

# New Drug Advisory Committee (NDAC)

## Missions and procedures

### POL013

#### Version 1.1

(Always refer to the Intranet to check the validity of this document)

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#### Distribution

Everybody

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## Table of contents

<b>1.</b>	<b>INTRODUCTION</b>	<b>4</b>
<b>2.</b>	<b>MISSIONS OF NDAC</b>	<b>4</b>
<b>3.</b>	<b>MEMBERSHIP ON NDAC</b>	<b>4</b>
<b>4.</b>	<b>PROCESS FOR NDAC ACTIVITIES</b>	<b>4</b>
4.1.	Drug acquisition strategy	5
4.2.	New drug coming into clinical trials at EORTC	5
4.3.	For expertise /advisory boards	5
4.4.	Specific networks	6
4.5.	Methodology	6
<b>5.</b>	<b>MEETINGS AND CONFIDENTIALITY</b>	<b>6</b>
<b>6.</b>	<b>MINUTES</b>	<b>6</b>
<b>7.</b>	<b>FINANCES</b>	<b>6</b>
<b>8.</b>	<b>LIST OF ABBREVIATIONS</b>	<b>7</b>
<b>9.</b>	<b>APPENDIX 1: NDAC MEMBERSHIP</b>	<b>7</b>

## 1. Introduction

A New Drug Advisory Committee (NDAC) is implemented as of October 10, 2002. Its role is to support and make recommendations to the clinical research groups in all aspects of New Drug Development including strategy approach and prioritization for development within the EORTC network. NDAC facilitates drug acquisition process for the EORTC.

## 2. Missions of NDAC

Depending on particular requests, NDAC will have the following missions:

- ◇ Stimulate, organize and prioritize new drug acquisition at the EORTC
- ◇ Review all Phase I and early phase II study agents prior to submission to Protocol Review Committee. Such agents in the remit of NDAC must be not registered and/or not having an established role in oncology
- ◇ Coordinate advisory boards performed for the pharmaceutical industry
- ◇ Stimulate interactions between new drug developers and EORTC disease oriented groups and/or Laboratory Research Division groups and facilitate the creation of specific networks.
- ◇ Support EORTC Data Center New Drug Development Program with methodology issues inherent to innovative agents with new mechanism of action in the approach of phase I and early phase II design

## 3. Membership on NDAC

There will be a chairman and a vice-chairman appointed for a period of three years. The vice-chairman will serve as support for the chairman. NDAC is composed of full members, Ex officio members and Data Center representatives.(Appendix 1). The chairman of NDAC is a full member of the EORTC board with voting rights.

### Full members:

There must be at least 2 new drug developers in oncology, 2 medical oncologists, 1 laboratory researcher and 1 chemist.

### Ex officio members:

The EORTC Translational Research Advisory Committee chairman and the EORTC Drug Acquisition Consultant.

### EORTC Data Center representatives:

The Translational Research Unit Administrator, the laboratory research project manager and the Assistant Director New Drug Development Program also acting as secretary for NDAC.

Chairmanship can be prolonged at discretion of EORTC Board

All members have to file a conflict of interest document and a confidentiality disclosure form.

## 4. Process for NDAC activities

## 4.1. Drug acquisition strategy

NDAC establishes the strategy of EORTC for new drug acquisition in cooperation with the drug acquisition consultant and New Drug Development Program. This activity is aimed at prioritizing and documenting the direction in which EORTC should focus its efforts and search for potential new drugs

The strategy is established by the chairman of NDAC in cooperation with NDDG chairman. The strategy can be established by categories of agents (cytotoxics, molecular target based drugs, anti-angiogenesis, immunological agents etc...) in order to ensure a wide and extended portfolio but can also be specifically oriented to a certain disease in which EORTC has expertise. Combined strategies are possible and those are not exclusive. Strategies are established according to scientifically relevant criteria: The Drug Acquisition Consultant reports to NDAC and NDDP according to specific procedures at pre-determined timepoints. The strategy for new drug acquisition is revisited at least twice a year.

## 4.2. New drug coming into clinical trials at EORTC

NDAC reviews new drugs/agents /therapeutic modalities and all related information whether preclinical/early clinical data offered to the EORTC for further development. This applies to any new agent or modality to be studied for the first time at the EORTC within the frame of Phase I or early phase II trials. For this purpose the committee will take into account issues such as novel mechanism of action, preclinical activity, potential safety profile etc. This committee will also suggest, if necessary, additional preclinical studies for potential breach of pre-clinical data as well as propose potential laboratory / facilities support for missing pre-clinical data (pre-clinical models available within the EORTC Laboratory Research Division-LRD). This activity is mainly to support NDDP and EORTC groups in designing study outlines for new projects to be submitted to EORTC PRC and to be developed as full protocol therefore conducted into the EORTC network. This expertise is extended to any issue of developing a new project in early drug development: starting dose, schedule, escalation scheme, (clinical) / laboratory / imaging , test / methodology to be used for end-points/ patient's entry criteria and follow up test. NDAC has direct expertise on such proposed trials to suggest pharmacokinetic/pharmacodynamic projects but all translational research activities linked to phase I and early phase II remain in the remit of the Translational Research Advisory Committee (TRAC)

The possibility is also offered to pharmaceutical/biotechnology companies to contact the NDAC for consultation on directives to complete preclinical development of new compounds or combined modality therapy. This committee will also propose potential EORTC resources for oversight pre-clinical data (formulation, PK/PD, efficacy, schedule, molecular target identification, and toxicology). This will be done in cooperation with the EORTC laboratory research division in order to appoint a laboratory researcher to a specific project.

