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

Webex meeting

12 June 2023

MINUTES

(from 14.00 till 17.00)

1. Welcome and adoption of the draft agenda

The Chair welcomed the national contact points.

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

The following Member States were not represented: LI, LT, LU, MT, PL

Participants had shared in writing prior to the meeting two AOB items that were addressed at the end of the meeting.

2. Changes in the membership of CTAG: new national contact points for IE and ES as well as a new CTCG observer

IE and ES appointed their new national contact point.
Greet Musch, CTCG co-chair and CTCG observer in CTAG, has retired. Marianne Lunzer, Chair of the CTCG, has become the new CTCG observer in CTAG (she is also the CTCG observer in CTEG).

3. Transition trials

National contact points were asked to inform of the measures intended to be put in place to ensure a smooth transition of those clinical trials that have been authorised under the Clinical Trials Directive (CTD) and have to be compliant with the Clinical Trials Regulation (CTR) by 31 January 2025. It is indeed critical that all sponsors (commercial including SMEs and non-commercial sponsors) are aware of this change of regulatory

framework. Some Members informed that they run thorough communication outreach to inform of this regulatory transition.

Members highlighted that the Commission's Questions & Answer document needs to be revised, specifically on chapter 11 dedicated to transition trials. Three key principles have been emphasised:

- It is the sponsor's responsibility to assess this compliance and declare in the cover letter that the clinical trial is in line with the requirements for transitioning from the CTD to CTR
- Sponsors have to submit a limited set of documents that were already assessed and authorized by the Member State concerned.
- The documents for these already authorised and ongoing trials shall not be re-assessed.

The EMA presented the number of clinical trials that are expected to transit in the coming months and provided a presentation on the activities related to transition trials in ACT EU.

The Commission stressed that a pragmatic approach is needed to ensure that health and safety of trial participants is guaranteed, and research results are not put in jeopardy.

The Commission stressed the need to have a common and pragmatic approach, and the responsibility of CTAG members is to inform national organisations of the agreed steps and planned procedures. The Commission concluded that a temporary CTAG sub-group would be set up with volunteers to review the Commission's Q&A document so that this is aligned with the CTCG guidance document on transition trials and with the EMA communications.

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4. Presentation on the project on IVDR/CTR/MDR interface

The national contact points have been informed of how they will be involved in the project. The first phase of the project will focus on analysing and identifying the challenges, covering four items:

(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.

Solutions to be developed on the basis of the outcome of the initiated analysis phase of this project.

Lead and main contributors to the project are national competent authorities from the relevant groups, namely Medical Device Coordination Group (MDCG) and the relevant clinical trials groups (Clinical Trials Coordination Group (CTCG), Clinical Trials Expert Group (CTEG), Clinical Trials coordination and Advisory Group (CTAG). Several MSs expressed interest. 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.

5. Information from DG SANTE on specific changes to the CTR brough by the Pharma reform in relation to centralised GMO/ERA evaluation

The Commission informed of the proposed changes specific to the CTR brough by the proposal of the pharmaceutical legislation reform in relation to centralised Genetically modified organism (GMO) and environment risk assessment (ERA) evaluation. The Commission clarified that this point in the agenda was to make CTAG members aware of this, and technical discussions and negotiations will take place in the appropriate setting.

6. Updates from DG SANTE on Union Controls

The Commission informed the group of the state of play concerning the Commission's legal view on the scope and depth of Union controls.

A number of surveys will be conducted staring from October 2023 and the group will be consulted in advance.

7. Debrief on EMA event of 9 June on clinical trials during public health emergencies

The national contact points have been invited to share their feedback and discuss any possible action to be developed in CTAG. The Commission clarified that the event was the starting point of a project led by the EMA to take stock of the lessons learned during COVID-19 pandemic and during the monkeypox outbreak. The vision is to be better coordinated and prompt to deal with public health emergencies should these arise again.

The role of CTAG members will be important as they need to ensure national coordination with the relevant national organisations and authorities. The Commission stressed that the CTR provides a regulatory framework for streamlining the clinical trial authorisation procedures, but there is room for flexibility which can be utilised for better cooperation and harmonisation.

The Commission reiterated its support to help Member States coordinate and harmonise as needed.

8. Implementation of the CTR: updates from DG SANTE on the CTR survey N.2

The Commission informed the group of the progress done with the preparation of the second edition of the survey on the implementation of the CTR. It will be launched in Q3 2023.

9. AOB

a. Use of conditional approval

It was requested to discuss the use of conditional approval. It was agreed that a small working group of volunteers will discuss this matter to prevent rejection and subsequent re-submission of the clinical trial application in specific situations. The overall scope of the flexibility allowed within the CTR is to keep the EU an attractive region to conduct clinical trials.

b. Interpretation of Article 53, Paragraph 2 of CTR

It was suggested to discuss the interpretation of Article 53, Paragraph 2 of the CTR.

The Commission explained that the title of an Article is not a legal. The interpretation should be focused on the content of both paragraphs 1 and 2. The sponsor is expected to submit to the Member States concerned, through the EU portal, **all inspection reports of third country** authorities concerning the clinical trial and, as per paragraph 1, thse inspections reports have to be “relevant for subject safety” which does not necessary mean “safety-related” and could cover good manufacturing practices reports. This topic will be tabled for the CTEG meeting on 11 July.

The next CTAG meeting is scheduled for 18 September 2023 and it will be virtual.