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Translational Research Advisory Committee (TRAC)

Role and Missions

POL014

Version 1.3

ALWAYS REFER TO THE EORTC INTERNET WEBSITE 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 Scientific strategy relating to translational research 4
 - 3.2 The role of TRAC 4
 - 3.3 The tasks of the TRAC..... 4
 - 3.3.1 To lead strategic Translational Research developments within the EORTC 4
 - 3.3.2 To provide expert advice on translational research projects..... 5
 - 3.3.3 TRAC 'sign off' at the PRC level..... 6
 - 3.3.4 Stimulate the Interaction of the Clinical (CRD) and Translational Research Division (TRD) 6
 - 3.3.5 To review progress reports of Board approved TR studies 6
 - 3.3.6 To support the TRU and EPOD units of the EORTC HQ..... 6
 - 3.4 TRAC membership 7
 - 3.4.1 The membership structure of TRAC 7
 - 3.4.2 Election, appointment and duration of office 7
 - 3.5 Responsibilities of the TRAC Members 8
 - 3.5.1 General responsibilities for TRAC members 8
 - 3.5.2 Responsibilities of the TRAC Chairman 8
 - 3.6 TRAC Meetings and Minutes 9
 - 3.7 Confidentiality 9
 - 3.8 Finances 9
- 4 REFERENCES 9
- 5 APPROVAL 10
- 6 DOCUMENT HISTORY 10

1 PURPOSE

This policy is to outline the missions and tasks of the Translational Research Advisory Committee (TRAC) and outline the interaction between TRAC and the translational research unit at the EORTC Headquarters (HQ).

2 DEFINITIONS

Clinical Research Division (CRD): A division comprised of the disease oriented groups.

Correlative TR: Translational research projects using tissue samples associated with EORTC clinical trials for additional studies for research purposes only and do not form part of the clinical trial design. These studies may be hypothesis generating or qualification/validation studies.

Early Project Optimization Department (EPOD): A unit at EORTC HQ dedicated strategically to actively participating in the development of group strategy, offering project support and optimization, and conducting pro-active project development. Operationally, it also serves as the port of entry for new projects into the EORTC and helps manage these projects during their early phase.

EORTC Centralized Biobank: A biobanking service coordinated by EORTC HQ for the collection, shipment, processing, storage and distribution of biological material using professional service-providers to obtain centralized high quality tissue, biological material collection at a designated EORTC approved provider.

Imaging group (IG): An EORTC cooperative group, which is part of the TRD. The IG has and will develop specific analytical and review procedures as well as quality control procedures, in the context of clinical trials conducted by the EORTC groups. The main objectives of the IG are to ensure standardization of image acquisition and quality assurance for EORTC trials, increase PET CT and functional MRI expertise across the network, and identify and implement predictive and prospective imaging biomarkers of interest, in addition to their own research projects.

Integrated TR: Molecular characterization that form part of the clinical trial design (e.g. biomarkers used in stratification, randomization or clinical trial 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 cooperative group, which is part of the TRD, aimed at reviewing tumor tissue specimens coming from cancer patients within EORTC clinical trials and conducting research and teaching in life sciences in addition to their own research projects. The PBG is focused on detection, characterization, determination, and potential clinical application of tumor tissue markers and blood markers, associated with cancer disease progression and cancer metastasis.

Pharmacology and Molecular Mechanisms Group (PAMM): An EORTC cooperative group, which is part of the TRD. The PAMM Group serves as umbrella for the Drug Discovery Committee. Its role 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): The process of applying new ideas, insights and discoveries generated through basic scientific inquiry to the treatment or prevention of human 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 Unit (TRU): A unit at EORTC HQ that actively participates and supports TRAC in developing translational research activities at the EORTC. The TRU also participates and coordinates the review of proposals at several stages in protocol development thereby ensuring a quality assurance mechanism for translational research at the EORTC.

Prospective Tissue Collection (PTC): Biological material collection that is planned and specified upfront in the clinical trial protocol.

