC participation in EU funded projects.

The EORTC participation in FP6 and FP7 extends to different types of projects such as the FP6 TRANSBIG [Translating molecular knowledge into early breast cancer management building on the BIG (Breast International Group) network for improved treatment tailoring]. The objective of the project is the validation of a genomic signature to profile early breast cancer patients and then adapt the treatment accordingly. The clinical trial that is being conducted to validate the signature, the EORTC 10041 MINDACT trial, is managed by the EORTC and involves the EORTC Breast Cancer Group. The EORTC also participates in the FP6 CHEMORES project (Molecular mechanisms underlying chemotherapy resistance, therapeutic escape, efficacy and toxicity).

Participation in FP7 involves the ECRIN-PPI (European Clinical Research Infrastructures network and biotherapy facilities: preparation phase for the infrastructure); FP7 ICREL (Impact in clinical research of European legislation); FP7 EuroCancerComs (Establishing an efficient network for cancer communication in Europe) and the Innovative Medicine Initiative (IMI) project PharmaTrain (Pharmaceutical Medicine Training Programs). The EORTC is participating in the BBMRI project (Biobanking and Biomolecular Resources Research Infrastructure: preparation phase for the infrastructure) as an associated organization.
The EORTC is participating in several recently approved FP7 projects which began in 2010: the Network of Excellence EurocanPlatform (A European Platform for Translational Cancer Research); Euro-BioImaging (European Biomedical Imaging Infrastructure), the preparatory phase of an ESFRI Research infrastructure. The EORTC is coordinating the recently approved IMI project QUIC-CONCEPT (Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy).

The EORTC also works in close collaboration with the European Medicines Agency (EMA). The EORTC/EMA collaboration focuses on improving the legislation related to drug development through revising the guidelines for anticancer therapy drug development.

The European Directive 2001/20/EC on Clinical trials was implemented in 2004 by the Member States. Since the development of this new directive, the EORTC has been interacting with both European and national authorities to address specific issues related to the implementation of the Directive in the context of non-commercial research. As academic sponsor of international clinical trials, the EORTC is at the forefront of the multi-stakeholder discussions for improving the regulatory and legal environment but also the funding perspectives for independent clinical research in Europe.
The National Cancer Institute (NCI) is the leading US agency for cancer research and treatment in the United States and is part of the National Institutes of Health (NIH). The NCI was established by the US Congress in 1937 and its programs were intensified in 1971 after passage of the National Cancer Act. The vast majority of NCI funds (80%) go to grants and contracts to universities, medical schools, cancer centers, research laboratories, and private firms. The NCI supports scientists all over the world in a broad spectrum of research activities.

European-NCI Collaborative Activities

A history of more than three decades of coordinated cancer treatment research between the EORTC and the NCI has brought great opportunities for more efficient development of new cancer therapeutics.

As part of the NCI’s global strategy, the NCI Liaison Office in Brussels was created in 1972 to search for potential new anticancer substances from European sources. The Office expanded quickly and has been pivotal in moving Europe and North America closer to a common linked network.

A European Collaborative Program initiated with the EORTC in the early 1970’s continues to be highly successful in promoting the exchange of information on new drugs for both pre-clinical and clinical evaluation. The compound acquisition, selection, screening, formulation, toxicology, and the clinical evaluation are now well integrated between Europe and the USA. Much of this success in new drug development has been facilitated by the close working relationship between the NCI, the EORTC, and the British Cancer Research United Kingdom (CRUK) in London.

European Collaborative Agreements

Collaborative Agreements signed between the NCI, EORTC, and CRUK define the role of each organization in the clinical development of new anticancer drugs. This expanded international collaboration also includes the exchange of information and new drug candidates of mutual interest at all stages of pre-clinical and clinical evaluation.

High priority drug candidates may, by mutual agreement, be assigned to any appropriate CRUK, EORTC, SENDO or NCI laboratory or clinic that can help with or carry out a necessary step in the development of the agent. Drugs are now developed in such a way that they may enter clinical trials on either side of the Atlantic. Initial clinical trials are conducted according to mutually-agreed protocols and in compliance with appropriate standards for the testing of experimental agents, so as to facilitate...
the acceptability of data by the appropriate regulatory authorities. Based on the current state-of-the-art, joint guidelines on pre-clinical toxicology are made available and updated as necessary.

In 2004, the NCI developed new regulatory guidelines with the Cancer Therapy Evaluation Program (CTEP) on the conduct, development and analysis of clinical trials with international collaborating institutions. Multiple joint protocols involving EORTC and NCI-sponsored Cooperative Groups are currently in progress. EORTC and NCI staffs are working closely to harmonize pharmacovigilance, data collection, and quality assurance.

The NCI Liaison Office (NCILO)

The NCI Liaison Office (NCILO) in Brussels, Belgium, situated adjacent to EORTC Headquarters, is part of the Office of International Affairs, NCI, and is an integral part of the NCI. Its role is to act as a European-based link to NCI cancer research and treatment programs in the United States. It facilitates the interchange of information, ideas, experimental drugs, scientific expertise, and scientists between Europe and the US NCI. It works in collaboration with the EORTC and CRUK as well as with other European cancer research institutes and pharmaceutical/chemical industries. Its role is to help create a network of cancer experts and cancer centers between Europe and the US NCI which work towards a common goal, to enable rapid progress in cancer research on an international scale.

The Office also assists other NCI divisions and programs with their European activities. Furthermore, it collects European cancer research protocols for the NCI International Cancer Research Data Bank Branch, Office of Communications and Education, NCI, for inclusion in NCI’s clinical database PDQ (Physician Data Query/Cancer Net ®). PDQ is a database which contains information on cancer treatment research. PDQ allows investigators to have access to both ongoing US and European protocols. In addition to the clinical studies under EORTC auspices, the inclusion of investigational protocols was extended to national groups in the early 1990s. These include protocols from e.g. CRUK, MRC, SCTN and SIOP from the UK, NKB from the Netherlands, SAKK from Switzerland, the German Cancer Society, FNCLCC from France, and from many other national groups. The NCI Liaison office actively seeks new European groups with an interest to submit their research protocols to PDQ.

The clinical trials database may be accessed via http://www.cancer.gov.

NCI Liaison Office and the International Network for Cancer Treatment and Research (INCTR)

The NCI LO collaborates with the International Network for Cancer Research and Treatment (INCTR), a unique organization dedicated to helping patients in developing countries, which is also located in Brussels and partially supported by the NCI’s Office of International Affairs.
**Telesynergy® Medical Consultation Workstation**

The NCI Liaison Office is the European hub for NCI’s TELESYNERGY® Medical Consultation WorkStation. The Telesynergy® Workstation allows numerous research collaborators at greatly separated geographic sites to interact as if they were in the same room, viewing the same medical images. By integrating powerful telecommunications technology into healthcare research and delivery, telemedicine enables clinical researchers to simultaneously communicate and view and manipulate data necessary for collaborations, including patient diagnosis and care, such as x-ray films and pathology samples. The telemedicine system has high quality, multi-site teleconferencing capabilities, and is also capable of transmitting most types of diagnostic-quality medical images and information from several different sources, such as a microscope, a patient examination camera, document camera, color video printer, DVD player/recorder, and PC applications.

By making the knowledge and experience of oncology experts accessible regardless of where in the world those experts are, TELESYNERGY® has the potential to dramatically accelerate cancer research and improve cancer care by facilitating unique collaborations and connections.

Amongst other collaborators, the European School of Oncology (ESO) makes regular use of the system for their live webcasts/e-grandrounds.

The TELESYNERGY® Workstation is available at very low cost to outside collaborators. Interested parties are welcome to use it.

For further information please feel free to contact the NCI Liaison Office
83 Av. E. Mounier, 1200 Brussels, Belgium
Phone: +32/2/772.22.17 – Fax: +32/2/770.47.54 – E-mail: NCILO@eortc.be
Website: [http://ncilobrussels.cancer.gov](http://ncilobrussels.cancer.gov)
Editor in Chief: John Smyth (until January 2011)  Alexander M.M. Eggermont (as of January 2011)

The European Journal of Cancer (EJC) is a truly multidisciplinary publication that seeks to publish papers of interest to the entire community involved in cancer research and its management. 2010 has been the busiest year on record for EJC with more than 2000 manuscripts submitted, and, given the high quality of many of these submissions, it is a challenge for the editors that they can only accept approximately 20%, but this in turn reflects on the quality of the journal. The editorial and publishing times continue to be extremely competitive with submission to a reviewer invitation averaging less than nine days and indeed submission to an editorial decision in 18 days - even for disappointed authors a clear decision within three weeks of submission is helpful! In 2010 we published Volume 46 which included 18 issues, where all accepted articles appeared as Articles in Press, on-line on Science Direct within six weeks of acceptance. At this stage articles are also made available on Pubmed increasing their visibility within the community. All articles were published in print within five months of acceptance in 2010. Our readership is now largely on-line, and there are approximately one million articles downloaded from Science Direct per year. The geographical distribution of usage is illustrated in the table below, showing as expected predominance from Western Europe but a significant readership from North America and Asia.

Geographical Distribution of Online Usage 2009

<table>
<thead>
<tr>
<th>Region</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Western Europe</td>
<td>41%</td>
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<td>North America</td>
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<td>Asia</td>
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<td>Australasia</td>
<td>4%</td>
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<tr>
<td>South America</td>
<td>2%</td>
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<tr>
<td>Middle East</td>
<td>3%</td>
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<tr>
<td>Eastern Europe</td>
<td>2%</td>
</tr>
<tr>
<td>Mid-America</td>
<td>0%</td>
</tr>
</tbody>
</table>

Analysis of the most popular articles either by downloads or those highly cited reveal a clear spread across the different disciplines of clinical research, translational research, epidemiology, and basic science. Two Special Issues published in 2010 have attracted particular interest: 46 (7) entitled “Stopping cancer in its tracks: Metastasis as a therapeutic target” was edited by P S Steeg and J Sleeman. The reviews highlight cancer metastasis as a target for new therapies emphasizing the progress in translating basic scientific knowledge to practical clinical managements. The second Special Issue published, 46 (14) entitled “Implementing cancer prevention in Europe” was edited by Jan Willem...
Coebergh and colleagues and highlights the fact that although mortality from cancer is decreasing in the European Union, its incidence is continuing to increase. The current economic crisis threatens to affect cancer incidence in many ways and cancer prevention strategies will become ever more important. This issue places special emphasis on the need to strengthen cancer prevention using a holistic and global approach, focusing on the biggest risk factors of smoking, obesity, alcohol and physical inactivity.

EJC is the official journal of the EORTC, ECCO, EACR and EUSOMA.

The editors of EJC are most grateful for the contribution in particular from members of EORTC both for the submission of original research and for their help in reviewing the very many papers submitted.

All correspondence and manuscript submissions should be addressed to:

The Editorial Office, European Journal of Cancer
Elsevier Science, The Boulevard
Langford Lane, Kidlington
Oxford, OX5 1GB
United Kingdom
Tel: +44 (0)1865 843282 - Fax: +44 (0)1865 84 39 77

Administrative Editor: Suzanne Peedell:
E-mail: ejcancer@elsevier.com
2. The EORTC Network
### EORTC Groups and Task Forces

<table>
<thead>
<tr>
<th>GROUP</th>
<th>CHAIR</th>
<th>SECRETARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain Tumor</td>
<td>W.WICK Heidelberg (DE)</td>
<td>E. BAUMERT Maastricht (NL)</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>T. CUFER Golnik (SL)</td>
<td>D. CAMERON Edinburgh (UK)</td>
</tr>
<tr>
<td>Children’s Leukemia</td>
<td>Y. BENOIT Gene (BE)</td>
<td>Y. BERTRAND Lyon (FR)</td>
</tr>
<tr>
<td>Gastrointestinal Tract Cancer</td>
<td>A. ROTH Geneva (CH)</td>
<td>M. DUORELIX Villejuif (FR)</td>
</tr>
<tr>
<td>Genito-Urinary Cancers</td>
<td>*</td>
<td></td>
</tr>
<tr>
<td>Gynecological Cancer</td>
<td>A. CASADO HERRAEZ Madrid (ES)</td>
<td>D. KATSAROS Torino (IT)</td>
</tr>
<tr>
<td>Head and Neck Cancer</td>
<td>J.A. LANGE Nijmegen (NL)</td>
<td>R. KNECHT Hamburg (DE)</td>
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<tr>
<td>Imaging</td>
<td>S. STROOBA Nedge (BE)</td>
<td>U. NESTLE Freiburg (DE)</td>
</tr>
<tr>
<td>Infectious Diseases</td>
<td>P. DONNELLY Nijmegen (NL)</td>
<td>M. BASSETTI Genova (IT)</td>
</tr>
<tr>
<td>Leukemia</td>
<td>J-P. MARIE Paris (FR)</td>
<td>M. LUBBERT Freiburg (DE)</td>
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<td>Lung Cancer</td>
<td>M. O’BRIEN Sutton (UK)</td>
<td>V. SURMONT Gent (BE)</td>
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<td>Lymphoma</td>
<td>R. VAN DER MAAZEN Nijmegen (NL)</td>
<td>P. MEIJNDERS Antwerpen (BE)</td>
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<tr>
<td>Melanoma</td>
<td>P. PATEL Nottingham (UK)</td>
<td>D. SCHADEndorf Essen (DE)</td>
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<tr>
<td>Pharmacology and Molecular Mechanisms</td>
<td>G.J. PETERS Amsterdam (NL)</td>
<td>E. CHATELUT Toulouse (FR)</td>
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<td>PathoBiology</td>
<td>M.G. DAIDONE Milano (IT)</td>
<td>J. DITTMER Halle (DE)</td>
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<td>Quality of Life</td>
<td>G. VELIKOVA Leeds (UK)</td>
<td>F. EFFICACE, Roma (IT) S. SINGER, Leipzig (DE)</td>
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<td>Radiation Oncology</td>
<td>V. GREGOIRE Brussels (BE)</td>
<td>Ph. POORTEMANS Tilburg (NL)</td>
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<tr>
<td>Soft Tissue and Bone Sarcoma</td>
<td>P. HOBENBERGER Mannheim (DE)</td>
<td>A. GRONCHI Milano (IT)</td>
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<table>
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<tr>
<th>TASK FORCE</th>
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<tbody>
<tr>
<td>Cancer in the Elderly</td>
<td>H.WILDERS Leuven (BE)</td>
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<td>Cutaneous Lymphoma</td>
<td>M. BAGOT Paris (FR)</td>
<td>P.L. ORTIZ-ROMERO Madrid (ES)</td>
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<tr>
<td>Endocrine Tumors</td>
<td>M. SCHLUMBERGER Villejuif (FR)</td>
<td>To be appointed</td>
</tr>
</tbody>
</table>

* A team comprised of Dr A. Bex, Dr N. Clarke, Dr C. Sternberg and Dr B. Tombal is leading the Group *ad interim* until elections take place.
Total accrual of patients in EORTC clinical studies in 2000 – 2010: 67 003 patients

European Union: 60165 pts (89,8 %)
- Austria 800
- Belgium 6904
- Bulgaria 49
- Cyprus 73
- Czech Republic 153
- Denmark 502
- Estonia 7
- Finland 33
- France 13312
- Germany 5501
- Greece 48
- Hungary 192
- Italy 6203
- Latvia 34
- Luxemburg 9
- Malta 20
- Poland 1074
- Portugal 632
- Republic of Ireland 90
- Romania 20
- Slovak Republic 446
- Slovenia 295
- Spain 2582
- Sweden 593
- The Netherlands 14 286
- United Kingdom 6307

Non-EU Countries: 3187 pts (4,8 %)
- Bosnia 8
- Croatia 346
- Macedonia 6
- Norway 454
- Russia 141
- Serbia 261
- Switzerland 1336
- Turkey 631
- Ukraine 4

Rest of the World: 3651 pts (5.4%)

A number of EORTC trials are conducted in collaboration with other clinical cancer research groups in Europe and also on other continents. These groups provide a complementary portfolio of cancer clinical trials to the EORTC network and bring a valuable contribution to the recruitment within EORTC intergroup trials.
Number of new patients entered in EORTC Clinical Studies per country

<table>
<thead>
<tr>
<th>Country</th>
<th>2009</th>
<th>2010</th>
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<tr>
<td>Austria</td>
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<td>32</td>
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<tr>
<td>Belgium</td>
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<td>United Kingdom</td>
<td>366</td>
<td>382</td>
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<tr>
<td><strong>TOTAL EU</strong></td>
<td>6011 patients</td>
<td>6483 patients</td>
<td>60165 patients</td>
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<table>
<thead>
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<th>Non-EU Countries (9)</th>
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<tbody>
<tr>
<td>Bosnia</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Croatia</td>
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<tr>
<td>Macedonia</td>
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<tr>
<td>Norway</td>
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<td>Russia</td>
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<td>Serbia</td>
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<td>Ukraine</td>
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<tr>
<td><strong>TOTAL Non-EU</strong></td>
<td>161 patients</td>
<td>194 patients</td>
<td>3187 patients</td>
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<td>Country</td>
<td>Total 2000-2010</td>
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<td>Argentina</td>
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<tr>
<td><strong>TOTAL Rest of the World</strong></td>
<td><strong>3651 patients</strong></td>
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## Patient accrual by EORTC Groups

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<thead>
<tr>
<th>EORTC Group</th>
<th>2009</th>
<th>2010</th>
<th>Accrual 2000-2010</th>
</tr>
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<tr>
<td>EORTC Brain Tumor Group</td>
<td>631</td>
<td>856</td>
<td>3044</td>
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<tr>
<td>EORTC Breast Cancer Group</td>
<td>1758</td>
<td>1569</td>
<td>10829</td>
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<td>EORTC Children’s Leukemia Group</td>
<td>4</td>
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<td>1916</td>
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<tr>
<td>EORTC Cutaneous Lymphoma Task Force</td>
<td>7</td>
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<tr>
<td>EORTC Gastrointestinal Tract Cancer Group</td>
<td>120</td>
<td>140</td>
<td>2836</td>
</tr>
<tr>
<td>EORTC Genito-Urinary Tract Cancer Group</td>
<td>87</td>
<td>88</td>
<td>6003</td>
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<td>EORTC Gynecological Cancer Group</td>
<td>40</td>
<td>56</td>
<td>3089</td>
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<tr>
<td>EORTC Head and Neck Cancer Group</td>
<td>39</td>
<td>-</td>
<td>557</td>
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<tr>
<td>EORTC Infectious Diseases Group</td>
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<td>-</td>
<td>957</td>
</tr>
<tr>
<td>EORTC Leukemia Group</td>
<td>62</td>
<td>35</td>
<td>2642</td>
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<tr>
<td>EORTC Lung Cancer Group</td>
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<td>74</td>
<td>1982</td>
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<td>EORTC Lymphoma Group</td>
<td>147</td>
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<td>1808</td>
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<td>EORTC Melanoma Group</td>
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<td>4366</td>
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<td>EORTC Quality of Life Group</td>
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<td>1593</td>
</tr>
<tr>
<td>EORTC Radiation Oncology Group</td>
<td>890</td>
<td>997</td>
<td>8761</td>
</tr>
<tr>
<td>EORTC Soft Tissue and Bone Sarcoma Group</td>
<td>286</td>
<td>69</td>
<td>4070</td>
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</table>

Patients recruited into EORTC trials involving several EORTC groups are included in the totals of each group participating in those studies (i.e., patients in those studies are counted twice in the total reported here). Therefore, to view the total number of patients entered in all EORTC trials, please see the table on page 68.
Nowadays, many cancer research groups conduct clinical trials, and within this framework closer collaboration between research groups is essential to minimize the number of competitive trials and to accrue large numbers of patients in a minimum period of time. These collaborative clinical trials are called “Intergroup” trials.

In order to guarantee the quality of these trials and to facilitate their coordination and logistics, the EORTC has developed policies specific to this type of trials. These policies were made taking into account the legal requirements in Europe but also the policies of major cancer research groups outside Europe (such as NCI policies).

Following these policies, all groups within a trial use the same protocol, the same set of CRFs, and a central database which is the first guarantee for consistency of results.

A Steering Committee composed of representatives from all participating groups decides on the scientific content of the trial and possible future use made of the material, data, and results. The data from all collaborating groups are gathered at one headquarter for cleaning and analysis in order to provide a global view of the data (particularly the safety data) and a homogeneous update and validation process.

Apart from the centralization of data, the coordinating center (whether it be EORTC Headquarters or another independent data center) globally ensures the coordination of the trial logistics and legal aspects.

This coordinating role became essential within the new legal framework in the EU. The EU lead group shall, among other tasks, ensure that request of EudraCT number, completion of the clinical trial application form and the reporting to the EUDRAVIGILANCE database are taken care of centrally.

The responsibilities are discussed on a trial-by-trial basis and fixed through written agreements between different partners.

These policies have been applied by the EORTC for several years and have resulted in an important number of collaborations with many European and overseas cancer clinical research groups.

During 2009, there were a total of 21 ongoing intergroup trials of which 12 were coordinated by EORTC Headquarters; the remaining nine trials were coordinated by other data centers. Four trials were large transatlantic intergroups in collaboration with NCI collaborative groups.

In 2010, there were a total of 23 intergroup trials ongoing of which 14 were coordinated by EORTC Headquarters; four intergroup trials were closed to recruitment. More intergroup trials are in the development process.
## Contribution by non-EORTC groups to EORTC Trials in 2010

### >100 Patients Entered by the Groups
- Borstkanker Onderzoeksgroup Nederland
- Federation Nationale des Centres de Lutte contre le Cancer
- West German Study Group
- Grupo espanol de estudio, tratamiento y otras estrategias ex
- Arbeitsgemeinschaft Internistische Onkologie
- Groupe d’Etudes des Lymphomes de l’Adulte
- Industry
- Gruppo Oncologico Italiano Ricerca Clinica
- Intergruppo Italiano Linfomi

### 20<100 Patients Entered by the Groups
- Australasian Gastro-Intestinal Trials Group
- National Cancer Research Institute - Breast Cancer Group
- Medical Research Council
- Belgian Group of Digestive Oncology
- Radiation Therapy Oncology Group
- Gruppo Italiano Malattie Ematologiche dell’Adul
to
- Trans-Tasman Radiation Oncology Group Inc
- ALMANAC Trialists Group

### <20 Patients Entered by the Groups
- Cooperative Trials Group for Neuro-Oncology
- Federation Francophone de Cancerologie Digestive
- French Acute Lymphoblastic Leukemia
- National Cancer Institute of Canada-Clinical Trial Group
- SI_IOL
- Italian Sarcoma Group
- French Sarcoma Group
The EORTC has established criteria to grant recognition to Institutions/Departments actively participating in EORTC clinical trials. This list of Institutions/Departments is updated on a yearly basis. An Institution can either be granted recognition as an ‘EORTC Affiliated Institution’ or as an ‘EORTC Affiliated Department’.

The criteria used to merit that recognition are:

**EORTC Affiliated Institution:**
1. Recruitment of 75 patients over a period of three years with a minimum of 15 patients entered in EORTC clinical trials per year.
2. Participation in at least three EORTC Groups.

**EORTC Affiliated Department:**
1. Recruitment of 75 patients over a period of three years with a minimum of 15 patients entered in EORTC clinical trials per year.
2. Participation in less than three EORTC Groups.

### EORTC Affiliated Institutions per Country 2011 (Review period 2008-2010)

**European Union**
- Belgium: 7
- France: 6
- Germany: 1
- Poland: 1
- The Netherlands: 8
- United Kingdom: 2

**Non-EU countries**
- Switzerland: 1
Ranking of EORTC Affiliated Institutions in 2011 (Review period 2008-2010)

The following institutions have been recognized in 2011 as EORTC affiliated institutions based on their participation in EORTC studies over the last three years.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Institution</th>
<th>Country</th>
<th>Number of EORTC Groups</th>
<th>Accrual 2009</th>
<th>Accrual 2010</th>
<th>Accrual 2008-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Institut Curie, Paris &amp; Saint-Cloud</td>
<td>France</td>
<td>4</td>
<td>256</td>
<td>299</td>
<td>755</td>
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<tr>
<td>2</td>
<td>Institut Gustave Roussy, Villejuif</td>
<td>France</td>
<td>9</td>
<td>176</td>
<td>239</td>
<td>559</td>
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<tr>
<td>3</td>
<td>The Netherlands Cancer Institute-Antoni Van Leeuwenhoekzieke, Amsterdam</td>
<td>The Netherlands</td>
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<td>147</td>
<td>503</td>
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<td>Belgium</td>
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<td>118</td>
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<td>Clinique Sainte Elisabeth, Namur</td>
<td>Belgium</td>
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<td>135</td>
<td>111</td>
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<td>6</td>
<td>Centre Georges-Francois-Leclerc, Dijon</td>
<td>France</td>
<td>3</td>
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<td>UZ Leuven, Leuven</td>
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<td>Arnhem’s Radiotherapeutisch Instituut, Arnhem &amp; Harderwijk</td>
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<td>9</td>
<td>Leiden University Medical Centre, Leiden</td>
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<td>Institut Bergonie, Bordeaux</td>
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<td>73</td>
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<td>UZ Rotterdam, Rotterdam</td>
<td>The Netherlands</td>
<td>7</td>
<td>56</td>
<td>48</td>
<td>165</td>
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<td>12</td>
<td>Christie Hospital, Manchester</td>
<td>United Kingdom</td>
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<td>48</td>
<td>65</td>
<td>156</td>
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<tr>
<td>13</td>
<td>Centre Leon Berard, Lyon</td>
<td>France</td>
<td>7</td>
<td>40</td>
<td>63</td>
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<tr>
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<td>Radboud University Nijmegen Medical Centre, Nijmegen</td>
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<td>40</td>
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<tr>
<td>15</td>
<td>Cliniques Universitaires St. Luc, Brussels</td>
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<td>39</td>
<td>33</td>
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<td>16</td>
<td>Onze Lieve Vrouw Gasthuis, Amsterdam</td>
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<td>40</td>
<td>139</td>
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<tr>
<td>17</td>
<td>Medisch Centrum Haaglanden, Den Haag &amp; Leidschendam</td>
<td>The Netherlands</td>
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<td>48</td>
<td>48</td>
<td>135</td>
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<tr>
<td>18</td>
<td>Centre Hospitalier Universitaire Vaudois, Lausanne</td>
<td>Switzerland</td>
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<td>47</td>
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<td>19</td>
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<td>Rank</td>
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<td>Accrual 2010</td>
<td>Accrual 2008-2010</td>
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<tr>
<td>20</td>
<td>Hôpital De Jolimont, Haine St Paul, Belgium</td>
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<td>22</td>
<td>H. Hartzienhuis, Roeselare, Belgium</td>
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<td>23</td>
<td>Western General Hospital, Edinburgh</td>
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<td>24</td>
<td>Cliniques universitaires de Mont Godinne, Yvoir</td>
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<td>University Medical Center Groningen, Groningen,</td>
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**TOTAL Number of Patients** | 1948 | 1892 | 5473 |

## Ranking of EORTC Affiliated Departments in 2011

(Review period 2008-2010)

The following institutions have been recognized in 2011 as **EORTC affiliated departments** based on their participation in EORTC studies over the last three years.

