



Brussels, SANTE D2

MEETING OF THE CLINICAL TRIAL COORDINATION AND ADVISORY GROUP

Hybrid meeting

27-28 November 2025

MINUTES

1. Welcome and adoption of the draft agenda

On 27 and 28 November 2025, the Clinical Trial Coordination and Advisory Group (CTAG) meeting took place in Brussels, Belgium. A draft agenda was adopted by consensus by the members of the CTAG group.

The following Member States were represented either in person or connected online: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, IS, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK.

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

EMA and CTCG observers joined the meeting.

2. Overview of the CTAG action plan

The Commission presented an overview of the CTAG action plan that was developed and endorsed by the group in September 2024 following a CTAG workshop organised in June 2024). 15 key issues impacting the efficiency and harmonization of clinical trials authorisation and conduct within the EU had been identified. These issues range from misalignment of timelines between Part I and Part II, Request for Information (RFI) process, to discrepancies in EU template acceptability, and the quality of translations.

The Commission explained that Europe is losing competitiveness compared with other jurisdictions (USA, China) in the conduct of clinical trials due to regulatory fragmentation, slow approval timelines, inconsistent implementation of the Clinical Trials Regulation (CTR) across EU and declining investments in clinical research. In this context the CTAG action plan should prioritise the actions to be taken to address issues to streamline the regulatory framework for clinical trials in Europe. Participants concurred that the action plan would also have to take into account the (upcoming) proposal for a revision of the CTR as part of the EU Biotech Act.

ACTIONS: The Commission together with members of CTAG will revise the CTAG action plan and select continuous actions to be further developed in 2026 once the EU Biotech Act proposal would be adopted.

3. Update to the CTR Q&A document

The chair of the CTCG meeting presented a proposal for several amendments for the CTR Q&A document. The proposal covers changes to Q 3.3 and 3.4 on non-substantial modifications and new questions related to consistency and clarity in reporting serious breaches, interim results, and inspection reporting. Proposals for improvements in formatting and presentation to maintain coherence across the document were also mentioned.

It was noted that CTR Q&A document is a large document, and it should contain only the aspects related to the implementation of the CTR. Meanwhile, other technical aspects could be provided in the existing EMA CTIS handbooks for sponsors or in the quick guidance for sponsors document, in particular on the aspects related to technical practicalities in CTIS (e.g. submission of interim results in CTIS).

Aspects related to summary results to be populated for early terminated trials or when no participants were recruited, these should be discussed and addressed in CTIS Forum group.

For CTR Q&A Q1.24 regarding patients facing documents aspects of the section 79., the change of the word “*exploratory*” to “*other*” was endorsed by CTAG members.

For CTR Q&A Q3.3 regarding sponsor’s responsibilities on the changes to a clinical trial, which are not NSM, but are relevant for the supervision of the trials (Art. 81.9), it was agreed by CTAG members that any documents provided by sponsor in CTIS are not automatically considered as authorised, therefore amendments in the text were introduced. Also, it was noted that CTIS will provide a banner for NSM related documentation that are submitted but not assessed by NCA meaning not authorised.

Also, some editorial elements were proposed to improve the readability of the CTR Q&A document.

ACTIONS: The Commission will assess every proposal for the CTR Q&A that was tabled for the discussion and endorsement for the CTAG group to ensure it is legal interpretation of the CTR requirements before publishing.

4. CTIS simplification and flexibilities

CTAG members discussed the application of Article 11 of CTR on partial submission, in order to address technical limitations with the submission of substantial modification applications using the Clinical Trials Information System (CTIS). The proposal for a workaround provides flexibilities regarding the submission in the CTIS.

With this proposal sponsors could potentially submit placeholder documents for Part II in this way to trigger technical decision-making process in CTIS. This would allow sponsors to submit at a later stage a substantial modification application with Part I in scope without withdrawing the initial partial application to Member States receiving Part I only and ensuring that these also participate in the review of a subsequent SM Part I applications. Member States receiving only Part I application would thus contribute effectively to assessments, leading to potential larger multinational clinical trials and reduced risks of non-authorisation or divergent Part I conditions for clinical trial applications. The proposal seeks to reduce workload, administrative burdens, and technical barriers, enhancing harmonization and coordination among Member States. The proposal also emphasises collaboration with ethics committees. Overall, the proposal aims to facilitate larger multinational clinical trials, enhance Member State collaboration, and streamline trial submission processes through increased flexibility and improved system coordination. The proposal will be applicable only for limited time until current technical limitation of CTIS functionalities will be adapted to ensure compliance with CTR requirements, including involvement in subsequent Part I SMs of MSCs receiving Part I only initial applications. The Commission pointed out that the proposal for amendments to the CTR in the future EU Biotech Act will address the issue of the adequation of Article 11 that is not currently technically available in CTIS.

