EORTC
Avenue E. Mounierlaan 83 / 11
Brussel 1200 Bruxelles
België - Belgique
Tel : +32 2 774 16 11
Fax : +32 2 772 35 45
E-mail : eortc@eortc.be
Web : http://www.eortc.be

EORTC Group of Patient Experts

If you're a (former) patient, a carer of a patient, or a patient advocate acting on behalf of a patient group we'd like to invite you to become a part of the EORTC group of patient experts supporting EORTC in the review of Patient Information Sheet & Informed Consent (PIS IC) and/or the concept of a proposal for a clinical study.

What is the aim of this group?

This group is a part of a wider EORTC initiative which aims to:

- increase patient involvement within the EORTC activities;
- improve our collaborations with patients and patient organizations;
- raise awareness of the work of the EORTC, including its research studies and their results within patient community;
- improve relevance of the EORTC research and to make more patient centered;
- avoid poor quality study proposals and unoriginal studies;
- offer researchers feedback and constructive criticism from patient community in order to improve the quality and relevance of their proposals.

What does EORTC ask patient experts to do?

1. Review of study concept

When medical researchers or clinicians wish to perform a clinical study within the EORTC, they first prepare a study concept, which is a relatively short description of the research idea and proposed methodology. To ensure research is relevant and of a high quality, study concept is peer reviewed by the EORTC Protocol Review Committee (PRC), which consists of disease specific experts, methodologists and independent external experts[1].

Since 2016, EORTC decided to include patient representatives's reviews to this review as external experts. Patient reviewers are not required to have any medical or scientific background, as your contribution aims to add a unique patient's perspactive. All we need are your answers to the following questions, which are posed to the traditional peer reviewers as well:

1. Are the study's aims and the issue and questions that the study plans to address relevant and important to you as a patient? Do you think it would be relevant to other patients with similar medical condition/diagnosis?
2. Are there any missing areas that you as a patient or a carer find relevant and which would enrich the study concept?
3. (Only for studies with randomization). Do you think the randomization of this study would be acceptable to patients?
4. From your perspective, would the treatment modalities (any of applicable modalities: drugs, radiation therapy, surgery etc…) be acceptable to patients? What about compliance? What challenges might patients face that should be considered?

[1] For more information, see http://www.eortc.org/about-us/management-structure/committees/protocol-review-committee/

5. From your perspective, would the treatment or intervention studied actually work in practice? What challenges might patients face that should be considered?
6. From your perspective, would the nature of visits, examination and tests planned actually work in practice? Is it feasible? What challenges might patients face that should be considered?
7. Are the outcomes (endpoints) that are being measured in the study outcomes that are important to you as a patient? Are there others that should have been considered?
8. Any other comments?

We are seeking an informed independent viewpoint presented in a clear and constructive language.

When your review is required, we will send you an invitation by email. You will see the title of the study concept and the name(s) of the Study Coordinator. You will have the opportunity to accept or decline the invitation to review by email at that time, in case you find deadlines are not feasible for you to meet at that specific period. As we need to respect timelines imposed by the study and related grants/funding, all reviewers are asked to provide their opinion within two weeks after having received the study concept.

All study concepts are confidential documents. If we invite you to review a study concept, we will ask you to sign confidentiality clauses and to disclose potential conflict of interests (if any).

A conflict of interests occurs when judgment concerning a primary interest (such as whether a study concept is accepted) might be influenced by a secondary interest (for example, the researcher is your doctor, or you've been paid to be a patient advocate by a company providing drug investigated in the study).

2. PIS IC Review

Patient information is one of the most important documents as it explains to patients and candidates to become part of the study what this research is all about. It needs to be written in an easily understandable language and it supports patients in making their choice.

Writing about clinical studies in the lay language is not that easy for researchers, as we learned. Therefore, it is essential we can rely on your help to ensure documents we issue are understandable, relevant and complete to adequately support patients' choice. Moreover, we all wish patient information to be short, though getting the right balance between completeness of information and document length is a real challenge as well. Your experience may help us to lighten this document from elements you do not find pertinent or relevant to the choice patients have to make.

Moreover, together with the PIS IC you will receive the full study protocol. We do not require your review of the full protocol as we do realise this document is frequently over hundred pages, but if you wish to make comments anyway, you are welcome to do so and we will consider your comments seriously (and specifically those on the acceptability of interventions and the schedule of visits and examinations).

