October, 2022

RULES OF PROCEDURE OF

CLINICAL TRIALS COORDINATION AND ADVISORY GROUP (CTAG)

THE CLINICAL TRIALS COORDINATION AND ADVISORY GROUP (CTAG),

Having regard to Article 85 of the Clinical Trials Regulation (EU) 536/2014 ("CTR"), which sets up a Clinical Trials Coordination and Advisory group (CTAG), composed of the national contact points referred to in Article 83 of the CTR,

Having regard to Article 85(6) of the CTR which defines that CTAG shall draw up rules of procedure that will be made public,

Having regard to the standard rules of procedure of expert groups[1],

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Point 1

Operation of the group

1. The group shall act at the request of the Commission, in compliance with its horizontal rules on expert groups[2] ('the horizontal rules').

Point 2

Chair

2. The group shall be chaired by a representative of the Commission

3. The Chair will:
   - i. preside the CTAG meetings;
   - ii. validate the minutes of the CTAG meetings and follow up on the implementation of specific agreed actions;
   - iii. plan the work of the CTAG meetings and propose the agenda taking into account suggestions by CTAG members;
   - iv. monitor that the rules of procedure are respected;

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1 Commission decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups C (2016) 3301, Annex 3.

2 C(2016) 3301.

v. ensure that at the beginning of each meeting any potential conflict of interest is declared regarding any particular item to be discussed
vi. decide when a vote is necessary
vii. ensure, the regulatory and scientific consistency of the actions, decisions and recommendations by CTAG
viii. coordinate the input from CTAG Members in the implementation of specific agreed actions
ix. represent the CTAG in its operations.

Point 3

Convening a meeting

4. Meetings of the group are convened by the Chair, either on its own initiative, or at the request of any member state.

5. Joint meetings of the group with other groups may be convened to discuss matters falling within their respective areas of responsibility.

6. In principle, meetings of the group shall be held on Commission premises or virtually, depending on the circumstances. In the event of virtual meetings, members participate through a remote connection. The decision to hold in-person or virtual meetings will be taken by the Chair, at the latest 20 calendar days before the date of pre-planned meetings. The possibility for hybrid meetings should be kept, when necessary.

7. Urgent business may be submitted to CTAG either to convene an extraordinary meeting or to be addressed by written procedure. This shall take place by decision of the Chair. In case of an extraordinary meeting the timelines related to provision of documents to the members may be shortened.

Point 4

Agenda

8. The secretariat shall draw up the agenda under the responsibility of the Chair and make it available to the members of the group.

9. The agenda shall be adopted by the group at the start of any meeting.

Point 5

Documentation for group members

10. The secretariat shall make available the invitation to the meeting and the draft agenda to the group members no later than 20 calendar days before the date of the meeting.

11. The secretariat shall make available to the group members the documents on which the group is consulted, no later than 10 calendar days before the date of the meeting.

12. In urgent or exceptional cases, the time limits mentioned in paragraphs 1 and 2 may be reduced to five calendar days before the date of the meeting.

Point 6

Opinions of the group

13. As far as possible, the group shall adopt its opinions, recommendations or reports by consensus.

14. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members. The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinions, recommendations or reports.

15. In case a member temporarily faces difficulties to connect remotely to a virtual meeting, it is acceptable that his/her vote is cast via email. In this latter scenario, the email must clearly indicate the member who is casting the vote, and the matter that is being voted upon, as well as the vote cast (against, abstained or in favour).

Point 7

Sub-groups

16. The CTAG may set up sub-groups for the purpose of examining specific questions on the basis of defined terms of reference. Sub-groups shall operate in compliance with the horizontal rules and shall report back to the CTAG. They shall be dissolved as soon as their mandate is fulfilled.

Point 8

Membership

17. The members of CTAG are the national contact points as designated by each Member State in accordance with Article 83. In case of absence from a meeting, the CTAG member should indicate this as soon as possible before the meeting and name a designated person to replace her/him at full capacity at this particular meeting.

18. Member States shall nominate a national contact point and shall be responsible for ensuring that their representatives provide a high level of expertise, and can represent the views and position of their Member State.

19. The replacement of those members who are no longer capable of contributing effectively to CTAG deliberations, or who, in the opinion of Commission , do not comply with the professional secrecy requirements set out in Article 339 of the Treaty[3] on the Functioning of the European Union or who resign, should be initiatied by the Commission.

