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Translational Research Advisory Committee (TRAC)

Role and Missions

POL014

Version 1.4

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1 PURPOSE

This policy outlines the missions and tasks of the Translational Research Advisory Committee (TRAC) and the interaction with the translational research team (TRT) at 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 materials collected within a trial that is designed and powered to address another hypothesis. These tests do not form part of the clinical trial design and may be hypothesis generating or qualification/validation studies.
- **Early Project Optimization Department (EPOD)**: An EORTC HQ unit for actively developing of group strategy, project support and optimization during their early phase.
- **EORTC Centralized Storage Facility**: an infrastructure validated by the EORTC responsible for centralized storage of human biological materials (and data) collected from multiple sites.
- **Human Biological Materials (HBM)**: Any type of tissue, body fluid or derivative, including (but not limited to) nucleic acids.
- **Imaging group (IG)**: An EORTC TRD cooperative 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 groups.
- **Integral TR**: Molecular characterization that must be performed in order for the trial to proceed, that are essential for the trial design (e.g. biomarkers used for stratification, randomization or as endpoints).
- **Network of Core Institutions (NOCI)**: A network of institutes across Europe with recognized laboratory expertise and high accruing capacity in EORTC trials and who have signed the NOCI consortium agreement.
- **New Drugs Advisory Committee (NDAC)**: An advisory committee that facilitates the introduction of new drugs into clinical trials within EORTC.
- **PathoBiology Group (PBG)**: An EORTC TRD cooperative group, focused on biobanking, quality assurance, biomarker discovery and validation and translation of these into the clinical arena.
- **Pharmacology and Molecular Mechanisms Group (PAMM)**: An EORTC TRD cooperative group, whose mission 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.
- **Translational Research (TR):** "Bench-to-bedside" translation of scientific discoveries arising from clinical, laboratory or population-based research into clinical applications to improve the prevention, diagnosis and/or treatment of a disease. In this policy, the definition is limited to research using HBM.
- **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

TR, including imaging and HBM collection, are key components of the EORTC scientific strategy (please see EORTC website for details). 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 side studies. 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 ensures the independence of the EORTC and guarantees scientific quality and relevance of TR projects. TRAC 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. In addition, TRAC will be represented in the NOCI Executive Steering Committee.

To support the TRT and EPOD units at EORTC HQ with:

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

3.3.1.1 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 developed by the EPOD unit (POL013).

3.3.1.2 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.

3.3.2 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.

3.3.2.1 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 full 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.

3.3.2.2 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 and to recommend when EORTC centralized storage facility should be used e.g. for key strategic HBM collections,
- 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,*

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

3.3.3 'Sign off' TR aspects of protocols at PRC

TRT may request TRAC support to perform a rapid check at later stages of study development e.g. to ensure the TR aspects full protocol resubmitted to the PRC are satisfactory.

Additionally, TRAC may be requested 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.

3.3.4 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.

3.4 TRAC membership

3.4.1 Membership structure

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

3.4.1.1 Full members

TRAC is headed by one TRAC Chairman and one TRAC Vice chairman. The Vice chairman will serve as support for the Chairman.

Each TRAC member is selected according to her/his field(s) of expertise in order to cover specific areas, including molecular biology, biochemistry, anatomopathology, clinical statistics, functional imaging and oncology expertise.

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

3.4.1.2 Ex-Officio members

The chair of the TRD.

The chair of the NDAC.

Members of the EORTC HQ TRT acting as secretary of the TRAC.

3.4.1.3 External reviewers

The TRAC Chairman may nominate review to external experts, where needed for specific TR studies. This person, if (s)he accepts, will be designated as 'TR External Reviewer'.

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.

3.4.2 Election, appointment and duration of office

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

The TRAC Chairman is nominated by the EORTC Board and appointed by the General Assembly on a three yearly basis. The TRAC Chairman is a full member of the EORTC Board with voting rights.

Each member of the TRAC is elected for a 3 year term, which is renewable.

3.5 Responsibilities of the TRAC members

3.5.1 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 accept 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 these statutes.

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 accept, to support the EORTC TRT:

- In interactions with Pharmaceutical Companies / Clinical Study Coordinator /Clinical Research Group regarding specific TR projects under discussion.
- To do her/his best to respond to requests from the EORTC TRT and to participate in meetings.

3.5.2 Responsibilities of the TRAC Chairman

The TRAC Chairman's specific responsibilities are the following:

To ensure 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.

To select 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.

Must cooperate with the TRT to organize meetings where needed.

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

3.6 TRAC meetings and minutes

TRAC meetings will be jointly organized by the TRAC secretariat and the TRAC Chairman.

At regular intervals teleconferences with the TRAC chair and TRD chair and EORTC HQ will be organized to discuss specific topics.

The TRAC chairman in collaboration with the TRD chair will organize a meeting with the TR persons of the clinical research groups once every 2 years.

The TRAC chairman in collaboration with the TRD chair will organize a meeting with the pathologists of the clinical groups once every 2 years.

The TRAC secretariat will provide secretarial assistance to support the work of the committee and to take the minutes the meetings. The minutes of the meetings must be sent to all TRAC members, Directors of the EORTC HQ, Director General and TRAC Secretariat no later than one month after each meeting. Between meetings all affairs will, if possible, be handled through email or mail correspondence and filed appropriately by the TRT.

3.7 Confidentiality

All information provided to the TRAC members and TR External Reviewers should be handled in strictest confidence.

None of this information, or information from discussions during TRAC meetings/advisory boards meetings, should be communicated outside the TRAC.

TRAC members and TR External Reviewers will be requested to sign conflict of interest disclosure forms.

3.8 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 policy.

For partnership meetings with industry, reviewers will receive compensation as consultant from Pharmaceutical companies for sponsored trials.

4 REFERENCES

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

5 APPROVAL

Version number	Board approval date
1.2	04/02/2010

6 DOCUMENT HISTORY

Version number	Brief description of change	Author	Date
1.0	Initial release	Frederic Lehmann	01/02/2003
1.1	Transfer to new template; no further modification	Alexandre Passioukov	14/02/2005
Version number	Brief description of change	Author	Effective date
1.2	Updated TRAC missions	Jacqueline Hall	16/02/2010
1.3	Administrative changes to ensure consistency with HQ procedures (sections 3.3.3, 3.5.1 and 3.6)	Jacqueline Hall	06/05/2010
1.4	Administrative changes to ensure consistency with HQ procedures (sections 2, 3.3, 3.4 and 3.5) & simplification	Jacqueline Hall	13/03/2013