Why review for us?

By contributing to the review of study concepts and/or PIS IC, you will be providing the PRC Chair and the study team with your unique perspective on aspects of the selected studies relevant to you, as patient representative.

Your contribution to the review of PIS IC helps mostly patient candidates to join our studies, as they will receive a better information to support their choice.

Moreover, through collaboration with EORTC, you get an opportunity to have a real voice in shaping the way researchers design international potentially proactive changing clinical research.

How long will it take you to review study concept or PIS IC?

Study concepts are typically 5 to 10 pages long. Each PIS IC is approximately 15 pages long. We will provide you with documents to review and a feedback sheet via email where you can put down your thoughts, responses, along with a space for your additional comments. You can review documents at your convinience, and the time you take to review is up to you, but we estimate it may take up to 2 hours.

What happens to your review?

Your comments on the study concept, alongside those from the traditional peer reviewers, will be used to guide the PRC Chair' decision about the study concept under consideration. It is not unusual for reviewers to disagree on the importance and relevance of the study concept, and it is the PRC Chair' job to weigh up the various comments and use their judgment to reach a decision. As such, it is extremely important that all reviewers provide reasons for their views. Once a decision has been made, all reviewers are copied into the detailed decision letter sent to the Study Coordinator, and they can then see the other reviewers' comments.

The study team will use your comments on the PIS IC to improve the document alongside those from other reviewers. We will ask our team members to provide a short feedback to your comments together with the final document.

What happens if you are unable to make the review?

If we send you an invitation to review, but you are unable to review it for any reason, you can simply decline the invitation in the email we send you. To avoid delays it is helpful if you decline an invitation to review quickly.

If you do not answer, you may receive a reminder. If you do decline an invitation to review we may still invite you to review in future if we receive a suitable study.

Will you be compensated for your work?

The EORTC is a non-for profit organization[2] and we are not able to pay you for this work.

However, we can offer you a complimentary participation to our cources and events, if you would wish to attend. But we would not always be in the capacity to cover your travel and accommodation expencies. Shall you wish to attend, please do not hesitate to send us an email to patient.involvement@eortc.org.

Upon request, we will also issue a statement certifying you as a part of the EORTC patient expert group with a reference to your valuable contribution.

What visibility will have your review?

Each EORTC protocol will specify that it was reviewed by patients / patient advocates (without providing your name).

[2] You can learn more about EORTC mission and activities at http://www.eortc.org/our-mission/.

What about your privacy?

Your privacy is important for us. The EORTC handles your data in strict confidentiality, under the provisions of the General Data Protection Regulation 2016/679, the Belgian Law of July 30, 2018 and its subsequent amendments (if any).

In this scope, you have the right to:

- withdraw your consent at any time,
- request access to your personal data and/or to have one copy of it free of charge
- rectify your personal data
- request the erasure of it
- receive a copy of the personal data you provided to us for the purpose of transmitting it to other party(ies), and to
- object / restrict its processing by EORTC.

It is your responsibility to update your personal data held in our system. However, EORTC may from time to time request you to update your data. You can ask anytime about whether your data are still being kept and used. To exercise this and other rights or to complain about the processing of your data by EORTC, you can contact us at any time at the following email address privacy@eortc.org .

Besides, you have the right to lodge a complaint with the competent supervisory authority if you believe your data are not being processed appropriately.

All the information you disclose to the EORTC is confidential and will not be shared with 3rd parties.

However, we may be obliged to disclose your personal data where required by applicable laws, court orders or government regulation.

The EORTC will act as data controller for your personal data and will only process it for the purposes explained to you in this document and only if you consent to this. The EORTC will store your personal data for a maxium of 2 years of archiving after you discontinue your involvement with us.

Please, be aware that your name (but not the contact details) may be stored for a longer period within the study related documentation for documenting patient review you have performed. The EORTC will restrict the number of persons having access to this information to the minimum. The archiving period for this documentation is regulated by the legislation on human research.

Please, do not hesitate to contact the EORTC Data Protection Officer, shall you have any question in relation to your privacy by sending an e-mail to privacy@eortc.org or by regular mail to “EORTC Data Protection Officer av Mounier 83/11, 1200 Brussels, BE.

For more information, please check our privacy policy (POL021) available on the website https://www.eortc.org/policies-guidelines/.