CTR Collaborate – Stakeholder Meeting Announcement

Save the Date: 11 September 2024, 13:00 to 17:30 CET (remote meeting)

CTCG, with the support of ACT EU Priority Action on Mapping and Governance, cordially invites all stakeholders to participate in a meeting to share information on the work completed by the participants of the different tracks within the CTR Collaborate project. The open part of the meeting will be live-streamed and can be attended without pre-registration.

The CTR Collaborate project started in May 2023 with the aim to promote interaction between NCAs and ECs in EU/EEA implementing the Clinical Trials Regulation (CTR) and the Implementing Regulation (EU) 2022/20 on safety cooperation. The vision of the project is to i) promote health through novel therapeutic strategies with medicinal products, ii) have more clinical trials in the EU/EEA to facilitate research and provide new treatment options for patients ensuring that the rights, safety and well-being of trial participants prevail over all other interests and iii) make the EU/EEA a more attractive location for conducting clinical trials.

To achieve these goals, the CTR Collaborate project focuses on several key objectives: i) it aims to ensure that clinical trials are safe and of high quality by maintaining high standards for CT applications and dossiers; ii) it aims to guarantee that assessments are conducted appropriately within legal timelines by harmonising procedures within and across Member States, while upholding ethical and regulatory standards; iii) the project aims to facilitate alignment between NCAs and ethics committees within and across Member States by building trust and a common understanding of CTR and endorsed guidances, ensuring effective collaboration across the EU/EEA.

The CTR Collaborate project has four focus areas: i) support external stakeholders, ii) promote effective and harmonised procedures, iii) promote training and information sharing, iv) support the creation of MedEthicsEU, a group of national representatives of Medical Research Ethics Committees in EU/EEA. The project is organised as different tracks with broad participation of EU/EEA members of NCAs and Ethics committees.

Meeting Agenda

In the open session, we intend to share details about the mapping exercise that has been the starting point of our activities. We will describe the responsibilities of ethics committees involved in part I assessment and provide more details relevant to understanding the EU/EEA landscape in this respect. Next, we will share issues identified, related to collaboration within and across Member States, the current role of the RMS, and technical aspects that influence the ability to collaborate effectively and communicate with applicants. Solutions proposed for the issues will be presented. Some work on implementing solutions is already ongoing by updating best practices, training, interaction with stakeholders as well as sharing MS experiences to optimise the way of working.

We would like to share details of all these activities and discuss what else needs to be done to improve the EU/EEA landscape, making it an attractive place to conduct clinical trials.

This open session will be followed by a closed session requiring pre-registration to allocate participants to different breakout sessions. These sessions aim to understand additional aspects of existing topics already discussed within the CTR Collaborate tracks, as well as new topics brought forward by registered participants.

The request to provide topics for the breakout sessions can be given directly as part of the registration process via the survey tool. A detailed meeting preparation package to prepare for the meeting will be shared two weeks in advance of the meeting and the topics for the break-out sessions will be

included. The survey tool will stay open to indicate your preference for a break-out session and/or refine your topic proposal.

Based on the presentations and discussions during the meeting, there will be an opportunity to provide additional input via Slido, which will be considered for future steps of the CTR Collaborate project.

Registrations can be submitted by 30 August 2024 at the latest. Please note there is a limit of two participants per institution or company for the breakout sessions. We request stakeholders to give preference to colleagues who are operationally active to truly understand the problems encountered in daily work.

By understanding the problems and bringing together all stakeholders involved in clinical trials, we will have the opportunity to build a better future.

Looking forward to an interactive and productive meeting.

Marianne Lunzer, co-lead of CTR Collaborate and CTCG chair

Monique Al, co-lead of CTR Collaborate and CTCG vice-chair