<table>
<thead>
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<th>Institution</th>
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<th>Accrual 2009</th>
<th>Accrual 2010</th>
<th>Accrual 2008-2010</th>
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<tr>
<td>1</td>
<td>Centre Regional Francois Baclesse, Caen</td>
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<td>University of Dundee - Ninewells Hospital, Dundee, scotland</td>
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<td>Chu Pitie-Salpetriere AP-HP, Paris</td>
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**TOTAL Number of Patients** | 223 | 169 | 546 |
3. EORTC Current Research and Strategies

Updated Information on all ongoing EORTC Protocols is available on the EORTC Website

www.eortc.be/protoc/default.html

For all EORTC Protocols, patients can be randomized online at the EORTC Website
<table>
<thead>
<tr>
<th>Protocol</th>
<th>Title</th>
<th>Target accrual</th>
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</thead>
<tbody>
<tr>
<td>EORTC Brain Tumor Group</td>
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<td></td>
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<tr>
<td>26053 22054</td>
<td>Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial.</td>
<td>748</td>
</tr>
<tr>
<td>Brigitta Baumert, Maastro Clinic, Maastricht Radiation Oncology, Maastricht Martin J. van den Bent, Erasmus University Medical Center, Rotterdam</td>
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<td></td>
</tr>
<tr>
<td>26062 22061</td>
<td>A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients</td>
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</tr>
<tr>
<td>Alba Brandes, Ospedale Bellaria, Bologna</td>
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<tr>
<td>26071 22072</td>
<td>Cilengitide in subjects with newly diagnosed glioblastoma and methylated MGMT promoter gene- a multicenter, open-label, controlled Phase III study, testing cilengitide in combination with standard treatment (temozolomide with concomitant radiation therapy, followed by temozolomide maintenance therapy) versus standard treatment alone (CENTRIC)</td>
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<tr>
<td>Roger Stupp, Centre Hospitalier Universitaire Vaudois, Lausanne</td>
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<td></td>
</tr>
<tr>
<td>26081 22086</td>
<td>Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-deletions of 1p and 19q.</td>
<td>544</td>
</tr>
<tr>
<td>Martin J. van den Bent, Erasmus University Medical Center, Rotterdam Wolfgang Wick, UniversitaetsKlinikum Heidelberg, Kopfklinik, Heidelberg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26082 22081</td>
<td>Radiation therapy and concurrent plus adjuvant Temsirolimus (CCI-779) versus chemo-irradiation with temozolomide in newly diagnosed glioblastoma without methylation of the MGMT gene promoter - a randomized multicenter, open-label, Phase II study.</td>
<td>108</td>
</tr>
<tr>
<td>Wolfgang Wick, UniversitaetsKlinikum Heidelberg, Kopfklinik, Heidelberg</td>
<td></td>
<td></td>
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<tr>
<td>26083</td>
<td>Randomized phase II of Lomustine versus lomustine-dasatinib in patients with recurrent Glioblastoma</td>
<td>108</td>
</tr>
<tr>
<td>Alba Brandes, Ospedale Bellaria, Bologna</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol</td>
<td>Title</td>
<td>Target accrual</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>10031 IBCSG 24-02</td>
<td>A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer: tamoxifen versus ovarian function suppression + tamoxifen versus ovarian function suppression + exemestane (SOFT). Study Coordinator: Marc Debled, Institut Bergonie, Bordeaux</td>
<td>3000</td>
</tr>
<tr>
<td>10041 MINDACT</td>
<td>MINDACT (Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid Chemo Therapy): A prospective, randomized study comparing the 70-gene signature with the common clinicopathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes” Study Coordinators: Fatima Cardoso, Champalimaud Cancer Center, Lisboa Martine Piccart, Institut Jules Bordet, Brussels Emiel Rutgers, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam</td>
<td>6000</td>
</tr>
<tr>
<td>10054 LAPATAX</td>
<td>A phase I-II study of Lapatinib and Docetaxel as neoadjuvant treatment for locally advanced breast cancer. Study Coordinators: Herve Bonnefoi, Institut Bergonie, Bordeaux David Cameron, Western General Hospital, Edinburgh</td>
<td>114</td>
</tr>
<tr>
<td>10085 Male BC</td>
<td>Clinical and biological characterization of Male Breast Cancer: an international retrospective EORTC, BIG and NABCG intergroup study. Study Coordinator: Fatima Cardoso, Champalimaud Cancer Center, Lisboa</td>
<td>1800</td>
</tr>
<tr>
<td>58051 Interfant</td>
<td>International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia Study Coordinator: Alice Ferster, Hôpital Universitaire Des Enfants Reine Fabiola, Brussels</td>
<td>445</td>
</tr>
<tr>
<td>21081</td>
<td>A phase III study of lenalidomide maintenance after debulking with gemcitabine or liposomal doxorubicin +/- radiotherapy in patients with advanced cutaneous T-cell lymphoma not previously treated with intravenous chemotherapy Study Coordinator: Martine Bagot, Hôpital Saint-Louis AP-HP, Paris</td>
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<td>40054 22062</td>
<td>Preoperative chemoradiotherapy and postoperative chemotherapy with capecitabine and oxaplatin vs.capecitabine alone in locally advanced rectal cancer (PETACC-6). Study Coordinators: Karin Haustermans, U.Z. Gasthuisberg, Leuven Hans Joachim Schmoll, Martin Luther Universitaet, Halle</td>
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<td>40071</td>
<td>Effectiveness of first line treatment with lapatinib and ECF/X in histologically proven adenocarcinoma of the stomach or the esophagogastric junction, metastatic or not amenable to curative surgery according to HER2 and EGFR status: a randomized phase II trial. <strong>Study Coordinator:</strong> Arnaud Roth, Hopital Cantonal Universitaire De Geneve, Geneve</td>
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<td>30061</td>
<td>Phase I study of cisplatin, gemcitabine (+ paclitaxel) and lapatinib as first line treatment in advanced/metastatic urothelial cancer <strong>Study Coordinator:</strong> Gedske Daugaard, Rigshospitalet, Copenhagen</td>
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<td>30072</td>
<td>A Phase III Randomised Double-blind Study Comparing Sorafenib With Placebo In Patients With Resected Primary Renal Cell Carcinoma at High or Intermediate Risk of Relapse <strong>Study Coordinators:</strong> Steven Joniau, U.Z. Gasthuisberg, Leuven Peter Mulders, Radboud University Nijmegen Medical Centre, Nijmegen</td>
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<td>30073</td>
<td>Randomized Phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma. Axel Bex (Study Coordinator) - The Netherlands Cancer Institute-Antoni Van Leeuwenhoekzienhuis, Amsterdam <strong>Study Coordinator:</strong> John B.A.G. Haanen, The Netherlands Cancer Institute-Antoni Van Leeuwenhoekzienhuis, Amsterdam</td>
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<td>55994</td>
<td>Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO Ib2, Ila &gt; 4 cm or IIIb cervical cancer. <strong>Study Coordinators:</strong> Alessandro Colombo, Ospedale Alessandro Manzoni, Lecco Stefano Greggi, Istituto Nazionale Per Lo Studio E La Cura Dei Tumori, Napoli Gemma Kenter, Academisch Medisch Centrum, Amsterdam Fabio Landoni, Istituto Europeo Di Oncologia, Milano</td>
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<td>06031</td>
<td>Gemtuzumab ozogamicin (GO) monotherapy versus standard supportive care for previously untreated AML in elderly patients who are not eligible for intensive chemotherapy: a randomized phase II/III trial (AML-19) of the EORTC-LG and GIMEMA-ALWP. <strong>Study Coordinator:</strong> Sergio Amadori, Azienda Ospedallera Universitaria, Policlinico Tor Vergata, Roma</td>
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<td>06061 AML-14A</td>
<td>Clafarabine in combination with a standard remissioninduction regimen (AraC and idarubicin) in patients 18-60 years old with previously untreated intermediate and bad risk acute myelogenous leukemia (AML) or high risk myelodysplasia (MDS) : a phase I-II study of the EORTC-LG and GIMEMA (AML-14A trial)</td>
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<td>06071 RATIFY</td>
<td>A phase III randomized, Double-blind study of induction (Daunorubicin/Cytarabine) and consolidation (high- dose Cytarabine) chemotherapy + Midostaurin (PKC 412) (IND # TBD) or Placebo in newly diagnosed patients &lt;60 years of age with FLT3 mutated acute myeloid leukemia (AML)</td>
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<td><strong>EORTC Lung Cancer Group</strong></td>
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<td>08072 22074</td>
<td>Concurrent once-daily versus twice-daily radiotherapy : A 2-arm randomised controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status (CONVERT).</td>
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<td><strong>EORTC Lymphoma Group</strong></td>
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<td>20051 H10</td>
<td>The H10 EORTC/GE/LA/IIL randomized Intergroup trial on early FDG-PET scan guided treatment adaptation versus standard combined modality treatment in patients with supradiaphragmatic stage I/II Hodgkin’s lymphoma.</td>
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<td><strong>EORTC Melanoma Group</strong></td>
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<td>18021</td>
<td>Intravenous versus intra-arterial fotemustine chemotherapy in patients with liver metastases from uveal melanoma : a randomized phase III study of the EORTC Melanoma Group.</td>
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<tr>
<td>18071</td>
<td>Adjuvant immunotherapy with anti-CTLA-4 monoclonal antibody (ipilimumab) versus placebo after complete resection of high-risk Stage III melanoma : A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group.</td>
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<td>22042 26042</td>
<td>Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma : a Phase II and observation study</td>
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<td>22043 30041</td>
<td>Post-operative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus post-operative external radiotherapy alone in pathological stage pT3a-b R0-1/pT2R1 N0M0, Gleason score 5-10 prostatic carcinoma. A phase III study. <strong>Study Coordinators:</strong> Michel Bolla, Chr De Grenoble - La Tronche, Grenoble Hein Van Poppel, U.Z. Gasthuisberg, Leuven</td>
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<td>22051 10052</td>
<td>Selective Use of Postoperative Radiotherapy AftEr MastectOmy (SUPREMO) <strong>Study Coordinator:</strong> Geertjan Van Tienhoven, Academisch Medisch Centrum, Amsterdam</td>
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<td>22085 10083</td>
<td>A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast. <strong>Study Coordinator:</strong> Helen Westenberg, Arnhem ‘S Radiotherapeutisch Instituut, Arnhem</td>
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**EORTC Soft Tissue and Bone Sarcoma Group**

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<td>62063</td>
<td>A phase III randomized study evaluating surgery of residual disease in patients with metastatic gastro-intestinal stromal tumor responding to Imatinib mesylate. <strong>Study Coordinator:</strong> Alessandro Gronchi, Istituto Nazionale Per Lo Studio E La Cura Dei Tumori, Milano</td>
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### Intergroup Trials Coordinated by the EORTC as of January 2011

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<td><strong>EORTC Brain Tumor Group</strong></td>
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<tr>
<td>26053</td>
<td>Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial.</td>
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<td><strong>EORTC Breast Cancer Group</strong></td>
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<td>10041</td>
<td>MINDACT (Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid Chemo Therapy): A prospective, randomized study comparing the 70-gene signature with the common clinicopathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes”</td>
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<td>10085</td>
<td>Clinical and biological characterization of Male Breast Cancer: an international retrospective EORTC, BIG and NABCG intergroup study.</td>
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<td><strong>EORTC Gastrointestinal Tract Cancer Group</strong></td>
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<tr>
<td>40054</td>
<td>Preoperative chemoradiotherapy and postoperative chemotherapy with capecitabine and oxaplatin vs. capecitabine alone in locally advanced rectal cancer (PETACC-6).</td>
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<td>EORTC Genito-Urinary Tract Cancer Group</td>
<td>Randomized Phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma. Other participating Groups: Canadian Urologic Oncology Group Wales Cancer Trial Unit</td>
<td>458</td>
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<tr>
<td>EORTC Leukemia Group</td>
<td>Gemtuzumab ozogamicin (GO) monotherapy versus standard supportive care for previously untreated AML in elderly patients who are not eligible for intensive chemotherapy: a randomized phase II/III trial (AML-19) of the EORTC-LG and GIMEMA-ALWP. Other participating Group: Gruppo Italiano Malattie Ematologiche dell’Adul</td>
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<td>Clofarabine in combination with a standard remission induction regimen (AraC and idarubicin) in patients 18-60 years old with previously untreated intermediate and bad risk acute myelogenous leukemia (AML) or high risk myelodysplasia (MDS): a phase I-II study of the EORTC-LG and GIMEMA (AML-14A trial) Other participating Group: Gruppo Italiano Malattie Ematologiche dell’Adul</td>
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<td>EORTC Lymphoma Group</td>
<td>The H10 EORTC/GELA/IIL randomized Intergroup trial on early FDG-PET scan guided treatment adaptation versus standard combined modality treatment in patients with supradiaphragmatic stage I/II Hodgkin’s lymphoma. Other participating Groups: Groupe d’Etudes des Lymphomes de l’Adul Intergruppo Italiano Linfomi</td>
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## Intergroup Trials
### Not Coordinated by the EORTC as of January 2011

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<td><strong>EORTC Leukemia Group</strong></td>
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<td>06071</td>
<td>A phase III randomized, Double-blind study of induction (Daunorubicin/Cytarabine) and consolidation (high-dose Cytarabine) chemotherapy + Midostaurin (PKC 412) (IND # TBD) or Placebo in newly diagnosed patients &lt;60 years of age with FLT3 mutated acute myeloid leukemia (AML) Coordinating Group: Cancer and Leukemia Group B</td>
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<td><strong>EORTC Lung Cancer Group</strong></td>
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<td>08072</td>
<td>Concurrent once-daily versus twice-daily radiotherapy : A 2-arm randomised controlled trial of concurrent chemoradiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status (CONVERT). Coordinating Group: Christie’s Hospital</td>
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<td>10031</td>
<td>A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer tamoxifen versus ovarian function suppression + tamoxifen versus ovarian function suppression + exemestane (SOFT). Coordinating Group: International Breast Cancer Study Group</td>
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<td>10071</td>
<td>A randomised, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer Coordinating Group: Breast European Adjuvant Studies Team</td>
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<td>Selective Use of Postoperative Radiotherapy After Mastectomy (SUPREMO) Coordinating Group: Scottish Cancer Trials Breast Group</td>
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<td>22085</td>
<td>A randomized phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast. Coordinating Group: Trans-Tasman Radiation Oncology Group Inc</td>
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<td>26062</td>
<td>A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients Coordinating Group: National Cancer Institute of Canada-Clinical Trial Group</td>
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<td>Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-deletions of 1p and 19q Coordinating Group: North Central Cancer Treatment Group</td>
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<td>30072</td>
<td>A Phase III Randomised Double-blind Study Comparing Sorafenib With Placebo In Patients With Resected Primary Renal Cell Carcinoma at High or Intermediate Risk of Relapse</td>
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<td>58051</td>
<td>International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia</td>
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**EORTC Genito-Urinary Tract Cancer Group**

**EORTC Children’s Leukemia Group**
Reports from the EORTC Groups and Task Forces

For updated information on any EORTC Group or Task Force or to request information about the schedule of a Group or Task Force meeting, please consult the EORTC website at www.eortc.be/Groups/default.asp where all details will be posted.
Brain Tumor Group

Structure of the Group

Chair  W. Wick, Heidelberg (DE)
Secretary  B.G. Baumert, Maastricht (NL)
Treasurer  M. Sanson, Paris (FR)

Committee Chairs
Pathology  M. Kros, Rotterdam (NL)
Translational Research  M. Hegi, Lausanne (CH)
Quality Assurance  P. Hau, Regensburg (DE)
Imaging  M. Bendszus, Heidelberg (DE)
Young Oncologists  E. Franceschi, Bologna (IT)
  M. Preusser, Vienna (AT)

The primary aim of the Brain Tumor Group (BTG) is to conduct, develop, coordinate and stimulate clinical and translational research for the treatment of primary and secondary brain tumors. The BTG aims at a better understanding of the development of brain tumors and at the development of novel and more efficacious treatments to prolong the lives of brain tumor patients and to improve their quality of life.

Recent Achievements

The EORTC 22033/26033 phase III trial for the treatment of low grade gliomas has been completed. The data are maturing and a translational research project is in development.

The successful and rapid completion of the landmark study in newly diagnosed glioblastoma multiforme (GBM), the EORTC 26981/22981-NCIC CE.3 trial, proved the role of chemotherapy early in the course of the disease concomitant with radiotherapy (RT). The results, published in the New England Journal of Medicine, have led to the rapid worldwide adoption of this treatment scheme as the new standard of care. Provocative results from this study, identifying O6-methylguanyl-methyltransferase (MGMT) promoter methylation as a predictive molecular marker, are being validated in a large ongoing intergroup study (a collaboration of the North American Radiation Therapy Oncology Group [RTOG] and the EORTC). In a joint effort, 1,173 patients were accrued in just over two years (16% from the EORTC). After completion of concomitant temozolomide [TMZ] and RT, patients were randomized to either the standard dose TMZ or an intensified dose-dense regimen aimed at improving response by depleting MGMT in the tumor tissue. Molecular markers and in particular MGMT promoter methylation status will be assessed in all patients.
The objective is to prospectively validate MGMT as a predictive marker for choosing alkylating agent chemotherapy, a first step toward individualized treatments, and at testing strategies to overcome resistance mediated by this repair protein. This study marks the first successful collaboration between a US Cooperative Group and the BTG. It has set the stage for the now almost standard collaboration of North-American Cooperative Groups and EORTC for several other subtypes of glioma, allowing the investigation, in a randomized fashion, of those burning questions concerning the management of primary brain tumors. Furthermore, all these trials now include mandatory submission and review of tumor material and characterization with modern molecular methods. This is an important step towards individualizing future therapies.

The joint EORTC Radiation Oncology Group (ROG)/BTG study on the treatment of brain metastases has been completed with 359 patients accrued. Results were presented at ASCO 2009. After radiosurgery or surgery of 1-3 brain metastases, adjuvant whole brain radiation therapy (WBRT) reduces the frequency of intracranial relapses and neurologic deaths but fails to prolong the time period of functional independence and overall survival time.

The recently completed EORTC 26951 trial investigating adjuvant procarbazine/ lomustine/ vincristine (PCV) chemotherapy after RT in the more chemosensitive anaplastic oligodendroglioma (AOD) and oligoastrocytoma (AOA) did not show a statistically significant difference in survival, although progression free survival was prolonged. We concluded that chemotherapy has a clear role in this disease. However, the timing of administration, initially/adjuvant or at progression, is of lesser importance.

Analysis of the health related quality of life (HRQOL) data from the EORTC 26981 and 26951 trials showed that the addition of chemotherapy has only a limited and transient negative impact on HRQOL during and shortly following treatment. Not unexpectedly, TMZ had a less negative impact than PCV. Baseline HRQOL data demonstrated no additional prognostic significance compared to clinical data. Future studies should include longitudinal HRQOL measurements especially following radiological recurrence. From a patient perspective, time to clinical deterioration may be a more relevant endpoint than time to progression if this progression is still asymptomatic. To meet this requirement, the validation of novel and more clinical endpoints is required.

Novel drugs have been tested in a series of phase I and phase II studies in GBM and anaplastic glioma. Recent agents under investigation are lonafarnib, enzastaurin, and sagopilone. Erlotinib, an epidermal growth factor (EGFR) tyrosine kinase inhibitor [TKI], has been evaluated in a randomized phase II trial. In contrast to previous reports from the US of promising activity of this drug as a single agent in recurrent glioma, our trial did not show significant activity in recurrent GBM; the finding of a molecular profile associated with response to EGFR TKIs in US trials could not be confirmed in this trial. A phase I study of combined chemo-irradiation (TMZ/RT) adding the VEGFR TKI PTK 787 demonstrated feasibility and safety. Unfortunately, the drug manufacturer decided to discontinue development of this agent and the planned randomized phase II study was not started.
**Project / Strategies for the coming years**

Playing a major role in intergroup set ups and following the closed RTOG trial, the BTG is leading the CATNON trial which addresses the role of concurrent and adjuvant TMZ in non-1p/19q deleted anaplastic glioma. This study is performed in cooperation with RTOG, NCI Canada, NOA Germany, COGNO Australia, and MRC in the UK.

A NCCTG led Phase III Intergroup Study of RT versus TMZ alone versus RT with concomitant and adjuvant TMZ for patients with newly diagnosed AOD or anaplastic mixed glioma with chromosomal co-deletions of 1p and 19q (CODEL trial) is being activated.

The BTG is pursuing the development of neurocognitive testing in active trials such as the CATNON and the CODEL.

In the back to back program in the newly diagnosed setting of high grade glioma patients, we are investigating the integrin inhibitor cilengitide in combination with standard TMZ chemoradiation followed by adjuvant TMZ chemotherapy. In an uncontrolled phase II study improved outcome was suggested in particular in the subgroup of patients with a methylated MGMT gene promoter, thus more sensitive to TMZ chemotherapy. This trial is being conducted in a close and novel collaboration with the manufacturer, Merck-Serono, as an international effort led jointly by the EORTC and the Sponsor.

For patients without MGMT promoter methylation, the currently recruiting phase II EORTC 26082 trial explores the activity of temsirolimus (CCI-779) an inhibitor of the mammalian target of rapamycin (mTOR).

For patients with recurrent GBM, the BTG is now conducting a phase III study with dasatinib in combination with TMZ (EORTC 26083). Two protocols addressing bevacizumab are in development. The first one will study the role of bevacizumab in combination with TMZ in recurrent grade II or III gliomas (EORTC 26091). The second one will address the sequence and the combination of bevacizumab and lomustine in recurrent GBMs (EORTC 26101).

The study on RT hypofractionation with or without TMZ in elderly GBM patients (co-project leaded by NCIC) is recruiting (EORTC 26062).

The atypical and malignant meningioma study in cooperation with the ROG is continuing.

A substantial inter-observer variation between pathologists on the diagnosis of Grade III gliomas has been demonstrated in the EORTC 26951 trial, and many of the tumors included in this study were observed to have molecular abnormalities one expects to occur in GBM. The virtual microscopy project for histopathological panel review of tumor slides collected in the EORTC 26951 and 26882 (Anaplastic Astrocytoma) trials is ongoing. It will allow reviewing the WHO criteria for gliomas.
Translational Research

In the EORTC 26981 glioblastoma trial, gene expression signatures associated with treatment resistance have been identified as independent prognostic factors in GBM patients treated with TMZ/RT and identify patients who may benefit from other additional treatment strategies.

Based on the molecular and clinical data collected in the EORTC 26951 trial, several translational research projects have been conducted. Molecular characterization demonstrated a different natural history in a subgroup of oligodendroglioma with 1p/19q deletion (recently identified as a translocation). These projects allowed the identification of IDH1 and IDH2 mutations and MGMT promoter methylation as prognostic factors in AOD and AOA but not as predictive factor of response to chemotherapy, and also allowed the characterization of the role of different biomarkers (EGFR amplification, 1p and 19q loss, loss of chromosome 10q or 10, trisomy of chromosome 7) for improving the diagnosis of AOD and AOA. In future trials, separate treatment strategies will be developed for this distinct biological entity with a more favorable prognosis.

In the low-grade glioma EORTC 22033/26033 trial, an ambitious program is in development. The main goals are the identification of new therapeutic targets, the identification and the development of diagnostic, prognostic and predictive biomarkers, the retro-translation into in vitro and in vivo models (human xenografts, genetically engineered mice) mimicking the disease for preclinical studies, and the design of new treatment approaches for low-grade gliomas.

A large Translational Research program is under discussion on the material collected in the CATNON trial. It aims to study and confirm the role of several molecular markers such as 1p/19q, IDH1/2 mutation, and MGMT promoter methylation. In addition, it will explore tumor genomic profiles through gene expression, copy number, micro RNA, and epigenetic analyses. This translational research program may help biomarker development, possibly identifying new markers, and lead to new therapeutic strategies such as targeting IDH.

Imaging

Increasing demand on the imaging and recent discussions on phenomena such as pseudoprogression (after RT and TMZ) and pseudoresponse (a restoration of the integrity of the blood-brain-barrier by antiangiogenic compounds) has led to the implementation of neuroradiology/imaging as a core committee of the BTG. This is in conjunction with the Imaging Group of the EORTC. First major steps are the design and set-up of a uniform imaging protocol for all future brain tumor trials. Further, a perfusion MRI protocol will be implemented into the transatlantic CATNON trial.
Quality Assurance

In collaboration with the ROG Quality Assurance (QA) Team, a special Facility Questionnaire was developed for use by non-EORTC participants in the CENTRIC study (Cilengitide). Transversal Quality Assurance in Radiotherapy (QART) programs are on-going for all BTG studies in cooperation with the ROG.

The activities of the QA Committee have been extended with the initiation of the intergroup RTOG-EORTC study on GBM. New members of the BTG wishing to participate in this study were site visited prior to the start of the study. Currently, for all BTG studies in which RT is part of the treatment, the Facility Questionnaire developed by the Radiation Oncology Group is used to evaluate the RT installation of all participating centers. Furthermore, minimum RT requirements are being defined for participation in BTG studies including dummy runs, all of which are oversee by the ROG with which the BTG closely collaborates.

The BTG has revitalized its own QA activities which will focus on quality criteria for medical oncology and is involved in document validation such as protocol.

Collaboration with other groups

Within the EORTC, the BTG collaborates for most trials with the ROG, specifically the ROG QA Team. Ongoing successful collaborations exist also with the EORTC Quality of Life Group aimed at developing improved tools allowing evaluation of the burden of brain cancer related symptoms, effect of treatment of symptoms but also toxicity, and finally quality of life adjusted outcome measurements.

Recently, collaboration with the EORTC Imaging group on the use of central MRI upload and reading has been developed.

Outside the EORTC, the BTG collaborates with the NCI-C (Canada), Cancer UK (Medical Research Council; MRC), the RTOG, and HUB (a brain tumor collaboration of ECOG, SWOG and NCCTG) as well as the Neuro-Oncology Group of the NOA and Australia based groups (TROG and COGNO).
Breast Cancer Group

Structure of the Group

Chair  T. Cufer, Golnik (SI)
Secretary  D. Cameron, Leeds (UK)
Treasurer  E. Rutgers, Amsterdam (NL)

Steering Committee Members

J. Bogaerts, Brussels (BE)
H. Bonnefoi, Bordeaux (FR)
E. Brain, Saint Cloud (FR) (Young Oncologist)
D. Cameron, Leeds (UK)
F. Cardoso, Lisbon (PT)
L. Cataliotti, Florence (IT)
T. Cufer, Golnik (SI)
S. Delaloge, Villejuif (FR)
J. Jassem, Gdansk (PL)
S. Marreaud, Brussels (BE)
E. Rutgers, Amsterdam (NL)
G. Van Tienhoven, Amsterdam (NL)
H. Westenberg, Arnhem (NL)
G. Werutsky, Brussels (BE)
K. Engelen, Brussels (BE)

Recent Achievements

The EORTC Breast Cancer Group (BCG) is a multidisciplinary group involving surgeons, medical oncologists, pathologists, radiation oncologists, basic scientists, and clinical research fellows. The main goals of the BCG are to carry high quality international clinical trials covering all areas of breast cancer care from in situ carcinoma to metastatic disease, to investigate new anticancer agents in phase I/II trials, and to ask therapeutic questions of strategic importance in large phase III trials.

The BCG has recruited a total of over 4000 patients into clinical trials including an average of 1340 patients per year over the last three years from 57 medical centers. These patients are included not only in EORTC studies but also in intergroup trials in which the EORTC collaborates.
The EORTC is one of the founding organizations of the Breast International Group (BIG), a worldwide network of breast cancer research groups. Intergroup collaboration is essential as it avoids duplication of efforts and wasting of resources.

The BCG members meet twice a year. Additional teleconferences of the Steering Committee are held every six weeks.

Every two years, the BCG organizes the ‘European Breast Cancer Conference’ (EBCC) in collaboration with the European Society of Mastology (EUSOMA) and Europa Donna, the European Breast Cancer Coalition. In March 2010, over 5000 participants from 96 countries attended the highly successful 7th EBCC held in Barcelona. This meeting continued the tradition of previous conferences by providing excellent opportunities for dialogue between clinicians, researchers, nurses, and patient advocates. The aim of these meetings is to create a platform for closer cooperation between the parties in order to stimulate both scientific progress and provide better standards of care for breast cancer in Europe and beyond. EBCC 8 will be held in Vienna in March 2012.

Over the past several years the EORTC has become increasingly active in the field of translational research, and the BCG has actively incorporated translational research elements in their protocols. In particular, translational research evaluating correlations between clinical outcomes and biologic tumor characteristics has become a high priority in the strategy of the BCG.

Examples of trials with a strong translational research component are the EORTC 10994 and EORTC 10041 trials. The EORTC 10994 p53 trial is an intergroup translational research trial designed and led by the EORTC to assess the potential predictive value of p53 status in patients with locally advanced/inflammatory or large operable breast cancer. This trial prospectively randomized 1856 patients to test the hypothesis that neoadjuvant taxane regimen confers a greater advantage over anthracycline regimen in p53 mutated tumors than in p53 wild type tumors. The results of this trial were presented at ASCO 2010. At a median follow up of 57 months, p53 did not demonstrate to be a predictive factor of response or resistance to taxanes; however, the prognostic value of p53 in early breast cancer has been confirmed.

The EORTC 10041 trial (MINDACT) is a multicentre, prospective, phase III trial which will accrue 6000 early stage breast cancer patients, either node negative or with 1-3 positive lymph nodes. It compares the 70-prognostic signature, a genomic test developed with micro-array technology, to traditional clinical-pathological methods for assessing the risk of breast cancer recurrence in women with early breast cancer. It is hypothesized that using the genomic test in addition to traditional methods will result in more accurate risk assessment so that in the future 10-20% of patients could safely avoid adjuvant chemotherapy and its potential side effects. The MINDACT trial design also includes two additional questions related to best treatment in terms of adjuvant chemotherapy and hormone therapy. The MINDACT trial already reached its first milestone in November 2008 by accruing the first 800 patients, the "pilot phase". The preliminary results of this phase, presented at EBCC 2010, demonstrate that the trial is logistically feasible, that the compliance rate of both physicians and patients is high, and that the overall process provides good quality data and biological materials. With an average accrual rate of 195 patients per month in the last six months, the trial is expected to finish recruitment by mid 2011.
The EORTC trial 10981-22023 AMAROS (After Mapping of the Axilla: Radiotherapy Or Surgery) is a phase III study comparing a complete axillary lymph node dissection with radiotherapy to the axilla in sentinel node positive patients, and sentinel node negative patients given no further axillary treatment but still being followed for the end-points of the study. Patients included have operable invasive breast cancer greater than 5mm and less than 5 cm without clinically compromised regional lymph nodes. The main objective of the trial is to provide equivalent local/regional control for patients with proven axillary lymph node metastasis, as detected by sentinel node biopsy, with reduced morbidity by treating with axillary radiotherapy instead of axillary lymph node dissection. The study completed accrual on April 2010 with 4,828 patients included. A new EORTC trial is planned which will follow the AMAROS trial. This is the POWER trial, POSitive Sentinel node: WAIT & see, Excision or Radiotherapy. The aim of this trial is to analyze the axillary recurrence rate in patients with proven (sub) micrometastases by sentinel node biopsy if no further axillary therapy is offered.

The EORTC 22051 trial (SUPREMO - Selective use of postoperative radiotherapy after mastectomy) is an interGroup trial, designed to determine the effect of ipsilateral chest wall irradiation following mastectomy and axillary clearance for women with operable breast cancer at ‘intermediate risk’ of loco-regional recurrence. The primary endpoint is overall survival and chest wall recurrence. The number of patients required is 1600, and the current accrual is approximately 810 patients. Accrual to date has been slower than anticipated, so that an amendment is planned to enlarge the eligibility criteria. This will extend enrolment to patients with clinical stage T3N0 or T1-2 N0-1 or T1-2 N0 with additional risk factors, patients who have received neoadjuvant systemic therapy, patients carrying BRCA one or two gene mutations, patients with histologically positive internal mammary sentinel nodes, and patients with pN1 in whom less than ten lymph nodes were obtained on an axillary clearance. This study prospectively studies the cardiac toxicity of the radiotherapy and collects tumor samples in order to be able to study biological characteristics of those tumors that do and do not recur both with and without radiotherapy.

The EORTC 10054 trial (Lapatax) is a phase I/II trial designed to compare the use of Lapatinib, Herceptin and the combination when given in conjunction with Docetaxel during FEC-D neoadjuvant chemotherapy for large operable and locally advanced breast cancer. The phase I part of the study determines the recommended doses of Lapatinib and Docetaxel. The dose determination study has confirmed that with primary prophylactic G-CSF, docetaxel 100 mg/m² can be safely and effectively given with lapatinib 1,250 mg daily continuously. Prior to treatment, frozen tumor and blood samples were taken to better define which tumors were particularly sensitive to either trastuzumab and/or lapatinib. The phase II part of the study was opened in October 2010. It will enroll 150 patients from European centers into a three- arm randomized trial whose primary endpoint is pathological complete response. All patients will receive FEC-D before primary surgery: three cycles of FEC (without anti-HER2 therapy) followed by three cycles of docetaxel plus either trastuzumab (conventional weekly schedule), monotherapy with lapatinib, or the combination of trastuzumab and lapatinib.

The EORTC 10071 ALTTO (Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation) trial is also an intergroup trial. It is a randomized, open label multi-center phase III study comparing the activity of lapatinib alone versus trastuzumab alone versus trastuzumab followed by lapatinib versus lapatinib concomitantly with trastuzumab in the adjuvant treatment of patients with ErbB2 over expressing and/or amplified breast cancer. The number of patients required is 8,400 and the current accrual is...
about 8,000 patients. The study also has a mandatory translational research component with collection of paraffin-embedded tumor tissue for central pathology review and blood samples after surgery for genomic DNA.

**Translational Research**

In order to make optimal use of limited available tissue in the EORTC 10994 trial (p53 study), the BCG created the TransTGIF group which is mainly involved in the development of sub-studies using biological material collected in the context of this trial. The TransTGIF group has steering and executive committees that evaluate all the sub-study proposals. In one study a TMA construct (tissue microarray) including more than 1000 non-frozen samples was performed. The BCG has already published three papers on translational research that they have conducted and have identified a new sub-type of breast cancer (molecular apocrine). This provides the first evidence in breast cancer that a gene-signature can predict differential response between therapies, and further evidence that stromal gene expression patterns are predictive of chemotherapy resistance (Identification of molecular apocrine breast tumors by microarray analysis, Oncogene, 2005; Validation of gene signatures that predict the response of breast cancer to neoadjuvant chemotherapy: a sub study of the EORTC 10994/BIG00-1 clinical trial, Lancet Oncol, 2007; A stroma-related gene signature predicts resistance to neoadjuvant chemotherapy in breast cancer, Nature Medicine, 2009). Reports on other projects performed by the TransTGIF group are in preparation.

In the EORTC 10041 trial (MINDACT), mandatory fresh tumor samples for microarray analysis are being stored for proteomic analysis. Representative paraffin tissue block samples have to be sent for central histopathology review and for the production of tissue microarrays; optional blood sample collection may be performed for genetics and proteomics and used for future research projects.

**Projects / Strategies for the coming years**

The BCG plans to focus its future research on three distinct but overlapping areas: local therapy studies, neo-adjuvant trials, and metastatic niche trials. For each of these areas the group has considered the prevailing EORTC Headquarters strategy of focusing on large practice changing studies and translational research with an emphasis on niche trials.

The future strategy of the BCG is to be built on the success of the group in the area of local therapy studies with an increasing focus on improving local control and the understanding of biology of local relapse. In addition, our priority is also to establish a fruitful and close collaboration with other EORTC groups that can contribute substantially to both the scientific and quality assurance (QA) issues in such projects. A good example of such collaboration is the collaborative work with the EORTC Radiation Oncology Group on the design and conduct of AMAROS and SUPREMO trials, and the detailed discussions that have taken place around the QA and treatment planning aspects of the proposed follow-on POWER trial. The BCG has just started, together with the EORTC Radiation Oncology...
Group, BIG, and TROG, a study in patients who receive breast conserving treatment for DCIS (ductal carcinoma in situ). The value of a boost irradiation is evaluated after whole breast irradiation given in a hypo- or conventional radiation fractionation schedule.

