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

18 September 2023

Minutes

(from 15.00 till 18.00)

1. Welcome and adoption of the draft agenda

The Chair welcomed the national contact points.

- The following Member States were represented: AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK
- The following Member States were not represented: BG, LI, LT, MT.
- EMA and CTCG observers were also connected.

Prior to the meeting, the group suggested in writing one agenda item to be added as AOB. In addition, at the meeting, the group asked information on the state of play of the written consultation that was conducted over summer on a number of subjects. The Commission services explained that no blocking comments were received neither on the documents circulated for endorsement or critical comments between 20/07 and 08/09 [(i) use of condition point 102 of the Commission Q&A document, (ii) new Q&A on exposure to radiation, and (iii) on site suitability template] nor on the suggested amendments to the Q&A n. 9.4 circulated between 31/08 and 08/09. [*Post-meeting note: the final version of these documents and of the revised Commission Q&A document have been shared again with the group for information on 29/09 and made publicly available*].

2. Transitional trials: monitoring of progress towards compliance by the deadline

At the previous CTAG meeting of June, the Commission had stressed that a pragmatic approach was needed to ensure that health and safety of trial participants is guaranteed, and research results are not put in jeopardy.

Over summer, progress has been made 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:

1. The Commission's guidance on transition trials has been updated and it is now a stand-alone document [link].

2. CTCG updated its "*Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under the Directive 2001/20/EC that will transition to the Regulation (EU) No. 536/2014*", and the Cover letter template.

3. The EMA hosted a CTIS webinar on 4 July and a workshop on 5 July where Commission and Member States representatives explained the transition process and detailed the different guidance documents.

The Commission recalled that it was the responsibility for sponsors to initiate the transition on time. The Commission shared its concerns about the low number of clinical trials that are transiting towards the new regulatory framework and encouraged Member States to monitor the transition process and to contact sponsors to recall their legal obligation.

Member States announced possible adaptations and simplification of the guidance material following some questions raised at the event EMA organised on that subject. The CTAG sub-group dealing with that guidance will be reactivated to propose these changes to CTAG.

The revised KPI report, that the EMA has been publishing on a monthly basis, now reports the number of clinical trials that have transitioned in the previous month. the reports are made available on the recently launched ACT EU website. The Network has to closely monitor the number of clinical trials that still have to transit to avoid that clinical trials under the CTD are still ongoing on 31 January 2025.

In particular, it is important to support academic sponsors and SMEs. It is noted that most of the questions come from academic and non-commercial sponsors: in the case where Member States already have specific training material for academic/non-commercial sponsors, it would be advisable to have (within the national websites listed in Annex III) a specific webpage with this material.

The Commission is open to have bilateral conversation with Member State as need be.

3. Updates from DG SANTE on Union Controls

The Commission services presented a summary of the outcome of the internal review of Union controls as referred to in Article 79 of the Clinical Trials Regulation: Union controls need to be understood as providing the Commission with the capacity to verify whether Member States correctly supervise compliance with the Regulation in practice. The Commission has a general legal competence to oversee the application by Member States of Union law.

Having said that, the scope of Union controls, including the type of activities being carried out, are not GCP inspections and are "organised in cooperation" with the Member States concerned.

The presentation was followed by a request to access the full documentation regarding this internal review. This request is currently under consideration.

The Commission services representative presented the next steps with regards to the Union Controls. As a first step, the Commission services proposed to share a draft 'Union Control questionnaire' to collect feedback from the national contact points on the clarity and on the content of the questions therein.

[*Post-meeting note|: the consultation for feedback run from 20/10 till 6/11 2023*]. This feedback will be taken into consideration to refine the questions before sending the questions for reply.

4. Use of Part II templates: review of current versions and need for new templates

The Commission services expressed intention to explore with a group of CTAG volunteers the extent the templates currently available on Eudralex vol. 10 are being used, if and how these have been adapted, and if there is the need to develop other templates within and beyond the context of the CTR. The use of common templates is a way to keep divergences of approach among different Member States to a minimum (recital 5 of the CTR).

5. AOB

a. **Ethics committees coordination:** the Commission services will host a meeting of representatives of the Ethics Committees from Member States on 16 October 2023 in Brussels. CTAG members can express their interest to attend the meeting and will be kept informed of the agenda and documents for the meeting.

a. **ACT EU Methodology workshop on 22/23 November 2023 (PA 8)**: DE informed the group of the workshop taking place in the context of Priority Action 8 of ACT-EU. With a view to progress the alignment process and ensure stakeholder needs are recognised and incorporated, an on-site multi-stakeholder Methodology Workshop will be held on 23 November 2023, while the 22 November will be an internal regulators meeting. The focus will be on discussing key topics related to Methodology guidance, with the aim to identify guidance needs.

6. Next meeting

The next CTAG meeting will be on 27 November 2023, and it will take place in Brussels at the Commission's premises.