At the time of the outline submission to the PRC, the NDAC (and TRAC) recommendations will appear.

## 4.3. For expertise /advisory boards

NDAC may be asked to provide general expertise for drug development to companies. This activity usually performed within the scope of advisory boards is to be discussed on a case by case basis. The acceptance to conduct an advisory board for an agent or a group of project(s) should be approved by the majority of NDAC full members. The practical organization of the advisory board is under the responsibility of NDDP. NDAC members should ideally attend such advisory boards. NDAC chairman may appoint other participants according to expertise needed and ultimate goal of the advisory board. NDAC should always recommend to industrial partners to consider performing part or total of the clinical development within the context of EORTC. Disease oriented group officers may be invited if tumor types to be explored are known in advance. If not the NDDP will have to report to the MA of the disease oriented group and chairman about the potential clinical trial openings. The NDDP is responsible to follow up the outcome of advisory boards and the development of clinical trials emerging from such advisory boards

TRAC expertise should be present on advisory boards to facilitate the implementation of translational research project alongside clinical development plans. The Chairman of TRAC nominates the persons to be

present on advisory boards according to level of expertise.

#### **4.4. Specific networks**

Optimal co-ordination and communication between EORTC groups especially new drug developers and disease specialists is mandatory in order to ensure a continuum from early clinical development into therapeutic strategies. This can be best achieved if specific networks of excellence in certain disease types are established which would allow rapid screening of potential new drugs. NDAC should promote within EORTC intergroup cooperation in order to maximize cross expertise between disease specialists and new drug development. NDAC sets priorities for selected agents in cooperation with the networks/groups in order to avoid self-competition within EORTC and speed up the performance of the trials. A rationale approach coordinated by NDAC sets priorities, order of events /trials, maximize resources, diminish accomplishment of trials and ensures earlier decision process for large pivotal phase III.

#### **4.5. Methodology**

NDAC stimulates and provides expertise for methodological research addressing specific aspects of new drug development in cooperation with NDDP

Methodological research is one of the missions of the Data Center/NDDP. New drug development is faced with a number of issues linked to specific target modulation, mild toxicity profile, biological surrogate end-points etc.... which challenge current methodology. While end-points and statistical designs have to be re-visited, concerted actions are needed between the laboratory researchers, the clinicians and the methodologists.

### **5. Meetings and Confidentiality**

At least two plenary NDAC-meetings in addition to advisory boards will be held each year mainly aimed at defining strategies and follow up achievements. Between meetings, all affairs will be handled through email or mail correspondence. Specific meetings may be handled for specific research projects. When possible, such meetings will be handled at the occasion of advisory boards. The committee will review the stage of development of all drugs in the system with the help of the NDDP/TR unit. All information provided to the members of the NDAC should be handled in strictest confidence. NDAC members will be requested to sign conflict of interest disclosure forms. None of this information, or information from discussions during NDAC meetings, should be communicated outside the NDAC.

### **6. Minutes**

The EORTC NDDP secretariat will provide secretarial assistance to support the work of the committee and to minute the meetings. Minutes of the meetings must be sent to all members and guests and to the members of the EORTC Executive Committee no later than one month after each meeting. The NDAC will also circulate regular reports to the EORTC group chairmen and to the executive committee to continuously keep them informed.

### **7. Finances**

For advisory boards, reviewers shall be paid as consultants by the Pharmaceutical companies for sponsored trials. The EORTC Executive Committee decides all financial matters in collaboration with the chairman of NDAC.

Finances might be a shared cost activity between NDDG and EORTC treasury until self-supporting.

## 8. List of abbreviations

Abbreviation	Full name
NDAC	New Drug Advisory Committee
NDDG	New Drug Development Group
NDDP	New Drug Development Program
PRC	Protocol Review Committee
TRAC	Translational Research Advisory Committee

## 9. Appendix 1: NDAC membership

Membership of the NDAC will include the following persons: October 2002-October 2005

### Full members

Member	City, Country	Expertise
Prof. J. Verweij (Chairman)	Rotterdam, The Netherlands	<i>New Drug Developer</i>
Prof. P. Fumoleau (Vice-Chairman)	Nantes, France	<i>New Drug Developer</i>
Dr. E. Raymond	Villejuif, France	<i>Medical Oncologist</i>
Dr. A. Burger	Freiburg, Germany	<i>Laboratory Reseracher</i>
Dr. P. Schoeffski	Hannover, Germany	<i>Medical Oncologist</i>
Prof. G. Eisenbrand	Kaiserslautern, Germany	<i>Ad hoc consultant chemist</i>
Prof M. Stevens	Nottingham, United Kingdom	<i>Chemist</i>

### Ex Officio

Member	City, Country	NDAC Function
Pr I. Stratford	Manchester, United Kingdom	Chairman, TRAC
Ms B. Hill	London, United Kingdom	Drug Acquisition Consultant

### Data Center staff

Member	EORTC DC Function	NDAC Function
Dr. D. Lacombe	NDDP Assistant Director	NDAC Secretary
Dr. F. Lehmann	TR Unit Administrator	NDAC Observer
Dr. A-S Govaerts	Laboratory research Project Manager	NDAC Observer