It is increasingly clear that further improvements in the systemic therapy of early breast cancer will require international collaboration between different groups. Over the past 15 years, BIG has formed a powerful platform for such collaboration and successfully delivered two large adjuvant trials in HER2+ breast cancer, ALTTO and HERA. The BCG has enrolled in these studies and plans to be an active contributor to such important international, inter-group collaborations as evidenced by its leading role in the EORTC-BIG MINDACT study.

In the neo-adjuvant arena, the BCG has successfully conducted the p53 trial (EORTC 10994) and is currently in the midst of opening a smaller randomized Phase II study comparing Lapatinib with Trastuzumab in the HER2+ sub-population which will also collect prospective samples for translational research.

Future work in the area of metastatic disease is likely to focus on niche trials, which is perhaps best evidenced by the current intergroup project in male breast cancer. A second example would be the proposed trials of concurrent radio- and targeted therapy in patients with triple negative and in patients with HER2+ metastatic breast cancer with brain metastases as well as numerous NOCI projects to be conducted in breast cancer population. Collaboration with the EORTC task force in elderly, can also be considered a niche, as although there is an ever increasing population of elderly patients with breast cancer, design and recruitment to such studies is more challenging and almost always only done by academic groups such as the EORTC.

Quality Assurance

There are two QA programs running in clinical trials within the BCG. One is in the MINDACT trial and the other is in the AMAROS trial. QA is very much present for surgical and radiotherapeutic aspects of the AMAROS trial. In order to ensure a high and homogenous level of quality in the complex MINDACT trial, a good interaction between the various disciplines and departments is required. A QA project has been in place since 2009. These have nicely structured components for each of the projects (FAQ, QA questionnaire, and QA metrics) and a fellow assigned to support the principal investigators and EORTC staff. This program fulfils all the criteria necessary to be successfully accomplished. In the POWER trial, which has a radiotherapy component, levels of QA in radiation therapy (QART) will be applied.

Encouraging young oncologists

The EORTC is deeply involved with medical education. The BCG has an active fellowship program where young physicians are trained and work on group projects either at EORTC Headquarters, where they participate on setting up and conducting clinical trials, or at active institutions, where they conduct clinical and translational research projects. During 2009, BCG allocated 17 grants to enable
young oncologists to attend the semi-annual group meetings, and in 2010, 12 young oncologists were granted. The BCG plans to continue to do this in 2011 and 2012. One of the strategies planned by the BCG is to create a “brain storming” session during the semi-annual group meetings. In this way the BCG hopes to encourage younger Oncologists to develop studies to be run by the BCG.
Children’s Leukemia Group

Structure of the Group

Chair  
Y. Benoit, Ghent (BE)

Secretary  
Y. Bertrand, Lyon (FR)

Treasurer  
P. Lutz, Strasbourg (FR)

EORTC Children’s Leukemia Group (CLG) meetings are held twice a year. The CLG comprises 28 pediatric centers in Belgium, France, and Portugal.

Young Oncologists / Scientists  
B. De Moerloose, Ghent (BE)
G. Plat, Toulouse (FR)

EORTC CLG Fellow  
F. Bautista Sirvent, Brussels (BE)

Recent Achievements

Open studies

EORTC 58051 trial: International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia. The CLG is participating in the large intergroup INTERFANT -2006 study for children less than 1 year of age. The study is presently open to patient entry for centers in Belgium, France, and Portugal.

Studies in development

EORTC 58081 study: Translational research - observational study for identification of new possible prognostic factors and future therapeutic targets in children with acute lymphoblastic leukemia (ALL).

This is an observational study with collection of patient data and parallel collection and analysis of biological samples (bone marrow, peripheral blood, tissue, and cerebrospinal fluid). The main study objective is to organize and perform biobanking using standardized procedures adapted to new technologies (microarrays, proteomics, etc.) in a prospective cohort of patients with ALL in parallel with collection of relevant patient clinical data. This biobank will give us the opportunity to perform translational studies with the following aims:

• Identify leukemia cell genetic alterations (e.g. mutations in T-ALL, miRNA’s in B-lineage ALL) associated with leukemogenesis. Determine how they associate, and how they determine clinical presentation and prognosis of children.

• Identify and explore molecular pathways affected by these genetic lesions in order to identify future therapeutic targets.
• Identify patient polymorphisms impacting individual response to corticosteroids and investigate their prognostic significance.

The study is being activated in Belgium, France, and Portugal and should open in late 2010.

EORTC 58LAE retrospective project: Assessment of the outcome of long term survivors of childhood ALL and Non-Hodgkin’s Lymphoma (NHL) from CLG trials conducted between 1971 and 1999. The outcome of pediatric patients with ALL has dramatically improved over the last 30 years. These improvements are linked to a better identification of prognostic factors and to a more effective but also more aggressive use of existing drugs, including the conditioning regimen of stem cell transplantation for patients with high risk features. For these reasons, one of the principal challenges for pediatric oncologists is nowadays the long term global outcome of children treated for ALL. This long term global outcome includes the long term survival and the long term disease status as well as the occurrence of late adverse effects, the incidence of second cancers, and the socioeconomic status of the survivors. The objective of this project is to assess the long term global outcome of childhood ALL patients enrolled in CLG trials between 1971 and 1998. This will be achieved through both review of the medical records and questionnaires to the surviving patients. The study will be activated in the last quarter of 2010."

Recently closed studies

EORTC 58951 trial: The value of: 1. dexamethasone versus prednisolone during induction and maintenance therapy, 2. prolonged versus conventional duration of L-Asparaginase therapy during consolidation and late intensification and of corticosteroid- vincristine pulses during maintenance, in ALL and NHL of childhood. A Randomized phase III study.

Study objectives:
1) to assess the value of dexamethasone versus prednisolone administered during induction regarding the event free survival (EFS) and survival in children with ALL and with NHL;
2) to assess the value of the increase of the number of administrations of L-Asparaginase during consolidation (protocol I) and during the late intensification (protocol II) regarding the disease free survival (DFS) and survival in patients without very high risk (VHR) patient features;
3) to assess the value of corticosteroid- vincristine pulses administered during maintenance therapy regarding the DFS and survival in patients with average risk characteristics. This third randomization is now closed (part of an international study).

The study was closed to accrual in August 2008 with a total of 2052 patients entered over ten years (December 1998 through August 2008). The results of the third study objective were published recently (De Moerloose et al. Blood, 2010). At a median follow-up of 6.3 years, there were 19 versus 34 events for pulses versus no pulses; 6-year disease-free survival rate was 90.6% (standard error [SE], 2.1%) and 82.8% (SE, 2.8%), respectively (hazard ratio = 0.54; 95% confidence interval, 0.31-0.94; P = .027). The final analysis for the first two study objectives is planned for 2011.
Projects / Strategies for the next years

A common protocol for newly diagnosed ALL is expected for the CLG and the French FRALLE group. The next study could also be discussed with the members of the International Berlin-Frankfurt-Munich study group (I-BFM) in order to have common stratification procedures. Discussions are ongoing concerning the risk groups and treatment options. VHR patients, in particular, need more accurately defined indications for hematopoietic stem cell transplantation and new therapies.

Concerning ALL frontline treatment, it is obvious that survival rates for the children with ALL have risen sharply over the past 30 years. In the early 1970s, survival rates were only around 20 percent, but with contemporary risk-directed therapy the cure rate for childhood ALL has risen to 80-85 percent. Some subgroups have even a cure rate of 95%. This raises the limits of our treatment ameliorations with all existing treatments and complicates frontline ALL clinical trials. Consequently, we need more international collaborations.

The first goal of these international studies is to try to obtain comparable stratification of patients and to focus on certain kinds of patients with poor prognoses in order to have a common therapeutic approach (i.e., non-remission after induction therapy, patients with high level of minimal residual disease (MRD) or MLL gene rearrangement). It seems more useful to have a good registry for such patients and to concentrate our efforts on the biological characteristics of the disease and the patient, particularly concerning the toxicity of the drugs (pharmacogenomics). The randomized trials could be restricted to patients with a more dismal prognosis (other B cell leukemias or T-cell leukemias). Other malignant diseases (myeloblastic and chronic myeloid leukemias) are also rare in pediatric hematology, and international collaboration is mandatory to address interesting questions.

A new three arm ALL relapse protocol (IntreALL) is being discussed in close cooperation with other European groups (in Germany, the United Kingdom, Italy, France, and the Nordic Countries).

An international protocol for pediatric NHL patients opened in 2005 and is being coordinated by I-BFM (A. Reiter, M. Zimmerman).

Translational Research

Research on molecular genetics of leukemic cells, detection of residual disease, pharmacogenetic studies of the host’s drug metabolizing enzymes, drug transporters, and drug targets are going to be needed if any further improvement of safety and efficacy of children leukemia therapy is to be achieved in the future. This is the reason why the CLG is focusing on translational research, both with the EORTC 58051 trial and the new EORTC 58081 trial and by performing correlative studies on the backbone of completed studies. More than 15 different correlative research studies are planned on the backbone of EORTC 58051 trial, and they include exploration of risk factors, minimal residual disease, prognostic significance of molecular genetics markers, and pharmacogenetics of corticosteroids toxicity. These analyses are planned to be performed in the course of 2010-2012.
Collaboration with other groups

The CLG has had long standing collaborations with the I-BFM, a group with whom they have conducted both retrospective and prospective studies.

There is also close collaboration with the Ponte di Legno Group, who are involved in the treatment of ALL (collaborative international studies, i.e. (t(4:11), t(9:22), t(1:19), hypodiploides, non-responders to the induction therapy, second malignancies, patients with Down syndrome).

A first international protocol for the treatment of ALL in infants was activated in 1999 (INTERFANT 99 Chairman R Pieters) and the members of the CLG have contributed to this trial.

A second protocol, Interfant 06, is ongoing, and the CLG is participating.

There is also a European trial for patients with refractory or relapsed AML evaluating the value of daunoxome in association with fludarabine, cytarabine and granulocyte-colony stimulating factor (G-CSF).

Collaboration with the French group FRALLE is ongoing to evaluate the possibility of a common trial: next trial for first line therapy in ALL.
Gastrointestinal Tract Cancer Group

Structure of the Group

Chair A. Roth, Geneva (CH)
Secretary M. Ducreux, Villejuif (FR)
Treasurer T. Ruers, Amsterdam (NL)
Past chair M. Lutz, Saarbruchen (DE)

Task Force Chairs:

Colorectal G. Folprecht, Dresden (DE)
Pancreas J.-L. Van Laethem, Brussels (BE)
Gastro-intestinal F. Lordick, Braunschweig (DE)
Hepatocellular Carcinoma A. Hendlisz, Brussels (BE)
Translational Research D. Aust, Dresden (DE)

Projects Leaders:

Imaging A. Hendlisz, Brussels (BE)
Elderly M. Peeters, Antwerp (BE)
Young Oncologists D. Arnold, Hamburg (DE)
E. Mitry, Boulogne-Bilancourt (FR)

Recent Achievements

Colorectal cancer

Trials closed to accrual
The EORTC 40052 trial is an intergroup collaboration within the PETACC framework, PETACC-8, coordinated by the Fédération Francophone de la Cancérologie Digestive (FFCD). This study compares adjuvant treatment of completely resected colon cancer with FOLFOX4 versus FOLFOX4 plus cetuximab. The trial was closed to accrual in November 2009 with 2565 patients randomized.

Trials open to accrual
The ongoing study of perioperative chemoradiotherapy in locally advanced rectal cancer, the EORTC 40054-22026 PETACC-6 trial, opened in 2008. In this trial, 1,090 eligible patients will be randomized between capecitabine with radiotherapy (RT) before surgery, followed by capecitabine after surgery and capecitabine with oxaliplatin and RT before surgery, followed by capecitabine and oxaliplatin after surgery. The primary endpoint is disease free survival. As of November 2010, 545 patients have been enrolled. The trial has been activated in Germany, Belgium, Israel, France and Australia. Activation of
remaining centers is ongoing. Accrual is expected to be completed by December 2011. This is the first GI Group study to use the remote data capture system (RDC) which should make it easier to enter patient data, decrease errors, and facilitate follow-up queries.

**Trials in activation process**

Following the EORTC 40983 EPOC (European Peri-Operative Colon) trial which arrived at the practice altering conclusion that perioperative FOLFOX4 chemotherapy is safe and reduces the risk of progression free survival (PFS) events by approximately 25% over surgery alone in patients with initially resectable liver-only metastases from CRC, the GI Group is launching the EORTC 40091 BOS2 trial, a randomized phase II trial evaluating the efficacy of FOLFOX alone, FOLFOX plus bevacizumab, and FOLFOX plus panitumumab as perioperative treatment in patients with resectable liver metastases from wild type KRAS CRC. The trial will enroll 360 patients with metachronous or synchronous liver metastases (up to eight) from CRC considered to be completely resectable. The primary endpoint is PFS rate at one year.

**Gastric cancer**

**Trials in activation process**

The GI Group Gastric Cancer Task Force has established a new trial, the EORTC 40071 trial: Effectiveness of first line treatment with lapatinib and ECF/X in metastatic gastric cancer according to HER2 and EGFR status: a randomized phase II trial. We will investigate if the addition of lapatinib to chemotherapy is susceptible to increase median PFS for patients whose tumors are HER2 positive by FISH and IHC. We will also explore the effect of adding lapatinib to chemotherapy in two additional populations: 1) patients that are HER2 negative by FISH, but HER2 positive by IHC, and 2) patients that are HER2 negative by IHC, but who are EGFR positive by FISH or IHC. Additionally, the study will assess the concordance of FISH and IHC determinations of HER2. It is planned to screen a total of 350 patients for their marker status.

Initiation packages were sent to the sites in July 2010, and activation of an initial six sites is planned during the start-up phase (Jules Bordet, Mainz, Leuven, Budapest, Lisbon, Gustave Roussy). This trial was presented at the ASCO 2010 Annual Meeting.

**Pancreatic cancer**

**Trials in activation process**

Following the randomized EORTC-40013-22012/FFCD-9203/GERCOR Phase II Study results (poster at ASCO 2010 and published in JCO 28(29), 2010) which concluded that adjuvant gemcitabine based CRT after R0 resection of pancreatic head cancer is feasible, well-tolerated, and not deleterious, the GI Group will participate to the joint RTOG 0848/EORTC 40084/22084 phase III study. This ongoing study is planned to open in Europe in Q1 of 2011 and will address two important questions: a) the impact of adding erlotinib and the underlying identification of its predictive biomarkers, and b) the impact of radiation therapy added to a full adjuvant gemcitabine course. OS is the primary endpoint. The protocol is open in 80 sites in the United States. 300 patients out of the projected 950 in the study will be accrued through the EORTC network.
Translational Research

In addition to its clinical activities, the GI Group has started an exhaustive program of translational research (TR) based mainly on the PETACC2, PETACC3 and EPOC trials. It has established an international network of pathologists and laboratories with decentralized tissue processing. Interaction with the EORTC virtual tumor bank has been developed so that it can function as backbone for this collaborative research.

The tumoral material from the PETACC-3 protocol, a phase III randomized trial of adjuvant chemotherapy in colon cancer, has been analyzed in terms of several markers including MSI, KRAS, BRAF, SMAD4, TS, 18qLOH, and p53. This work allowed the investigation of the prognostic value of KRAS and BRAF according to the MSI status of the tumors in a large homogeneous patient population.

For the PETACC-2 TR project, tissue microarrays have been prepared on 650 cases, DNA extraction has been performed on 300 cases, 300 slides have been sent to the virtual tumor bank, and RNA analyses have also been launched. TR analyses are ongoing.

Histopathological analysis was performed on the tissue from liver metastases of CRC in the EPOC protocol.

The ongoing PETACC-8 trial also includes an ambitious TR program including DNA analysis for LOH, mitochondrial mutations, SNP of metabolizing enzymes, and establishes tissue arrays for analysis of EGF-R homo- and hetero-dimer formation.

The GI Group is developing a TR program for the EndoTAG trial proposal (EORTC 40093), a phase III trial of EndoTAG-1 plus gemcitabine versus gemcitabine alone in patients with unresectable locally advanced/metastatic adenocarcinoma of the pancreas. EndoTAG-1 represents a promising candidate for the treatment of solid malignancies, both for taxane sensitive and taxane-insensitive tumors.

Collaboration with the other groups

The GI Group has an intergroup collaboration with national groups in the framework of the PETACC structure and is presently developing PETACC-9. Collaborations are also ongoing with other EORTC Groups, such as the Radiation Oncology, Imaging, Quality of Life, and Pathobiology Groups, as well as the EORTC Cancer in the Elderly Task Force.

The EORTC is planning to join the POWER trial recently developed by the AIO (EORTC 40101 trial).

Projects / Strategies for the coming years

This summer the GI Group established a new strategy plan and decided to concentrate its efforts for the next three years on the following five priorities:

- TR in collaboration with the Pathobiology and PAMM Groups;
- PET-scan imaging in collaboration with the Imaging Group;
- Management of liver metastasis from CRC;
- Management of elderly patients in collaboration with the ETF;
- Development of a young investigator promotion program.

With this ambitious strategy plan the GI Group hopes to improve synergies in the development of innovative concepts.

**New trial projects were developed along these lines:**

The EORTC 40081-22083 protocol, IMAGE Response-guided therapy of locally advanced adenocarcinoma of the gastroesophageal junction, has been developed in collaboration with the EORTC Radiation Oncology Group. The trial aims to implement a PET imaging-based treatment algorithm into the neoadjuvant and multimodal care of locally advanced adenocarcinoma at the esophago-gastric junction (EGJ). The current study proposal separates patients who undergo preoperative chemotherapy for locally advanced EGJ cancer into two biologically distinct subgroups: one subgroup for early metabolic responders (with a relatively good prognosis) who will receive standard chemotherapy, and another subgroup for metabolic nonresponders for whom the protocol foresees a randomization into early discontinuation of chemotherapy followed by immediate resection versus an intensified salvage chemoradiation regimen followed by elective resection.

The EORTC 40092 CLOCC2 trial was developed following the EORTC 40004 CLOCC trial, a randomized phase III study of local treatment of liver metastases by radiofrequency ablation (RFA) combined with chemotherapy versus chemotherapy alone in patients with unresectable colorectal liver metastases (ASCO 2010). The CLOCC 2 trial is an innovative study concept combining antigen release and an immune-stimulating antibody for treatment of liver metastases.

The EORTC 40085-75083 trial, Treatment of KRAS wild type advanced CRC patients with 5-FU versus 5-FU+ Cetuximab based on a comprehensive geriatric assessment, was developed in collaboration with the EORTC Cancer in the Elderly Task Force (ETF). This study will enroll patients with advanced CRC who are aged ≥ 80 years or ≥ 70 years having functional limitation.

A recent proposal of the GI Group Colorectal Cancer Task Force is a phase II trial of epidermal growth factor receptor (EGFR) antibody monotherapy in selected patients with metastatic CRC. The aim of this trial will be to explore whether a chemotherapy-free, antibody-based schedule with an EGFR antibody has an acceptable activity for first line therapy of CRC patients with high probability of response to EGFR. In parallel, together with EORTC Headquarters and the Translational Research task force, the setting of a GI screening platform will be advanced. The concept for future studies will be to investigate patients’ tumor for molecular markers in a centralized, multi-laboratory screening platform and, according to the results, offer patients to participate in one of a set of different parallel studies according to their tumor molecular pedigree.
Genito-Urinary Cancers Group

Structure of the Group

A team comprised of Dr A. Bex, Dr N. Clarke, Dr C. Sternberg and Dr B. Tombal is leading the Group ad interim until elections take place.

Activities report of the former Genito-Urinary Tract Cancer Group

Non-muscle invasive bladder carcinoma

The long term results of the EORTC 30911 trial comparing intravesical BCG to intravesical epirubicin have been published and concluded that BCG is superior for both overall and disease specific survival.

The final analysis of randomized phase II trial 30993 assessing BCG and sequential MMC/BCG found similar complete response rates in the two treatment groups.

Muscle invasive bladder carcinoma

The GU has successfully completed the muscle invasive bladder carcinoma study, the EORTC 30987 trial, which investigated adding paclitaxel to the standard doublet chemotherapeutic regimen of gemcitabine/cisplatin. The study showed that the triplet was well tolerated but did not add to the standard chemotherapy regimen in terms of a better outcome indicating that novel targeted drugs need to be considered in order to improve the outcome of metastatic bladder carcinoma patients. A translational research project will investigate the predictive value of expression of ERCC1 and other DNA-repair related enzymes with respect to differential chemosensitivity to Cisplatin/Gemcitabine +/- Paclitaxel.

For metastatic patients with poor renal function, another triplet chemotherapy substituting the nephrotoxic cisplatin by carboplatin (Carboplatin, Vinblastine and Methotrexate) was compared to a doublet (Carboplatin plus Gemcitabine) in the EORTC 30986 trial. The phase II part of the study has been published in the Journal of Clinical Oncology and a manuscript for the phase III part is in preparation.

Renal Cell carcinoma

The EORTC 30012 trial, conducted together with the MRC, which compared interferon-alpha, IL-2 plus 5-FU to interferon alone has been published in The Lancet.
The final analysis of the EORTC 30904 trial comparing radical nephrectomy to elective kidney sparing surgery in 541 low stage patients with renal cell carcinoma has been completed and found no significant difference in efficacy in the target population of clinically and pathologically eligible patients.

Testicular cancer

Two major trials have been performed in testicular cancer: the aim of one of these trials is to investigate the role of intensified, high-dose chemotherapy in patients with a poor prognosis; the other trial is a unique worldwide trial in which the addition of Taxol to the standard regimen BEP (bleomycin, etoposide, and cisplatin) is investigated in intermediate risk patients. The trial in poor prognosis patients could not demonstrate that high-dose chemotherapy given as part of first-line therapy improves outcome in patients with poor prognosis Germ cell cancer (Daugaard et al. Annals Oncology 2010). The results of the trial in intermediate prognosis are expected in 2011.

Prostate cancer

The EORTC 30985 trial, an intergroup phase III study with SWOG 9346 trial which studies intermittent androgen deprivation in patients with stage D2 prostate cancer, has been completed and follow-up continues for at least another year.

The long term updated results of the EORTC 22911 trial were also obtained and were reported at the ESTRO and ASTRO congresses. The study investigates the value of immediate adjuvant irradiation after prostatectomy for patients presenting postoperatively with pathological factors indicative of a high risk of relapse.

The final update of the EORTC 30891 trial was also conducted this year. The EORTC 30891 trial compared immediate endocrine treatment with orchiectomy or LH-RH analog to deferred treatment initiated at the time of symptomatic disease progression or life-threatening complications in 985 patients with T0-4 N0-2 M0 prostate cancer. We report updated results with 12.9 years of median follow-up.

Ongoing and Future trials

Prostate Carcinoma

A new study has started recruiting as a follow-up to the EORTC 22911 trial, where adjuvant radiotherapy was compared to radiotherapy alone in patients with pT3 disease. This new study, the EORTC 30041-22043 phase III trial, will look at adjuvant radiotherapy with or without six months of hormonal therapy in prostate carcinoma patients with positive surgical margins following radical prostatectomy. The study will once again be conducted in collaboration with the EORTC Radiation Oncology Group.
Several other projects are being explored including two for which a close collaboration with the Radiation Oncology Group will be sought. These include a trial to investigate the potential benefit of adjuvant radiotherapy to the nodal areas (iliac vessels) versus active monitoring and salvage treatment at progression for improving the clinical progression free survival of patients who have undergone radical prostatectomy and extended pelvic lymph node dissection (ePLND) who present post-operatively with pathologic stage pT2-4 R0-1 N1 M0, Gleason score 6-10 prostate cancer and another trial to investigate if prostate irradiation increases the survival of patients with newly diagnosed metastatic bone disease. Further projects are built around the idea of developing based on the use of MRI of the axial skeleton an objective response criterion similar to RECIST, to become a standard tool to assess tumor responses objectively in bone metastases arising from prostate cancer. Template protocols for phase randomized phase I/II trials testing a new drug to combine the combination of a new drug with an anti-androgen versus anti-androgen alone in patients failing first line treatment with LHRH agonists who show bony metastases but do not require regular analgesia and have PSA doubling time >3 months and =12 months. The translational research on bone imaging is closely built into this template protocol. The GU is currently actively seeking drugs that for which this kind of protocol and setting would be suitable.

**Bladder Carcinoma**

At present there are no new studies in non-muscle invasive bladder cancer (NMIBC), but evaluation of closed studies is ongoing and several manuscripts are in preparation.

Funding is being sought for a TUR quality control study, the EORTC 30082 trial.

In the phase I EORTC 30061 trial, the standard chemotherapy regimen +/- lapatinib, a dual Her-1 and Her-2 blocker is being investigated to determine whether the addition of a novel targeted agent will contribute to the outcome of advanced bladder cancer patients.

**Renal Cell Carcinoma**

The MRC/EORTC 30072 (SORCE) trial is being conducted in EORTC sites in The Netherlands, Belgium, and Italy. This trial investigates the role of adjuvant treatment with sorafenib in intermediate and high risk patients.

Another study which has started recruiting, the EORTC SURTIME 30073 trial: Presurgical sunitinib followed by nephrectomy and sunitinib versus nephrectomy followed by sunitinib, is a randomized phase III trial assessing the timing of radical nephrectomy in patients with synchronous metastatic renal cell carcinoma.
**Projects / Strategies for the coming years**

The GU aims at strengthening the network of clinicians from many disciplines including urologists, medical oncologists, and radiation oncologists, enhancing the contribution of pathologists, radiologists, epidemiologists, as well as basic scientists, to fully exploit the potential of a multidisciplinary group dedicated to uro-oncology. The GU’s objectives over the next two years will be to expand its portfolio of clinical trials intended to change clinical practice. Key elements to the success of the GU will be the integration of and close collaboration with basic scientists to enhance communication and the ability to formulate the right questions to be tested in new clinical studies.

**Biobanking**

Essential to carrying out translational research is the sharing of patient tissue, the adequate collection of tissue, and a full clinical dataset. In relation to already performed or ongoing studies, tissue collections will be arranged in order to identify prognostic and predictive factors and biomarkers with great clinical utility. Emphasis will be placed on the prospective collection of malignant and normal tissue from patients entering EORTC trials to investigate critical molecular pathways associated with tumor progression and metastasis and assessment of molecular determinants of treatment efficacy. Expression profiles will require validation in independent sets to identify subsets of patients who may benefit from tailored treatment.

**Attracting Young Oncologists / Scientists**

A key to the success of the GU in the coming years will be the involvement of more young investigators. The GU will actively pursue the identification of promising young oncologists and give them the opportunity to present their ongoing research at the bi-annual meetings. Already, various initiatives have been taken by younger member oncologists. With the support from the Group, a translational research grant was obtained from the EORTC which will help to exploit the clinical utility of MRI in prostate cancer patients (B. Tombal). Similarly, the role of surgery and radiotherapy will be further explored by two other young members.

**Brainstorming Sessions**

In order to indentify the key issues and develop new trials, open brainstorming meetings held by the various Disease Committees and their subgroups are encouraged.
Visibility of the GU

Making contributions to international meetings will be actively encouraged. The long standing contribution to the annual EAU Congress will be broadened and further international activities at various global meetings will be actively explored. In line with this goal, the first International Bladder Cancer Meeting was organized in 2010. Many international renowned speakers as well as EORTC GU member experts participated in this highly successful multidisciplinary meeting. The GU will invest in publicizing the start of each new trial in the various countries to enhance awareness. Recent meetings have been well attended and new members have been attracted indicating the GU’s good spirit and great enthusiasm.

Translational Research

Functional Imaging

In prostate cancer, for instance, there is a clear need to develop ways of measuring metastatic spread to the bone in high risk patients in relatively early stages of the disease as well as better measuring responses in more advanced disease through, for example, developing and validating skeletal MRI imaging and by identifying bone and other biomarkers.

Translational Research Grant

The GU was awarded a grant from the EORTC Board for a project studying skeletal MR imaging in patients with prostate cancer. This project will study the role of axial skeletal MRI compared to traditional bone scan in evaluating patients with prostate cancer and assess if this imaging modality can be used for modifying RECIST to determine response to treatment.

Collaboration with other Groups (EORTC and others)

Other EORTC Groups

The long-standing successful collaboration with the Radiation Oncology Group will be continued in yet another large trial in prostate cancer patients (EORTC 30041-22034 trial, M. Bolla and H. van Poppel are the principal investigators).
Medical Research Council (MRC) and Other Global Cooperative Groups

The existing close collaboration with the MRC will be continued (SORCE trial). Recent contacts with members of SWOG (Southwest Oncology Group) could mark increased close collaboration with that Group. Collaboration with other international Groups will be explored to develop a stronger intergroup network which will be in a better position to explore the efficacy of new forms of treatment in rarer uro-oncological diseases in a more rapid manner in keeping with the new era.

European Association of Urology (EAU)

Collaboration with other clinical research groups within Europe such as with the EAU is also being explored. There is already a link between the GU Group and the EAU (affiliated membership and presentation of GU Group data during the annual EAU Congress) and collaboration with the EAU Research Foundation would enhance this connection and facilitate the exploration of possible joint studies.

Herbert Irving Comprehensive Cancer Center

Recently the Group has started to explore a close collaboration with the Herbert Irving Comprehensive Cancer Center in New York (Prof. C. Cordon-Cardo) aimed at studies in both prostate and renal cancer. In prostate cancer, collaboration will focus on the validation of early studies on the predictive accuracy of the “systems pathology” approach which will be instrumental in designing novel future studies.
The EORTC Gynecological Cancer Group (GCG) is a multi disciplinary clinical disease orientated group composed of gynecological oncologists, clinical/medical oncologists, radiation oncologists and pathologists together with a number of data managers/trial coordinators and nurses. The group has a strong past portfolio of clinical trials which have influenced international clinical practice mainly in ovarian cancer and in the 1980’s and 1990’s in some of the rarer tumors.
Recent Achievements

One study currently open to patient entry, the EORTC 55994 trial, is investigating the role of neoadjuvant chemotherapy followed by radical hysterectomy and lymph node dissection versus concomitant chemo/radiation in early/intermediate cervical cancer. This important study is likely to significantly impact future practice internationally. This study has passed the milestone of 500 patients accrued out of the planned 686 patients. At present the gold standard of treatment remains concomitant chemo/radiation, and the results of this Trial will be awaited with considerable expectation.

On 19 February 2008 the first line trial in ovarian cancer, EORTC 55041 comparing standard chemotherapy versus combination chemotherapy and maintenance erlotinib (tarceva), was closed. This study was one of the first randomized trials in ovarian cancer testing a new biological agent in the first line setting. This study recruited remarkably quickly and is a fine example of the international collaboration and co-operation that can be achieved. High-quality, well designed translational research projects have been associated with this trial, and we hope that we will see results in 2011.

In September 2010 the landmark EORTC 55971 trial, conventional surgery followed by chemotherapy with or without interval debulking was compared with neoadjuvant chemotherapy and delayed primary surgery in Stage IIIC and Stage IV ovarian cancer, was published in the New England Journal of Medicine. This Study eventually accrued over 700 patients, and the conclusion of the trial is that among this group survival after neoadjuvant chemotherapy followed by interval debulking surgery is similar to survival after primary debulking surgery followed by chemotherapy. Based on this platform, a new comprehensive trial (EORTC 55093) is currently being developed with novel targeted agents for use in this group of patients with Stage IIIC and IV disease. There is a unique opportunity to collect tissue specimens before and after therapy and also to evaluate complex functional imaging techniques.

An upcoming publication will present results of the EORTC 55984 trial which showed addition of taxol (paclitaxel) to the standard treatment arm of adriamycin and cisplatin (AP) regimen produced similar overall survival and progression free survival outcomes compared to AP regimen in metastatic/relapsed or locally advanced inoperable endometrial cancer.

