

Dr. Pierre DELTENRE
Gastro-entérologie médicale
Hôpital Erasme

Brussels, July 31, 2023

Comité d’Ethique
hospitalo-facultaire
Erasme - ULB
(021 / 406)

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Dear Dr. DELTENRE,

Please find further on the answer of the Ethics Committee concerning the below mentioned study.

ETHICS COMMITTEE APPROVAL

We, undersigned, "Board Members" of Ethics Committee Erasme Hospital
808, route de Lennik
B-1070 Brussels, Belgium

confirm that the documents submitted for approval were initially examined on the meeting held on 11/07/2023 (dd/mm/yyyy).

After examination of the answers to the comments received the 26/07/2023, the Ethics Committee gave its agreement on 31/07/2023 to the following documents:

- Protocol (References : P2023/254 / NA) entitled: "*The natural history of early porto-sinusoidal vascular disorder.*" (Your Ref.: Version undefined)

The following document(s), included in the submission file, has/have also been reviewed:

- Ethics Committees Application form signed the 11/06/2023
- Clinical Trial Agreement: Draft or not yet signed by all the concerned parties
- eCRF, modified
- GDPR Statement dated July 24, 2023

We also confirm the suitability of the local investigator and his team and the quality of local facilities.

This agreement is valid from 31/07/2023 till 31/12/2025 provided that the Ethics Committee received the local clinical trial agreement as required by the Belgian law of May the 7th, 2004.

The Committee reminds the investigator of his personal responsibility for this project. We consider **your responsibility**, in accordance with the recommendations of ICH-GCP (E6):

Point 3.3.6.: no subject should be admitted to a trial before the IRB/IEC issues its written approval/favourable opinion of the trial.

Point 3.3.7.: no deviations from, or changes of, the protocol should be initiated without prior written IRB/IEC approval/favourable opinion of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)).

Moreover, annual trial status and end trial results will be transmitted to the Committee.

The list of the names and qualifications of the members of the Ethics Committee is added in appendix.

We hereby confirm that this Ethics Committee is organized and operates according to ICH GCP and the applicable law and regulations.



Pr J.-M. BOEYNAEMS
Chairman

Liste des Membres CE Erasme-ULB 2020 – 2024

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Mme M. PAESMANS, Experte en méthodologie et statisticienne, F, Scientifique, Affiliée
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