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 Scientific strategy relating to translational research

Translational research, including imaging and biobanking, are an important component of the EORTC scientific strategy. TR may be mandatory for the trial in the case where TR is integrated into the trial design for example as eligibility criteria, stratification criteria or endpoints. In addition, TR studies may be correlative side studies using the biological material collected from the trial. The inclusion of correlative TR projects is not mandatory in all EORTC clinical studies.

Please refer to the EORTC website for details of the EORTC scientific strategy.

3.2 The role of TRAC

The role of TRAC is to ensure the independence of the EORTC and to guarantee scientific quality and relevance of TR so as to increase the scientific visibility of EORTC activities. TRAC supports and provides expert both scientific and practical advice on TR projects conducted within the EORTC. As an advisory committee, TRAC acts also as a permanent EORTC forum between the Clinical (CRD) and Translational Research Divisions (TRD) by fostering interest in translational research within Clinical Research Groups and promoting clinical development ideas/concepts emerging from EORTC Groups. Each TRAC member will act as a voluntary consultant for the EORTC.

3.3 The tasks of the TRAC

3.3.1 To lead strategic Translational Research developments within the EORTC

To suggest new initiatives that will aid the development the scientific / TR strategy, cross-fertilization of expertise across clinical trials and diseases and hence to expedite movement of TR projects towards clinical application. TRAC can make recommendations for translational research strategy developments to the ExCo and Board. In addition, TRAC will be represented in the NOCI Executive Steering Committee.

3.3.1.1 To support the scientific strategy of the EORTC Clinical Groups

To assist EORTC Clinical Groups with optimizing TR studies and integrating TR into their scientific strategy. In particular, TRAC will interact with NDAC to give advice on group strategy developments linking clinical with translational research aspects, through review and advice on of the group strategy developed by the early project optimization development (EPOD) department unit (POL013).

3.3.1.2 Participation in partnership meetings with industry to stimulate co-development of drugs and diagnostics

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

3.3.2 To provide expert advice on translational research projects

To review and provide expert advice on any clinical study and Translational Research Projects conducted within the EORTC both from a scientific and practical perspective.

This applies to:

- integrated TR where molecular characteristic assessment is integrated into trial design
- correlative TR projects prospectively planned in the clinical trial protocol
- retrospective tissue access requests for correlative TR projects not foreseen in the protocol that use archived biological material (see EORTC biobanking policy for details)

All new study concepts will be reviewed by TRAC, including those where funding is not yet secured or no TR is yet proposed in the protocol.

For new study concepts the TRAC chair(s) will provide an initial feedback before the Executive Committee (ExCo) review to communicate major concerns and advice on the most promising directions for TR development. Major comments will be communicated to the ExCo. The TRAC chair will also designate two TRAC members to perform the full TRAC review; comments will be compiled and communicated to the study team anonymously.

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

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

Whether the inclusion of TR (including imaging or biobanking) is recommended or not. If TR is advised, which key areas of TR 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).

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

The scientific merit of the TR (clinical and biological relevance) and its relation to the clinical trial

The practical feasibility and the appropriateness of the labs and techniques suggested, including the review of all biological endpoints

To advise if biobanking should take place, if so to evaluate/ prioritize the biological specimen to be collected. To recommend when EORTC centralized biobanking is necessary e.g. for key strategic biological material collections

To stimulate discussion with members of the TRD. This includes highlighting where a validated biological endpoint could be used or proposing prospective validation of markers for potential future application in clinical trials

To propose additional and/or alternative TR projects and experts or labs with the appropriate expertise

Note: TRAC must strongly consider feasibility in their evaluations. TRAC is encouraged to recommend external experts if the project is outside their area of expertise. In particular, interaction with TRD Groups will be sought.

3.3.3 TRAC 'sign off' at the PRC level

In order to check if the early advice of the TRAC was implemented in TR project development, TRU may request TRAC support to perform a rapid check at later stages of study development e.g. to ensure the TR aspects full protocol submitted to the PRC are satisfactory.

Additionally, TRAC may be requested to support the review of TR chapter of the full protocol in the following situation:

A new translational research project has been added as a protocol amendment and is submitted to the PRC for review.