Results of another landmark trial, EORTC 55955-MRC OV05, a randomized trial in relapsed ovarian cancer of early treatment based on confirmed elevation of CA125 versus delayed treatment based on clinical relapse, were published (The Lancet 376 (9747):1155-1163, Oct. 2010). The conclusion was that there is no evidence of a survival benefit or better quality of life with early treatment of relapse based on a raised CA125 level alone, and therefore no value in the routine measurement of CA125 in the follow-up of ovarian cancer patients who attain a complete response after first-line treatment.

Over the past two years, the GCG group has been focusing on conceiving and creating its own portfolio of trials. There are currently several projects at various degrees of development:

- EORTC 55092 trial: Phase IB-II, open label, multicenter feasibility study of pazopanib in combination with Paclitaxel and Carboplatin in patients with platin-refractory/resistant ovarian, fallopian tube or...
peritoneal carcinoma. A PET fluciclatide substudy to the phase II part of the protocol in a limited number of centers has also been initiated.

- EORTC 55093 trial: Randomized phase II of neo-adjuvant chemotherapy with or without EVRI (BMS 690514) or IGFR-1 inhibitor (BMS 754807) in subjects with advanced (FIGO stage IIc-IV) ovarian, fallopian tube or primary peritoneal cancer.

- EORTC 55104 trial: trabectedin carboplatin combination, with or without taxol: a Phase I study in cisplatin-sensitive recurrent ovarian cancer patients treated with one or a maximum of two previous lines of chemotherapy. This study looks broadly at the issue of developing a feasible trabectedin carboplatin combination and a future first-line study in ovarian cancer.

- EORTC 55102 trial: A phase III trial of postoperative chemotherapy or no further treatment for patients with stage I-II medium or high risk endometrial cancer. This study will be an international collaboration with the NSGO and other international gynecological cancer platforms which will certainly have an impact on clinical practice.

**Future Directions and Strategies**

The plans to work co-operatively with other European partners in intergroup studies imply wide discussion of the whole process of planning and developing intergroup studies, and it highlights the importance of early collaboration for regulatory issues, data ownership, etc. The GCG remains hopeful that there will be new frontline studies in ovarian cancer opening in 2011/12. In addition, the GCG has been working on new trials in the fields of advanced cervical and vulvar cancers as well as some rare cancers which they will continue to develop over the coming year.

**Quality Assurance**

The Quality Assurance Group within the GCG has reviewed both recent open protocols and historical ones and are continuing to make good progress in improving the quality of data collection. Dr. Leen Verleye, an EORTC Fellow dedicated to the GCG, has had several important papers accepted on surgical Quality Control in ovarian and cervical cancer trials as well as Quality Standards in pathology reports in the EORTC 55971 trial.

**Translational Research**

The Translational Research Group within the GCG has continued its efforts collecting material from patients in previous trials and carrying out some valuable and useful work. Simultaneously, a future thrust of the group led by Dr. Els Berns (Rotterdam) has been in looking at molecular signatures and other molecular markers which may identify adverse risk patients or predict...
responses to treatment. We have also increased the annual commitment of support for translational research. The translational research work of Dr. Jozien Hellemans was recognized through various publications about the mechanisms of chemotherapy resistance of ovarian cancer. Dr. Evelyn Despierre from Leuven is currently working on two translational research projects based on the EORTC 55971 and 55041 trials.

**Collaboration with other groups**

The GCG is well represented in transversal groups within the EORTC. Dr. Els Witteveen from Utrecht was appointed as GCG representative for the Cancer in the Elderly Task Force, and Dr. Els Berns (Rotterdam) is a full member of the EORTC Pathobiology Group. Collaboration with the EORTC Quality of Life Group resulted in the publication of the validated endometrial module (EN-24) questionnaire by Dr. Eva Greimel and her coworkers. Together with the GCG members a new vulva cancer quality of life module is currently under development. We are active members of the Gynecological Cancer InterGroup (GCIG) and the ENGOT platform (European Network of Gynecologic Oncology Trials).
**Recent Achievements**

**Larynx preservation**

The aim of the EORTC 24954 trial was to compare sequential CT and RT with alternating chemo-radiotherapy in resectable hypopharynx and larynx cancers. Results of the quality of life analysis were presented at the Group Meeting in March 2010 and will be published in 2011.

**Locally advanced setting**

In EORTC 24971 trial the role of neoadjuvant chemotherapy (NACT) was evaluated in patients with non-resectable locally advanced head and neck cancer and the study showed that with the introduction of taxanes the role of NACT has changed. Quality of life assessment was included in the trial and the results have been published in the British Journal of Cancer in 2010. The conclusion is that induction chemotherapy with TPF before RT not only improves survival and reduces toxicity compared with PF but also seems to improve global HRQOL in a more sustainable manner.

A phase II study (EORTC 24061) building upon the results of the previous EORTC 24971 trial in the non-resectable setting has been opened in 2008. In this study, the feasibility and efficacy of four cycles of TPF regimen (docetaxel, cisplatin, 5-fluorouracil) combined with the EGFR inhibitor cetuximab...
followed by the concomitant use of radiotherapy and one platinum compound, cisplatin or carboplatin (for radio sensitization), plus cetuximab was being studied. This trial was closed in 2010 after recruitment of 47 patients due to an unexpectedly high rate of toxicities, the causes of which are under discussion with leading experts in the field who run trials studying the same combination.

Postoperative setting
The protocol for a new phase III trial (EORTC 22071-24071 study) in the postoperative setting was finalized in 2010. This protocol was developed in close collaboration with the EORTC Radiation Oncology Group. Based on the results of the EORTC 22931 trial, high risk patients after curative surgery will be randomly assigned to receive postoperative chemoradiation versus postoperative chemoradiation in combination with EGFR-inhibition (panitumumab). The study is currently in regulatory process and will accrue the first patients by January 2011.

Projects / Strategies for the coming years

HNCG strategy and meetings structure
During the HNCG meeting in March 2010, a dedicated meeting was arranged to redefine the strategy of the group with the collaboration of EPOD (Early Project Optimization Department). Several potential projects were discussed and the collaboration among different disciplines (radiation oncology, surgery, and medical oncology) was strengthened during this meeting.

Locally advanced setting
A multicenter, phase III randomized 3-armed study (EORTC 24081) is under submission to EORTC Protocol Review Committee. Patients with locally advanced head and neck squamous cell carcinoma will be included. This study has the following three arms: 1) Induction chemotherapy with TPF (EORTC-like) followed by bio-radiation (anti-EGFR Monoclonal Ab), 2) Concomitant chemoradiation with cisplatin plus anti-EGFR Monoclonal Ab, and 3) Standard concomitant chemoradiation with cisplatin. This study is development in close collaboration with the EORTC Radiation Oncology Group, and will benefit of an extensive and ambitious program of quality assurance of radiotherapy. Intergroup collaboration will also be implemented.

Recurrent / metastatic setting
There are currently two draft proposals in this setting, under discussion with companies.
**Translational Research**

The HNCG is strongly focusing on translational research projects. The HNCG is in the position to have access to extended clinical data of a number of databases of prospective randomized studies that could be used for translational research purposes. The group took actions to actively involve investigators in the field of preclinical and translational research in the group activities and meetings, and this led to three different translational research project that are currently under development. The HNCG plans to correlate tumor HPV DNA and p16 protein status with therapeutic response and survival in the cohort of patients treated within the EORTC 24971/TAX323 phase III clinical trial. In addition, functional p53 status and β-tubulin expression status will be correlated with response to docetaxel to see whether these biomarkers have the potential to be used both as prognostic and predictive factors. Another research project aims to evaluate the association of excision repair cross complementation group (ERCC1) expression with therapeutic response and survival among patients treated with postoperative irradiation with or without concomitant cisplatin in the EORTC 22931 phase III clinical trial.

Translational research studies are also included in the EORTC 22071-24071 trial, of which one proposal in collaboration with the EORTC Radiation Oncology Group is NOCI-granted. This proposal is focusing on the prediction of radiation-induced normal tissue toxicity based on in vitro lymphocyte apoptosis test and SNPs analysis. In case of positive results of this TR project, in the future we could identify at diagnosis patients that need specific measures to prevent late radiation-induced toxicity (new radiation delivery techniques, use of protective agents, preventive swallowing exercises). Conversely, treatment intensification would be made possible in the patients that are identified as not being at risk of severe radiation-induced toxicity.

A strong TR component is also present in the study proposal granted by NOCI in 2010. This is a window study in patients affected by locally advanced HNSCC that is deemed to be treated by surgery. The patients will be treated with the administration of a pan-Her inhibitor or an anti ALK/c-Met inhibitor before surgery, and the activity of the drugs will be evaluated with advanced imaging technique and analysis of the different downstream molecular pathways to explain tumor response and resistance mechanisms.

**Quality of Life**

Quality of life assessment will also be included in all new phase III studies, as these new studies do focus on the right balance between efficacy and toxicity. A new proposal on quality of life included in the locally advanced trial (EORTC 24081-22081) will be presented during the next group meeting. Quality of life projects are included in the EORTC 22071-24071 and 24081 trials. The HNCG will also participate in a proposal of the EORTC Quality of Life Group aimed at adjusting the EORTC QLQ-H&N35 to new treatment regimens.
Collaboration with other groups

Joint sessions with the EORTC Radiation Oncology Group during the EGAM meetings are currently standard. A fruitful discussion with the members of the EORTC Radiation Oncology Group resulted in the aforementioned common proposals with this group. In addition, a number of meetings have taken place between representatives of both groups, which resulted in new plans for future collaborations. Formal collaboration also exists with the GETTEC (Groupe d’Étude des Tumeurs de la Tête et du Cou), and representation at each other’s meetings has been arranged.

As previously mentioned, the HNCG is working towards improving collaborations with other EORTC groups, especially the Imaging and Pathobiology groups.
Imaging Group

Structure of the Group

Chair
S. Stroobants, Edegem (BE)
Vice Chair
N.M. Desouza, Sutton (UK)
Secretary
U. Nestle, Freiburg (DE)
Treasurer
O.S. Hoekstra, Amsterdam (NL)

Imaging data have the potential to provide information on disease profiling pertaining to diagnosis, prognosis, selection of therapy, monitoring of response to therapy and pharmacokinetic information of drugs. The Imaging Group (IG) operates to establish and maintain the scientific and clinical value of advanced imaging. Moreover, the IG has and will develop specific analytical and review procedures as well as quality control procedures, in the context of clinical trials conducted by the EORTC groups.

The main objectives of the IG, in line with EORTC strategy, are to:
• Ensure standardization of image acquisition and quality assurance for EORTC trials (computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), image-guided radiotherapy (RT), and ultrasound (US));
• Increase PET CT expertise across the network;
• Increase functional MRI expertise across the network;
• Within the framework of personalized medicine, identify and implement predictive and prospective imaging biomarkers of interest.
• IG Committees are charged with overseeing the achievement of these objectives.

IG Committee Chairs

Clinical Trials Advisory
S. Stroobants, Edegem (BE)
N.M. Desouza, Sutton (UK)

Nuclear Medicine Technologies
R. Boellaard, Amsterdam (NL)
M. O’Doherty, London (UK)

Radiology Technologies
F. Lecouvet, Brussels (BE)
N. Lassau, Villejuif (FR)
C. Schaefer-Prokop, Amerfoort (NL)

Imaging in Radiotherapy
W. Oyen, Nijmegen (NL)
U. Nestle, Freiburg (DE)
G. Villeirs, Gent (BE)

IT infrastructure
A. Jackson, Manchester (UK)

Education and Training
P. Parizel, Edegem (BE)
E. Coomans, Amsterdam (NL)
Recent Achievements

The IG, a new group within the EORTC, held its first meeting on 15 January 2010 at the Universiteit Antwerpen, Belgium. The goal of this first meeting was to introduce the structure and strategic plan of the IG to the EORTC Community and to present current opportunities for integrating imaging into EORTC clinical trials. The meeting was attended by over 100 persons representing the multidisciplinary field of imaging.

The IG held its second meeting at the VUmc Amsterdam, The Netherlands on 17 September 2010. A goal of this meeting was to discuss the technical status of standard operating procedures per imaging modality, e.g. US, CT, MRI, PET, and RT, with respect to patient preparation, scanner calibration, acquisition parameters, reconstruction parameters, display requirements, and data-analysis.

IMI (Innovative Medicines Initiative): The IG is involved with the QuIC-ConCePT (Quantitative Imaging in Cancer: Connecting Cellular Processes with Therapy) consortium. This consortium was created under the auspices of EORTC, CR-UK (Cancer Research UK), EIBIR (European Institute for Biomedical Imaging Research), EANM (European Association of Nuclear Medicine), and ESMI (European Society for Molecular Imaging), together with eight EFPIA partners. This project has two main objectives: 1) qualify three specific imaging biomarkers (IBs) of tumor cell proliferation, apoptosis, and necrosis, to allow the drug developer to demonstrate reliably the modulation of these pathologic processes in tumors in patients in future trials, and 2) evaluate and introduce IBs of invasion and metastasis.

EORTC 20051 trial: The H10 EORTC/GELA randomized Intergroup trial on early 18F fluorodeoxyglucose (FDG) PET scan guided treatment adaptation versus standard combined modality treatment in patients with supradiaphragmatic stage I/II Hodgkin’s lymphoma. The part of this study related to the primary objective was closed because it was unlikely to meet that objective. The study remains open to accrual until mid 2011 for the secondary objective: Is intensified treatment superior to standard treatment in PET positive patients after 2 cycles of ABVD?

Project / strategies for the coming years

The IG is currently preparing studies in collaboration with the EORTC Gastrointestinal Tract Cancer, Lymphoma, Radiation Oncology, Head and Neck Cancer, Soft Tissue and Bone Sarcoma, Genito-urinary Tract Cancer, Brain Tumor, Gynecological Cancer, and Lung Cancer Groups, as well as with NOCI.
**Translational Research**

EORTC 22071-24071 trial: Randomized Phase III trial on postoperative chemoradiation in combination with anti EGFR-antibody versus postoperative chemoradiation in head and neck squamous cell carcinomas (HNSCC) with high risk of locoregional recurrence. The IG, in collaboration with the EORTC Head and Neck Cancer and Radiation Oncology Groups, plans to assess response to a test dose in a subset of patients. The IG is also collaborating with the EANM which will perform quantitative FDG PET accreditation of the centers participating in this study.

EORTC 62072 Trial: A randomized double blind phase III trial of Pazopanib versus placebo in patients with soft tissue sarcoma whose disease has progressed during or following prior therapy. The imaging aim in this trial is to evaluate predictive value of early FDG PET changes in 50 patients at selected institutions.

**Collaboration with other groups (EORTC and others)**

An EORTC Imaging Platform has been set up to allow exchange and central review of images coming from patients treated in EORTC clinical trials. The platform is maintained by Keosys in collaboration with the EORTC IT Department and the IG.

To help provide additional support for imaging in EORTC clinical trials, Ivalina Hristova has joined EORTC Headquarters as Medical Imaging Officer.
Infectious Diseases Group

Structure of the Group

Chair P. Donnelly, Nijmegen (NL)
Secretary M. Bassetti, Genova (IT)
Treasurer R. de Bock, Antwerp (BE)
Other members O. Marchetti, Lausanne (CH)
C. Cordonnier, Creteil (FR)
P. Verweij, Nijmegen (NL)
Young Scientist M. Bassetti, Genova (IT)

The Scientific Committee comprises the Chair, the Trial Coordinators, the Data Review Committee (DRC) Coordinators, the Clinical Research Physician, the Statistician, and the Data Manager.

M. Paesmans has been officially appointed as the statistician to the Infectious Diseases Group (IDG).

Recent Achievements Symposia and Meetings

Joint EORTC IDG Educational Workshop on “Definitions and treatment outcome criteria in invasive fungal infections: an interactive workshop to reach a broader consensus” during the 19th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), Helsinki, 16-19 May 2009.


The 2009 and 2010 EORTC Infectious Disease Group meetings were held in Santorini (October 2009) and in Vienna (March 2010).

The EORTC Workshop in Fungal Infectious Diseases during the 20th ECCMID was a successful initiative with 170 attendees.
Projects / Strategies

Ongoing research projects

EORTC 65031 trial: Epidemiological study of fungemia in cancer patients. The objective of the study is to assess the incidence, species distribution, risk factors and outcome of bloodstream fungal infections in cancer patients. The study was activated in 2005 and recruited 304 patients. The final analysis should be presented by 2011.

European Conference on Infections in Leukemia (ECIL-2). This is a collaborative project of the IDG, the Infectious Diseases Working Party (IDWP) of the European Organization for Bone Marrow Transplantation (EBMT), the European Leukemia Net, and the International Immunocompromised Host Society (ICHS). The 3rd ECIL Conference took place in Juan-les Pins, France on 25-26 September 2009 with the themes Update of the previous ECILs antifungal guidelines (prophylaxis, empiric treatment, treatment), Zygomycosis, and on non-invasive diagnostic procedures for invasive fungal diseases (IFDs).

Microbiology Reference Laboratories (MRL). The Institute of Microbiology, Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland is the IDG reference center for bacteria and yeasts, and the Department of Medical Microbiology, Radboud University Nijmegen Medical Center, Nijmegen, The Netherlands, is the reference center for filamentous fungi. MRL are in charge of the quality control program regarding species identification and susceptibility testing in ongoing clinical trials of the IDG. They are also in charge of keeping a repository of the microbial strains collected in clinical trials. Instructions for international shipment of microbial strains will be issued in compliance with IATA regulations.

Future projects

The IDG has a proud history and is following in the footsteps of many illustrious pioneers. Now, as then, we are facing several challenges as a group that will define our future in order to revitalize interest in the scientific community regarding the research and treatment of infectious complications among patients with cancer. Our thrust will be four-fold:

1) Clinical trials - exploratory, observational and intervention;
2) Diagnostic validation and utility studies;
3) Epidemiological studies and, importantly;
4) Education and training which will involve fellowships, training courses, seminars and educational sessions at international conferences including the Trends in Medical Mycology, The European Congress of Clinical Microbiology and Infection and the International Society of Human and Animal Mycology (ISHAM).
Collaborations with other Groups

In order to perform high quality projects likely to have a major scientific impact, the collaboration with other EORTC Groups, particularly with the EORTC Leukemia Group, and with other international research organizations active in the field is a top priority. An alliance has been formed between the European Aspergillus PCR Initiative (EAPCRI), a working group of the ISHAM, and the Infectious Diseases Working Party (IDWP) of the European Group for Blood and Marrow Transplantation (EBMT) to help propose and validate a standard for aspergillus PCR that can be used to screen high-risk patients. This strategy should allow more rapid and efficient recruitment of patients. Contacts have been with the following: the EORTC Leukemia Group, the European Leukemia Net, the Immunocompromised Host Society (ICHS), the Infection group of the Multinational Association for Supportive Care in Cancer (MASCC), the European Confederation of Medical Mycology, and the US Mycosis Study Group (MSG).

It is essential to conduct high quality clinical trials addressing clinically relevant issues for the prevention, diagnosis, and management of infections among cancer patients and to create a seamless interaction between the IDG, EORTC Headquarters, other organizations with a shared interest, and potential study sponsors. The Early Project Optimization Department (EPOD) and the Medical Department at EORTC Headquarters will help assist in study design, protocol development, assessment of feasibility, and allocation of resources.

MSG005: Recategorization of the cases of the Global Comparative Aspergillus study. A project of EORTC / MSG collaborative analysis.

Research projects in development

Clinical trials:
• EORTC 65091 trial, Empirical versus pre-emptive antifungal therapy in patients with hematological malignancies. A therapeutic phase III strategy study (joint effort with the EORTC Leukemia Group, the ISHAM-EAPCRI, and the EBMT-IDWP). In this project there is a strong component of translational research including the validation of a standardized aspergillus PCR proposed by the ISHAM Working Group European Aspergillus PCR initiative (EAPCRI), the Validation of beta-D-glucan for the early diagnosis and follow-up of IFDs and the validation of potential genetic dingle nucleotide polymorphisms (SNPs) signatures associated with the development of IFDs.
• A prospective, placebo controlled trial of quinolone prophylaxis for neutropenic patients in the setting of high-level resistance among Gram-negative bacilli (joint effort with the EORTC Leukemia Group, the Infection group of the MASCC and the EBMT-IDWP).
Observational studies:
• A prospective study to test the feasibility to perform allogeneic reduced intensity conditioning/nonmyeloablative Stem Cell Transplantation (SCT) in 51-75 year old patients with myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML) (joint effort with the EORTC Leukemia Group).
• Observational study of the development of antibacterial resistance among patients with cancer (joint effort with the EORTC Leukemia Group, the Infection Group of the MASCC, and the EBMT-IDWP).

Exploratory studies:
• Developing pharmacokinetic profiles of antimicrobial drugs to optimize therapy of patients who develop infections whilst undergoing chemotherapy for cancer or receiving a stem cell transplant.

Diagnostic validation and utility studies:
• Prospective study to explore inflammatory markers e.g. CRP and indicators of toxicity, citrulline for their potential utility as specific risk factors for infection (joint effort with the EORTC Leukemia Group, the Infection Group of the MASCC, and the EBMT-IDWP).
• Establishing the optimal sampling conditions, diagnostic accuracy and clinical utility of blood cultures (joint effort with the EORTC Leukemia Group, the Infection group of the MASCC, and the EBMT-IDWP).
• Prospective study to explore prognostic factors for invasive aspergillosis (joint effort with the EORTC Leukemia Group, the Infection Group of the MASCC, and the EBMT-IDWP).
• Clinical validation of the standard for Aspergillus PCR to screen for invasive aspergillosis (joint effort with EORTC Leukemia Group, the ISHAM-EAPCRI, and EBMT-IDWP).
• Prospective study to explore the value of biomarkers of separately and in combination for the early detection of invasive fungal infection.

Epidemiological studies:
• European register of invasive aspergillosis using ECMM-internet register.

Education and training:
• The IDG is organizing a symposium for the ISHAM conference to be held 10-12 June 2012 in Berlin, Germany.
• Training courses and seminars using the full potential digital communications of WEB casting, Web Events and WEBinars.

Fellowships:
• One fellowship leading to a PhD concerns the prospective epidemiology and diagnosis of IFDs.
• A second fellowship on the prospective epidemiology and clinical impact of bacteremia due to resistant bacteria is envisaged.

IDG Web Site:
Greater reliance will be placed on the IDG web site to disseminate information and archive documents within the EORTC web site. Partner societies will be asked to provide cross-links to allow ready and easy access.
Leukemia Group

Structure of the Group

Chair J.-P. Marie, Paris (FR)
Secretary M. Lübbert, Freiburg (DE)
Treasurer P. Muus, Nijmegen (NL)
Young Oncologist / Scientist F. Baron, Liège (BE)
D. Selleslag, Brugge (BE)

The aim of the EORTC Leukemia Group (LG) is to organize, conduct, coordinate, and stimulate trials for patients with myeloid or lymphoid leukemias and myelodysplastic syndromes (MDS). The LG includes 52 qualified hematology centers located in 13 different European countries. In the period between 2007-2009, approximately 350 patients were included in LG trials. Biological investigations are coordinated by subcommittees of experts on cytogenetics, molecular biology, cytology, and immunology. The LG conducts meetings on a bi-annual basis.

Recent Achievements

Acute Myeloid Leukemia (AML) in “young” patients (< 60 years)

Final results of the AML-10 phase III EORTC-GIMEMA 06931 trial comparing Daunorubicin versus mitoxantrone versus idarubicin as induction and consolidation chemotherapy were published (Mandelli et al. J Clin Oncol. 2009).

The AML-12 EORTC-GIMEMA 06991 trial included randomization at diagnosis for remission induction using high-dose ARA-C compared to the “best” remission induction schedule of the previous AML-10 trial: a total of 2112 patients were registered (the randomization was completed in January 2008). A second randomization evaluated the role of maintenance therapy with low-dose subcutaneous interleukin-2 versus no further treatment; a total of 550 patients were randomized for this second step (randomization closed in June 2008). Younger patients (<45-55 years) with an HLA identical family donor were scheduled for allogeneic transplantation. The final analysis is foreseen in 2011.

An EORTC/GIMEMA network of laboratories in The Netherlands, Belgium, and Italy and coordinated by Dr Joop Jansen (EORTC) and Dr Francesco LoCoco (GIMEMA) monitored minimal residual disease by molecular techniques to identify prognostic factors.

The phase I-II EORTC-GIMEMA 0606 trial is testing the addition of low dose clofarabine to the idarubicin-ARA-C combination and is now open in a limited number of large centers for the phase I
part of this trial. The maximum tolerable dose (MTD) has been reached and the expansion cohort is continuing with the expected recommended dose. Preparations are underway for initiating the phase II part of this trial.

The LG is also participating in a large intergroup study, the EORTC 06071 trial, led by CALGB for young patients with flt3-positive AML. This study aims to determine if the addition of midostaurin to daunorubicin/cytarabine induction followed by high-dose cytarabine consolidation and continuation therapy improves the outcome of these patients. This study has reached full accrual, however there is a proposal to accrue more patients.

In elderly patients (> 60 years) with AML, the LG completed the EORTC 06012 AML-17 intergroup trial with GIMEMA. In 61-75 year old patients in good physical condition, this trial assessed the anti-leukemic activity of a sequential treatment with Mylotarg (anti-CD33+calicheamycin) followed by “standard” chemotherapy with mitoxantrone, Ara-C and Etoposide as a front-line therapy in previously untreated AML. This regimen is compared to “standard” chemotherapy. The target sample size for this study was reached and the accrual was closed in August 2007 with a total of 473 patients randomized. Patient follow-up and data collection are ongoing.

The EORTC-GIMEMA 06031AML-19 trial was designed for “frail” patients (> 75 or 61-75 years with co-morbidty) who are usually not treated with intensive chemotherapy. The aim of this phase II-III trial is to compare low doses of Mylotarg versus palliative care. During the phase II part, activity of two different schedules of low dose Mylotarg have been assessed (84 patients have been entered in the phase II), and results were published recently (Amadori et al, Br J Haematol. 2010). The phase III part has been open to accrual since September 2007 and patients are being randomized between supportive care and the “best” low dose Mylotarg schedule following analysis of the phase II results. For this trial, 125 of the 184 patients needed have been entered. Discussions are ongoing with Pfizer on the possibility of upgrading this to a registration trial after the recent rejection of Mylotarg by FDA in AML patients treated with Mylotarg and chemotherapy.

**Myelodysplastic Syndromes**

Final results of the prospective EORTC 06961 CRIANT trial which assessed the value of allogeneic stem cell transplantation versus autologous stem cell transplantation and chemotherapy in patients with MDS and secondary AML (sAML) were published recently (de Witte T, et al. Haematologica. 2010).

The randomized EORTC 06011 phase III trial of the LG and the German MDS Group assessing the value of decitabine versus best supportive care in high risk MDS patients >60 years old, recruited 233 patients in 46 centers. The final results were presented at the 2008 American Society of Hematology (ASH) meeting. The manuscript was accepted to be published pending modifications by JCO.

The EORTC 06013 phase II trial assessing the activity and toxicity of Idarubicin and Ara-C in combination with Gemtuzumab-Ozogamycin (IAGO) in untreated high risk MDS or sAML patients recruited 31 patients in five centers. The accrual was completed in 2006. The database was locked in 2010, and the final analysis report was performed.
The randomized phase II EORTC 06023 trial assessing the value of two doses of infliximab (Remicade) in patients with MDS and a relatively low risk of developing acute leukemia recruited 46 patients in 19 centers. The accrual was completed in 2006, and the database was locked in 2010. At the time of the final analysis the median follow-up was five years. A manuscript is in preparation.

Two new studies for patients with MDS have been approved by the EORTC Executive Committee.

**Acute Lymphoblastic Leukemia (ALL)**

Final results of the ALL-4 phase III trial comparing Dexamethasone versus prednisolone in adults with ALL or lymphoblastic lymphoma were published recently (Labar et al. Haematologica. 2010).

A new ALL first line therapy (with stratification: 18-40 years, 41-70 years) with a randomization for -/-/+ clofarabine i.v. during induction and intensification using a pediatric-like regimen in “young” ALL has been activated by HOVON (HOVON 100 ALL) and will soon be activated by the EORTC (the EORTC 06083 trial). The primary endpoint will be event free survival (EFS), and the secondary endpoint will be molecular residual disease.

**Projects / Strategies for the Future**

**Projects**

Two new studies for patients with MDS have been approved by the EORTC Executive Committee.

EORTC 06102 trial: Randomized Phase III Study to compare the efficacy and safety of Vidaza versus best supportive care (BSC) in low- and intermediate-1 risk MDS patients: a study of the LG - German MDS Study Group. Recently, the use of hypomethylating agents, such as vidaza or decitabine, has emerged as a possible new treatment option for patients with MDS. These drugs induce the re-expression of previously silenced genes that are relevant for cell growth, differentiation, and apoptotic processes, thus providing a rationale for an epigenetic therapy in MDS. Recent data have demonstrated that vidaza is the first agent to induce a significant survival advantage compared with conventional care regimens in patients with high risk MDS in a large, international, randomized, phase III trial (AZA-001). The proposed study will include all these patients with unmet medical need in order to answer the question of efficacy, safety, and quality of life of vidaza versus BSC in low/int-1 risk MDS patients.

EORTC 06101 trial: A Randomized Phase III Study of vorinostat (MK-0683) in combination with vidaza versus vidaza alone in patients with Intermediate-2 or high risk MDS or high risk Chronic Myelomonocytic Leukemia (CMML). Hypomethylating agents and histone deacetylase (HDAC) inhibitors have each, as single drugs, demonstrated clinical responses in patients with MDS. Vorinostat, when combined with vidaza, may enhance clinical activity with less toxicity than other alternative regimens such as intensive antileukemic chemotherapy or allogeneic stem cell transplantation.
Strategies

Platforms for special population

The LG together with the EORTC Headquarters team is developing a strategic platform for elderly AML with participation of the Cancer in the Elderly Task Force and the Infectious Disease Group. The objectives are to better assess the fitness for treatment and quality of life in this poor risk population by developing a better understanding of the disease biology and designing adaptive strategies for using innovative agents. The platform will also include strategies for supportive care and a registry to explore the feasibility of reduced intensity conditioning for bone marrow transplant in subsets of the elderly population.

Collaboration with other groups

The LG has a very close relationship with the Italian GIMEMA group, and many clinical studies are joint studies of these two groups. This combination is very advantageous for both groups, since this intergroup is the largest group for leukemia research in the world. Our group also has a fruitful collaboration with the German MDS Study Group and, more recently, with the Dutch HOVON group for adult ALL.

The LG is a member of the AML Collaborative Group, which comprises all co-operative groups (MRC, HOVON, ECOG, etc.) performing meta-analyses in AML. The EORTC statistician was involved in the set-up of a new meeting which was held in the UK in September 2008. Data from several EORTC trials assessing the value of stem cell transplantation (SCT) were provided by the EORTC statisticians to the MRC secretariat.

Several LG centers are active participants in the European Leukemia Network, financed by the European Commission (Network of Excellence) since 2004, and participate actively in the MDS, ALL, and SCT working groups. Many members of the LG are also participating in European Cooperative Group for Blood and Marrow Transplantation (EBMT) activities. The EORTC statistician is involved in projects (guidelines, courses) of the EBMT Statistical Subcommittee.

Translational Research

Cytogenetics and molecular biology are now mandatory for all patients with AML or MDS. A broad molecular analysis is linked to each clinical trial permitting identification of new prognostic molecular markers, and the development of RNA, DNA and frozen cell banks allows for better adherence to these programs. Systematic evaluation of TCR or IgH gene rearrangements is planned in the next EORTC/HOVON adult ALL trial.

