Newsletter
Ethics Committee Research UZ/KU Leuven
Number 4 – December 2018

Dear researchers and teams

Through this newsletter we wish to provide you with information that can help you and us in optimally conducting and supporting high-quality clinical research with respect for the well-being and privacy of each patient and volunteer.

We wish you all a Merry Christmas and a happy 2019!

Kind regards,

Ethics Committee Research UZ/KU Leuven
Members: Dominique Bullens, Simon Brumagne, Pascal Borry, Xavier Bossuyt, Lut De Groote, Jan de Hoon, Hélène De Somer, Jean-Jacques Derèze, Ellen Goetstouwers, Lieve Goossens, Stefanie Goris, Kristof Muylaert, Katrin Roggeman, Miet Schetz, Karin Sipido, Anne Smits, Mathijs Swaak, Josse Thomas, José Thomas, Ben Van Calster, Jan Verhaegen, Gregor Verhoef, Minne Casteels
Staff: Valerie Alderweireldt, Eveline Claes, Britt Keyaert, Monique Leys, Lian Rijkers, Ruth Storme, Greet Verbeeck, Sofie Vervoort

1. Members of EC Research

We welcome 2 patient representatives and one representative of healthy volunteers in our committee.

2. File submission

Initial studies or responses to comments can be received by EC Research on Fridays before 12 am and on other working days before 5 pm. Replies or applications received later will be considered as received on the next working day.

3. Suitability of researchers and facilities

According to the Law of 7 May 2004, an ethics committee is required to ensure the protection of the rights, safety and well-being of subjects participating in a clinical trial by, among other things, expressing an opinion on the **protocol** of the study, the **suitability** of the **researchers**, the **facilities** and the methods and documents used to inform the subjects and obtain their informed written consent.

We would therefore ask you that each application form clearly describes **where** and **by whom** the study will be conducted.

4. Recruitment for clinical studies

EC Research should always be informed about the tools used to announce a study. These may include e.g. posters, leaflets and various forms of advertising via the internet (website, social media, etc.). The necessary documents have to be submitted for approval together with the submission file and it has to be explained where, how and under which conditions each advertisement will be published/sent.

Compliance with the following conditions is requested :

- Provide short, objective and neutral information (no marketing or promotional language);
- Do not include a list of purely medical inclusion/exclusion criteria. These are intended for the physician and could be misinterpreted by the participant;
- If applicable mention “a fair compensation is provided” *or* the amount per study visit, but not the total amount;
- Always include the S-number of the study on the advertisement, and the approval by EC Research and, if applicable, the approval by FAGG;
- The contact details of the principal investigator or the research centre may be included.

The privacy of potential **patient** participants remains a major concern when using social media. The request for participation in a study is preferably approached within the context of the doctor-patient relationship.

When advertising on social media, there is a risk that confidential (medical) data may end up in the hands of unauthorised persons and be used for other purposes. In particular, the use of social media does not seem appropriate because of the implicit danger of using profiles in which potential interested participants can be identified as suffering from a certain pathology. For these reasons, EC continues to warn about the dangers of the internet and social media in patient recruitment and EC requests to explicitly inactivate the possibility of "liking"/commenting in social media when recruiting patients.

5. Retrospective study

A retrospective study is a study based on data from the past already available in existing patient files, medical files or administrative files (cf. article 3, §2 of the Law of 7 May 2004). In the case of retrospective studies, please always indicate the end date of the data collected; this date must of course be in the past.

In UZ Leuven, a lot of retrospective studies are done in which patient data from possibly different departments are collected. EC Research therefore requires that the head/staff of the clinical department or the responsible care program are informed about and concur with this study; this is the PI's responsibility.
When using data in retrospective research, collegiality and respect for the work and input of colleagues contribute to good collaboration.
We therefore ask you to involve in such retrospective research the colleagues who have given intellectual input in your research (as co-researcher, co-author). Contacting the treating physicians will also help to avoid the same patients being published more than once in case studies (case reports and case series).

Finally, we would like to ask you to also pay attention to the statistics used in retrospective studies.

6. Phases of clinical studies

FAGG informed us that they regularly receive academic Phase 3 studies which are labeled by the investigator as Phase IV. Therefore we highlight some of the legal definitions:

"clinical study" means research in humans intended to:

a) to identify or confirm the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
b) to identify any adverse reactions to one or more medicinal products, or
c) to study the resorption, distribution, metabolism and excretion of one or more medicinal products;

to determine the safety and/or efficacy of those medicinal products

"Clinical trial': a clinical study meeting one or more of the following conditions:

a) the classification of the subject to a particular therapeutic strategy shall be determined in advance and shall not be part of the normal clinical practice of the Member State concerned;

b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study, or

c) additional diagnostic or monitoring procedures shall be applied to subjects in addition to normal clinical practice.

For clinical trials, a Clinical trial Application form (EudraCT form, annex I) must always be completed, indicating the phase of the study.
The definition of **Phase I** studies according to the Law of 7May 2004 is as follows :

"Phase 1 trial": study performed on healthy volunteers or on certain types of patients without therapeutic purposes and covering one or more of the following aspects: evaluation of initial safety and tolerance, pharmacokinetics, pharmacodynamics, initial efficacy measurement.

According to the Law of 7May 2004, a delay of 15 days is applicable to monocentric Phase 1 studies.
Bioequivalence studies are generally considered as Phase I studies.
A study can only be a Phase 4 if the medicinal product is used according to the labeling in the SmPC: same indication, same population, same dosage.

A marketed product which is tested in e.g. a novel indication should not go through another Phase 1, but through a **Phase III** (or potentially Phase II) as in most cases the aspects studied in Phases I and II are already known, and it is rather efficacy in the new indication which is studied.

7. Contact EC Research UZ/KU Leuven

- EC Research is closed from 20 December 2018 to 1 January 2019.
- EC Research can be reached by telephone between 10 am and 11 am. Communication via mail is preferred, via ec@uzleuven.be

Info

Information

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www.uzleuven.be/ethische-commissie/onderzoek
Telephone: 016 34 86 00 (between 10 am and 11 am)