EMA/346295/2024

Meeting highlights – ACT EU Multi-stakeholder Platform Advisory Group

04 July 2024, 09:30-17:00 (CEST), Webex

Co-Chairs: Maria Jesús Lamas (Regulatory co-chair), Denis Lacombe (Stakeholder co-chair)

Opening remarks and outline of the day

The co-chairs welcomed participants to the Multi-stakeholder Advisory Group (MSP AG) meeting, underlining the importance of in-depth discussions on ACT EU activities and their impact on addressing stakeholders' needs. They highlighted the importance of having an open dialogue on real-life stakeholders' examples to identify key priorities and gaps for consideration by the ACT EU steering group during the revision of the ACT EU workplan.

1: ACT EU overview and discussion

An update was provided on the progress and upcoming plans on ACT EU initiative. Information on the presentations and priority actions (PAs) and their activities is available in the following link.
The MSP AG expressed general satisfaction with the progress made so far. However, the following points were discussed more in detail and identified as areas that would benefit from a more tailored exchange with the MSP AG at this stage: support to non-commercial sponsors, ensuring adequate funding for multinational trials, consolidated pilots of advice for clinical trials, addressing training needs for academia and small and medium enterprise (SME). The urgency of addressing the concerns raised, especially for CTR implementation, was acknowledged and further consideration will be given to involving more stakeholders in certain activities and simplifying processes. During the meeting it was mentioned how a multitude of activities are already in place to address the challenges originating from the changes to the EU regulatory framework for clinical trials. These initiatives include:

- CTR collaborate, led by CTCG and anchored to the ACT EU priority action on mapping and governance;
- Regular CTR surveys addressed to sponsors, led by the European Commission and part of the priority action looking at the CTR implementation;
- The establishment of MedEthicsEU;
- Activities of the European Commission Clinical Trials Coordination and Advisory Group (CTAG).

CTR implementation and support to non-commercial sponsors

The discussion focused on current activities to support particularly non-commercial sponsors. This included mapping existing initiatives at national level, and planning the establishment of a regulatory helpdesk which will offer dedicated support for using CTIS. Challenges in securing funding

for multinational clinical trials and the need for clearer definitions of non-commercial sponsors were highlighted. The challenges encountered by non-commercial sponsors were acknowledged, and the possibility of extending the information to include stakeholder initiatives were discussed.

Action:

- Consider sponsor input to complement the mapping of existing support initiatives
- Establishing a regulatory helpdesk to support non-commercial sponsors on regulatory and CTIS related matters. This helpdesk will work closely with the national contacts providing support to non-commercial sponsors.

EU level funding to support academic sponsors A paper with possible areas for EU-level funding to support academic sponsors conduct clinical trials was presented. The paper includes proposals covering the development of a Member State Network of national helpdesks, regulatory science training programmes for academia, encouraging clinical research network development and collaboration and the development of standard site agreements and other templates. The need for sustainable networks, EU-level funding, and effective coordination among funders was highlighted, with emphasis on addressing network gaps. The MSP AG stressed the importance of designing a comprehensive funding system that supports both non-commercial sponsors and SMEs, and also includes the medical device sector.
Prior to finalisation of the paper feedback from academic stakeholders will be solicited. The MSP AG will discuss at its next meeting the best approach to this consultation.

Action:

- MSP AG to provide further feedback on the best approach to consult academic stakeholders during the follow-up discussion at the next MSP AG meeting on 27 September 2024.

Consolidated pilots on scientific advice (SAWP/CTCG) and Pre-CTA
Clarifications on scope and process of the two pilots were provided, confirming their applicability to both commercial and non-commercial sponsors. Additionally, considerations regarding possible KPIs to measure the results of the two pilots were discussed. The need to ensure harmonisation in conducting clinical trials, consider the inclusion of other groups (i.e. PDCO, ethics committee) and ensure adequate support mechanisms were also addressed.

Training curriculum, training needs for academia and SME
The MSP AG flagged the importance of developing a comprehensive training strategy that encompasses regulatory, operational, and management aspects in addition to providing hands-on experience.

Action:

- Consider establishing a focus group to explore how to address training gaps in collaboration with the ACT EU priority action on Clinical Trials training curriculum.

The session concluded with a commitment to continue collaboration among stakeholders to achieve the goals set by ACT EU to improve the clinical trial environment in the EU. Availability of funding, training, and harmonisation of procedures are considered key areas to look at.

2: Stakeholder presentation on critical use-cases

Following a call to MSP AG permanent and *ad hoc* representatives to submit real-life examples describing challenges specific to each stakeholder group, 9 out of the 21 submitted topics were presented and discussed during the meeting.

2.1 CTA review process and CTR implementation

Three presentations were provided by representatives from Vaccines Europe, EORTC and EFPIA. The need to address dis-harmonisation and inconsistencies across the EU regarding CTR implementation was highlighted. The MSP AG stressed the need to urgently address, amongst others, issues with national requirements, the lack of harmonisation in assessment, the inflexibility in the CTA process and in the CTIS system, and the definition of low intervention clinical trial. Removing complexities and administrative burden, ensuring standardised approaches and definitions across the pharmaceutical and medical device sectors were further emphasized as urgent steps to further incentivise the EU clinical trial environment.

