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Translational Research Advisory Committee (TRAC)

Role and Mission

POL014

Version 1.5

ALWAYS REFER TO THE INTRANET TO CHECK THE VALIDITY OF THIS DOCUMENT

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Table of Contents

1	PURPOSE	3
2	DEFINITIONS	3
3	POLICY	4
3.1	EORTC scientific strategy	4
3.2	The role of TRAC	4
3.3	The tasks of TRAC	4
3.3.1	To provide advice on EORTC strategy.....	4
3.3.2	To support the scientific strategy of the EORTC Clinical Groups.....	4
3.3.3	To participate in partnership meetings with companies.....	4
3.3.4	To provide scientific advice on projects	4
3.4	For each study TRAC is requested to provide the following advice:	5
3.5	‘Sign off’ TR aspects of protocols at PRC	5
3.6	Stimulate CRD-TRD interaction.....	5
4	TRAC MEMBERSHIP	6
4.1	Membership structure.....	6
4.1.1	Full members	6
4.1.2	Ex-Officio members	6
4.1.3	External reviewers	6
4.2	Election, appointment and duration of office	6
5	RESPONSIBILITIES OF THE TRAC MEMBERS	6
5.1	General responsibilities	6
5.2	Responsibilities of the TRAC Chair.....	7
6	CONFIDENTIALITY	7
7	FINANCES	7
8	REFERENCES	7
9	DOCUMENT HISTORY	8

1 PURPOSE

This policy outlines the missions and tasks of the Translational Research Advisory Committee (TRAC) and the interaction with the EORTC Headquarters (HQ).

2 DEFINITIONS

- ◆ **Clinical Research Division (CRD):** A division comprised of the disease-oriented groups.
- ◆ **Correlative TR:** Translational research conducted with human biological material collected within a trial designed to address another hypothesis. These tests do not form part of the clinical trial design and may be hypothesis generating or qualification/validation studies.
- ◆ **EORTC Centralized Storage Facility:** an infrastructure validated by EORTC, responsible for centralized storage of human biological material collected from multiple sites.
- ◆ **Human Biological Material (HBM):** Any type of human tissue, body fluid or derivative.
- ◆ **Imaging group (IG):** An EORTC TRD group focused on maintaining the scientific and clinical value of advanced imaging, specific analytical, and review and quality control procedures, in the context of clinical trials conducted by the EORTC disease-oriented groups.
- ◆ **Integral TR:** Molecular characterization that must be performed in order for the trial to proceed, and is essential for the trial design (e.g. biomarkers used for stratification, randomization or as endpoints).
- ◆ **New Drug Advisory Committee (NDAC):** An advisory committee that facilitates the introduction of new drugs into EORTC clinical trials.
- ◆ **PathoBiology Group (PBG):** An EORTC TRD group, focused on biobanking, quality assurance, biomarker discovery and validation .
- ◆ **Pharmacology and Molecular Mechanisms Group (PAMM):** An EORTC TRD group, whose mission is to stimulate research in Europe in the fields of pharmacology, pharmacokinetics, pharmacodynamics, pharmacogenetics and pharmacogenomics, on the molecular mechanisms of anticancer drug effects, and drug-related molecular pathology.
- ◆ **Translational Research (TR):** A term used to describe the process by which the results of research done in the laboratory are used to develop new ways to diagnose and treat disease.
- ◆ **Translational Research Advisory Committee (TRAC):** An advisory committee that supports and provides expert advice from a scientific and practical perspective on TR projects conducted within the EORTC.
- ◆ **Translational Research Division (TRD):** Comprised of the PAMM, Imaging and PBG groups
- ◆ **Translational Research Team (TRT):** A team at EORTC HQ that actively participates in developing translational research activities at the EORTC. The TRT supports TRAC for coordination of project review during protocol development.
- ◆ **Protocol Review Committee (PRC):** An independent panel of experts. The PRC reviews and approves all clinical studies proposed by EORTC Groups prior activation.

3 POLICY

3.1 EORTC scientific strategy

Translational Research is a key component of the EORTC scientific strategy. TR may be mandatory where it is integral to the trial design e.g. eligibility criteria, stratification criteria or surrogate endpoints. TR studies may also be correlative studies for knowledge development about cancer biology or for new biomarker discovery. The inclusion of correlative TR projects is recommended but not mandatory in all EORTC clinical studies.

