User Guide
for registering a study in the UZ/KU Leuven central clinical research database

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1. Purpose

This User Guide describes provides hands-on tips & tricks for registering a study in the UZ Leuven central study database by completing the online registration form.

2. Scope

This guide serves as tool for users tasked with registering a study at the CTC in view of obtaining the mandatory study number (S-number) and review by the internal study stakeholders.

3. Instructions

For a visual overview of the study registration process flow within UZ/KU Leuven, and the steps associated herewith, please refer to:
https://www.uzleuven.be/nl/clinical-trial-center/flow-opstart-klinische-studie

3.1 Ensure the study information in the online registration form is accurate and complete as it serves as the basis for further evaluation of your application. A well-completed registration form facilitates review of the study by internal UZ Leuven stakeholders.

3.2 Upon submitting the completed registration form, the Principle Investigator (PI) and the identified study contact person at UZ/KU Leuven (e.g. the Clinical Trial Assistant) will be notified via email that a study has been registered. The PI will be asked to accept or decline the study. Due to IT restrictions, CTC will accept trial registrations on behalf of KUL investigators. Afterwards the S-number is automatically generated and sent to the PI, the identified study contact person at UZ/KU Leuven and the applicant, via email. The sponsor (if not UZ/KUL) and CRO (if applicable) will also receive the S-number. Sub-Investigators will not receive notification of the assigned S-number. Correct completion of the applicant details in the registration form will ensure the relevant parties will be notified of the study-specific S-number when assigned.

3.3 Clarification of used terms:

a. Monocentric: Only one research site will recruit study participants, so there is only one Principal Investigator.

b. Multicentric: More than one research site will recruit study participants, so more than one Principal Investigator will be involved.

c. National coordinator: In case of multiple participating sites in Belgium, one Investigator may be appointed as national coordinator to take the lead in Belgium with regards to, for example, adapting study-specific documents to national requirements, coordinating submissions to Ethics Committee(s) (ECs) and/or to Competent Authorities (CA).

For national monocentric studies this section of the registration form should be marked as 'No'.

d. Central EC: Check this box for monocentric studies in UZ/KU Leuven, and for multicentric studies for which UZ/KU Leuven is Sponsor and which are not submitted under the new clinical trial regulation (CTR) (see f. below). In such cases the EC of UZ Leuven (which is a recognized EC) will act as the central EC and will provide a single opinion (for all participating research sites in Belgium).

e. Local EC: Check this box when the EC of UZ Leuven will assume the role of local EC (i.e. UZ/KU Leuven is merely a participating research site, and the EC of UZ Leuven is not mandated to provide a single opinion for all participating research sites in Belgium). Acting as local EC, the EC of UZ Leuven will only advise the central EC on Informed Consent (IC) related procedures, on the suitability of the local UZ/KU Leuven research facilities and on the qualifications of the PI and supporting staff.

f. Central submission according to the new clinical trial regulation:
This box must only be checked for prospective interventional clinical trials with an investigational drug, submitted for EC/CA review according to the procedure described in the new clinical trial regulation (which allows for a single submission to obtain parallel review from both a recognized central EC and the FAMHP).

g. Study Type: Check the appropriate box, as follows:

- *EudraCT study:* A prospective interventional trial investigating one or more investigational drugs.
- *Secondary use of human body materials:* Previously obtained human body material (e.g. from a previous study), or residuary material obtained for the purpose of standard clinical care/diagnostics, will now be analyzed as part of the clinical research study for which the online registration form is being completed. *Non-EudraCT studies:* all other studies. The study type will be further specified in the next steps of the registration form.

h. Sponsor: Indicate who commissions the study: a commercial (for profit) firm, or an academic institution (e.g. Investigator driven research)

The Sponsor of the study is the party who took the initiative for the study and designed the study concept. This isn't necessarily the party providing funding for the study.

i. CRF: Case Report Form. The database that will be used for collecting all study data, e.g. REDCap.

j. CRO: These details only need to be complete when a CRO (Contract Research Organisation) is involved with managing the study on behalf of the Sponsor.

k. Retrospective: Check this box if all data necessary for the study are already available in the patient's medical records or other administrative records and study participants will not actively be involved or be contacted for missing data.

3.4 Any important information concerning the study, may be added in the comment field.

3.5 After submission of the online registration form, any changes to the registered information can be requested by e-mail to CTC@uzleuven.be.
Ensure to clearly indicate "change to study registration info" along with the study-specific S-number (preferable) or other study identifiers (such as protocol number or

title) in the e-mail subject line. Provide details of which information needs updating, in the body of the email.

3.6 Because anyone can register a study, the PI and the UZ/KU Leuven contact person mentioned in the registration form will receive an automated e-mail to accept or decline the study registration. Attention: Study review will not commence until the PI/contact person accepted the study registration. Due to IT restrictions, CTC will accept registrations on behalf of KUL Investigators.

3.7 As soon as an S-number is assigned, supporting UZ Leuven departments (such as radiology, pathology, biobank, the laboratory etc.) should be contacted by the applicant or study team, and the GDPR questionnaire should be completed. If no supporting departments are required to conduct the study, only the GDPR questionnaire which is required to qualify for EC-review, should be completed (https://www.uzleuven.be/nl/clinical-trial-center/ctc-gdpr-questionnaire).

3.8 Attention: the study may not be submitted for EC-review (whether central, local or under the new CTR-procedure) until the study registration has been fully reviewed and validated by the UZ Leuven CTC (for more information please refer to: https://www.uzleuven.be/nl/clinical-trial-center/flow-opstart-klinische-studie). If no questions arise during the review of your application, you will receive an automated validation e-mail. The UZ Leuven EC won't accept the study application if no CTC validation was granted.

Please note, that the Sponsor/study team is responsible for submitting the study for ethics/regulatory review (as applicable), as this is not triggered automatically by the CTC validation.

4. Version history

Version	Reason for change
1.0_02Apr2021	New document