The LG TET2 project (“Prognostic impact of mutations and correlation with known genetic defects of the novel oncogene/tumor suppressor TET2 in de novo acute myeloid leukemia patients: translational...
research study of the EORTC phase III study 06991”) presented by S. Langemeijer and J. Jansen (Nijmegen, Netherland) at the 2009 EGAM meeting and granted by the EORTC Board, was performed, so far, on the samples of four main EORTC centers. The results will be available soon.

Quality Assurance

Independent review of cytology, cytogenetics, molecular biology, and immunology by four subcommittees and occasional site visits to participating centers have led to improvement in quality of the studies of the LG.
**Structure of the Group**

Chair  
M. O’Brien, Sutton (UK)

Secretary  
V. Surmont, Gent (BE)

Treasurer  
B. Biesma, ‘S Hertogenbosch (NL)

**Steering Committee Members**

Sub-chair Surgery  
P. Van Schil, Antwerp (BE)

Sub-chair Pathology  
K. Kerr, Aberdeen (UK)

Sub-chair Oncology  
D. Fennell, Belfast (UK)

Sub-chair Radiotherapy  
C. Favre-Finn, Manchester (UK)

Sub-chair Quality Assurance  
R. Gafar, Cairo (EG)

Sub-chair Radiology  
C. Fink, Mannheim (DE)

Young Oncologists  
R. Dziadziuszko, Gdansk (PL)
L. Greillier, Marseille (FR)

**Recent Achievements**

In 2009, two trials were closed to patient entry: the EORTC 08062 trial was closed after attaining full accrual, the EORTC 08021 trial was closed due to poor accrual. Final analysis report was completed for the EORTC 08021 trial. A total of 65 patients were entered in EORTC Lung Cancer Group trials in 2009.

During first half of 2010 two trials, one in non small cell lung cancer (NSCLC) and the other in mesothelioma, were fully developed. Two trials were closed to patient entry: the EORTC 08052 trial was closed after attaining full accrual, and the EORTC 08061 trial was closed due to poor accrual. The final analysis report was completed for the EORTC 08062 trial.

A dedicated NSCLC Strategy meeting was held at EORTC Headquarters on 06 October 2010. This meeting was organized by EPOD who will be developing concepts based on discussions held at this meeting.

**NSCLC**

EORTC 08021 trial: A randomized phase III study of follow-up with or without adjuvant gefitinib (Iressa) following chemotherapy in patients with advanced NSCLC. This trial closed in 2008 due to slow accrual. The slow accrual was triggered by the negative results in SWOG 0023 and ISEL (IRESSA
Survival Evaluation in Lung cancer) studies. Iressa has recently been licensed for use in patients with epidermal growth factor receptor (EGFR) mutations. Abstracts concerning this trial were presented at ASCO 2010 and at ESMO 2010 as poster discussions.

EORTC 22055 -08053 trial: Lung Adjuvant Radiotherapy Trial (ART) evaluating the role of postoperative conformal radiotherapy after complete resection of NSCLC with N2 mediastinal involvement. This trial was closed prior to recruiting its first patient. Despite the relevance of the question addressed by this protocol, its feasibility is being reevaluated.

EORTC 08092 (MAPPING) trial: Double blind randomized phase III study of maintenance Pazopanib versus placebo in NSCLC patients non progressive after first line chemotherapy. This study is in regulatory process.

EORTC 75082 - 08086 trial: Randomized phase II trial of abraxane versus navelbine for patients aged 70 or older with NSCLC. This study is under development in collaboration with the EORTC Cancer in the Elderly Task Force. Recent results presented at ASCO 2010 are leading to a redefinition of the patient population.

Small Cell Lung Cancer (SCLC)

EORTC 22074 - 08072 trial: CONVERT: 2-arm randomized controlled trial of concurrent chemo-radiotherapy comparing twice-daily and once-daily radiotherapy schedules in patients with limited stage small cell lung cancer (SCLC) and good performance status, a phase III trial being conducted together with the EORTC Radiation Oncology Group and Medical Research Council, has started. This is the only phase III trial in LS-SCLC in Europe. The study is considered to be of great importance for patients with limited stage SCLC and is designed to answer the question of dosing and timing of radiation to the chest. Patients are randomized to receive twice daily radiation with concurrent chemotherapy versus four courses of chemotherapy followed by high dose radiation of 66 Gy.

EORTC 08061 trial: Phase II study of sunitinib in patients with SCLC either chemonaive (ED) or presenting a sensitive relapse. 48 patients are planned to be entered in two different groups and be treated with the oral agent sunitinib for four weeks. The primary end point is disease control at four weeks determined by CT and PET scan. Non-responding patients are planned to be given standard chemotherapy after evaluation. The study opened in 2008 and has specific FDG-PET scanning and translational research questions. The trial has been closed due to poor accrual in June 2010.

EORTC 08062 trial: Randomized phase II study of amrubicin as single agent or in combination with cisplatin versus etoposide/cisplatin as first-line treatment in patients with extensive stage SCLC. Promising results that were recently reported from Japanese studies in SCLC are now being tested in caucasian patients. The activity of amrubicin single agent or amrubicin with cisplatin versus the standard treatment cisplatin/etoposide was investigated. The study completed recruitment and was analyzed in 2010. The primary endpoint is response rate; secondary endpoints focus on progression free survival, toxicity, and overall survival. A poster was presented at ASCO 2010 and publication of the final results is expected by the end of 2010.
**Mesothelioma**

EORTC 08031 trial: A phase II feasibility trial of induction chemotherapy followed by extra pleural pneumonectomy and postoperative radiotherapy in patients with malignant pleural mesothelioma. The study investigated the feasibility of combining induction chemotherapy, extra pleural pneumonectomy and hemi-thoracic irradiation in patients with early stage mesothelioma. The endpoint is the number of patients alive and without significant toxicity or disease at 90 days after the last treatment, and the data suggest that this is only possible in <50% of patients. Publication will appear in ERJ at the end of 2010. Translational research related to this study is ongoing.

EORTC 08052 trial: A phase II study of bortezomib (Velcade) with cisplatin as first-line treatment of malignant mesothelioma. This trial is assessing the effect of bortezomib with cisplatin in patients with inoperable malignant mesothelioma. The primary endpoint is progression free survival at 18 weeks; secondary endpoints are overall survival and toxicity. A translational research component of this study is linked to the EORTC 08031 trial. The study has completed recruitment and will be analyzed first quarter 2011.

EORTC 08091 trial Randomized phase II study of cisplatin plus pemetrexed with either TRAIL-Receptor-2 agonist (CS-1008) or placebo as first line therapy for malignant pleural mesothelioma. After full protocol development the project has been withdrawn by the company producing CS-1008.

**Projects / Strategies for the coming years**

The LCG worked closely in 2010 with EORTC Headquarters to develop a strategy for the coming years focusing initially on NSCLC. Currently several new projects are under discussion in the LCG, among them four concern NSCLC. The LCG strategy meeting held in October 2010 placed emphasis on early disease and pre-surgical settings. The group has dedicated members with strong expertise in mesothelioma, translational research, as well as nuclear medicine.

**Quality Assurance**

Quality assurance remains an important issue with emphasis being placed on the selection of new members and timelines of submitting patient research data. The increased regulation associated with opening clinical trials has meant limiting individual studies to a small number of countries with corresponding negative effects on recruitment.
Translational Research

Translational research is an important component of our studies, and data collection and tissue storage for future use are considered very important. Our pathology Sub-chair and Young Oncologist have been active in developing protocols for tissue transport and research. A customized secure web-based portal has been developed for virtual tissue archiving of samples from the EORTC 08031 trial and will be used as a platform for centralized review of biomarkers in future clinical trials. Tissue microarrays have been developed in collaboration with LCG centers in Aberdeen and Belfast enabling multiple biomarker evaluation. For tissue collected in the EORTC 08092 (MAPPING) trial, the medical oncology sub-chair Dr. D. Fennell will coordinate tissue banking in the Northern Ireland Cancer which is linked to the Queen’s University Belfast core technology unit. This will enable rapid tissue processing, nucleic acid extraction, and the ability to conduct an array of molecular tests including expression or micro RNA array analysis, DNA copy number analysis, or quantitative PCR. This should support future development of personalized therapies based on tumor genetic profiles. The LCG will continue to invest in these studies.

Collaboration with other groups

The LCG has ongoing collaborations with EORTC Imaging Group and the Cancer in the Elderly Task Force and plans future collaboration with the Pathobiology and Head and Neck Cancer Groups. An EU Framework 7 grant has been submitted with the European Thoracic Oncology Platform (ETOP) to conduct a phase II/III clinical trial of obatoclax in malignant pleural mesothelioma.
Lymphoma Group

Structure of the Group

Chair
R.W.M. van der Maazen, Nijmegen (NL)
Secretary
P. Meijnders, Antwerp (BE)
Treasurer
Y. Lievens, Leuven (BE)

Executive Committee

The EORTC Lymphoma Group (LYMG) Executive Committee consists of the Chair, the Secretary, the Treasurer and the following members:

Scientific Steering Committee

The LYMGE Scientific Steering Committee sets the scientific strategy of the Group. It organizes scientific meetings and/or brainstorming sessions for the whole group, evaluates ongoing studies together with the study coordinators, and considers the need for amendments. The SSC meetings are open to all members.
Coordinator
J.M.M. Raemaekers, Nijmegen (NL)
Young investigators
M. van der Kaaij, Groningen (NL)
W. Plattel, Groningen (NL)

Pathology Committee

The LYMGE Pathology Committee is active in the collection of pathology material from ongoing studies and performs and supports scientific side studies based on material from trials.
Coordinator
D. de Jong, Amsterdam (NL)
Member
A. Diepstra, Groningen (NL)

Radiotherapy Committee

Focuses on new strategies in radiotherapy and develops quality control and assurance programs for ongoing and new studies.
Coordinator  T. Girinsky, Villejuif (FR)
Members  B.M.P. Aleman, Amsterdam (NL)
          M. Beijert, Groningen (NL)
          Y. Lievens, Leuven (BE)
          R.W.M. van der Maazen, Nijmegen (NL)
          P. Meijnders, Antwerp (BE)
          E. Noordijk, Oegstgeest (NL)
          P. Poortmans, Tilburg (NL)
          P. Richaud, Bordeaux (FR)
          L. Specht, Copenhagen (DK)

Translational Research Committee
The main focus of the group is to perform academic multicentric randomized trials. The need for implementing translational research questions in such trials has been acknowledged and projects have been started on evaluable trials on HL with the research group of Prof. A. van den Berg, Dr A. Diepstra and Dr G. van Imhoff (University of Groningen, NL) in collaboration with Dr. D. de Jong (Amsterdam, NL), and molecular side studies are ongoing on a recently conducted NHL trial (Dr. D. de Jong, Amsterdam, NL).

Imaging Expert  M. Hutchings, Copenhagen (DK)

Recent Achievements

On-going trials and research projects
EORTC 20051- H10 trial (J.M.M. Raemaekers): an Intergroup (EORTC, GELA & IIL) phase III randomized trial on early $^{18}$F fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) scan guided treatment adaptation versus standard combined modality treatment in patients with supradiaphragmatic stage I/II Hodgkin’s Lymphoma (HL). An oral presentation about the trial was given at the 51st ASH Annual Meeting and Exposition in December 2009 by M. André (GELA). An interim analysis of efficacy was performed and reviewed in June 2010 by the IDMC. Because of the unlikelihood to meet the primary objective of the study, this part of the study was closed. The study remains open to accrual until mid 2011 for the secondary objective (Is intensified treatment superior to standard treatment in PET positive patients after 2 cycles of ABVD?). Two questions based on the PET scan after two cycles of adriamycin (doxorubicin), bleomycin, vinblastine, and dacarbazine (ABVD) are being investigated, namely a comparison of visual and quantitative assessment of the PET scan and the incidence of positive PET scan in relation to the presence or absence of bulky mediastinum.

EORTC 20012 trial (P. Carde): an Intergroup (EORTC, GELA, ALLG, NCRI LYG, GELCAB, NCIC, and NLG) phase III randomized trial comparing BEACOPP (cyclophosphamide, doxorubicin, etoposide, procarbazine, prednisone, bleomycin, vincristine; four cycles escalated + four cycles baseline) versus ABVD, eight cycles, in high risk stage III & IV HL having reached complete remission after six cycles. The required number of patients was reached in January 2010, and the final analysis is expected to take place in 2011.
EORTC 20971 trial (M. Beijert): a phase III randomized trial of low-dose total body irradiation and involved field radiotherapy versus involved field radiotherapy in patients with localized stage I and II low-grade non-Hodgkin’s lymphoma (NHL). The trial included 204 patients but was closed due to too slow accrual in March 2009. A translational research project is currently ongoing regarding genetic classification of this very exceptional group of follicular lymphoma (D. de Jong, Amsterdam, NL).

EORTC 20931-HB trial (H. Eghbali and C. Fermé): a phase III trial in stage I-II supradiaphragmatic HL aiming to evaluate the treatment efficacy and (long term) toxicity in three different prognostic subgroups. The results of the quality of life analysis have been published (Lancet Oncology, 2009). The final analysis has been performed and publication is expected in 2011.

The results of the HDR2 study (for relapsed and refractory HL) performed in collaboration with the German Hodgkin’s Lymphoma Study group (GHSG) were accepted for publication (JCO, 2010).

EORTC 20992 trial (P. Soubeyran): a phase II trial in diffuse large B-cell and peripheral T-cell NHL in the frail elderly. The results of the trial have been accepted for publication in the Journal of Geriatric Oncology in 2010.

EORTC 20021 trial (I. Aurer): This randomized phase II study has investigated the addition of gemcitabine to standard chemotherapy (R)-CHOP in untreated aggressive Non-Hodgkin’s Lymphoma and will be published in the European Journal of Haematology in 2010 or 2011.

Long-term survivorship in European patients treated for HL (M. Henry-Amar): The Group has included more than 6000 patients in EORTC/GELA HL trials over the last 45 years. The purpose of this cross sectional study is to evaluate the consequences of the disease and its treatment on social, professional and private life as well as detection of late side effects in survivors enrolled during this period of time. In the first part of the project, completed in October 2010, 3604 living patients received a Life Situation Questionnaire (LSQ) which includes questions in six domains (general, parenthood, education/work, health, social life, support) and will provide extensive information on the quality of life of these long-term survivors. Analysis of these LSQ questionnaires is currently in process. Two publications are expected to be published soon: one concerns the age of menopause and occurrence of premature ovarian failure (POF) and early menopause in female patients treated for HL, and the other concerns parenthood of both male and female patients after treatment for HL.

The second part of this project will be to perform a clinical update to evaluate the long term physical adverse effect of treatment and outcome. For this purpose, a medical questionnaire will be sent to all participating sites early 2011. Part of this project is financed by the Lance Armstrong Foundation.

Projects / Strategies for the next years

Hodgkin’s Lymphoma remains the priority of the Group.
**Early Stage Hodgkin’s Lymphoma**

Among the patients treated within two clinical trials in stage I-II HL (the H7 trial, studying comprehensive management tailored to prognostic factors, and the H8 trial, evaluating treatment efficacy and (long term) toxicity in three different prognostic subgroups) the subgroup of patients with very favorable characteristics was treated with mantle field radiotherapy only. This subgroup of patients is being evaluated and results will be published in 2011.

Final results of the H9 trial evaluating the treatment efficacy, (long term) toxicity, and Quality of Life in two different prognostic subgroups (favorable and unfavorable) will be published in 2011.

The current research strategy is to decrease the level of toxicity of the standard combined modality treatment. New initiatives are being prepared together with GELA and IIL (H12).

**Advanced Stage Hodgkin’s Lymphoma**

A new study, the EORTC 20101-H11 trial (M. Hutchings) was endorsed by the Executive Committee in May 2010. The main objective of this trial is to show that ABVD based response adapted therapy for advanced stage HL with treatment intensification in case of a positive FDG-PET after one cycle of ABVD has non-inferior efficacy compared with the intensive BEACOPP regimen (now considered as standard treatment by many). The aim of this strategy is to limit the intensified treatment and its toxicity to those patients who really need it to be cured.

**Relapsed or Refractory Hodgkin’s Lymphoma**

Preparations are ongoing for a new study for patients with relapsed or refractory HL (HDR3) that will focus on the induction chemotherapy schedule (adding the mTOR inhibitor Everolimus, HDR3i) and the possible role of maintenance therapy after autologous stem cell transplantation with an HDAC inhibitor (Panobinostat, HDR3m). The maintenance part is a Novartis driven trial for participation with individual EORTC centers (J. Baars and I. Aurer).

**Fatigue Project**

Within the population which participated in the cross sectional long term survivorship study, a nested case control study is currently under preparation focusing on the assessment of unexplained, i.e., non medical, persistent fatigue and identification of risk factors. Biological mechanisms to understand this persistent fatigue will also be investigated as an exploratory endpoint (M. Henry-Amar).

**Quality Assurance**

The LYM Radiotherapy Committee continues to perform early retrospective quality control to develop new radiotherapy guidelines and takes responsibility for the implementation of these guidelines (T. Girinsky).
The LYMG Pathology Committee has extensive experience in reviewing material from patients included in trials (D. de Jong).

A new platform for central review of PET allowing reviewers to work online in a timely manner (EORTC Imaging Platform) will be used for the new upcoming trials.

**Translational Research**

Expression of Thymus and Activation Regulated Cytokine (TARC) is elevated in HL cell lines and tissues. TARC can be demonstrated in the serum of patients with untreated HL. It could be used as an early predictor of refractory or recurrent disease (contacts with the group of Prof. Van den Berg, University Hospital Groningen, NL). A prospective correlative translational research focusing on TARC is included in the new trial in advanced stage HL (H11) (G. van Imhoff, M. Hutchings).

Follicular lymphoma (FL) rarely presents as localized disease. The structure of the translocation t(14;18) suggests a primary oncogenetic origin in precursor B-cells possibly in the bone marrow, suggesting that nodal FL should be regarded as disseminated disease per definition and contradicting the possibility for localized disease. In a series of patients treated within the EORTC 20971 trial for limited stage nodal low-grade B-cell lymphoma, the morphological, immunological, and molecular characteristics of the tumor are currently being investigated in order to better characterize the rare group of low-stage nodal FL (D. de Jong).

**Collaboration with other groups**

- EORTC Radiotherapy Group / QA group: P. Poortmans
- EORTC Imaging Group: M. Hutchings
- International Cochrane Review group: L. Specht
- German Hodgkin Study Group: J.M.M. Raemaekers
- International Mantle Cell Network: J.C. Kluin-Nelemans
- Intergruppo Italiano Linfomi: J.M.M. Raemaekers, T. Girinsky
Melanoma Group

Structure of the Group

Chair
P. Patel, Nottingham (UK)
Chair elect
A. Testori, Milan (IT)
Secretary
D. Schadendorf, Essen (DE)
Treasurer
G. Ghanem, Brussels (BE)

The Melanoma Group (MG) has eight committees concerned with the management of cutaneous and ocular melanoma, the development of new treatment strategies, and basic science conducting epidemiologic, genetic, and pathologic studies in melanoma. The Translational Research Committee acts as an umbrella committee to foster lateral interactions between the research interests of the group in pathology, genetics, and epidemiology.

Chair Adjuvant Therapy Committee
A.M.M. Eggermont, Villejuif (FR)
Chair Epidemiology Committee
J. G. Coebergh, Rotterdam (NL)
Chair Genetics Committee
J. Newton Bishop, Leeds (UK)
Chair Ocular Melanoma Committee
S. Leyvraz, Lausanne (CH)
Chair Pathology Committee
M. Cook, Guildford (UK)
Chair Stage IV Melanoma Committee
U. Keilholz, Berlin (DE)
Chair Surgery Committee
A. Testori, Milan (IT)
Chair Translational Research Committee
D. Schadendorf, Essen (DE)
Young Oncologists / Scientists
A. Van Akkooi, Rotterdam (NL)
L. van Kempen, Montreal (CA)

Recent Achievements

Completed trials

STAGE IV

EORTC 18032 trial: Extended schedule, escalated dose Temozolomide (TMZ) versus Dacarbazine (DTIC) in Stage IV metastatic melanoma: a randomized phase III study. Study coordinator: P. Patel

This trial, the largest ever to date in stage IV melanoma, evaluated the use of an extended schedule, escalated dose TMZ in stage IV melanoma. The trial recruited 859 patients over four years. There was no significant difference in overall survival (OS): median survival was 0.76 (TMZ) and 0.78 y (DTIC); hazard ratio 0.99. Median progression free survival (PFS) was equal in both arms: 0.19 vs. 0.18 mo.
Overall RR was 14.5 versus 9.8% (TMZ versus DTIC). The main toxicities were hematological and were more pronounced in the TMZ arm (41.3% versus 23.6% grade 3 / 4).

**EORTC 16032-18031 trial:** Randomized, open phase II study of immunization with the recombinant MAGE-3 protein combined with adjuvant AS02B or AS15 in patients with unresectable and progressive metastatic cutaneous melanoma. Study coordinator: W. Kruit

This trial evaluated the activity and toxicity of two adjuvants, AS02B and AS15, in combination with MAGE-3 protein in the treatment of metastatic cutaneous melanoma. This trial screened 165 and randomized 75 patients. In the AS15 arm (N=36), three patients reached CR and one patient reached PR. In the AS02B arm (N=36), one PR was reported. In addition, eight (AS15 group) versus five (AS02B arm) patients received vaccinations during >16 weeks from randomization. Anti-MAGE-3 antibody titers were higher in the AS15 arm than in the AS02B arm.

**STAGE III**

**EORTC 18952 trial:** Randomized phase III trial. Post-operative adjuvant Interferon-alpha 2b (Intron-A) treatment after resection of thick primary melanoma and/or regional lymph node metastases “intermediate-high dose” versus “intermediate-low dose” Interferon-alpha versus observation. The study is in long term follow up. First results were published (A. Eggermont et al., Lancet 2005)

**EORTC 18991 trial:** Randomized phase III: Adjuvant PEG Intron (5 years) versus observation after regional lymph node dissection in AJCC Stage III (TxN1M0) melanoma patients: a multicenter randomized phase III trial. Study coordinator: A. M. M. Eggermont

This trial investigated the effect of long-term therapy with the long-acting pegylated interferon alpha 2b (PEG-Intron) versus observation on relapse-free survival (RFS), distant metastasis-free survival (DMFS) and OS, in high risk melanoma patients after full lymph node dissection of positive regional lymph nodes. The study accrued 1256 patients. The median length of treatment with PEG-Intron was 12 months. At 3.8 years median follow-up, 328 recurrence events had occurred in the PEG-Intron group compared with 368 in the observation group (hazard ratio 0.82, 95% CI 0.71–0.96; p=0.01); the 4-year rate of RFS was 45.6% in the PEG-Intron group and 38.9% in the observation group. There was no difference in OS between the groups. Grade 3 adverse events occurred in 246 (40%) patients in the PEG-Intron group and 60 (10%) in the observation group; grade 4 adverse events occurred in 5% (PEG-Intron) versus 2% (observation). In the PEG-Intron group, the most common grade 3 or 4 adverse events were fatigue (16%), hepatotoxicity (11%), and depression (6%). Treatment with PEG-Intron was discontinued because of toxicity in 191 (31%) patients (A. Eggermont et al. Lancet 372 (9633): 117-126, 2008).

The EORTC QoL Department performed the analysis of the QoL data. Significant and clinically meaningful differences occurred with PEG-Intron group compared to the observation group and showed decreased global HRQoL at month three (-11.6 points) and year two (-10.5 points). Many of the other scales showed statistically significant differences between scores when comparing the two groups. From a clinical point of view important differences were found for two functioning scales (social and role functioning) and three symptoms (appetite loss, fatigue and dyspnea) with the PEG-Intron group being most impaired (A. Bottomley et al. J Clin Oncol. 27 (18): 2916-2923, 2009).

Currently the 18991 study is under FDA revision and is in long term follow up.
Most recent publications related to the study:
The lack of the prognostic significance of the appearance of auto antibodies in patients entered in the EORTC 18991 trial confirmed the previous findings of the EORTC 18952 study and Nordic IFN trial. The results were published recently (Bouwhuis M et al., J Clin Oncol 28(14): 2460-2466, 2010).

In the study, detection of circulating tumor cells by RT-PCR for tyrosinase and Mart-1/Melan-A appeared to be a time-dependent moderate prognostic factor for subsequent development of distant metastasis in stage III melanoma patients (Fusi, A et al., Eur J Cancer. 45(18):3189-97, 2009).

STAGE II

**EORTC 18961 trial**: Post-operative adjuvant ganglioside GM2-KLH/QS21 vaccination treatment after resection of high risk primary melanoma (> 1.5 mm) (TNM: T3-4N0M0: stage II). A 2-arm multi-center randomized phase III trial. **Study coordinator: A. M. M. Eggermont**

This trial investigated whether following excision of a high risk primary melanoma (>1.5mm) treatment with the ganglioside vaccine GM2-KLH/QS21 for a period of three years would improve DFS and OS. The study reached the required number of patients and was closed to patient entry in December 2005. An interim analysis took place in 2007. For the primary endpoint DFS, the criteria for stopping for futility were met. The IDMC thus recommended that the trial be stopped as it was highly unlikely that a benefit of the vaccine would be observed. The recommendation was immediately endorsed by the MG Executive Committee and the treatment with the vaccine was stopped in the patients still receiving treatment. Thereafter, patients continue to be followed for RFS, DMFS and OS endpoints. At a median follow-up of 4.2 years, the number of events for the final analysis was reached. Final results were presented at the ASCO 2010 meeting (A. Eggermont et al, J Clin Oncol 28:15s, (suppl; abstr 8505), 2010), and a manuscript is being prepared for publication.

Ongoing Studies

**EORTC 18021 trial**: Intravenous versus intra-arterial fotemustine chemotherapy in patients with liver metastases from uveal melanoma: a randomized phase III study. **Study coordinator: S. Leyvraz**

This trial was activated in 2004 and targets 262 patients. This protocol runs within a network of EORTC institutions experienced with uveal melanoma and having facilities for intra-arterial hepatic perfusion. A total of 168 patients were randomized so far (October 2010). The accrual rate decreased in the last year. In the near future, an unplanned interim analysis will probably be done and submitted to the IDMC.

**EORTC 18071 trial**: Adjuvant Immunotherapy with anti-CTLA-4 Monoclonal Antibody (ipilimumab) versus Placebo after complete Resection of high-risk Stage III Melanoma: A randomized, double-blind Phase III Trial. **Study coordinator: A. Eggermont**

The primary objective of this study is to prospectively assess whether post-operative adjuvant therapy with ipilimumab improves RFS, OS and DMFS as compared to placebo in high-risk patients with complete resection of Stage IIIA (< 1 mm metastasis), IIIB and IIIC (no in-transit metastasis) melanoma. The recruitment started in 2008. 60% of the required 950 patients have been randomized already (October 2010).
**Translational Research**

There is an evidence level 2 that sentinel node (SN) is the best staging procedure in cutaneous melanoma. Patients with negative SN constitute a homogeneous group of patients with good prognosis (85% 5-year survival rate). Therefore, only patients staged by SN procedure will be included in adjuvant trials. This SN micro-staging should systematically follow the protocol established by the MG, as differences in pathology protocols can lead to variations in the SN reliability. In the meantime, there is a need to better understand the individual susceptibility to melanoma relapse: 50% of patients with a micro-metastatic SN will die from their disease. There is a need to better understand at the N1 stage which factors influence the risk for relapse. A constitutional genetics study has been launched to address this issue.

It has been demonstrated by the Erasmus group that SNs with micro-metastases below 0.1 mm in diameter are associated with virtually the same prognosis as negative SNs (Ann Oncol. 2006; 17:1578-85 and Br J Surg 94: 1293-9, 2007). Whether SNs with small micro-metastases should lead to CLND or not will be addressed by a controlled study currently in preparation. The MG is conducting a registration study examining the outcome of conservative management in low risk minimal microscopic SN positive patients (MINUTUB study). The MG has also investigated whether the ultrasound guides FNAC prior to surgical SN staging is a cost-effective approach (C.A. Voit et al., Melanoma Res. 20(4):357-9, 2010).

Gogas and colleagues have reported that patients treated with adjuvant interferon who developed auto-antibodies against thyroglobulin, antinuclear factors, or cardiolipin had a significantly better outcome than patients that did not develop these signs of autoimmunity (N Engl J Med 354:709-18, 2006). These results however have not been confirmed by our studies (see above).

A potentially very important interaction between response to adjuvant interferon and ulceration was demonstrated in a retrospective analysis of the EORTC 18952 and 18991 studies. The results, presented in an oral presentation at ASCO 2009 (Eggermont et al. J Clin Oncol 27:15s (suppl; abstr 9007), 2009), show a significant benefit of adjuvant interferon versus observation only in patients with ulcerated primaries. The effect was more marked in patients with stage II disease and microscopic stage III disease. The study forms the basis for the planned adjuvant study targeting patients with ulcerated primaries.

**Projects / Strategies for coming years**

Two new studies are being planned

EORTC 18081 trial: Adjuvant Pegylated-Interferon-alpha2b for 2 years versus Observation in patients with an ulcerated primary cutaneous melanoma (T1b-T4bN0M0): a randomized phase III trial of the Melanoma Group. The protocol, approved by the EORTC PRC, is being reviewed by the FDA.

EORTC 18091 trial: A Phase I/II Open Label Multicenter Study of ONTAK® as Treatment for advanced melanoma (stage IIIc and stage IVM1a): a trial of the EORTC Melanoma Group. The outline
was approved by the EORTC Executive Committee, and is being reviewed by the PRC. Uveal melanoma is the focus of several new concepts.

**Collaboration with other groups**

**EORTC PathoBiology Group and EORTC Tissue Bank:**
Pathology quality assurance for the MG trials and tissue collection for translational research make use of the virtual microscope platform implemented at EORTC Headquarters. The establishment of the MG biobank related to the MG trials should continue to permit rapid and detailed analyses of specific questions.

**CHEMORES**
Members of the MG are also active participants in the FP6 funded CHEMORES (Tumor Chemotherapy Resistance), an integrated project involving clinicians and scientists at 17 universities, organizations for cancer research, and research-oriented biotechnology companies in eight European countries. CHEMORES aims to improve cancer treatment by obtaining increased knowledge on mechanisms of chemotherapy resistance.

Within CHEMORES, the MG is also collaborating with the AIM HIGH Study Group and the Nordic Adjuvant Group to constitute in Europe two unique centralized collections of tissue blocks. This strategy is part of an international collaborative effort initiated by Pr. Julia Newton Bishop to investigate predictive factors of interferon treatment in melanomas.
Pathobiology Group

Structure of the Group

Chair: M.G. Daidone, Milan (IT)
Chair-elect: J. Martens, Rotterdam (NL)
Secretary: J. Dittmer, Halle (DE)
Treasurer: A. Geurts, Nijmegen (NL)
Translation Research Chair: M. Schmitt, Munich (DE)
Clinical Trial Representatives: N. Harbeck, Cologne (DE)
C. Thomssen, Halle (DE)
Biorepositories Chair: A. Paradiso, Bari (IT)
Quality Assurance Biomarkers Chair: F. Sweep, Nijmegen (NL)
Quality Assurance Pathobiology Chair: R. Salgado, Antwerp (BE)
NCI-EORTC Affairs: N. Brunner, Copenhagen (DK)
Clinical Affairs: F. Cardoso, Lisbon (PT)
S. Sleijfer, Rotterdam (NL)
Basic Affairs: J. Foekens, Rotterdam (NL)
J. Kos, Lubiana (SI)
Young Investigator Tumor Biology: O. Gluz, Cologne (DE)
Young Investigator Pathology: L. Libbrecht, Ghent (BE)

The Executive Committee of the PBG is comprised of the Chair, Chair-elect, Secretary, and Treasurer.
The Steering Committee of the PBG is comprised of the members of the Executive Committee,
Translational Research Chair, Clinical Trial Representatives, Biorepositories Chair, Quality Assurance
Biomarkers and Pathology Chairs, NCI-EORTC Affairs Officer, Clinical and Basic Affairs Officers, and
the Young Investigators for Tumor Biology and Pathology.
The EORTC Pathobiology Group (PGB) was established in November 2005 by merger of the
Pathology and the Receptor and Biomarker Groups.

