Leuven, 03 Dec 2020

Ethics Committee
Research UZ/KU Leuven
Herestraat 49
B 3000 Leuven (Belgium)

Email : ec@uzleuven.be

prof. Ben Van Calster

Our reference:	EudraCT-nr:	Belg. Regnr:
S64709		

Retrospective use of data from the international ovarian tumor analysis (IOTA) group as illustrative case study in methodological studies.

Dear colleague

The Ethics Committee Research (EC Research) of University Hospitals Leuven (UZ Leuven) has examined and discussed the above mentioned dossier at its meeting of 16 Nov 2020.

EC Research has no objection to the project provided that the data is managed confidentially and in compliance with the Belgian legislation on privacy.

EC Research emphasizes the responsibility of the PI/promotor of this study concerning the privacy of the person/patient data in contact with patients, or when accessing patient data, including the correct implementation thereof by coworkers and students. The PI/promotor is responsible for the implementation of the project proposal in accordance with applicable laws and regulations including, but not limited to, the EU regulation 2016/679 (General Data Protection Regulation), the Belgian Law on patients' rights of 22/8/2002, and the policy of the institution where the research will be carried out.

EC refers to the ICH/GCP guidelines on its website, and confirms that a GCP-training is required from each investigator. It is the responsibility of the principal investigator that each member of the study team has a valid GCP-certificate.

This project does not fall within the scope of the Law of 7/5/2004.

EC Research 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.

For the assessment of this dossier, documents/answers submitted on 04 Nov 2020, 05 Nov 2020 and 03 Dec 2020 have been taken into account.

This letter concerns:

Protocol:
Version 2
December 3rd, 2020
GDPR questionnaire:
PRET 10/09/2020

EC Research confirms working in accordance with the ICH-GCP principles (International Conference on Harmonization Guidelines on Good Clinical Practice), the latest version of the Declaration of Helsinki, the Oviedo Convention on Human Rights and Biomedicine and applicable laws and regulations.

EC Research confirms that - in case of conflict of interest - involved members do not take part in the vote concerning the study.

List of members: see appendix.

Points of concern: (if applicable)

The conformity of translated documents compared to the Dutch documents, is the responsibility of the sponsor.

Provided that there is a Clinical Trial Agreement, the study can only start when the Clinical Trial Agreement has been approved and signed by the CEO of UZ Leuven (and/or by an authorized representative of KU Leuven R&D).

Please take into account the regulations of the hospital concerning tissue management and the regulations of the law of December 19, 2008.

This advice of EC Research does not imply that she will assume responsibility for the planned study. You will remain responsible for the study. In addition, you should ensure that your opinion as an involved researcher is reproduced in publications, reports for the government, etc. which are the result of this study.

We request you to inform us if the study will not be initiated, or when it will be closed or prematurely ended (stating the reason).

Yours sincerely,

Prof. Dr. Minne Casteels
Chair
Ethics Committee Research UZ Leuven

List of members EC Research UZ/KU Leuven on 16 Nov 2020:

Chair	prof. dr. Maria-Reinhilde Casteels	Clinical Pharmacology
Vice chair	prof. dr. Dominique Bullens	Paediatrics
	De heer Aernout De Raemaeker	Medical Legislation alternate
	De heer Jean-Jacques Derèze	Medical Legislation alternate
	De heer Mathijs Swaak	Healthy volunteer repres.
	Mevr. Angélique Rézer	Medical Legislation alternate
	Mevr. Eva Puttevils	Nurse
	Mevr. Katelijne Van Overwalle	Pt representative (alternate)
	Mevr. Lia De Wilde	Pt representative (alternate)
	Mevr. Liliane Vandergeeten	Pt representative (alternate)
	Mevr. Marilien Vandeputte	Nurse
	Mevr. Michèle Dekervel	Medical Legislation alternate
	Mevr. Teresia De Fraye	Pt representative
	Mevr. Veerle Vanparys	Pharmacist (alternate)
	apr. J.R. Thomas	Clinical Pharmacology
	apr. Stefanie Goris	Pharmacist (alternate)
	dr. Kristel Van Landuyt	Reumatology
	dr. Lut De Groote	General Practitioner
	dr. Marleen Renard	Paediatrics
	prof. André Loeckx	Pt representative (alternate)
	prof. Ben Van Calster	Statistics
	prof. Guy Bosmans	Clinical Psycology (alternate)
	prof. Pascal Borry	Ethics
	prof. dr. Anne Smits	Paediatrics
	prof. dr. Anne Uyttebroeck	Paediatrics
	prof. dr. Ariel Alonso	Statistics (alternate)
	prof. dr. Benoit Nemery	Pneumology
	prof. dr. Gregor Verhoef	Haematology
	prof. dr. Jan Verhaegen	Laboratory Medicine
	prof. dr. Jan de Hoon	Clinical Pharmacology
	prof. dr. Karin Sipido	Experimental Cardiology
	prof. dr. Koen Luyckx	Clinical Psycology (alternate)
	prof. dr. Maria Schetz	Intensive care
	prof. dr. Simon Brumagne	Physiotherapy
	prof. dr. Xavier Bossuyt	Immunology