3.2 The role of TRAC

TRAC is an advisory committee. TRAC acts as a permanent EORTC forum for exchange between the Clinical (CRD) and Translational Research Divisions (TRD) by fostering interest in TR within Clinical Research Groups and promoting clinical development ideas/concepts emerging from EORTC Groups.

TRAC strives to guarantee scientific quality and relevance of TR projects and provides both scientific and feasibility advice on TR projects conducted within the EORTC.

3.3 The tasks of TRAC

3.3.1 To provide advice on EORTC strategy

To suggest new initiatives that will aid the development the scientific / TR strategy, cross-fertilization of expertise across clinical trials and expedite movement of TR projects towards clinical application. TRAC can recommend strategy developments to the EORTC Board.

To support EORTC HQ with:

- ◆ Reviewing specific policies and procedures proposed by the TRT,
- ◆ Reviewing strategic developments,
- ◆ Reviewing and assessing the EORTC TR program conducted by EORTC Groups,
- ◆ Supporting HQ in interaction with Pharmaceutical Companies / Study Coordinator / Clinical Research Group, if necessary.

3.3.2 To support the scientific strategy of the EORTC Clinical Groups

To assist EORTC Clinical Groups with optimizing TR studies. In particular, TRAC will interact with NDAC to give advice on group strategy developments linking clinical with TR aspects, through review and advise on of the group strategy (POL013).

3.3.3 To participate in partnership meetings with companies

TRAC will work in collaboration with NDAC and companies by participation in dedicated partnership meetings to stimulate co-development of drugs and diagnostics.

3.3.4 To provide scientific advice on projects

All TR will be reviewed by TRAC, including when funding is not secured or no TR is proposed.

TRAC will review:

- ◆ integral TR in the protocol,
- ◆ correlative TR in the protocol,
- ◆ tissue access requests i.e. TR projects not foreseen in the protocol that use archived HBM (see EORTC POL020 for details),
- ◆ interim progress reports and full reports of Board approved TR studies.

In the case of intergroup studies: TRAC may be requested to review TR projects, as needed.

3.3.4.1 Project flow

Study concepts will be sent to the TRAC chair(s) who will provide an initial feedback to communicate major concerns and the most promising directions for development. The TRAC chair will then designate two TRAC members to perform the TRAC review; comments will be compiled and communicated to the study team anonymously and to the PRC.

New TR project proposals (not written in the trial protocol) will reviewed by TRAC for biological interest, clinical application and statistical robustness.

3.4 For each study TRAC is requested to provide the following advice:

- ◆ Whether the inclusion of TR is recommended or not (including imaging or HBM collection and storage),
- ◆ If TR is advised, which key areas should be developed and if this should be done prospectively (included in the trial protocol) or retrospectively (e.g. submit a separate access to tissue request at a later date),
- ◆ To propose additional and/or alternative TR projects and experts or labs with the appropriate expertise,
- ◆ To advise/prioritize the HBM to be collected,

Where TR projects are proposed these should be evaluated by the following criteria:

- ◆ *The scientific merit (clinical and biological relevance)*
- ◆ *The relation to the clinical trial*
- ◆ *The appropriateness of the labs and techniques suggested, including the review of biological endpoints*

TRAC must strongly consider feasibility in their evaluations. TRAC is encouraged to recommend external experts if the project is outside the area of expertise of available reviewers.

3.5 ‘Sign off’ TR aspects of protocols at PRC

EORTC HQ may request TRAC to support the review of TR in the full protocol when a new TR project has been added as a protocol amendment and is submitted to the PRC for review.

3.6 Stimulate CRD-TRD interaction

To stimulate interaction between clinical (CRD) translational (TRD) investigators to ensure optimal flow of information between EORTC TRD and CRD and contribute to the reinforcement of the EORTC platform of pathologists and laboratory scientists.

4 TRAC MEMBERSHIP

4.1 Membership structure

TRAC is comprised of permanent members and ex-officio members. The main disciplines of TR in oncology are represented.

4.1.1 Full members

TRAC is led by one Chair and one Vice chair.

