



EUROPEAN COMMISSION
DIRECTORATE- GENERAL FOR HEALTH AND FOOD SAFETY
Health systems and products
Medicinal products – quality, safety and innovation

Brussels, SANTE D2

MEETING OF THE CLINICAL TRIAL COORDINATION AND ADVISORY GROUP

Virtual meeting, WebEx

19 February 2024

MINUTES

1. Welcome and adoption of the draft agenda

On 19 February 2024, the Clinical Trial Coordination and Advisory Group (CTAG) held the first 2024 meeting. The Chair welcomed the national contact points and the agenda was adopted.

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

The following Member States were not represented: ES, HR, LI, LT, MT.

EMA and CTCG observers joined the meeting too.

2. COMBINE project

CTAG members were informed of the state of play of the COMBINE project, of the draft analysis report and next steps. The first phase of the project is an analysis and understanding of the state of play of the interface between clinical trials, in-vitro diagnostics, and medical devices regulatory frameworks. Stakeholders provided input which was taken into consideration in the draft analysis report. The analysis phase led to a list of solutions which cover four areas: Coordinated assessment, alignment, guidance/clarity, and communication/dialogue. The next step will be the preparation of a programme, which will provide an overview of the actions to be developed across the different legislations, taking into consideration ongoing activities and work prioritisation.

CTAG will be consulted via written procedure to provide feedback on the draft analysis report and it will be asked to endorse it. CTAG members were informed that their contribution should build on coordination with the national responsible authority for medical devices and in-vitro diagnostics.

3. Workshop proposals on submission of Substantial Modification and Additional Member States Concerned applications

EMA presented proposals to amend the COM Questions & Answer document on submission of substantial modification (SM) and Additional Member State Concerned (AMSC) applications. These proposals stem from a workshop hosted by the EMA on 7 December 2023 attended by some Member States and Sponsor Product Owners/Subject Matter experts. The proposed changes to the COM Q&A build on real life experience with CTIS use, and they would be expected to speed up submissions of clinical trials applications while adhering to the requirements of the CTR.

Overall, CTAG members agreed that sponsors should first and foremost submit complete and high-quality dossier applications (both part I and II at the same time) in all the Member States they intend to set up and conduct the clinical trial.

At the same time, it was acknowledged that Article 11 of the CTR allows sponsors to submit only Part I of the initial application.

Pragmatic alternatives are to be discussed and agreed in an ad hoc CTAG meeting to make partial submission possible without forcing sponsors to withdraw partial applications at the time there is a need for a first SM Part I.

4. IMPD-Q

After a few rounds of consultations, CTAG endorsed the revised text and the COM Q&A will be amended accordingly.

5. Union Controls

COM warmly invited CTAG members to submit their replies to the Union Control questionnaire by 29 February 2024. Should Member States not reply to the questions, this will be recorded in their report. In view of the implementation of the CTIS Transparency rules, the Union Control final reports will only be accessible to the national authorities via the Authority Workspace in CTIS.

6. Transition trials

- a. Part II documents. As an action point stemming from the previous CTAG meeting of November 2023, a table has been created to provide an overview of Part II documents requested for the transitional trial application. This table informs sponsors which documents they are expected to submit. This table will be included as an annex to the Commission Guidance document on Transitional Trials¹.

¹ Guidance on Transition trials. Link : https://health.ec.europa.eu/document/download/10c83e6b-2587-420d-9204-d49c2f75f476_en?filename=transition_ct_dir-reg_guidance_en.pdf

- b. Communication campaign. The EMA gave an overview of the communication strategy developed to support the transition from the Clinical Trials Directive to the Clinical Trials Regulation, moving the clinical trials registered in EudraCT to the Clinical Trials Information System (CTIS).

COM reminded CTAG members to:

- Comply with the agreed timeline of 22 days (+ days for RFIs) for the approval of the transitional application;
- To keep EudraCT up-to-date; and
- Keep informing the sponsors active in their countries of their duties and support them as needed.

COM informed CTAG members that a letter will be sent to the Permanent Representatives to inform them of the legal obligations.

7. Auxiliary Medicinal Products in Clinical Trials (AxMP)

CTAG endorsed the revised document² and this will be amended accordingly.

8. ICH M11- SME working group

EMA invited CTAG members to volunteer to join a Subject Matter Expert working group on ICH M11 on clinical study protocol template and specifications.

9. EU-level group of medical research ethics committees

CTAG members were informed of the launch of the MedEthicsEU group. The kick off meeting took place on 15 February which was attended by DG SANTE Director General. The mandate of the group will be the strengthening of the cooperation between medical research ethics committees (MRECs). The tasks will primarily include an EU mapping of the MRECs organisations in Member States, then a workplan will be drafted on the basis of a survey on priority issues for MRECs. The proposed membership list will be submitted to CTAG for confirmation of nominations.

10. Safety assessment cooperation and facilitated conduct of clinical trials (SAFE CT)

CTAG members were informed of the state of play of the Joint Action (2022- 2025) and of the next steps.

11. AOB

² Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use , 28 June 2017. [Link](#)

COM reported on the progress with the analysis of the CTR survey report n.2 and on the plans for 2024 for the KPI reports.

COM will organise an ad hoc meeting to discuss changes to the COM Q&A document. Next provisional CTAG meeting is on 22 April 2024.