Recent Achievements

Translational research (TR) is an essential component of the PBG mission in order to assess and qualify
the scientific and clinical value of biomolecular markers/molecular signatures in tissue, cells, plasma,
serum, and other bodily fluids, and to carry out studies to provide relevant information for patient
management with high level of evidence for clinical implementation of cancer biomarkers and
molecular profiles. Specifically, the PBG has been involved in TR activities focused mainly on solid
tumors with the most prominent being breast, colorectal, and ovarian cancers, and glioblastoma. These activities include:

- Multicenter studies to clinically validate:
  - the biochemical markers uPA and PAI-1 (recommended by the ASCO breast cancer consensus panel for their clinical utility in early breast cancer patients, J Clin Oncol 2007; 25:5287-5312) as risk selection criteria in node-negative breast cancer patients and compare their predictive role with that of clinico-pathological factors;
  - the Rotterdam 76-gene profile for lymph node-negative breast cancer patients receiving local-regional treatment and/or adjuvant Tamoxifen;
  - molecular-based risk assessment according to OncotypeDX and uPA/PAI-1 in primary HER2-negative breast cancer submitted to anthracycline-free chemotherapy: the WSG PLAN B trial.

- Development of *in vivo* proof of concept for tissue and plasma levels of TIMP-1 including prospective studies to evaluate the clinical significance of plasma levels for early recurrence in colorectal cancer patients and studies on plasma TIMP-1 as a marker for minimal residual disease in colorectal and breast cancer and development of specific TIMP-1 assay test kits.

- Participation in several genomic and proteomic projects on different cancer types to challenge gene signatures and epigenetic biomarkers with patient’s prognosis and response to chemo/endocrine therapy.

- Studies on the DNA-methylation profile of CpG islands within promoter regions of candidate genes in breast and brain tumors of patients subjected to different types of systemic treatments.

- Investigations on molecular markers associated with invasion and metastasis (kallikreins, cathepsins, in addition to uPA/PAI-1, uPAR, TIMP-1), with hypoxia and angiogenesis (VEGF, HIF-1α, carbonic anhydrase IX) and with cell survival (apoptosis and telomere maintenance mechanisms) in different tumor types.

- Treatment-related activities:
  - investigations on molecular markers predictive of treatment response (uPA, PAI-1, Y-B1, TIMP-1, PSA-t, PITX2, CXCL9, GPR30, survivin) and associated with apoptosis (the cytokeratin-based novel biomarkers M30 and M65);
  - *ex vivo* investigations of mechanisms and patterns of chemoresistance in tissue and blood components of patients with lung cancer or melanoma (www.chemores.org);
  - cytoskeleton and paclitaxel sensitivity in breast cancer: the role of beta-tubulins;
  - development of surrogate markers to determine effect of uPA inhibitors (www.wilex.com);
  - small molecule targeting of heat shock protein 90 chaperone function: rational identification of a new anticancer lead;
  - identification of novel angiogenesis targets;
  - deregulation of cytidine deaminase in gemcitabine-treated patients;
  - pathway analysis and designing of future targeted therapies to overcome resistance to EGFR tyrosine kinase inhibitor in different tumor types (glioblastoma, NSCLC);
  - targeting radioresistance-related pathways for the modulation of radiation response.

- Task force on micrometastasis: evaluation and standardization of new technologies for the detection and characterization of micrometastases, demonstration of usefulness of prognostic/predictive screening for micrometastatic cells in bone marrow/blood of cancer patients plus detection of circulating tumor cells in the peripheral blood of breast cancer patients.
• Application of novel antibody-coated Seldinger guide wire nanodetectors and antibody-coated bead systems (CellSearch, Adnagene) to track and enrich circulating tumor cells in vivo (www.gilupi.com).
• Preclinical and clinical studies on triple negative breast cancers.
• Identification of putative cancer stem cell markers and set-up of highly tumorigenic cell cultures as tools to investigate the activity of conventional and investigational new drugs.

Projects / Strategies for the next years

Future PGB activities will be directed towards:
• Improving interactions with disease oriented group and Network of Core Institutions (NOCI) Pathologists.
• Supporting EORTC Headquarters in biobanking activities and in the setting-up and disseminating Standard Operating Procedures (SOPs).
• Stimulating ideas for research and advice on biomaterial collections within the context of TR studies/protocols.
• Extending quality control to provide support to EORTC TR trials on:
  o CTCs (circulating tumor cells);
  o RNA biomarkers;
  o mutation detection (colon cancer; lung cancer);
  o biobanking.
• Evolving to pathway/target orientated strategies:
  o development of experimental models for in vitro-in vivo studies;
  o target identification & validation, functional studies.

As a translational aspect, the PBG aims to conduct research and teach in the life science area focusing on detection, characterization, determination, and potential clinical application of cancer biomarkers associated with cancer disease progression and cancer metastasis. Markers will be investigated which provide information about:
• diagnosis;
• prognosis;
• selection of therapy;
• monitoring of treatment response and side effects;
• assessment of individual risk;
• detection of micrometastases;
• molecular basis of carcinogenesis in specific tissues;
• identification of biologically / clinically relevant molecular targets for new therapies.

Guiding principles are provided and discussed on how to inform physician scientists and cancer researchers about quality control systems to enable a consistent assessment of the clinical value of cancer biomarkers. A solid understanding of good laboratory practice for tumor tissue or blood sample collection and storage, tissue processing, assay methods, reference materials, and SOPs is often missing. Therefore, the PBG advises on procedures, test kits, and test reagents to be utilized for tumor
biomarker determinations. Thus, the PBG is willing to take an active part in advising the EORTC disease oriented groups regarding tissue/blood storage and handling, cancer biomarker assessment, SOPs, biochemical/cellular methodologies and technologies as well concerning good laboratory practice, quality assessment and quality assurance (QA).

To improve the TR cooperation within EORTC (pre)clinical trials, the PBG intends to organize joint meetings with several of the EORTC disease oriented groups and also in the context of NOCI. The PBG will engage more actively in the translational cancer research component of EORTC clinical trials, and several PBG members are members of the Translational Research Advisory Committee (TRAC).

In accordance with EORTC Headquarters’ philosophy, the PBG strongly aims at encouraging young scientists/clinicians to become active PBG members in order to guarantee continuity within the PBG and to train these young scientists/clinicians in the field of cancer biomarker investigation and clinical oncology.

**Quality Assurance**

The PBG QA center (Nijmegen) has extensive experience beginning in 1979 in performing QA studies on cancer biomarkers both within and outside the EORTC. This includes quality assessment and QA of the reagents and test systems employed, e.g. pre-analytical processing and commercial kits for existing markers, and of the equipment used to quantify the biomarker content in tumor tissue extracts or other body fluids. These still represent important tasks of the PBG.

Currently, owing to rapid gene profiling activities, tumor associated biomarkers in tissues or body fluids are becoming increasingly important also for their use in clinical decision making. This repertoire of potential biomarkers is increasing steadily as is the variety of methods used for their measurements, although standardization and quality control of these measurements is often lacking as are guidelines on interpretation of results. This is not always known to the clinicians or the basic scientists, and even worse, assay results from unvalidated biomarker studies are repeatedly being made available to the public in scientific publications. Establishing guidelines and informing the medically trained cancer researcher is of high priority for the PBG.

On a regular basis the PBG advises on common methodologies for tumor biomarker assays and ensures that appropriate external quality assessment schemes are available. As most of the cancer trials involve multicenter cooperation, special emphasis by the PBG is put on the quality and performance of the assays, on their reproducibility and on the collaboration with clinical groups of the EORTC, European Commission, Health Authorities, and other national and international bodies that have scientific and social interest in the supply of optimal information about the quality and performance of tumor biomarker tests and their relevance for cancer patient management. The PBG is also prepared to assist in the development of guidelines regarding tissue banking.

The PBG will therefore continue to:
- focus attention on biomarker development and clinical implementation;
- support high-level QA programs when assessing cancer biomarkers: recently the portfolio of biomarkers under QA procedures includes, besides uPA and PAI-1, also PCR assays for determining
HER2 amplification in FFPE breast cancer samples, and circulating tumor cell quantification;
- set up SOPs and develop internal and external reference materials for tumor biomarker assays plus
writing and communication of SOPs on specimen handling and processing.

**Translational Research**

The PBG does not conduct EORTC sponsored clinical trials on its own but attempts to perform cancer biomarker studies on clinical materials (tissue and body fluids) obtained from clinical EORTC groups as part of EORTC clinical studies and is involved in quality assessment and QA measures. To conduct and facilitate translational cancer research, physician scientists, pathologists, clinical chemists, basic scientists (i.e., molecular and cell biologists, biochemists), and statisticians representing different European clinical and/or research centers, including the NOCI, are working closely together.

Within this scenario, the PBG is conducting or taking part in several tasks:
- Harmonization of pathology review across EORTC trials plus collaboration in the organization and maintenance of physical and virtual tumor bank(s) with specimens from cancer patients enrolled in clinical trials and associated clinico-pathologic databases.
- Transnational multicenter studies to validate gene signatures (multiplex cancer biomarker panel) and cancer biomarkers predicting disease progression and/or treatment response/failure in patients with solid malignant tumors.
- Handling of legal issues related to tissue and blood collection.

In particular, PBG activity within the novel EORTC policies for biobanking has substantially improved in the last year, with a strong and intense collaboration between PBG members and key persons in the Translational Research Unit at EORTC Headquarters.

**Collaboration with other groups**

Within the EORTC: a strong collaboration of individual PBG members with members of the EORTC Translational Research Division, the Pharmacology and Molecular Mechanisms and the Imaging Groups, is ongoing and mainly encompasses research activities regarding signal transduction pathways and metabolic activity of cancer therapeutics. Furthermore, PBG members participate actively in several EORTC Clinical Research Division Groups including the Brain Tumor, Breast Cancer, Gastrointestinal Tract Cancer, Genito-Urinary Tract Cancer, Gynecological Cancer, Head and Neck Cancer, Lung Cancer, Soft Tissue and Bone Sarcoma, Melanoma, and Radiation Oncology Groups to facilitate basic and clinical exchange and to enforce translational cancer research.

Outside EORTC: PBG members participate actively in several non-EORTC Groups/Societies, including EGTM, NCI and EDRN, ISOBM, GBG, IPS, ISFP, BIG, TRANSBIG, ASCO, AACR, EACR and ESMO.

PBG members are organizing and actively participating in the annual EORTC-NCI-ASCO (ENASCO) meetings in Brussels and in the USA.
Pharmacology and Molecular Mechanisms Group

Structure of the Group

Chair: G.J. Peters, Amsterdam (NL)
Secretary: E. Chatelut, Toulouse (FR)
Treasurer: A.K. Larsen, Paris (FR)
Chair, Drug Discovery Committee: G.J. Peters, Amsterdam (NL)

Steering Committee

A.M. Burger, Detroit (US)  E. Raymond, Paris (FR)
I. Fichtner, Berlin (DE)  J. Robert, Bordeaux (FR)
M. Hegi, Lausanne (CH)  A. Skladanowsky, Gdansk (PL)
D. Jodrell, Cambridge (UK)  N. Zaffaroni, Milan (IT)

Young Oncologists/Scientists

S. Faivre, Paris (FR)  A. Westwell, Cardiff (UK)

The aim of the Pharmacology and Molecular Mechanisms (PAMM) Group is to stimulate research in Europe in the fields of pharmacology, pharmacokinetics, pharmacodynamics, pharmacogenetics and pharmacogenomics, and on the molecular mechanisms of anticancer drug effects and drug-related molecular pathology. In addition, the PAMM Group serves as a master organization for other EORTC groups such as the former Screening and Pharmacology Group (SPG) which now fully operates as the Drug Discovery Committee (DDC).

Recent Achievements

The annual scientific winter meetings of the Group were held in January 2010 in Toulouse, France and in February 2011 in Gdansk, Poland. This is the first PAMM meeting in the former Eastern Europe. Following the intense interactions with the Pathobiology Group (PBG) during the meetings in 2008 and 2009, this interaction was continued during the small EGAM in 2010 as well as during the PBG meeting in Marseille which was attended by several PAMM committee members. In addition several informal contacts exist between PAMM and PBG committee members. This serves as a good basis for further interactions with the PBG.

During the DDC meeting in Toulouse the future of the committee was discussed in order to better position the group within the EORTC. The NCI-EORTC drug screening initiative provides a unique evaluation platform in Europe for characterization of novel chemical entities (NCE). The group is currently summarizing the achievements in order to emphasize its role in European drug discovery and
development. Moreover, there is a good interaction with the newly formed Imaging Group which was part of the PAMM group as an Imaging Committee. During the small EGAM, several connections with various clinical groups as well as the Cancer in the Elderly Task Force were initiated. These are and will be fostered in the coming years.

Projects / Strategies for the next years

Future strategy is to link the PAMM Group activities more closely to the activities of the EORTC disease-oriented groups. Various initiatives from both the PAMM Group and the disease oriented groups were undertaken during the 2009 EGAM meeting. PAMM promotes young clinical investigators with interest in translational research to become members of PAMM. PAMM is in a unique position, since it provides valuable drug expertise alongside the traditional pathology directed expertise of most translational research officers of the disease oriented groups. This not only enables the performance of drug monitoring but also the evaluation of pharmacodynamic events in relation to pharmacogenomics.

These analyses as well as polymorphisms have already provided the basis for tailored therapy designed to give the right drug at the right time to the right patient. Together with the imaging technology expertise of the Imaging Group, this will give invaluable support to clinical studies. Currently the group aims to standardize methodology for geno – and phenotyping; naturally this approach assumes that all laboratories adhere to classical PAMM quality assurance. The new developments such as resistance to targeted drugs should adhere to strict quality controls. A PAMM quality label will be given to laboratories with suitable expertise.

The PAMM Group with its DDC forms a large reservoir of expertise for optimizing drug development and will be of invaluable help for EPOD, the Translational Research Advisory Committee (TRAC), as well as the New Drug Advisory Committee (NDAC). A good integration of these activities will optimize the identification, evaluation, and development of novel anticancer agents at an early phase, but also when they enter large randomized Phase III trials.

Collaboration with other groups

Within the EORTC Network
Collaborations with Translational Research Division (Pathobiology, Imaging) and Clinical Research Division (Soft Tissue and Bone Sarcoma, Lung Cancer, Lymphoma, Radiation Oncology, and Cancer in the Elderly) groups and task force have already been established and are now being developed.

Outside the EORTC Network
Collaborations exist with the Southern Europe New Drug Organization (SEND0) and Central European Society for Anticancer Drug Research (CESAR). The PAMM Group is also represented in the Executive Committees of several international organizations focused on specific drugs or groups of compounds. Moreover, the DDC has close links with the NCI, who regularly attends the DDC meetings.
Quality of Life Group

Structure of the Group

Chair
G. Velikova, Leeds (UK)
Chair-elect
M. Groenvold, Copenhagen (DK)
Joint Secretaries
F. Efficace, Rome (IT)  
S. Singer, Leipzig (DE)
Treasurer
T. Young, London (UK)

Module Development Committee
C. Johnson, Southampton (UK)
Translation Committee
E. Greimel, Graz (AT)
Newsletter Editor
L. van de Poll-Franse, Eindhoven (NL)
Young Investigator
S. Singer, Leipzig (DE)
QoL Department Representative
A. Bottomley, Brussels (BE)

Recent Achievements

The EORTC Quality of Life Group (QLG) is a multidisciplinary group including oncologists, surgeons, radiotherapists, nurses, behavioral scientists, psychometricians, and statisticians. A central activity of the QLG is the development of a modular system for assessing the health related quality of life (HRQoL) of patients with cancer for use in clinical trials and potentially in clinical practice. This modular system includes a core questionnaire, the EORTC QLQ-C30, and a range of supplementary, disease-specific and/or treatment-specific questionnaire modules. Several systematic reviews have indicated that the QLQ-C30 is the most widely used HRQoL questionnaire in randomized clinical trials. The modular assessment system has been expanded to include a wider range of issues of importance to cancer patients, including their information needs, satisfaction with care, and spiritual well-being.

Module development and translations

Fourteen internationally validated questionnaire modules are currently available for patients with lung, breast, head and neck, multiple myeloma, esophageal, gastric, esophago-gastric, prostate, ovarian, brain, and cervical cancers, colorectal cancer liver metastases, satisfaction with inpatient care, and information needs of cancer patients. A 15-item version of the core QLQ-C30 questionnaire, the QLQ-C15PAL has been developed for use with patients in the palliative care setting.

Nineteen other modules are provisionally approved and may be used with the understanding that their psychometric evaluation has not yet been completed (examples include pancreatic, bladder, and liver
cancers, bone metastases, ophthalmic module, gastrointestinal neuroendocrine tumors, chronic lymphocytic leukemia, hepatocellular carcinoma, peripheral neuropathy, and high-dose chemotherapy).

The core questionnaires and the modules are available to academic users free of charge, and for a fee for commercial users from the pharmaceutical industry. The income funds the QLG’s research, further module development, and translations for academic use.

All newly developed questionnaires are translated in at least five key languages. In ever increasing globalization of clinical trials the issues of the quality of translations and cultural equivalence of any subjective measures is of paramount importance. The QLG is an international leader in developing guidelines for translations.

The QLG created the EORTC Item Bank, a searchable database that contains all items developed by the QLG including their translations. It is a very rich resource for developing questionnaires as it ensures compatibility between different EORTC questionnaires and their translations, avoids duplication of work, and makes possible creation of ad hoc trial/research specific questionnaires while still using well developed and validated items. The Item Bank was recently redesigned to include recently developed questionnaires and to allow more flexible use by researchers.

**Quality Assurance**

The process of module development is described in detail in a comprehensive manual that provides step by step procedures from early development through international field testing. Continuous peer review is carried out by the Module Development Committee which is working on a major revision of the guidelines themselves in order to better reflect modern demands on questionnaires. Translations of questionnaires into more than 60 languages are conducted via rigorous, standardized, forward-backward procedures as documented in the translation guidelines manual and are coordinated by the EORTC Quality of Life Department.

To ensure proper use of the questionnaires developed by the QLG, a user’s manual is available including scoring instructions and syntax files for commonly used statistical software programs. The scoring manual has recently been updated. The QLG has also generated a guidance manual for the conduct of clinical trial based HRQoL investigations. All of these manuals, known as “blue books”, are available for download from the QLG website.

**Other projects and future research**

The “higher order factors” project led by Neil Aaronson and Chad Gundy, Amsterdam, The Netherlands, is intended to develop, and test the suitability of, an algorithm for computing factors which will summarize the 15 dimensional profile generated by the 30-item EORTC QLQ-C30 questionnaire into a small number of summary scales. Having a small number of HRQoL outcomes can...
be quite useful in clinical trials and might facilitate sample size calculations and avoid multiple testing in statistical analyses of HRQoL outcomes.

**Computer-adaptive tests for EORTC QLQ-C30** project aims to generate a dynamic, computer adaptive version of the EORTC QLQ-C30 based on modern psychometric theory and techniques. The basic idea of computer-adaptive testing (CAT) is to tailor the questionnaire to the individual respondent. Based on the responses to the preceding items it is estimated which item should be asked next to obtain maximal information on that individual’s HRQoL (symptom level, functional status, etc.). Ultimately, computer-adaptive questionnaires will improve the measurement of HRQOL in clinical trials, making it briefer, more relevant to patients, and more sensitive to differences and changes over time.

**Electronic administration of the QLQ-C30.** Although this has been done by individual researchers, formal development and validation of an electronic version had not been undertaken previously. Under the auspices of Dr. Holzer, a Computer based Health Evaluation System (CHES) has been developed to assess and present patient reported outcomes in both research and routine oncologic practice.

**HRQoL of mid to long term survivors of testicular and prostate cancer from EORTC Phase III clinical trials.** It has been estimated that there are currently more than 10 million cancer survivors, and large cohorts of patients enjoy disease-free survival of five years or longer. There is increasing interest worldwide in evaluating the longer term impact of cancer and its treatment. To better understand the physical, functional and psychosocial health problems and needs of cancer survivors, we need to supplement the currently available HRQoL measures with questionnaires specifically designed for the period of cancer survivorship. This pilot study represents a first step toward developing an HRQL-focused cancer survivorship research program within the EORTC and is a collaboration with the EORTC Genito-Urinary Tract Cancer Group. We focus on two important genito-urinary cancers: testicular cancer and prostate cancer. The study involves two elements: (1) development and testing of the logistics required to conduct survivorship studies within the context of the EORTC; (2) preliminary testing of a HRQL questionnaire battery assessing the HRQoL of long term cancer survivors.

**Collaboration with other groups (EORTC and others)**

Collaboration with other EORTC clinical groups in implementing quality of life as an outcome measure in clinical trials is ongoing. This collaboration is led by the Quality of Life Department and its director, Dr. Bottomley, with participation of experts from the QLG contributing to specific trials. Examples of such successful collaborations include the Brain Cancer Group (M. Taphoorn, The Netherlands) and the Gynecological Cancer Group (E. Griemel, Austria). These collaborations have generated interesting trial results furthering our knowledge of treatment impact on quality of life of cancer patients and contributing to evidence-based changes in clinical practice.
The QLG works with the EORTC Cancer in the Elderly Task Force (ETF) towards the development of a HRQoL assessment for older people with cancer. This has been facilitated by formal representation of the QLG at the ETF meetings (C. Johnson, UK).

Other collaborative projects include involving the EORTC Leukemia Group in looking at patient reported quality of life and symptoms in myelodysplastic syndromes. The project is led by one of our young investigators, Dr. F. Efficace, Italy. In addition, Dr. S. Singer collaborates with the EORTC Head and Neck Cancer Group on updating the H&N35 module to better suit modern clinical practice.

The QLG continues to collaborate with the National Cancer Institute Canada (NCIC) on various HRQoL-related activities. The NCIC is represented in the QLG by the chair of the NCIC Clinical Trials Group Quality of Life Committee. The QLG also has continuing links with the UK Medical Research Council for the conduct of intergroup clinical trials in which HRQoL outcomes are being assessed.
Radiation Oncology Group

Structure of the Group

Chair
V. Grégoire, Brussels (BE)

Secretary
P. Poortmans, Tilburg (NL)

Treasurer
P. Maingon, Dijon (FR)

NOCI Liaison
G. van Tienhoven, Amsterdam (NL)

QA Officers
P. Poortmans, Tilburg (NL)
P. Maingon, Dijon (FR)
C. Hurkmans, Eindhoven (NL)
D. Weber, Geneva (CH)

Administrator
F. Godson, Lausanne (CH)

Steering Committee

The Radiation Oncology Group (ROG) Steering Committee is comprised of the Executive Committee, Committee Chairs (Publications, Membership, Website), Working Party Coordinators, Radiation Technologists’ Section Chair, EORTC Headquarters Team

Young Oncologist
E. Dieleman, Amsterdam, (NL)

Membership Committee
F. van den Bergh, Groningen, (NL)

PR and Website Committee
A. Kuten, Haifa (IL)

Quality Assurance Strategic Committee
C. Hurkmans, Eindhoven (NL)
D. Weber, Geneva (CH)
K. Haustermans, Leuven (BE)
M. van Os, Rotterdam (NL)
P. Poortmans, Tilburg (NL)
F. Godson, Lausanne (CH)

Publications Committee
D. Weber, Geneva (CH)

Working Party Coordinators

Brain Tumors
D. Weber, Geneva (CH)
S. Erridge, Edinburgh (UK)

Head and Neck
W. Budach, Düsseldorf (DE)
J.A. Langendijk, Groningen (NL)

Breast
A. Kuten, Haifa (IL)
H. Westenberg, Arnhem (NL)

Lung
C. Le Péchoux, Villejuif (FR)

Gastrointestinal Tract
O. Matzinger, Lausanne (CH)
P. Maingon, Dijon (FR)

Genito-Urinary Tract
C. Scrase, Ipswich (UK)
F. van den Bergh, Groningen (NL)
QA Team (Medical Advisors)

Brain Tumors
- B. Baumert, Maastricht (NL)
- S. Erridge, Edinburgh (UK)

Head and Neck
- J.A. Langendijk, Groningen (NL)
- S. Nuys, Leuven (BE)

Breast
- P. Poortmans, Tilburg (NL)
- W. Budach, Düsseldorf (DE)

Lung
- U. Nestle (Freiburg (DE)
- X. Geets, Brussels (BE)

Gastro-Intestinal
- P. Maingon, Dijon (FR)
- O. Matzinger, Lausanne (CH)

Genito-Urinary
- C. Scrase, Ipswich (UK)
- F. van den Bergh, Groningen (NL)

Physicist advisors
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- G. Garavaglia, Lausanne (CH)
- C. Hurkmans, Eindhoven (NL)
- A. Monti, Como (IT)
- M. Tomsej, Charleroi (BE)

RT Technologists
- F. Duclos, Lausanne (CH)
- M. van Os, Rotterdam (NL)

Observers
- EORTC HQ QART Manager
- EORTC HQ Clinical Research Physician

Manager
- F. Godson (ROG Administrator)

Radiation Technologists Section (RTT)

Chair
- F. Duclos, Lausanne (CH)

Secretary
- B. Pastoors, Geneva (CH)

Projects Supervisors
- B. Speleers, Ghent (BE)
- G. Gleeson, Galway (IR)

Scientific Supervisors
- H.-P. van der Laan, Groningen (NL)
- M. van Os, Rotterdam (NL)
- V. Lengkeek, Bern (CH)

EORTC Headquarters Team

L. Pylkkanen (Clinical Research Physician)
N. Gosselin (Project Manager)
I. Meuldiers (Data Manager)

L. Collette (Statistician)
S. Morren (Data Manager)
To be appointed (QART Manager)

Recent Achievements

Completion of the EORTC 22952-26001 trial: No radiotherapy versus whole brain irradiation (WBI) after surgical resection or radiosurgery of one to three brain metastases from a solid primary tumor (R.-P. Müller, M. Kocher, R. Soffietti. First study results have been accepted for publication in JCO 2010). The study ran from November 1996 to November 2007 and accrued 359 patients from 26
centers. The primary endpoint was time to deterioration of WHO performance status to WHO >2, with secondary end points overall survival (OS), progression free survival (PFS), time to intra/extracranial progression, and quality of Life (QoL). Patients having had local treatment for brain metastases were randomized to have WBI or no irradiation. There was no significant difference for survival with PS ≤2 (p>0.1), nor a significant difference for overall survival. There was a longer PFS with WBI with significant reduction of intracranial progression in previous and new sites. An oral abstract was presented at ASCO 2009. QoL is being analyzed within this trial, and results were presented at ASCO 2010. The results of a phase I/II study on concomitant and adjuvant temozolomide and radiotherapy with PTK787/ZK222584 (PTK/ZK) in newly diagnosed glioblastoma has been published this year (Brandes et al., Eur J Cancer 2010).

A report of dummy run and conformity indices in the ongoing low grade glioma EORTC 22033-26033 trial: first evaluation of quality of radiotherapy planning was published in Radiotherapy and Oncology (Musat E. et al.).

Final update of the EORTC 22863 trial results, assessing 3-years of androgen deprivation therapy concomitant and adjuvant to irradiation for patients with prostate cancer of high metastatic potential. The update confirmed earlier findings that long term androgen deprivation therapy significantly improves long term outcome (survival and PFS): The 10-year clinical disease- free survival was 22.7% in the radiotherapy-alone group and 47.7% (HR=0.42, CI: 0.33-0.55, p<0.0001) in the combined treatment group. The 10-year OS was 39.8% and 58.1% respectively (HR=0.60, CI: 0.45-0.80, p=0.0004) and 10-year prostate-cancer mortality 31.0% and 11.2% (p<0.001). With regard to cardiovascular mortality, no significant difference was observed either among patients who presented with cardiovascular problems at study entry, or among those who had no such problems. Results of this trial will be published in Lancet Oncology (M. Bolla et al, in press).

Long term updated results of the EORTC 22911 trial were also obtained and reported at the ESTRO and ASTRO congresses by Prof. Michel Bolla. The study investigates the value of immediate adjuvant irradiation after prostatectomy for patients presenting postoperatively with pathological factors indicative of a high risk of relapse. The results are also being submitted to Urology Congresses for presentation in 2011, with publication of the 10-year results planned for 2011.

Results of toxicity at three years with and without irradiation of the internal mammary and medial supraclavicular lymph node chain in stage I to III breast cancer, EORTC 22922/10925 trial, have been reported (Matzinger et al. Acta Oncologica 2010).

The results of the randomized phase II/III study comparing gemcitabine followed by gemcitabine plus concomitant radiation (50.4 Gy) versus gemcitabine alone after curative pancreaticoduodenectomy for pancreatic head cancer, carried out jointly with the EORTC Gastrointestinal Tract Cancer Group, have been published (Van Laethem et al., J Clin Oncol 2010).
Projects / Strategies for the coming years

The specific role of the ROG lies in studying the fundamental questions related to optimal loco-regional treatments leading to maximal loco-regional control and survival rates while minimizing mutilation and side effects. Our emphasis, on the one hand, is on the design of randomized phase III trials aimed at answering a clinical question which directly contributes to the definition of new standards of care, and on the other hand, it is on carefully selected phase II studies in rare tumor types such as sarcoma.

Currently we have a number of new trials under development.

- The phase III EORTC 24081-22081 trial assessing the addition of an EGFR inhibitor to standard adjuvant chemoradiation in patients affected by head and neck squamous cell carcinoma.
- The phase III EORTC 22071-24071 trial assessing the value of induction chemotherapy and the addition of an EGFR inhibitor to standard chemoradiation in locally advanced head and neck squamous cell carcinoma.
- New studies in glioma in collaboration with the EORTC Brain Tumor Group are in the process of being opened:
  - The use of temsirolimus in non-methylated glioblastomas, temozolomide and radiation therapy in elderly glioblastoma patients;
  - Temozolomide and radiation therapy in anaplastic glioma;
  - Investigation of the use of temozolomide and radiation therapy in anaplastic oligodendroglioma and anaplastic mixed glioma.
- The CENTRIC study on the use of cilengitide in combination with standard treatment for glioblastoma patients with methylated MGMT gene promoter is being initiated worldwide.
- A phase II study currently running on atypical and malignant meningioma.
- A fruitful collaboration with TROG within the DCIS study.
- An RTOG-led study on pancreas cancer.
- Further development of the IMAGE protocol (Imaging in Gastro-Esophageal cancer).
- A project on anal cancer (PARADAC) will be completed. This is a joint project concerning more or less all recent anal cancer studies out of which it is hoped to plan future work in this area.

Our aim is to integrate translational research and where applicable functional imaging into all new studies as this may permit a fundamental advance in the understanding of a particular disease.

Quality Assurance

The ROG QA Team is involved in evaluation of submitted Facility Questionnaires (FQ) and review of external reference dosimetry audit results, also providing advice and support in the development of protocol descriptions for all new studies involving radiotherapy together with the accompanying case report forms. The QA Team is also involved in the evaluation of dummy run procedures and in the retrospective review of treatment of trial cases.
A special dedicated Facility Questionnaire was developed for use by non-EORTC centers participating in the Merck study on the use of Cilengitide in glioblastoma (CENTRIC). Currently, 208 of the 234 submitted questionnaires have been evaluated and validated by the ROG QA Team.

With the initiation of the malignant meningioma EORTC 22042 trial and the collaboration with the ATC in the US, the on-line review of dummy run procedures has been started. It is hoped that this procedure will now be possible via the EORTC through the use of the recently acquired review platform for quality assurance, VODCA, and which will become the norm in all studies with radiotherapy. Patient data will be uploaded by the participating centers for review/validation by a member of the QA Team.

