The EORTC Strategy for New Drug Development

The EORTC is a leading pan-European partner in conducting high-quality research on cancer treatment

EORTC

Comprehensive scientific project management including:

- Clinical protocol with peer review
- Integrated translational research programmes
- Quality assurance and regulatory affairs
- Access to a network of dedicated clinical oncologists

The EORTC is a primary partner in all fields of cancer research leading to state-of-the-art treatments. The EORTC is a not-for-profit organisation.This pan-European research organisation plays a significant role in the development of innovative anti-cancer agents and in defining more effective strategies to improve survival and quality of life of all patients with cancer.

The EORTC Data Center infrastructure provides a unique central facility to support effective new drug development in cooperation with industry.

Benefits of the New Drug Development Programme (NDDP) for the pharmaceutical industry

- The NDDP **offers optimal project management** to high-quality early clinical studies, with integrated pre-clinical and translational research activities effectively combining the scientific expertise of leading scientists and clinicians.
- All EORTC projects are **peer reviewed** and approval by the **EORTC Protocol Review Committee (PRC)** is mandatory.
- Studies of new agents via the NDDP benefit from **expert reviewing** by the **New Drug Advisory Committee (NDAC)** and the **Translational Research Advisory Commitee (TRAC)**, which cooperate to ensure a fully comprehensive approach.
- All EORTC studies are **conducted according to international standards (GLP, GMP and ICH-GCP)**, so speeding up the introduction of new compounds into clinical practice.
- The EORTC has been a pioneer in the **quality assurance of cancer clinical trials** and the NDDP continually reassesses its output to maintain high-quality criteria.

The current NDDG Board (2002-2005) consists of:

Chairman: Dr. C. Twelves, United Kingdom

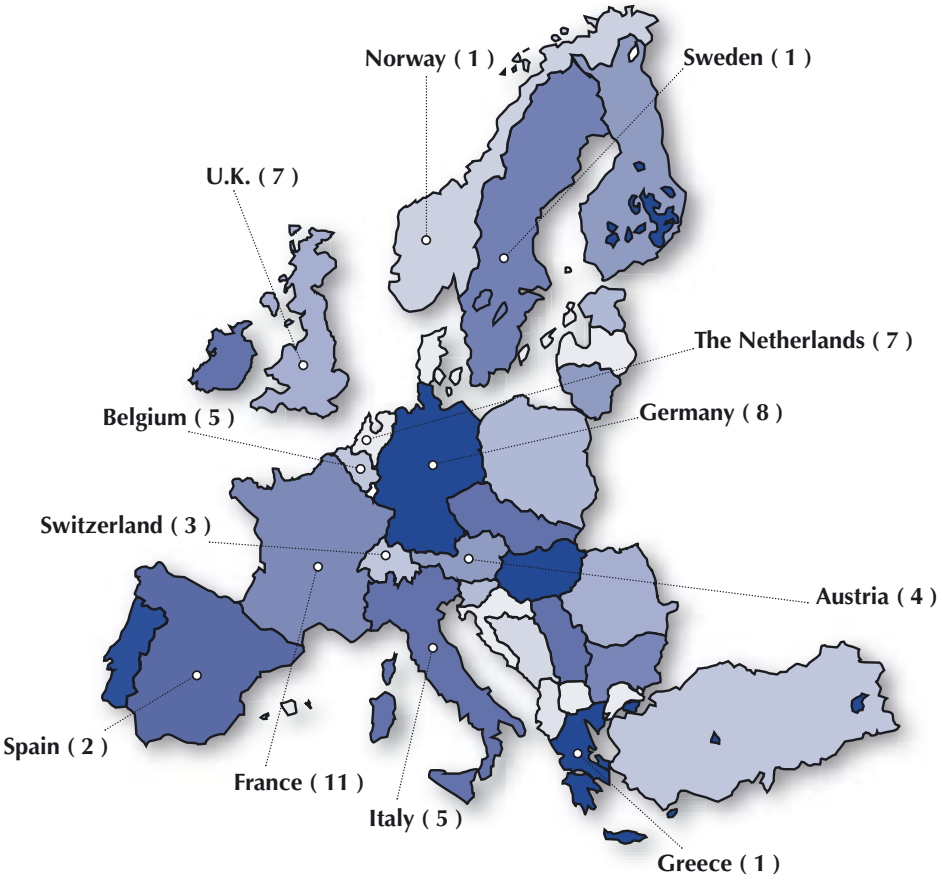
Vice Chairman: Prof. C. Punt, the Netherlands
(immunological agents)

