



Brussels, SANTE D2

MEETING OF THE EXPERT GROUP ON CLINICAL TRIALS

Webex meeting

11 July 2023

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(from 14.00 till 18.00)

1. Welcome and adoption of the draft agenda

The Chair welcomed the Expert Group on Clinical Trials (CTEG) and the agenda was adopted. AOBs were suggested ahead of the meeting in writing.

The following Member States were represented: AT, BE, CY, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LU, LV, NL, NO, PL, SE, SI, SK.

The following Member States were not represented: BG, CZ, HR, IS, LI, LT, MT, PT, RO.

There were observers from the European Medicines Agency (EMA) and the Clinical Trials Coordination Group (CTCG).

2. Transition trials

The Commission provided an overview of the most recent activities with regards this subject.

After the CTAG meeting of 12 June, the Commission set up a working group to discuss the Commission Questions & Answer document. At the meeting, CTEG agreed on the minimum set of documents (already outlined in the Commission Q&A document) to allow the transition from the directive to the regulation regime. For the other documents already approved under the clinical trials directive, sponsors should include in the cover letter a statement that a positive opinion was already provided. Also, the experts agreed on the fact that sponsors have to clarify in the cover letter the basis of the consolidation of the protocols.

[Post-meeting note: The chapter on transition trials was deleted from the Q&A document and, upon endorsement by CTAG via written procedure, a standalone

guidance document was issued on 19 July and it is available at this link [transition_ct_dir-reg_guidance_en.pdf \(europa.eu\)](https://transition.ct.dir-reg.guidance.europa.eu)].

3. Use of conditions

Building on previous discussions, the group agreed on reviewing the Commission Q&A document. The group agreed on a possible revision and this possible amendment will be subject to endorsement by CTAG in September 2023.

4. Proposed question on exposure to radiation in Commission's Q&A document

In February 2023, CTEG showed support to find common ground on assessing radiation exposure, and since then a small working group came together to discuss the subject starting from analysis Article 6 paragraph 1 (b) and annex I section D of the regulation. On this basis, the working group drafted a Question and Answer to explain to sponsors what they are expected to provide in their dossier and therefore avoid RFIs on this topic due to lack of information. All members of CTEG were then consulted. As a conclusion, the group welcomed the proposed text. As next step, the Commission will consult CTAG for formal endorsement and adoption of the new Q&A.

5. Proposal to clarify the Commission's Q&A document with regards to disclosure of the names of the ethics committees

This proposal is coming from the discussion held in the previous CTEG meeting when *“The majority of the CTEG members agreed that listing the names of ethics committees is not mandatory as it is not requested in the CTR”*. Member States decide how to disclose the ethics committee names as appropriate. As this is a matter of competence of the Member States, the group agreed that the Commission's Q&A is not a suitable document for clarifying this.

6. Proposal to modify the Site Suitability template: addition of a unique identification number of the site (where applicable) and of the position of the principle investigator

Some countries use a unique identification number to identify the exact clinical trial site. This is of particular importance when many sites are under the responsibility of the same person, in case sites have similar names, and in case many sites are part of the same hospital. The group agreed with modifying accordingly the site suitability template.

As next step, the Commission will consult CTAG for formal endorsement and adoption of the revised template.

7. Proposal to revise Commission's Q&A document: No. 9.4

The EMA introduced the topic and invited group to send comments by 8 September 2023.

8. Proposal to revise the template statement on compliance Regulation (EU) 2016/679

The EMA introduced this topic and presented a proposal to review the current template. EMA and the experts will further liaise on the subject.

9. Information on the project about the interface between Regulation (EU) 536/2014 (CTR), Regulation (EU) 2017/745 on medical devices, and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

The experts have been informed of how they will be involved in the project. The project will be structured as follows:

- (1) Creating an issue list: clarify problems that cause delays in combined studies in terms of scientific, procedural and legal issues, and whether they pertain to a single legal framework or to the interface
- (2) Mapping the authority landscape for the three pieces of legislation: mapping of competent authority landscape for the different Regulations
- (3) Mapping of ongoing work: mapping of ongoing projects related to the MDR/IVDR/CTR interface
- (4) Proposing solutions: Proposal of solutions that could address the issues identified, taking into account also the mapping of landscape and ongoing work.

Lead and main contributors to the project are national competent authorities from the relevant groups. The Commission (SANTE D.2/SANTE D.3) is the chair of the project board and has the role to steer this Member State-driven project. The EMA will contribute to the project in line with its remit established by the CTR.

10. Q&A on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

The group was informed that they would be invited to provide comments in order to adequately respond to queries received on the subject.

11. AOB and next steps

The group was informed of the latest state of play of the decentralized clinical trial implementation phase and closure of the project.

Provisional date for the next CTEG meeting: 16 October 2023. Experts have been invited to suggest agenda topics.