20. In case there is a change of a national contact point, this shall be communicated by the Member State within 30 calendar days and a new national contact point should be nominated immediately or as soon as possible. The secretariat will monitor the proper

[3] Treaty on the Functioning of the European Union, Article 339 describes that the "members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components."

implementation of the procedure and verify that all information provided is accurate and up-to-date at all times.

21. In addition to their task of representing the view of their Member State, the members of the CTAG shall ensure that there is appropriate coordination between the organisations involved in the implementation of the CTR in their Member State, including but not limited to the national competent authorities and ethics committees.

22. In addition, CTAG representatives are part of the Emergency Task Force as per point (e) of Article 15 (3) of Regulation (EU) 2022/123, with the task to provide a cross-trial expert perspective on general and product-related matters in case of a public health emergency and to report back on horizontal matters to CTAG members.

Point 9

Invited experts

23. Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the group or sub-groups on an ad hoc basis. Invited experts will be provided with the necessary access to those documents that are needed for their contribution.

Point 10

Observers

24. Organisations and public entities other than Member States' authorities may be granted an observer status, in compliance with the horizontal rules, by direct invitation.

25. Organisations/public entities appointed as observers shall nominate their representatives.

26. The European Medicines Agency and the Clinical Trials Coordination Group of the Heads of Medicines Agency are granted an observer status and shall nominate one representative.

27. Observers and their representatives may be permitted by the Chair to take part in the discussions of the group and sub-groups and provide expertise. However, they shall not have voting rights and shall not participate in the formulation of recommendations or advice of the group and its sub-groups. Their positions shall be stated, where relevant, in the minutes of the CTAG meeting.

Point 11

Written procedure

28. If necessary, the group's opinion or recommendation on a specific question may be delivered via a written procedure. To this end, the secretariat shall make available to the group members the document(s) on which the group is being consulted, with a deadline to submit an opinion or comments. Comments arriving after the deadline might not be taken into account.

29. However, if at least one third of the of group members asks for the question to be examined at a meeting of the group, the written procedure shall be terminated and the Chair shall convene a meeting of the group as soon as possible.

Point 12

Secretariat

30. Commission shall provide secretarial support for the group and any sub-groups.

Point 13

Minutes of the meetings

31. Minutes on the discussion on each point on the agenda and on the opinions delivered by the group shall be meaningful and complete. Minutes shall be drafted by the secretariat under the responsibility of the Chair and adopted by CTAG.

Point 14

Attendance list

32. At each meeting, the secretariat shall draw up, under the responsibility of the Chair, an attendance list also specifying, where appropriate, the organisations, Member States' authorities or other public entities to which the participants belong[4].

Point 15

Conflicts of interest

33. Members, observers and, as appropriate, invited experts shall not have any conflicts of interest and shall be independent of any sponsor, clinical trial site and investigators involved in and of persons financing clinical trials, as well as free of any other undue influence, which could affect their impartiality.

34. When a Member is unable to participate in a meeting, part of meeting, or discussion topic due to conflict of interest, he/she must inform the Secretariat in advance or during the meeting. Conflicts of interest shall be reported in writing, e.g. in the minutes of the group's meeting. Information registered must be adequate, relevant and not going beyond what is necessary for the purpose of the management of the conflict of interest.

Point 16

Correspondence

35. Correspondence relating to the CTAG shall be addressed to the Commission via the functional mailbox, unless the contact for a specific correspondence has been identified by name.

36. Correspondence for group members shall be sent to their official e-mail address which they provide for that purpose.

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[4] The names of the representatives of organisations, Member States' authorities or other public entities may be included only subject to their prior freely given, specific, informed and unambiguous consent, in compliance with Article 3(15) and Article 7 of Regulation 2018/1725.

Point 17

Transparency

37. The group [and its sub-groups] shall be registered on the Register of Commission expert groups and other similar entities ('the Register of expert groups').

38. As concerns the group composition, the following data shall be published on the Register of expert groups:

    (1) the name and contact email of the CTAG Members and their affiliate association

    (2) the name and contact email of observers and their affiliate association.

39. DG SANTE shall make available all relevant documents, including the agendas, the minutes and the participants' submissions, on the Register of expert groups. In particular, DG SANTE shall publish the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be possible where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001[5].

Point 18

Access to documents

40. Applications for public access to documents held by the group shall be handled in accordance with Regulation (EC) No 1049/2001[6].

Point 19

Deliberations

41. In agreement with Commission, the group may, by simple majority of its members, decide that deliberations shall be public.

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[5] These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

[6] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).