The EORTC is the leading pan-European partner for high-quality clinical research

**THE EORTC PROVIDES:**

- A NETWORK OF HIGH-QUALITY, DEDICATED CLINICAL RESEARCHERS
- COMPREHENSIVE SCIENTIFIC PROJECT MANAGEMENT
- EXPERTISE IN QUALITY ASSURANCE AND REGULATORY AFFAIRS
- INTEGRATED CLINICAL AND TRANSLATIONAL RESEARCH PROGRAMMES

The EORTC Strategy for New Drug Development
The EORTC is a pan-European organisation that plays a major role in the development of innovative anti-cancer agents and in novel strategies to improve the survival and quality of life of all patients with cancer.

The New Drug Development Programme (NDDP) was established in 1998 within the Data Centre as a central facility to support all stages of new drug development in cooperation with industry.

The New Drug Development Group (NDDG) conducts high-quality early clinical trials supported by the New Drug Development Programme and linking with the EORTC Laboratory Research Division Groups to carry out translational research.

1.1. Benefits of the EORTC for the pharmaceutical industry

- The New Drug Development Group offers a unique network of committed early clinical trialists across Europe who have contributed to the successful development of several drugs now approved for use in the clinic.

- The New Drug Development Programme provides optimal project management to high-quality early clinical studies, integrating pre-clinical and translational research combining the expertise of leading European scientists and clinicians.

- All EORTC studies are conducted according to international standards (GLP, GMP and ICH-GCP). The EORTC has been a pioneer in the quality assurance of cancer clinical trials; its working procedures and standard operating procedures are FDA approved, allowing quicker drug registration by the FDA (drug master file N°: 13059).

- EORTC Clinical Groups have expertise in Phase II and III trials with a track record of recruitment in both rare and common cancers allowing a rapid transition from early trials to large, disease specific randomized studies.

1.2. The EORTC search for new partners in drug development is led by:

Professor Chris Twelves – Chairman of the New Drug Development Group
Dr Denis Lacombe – Assistant Director for Medical Affairs and for the New Drug Development Programme
Dr Bridget Hill – Drug Acquisition Consultant

This activity is co-ordinated by the New Drug Advisory Committee (NDAC), chaired by Professor Jaap Verweij, to ensure prioritization of areas of interest, collaboration with other EORTC clinical groups, and to provide advisory boards for the pharmaceutical industry.
Established in Brussels within the EORTC Data Center only 5 years ago, the New Drug Development Programme manages early clinical trials and pivotal trials supported by the pharmaceutical industry that are conducted by the New Drug Development Group or disease-orientated clinical groups within the EORTC Clinical Research Division.

The New Drug Development Programme aims to provide the new drug development group and other clinical groups with:

- methodological expertise for developing and conducting phase I-II trials
- expertise in protocol preparation, data management, monitoring and trial reporting
- technical support for a European platform to initiate clinical trials (coordination of pharmacokinetic projects, drug distribution, collaborative translational research projects etc)
- assistance in interacting with pharmaceutical companies, the NCI, with other specialty units at the EORTC Data Center to ensure comprehensive support (Regulatory Affairs Unit, Safety Desk, Monitoring Unit, etc) as well as with other EORTC Clinical Research Division Groups.

The New Drug Development Programme has 20 highly trained staff, dedicated to cooperation with industry. In particular a project management platform addresses compliance to pre-agreed milestones and timelines.

2.1. Structure of the New Drug Development Programme
2.2. Commitment to speed and quality

Studies designed to become part of a new drug application need to be compliant with regulatory and ICH-GCP requirements and must be completed on time for which the New Drug Development Programme has established a comprehensive project management system that is open to audit.

The EORTC is one of Europe’s leading players in the development of new technologies to facilitate clinical cancer research. Specific software has been developed and validated for automatic computer registration/randomization of patients 24 hours a day seven days a week, automatic cross-checks of clinical trial data, transfer and storage of radiology or pathology images and export of databases in various formats to allow transfer to industrial partners.

The New Drug Development Programme offers a tried and tested structure for clinical trials from which the pharmaceutical industry can select the elements that meet their needs including:

- Master protocols that speed up protocol development
- Unequalled experience in dealing with regulatory authorities across Europe
- Standard SAE forms handled by a designated safety desk
- Day to day monitoring can be contracted out to a CRO working according to EORTC Study Outline Procedures (SOPs).