3.3.4 Stimulate the Interaction of the Clinical (CRD) and Translational Research Division (TRD)

To promote and stimulate interaction between the Clinical (CRD) and Translational Research Divisions (TRD) 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.

3.3.5 To review progress reports of Board approved TR studies

To review the interim progress reports and full reports of selected TR studies approved by the Board.

3.3.6 To support the TRU and EPOD units of the EORTC HQ

This includes:

Reviewing specific policies and Standard Operating Procedures proposed by the TRU.

Reviewing strategic developments such as the tumour specific key pathways oriented approaches.

Supporting the TRU in its Quality Assurance assessment of TR laboratories performing EORTC TR projects.

Reviewing and assessing the EORTC Quality Assurance TR program: By prospectively reviewing the effectiveness of the TR studies conducted by EORTC Groups and the TRU support to this task.

Supporting TRU in interaction with Pharmaceutical Companies / Study Coordinator / Clinical Research Group regarding specific TR Projects in discussion, if necessary.

3.4 TRAC membership

3.4.1 The membership structure of TRAC

TRAC is comprised of permanent members and additional ex-officio members. All the main disciplines of translational research in oncology are represented in the review panel.

3.4.1.1 Full members

The 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).

These nominations take into account a balance between pre-clinical and clinical experts.

3.4.1.2 Ex-Officio Members

The chair of the translational research division (TRD).

The chair of the new drug advisory committee (NDAC).

The head of the translational research unit EORTC HQ, acting as secretary of the TRAC.

3.4.1.3 External Reviewers

TRAC may ask advice from external pre-clinical and clinical experts on specific TR studies proposed. 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 advice on specific areas of their expertise.

TR External Reviewers are nominated by the TRAC Chairman.

All the TR External 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 ExCo and appointed by the TRAC Chairman.

The TRAC Chairman is nominated by the EORTC ExCo 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 for TRAC members

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 to follow 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.

To inform the TRAC secretariat of any prolonged absence (e.g. a holiday period).

To accept, if needed, to support the EORTC TRU:

In any further interactions with Pharmaceutical Companies / Clinical Study Coordinator /Clinical Research Group regarding one specific TR Project in discussion.

To do her/his best to respond to any request from the EORTC TRU to participate in meetings dedicated to EORTC Translational Research or to Advisory Board/partnership meetings organized at the EORTC HQ.

To attend TRAC meetings.

3.5.2 Responsibilities of the TRAC Chairman

The TRAC Chairman's specific responsibilities are the following:

The TRAC Chairman must ensure that all actions of the TRAC uphold the reputation of the EORTC and its scientific visibility.

The TRAC Chairman, with the support of the TR Unit, must ensure that TRAC actions are in line with EORTC policies.

The TRAC Chairman reviews the composition of the TRAC membership after his/her appointment and may propose new members to the EORTC ExCo.

The TRAC Chairman must identify specific problems, which members of the TRAC or the TR Unit may encounter and seek to provide support in overcoming them, whenever possible.

The TRAC Chair can select external reviewers (delegation principle) and the TRAC secretariat should be informed. The TRAC secretariat will coordinate the interaction and contact the external reviewers and collect the comments.

The TRAC Chairman ensures a pivotal position in all TRAC review procedures and reviews all TR grants allocated by the EORTC board.

The TRAC Chairman must cooperate with the TR Unit to organize TRAC meetings.

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

3.6 TRAC Meetings and Minutes

A TRAC preparative meeting will be held after a new TRAC Chair is elected to introduce the TRAC chair and vice-chair and the chair of the TRD to EORTC HQ functioning.

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 to discuss topical issues will be requested.

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.

Agenda: TRAC will review the stage of development of all TR projects, comment on the TRAC review process, the activities of the TR unit and define strategies to achieve the general tasks of the TRAC.

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, Scientific Director 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 TR unit.

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

5 APPROVAL

| Version number | Board approval date |
|----------------|---------------------|
| 1.2 | 04/02/2010 |

6 DOCUMENT HISTORY

| Version number | Brief description of change | Author | Issue 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 |