EORTC and ECPC reply to the public consultation on the Summary of Clinical Trial Results for Laypersons.

EORTC is an international non-profit research association under Belgian law conducting clinical trials in Europe since 1962. EORTC, the European Organisation for Research and Treatment of Cancer (EORTC) aims to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patient quality of life. EORTC is committed to offer cancer patients information, education and tools to better understand and participate in clinical trials.

ECPC is the largest European cancer patients' umbrella organization, representing more than 400 organisations in 46 EU and non-EU countries. ECPC's mission is to empower European cancer patients through the dissemination of fundamental information regarding cancer; foster co-operation among cancer patients' organisations through joint activities; ensure that state-of-the-art cancer care practices are shared across the EU; make cancer a priority for action on the European health policy agenda; have an active role in shaping European and national healthcare policies that impact on cancer patients; to contribute to change or create EU and national laws to satisfy cancer patients' needs; to call for research on survivorship issues and advocate for better healthcare and social services for them.

EORTC and ECPC* are both interested in bringing timely and accurate clinical trials information to cancer patients so that they can make informed decisions. In view of their common interests in cancer patient information and education in clinical trials and cancer research, they decided to jointly comment to present consultation to show their common commitment.

EORTC and ECPC welcome this document which is very practical, well documented and comprehensive.We understand the content (items) to be put in the lay summary are set-down in the regulation and this cannot be modified. However, shall any sponsor choose to maximize the level of details provided, the lay summary will become too complex with an impressive number of pages. EORTC and ECPC recommend that a general suggestion is formulated about the maximum number of pages that a lay summary shall reasonably have.
In particular, we specifically appreciate lines 71/76 "Develop the summary for a general public audience and do not assume any prior knowledge of the trial. Develop the layout and content for each section in terms of style, language and literacy level to meet the needs of the general public.Keep the document as short as possible. Focus on unambiguous, factual information", as well as Lines 95/96 "Communications written for the public should use simple everyday language to ensure ease of reading and understanding.", which also reflect the philosophy of both EORTC and ECPC.

EORTC and ECPC propose to abandon the extensive use of the terms "lay," "laypersons," "lay summaries," "lay language," "lay title," and "lay audience" as they do not contribute in producing clear, understandable summaries for trial participants and the public at large. Moreover, the term "Layperson" (Dictionary. Com: a person who is not a member of a given profession, as law or medicine) is often used in medicine and biomedical research, as opposed to health professionals and researchers, making proof of an elitist approach, separating them of the patients and people in general.

The extensive use of these terms in the consultancy text and that of the EMA No 536/2104, is, we believe, an unintended artificial barrier towards patients, carers and the general public. We recommend, throughout the document and Annexes, the use of terms, devoid of unintended interpretation such as "patients," "people," "the public", "persons," "general summary," "simple language". Another term that should be replaced is "subject". This term is not appropriate and we suggest to replace it with "patient".

EORTC and ECPC understand the patient summary will be posted on the EU portal and will be publicly available through this dissemination means. It is acknowleged that EMA has a working group that focus specifically on the public access to the portal. We would however like to emphasise the importance to make the access user friendly including for non-professional users. The simple language summaries can be considered as successful in their purpose as the number of people who actually consult them. EMA should facilitate access and promote the simple language summaries on EMA's website. This suggestion follows a more general recommendation on the need to make the EU trial registry more accessible, user-friendly and, ultimately, useful. At this point, it is not even possible to filter out all cancer trials as different terms (generic and/or specific) are used (cancer, carcinoma, lymphoma, malignant tumor etc…). This greatly hampers the capacity of patients and their carers to gather information about the very existence of the trials, before they have access to the simple language summary.
Therefore, the dissemination and communication strategy of the layman summary should undergo a thorough revision in parallel with a revision of the design of the EU trial registry.

Specific comments.

Annex 1:
2**. Name and contact of sponsor**: as most of trials are run with coded data, EORTC and ECPC recommend to add systematically a disclimer such as "If you are or have participated to this trial and you are interested to have information which is specific to your case, please contact your medical team. Study sponsor is not allowed to know your identity and therefore, will not be in the capacity to answer questions that are relevant to your specific case."

7**. Overall results**: EORTC and ECPC recommend that beyond the statement that "in case of small number of endpoints, they shall all be reported" to clearly recommend that' in case of multiple endpoints, only key endpoints of most interest to patients shall be detailed (with a reference to the non-lay summary for others)'.

In the same section the proposal of plain English language to describe a non-inferiority trial is not correct as it has nothing to do with the capacity to run a placebo controlled trial. EORTC and ECPC would suggest the following wording: "Non-inferiority studies compare a new treatment with an established treatment (drug or non-drug). Researchers try to find if the new treatment would have similar efficacy (not being significantly worse); usually it is expected that this new treatment would have some other advantages, such as having less secondary effects, be less costly or offer a better quality of life '.

Side Effects: We propose to replace the term "side effects" with "adverse reactions", as the term is already used in Annex V para. 6 6. Description of adverse reactions and their frequency. There should be consistency in the use of terms throughout the text.

Finally, EORTC and ECPC support the review of this document to correspond to science advances, social developments and technology advances for dissemination. EORTC and ECPC consent to the publication of their comments to the consultation in whole or in part. We declare that nothing within

our response is unlawful or would infringe the rights of any third party in a manner that would prevent publication.

Contact points

European Organisation for the Research and Treatment of Cancer - EORTC
Avenue E Mounier 83 Bte 11
1200 Brussels, Belgium
Phone: + 32 2 774 16 11 • Fax: + 32 2 772 35 45
Email: anastassia.negrouk@eortc.org

European Cancer Patient Coalition – ECPC
Rue Montoyer 40
1000 Brussels, Belgium
Phone: +32 2 342 01 04
Email: francesco.florindi@ecpc.org