The MSP AG was informed about the ongoing efforts to address the points made through initiatives promoting best practices. These include the establishment of CTR Collaborate, the regular Clinical Trials Coordination Group (CTCG) Assessors round table (ART), the recent creation of MedEthicsEU, and activities led by the European Commission Clinical Trials Coordination and Advisory Group (CTAG).

A CTR Collaborate event will be held on 11 September, accessible via this link.

The MSP AG agreed to further reflect on the outlined aspects with a dedicated focus group.

Action:

- Explore the establishment of a stakeholders' focus group to interact with CTR Collaborate.

2.2 CTA and Scientific advice mechanisms

KWF provided a presentation outlining the challenges faced by academic developers and emphasised the need for budget support. The MSP AG further highlighted the necessity for better training, access to information, enhanced academic/regulators interaction, access to scientific advice and implementation of a co-funding model applicable to both academic sponsors and SMEs. The overall aim is to improve the promotion and conduct of clinical trials in the EU. A proposal was made to consider a KWF-funded trial as a pilot to follow all the steps of a clinical trial lifecycle. The ACT EU team acknowledged these points and clarified the current available support such as the academia mailbox, academia briefing, and the dedicated ACT EU priory action on support for non-commercial sponsors.

2.3 Ensure EU ecosystem is set up for future methodological innovations

Two presentations were provided by EURORDIS and TEDDY on how to future-proof the EU ecosystem in terms of methodological innovation. The MSP AG acknowledged the need to enhance the ecosystem through knowledge sharing and process simplification beyond the EU/EEA. Issues were raised regarding identified discrepancies between Paediatric investigation plan (PIP) recommendations and clinical trial applications for paediatric trials, which are being addressed through a closer interaction between PDCO/CTCG and EMA, as well as issues on long funding pathways.

The group agreed to further explore possible solutions in a dedicated workshop on platform trials/complex trials, with particular focus on the paediatric population, including participation from relevant representatives within the EU network.

Action:

- ACT EU matrix to explore a dedicated workshop on complex trials/platform trials under the ACT EU priority action on methodology.

2.4 Access to innovative medicines for EU patients and sharing specific challenges

UMC Utrecht provided a presentation on the operational barriers experienced when conducting multi-national investigator-initiated trials (IITs), taking into consideration that a one-size-fits-all approach might not always be suitable. The issues raised were both regulatory and operational. It was mentioned that clinical trials need to be patient-oriented and flexible, with a risk-based approach being considered, particularly for low intervention trials, considering ongoing ICH E6 R3 revision. The OECD framework was mentioned as an approach to simplifying regulatory processes by introducing a stratified approach that is based on the marketing authorisation status of the medicinal product being investigated. Regarding training, the need for more support and knowledge sharing for new generations of investigators was also flagged, along with target training material on the use of CTIS.

2.5 Patient engagement in clinical trials for paediatric population

Meaningful patient involvement in clinical trials for the paediatric population was brought to the attention of the MSP AG by eYPAGnet. The group agreed on the importance of transformative changes to boost patient involvement in clinical trials and the need to optimise parents'/patients' input across the various aspects of the clinical trial life cycle. CTCG is working on a project focused on this aspect. The ACT EU team supported this point and confirmed planned discussions on this topic at the 2025 DIA workshop. Additionally, they will bring this topic to the attention of the ACT EU Steering Group as part of the revision of the ACT EU workplan.

Action:

- ACT EU team will bring topic to the attention of the ACT EU Steering Group as part of the revision of the ACT EU workplan.

2.6 Clinical trials data accessibility

The CDDF presentation addressed accessibility to data about clinical trials, considering CTIS and EudraCT public websites as possible data sources for downloading and accessing relevant information. The focus is on public information about ongoing trials available for recruitment in the EU, as this information has in the last few years tended to come from US data sources (e.g., clinicaltrials.gov). The presentation highlighted the use of CTIS (and EudraCT) public data to describe the oncology research landscape in EU and to help build and expand networks for multistate clinical trials in oncology and specific priority areas within oncology. EMA team clarified that enhanced features of the CTIS public portal are expected to be implemented in September, allowing export of information.

3: Consolidation discussion, summarising and closing

3.1 Consolidation discussion, summarising and closing

The co-chairs were pleased with the valuable contribution and engagement achieved during the meeting. They emphasized that the feedback and input received from the group will be assessed and considered for further discussion with the ACT EU Steering Group This will help determine how each reported priority, including those not discussed during the meeting, could be addressed in the planned revision of the ACT EU workplan at the end of the year.

The stakeholder representatives re-emphasized the need for simplification, harmonisation and urgent action. The sense of urgency to address the identified issues, identify concrete actions and implement solutions swiftly was acknowledged by the co-chairs, Commission representative and EMA representative. The meeting conclusion also underscored the importance of collaboration among all stakeholders, including regulators, sponsors, and patient groups. Future workshops, meetings, and clear action plans were proposed to ensure that the discussed improvements are put into practice.