The following Member States supported the use of the proposal for a workaround to allow the submission of substantial modification applications in case of initial partial submission application (Part I only): AT, BE, BG, CY, CZ, DE, DK, EE, GR, ES, FI, HR, HU, IE, IS, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK. FR indicated that full dossier submission would still be required for trial in its territory. LI and MT being absent from the meeting, no opinion was expressed. Participants agreed that a CTCG guidance for sponsors describing the workaround will be attached to the minutes of this CTAG meeting. (Please find the CTCG Guidance for Sponsors on Article 11 and other relevant documents under 'Key Documents List' on the [HMA website](#))

ACTION: Commission to attach the CTCG guidance for sponsors to the minutes of the meeting and to circulate for review to CTAG members. Post meeting note:

- In the context of the consultation on a proposal to move translations of patient facing documents from Part I to Part II, no comments were received from CTAG members and the proposal was endorsed (see point 5.2 below). As a consequence, the Guidance for Sponsor was adapted.
- Also Chapter III of the EU Q&A had to be revised to reflect the approach supported by a majority of Member States.

5. MedEthicsEU update

5.1. Template for recruitment and informed consent procedures for clinical trials within the EU

The chair of the MedEthicsEU presented a proposal for the revision of the standardized template for recruitment and informed consent procedures for clinical trials within the EU,

as mandated by Regulation (EU) No. 536/2014. It was developed by MedEthicsEU group. The content of the template is mandatory for all clinical trials. The template would be recommended for use for all clinical trials conducted in member states concerned.

The document also covers procedures for special populations including recruiting incapacitated adults, minors, and participants requiring consent witnessed by an impartial witness or during emergency situations. Specific national requirements and legislation are considered for these procedures. Overall, the proposal emphasizes compliance with CTR, protection of participant rights, and adherence to national laws throughout the recruitment and informed consent processes for clinical trials.

The CTAG members discussed aspects related to the application at national level and translation into national languages. The aim of the EU template is to provide added value for the entire EU with harmonised application. CTAG members agreed on the endorsement via written procedure.

ACTION: All members of CTAG were invited to review and to provide critical comments regarding the proposal that is available on CIRCABC via written procedure.

5.2. Proposal for moving the translations of patient facing documents to the Part II section

The chair of MedEthicsEU presented a proposal regarding the handling of the translations of patient-facing translations. The proposal suggests changing the submission process and location of translated patient-facing documents within the Clinical Trials Information System (CTIS).

The proposal recommends moving the translations of patient-facing documents from Part I of the CTIS protocol section to Part II. This aims to streamline processes and reduce the administrative and financial burden associated with translations. Regarding the assessment, in Part I, patient-facing documents should be in EN or in the language of the protocol, emphasizing the assessment of their scientific value and justification. Meanwhile in Part II, translated patient-facing documents should be uploaded in the section titled “Compliance with national requirements on data protection,” focusing on whether the language is understandable to trial participants.

The change is proposed because under the current system there is a high number of documents without a clear overview, making it difficult to find approved protocol versions. Overall, the proposal aims to improve clarity, reduce unnecessary administrative burden, and enhance the usability of patient-facing documents in clinical trials across Member States. Upon agreement, there will be a need to update CTIS guidance and conventions, along with publication and communication of the changes. CTAG members agreed on the endorsement via written procedure.

ACTION: All members of CTAG were invited to review and to provide critical comments regarding the proposal that is available on CIRCABC via written procedure.

6. Debrief of the Heads of Medicines Agency (HMA) workshop on pre-pilot on accelerated procedure for clinical trial authorisation (26 November 2025)

The CTAG member representing AT presented the main outcomes of the workshop organised under the HMA auspices regarding the proposal for the streamlining and enhancement of the clinical trial authorisation timelines in the EU/EEA under the current CTR.

The proposal introduced “FAST” pre-pilot initiative to facilitate and accelerate multinational clinical trials, providing sponsors a predictable timeline for evaluation and authorization. Until then, 14 EU Member States had agreed to participate, with additional confirmations expected, showcasing broad support. The initiative focuses on trials with significant medical need and innovative treatments, ensuring efficient workload distribution. The pilot would be aligned with the EU4Health annual work programme 2025 **Joint Action HS-g-25-27: Support to the implementation of the Clinical Trials Regulation and improvement of the clinical trials landscape in the EU and EEA.** Overall, the proposal aims to boost Europe's competitiveness in biomedical research, expedite the availability of scientific advances to patients, and foster collaboration within member states.

ACTION: No direct actions for CTAG members. AT - coordinator country will coordinate and communicate next steps and processes, as needed.

7. Building synergies on activities for clinical trials between ACT EU and EU4Health

7.1. ACT EU initiatives

EMA presented highlights of the activities of the ACT EU initiative related to support for non-commercial sponsors for academia: webinars, establishment of a helpdesk, and published exploratory analysis on funding academic sponsors to conduct multi-national clinical trials. There is continued offer for support for academic sponsors through webinars and regulatory assistance. On the aspects related to training needs in clinical trials, it was noted that EMA completed analysis of training needs that was published, and training signposting and mapping is planned over the period 2025/2026. Collaboration on training initiative with WHO in the context of the WHO Global Clinical Trials Forum is also taking place.

