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 TRIALS COORDINATION AND ADVISORY GROUP

Webex meeting

19 October 2022
(from 09.30 till 13.00)

MINUTES

1. Welcome and introductions

The Chair opened the meeting of the Clinical Trials Coordination and Advisory Group (CTAG).

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

The following Member States were not represented: AT, LI, MT.

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

The Chair informed the group of the new DG SANTE organisation, following which Unit DG SANTE B4 becomes DG SANTE D2. Consequently, the functional mailbox to reach the secretariat is now SANTE-CONSULT-D2@ec.europa.eu. CTAG members are invited to contact directly the policy officers working on the file.

The Chair outlined the objectives of the meeting:

i) to focus on implementation of the Clinical Trials Regulation (CTR) No. 536/2014 at national level. The obligation is in place since 31 January 2022, and from 31 January 2023 the new clinical trial applications will have to be submitted via the Clinical Trials Information System (CTIS).

ii) to discuss how any remaining or possible future challenges are being addressed to ensure full compliance.

2. Adoption of the draft agenda

When reviewing and adopting the agenda, none of the attendees indicated any conflict of interest. The agenda was adopted as proposed.

Some Member States recommended the delivery of the preparatory material in compliance with the Rules of Procedure of the group. The Commission took note of this feedback and committed to do its best to share the preparatory documents no later than 10 calendar days before the date of the meeting, as some emergencies or unexpected events may lead to limited exemptions.

Some Member States encouraged the Commission to schedule meetings to discuss matters for which there might be divergent opinions and avoid solely written procedures. Also, it was pointed out that more regular meetings would be welcome.

3. Survey on CTR implementation: blocking issues, solutions, and the way forward

The Commission explained that all Member States are expected to apply the rules set in the CTR that became applicable on 31 January 2022 and, therefore, to be in full compliance with all its provisions, including the ability to accept applications via CTIS.

The Commission reiterated its availability for bilateral discussions if needed, noting that the implementation of the CTR is a collective endeavour.

To monitor and assess the implementation of the CTR, a survey was launched between 18 July and 9 September 2022 to collect feedback from sponsors in order to:

(i) understand the overarching hurdles that hamper a smooth implementation of the CTR which became applicable on 31 January 2022;

(ii) capture how clear the requirements of the CTR are to the stakeholders.

The Commission presented the results of the survey. The respondents to the survey provided detailed comments pointing to issues related with CTIS (bugs, lack of functionalities), with the CTR itself (difficulties with the new provisions on transparency), on the lack of preparedness of certain Member States and additional national requirements beyond the CTR rules.

The Commission recalled that sponsors were requested to provide feedback from their experience and the comments received did not necessarily describe the present situation. Indeed, in the meantime bugs in CTIS were corrected, Member States have adapted their national legislation, a delegated act was adopted (See AOB), and guidance materials were developed.

The EMA informed that major blockers that are preventing the users to work smoothly on CTIS have been identified and that the service providers were committed to solve these blockers before 31 January 2023, date from which the use of CTIS will be compulsory. Member States expressed concerns about CTIS performance and some of the persisting blocking issues, calling for a fully operational system to be delivered on time. The Commission joined this call and encouraged good coordination at national level to ensure that the positions expressed at the EMA management board reflect the Member States needs expressed in this group.

Member States also called for a regular repetition of such survey.

The Commission announced that the next steps would consist in identifying the persisting issues, prioritising them and allocating them to the different entities for possible resolution (EMA, Commission, Member States, CTAG, Commission Expert Group on Clinical Trials (CTEG), Clinical Trial Coordination Group (CTCG)). A sub-group of CTAG would be set up to prepare the work of an *ad hoc* CTAG plenary meeting in December 2022 dedicated to that follow-up.

4. Union Controls

The Commission recalled the concerns expressed by Member States concerning the scope of the Union controls performed in the frame of the CTR. Notwithstanding that Union Controls is a critical method to verify whether Member States correctly supervise compliance with the CTR, the Commission has decided to pause the Union Controls until there is an internal review of the legal provisions. In relation to those Union Controls that had already started, the Commission has been liaising bi-laterally with the concerned Member State to seek agreement as to how to proceed.

5. Proposals by ES and NL to facilitate clinical trial applications and CTR implementation

ES and NL presented a set of proposals to facilitate clinical trial applications and the CTR implementation. These proposals consisted in rationalising and optimising the work of the different groups involved in the implementation and enforcement of the CTR, updating and complementing guidance materials, developing a kit of first understanding of the CTR (a document summarising the new rules and pointing to the different guidance materials).

The Commission welcomed these proposals and indicated that they will be considered, notably in the context of the survey follow-ups. Collaboration with the CTEG and other interested parties will be sought as appropriate.

6. AOB and next meeting

- Delegated Regulation on labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use

The Commission informed that the Delegation Regulation on labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use was adopted on 6 September 2022, and that the European Parliament and the Council had two months to formulate any objections.

- Information from a CTAG representative in the Emergency Task Force

The CTAG representative in the Emergency Task Force (ETF) provided a summary of recent ETF activities. Since March 2022, CTAG is represented in the ETF as stated in the Crisis preparedness Regulation (EU) 2022/123. The meeting agreed that the Clinical Trial Regulation definitions of ‘clinical study’ and ‘clinical trial’ apply for ETF advices on trial protocols. Also, the CTAG Rules of Procedures regarding representation of CTAG in ETF could be amended with a reference to Article 15 of the Regulation (EU) 2022/123. Lastly,

it was clarified that remuneration of ETF scientific advice input by clinical trial experts should be discussed within ETF, since this is not within the remit of CTAG.

- Provisional date for the next CTAG meeting: 14 December 2022.