Secretary: Dr. F. Caponigro, Italy

Added-value of working with the EORTC

- Established in Brussels in 1998 within the EORTC Data Center, the **EORTC NDDP** manages early clinical trials and pivotal trials supported by the pharmaceutical industry and conducted by the **New Drug Development Group (NDDG)** or **by disease-orientated clinical groups within the EORTC Clinical Research Division Groups (CRDG).**
- The NDDG is a **network of medical oncologists specifically dedicated to conducting phase I and early phase II studies.** This network has an annual accrual, of at least 250 patients. It promotes cooperation in the evaluation of innovative agents (including small molecules, monoclonal antibodies, gene therapy, vaccines ...) and assists in creating specific tumour networks or those oriented to immunological approaches. Further developments are promoted, including health economic evaluations and quality of life assessments.
- 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 tumour tissue and to relevant clinical databases, this also facilitates translational research, coordinated by the **Translational Research Unit (TRU)**, in EORTC trials. TRU and TRAC address optimal and comprehensive translational research aspects of new agents.
- 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 following widely - accepted methodologies and validation procedures to enable, for example, automatic computer registration/randomization of patients, available 24 hours a day seven days a week, management of clinical trial data with automatic cross-checks, transfer and storage of images for pathology and imaging and export of databases in various file types to allow transfer to industrial partners.
- The EORTC's working procedures and standard operating procedures for evaluating new anti-cancer agents and conducting clinical studies are **FDA approved** which allows quicker drug registration by the FDA (drug master file N°: 13059)

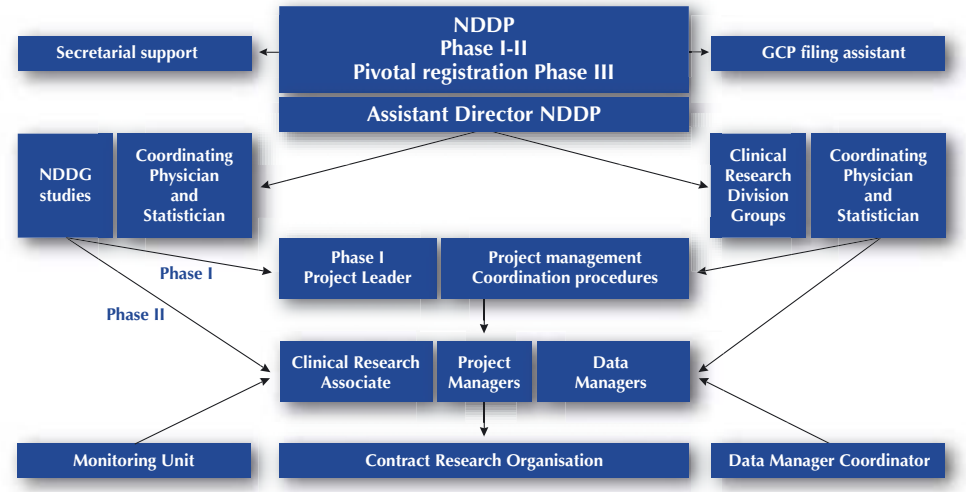
Clinical Centers within the EORTC NDDG Network



The NDDP aims to provide the NDDG and the EORTC CRDG 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....)
- assistance in interacting with pharmaceutical companies, the NCI and all involved parties, with other specialty units at the EORTC Data Center to ensure comprehensive support (Regulatory Affairs Unit, Safety Desk, Monitoring Unit, ...), as well as with other EORTC CRDG.