Each TRAC member is selected according to field of expertise in order to cover specific areas, including molecular biology, biochemistry, pathology, clinical statistics, functional imaging, and oncology.

TRAC includes representatives of the TRD, including the Pharmacology and Molecular Mechanisms (PAMM), Imaging (IG), and PathoBiology Group (PBG).

4.1.2 Ex-Officio members

The chair of the TRD.

The chair of the NDAC.

Members of EORTC HQ acting as secretary of the TRAC.

4.1.3 External reviewers

The TRAC Chairman may nominate review to external experts (“TR External Reviewers”), where needed for specific TR studies. TR External Reviewers are not full members of the TRAC but will be co-opted as voluntary consultants to advise on specific areas of their expertise for the given project.

All Reviewers comply with the EORTC conflict of interest and confidentiality policy (ref.: POL001). This process must be performed under EORTC confidentiality and will be managed through the EORTC TRAC secretariat.

4.2 Election, appointment and duration of office

The TRAC full members are nominated by the EORTC Board and appointed by the TRAC Chair.

The TRAC Chair is nominated by the EORTC Board and appointed by the General Assembly for a renewable three-year term. The TRAC Chairman is a full member of the EORTC Board with voting rights.

5 RESPONSIBILITIES OF THE TRAC MEMBERS

5.1 General responsibilities

Each TRAC member acts as a voluntary consultant for the EORTC.

TRAC members should comply with the following “EORTC Standard of Conduct for Peer Reviewers”:

To sign and respect the conflict of interest / confidentiality policy of EORTC (Ref.: POL 001).

To accept the TRAC Missions, Tasks, Responsibilities and Procedures as described in this policy.

To rapidly respond to requests. All members accept to give prompt replies to (e) mails/queries received in her/his position and will inform the TRAC secretariat of any prolonged absence (e.g. a holiday period).

To support the EORTC HQ in interactions with Pharmaceutical Companies / Clinical Study Coordinator /Clinical Research Group regarding specific TR projects under discussion.

5.2 Responsibilities of the TRAC Chair

The TRAC Chair's specific responsibilities are the following:

Ensures that all actions of the TRAC uphold the reputation of the EORTC and its scientific visibility.

Ensures that TRAC actions are in line with EORTC policies.

Reviews the composition of the TRAC membership after his/her appointment and may propose new members to the EORTC Board.

Selects external reviewers (delegation principle) where needed and inform the TRAC secretariat. The TRAC secretariat will coordinate the interaction.

Has a pivotal position in all TRAC review procedures.

Cooperates with EORTC HQ to organize meetings where needed.

The TRAC Chair is also appointed as a New Drug Advisory Committee (NDAC) Ex-Officio member.

6 CONFIDENTIALITY

All information provided to the TRAC members and TR External Reviewers should be handled in strictest confidence. TRAC members and TR External Reviewers will be requested to sign conflict of interest disclosure forms.

7 FINANCES

TRAC members and TR External Reviewers are voluntary consultants.

Travelling and hotel expenses for attending to TRAC meetings organized at the EORTC HQ will be refunded according to EORTC travel policy.

8 REFERENCES

- ◆ Conflict of Interest - Confidentiality: POL001
- ◆ New Drug Advisory Committee (NDAC): POL013
- ◆ Collection and Use of Human Biological Material: POL020

9 DOCUMENT HISTORY

Version N°	Brief description of change	Author	Effective date
1.0	Initial release	Frederic Lehmann	01 Feb 2003
1.1	Transfer to new template; no further modification	Alexandre Passioukov	14 Feb 2005
1.2	Updated TRAC missions	Jacqueline Hall	16 Feb 2010
1.3	Administrative changes to ensure consistency with HQ procedures (sections 3.3.3, 3.5.1 and 3.6)	Jacqueline Hall	06 May 2010
1.4	Administrative changes to ensure consistency with HQ procedures (sections 2, 3.3, 3.4 and 3.5) & simplification	Jacqueline Hall	13 Mar 2013
1.4	No change	Yan Liu	26 Oct 2016
1.5	Administrative changes to ensure consistency with HQ procedures (sections 2, 3, 6, 7, 8) & simplification	Yan Liu	26 Mar 2018