The QA Team is increasingly involved in the development of new studies including those of the EORTC disease-oriented groups in which radiotherapy is part of the treatment. New procedures have been written to streamline development of protocols that have been endorsed by the EORTC Executive Committee.

**Translational Research**

In studies led by the ROG, translational research activities include the following:

- Study of the impact of 1p deletions in low grade glioma and the prognostic effect of these deletions on PFS in each treatment arm.
- Correlation of molecular characteristics of tumor tissue from malignant meningioma with the natural history of the disease and with the patient’s response to radiation therapy.
- Identification of key molecular pathways for the future identification of patients most likely to benefit from radiation therapy in breast cancer, including the search for pharmacogenetic markers of relapse/outcome.
- Assessment of late treatment effects and prediction of lung toxicity. This is also important for patients receiving radiation therapy to the lungs in the treatment of breast cancer, lymphoma, and esophageal cancer.
- Validation of assays of intrinsic radiosensitivity expected to predict the risk of late radiation-induced toxicity in patients with head and neck squamous cell carcinoma treated with adjuvant chemoradiation +/- EGFR inhibitor within the EORTC 22071-24071 trial. This project was presented at EGAM 2009 and will receive funding by the EORTC. It will allow the identification of patients at risk for severe normal tissue toxicities and allow subsequent selection of patients that are suitable candidates for preventive measures. It will also provide essential information for radiotherapy treatment optimization aiming at prevention of these complications.

The methods used for these various translational research studies include the construction of micro-arrays, genotyping, and proteomics.
Radiation Technologists’ Section (RTT)

The RTT has been putting efforts into building a European network of RT Technologists. According to their specific field of expertise, RT Technologists are asked to participate in projects and to review trial protocols. For this purpose, F. Duclos, RTT Chair, regularly reports on the section’s activities at international meetings.

Parallel to the regular ROG meetings, the RTT organizes international symposia with specific topics such as “Positioning: fixation and verification” held in Leuven in 2008, “Accuracy in dose delivery” held in Leeds, and the analysis of data concerning acute reactions seen in the EORTC 22991 trial on early prostate cancer, for which a specific weekly questionnaire was designed by the RTT, was presented at the 2009 EGAM meeting and will be published shortly.

The RTT has just initiated a new and ambitious project on the delineation of Organs at Risk with the ultimate goal of producing an atlas of guidelines. This will be a very useful but immense task! But we are up to the challenge!

Collaboration with other groups (EORTC and others)

The ROG currently collaborates with the EORTC Brain Tumor, Head and Neck Cancer, Lymphoma, Soft Tissue and Bone Sarcoma, Gastro-Intestinal Tract Cancer, Genito-Urinary Tract Cancer, Breast Cancer and Lung Cancer groups. Collaboration is ongoing with the Radiation Therapy Oncology Group (RTOG) and the North Central Cancer Treatment Group (NCCTG) in the US, the NCI-C (Canada), the Scottish Cancer Trials Breast Group, the Borstkanker Onderzoeksgroep Nederland (BOOG), the Intergroupe Francophone de Cancerologie Thoracique (IFCT), the Pan-European Trials in Adjuvant Colon Cancer (PETACC), the French Fédération Nationale des Centres de Lutte contre le Cancer (FNCLCC) and the Trans-Tasman Radiation Oncology Group (TROG) from Australia.
Soft Tissue and Bone Sarcoma Group

Structure of the Group

Chair P. Hohenberger, Mannheim (DE)
Vice-Chair W.T.A. van der Graaf, Nijmegen (NL)
Secretary A. Gronchi, Milano (IT)
Treasurer I. Judson, London (UK)

Committees

Chair Pathology A.P. Dei Tos, Treviso (IT)
Chair Local Treatment A. Gronchi, Milano (IT)
Chair Systemic Treatment P. Reichardt, Bad Saarow (DE)
Chair Translational Research W.T.A. van der Graaf, Nijmegen (NL)
Young Oncologists A. Blesius, Paris (FR)
L. Lindner, Munich (DE)

Membership and Principles

The Soft Tissue and Bone Sarcoma Group (STBSG) includes 47 full and 5 probationary members from 12 countries. The STBSG has a strict membership policy with regard to presence at group meetings, study accrual, and data quality. The pathological slides of all patients included in a clinical trial have to be reviewed centrally, and a level of 75% reviewed cases per trial and per center is required. The pathology subcommittee allocates the review of histological slides and/or blocks according to expertise and regional distribution to its members. All claimed responses have to be confirmed independently if response is the primary endpoint of the trial.

Meetings

Two meetings are held each year. The first day is dedicated to scientific questions, this time focusing on an interdisciplinary symposium on bone sarcoma in cooperation with EuroBoNeT, the European network promoting research into pathology, biology and genetics of bone tumors.

The four STBSG Committees meet to review their work, objectives, and projects which are summarized during the General Meeting. The General Meeting is open to all members as well as to outside parties such as collaborators from the pharmaceutical industry and mainly concerns discussions of ongoing trials. Key members from other co-operative groups are invited to present the work of their group in order to foster intergroup collaboration. The business meeting is for full members only with strategic and financial matters to be discussed.
Recent Achievements

Clinical trials

The following studies were open for accrual within STBSG from 2009 through 2010:

EORTC 62012 trial: A phase III randomized trial of single agent doxorubicin versus doxorubicin plus ifosfamide in the first line treatment of advanced or metastatic soft tissue sarcoma (closed to entry at 455 patients in May 2010).

EORTC 62052 trial: A phase II randomized trial of infusional E7389 in pretreated patients with advanced and/or metastatic soft tissue sarcomas (closed to patient entry in September 2009, analyzed in 2010).

EORTC 62063 trial: A phase III randomized study evaluating surgery of residual disease in patients with metastatic gastro-intestinal stromal tumors responding to imatinib mesylate. Study coordinator is A. Gronchi, Milano.

EORTC 62072 trial: A randomized double blind phase III trial of pazopanib versus placebo in patients with soft tissue sarcoma whose disease has progressed during or following prior therapy (PALETTE). Study coordinator is Winette van der Graaf, Nijmegen (closed to entry at 372 patients in February 2010).

New studies to be opened in 2011

EORTC 62091 trial: A phase Ib/III multicenter study comparing the efficacy of trabectedin administered as a 3 hour or 24 hour infusion to doxorubicin in patients with advanced or metastatic untreated soft tissue sarcoma (TRUSTS). Study coordinator is Binh Bui-Nguyen, Bordeaux (Intergroup with US group, SARC).

EORTC 62092-22092 trial: A phase III randomized study of pre-operative radiation plus surgery versus surgery alone for patients with retroperitoneal sarcomas. Study coordinators are Sylvie Bonvalot, Paris (for STBSG), and R. Haas, Amsterdam. (Intergroup with Radiation Oncology Group).

Study results to expected in 2011

EORTC 62991-22998 trial: Phase II pilot study of moderate dose radiotherapy for inoperable aggressive fibromatoses. Study coordinator is Ronald Keus, Nijmegen. After entering the final patient in April 2008, the primary endpoint of the study of progression free survival at 3 years will be analyzed.

Studies on a unique retrospective data base

The database of over 3000 patients treated with systemic chemotherapy for advanced soft tissue sarcoma (STS), and more than 2000 patients treated in first line setting, continues to prove extremely valuable. The STBSG funded a postdoctoral fellow (Monia Ouali, who has since joined the EORTC Statistic Department), and they hosted a clinical fellow (Nicolas Penel). Both fellows were under the
supervision of Martine van Glabbeke. They performed analyses of the database on topics approved by
the STBSG board. These include:

- DB-62-083 Project on neurogenic sarcoma in patients in first line therapy of advanced disease based
  on several EORTC-STBSG studies (J. Kroep, ASCO 2010, publication in Ann.Oncol 2010).
- Prognostic factor for early in patients receiving classical chemotherapy (N. Penel, presentation
during CTOS 2010).

These exploratory studies are hypothesis-generating and the findings have been discussed in light of an
in-depth review of literature data.

- Testing the new regimens with advanced soft tissue sarcoma: analysis of publications from the last
- Angiosarcoma: state of the art and perspectives. (N. Penel, Critical Reviews in Oncology and
  Hematology 2010, published).

Translational Research

Translational research is not only conducted in the field of molecular characterization of sarcomas and
detection of prognostic and predictive signatures, but also integration of recent developments in
functional imaging is considered to be of major interest. It is particularly intended to attract young
researchers working in this field and open fields of collaboration between centers even outside trials.
Applications can be made to the Board of the group for initial (‘kick-off’) funding of research ideas up to
25,000€.

- EORTC 62043 trial on pazopanib in STS: translational research data were presented as a poster at
  ASCO 2010, and a manuscript is in preparation.
- EORTC 62072 trial on pazopanib in STS: this trial was accompanied by a program of functional imaging
to elucidate response characteristics.
- EORTC 62052 trial on E7389 in STS: translational research program established in 2010. Results are
  expected to be available in 2011.
- EORTC 62061 trial on brostallicin in STS: translational research program established in 2010. Results
  are expected to be available in 2011.

Projects / Strategies for the coming years

Clinical Research

Beyond those mentioned above, several phase II and III studies are scheduled for activation in 2011, e.g.
on first line therapy of soft tissue sarcoma, treatment of bone sarcomas, and second line treatment of
desmoids.
Data base projects

New projects accepted by the Board:

• DB-62-081: The relevance of doxorubicin dose intensity on response and outcome (S. Sleijfer).

• DB-62-091 Effects of anthracycline based chemotherapy in patients with locally advanced or metastatic angiosarcoma (R. Young, P. Woll).

Collaboration with other groups

STBSG is developing a trial exploring the contribution of preoperative radiation therapy to disease free survival and overall survival in retroperitoneal sarcoma in conjunction with the Radiation Oncology Group and will mainly use the quality control measures established there.

ContiCaNet (Chair: Pr. J.Y Blay) and EuroBoNet (Chair: Pr. Pancras Hogendoorn, former chair of the Pathology Committee of the STBS) are EU sponsored networks of excellence with several groups members also working within these cooperations. The Chairs provide perfect links anchoring the translational research studies of STBSG members to high level laboratories.

STBSG was involved in the founding of a World Sarcoma Network (WSN), a collaboration between European, American and Australian sarcoma centers, to explore and develop trials in very rare sarcoma subtypes not manageable through current data centers or industry.

STBSG is also committed to the development of intergroup studies with national sarcoma groups or in collaboration with large institutions and cooperative groups from the US. The first transatlantic EORTC-SARC study, TRUSTS (EORTC 62091) will soon be activated.

The group’s website has been further developed at www.eortc-stbsg.org, and is being used for meeting announcements as well as for delivery of publication reports and minutes of the group meetings. The site provides links to the expert member institutions.

In recognition of the contribution made by the STBSG to sarcoma research, the Group is well represented on the Connective Tissue Oncology Society (CTOS) Board. Members of the Board of directors include STBSG members Axel Le Cesne (conference chair 2010), Alessandro Gronchi, Anders Krarup-Hansen, Patrick Schöffski, Paolo dei Tos, Jeremy Whelan and Ian Judson.
Cancer in the Elderly Task Force

Structure of the Task Force

Chair
H. Wildiers, Leuven (BE)

Secretary
U. Wedding, Jena (DE)

Treasurer
A. Ring, Brighton (UK)

Young oncologists
B. Deschler, Freiburg (DE)
V. Girre, Paris (FR)

Recent Achievements

The EORTC Cancer in the Elderly Task Force (ETF) has had a mainly advisory function in the past but is currently very active in developing clinical trials in collaboration with the EORTC disease oriented groups. Four proposals have already been submitted to the EORTC Executive Committee of which two are in a final stage of development.

A standardized Elderly Minimal Dataset (MinDS) has been established by the ETF with the purpose of harmonizing the collection of data relevant to the elderly and to enable cross study/practice comparisons in the future. It was emphasized that the dataset does not need to be restrictive nor comprehensive but rather should form the backbone upon which individual investigators could add assessment tools pertinent to the particular study or local specific interests. It is also anticipated that this dataset will evolve over time with addition, removal, or refinement of tools as more data become available. A key aspect of the dataset is that it includes instructions for completion of the tools as there are some controversies in this area. The MinDS includes four elements: Charlson Co-morbidity Index (CCI), G8 Geriatric Assessment Screening Tool, Instrumental Activities of Daily Living (IADL, and Social Situation. An ETF paper including the MinDS has been accepted for publication in Annals of Oncology (see below).

The ETF has collaborated with the EORTC Quality of Life Group in developing an elderly specific tool, the QLQ-ELD15 scale. This quality of life scale will also be integrated in future elderly studies.

The ETF is also active in developing specific methodology for clinical trials in the elderly. Two papers regarding standardization and unmet need of clinical trials in elderly population were written in 2010:  
• EORTC workshop on clinical trial methodology in older individuals (Annals of Oncology, Pallis et al, 3. EORTC Current Research and Strategies 166
This paper is a summary of a workshop (under the auspices of EORTC) on clinical trial methodology in older cancer patients that was held at EORTC Headquarters in December 2009. Consensus was reached on which elements the MinDS tool should include.

A template letter for reviewing EORTC study proposals from other EORTC groups through the Protocol Review Committee was generated by the ETF. We want to provide a global strategy across tumor types and different settings. The suggestions include the necessity to mention up front in protocols that an age related sub-analysis will be performed (e.g. with age cutoff at 70y). This sub-analysis should focus both on efficacy and toxicity, since there are several data showing that toxicity increases significantly in older people, and that the ‘small/moderate’ benefit in progression free survival could be counterbalanced by toxicity (while more benefit might be present in younger patients). Secondly, we emphasize the need to have a sufficient amount of elderly patients in large clinical trials. It is important that the study population is similar to the real population. This could be done for instance by requiring a minimum fixed percentage of patients 70+ (avoiding too much selection of only younger patients in clinical trials). The percentage could differ in different setting. Thirdly, in parallel with other studies, and according to international guidelines and EORTC proposal, we would recommend a ‘minimum geriatric assessment in all patients above age 70 (cfr supra: minimum dataset).

When the official ETF statutes and membership rules were created in 2009, the ETF included 49 members. Since then, membership has grown to 69 members.

Projects / Strategies for the coming years

In collaboration with the EORTC disease oriented groups, the ETF has established several projects/ideas which are at various degrees of development:

- **EORTC 40085-75083 trial in colorectal cancer (M. Peeters):** A phase III randomized trial of 5-FU+ cetuximab versus 5-FU alone in patients with metastatic colorectal cancer and wild type kras status. The trial will be performed together with the EORTC Gastrointestinal Tract Cancer Group. The main objective is to determine if elderly, especially ‘unfit’ elderly, derive benefit in terms of progression free survival from a regimen consisting of less toxic chemotherapy plus a biological agent with limited toxicity. Accrual of 228 patients (136 kras wild type) is required, and recruitment is expected to start in the second half of 2011.

- **EORTC 75091-10095 trial in breast cancer (H. Wildiers):** A phase II randomized trial of pertuzumab + trastuzumab (PH) versus chemotherapy + trastuzumab as first line chemotherapy in elderly patients with metastatic Her2 positive breast cancer. This is a collaboration between the ETF and the EORTC Breast Cancer Group. The objective is to assess the efficacy (progression free survival) and the toxicity of PH as compared to classical chemotherapy and trastuzumab in a general elderly population. Accrual of 154 patients is planned.

A trial in lung cancer was about to initiate, but due to new published results on combination chemotherapy versus single agent chemotherapy, the design needs to be revised.
Translational Research

The ETF would like to initiate a biobank for peripheral blood to study potential ageing biomarkers. Given the paucity of large clinical trials currently running in the elderly population, it is of crucial importance to create a European biobank of biological samples which can be used for future research projects. In a first step this biobank will involve the collection and storage of blood samples. Ageing markers of interest are: telomere Length, expression of p16 in peripheral leukocytes, circulating IL-6, TNF-α and IL-10, CMV IgG and IgM, and single nucleotide polymorphisms (SNPs) in apoE and FOXO3A genes.

A template protocol for biobanking in elderly trials has been established that can be built into different protocols.

Collaboration with other groups

Within EORTC

The aim of the ETF is to develop elderly specific trials for those patients who are not candidates for standard treatment. This aim will be achieved in collaboration with the EORTC disease orientated groups. Collaborations with the Breast Cancer, Lung Cancer, Leukemia, Gastrointestinal Tract Cancer, and Brain Tumor Groups have been established. Collaboration with the Quality of Life Group continues in the validation of an elderly specific quality of life questionnaire.

Outside the EORTC

For the above mentioned trial on metastatic colorectal cancer, collaboration with the AIO (Arbeitsgemeinschaft Internistische Onkologie) of the German Cancer Society has been established.

For geriatric assessment, close collaboration is ongoing with the French geriatric cancer units who developed the G8 screening tool.

National groups, in which several ETF members are actively involved, will also be contacted for support of clinical trials. For example, there are strong interactions with the French geriatric oncology group, GERICO.

Pan-European cooperation

Under the auspices of EORTC, a workshop on clinical trial methodology in older cancer patients was held at EORTC Headquarters in December 2009. Consensus was reached on which elements the MinDS tool should include.

A second ETF multidisciplinary workshop on clinical trial methodology will be held at the end of 2011 during the SIOG (Société Internationale d’Oncologie Gériatrique) conference in Paris.
## Structure of the Task Force

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair</td>
<td>M. Bagot, Paris (FR)</td>
</tr>
<tr>
<td>Secretary</td>
<td>P.L. Ortiz-Romero, Madrid (ES)</td>
</tr>
<tr>
<td>Treasurer</td>
<td>M. Vermeer, Leiden (NL)</td>
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<tr>
<td>Translational Research</td>
<td>M. Vermeer, Leiden (NL)</td>
</tr>
<tr>
<td>NDAC liaison</td>
<td>R. Knobler, Vienna (AT)</td>
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<td>Young Oncologist</td>
<td>M.S. Rodriguez-Pinilla, Madrid (ES)</td>
</tr>
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## Recent Achievements

### Closed Trials

**EORTC 21011 trial**: A randomized, open-label phase III trial to evaluate the safety and efficacy of targretin capsules combined with PUVA (Psoralens, P, in combination with ultraviolet light, UVA) compared to PUVA treatment alone in patients with stage IB-IIA cutaneous T-cell lymphoma (CTCL). This study was activated in October 2003 and was closed due to poor accrual in May 2010. 94/145 patients were included. Final Analysis is expected to take place in the first quarter of 2011.

**EORTC 21012 trial**: Phase II clinical trial with caelyx mono-chemotherapy in patients with advanced Mycosis Fungoides stage IIb, IVa and IVb with or without previous chemotherapy. The study is closed for recruiting, and the statistical analysis has been performed. A poster abstract was presented at the ASH 2010 meeting and a primary publication is in preparation.

### Ongoing trials

**EORTC 21081 trial**: A phase III study of lenalidomide maintenance after debulking with gemcitabine or liposomal doxorubicin +/- radiotherapy in patients with advanced cutaneous T-cell lymphoma not previously treated with intravenous chemotherapy. This trial has started recruiting patients.

### Projects/Strategies for the coming years

#### Clinical Trials

An EORTC Cutaneous Lymphoma Task Force (CLTF) clinical trial platform has been discussed and built in order to improve the treatment of patients with advanced cutaneous T-cell lymphoma (CTCL). The CTCL platform includes three successive trials. The ongoing EORTC 21081 trial is the first trial in this platform.
The EORTC 21082 trial is the second trial in the CTCL platform. The protocol for this trial, “Progression free survival comparison between suberoylanilide hydroxamic acid (SAHA, Vorinostat), and the combination of SAHA and bortezomib (Velcade) in refractory or recurrent advanced CTCL. A randomized study”, is being finalized.

A third trial in this CTCL platform is under discussion with the European Bone Marrow Transplant Group (EBMT). The aim of the trial is to evaluate reduced intensity allo-stem cell transplantation in a series of patients with advanced refractory CTCL. A proposal for the study has recently been submitted to FP7.

**Quality Assurance**

All clinical trial activities within the CLTF are coordinated through and supported by EORTC Headquarters. Central review of all clinical and pathology data for the trials is ongoing.

**Translational Research**

Translational Research studies will be developed to complement the CTCL platform (microarray-based transcriptome analysis and cytokine analysis).

In a collaborative translational research study coordinated by M. Vermeer, novel diagnostic markers in Sezary syndrome are being evaluated.

**Collaboration with other groups**

A satellite session with the EORTC Radiation Oncology Group was held during the Annual Clinical Meeting in Copenhagen in September 2008. This session focused on updating the CLTF guidelines for the use of Total Skin Electron Beam Radiation in cutaneous T-cell lymphomas. Another session was organized during the Annual Clinical Meeting held in Athens in October 2009.

The CLTF is developing appropriate endpoints and methods of disease assessment in conjunction with the International Society for Cutaneous Lymphomas (ISCL) and United States Cutaneous Lymphoma Consortium (USCLC) for use in CTCL trials.

In collaboration with the EBMT, the CTCL trial platform is being developed and a manuscript is in preparation.
Endocrine Tumors Task Force

Structure of the Task Force

Chair
M. Schlumberger, Villejuif (FR)

Secretary
To be appointed

Treasurer
To be appointed

The EnTF will aim to develop, conduct, coordinate and stimulate research on patients with thyroid and adrenal gland cancers. All physicians interested in this field are encouraged to contact EORTC Headquarters.

Endocrine tumors are rare and historically often unaddressed entities; this is compounded by the scarcity of large, well designed, practice changing academic clinical trials in this field. Endocrine tumors are an unmet therapeutic need. Furthermore, endocrine tumors are being diagnosed more frequently due to increased monitoring of thyroid nodules after Chernobyl and the increased number of incidentaloma.

Due to recent advances in understanding tumor biology and genetics and to the emergence of a range of new targeted molecules, there are real opportunities to offer patients with endocrine tumors new treatments which will hopefully lead to improvements in survival and quality of life. The EORTC, as an international network with a track record for rare tumors and strengths in biobanking and translational research, aims to evaluate targeted molecules to bring new effective treatments to thyroid and adrenal gland tumor sufferers.

The EnTF currently involves institutions in Belgium, Denmark, Egypt, France, Germany, Greece, Italy, Poland, Portugal, Switzerland, The Netherlands, the United Kingdom, and Slovenia, and it is continuing to expand throughout Europe.

Within the EnTF there will be a fair balance of endocrinologists and oncologists.

Project / Strategies for the coming years

Though the strategy of the EnTF is currently under construction, a large phase III trial addressing a tyrosine kinase inhibitor (TKI) targeting the vascular endothelial growth factor (VEGF) receptor is in advanced discussion for differentiated thyroid cancer.
Collaboration with other groups (EORTC and others)

The EnTF has already established links with the EORTC Imaging Group, and preliminary discussions are taking place with the European Network for the Study of Adrenal Tumors (ENS@T), a European academic group addressing adrenal gland tumors for complementary synergy.
4. Reports from the EORTC Headquarters

EORTC Headquarters Coordinating Committee Members
(from left to right)
Andrew Bottomley, Jocelyne Flament, Martine Van Glabbeke, Sandrine Marréaud, Laurence Collette, Jan Bogaerts, Françoise Meunier, Pascal Ruyskart, Denis Lacombe, Richard Sylvester, Ann Marinus, Caroline Gilotay
Introduction

EORTC Headquarters, established in 1974, is a unique central facility within Europe that offers a comprehensive approach to clinical as well as translational cancer research and to the management of cancer clinical trials.

EORTC Headquarters provides expertise over a broad range of activities and research areas including protocol and case report form development, national and international regulatory filings, data management, statistics, oncology, information technology, and other disciplines such as Quality of Life. EORTC Headquarters ensures, from an independent, objective and academic point of view, the performance of trials of the highest quality from design through final analysis to the publication of study results.

In line with its aim to achieve optimal scientific results, EORTC Headquarters staff conducts research projects concerning methodology, and, through their participation as faculty at courses, workshops and congresses, or at events organized by EORTC Headquarters itself, many EORTC Headquarters staff members contribute to the education of healthcare professionals working in the field of cancer research.

The EORTC is the only European organization that unites European cancer experts from all disciplines to establish transnational collaborations that facilitate, accelerate, conduct, and coordinate independent clinical and translational research on all types of cancer in Europe. The past four decades have proven beyond a doubt, that this form of collaboration is both successful and necessary in order to achieve important advances in the treatment of cancer and define new therapeutic strategies that are either more effective or less toxic.

EORTC Headquarters is integral to the functioning of the EORTC, and it acts as a guardian with respect to the principles of independence and standards of quality for conducting clinical and translational cancer research.

Progress Report

EORTC Headquarters Management of Clinical Trials

EORTC Headquarters provides support for the management of all EORTC clinical trials. The following table lists the number of trials that were open to recruitment in 2009 and 2010, the number of each type of trial by trial phase, and the total targeted accrual for these trials.
Early Project Optimization Department (EPOD)

EPOD was created in 2008 in response to the global EORTC scientific strategy and the new EORTC project prioritization process. EPOD’s roles are multiple and, responding to changing demands, flexible. These roles are summarized below, however EPOD support remains optional.

How can EPOD be useful to an EORTC Disease Orientated Group?

EPOD can help:
• set up a global strategy for a given disease or subpopulation;
• optimize a project to meet the EORTC scientific strategy;
• help to select a pathway/a target of interest;
• optimally select an agent by providing details of all agents against a particular target and their status of development;
• help mature translational research projects both scientifically and operationally;
• facilitate Pharmaceutical company interactions via regular interactions and by organizing partnership meetings and advisory boards;
• optimize cross expertise within EORTC by facilitating the contact and communication between different Disease Orientated Groups, modality based groups (ROG, ETF, IG) and the Translational Research Division;
• harness the expertise of peer review committees, e.g. NDAC and TRAC.

Operationally, EPOD serves as the port of entry for new projects into the EORTC and helps manage these projects during their early phase.

The current strategy of a group, as the result of a common effort between the respective group, EPOD and the EORTC HQ team, is defined by the patient population, the available treatments, the group’s ongoing trials, the drug pipeline, and the biological markers of the disease. A project proposal strategy would concentrate on the specific population in need or concept and include new drugs, drug combinations, multimodalities, screening platforms, and translational research proposals specifically aimed for the population/proposal. By providing context and strategy, the group strategy facilitates the development and improves the quality of project proposals.

To date, EPOD has completed full strategy assessments with the Cutaneous Lymphoma Task Force, as well as for ovarian cancer, Hodgkin’s lymphoma, Children’s Leukemia, acute myelogenous leukemia...
(AM), pancreatic cancer, colorectal cancer, non small cell lung cancer (NSCLC), mesothelioma, head and neck squamous cell carcinoma (HNSCC), cutaneous melanoma, and ocular melanoma. Several strategies have also been completed addressing specific subpopulations, e.g. bone metastases, brain metastases, and elderly breast cancer.

EPOD also provides help to optimize project proposals. Recent examples are the support given to the development of projects selected from the NOCI 2010 call. EPOD orchestrates early and timely involvement of experts and key opinion leaders (NDAC, TRAC, Translational Research Division, Imaging Group, etc.) and ensures that interactions with industrial partners are developed and optimized. The intent is to improve the quality of project proposals prior to review by the Executive Committee and increase the overall efficiency of project development.

Statistics Department

Description

The statisticians within the Statistics Department at the EORTC HQ provide methodological and statistical support for the design, implementation, conduct, analysis, and reporting of EORTC clinical trials and other scientific projects. They work together with Data Managers, Project Managers, and Clinical Research Physicians as part of EORTC HQ teams supporting the studies carried out by the EORTC Clinical Groups.

In particular, the statisticians provide advice to the EORTC Groups and study coordinators on the optimal statistical design to be used in the conduct of their studies and help to write the protocol outline, the full protocol, and the case report forms. They interact with Data Managers to ensure data quality control, carry out interim and final statistical analyses, and help to prepare the resulting publications and presentations. The statisticians also support EORTC groups in preparing grant applications for EU funding.

On 1 September 2010, Richard Sylvester stepped down as Head of Department after 35 years of service, passing on the reigns to Jan Bogaerts. Richard will continue to support EORTC Headquarters activities as Senior Statistical Scientist. In September 2010, there were 15 statisticians and one statistical fellow at EORTC HQ. Each statistician works with one or more of the clinical groups and most have specific applied methodological research projects.

Achievements

The primary achievements of the statistics department remain the ongoing support of all group studies, interim and final analyses, and manuscripts which are described throughout this report.

Training and teaching

A twice monthly meeting of the “Stats Club” ensures that the statisticians remain current with clinical trial methodology. They also participate as faculty members in various courses organized either by the EORTC (for example the yearly 4-day course “Clinical Trial Statistics for Non-Statisticians”, which is organized by the Statistics Department, and the 4-day course “Methodology of Cancer Clinical Trials:
the next Generation’’) or together with other cancer research organizations, for example the joint ECCO-AACR-EORTC-ESMO Workshop ‘Methods in Clinical Cancer Research’ at Flims, Switzerland. One statistician (C. Coens) is also providing statistical guidance to fellows in the Quality of Life Department.

**Processes**

The more senior statisticians have additional administrative and scientific responsibilities, for example with EORTC committees such as the IDMC and for a number of EORTC Policies pertaining to data sharing, publication of results and interim monitoring. Updates of the internal department work instructions (WINs) are ongoing and have resulted in improved quality control on programming, reporting and documentation. For example, all primary results are validated by a black-box (blinded) peer programming process.

**Scientific collaboration**

The department maintains many links with other academic statistics departments and groups and currently have active scientific projects with:

- Institut Curie: phase I for non-cytotoxic agents
- Institut Gustave Roussey: teaching, exchange of results
- Centre Georges François Leclerc, Dijon; Centres de Traitement des Données de l’Institut Bergonié, Bordeaux, du Centre Val d’Aurelle, Montpellier, et du Centre Oscar Lambret, Lille: DATECAN project (Guidelines for definitions and analyses of time to event data in cancer randomized clinical trials)
- Jules Bordet Institute/Université Libre de Bruxelles: scientific presentations, teaching collaboration
- Université Catholique de Louvain: research on frailty models together with Daegu Haany University, South Korea.
- Université de Liege: research on partial proportional odds model with application to Quality of Life data
- Leiden University Medical Center (LUMC): collaboration on research projects, teaching

**Expert advice to other organizations**

Stefan Suciu is a core member of the external scientific advisory group for oncology at the European Medical Agency. He is also a member of the EBMT (European Bone Marrow Transplantation) Statistician Subcommittee. Richard Sylvester is a member of the EAU Guidelines Office Board and the EAU Non Muscle Invasive Bladder Cancer Guidelines Committee. Statisticians commonly peer review work for major journals and are members of a number of editorial boards. Corneel Coens is member of the UK Clinical Trials Awards and Advisory Committee (CTAAC). Several senior statisticians are part of other organizations’ IDMC boards.
Meta-analyses

As in previous years, work has continued in the field of meta-analyses. An individual patient data meta-analysis of the long term outcome with intravesical mitomycin C (MMC) versus bacillus Calmette-Guerin (BCG) for non muscle invasive bladder cancer was carried out by R. Sylvester (Eur Urol, 2009).