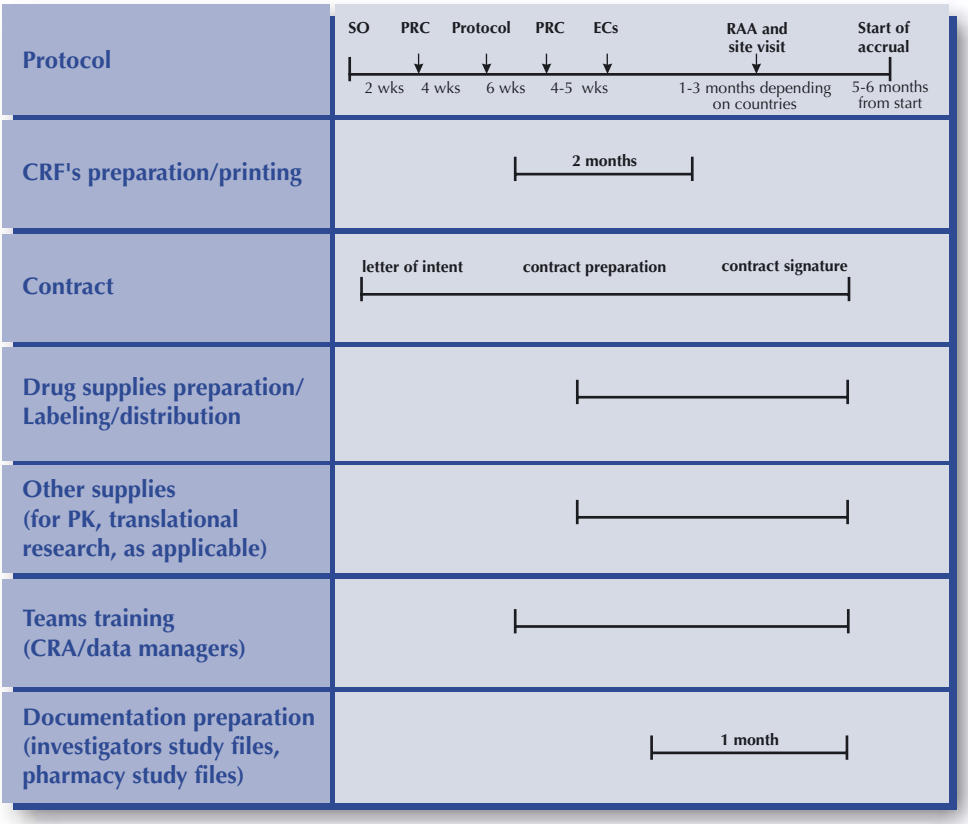
The NDDP is equipped with 20 highly trained staff, dedicated to cooperation with industry. In particular a project management platform addresses compliance to pre-agreed milestones and timelines. Day to day monitoring can be contracted out to a **Contract Research Organisation (CRO)** working according to EORTC **Study Outline Protocols (SOPs)**.



1. THE NDDP's 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. The NDDP has established an environment concerned with quality and commitment to punctual delivery of clinical data and implements a comprehensive project management system for clinical trials conducted in cooperation with industry.

Study development process at EORTC



SO: Study Outline
PRC: Protocol Review Committee
ECs: Ethical Committees
RAA: Regulatory Authorities Approval
CRF: Case Report Forms

2. THE NDDP's DRUG DEVELOPMENT PROCESS

The drug development process for any given new drug **is structured in detail** before project initiation. The final approved project plan, detailing 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 NDDP and NDDG or CRDG, 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. COOPERATION WITH THE EORTC CLINICAL RESEARCH DIVISION GROUPS

Through the NDDP, 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 Tumour Group
- Genito-urinary Tract Cancer
- Gynecological Cancer Group
- Lung Cancer Group; Breast Cancer Group
- Melanoma Group and the Sarcoma Group.

Cooperation between new drug developers and disease tumour oriented specialists allows the creation of specific networks. Such networks have developed through the support of the NDDP master documents (protocol, CRFs) and procedures allowing rapid 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. More recently, 3 Brain Tumour Group institutions have been accepted for early clinical trials conducted by the NDDG.

http://www.eortc.be

FOR MORE SPECIFIC INFORMATION, PLEASE CONTACT:

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