Regarding support and collaboration offerings for academia, EMA invites academia in dedicated briefing meetings, EMA Innovation Task Force meetings, also provides scientific advice, and collaboration management meetings. Finally, EMA reported on the outcomes of the pilots on consolidated scientific and regulatory advice¹ that have been launched in 2024 under ACT EU and are available also for non-commercial sponsors. The presentation emphasised the feedback from assessors and sponsors, pointing out the advice impact on the CTA and its added value.

ACTION: no follow up actions for CTAG members.

7.2. Outcomes of the IncreaseNet activities for clinical

A representative of the Joint Action IncreaseNET² presented the project that focuses on enhancing the capacity, competence, and confidence of regulatory assessors in the EU medicines regulatory network. The creation of curricula, e-learning materials, and induction programs to improve regulatory expertise. The project includes a system for practical training involving workshops and peer support, strategies for work-sharing and collaboration to enhance capacity across the network, initiatives for training on new technologies and facilitating data sharing between regulators and academia. Although primarily focused on assessment of marketing authorisation application, the working package on training development also covers a topic area on clinical trials (i.e. CT design, best practice guides, how to write draft assessment report and CT case studies. Participants concurred that future JA on capacity building on clinical trials should build on the work already done in the context of IncreaseNet and should avoid duplication of work.

ACTION: no follow up actions for CTAG members.

8. Activities under EU4Health AWP2025

8.1. Proposal on the call for Joint Action to support implementation of the Clinical Trials Regulation (AT – coordinator country)

The volunteering coordinator country (AT) of the Joint Action HS-g-25-27 presented key elements of a possible proposal for a project aiming at fostering the capacity of the Member States to implementing the Clinical Trials Regulation in a harmonised way throughout the EU and EEA. The aim of the proposal to create a predictable and collaborative assessment by harmonizing procedural practices and strengthening the capacity of NCAs, Ethics Committees, and GCP Inspectors. A number of work packages (WPs) are planned, which would involve various phases focusing on coordination, legal mapping, piloting new assessment models, training, ethics committee collaboration, innovative trial guidance, inspection integration, twinning and mentoring, evaluation, sustainability, and communication. Pilot programs will look at real-life assessments to test new RMS–MSC procedures and feed results into future work packages. Establishing an EU Training Academy and creating training modules for NCA assessors, GCP inspectors, and ethics committee members is also envisaged. The guidance for complex and innovative trial concepts involving AI, software designs, and ATMPs would be covered as well. The submission of the proposal is due by mid- February 2026.

¹ [Consolidated advice pilots interim report March 2026](#)

² [IncreaseNET – JAZMP](#)

8.2. Proposal on the call for Joint Action to support non-commercial sponsors (CZ – coordinator country)

The volunteering coordinator country (CZ) of the Joint Action HS-g-25-28 presented main outcomes regarding possible proposal on the EU initiative aimed at supporting non-commercial sponsors engaged in clinical trials.

The project proposes different WPs focusing on coordination, communication, evaluation, needs assessment, training, scientific advice, and sustainability. Each WP contributes to the overall goal of enhancing non-commercial clinical trial processes. The project would cover several areas, notably: development of training programs to improve the quality and compliance of clinical trial applications, particularly for rare diseases, creation of harmonised templates and guidance to reduce administrative burdens for sponsors, identification and mapping of bottlenecks for non-commercial sponsors, with recommendations on how to improve trial feasibility, facilitation of exchange programs and impact analysis to ensure sustainability and integration of best practices across Member States. The initiative aims to strengthen the regulatory and operational frameworks for non-commercial clinical trials within the EU.

ACTION: No direct actions for CTAG members. Coordinator countries will coordinate and communicate next steps and processes, as needed.

9. Union Controls – update on the GCP inspections survey

The Commission provided an update on the recent outcome of the GCP inspections survey. Currently GCP inspectors mostly have university-level education in fields like medicine, pharmacy, pharmacology, and toxicology. Inspectors are empowered to enter clinical trial sites, access records, and interview relevant individuals, including clinical trial subjects under specific circumstances. There are defined duties for inspectors, and legislation includes provisions for appointing experts, verifying compliance, and following up on significant non-compliance. Provisions are in place for unannounced inspections, access to data across member states, and mutual recognition of inspection reports. Opinions on resource allocation vary, and inspection fees may be waived or reduced for non-commercial sponsors. The findings are based on preliminary data from survey responses within 27 Member States and two additional countries, aiming to coordinate effective GCP inspections and compliance.

ACTION: no follow up actions for CTAG members.

10. AOB : Next CTAG meeting

The next CTAG meeting will be virtual on 25 February 2026.