The EORTC Statistics Department also participated in a number of meta-analysis research projects on:
• a meta-analysis of chemotherapy in head and neck cancer (Radiother Oncol, 2009);
• Multicenter analysis of oncological and survival outcomes following anastomotic leakage after rectal cancer surgery (Br J Surg 2009);
• an individual patient data based meta-analysis of the effect of preoperative chemo-radiotherapy in resectable esophageal carcinoma (JAMA 2010);
• characterization and outcome of acute lymphoblastic leukemia patients through contribution to the Ponte-di-Legno Group (Leukemia 2009);
• Overview of the Randomized Trials of Radiotherapy in Ductal Carcinoma in Situ (DCIS) of the Breast breast cancer through the Early Breast Cancer Trials Collaborative Group in Oxford (EBCTCG);
• Individual patient data Meta-Analysis of Radiotherapy for Carcinomas of the Head and neck (MARCH);
• an overview of the value of addition of vincristine plus steroid pulses in maintenance treatment for childhood acute lymphoblastic leukemia - an individual patient data meta-analysis involving 5,659 children through the Childhood Leukemia Meta-Analysis Group (Br J Haematol, 2010)
• A Meta-Analysis of Concomitant Versus Sequential Radiochemotherapy in Locally Advanced Non–Small-Cell Lung Cancer (JCO 2010) and meta-analyses of adjuvant chemotherapy, with or without postoperative radiotherapy, in operable non-small-cell lung cancer (Lancet Oncology 2010)

Research projects

Research projects performed by members of the Statistics Department included the following:
• Non muscle invasive bladder cancer. In addition to the MMC - BCG meta-analysis, the effect of age in patients treated with maintenance BCG was studied (EAU, 2009). Together with former statistical staff now at Belgian universities, the methodology of frailty models was extended to the validation of prognostic indices using data from 7 EORTC bladder cancer trials (Lifetime data analysis, 2009).
• A review paper concerning the need for local treatment of the prostate for patients with advanced prostate cancer or disease involving the lymph nodes who are treated with androgen deprivation therapy, (Eur Urol , 2010).
• Lack of prognostic and predictive importance of serial autoimmune antibodies in EORTC adjuvant Interferon melanoma trial 18952 and the Nordic IFN Melanoma trial (JNCl, 2009) and in the EORTC adjuvant PEG-Interferon melanoma trial 18991 (JCO, 2010).
• Prognostic importance of serial assessment of S100B in stage Iib – Stage III melanoma patients included in EORTC trial 18952 (EJC, submitted).
• Prognostic importance of serial circulating melanoma cell levels regarding distant metastasis-free survival in stage III melanoma patients with or without adjuvant interferon treatment (EORTC 18991) (EJC, 2009).
• Prognostic significance of serum galectin-3 in American Joint Committee on Cancer stage III and stage IV melanoma patients (Melanoma Research, 2009).
• The evaluation of the incidence of second neoplasms subsequent to therapy for childhood acute lymphoblastic leukemia or lymphoblastic lymphoma (Pediatric Blood & Cancer, accepted).
• Prognostic significance of the initial cerebro-spinal fluid involvement of children with acute lymphoblastic leukemia treated without cranial irradiation (EORTC 58881) (EJC, accepted).
• First line chemotherapy for malignant peripheral nerve sheath tumor (MPNST) versus other histologic soft tissue sarcoma (STS) subtypes and as a prognostic factor for MPNST: An EORTC soft tissue and bone sarcoma group (STBSG) study. (presented at ASCO 2010).
• A meta-analysis of trials assessing the role of STI-571 in unresectable or metastatic GIST expressing the KIT receptor tyrosine kinase were performed at the EORTC statistics department (EJC, 2010).
• Pattern of care in locally advanced breast cancer. (Breast 2010, Epub)- The RECIST version 1.1 (Response Evaluation Criteria in Solid Tumors, EJC 2009) warehouse of detailed tumor measurement information (16 Phase III trials, over 10,000 patients) continues to be maintained at EORTC Headquarters and preparations are ongoing for the next update.
• Standardized definition of time to event endpoints for cancer clinical trials (DATECAN), with current focus on pancreatic cancer and sarcomas.
• A pooled analysis of trials of radiation therapy for anal cancer (PARADAC) is ongoing and is expected to produce its first results in 2011.
• Methodological research on reporting of quality of life data together with other members of the Quality of Life Department continues (validation of the EORTC QLQ-BN20, Eur J Cancer 2010) as do collaborations with the Quality of Life Department in a project and the University of Liege on methods for the analysis of ordinal longitudinal quality of life data.
• A PhD thesis (T. Gorlia) on the diagnosis and prognosis of brain tumors is nearing completion and continues to produce interesting results: the assessment of the value of molecular characteristics to supplement the prognostic information provided by clinical and histo-pathological information for anaplastic oligodendrogial tumors (Neuro Oncol 2009, ePub). Furthermore, two pooled analyses in low grade gliomas and recurrent glioblastomas are ongoing in order to identify new prognostic factors, built new prognostic models. The surrogacy value of different endpoints (eg response, PFS) will also be assessed and new prognostic models will be built.

Statistical Fellowship

Gloria Tridello joined the department as a fellow in April 2009. She performed analyses to support the Quality of Life Unit and the Breast Cancer, Head and Neck Cancer and Radiation Oncology Groups. This led Gloria to make presentations at several congresses:
• ASCO 2010: “Quality of life results of an EORTC phase III randomized trial of adjuvant whole brain radiotherapy versus observation after radio surgery or surgical resection of one to three cerebral metastases of solid tumors.”
• Young Statisticians’ Meeting in Liverpool on 30-31 March 2010: “Analysis of longitudinal patient reported endpoints in a clinical trial with non-ignorable missing data”.

Her work has resulted in an interest for research in the field of interval censoring where she is currently undertaking to start a PhD on applying this technique in clinical research.
The TRU plays a central coordinating role at EORTC Headquarters to establish translational research (TR) support that will stimulate innovative research projects and ensure quality assurance and seamless implementation of TR throughout the EORTC. The mission of the TRU is to support high quality TR through close interaction with the EORTC Translational Research Advisory Committee (TRAC), the Translational Research Division Groups (e.g., the Pathobiology, Pharmacology and Molecular Mechanisms, and Imaging Groups) and the specialized units of the EORTC Headquarters.

The current focus of the TRU is to build on the wealth of experience from individual projects, the EORTC tumor bank, and expertise in the EORTC network both for exchange of expertise in individual projects and for developing processes to simplifying and facilitate the implementation of innovative TR projects.

The TRU coordinates with TRAC at an early stage of protocol development for the stimulation of TR concepts and for quality assurance related issues. This is in addition to the regular EORTC Protocol Review Committee linked function of review of TR proposals included as part of the clinical trial protocol to ensure adequacy of protocols in relation to human biological materials (HBM) collection and TR. In addition to the PRC linked function, where applicable, the TRU will coordinate the TRAC review of new TR concepts not specified in the clinical protocol that require access to HBM. In addition, TRAC continues to monitor the progress of all ongoing Board approved EORTC TR through the timely review of scientific reports.

With the release of the updated TRAC policy (POL014), the TRU introduced a streamlined system to distinguish between TR that forms an integrated part of the clinical trial design (‘integrated TR’) and separate TR studies that use prospectively or retrospectively HBM collected within the scope of the clinical study but are not essential to the trial design, called ‘correlative TR’. The TRAC review is coordinated to meet the different needs of these two types of TR.

Ongoing projects: Human biological materials collection

The emphasis remains on the prospective collection of HBM from patients entering EORTC trials to investigate critical molecular pathways associated with tumor progression and metastasis and assessment of molecular determinants of treatment efficacy.

Pilot projects for prospective biological material collection and biobanking, such as the EORTC 22043-30041 prostatic carcinoma trial and the EORTC 22071-24071 head and neck squamous cell carcinoma trial have been initiated and are ongoing. In conjunction with the EORTC Project Management Unit, service providers have been audited and selected to enable secured sample storage, shipment and processing (mainly focused on Tissue Micro-Array construction and molecular biology services).

Standard operating procedures and guidelines for biological material collection and management have been developed. In addition, the TRU is working closely with the IT Department and Project Management Unit for the in-house development of integrated tools for managing biological material shipments which will be piloted in the TR and biobanking study, EORTC 58081 in Children’s Leukemia.
The TRU continues to support the EORTC’s role as a partner to an FP6 EU CHEMORES project (chemo-resistance in melanoma and lung cancer) initiated in 2006. Much activity took place in 2010 in terms of follow up and centralization of biological material in several melanoma trials (the EORTC 18951, 18992 and 18032 trials) and a pilot phase of the laboratory studies in genomic profiling have been completed.

These initiatives, as well as other EORTC groups’ experiences, have served as models to develop templates, standard operating procedures (SOPs), ethical and legal frameworks and logistical checklists forming the basis of the EORTC policy on HBM collection, storage and use (POL020).

EORTC policy on human biological materials collection, storage and use

Access to appropriate HBM, e.g. tissues, blood or other bodily fluids in both sufficient quantity and quality, is essential to carrying out TR, and importantly, that these are linked to high quality, full, clinical datasets. The TRU, in strong collaboration with the EORTC Pathobiology Group (PBG), have developed an updated policy for human biological material collection, storage and use. This framework aims to progressively develop EORTC bio-resources and to support investigators’ TR and pathology review program by securing the most up to date international standards in HBM collection.

The policy principles are applicable to the collection, storage, and use of biological materials and associated data from patients participating in EORTC clinical studies. The updated policy promotes best practice in biobanking and will be in accordance with current international legal and ethical standards for storage and future use of HBM. Key topics of custodianship of HBM collected from patients enrolled in EORTC clinical studies, ethical principles, confidentiality and data protection, access to HBM, establishment of EORTC group biobanks, and publication of resulting research are covered. This policy builds on the extensive expertise of the EORTC groups, the PBG, pilot projects, and EORTC tumor bank activities.

Also in collaboration with the PBG and TRAC, the EORTC HQ has developed practical tools for the prospective collection of HBM, including a checklist to support logistical planning and HBM collection set up. Through these HBM collection initiatives, the EORTC will be able to prospectively collect detailed molecular data to complement its clinical and quality of life databases, its radiotherapy database, and its recently established imaging database. These resources, in toto, will add further dimensions to the analysis of endpoints in clinical trials.

Exchange of expertise and interaction in the EORTC network

Recognizing the key role of pathologists in TR and HBM collection, a highly successful meeting ‘Fostering the Role of Pathology and Biobanking in EORTC Clinical Research’ in September 2010 was organized. The objectives of finalizing the principles of the EORTC biobanking policy and maximizing EORTC networking by stimulating interaction between EORTC Group Pathologists, NOCI pathologists, and the PBG were well met.

The TRU has also been active in training and dissemination of best standards for HBM collection together with the PBG through presentations at the EORTC methods, an OECI course held in November 2010 on “Biobanking for cancer research: Rules and Roles”, and a workshop at the 22th
EORTC-NCI-AACR symposium on “Molecular Targets and Cancer Therapeutics” held in November 2010. In addition, the TRU contributed to the EORTC statistics for non-statisticians course held in July 2010, with a presentation on the development of complex classifiers from gene expression data highlighting the need for good quality biological materials for research.

Virtual microscopy: Ongoing projects

The TRU in collaboration with the EORTC IT department continues to maintain the VTB system. The upgraded VTB system has been used for the pathology review program as well as TR in the following activities:

• A pilot project, the PETACC-2 trial (EORTC 40963), was run with a full integration of a clinical dataset (700 patients) with the inventory of the HBM used in this program, as well as digitized images of Tissue Micro-Arrays and full section slides.

• A program in central pathology review support for several EORTC Brain Group trials is ongoing, this involves the:
  o EORTC 26951 trial (slides for 275 patients);
  o EORTC 26882 trial (slides for 416 patients, anaplastic oligodendroglioma, anaplastic astrocytoma, mixed oligoastrocytoma, anaplastic mixed oligoastrocytoma, astrocytoma, oligodendroglioma, and glioblastoma);
  o as well as uploading slides from the EORTC 26981 trial (slides for 314 patients, glioblastoma multiforme).

In total approximately 1680 virtual slides from these three trials have been centralized and will be made available through secure EORTC servers with associated forms to support the work of the panel of pathologists. This resource will be used to improve histological diagnosis of glioma typing and grading by better defining key histological features and panel review.

Regulatory Affairs and Intergroup Unit (RAIU)

The RAIU is responsible for the submission of new EORTC clinical studies and major protocol amendments to the appropriate regulatory authority and ethics committees. This unit also cooperates on specific projects with the pharmaceutical industry when required. The RAIU is continuously updating its procedures to ensure compliance with the legal provisions governed by the European Clinical Trial Directive 2001/20/EC and its various national implementations.

During 2009 and 2010, RAIU managed a portfolio of more than 120 trials, either in activation, already recruiting, in follow-up, or ending trials. Sixteen new trials started regulatory submissions during 2009-2010 via EORTC RAIU.

With the increased emergence of translational research projects, the RAIU is investigating existing legislation related to biobanking and in the use of human tissues and cells for research purposes. Several retrospective projects on human biological material has been submitted and approved by the competent EC authorities.
Intergroup Trials and Activities

The RAIU facilitates the setting up of intergroup trials between the EORTC and other groups.

Eight new intergroup trials were opened during the course of 2009-2010. The EORTC is the coordinating group for two trials and participates in four trials coordinated by other groups.

Both the UK and the French liaison offices were functional during 2009-2010, and discussions have begun concerning a liaison office in Poland. The French Liaison Office is now located at the Federation Nationale des Centres de Lutte Contre le Cancer in France and facilitates initiation of trials in France.

Data Management Department

Data Management of EORTC trials is conducted by a team which comprises 33 full time Data Managers.

In 2010, 275000 forms were validated among 105 trials.

Besides its data cleaning duties, Data Management is responsible for designing the CRFs and other data management tools as well as for designing the clinical database and the patient registration/randomization programs. The Data Managers also generate the bi-annual Trial Status Reports used as support documents for the various EORTC Group Meetings.

Lately the Data Management unit has placed effort in trying to simplify the work of investigators concerning data completion. As a result of this, the use of conventions lists aimed at reducing the number of queries is being generalized across our studies. Also, a new generation of much more legible form requests is being developed.

Pharmacovigilance Unit (PVU)

The PVU was founded in 1996 with the aim to implement procedures which would guarantee the safety of patients in EORTC trials and compliance with European laws and regulations. Since the founding of the European Medicine Agency (EMA) and the Clinical Trial Directive (2001/20/EC) this area has evolved enormously, and, consequently, strict reporting rules are now in place to guarantee even more the patient’s safety in clinical trials.

The PVU wrote and implemented working procedures and infrastructure for Serious Adverse Event (SAE) collection and reporting. Protocol specific chapters were written, CRFs were created, and training was given.

It is necessary to be kept informed of all changes in the laws and regulations which affect current working procedures. It is therefore a privilege that the PVU is also represented at the Eudravigilance Expert Working group with the aim to ensure that new guidance documents on the safety reporting in clinical trials are also feasible for non-commercial sponsors.

As reporting of safety information in clinical trials is sensitive and requires rapid action, a safety database needed to be put in place to help the PVU report specific SAEs in a rapid and secure manner to Competent Authorities, Ethics Committees, investigators, and the EMA.
In 2010 the PVU developed, validated, and implemented a new safety software system called SAfE, an in-house developed software. It will allow the PVU to collect all SAEs, facilitate the reconciliation with the clinical database, report electronically to CAs, the EMA, and pharmaceutical companies, and facilitate the creation and tracking of annual safety reports.

Quality of Life (QOL) Department

The Quality of Life (QOL) Department is responsible for developing and analyzing the QOL component of EORTC clinical trials and acts as a support for selective projects undertaken by the EORTC Quality of Life Group (QLG). The QOL Department also has an ongoing and active research program in a number of key areas in the field of QOL and symptom research.

EORTC trials

The QOL Department continues to collaborate actively with the EORTC disease oriented Groups, supporting the implementation of QOL into clinical trials. During 2009-2010 QOL studies were activated in several new clinical trials. Five large scale phase III clinical trials with QOL data were published in collaboration with various EORTC disease oriented groups including the Lung Cancer, Brain Tumor, Radiation Oncology, Melanoma, Head and Neck Cancer, and Gynecological Cancer Groups.

PROBE research

During 2009-2010 the QOL department has continued to work on the PROBE research project, a project funded by the Pfizer Foundation as part of its Global Health Partnership Program. PROBE's aim is to explore QOL and psychosocial issues in cancer patients. During this period, research findings from PROBE resulted in ten peer reviewed abstracts being presented at conferences such as ASCO, UICC and ISPOR. Furthermore, in November 2009 an EORTC Course, “Quality of Life, Symptom Research, and Patient Reported Outcomes in Cancer Clinical Trials”, was hosted in Brussels. This course presented results from PROBE as well as views of key opinion leaders from around the globe and was attended by over 250 health care professionals. All presentations at this meeting were recorded and are accessible online (see www.eortc.be/probe/videos.htm).

Collaboration with the QLG

The QOL Department maintains a close relationship with the QLG and participates in the development process of various new QLG modules such as LMC21 (colorectal liver metastases) and CR29 (colorectal cancer). In early 2009, results of the QLG supported study to validate the brain cancer module via analysis of data held in the QOL Department were published in 2010.

The QOL Department continues to encounter a constantly rising number of worldwide requests for EORTC QOL measures. During the period 2009-2010, the EORTC QLG core and disease-specific questionnaires were translated into over 50 languages. The total number of validated translations now exceeds 640, and more than 230 additional translations are in progress or being pilot tested. Much time
and effort is devoted to checking translations, harmonizing response scales and items, and achieving consistency across translations and cultural adaptations.

Other research activities

In addition to the PROBE scientific output noted above, the QOL Department has successfully presented 25 peer reviewed abstracts at international scientific congress, e.g. ASCO, UICC, and ISQQOL. Furthermore, in collaboration with many EORTC Groups and International bodies, a total of 15 articles were published in peer reviewed journals such as the Journal of Clinical Oncology and The Lancet Oncology. Three book chapters on QOL research methodology were also published in 2009-2010. Six articles on topics such as QOL in relation to symptoms clusters, clinical significance of QOL results, and QOL policy are currently in press.

A joint EORTC external research project in collaboration with the University of Liege is currently ongoing; it focuses on the longitudinal analysis of QOL data as ordinal data as well as on the complex issue of missing data.

During 2009-2010, several QOL Department staff were invited to make presentations at international conferences, and QOL Department staff also taught in numerous national and international oncology courses.

Looking to the future, proposals for new clinical trials with QOL are under discussion, a number of additional papers are in preparation, and the QOL Department is organizing a major EORTC conference on QOL, symptom research, and patient reported outcomes in cancer clinical trials to be held in September 2011 and hosted in collaboration with the European Parliament.

Quality Control Unit

The Quality Control Unit (QCU) is responsible for ongoing quality assessment of clinical trials at EORTC Headquarters and at investigational sites.

Within EORTC Headquarters, the QCU is responsible for checking the quality and reliability of clinical databases through a selection of open studies. In 2010, six studies were quality controlled. Reports are shared with the Data Management Unit and, consequently, additional steps are decided based on the observations.

The QCU is also responsible for identifying and tracking sites with persistent missing data by means of a central Data Timeliness procedure conducted on an annual basis. This process is in addition to the standard tri-monthly form request performed by the Data Management Unit. Following the Data Timeliness procedure of 2010, 42 warning letters were sent to sites with persistently overdue data and corrective actions were put in place.

At the investigational sites, the QCU is responsible for assessing data quality and compliance with ICH-GCP and protocol requirements. This is achieved through direct source data verification by the Clinical Research Assistants.
The EORTC QCU performs on site monitoring in studies of medium and high risk level and/or when required by contracts.

In order to quantify the potential risks associated with patient participation into a clinical trial, the EORTC QCU has developed a “study risk assessment” grid adapted to oncology trials.

In 2009, 342 site visits were made in participating institutions, and 122 site visits were made in 2010.

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<th>Year</th>
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<th>Quality Assurance</th>
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<tbody>
<tr>
<td>2009</td>
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<td>9</td>
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<tr>
<td>2010</td>
<td>9</td>
<td>6</td>
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<table>
<thead>
<tr>
<th>Year</th>
<th>Institutions</th>
<th>Total of_nbr_site_visits</th>
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<tbody>
<tr>
<td>2009</td>
<td>100</td>
<td>464</td>
</tr>
<tr>
<td>2010</td>
<td>15</td>
<td>26</td>
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</table>

**Quality Systems & Compliance Unit (QS&C)**

The QS&C promotes and encourages quality awareness throughout the organization and provides expertise in the development and maintenance of the quality management system pertaining to clinical study activities. This team contributes to minimizing the risk of non-compliance, coordinates internal and external audit programs, and provides the necessary training and assistance to achieve these goals.

The QS&C participated in the organization of training courses related to Standard Operating Procedures (SOPs), Work Instructions (WINs), and the second edition of a GCP course for investigators in collaboration with EFGCP (European Forum for Good Clinical Practice). Furthermore the unit provided help to the various units and departments in order to harmonize trainings and training documentation.

In 2009, 31 SOPs and WINs were presented which represented 103 training sessions. In 2010, EORTC initiated the creation of webcasts for trainings concerning SOPs and WINs; training sessions are recorded and then made available to all Headquarters staff thereby facilitating training for newcomers and retraining of staff. There are currently ten webcast trainings available.

In 2009, the pharmaceutical industry audited two EORTC sites and one audit of EORTC Headquarters involving two disease/treatment-oriented groups.

In 2009, the EORTC was inspected by the UK regulatory agency (MHRA) which visited EORTC UK sites regarding their participation in EORTC trials. In this frame, the QS&C performed eight inspection preparation visits and attended the four inspections which involved three disease/treatment oriented groups. In 2010, one EORTC site was inspected by the Swiss regulatory agency (Swissmedic).

In 2009 and 2010, the QS&C also performed seven external audits (as per contract with a third party), three audits of affiliated institutions, one sponsor audit preparation visit, and attended two sponsor audits involving three disease/treatment oriented groups.

The Data Timeliness Procedure is conducted on an annual basis. In 2009 and 2010, a limited number of centers were temporarily closed as a result of persistently missing information and noncompliance issues.
Quality Assurance for Radiotherapy (QART) Unit

QART at the EORTC builds on 28 years of experience of the EORTC Radiation Oncology Group (ROG) in pioneering QART in the clinical trial setting in Europe and internationally. The QART team develops, administers, and analyses Quality Assurance procedures with the aim of ensuring the quality of radiotherapy across the broad spectrum of EORTC trials. The QART team at EORTC Headquarters includes the QART manager, the Emmanuel van der Schueren Fellow (supported by the Vlaamse Liga tegen Kanker), and the ROG Clinical Research Physician.

In 2009, the EORTC invested in the VODCA (Visualization of Data for Cancer Analysis) software package which was designed specifically for the administration, organization, and analysis of radiotherapy digital data in the setting of multicenter clinical trials. In 2010 with the assistance IT Department and the Project Management and Data Management Units, the QART team successfully integrated VODCA into existing EORTC facilities. The QART platform now consists of web forms for dummy run and individual case submission and evaluation, VODCA, and the EORTC QART uploader© for radiotherapy-related data transfer. In the first half of 2010, the QART team successfully launched an Individual Case Review (ICR) procedure using this platform. Based on feedback from the participating sites and study central reviewers, the QART team will work to further augment the system.

Building on Emmanuel van der Schueren Fellowship achievements from 2009, the QART team established methodology for prospective Normal Tissue Complication Probability (NTCP) modeling, an additional beneficial aspect of existing QART data collection. By analyzing radiotherapy treatment planning information digitally, NTCP modeling can correlate dosimetric parameters with clinical outcomes such as quality of life. Future links with translational and imaging projects can also be explored.

The QART team also recently developed the theoretical and practical framework for the credentialing of advanced technologies such as intensity-modulated radiotherapy within EORTC trials, performing a successful pilot study using an anthropomorphic phantom.

The QART team is currently overseeing radiotherapy aspects of eleven ongoing and five forthcoming trials, collaborating with the Brain Tumor, Breast Cancer, Head & Neck Cancer, Gastrointestinal Tract Cancer, Genito-Urinary Tract Cancer, and Soft Tissue and Bone Sarcoma groups. The QART team remains committed to developing new strategies to address the complexity of advanced radiotherapy techniques with the knowledge that high quality treatment within clinical trials will benefit all patients receiving radiotherapy.

Information Technology (IT) Department

The IT Department is responsible for the development of software and systems used to manage cancer clinical trials. VISTA TRIALS is the Clinical Data Management System (CDMS) developed by the IT Department and used to manage all clinical data activities at EORTC Headquarters. VISTA TRIALS is a suite of applications ranging from double data entry, database definition, up to the SAS export module, including ORTA, the web-based patient registration and randomization tool. Satellite applications are linked to VISTA TRIALS, such as the Regulatory system or the recently developed Contract...
Management Tool (CMT). VISTA TRIALS is a community trademark owned by the EORTC. The source code of VISTA TRIALS is registered with the Benelux Office for Intellectual Property as an I-Depot.

After more than five years of existence, the remote data entry application (VISTA RDC) went through a major update this year. The system can now handle complex eligibility checking, dynamic treatment allocation, and form consistency checks. This version was developed in order to run the MINDACT protocol.

Until 2010, the Pharmacovigilance Unit had been using an off-the-shelf system to run their activities. After an in depth analysis, it was decided to replace this system with an in-house development. Because it was designed in close collaboration with its users, the new SAfE application will provide them with the exact tool they need for SAE recording, and management, including E2B reporting to authorities and links with MedDRA and WHO dictionaries.

The new EORTC Imaging Platform has been set up. It provides all the EORTC centers with an easy upload portal that allows them to transmit patient’s images in a secured and protected way. The reviewing functionalities have been improved with the integration of VISIO+, the Keosys viewer. Collected images are stored centrally and linked to the patient’s clinical data. The central review can be performed from any Internet workstation and does not require software installation.

The software developed at EORTC Headquarters follows a standard System Development Life Cycle (SDLC) in order to comply with the regulations of the US FDA (United States Food and Drug Administration), 21-CFR part 11 (electronic records – electronic signature).

The configuration of the EORTC computer system is based on client/server technology mainly powered by Windows and Red Hat Linux servers.

**Human Resources**

As of January 2011, the EORTC Headquarters staff consisted of 180 members (125 females, 56 males representing 19 different nationalities) of which 162 are full-time and 18 part-time employees and include 9 research fellows, 5 interim staff, and 2 consultants.

**Scientific Output (2009 – 2010)**

In 2009 and 2010 EORTC Headquarters staff presented at various courses, symposia, and conferences and published the following number of publications:

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<td>Miscellaneous</td>
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<td><strong>Total</strong></td>
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**Education Office**

The EORTC Education Office provides logistics support for the organization of EORTC courses (on the methodology of clinical trials, statistics, data management, quality of life, and other topics) as well as for EORTC conferences including EGAM (EORTC Groups Annual Meeting), and ENASCO (EORTC-NCI-ASCO Meeting on Molecular Markers in Cancer).

For further information, please contact:

danielle.zimmermann@eortc.be (Education Office Coordinator)

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**Communications Office**

The Communication Office aims to increase the visibility of EORTC research activities and raise public and media awareness of the importance of cancer clinical research in Europe. It provides information on an ongoing basis to the various European cancer leagues, the scientific community, patients, and the public.

For further assistance, please contact:

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or

stephanie.vandergooten@eortc.be (Assistant)

or

jennifer.crespo@eortc.be (Administrative Assistant)
5. Courses and Conferences

The EORTC Headquarters staff members are involved in the organization and teaching of the following courses and meetings:

**EORTC Courses in 2010**

- **Clinical Trial Statistics for Non Statisticians**  
  *(Brussels, Belgium, 15-18 June)*

  This course was designed as an introduction to the statistical principles which form the basis for the design and analysis of cancer clinical trials. It focused on the philosophy and understanding of the statistical principles that are used on a day-to-day basis in conducting clinical trials and did not simply present statistical formulae in a cookbook fashion. This course was aimed at non statisticians (medical doctors, data managers, etc.) who were already working in the field of clinical trials and who have had an introductory course in statistics, or at statisticians with little or no experience in clinical trials. For those persons who wanted a review of the basic statistical concepts, an optional half day introduction to statistical methods was organized.

- **Methodology of Cancer Clinical Trials: The Next Generation**  
  *(Brussels, Belgium, 7-10 September)*

  This course was designed at an advanced level and was oriented towards medical doctors, specialists in oncology, experienced data managers, oncology nurses and those working in the pharmaceutical industry who were involved in cancer clinical trials. The course was focused on the new aspects and methodological challenges of modern cancer clinical trials. The course addressed new clinical trials features aimed at understanding the biology of the disease and document molecular determinants whether host or disease related which may be prognostic or predictive for patient outcome. As innovative approaches were discussed, attendees were expected to already have a good understanding of the basis of clinical trial methodology.

- **One-Day Introduction to EORTC Trials**  
  *(Brussels, Belgium, 15 October)*

  This course was dedicated to newly participating members (investigators, data managers, research nurses, etc.), and industry representatives. The purpose of this introductory workshop was to give guidance for participating in EORTC clinical trials activities. Participants received information about the functioning of the EORTC and about Trials methodology, investigator / site quality requirements and control, patient safety management, adequate data collection and pitfalls for reliable data. Furthermore, participants were shown our on-line registration /randomization process and remote data capture system. It also provided an opportunity to visit the EORTC Headquarters and to have informal discussions with the Headquarters staff.
EORTC Meeting in 2010

- EORTC Strategy Meeting (La Hulpe, Belgium, 18 - 19 March)

This strategic meeting was aimed at advancing the EORTC scientific strategy and fostering interaction between the Board and the groups on the groups’ strategies and on the EORTC translational research agenda including imaging, biobanking, and NOCI.

EORTC Courses in 2011

- Clinical Trial Statistics for Non Statisticians (Brussels, Belgium, 14 - 17 June)
- One-Day Introduction to EORTC Trials (Brussels, Belgium, Fall)

EORTC Meetings in 2011

- EORTC Groups Annual Meeting, EGAM (Brussels, Belgium, 1 - 4 March)
- EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer (Brussels, Belgium, 27 - 29 October), with a tutorial on 26 October and 27 October (morning)

EORTC Courses in 2012

- Clinical Trial Statistics for Non Statisticians (Brussels, Belgium, Spring)
- One-Day Introduction to EORTC Trials (Brussels, Belgium, Fall)

EORTC Meeting in 2012

- EORTC: Celebrating 50 Years of Research and Treatment of Cancer in Europe (Brussels, Belgium, 15 - 16 March)

For further assistance, please visit the Education Office website: http://www.eortc.be/Seminar/Educationpgm/Programs/prog2011.htm or contact: danielle.zimmermann@eortc.be (EORTC Education Office Coordinator)
International Courses and Conferences involving the EORTC

• EORTC - EANO “Trends in Central Nervous System Malignancies
  25 - 26 March 2011, Bucharest, Romania
  The main focus of the joint EORTC-EANO Conferences is to progress the neuro-oncology field, accelerate the translation of cutting edge discovery at the clinical level, and further promote international scientific cooperation, debate and exchange.

• 13th Joint ECCO - AACR - EORTC - ESMO Workshop on Methods in Clinical Cancer Research
  18 - 24 June 2011, Waldhaus Flims, Switzerland
  The ‘Methods in Clinical Cancer Research’ Workshop was established to reverse the decline in numbers of clinical scientists. The major aim of the Workshop is to develop a strong, expanding base of well-trained clinical researchers by providing them with the training they need to develop and conduct better clinical/translational trial designs.

• EORTC - NCI - AACR International Conference on Molecular Targets in Cancer Therapeutics
  16 - 19 November 2010, Berlin, Germany
  This Symposium focuses on the many recent advances in the early development of promising new compounds, which are on different levels of preclinical and clinical development. It gathers delegates from all over the world and ignites a huge exchange of information and promotes and develops global partnerships in translational research.

• AACR - NCI - EORTC International Conference on Molecular Targets in Cancer Therapeutics
  12 - 16 November 2011, San Francisco (CA), USA

• EORTC - NCI - AACR International Conference on Molecular Targets in Cancer Therapeutics
  06 - 09 November 2012, Geneva, Switzerland
6. EORTC Directory

François Meunier, EORTC Director General
Denis Lacombe, EORTC Director Headquarters
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