20 August 2024
EMA/83223/2022

Mandate of the ACT EU Steering Group

1. General considerations

Both the European Medicines Regulatory Network strategy to 2025 and the Pharmaceutical Strategy 2020 have put forward recommendations to foster innovation in clinical trials and breaking down silos, stemming from a need to improve the environment for clinical research in the EU, to increase its efficiency and to integrate it better in the European health system.

To deliver on these recommendations, both the HMA and the EMA Management Board endorsed at the end of 2021 the objectives and priorities of a Commission-HMA-EMA co-led European initiative: Accelerating Clinical Trials in the EU (ACT EU).

In 2022, it was agreed to establish an "ACT EU Steering Group" that would steer the vision and mission of the initiative and oversee the development of the clinical trial environment. The ACT EU Multi-Stakeholder Platform Advisory Group was established in May 2024 and it advises the ACT EU Steering Group on strategic and operational matters.

The ACT EU Steering Group vision is to have better, faster, optimised clinical trials in Europe by facilitating harmonisation, innovation and collaboration with stakeholders and regulators.

The ACT EU Steering Group is the evolution of the "EU CTR Coordination Group" that was established in 2014 to coordinate the activities of various working groups and parties contributing to the preparation of implementation of the Clinical Trials Regulation and, in addition, to identify and propose solutions to critical issues. From 2018, the Coordination Group focused mainly on the delivery of the Clinical Trials Information System (CTIS) to enable the entry into application of the Regulation and some of its roles on CTIS were maintained until early 2022.

In December 2023, the EMA Management Board endorsed the transition of CTIS towards the EMA SAFe Agile portfolio. As of April 2024, the transition of CTIS to SAFe Agile was complete. Escalation from SAFe Agile is therefore to the EMA Management Board as of April 2024. The EMA Management Board sets the Agency's budget, approves the annual work programme and is responsible for ensuring that the Agency works effectively and co-operates successfully with partner organisations across the EU and beyond. It generally meets four times a year.

Nevertheless, the Steering Group will remain informed on CTIS, receiving an update every calendar quarter with KPIs and targets against which progress can be noted. This means that sequential process of information must be ensured so that the discussion in ACT EU Steering Group can help the EMA Management Board to take informed decisions as needed. The Steering Group will also be informed of urgent or pressing matters on an *ad hoc* basis as needed. The Steering Group will also have the opportunity to provide suggestions and feedback for improvements to the CTIS Agile product team.

2. Mandate

The mandate of the ACT EU Steering Group is to:

(a) Agree on the programme management structure to achieve the ACT EU objectives, based on the objectives and priority actions defined in the ACT EU founding document, as amended, (document in annex). The Steering Group can propose updates to that founding document for adoption by the EMA MB and HMA, as needed. The Steering Group may propose the creation of workstreams encompassing multiple priority actions.

(b) Oversee the set up and activities of the priority actions through the nomination of priority action coordinators and co-leads, with experts from EMA, HMA and EC, where applicable and the adoption of a multi-annual workplan with concrete deliverables, milestones and key performance indicators (KPI) with targets against which progress can be assessed.

(c) Coordinate and where possible consolidate the activities of the various working groups and parties involved in clinical trials in the EU, including streamlining or proposing streamlining.

(d) Provide direction and monitor the activities and deliverables from the different priority actions against the ACT EU objectives and workplan. Sign off ACT EU deliverables (e.g. guidance jointly developed by several groups); all deliverables put forward for endorsement will have been reviewed by the Trilateral Programme Board in advance. Monitor the health of the clinical trial environment in the EU, based on agreed (key) performance indicators and on the feedback received by sponsors.

(e) The Steering Group has delegated the management of the review of ACT EU website content to the EMA.

(f) Arbitrate in case of disagreement between working groups or other parties related to ACT EU priority actions.

(g) Identify critical issues related to the broad environment of clinical research, with the aim of recommending solutions to the European Commission, the EMA Management Board and/or the Heads of Medicines Agencies.

(h) Adopt the composition of the ACT EU Multi-stakeholder platform advisory group. Appoint the regulatory and stakeholder co-chairs. Discuss the views and strategic advice from the MSP AG on the ACT EU multi-annual workplan. Receive regular reports from the MSP AG meetings.

The ACT EU Steering Group has a decision-making role and will report to the EMA Management Board and HMA.

3. Membership

The chair of the ACT EU Steering group is provided by the Commission and includes nominated members from:

- The HMA (including the chair from the MG) – maximum 5 members
- The European Commission – maximum 2 members (in addition to the chair)
- The European Medicines Agency – maximum 2 members

In addition, the following will also be members:

- The chair of the EMA Management Board
- The chair of the Clinical Trials Coordination Group
- The chair of the Committee for Medicinal Products for Human Use (CHMP)
- A representative from the Network Portfolio Advisory Group (NPAG)

Members may delegate an alternate when they cannot attend a meeting. Nominations and changes in membership need to be notified to the secretariat as soon as possible. Observers may attend the meeting after approval by the chair.

4. Meeting arrangements

In order to fulfil its mandate, the ACT EU Steering Group will meet once a month and on an as-needed basis, via videoconferences.

The Steering Group can decide to create subgroups to cover specific elements of its mandate. Subgroups can invite other experts if necessary for the execution of their task.

The secretariat (invitations, agenda, minutes) of the group and its subgroups will be supported by the EMA, who join the Steering Group meeting as non-voting attendees.

Relevant documents to inform the discussions will be shared with the Steering Group at least 5 working days in advance unless exceptional circumstances occur.

5. Decisions by the group

The ACT EU Steering Group can adopt rules of procedure to describe the details of its processes.

As far as possible, the group shall adopt its opinions, recommendations or reports by consensus. In the event of a vote, the outcome of the vote shall be decided by simple majority of the members present at the meeting, provided a least one vote from each of the organisations (HMA, EMA, European Commission) was cast in favour of the majority vote. 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.