NDDP interaction with outside partners
### 2.3. The Drug Development Process

The drug development process for any given new drug is structured in detail before project initiation.

<table>
<thead>
<tr>
<th>Protocol</th>
<th>SO</th>
<th>PRC</th>
<th>Protocol</th>
<th>PRC</th>
<th>ECs</th>
<th>RAA and site visit</th>
<th>Start of accrual</th>
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</thead>
<tbody>
<tr>
<td>SO</td>
<td>2 wks</td>
<td>4 wks</td>
<td>6 wks</td>
<td>4-5 wks</td>
<td>1-3 months depending on countries</td>
<td>5-6 months from start</td>
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**SO**: Study Outline  
**PRC**: Protocol Review Committee  
**ECs**: Ethical Committees  
**RAA**: Regulatory Authorities Approval  
**CRF**: Case Report Forms

The final approved project plan, detailing types of studies to be performed, their cost and timing and important milestones, is considered the ‘contract’ to which all parties are committed.

In this way, the pharmaceutical industry, the EORTC New Drug Development Programme and New Drug Development Group or Clinical Research Division Group, including the investigators, have a clear understanding of the project from the beginning, in terms of what has to be done and when it should be done.
3.1. The EORTC New Drug Development Group

The New Drug Development Group Board (2003-2006) consists of:
- Chairman: Prof. C. Twelves, Leeds/Bradford, United Kingdom
- Vice Chairman (immunological agents): Prof. C. Punt, Nijmegen, the Netherlands
- Secretary: Dr. F. Caponigro, Naples, Italy

Past Chairmen of the Group include: Prof. P. Fumoleau, Prof. J. Verweij and Prof. S. Kaye

The New Drug Development Group is a network of medical oncologists specifically dedicated to conducting Phase I and early Phase II studies.

The Group comprises a core of around 15 centres with particular expertise in Phase I trials and 40 with an interest in early Phase II trials, all operating to quality standards established with the New Drug Development Programme. Trial centers are identified in discussion with pharmaceutical partners.

This network can accrue annually at least 250 patients into Phase I and early Phase II trials. It promotes cooperation in the evaluation of innovative agents, including small molecules, monoclonal antibodies, gene therapy, and vaccines.

The New Drug Development Group-EORTC has contributed to trials leading to the approval of docetaxel, topotecan, irinotecan and yondelis.
4.1. EORTC Clinical Research Groups

Through the New Drug Development Programme, early drug developers and tumour disease-oriented specialists can collaborate at an early stage to develop new drugs and ensure a swift passage from phase I to phase III studies. Quality assurance programmes are in place in order to allow disease-orientated group centers to join phase II studies.

Over the last 3 years, 17 early phase II studies have been conducted in cooperation with several EORTC groups including:

- Brain Tumor Group
- Genito-urinary Tract Cancer
- Gynecological Cancer Group
- Lung Cancer Group
- Breast Cancer Group
- Melanoma Group
- Sarcoma Group

Cooperation between new drug developers and disease/tumor oriented specialists allows the creation of specific networks. Such networks have developed through the support of the new Drug Development Programme master documents (protocol, CRFs) and procedures allowing rapid study activation protocol development.

As an example, in less than two years, the EORTC high grade glioma drug development network with clinical centers in Austria, Belgium, France, Italy, the Netherlands, Switzerland and the U.K., has conducted 4 early phase II studies screening 4 different agents and accruing 200 patients selected for recurrent glioblastoma multiforme.

4.2. Translational Research and the EORTC Laboratory Research Division Groups

The EORTC has initiated a European tumour bank project to improve and harmonize histological review and the use of telepathology. By providing rapid access to tumor tissue and to relevant clinical databases.

Translational research is coordinated by the Translational Research Unit (TRU) at the Data Centre and TRAC (the Translational Research Advisory Committee) which address optimal and comprehensive translational research aspects of new agents.

There are close links between the New Drug Development Group/New Drug Development Programme and the Pharmacology and Molecular Mechanisms Group (PAMM; Chairman Professor J. Schellens) through which pharmacokinetic and pharmacodynamic studies can be carried out. The New Drug Development Group/New Drug Development Programme also work closely with the Functional Imaging Group (FIG) (Chairman: O. Hoekstra) which can incorporate PET, MRI or dynamic CT work in early clinical trials.
FOR MORE SPECIFIC INFORMATION, PLEASE CONTACT:

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