

Recommendation of the College Board regarding pre-recruitment for phase I clinical trials

The version 2.0. of this advice was endorsed by the College Board during the meeting of 11/10/2024. This version 2.1. was endorsed by the College Board on 25/01/2025.

To keep the remarkable position of Belgium in high-quality early phase clinical research, **prerecruitment** is extremely important for Phase I studies as defined in art 3, 8° of the law of 7 May 2017 (including vaccine trials).

According to CTR, the start of a clinical trial means the first act of recruitment of a potential subject for a specific clinical trial, unless defined differently in the protocol. As the prerecruitment takes place before the official CTR study start, it is **not part** of the clinical trial under CTR¹. Therefore, the College considers that this can be evaluated by one of the ethics committees (ECs) recognized under the law of 7 May 2017. All documents would be approved by the latter EC. All these documents should mention “*approved by the ethics committee of XXX (name EC) dd/mm/yyyy*”. If new items are added to any approved document/template, this document must be re-approved.

For transparency reasons, the documents and their approval by the EC should be added to the dossier submitted under CTR. This may help to assure the evaluating EC, assigned by the College, of the careful prerecruitment procedure: (1) does the prerecruitment take place before the study start under CTR as defined by the protocol and (2) have prerecruitment documents been evaluated previously.

As the prerecruitment documents are not part of the clinical trial under CTR, they should not be re-evaluated under CTR by the EC assigned by the College.

¹CTR: Clinical Trial Regulation, Regulation (EU) No 536/2014