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Accelerating Clinical Trials in the European Union (ACT EU)

Concept paper: an EU multi-stakeholder platform for improving the EU clinical trials environment

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This concept paper provides the outline of the ACT EU multi-stakeholder platform following consultation with stakeholders.

Background

In recent years the clinical research landscape has faced increasing complexity, with a lack of harmonisation of regulations and fragmentation of activities and responsibilities across Member States. The EU Clinical Trials Regulation (CTR), which came into force in January 2022, is intended to introduce greater harmonisation in the way clinical trials are authorised in the EU. As regulations change and advances are made in methodologies and technology, the EU clinical trials environment needs to ensure that this progress reflects the needs of key stakeholders.

Accelerating Clinical Trials in the EU (ACT EU) is a joint initiative of the European Commission, Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA). The vision of ACT EU is to make the EU a more attractive region for clinical research by improving and transforming the EU clinical trials environment. Recognising the important role of stakeholders in the future of the clinical trials environment in the EU, the ACT EU initiative encompasses the establishment of a multi-stakeholder platform.

The establishment of an MSP is reflected in the ACT EU multi annual workplan and has been endorsed by clinical trials stakeholders (public consultation on the ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion; ACT EU multi-stakeholder kick-off workshop).

ACT EU multi-stakeholder platform

Scope of the ACT EU multi-stakeholder platform

The ACT EU multi-stakeholder platform (ACT EU MSP) is a vehicle for facilitating dialogue and collaboration between regulators and clinical trials stakeholders to further improve the clinical research environment in the EU. The ACT EU MSP makes use of engagement tools and initiatives to bring together key stakeholders, allowing them to collaborate and share their views on relevant topics relating to the ACT EU activities.

The scope of the platform therefore encompasses all aspects of clinical trials, including design, conduct, analyses of results, regulatory aspects, transparency and patient engagement.

Objectives of the ACT EU multi-stakeholder platform

As outlined in Figure 1, the MSP objectives are as follows:

- accelerate change and innovation in how EU clinical trials are regulated, designed, conducted and evaluated, to maximise efficiency and guarantee value for patients and citizens. To achieve this, it is critical that stakeholders can provide their views on ACT EU activities, including their prioritisation, for example by identifying, discussing and proposing solutions to address all challenges linked to scientific, technical and regulatory aspects of clinical trials, from their design to their implementation;
- establish regular forums to bring clinical trial stakeholders together to allow an exchange of views with regulators and among themselves;
- gain a better understanding of the needs, perspectives and roles of different stakeholders, which will build trust and open new avenues to drive change;
- identify stakeholders' training and capacity-building needs;
- encourage and inform change across scientific, operational, legal, and regulatory areas;
- ensure timely transparency and sharing of positions reached with the relevant stakeholder groups.

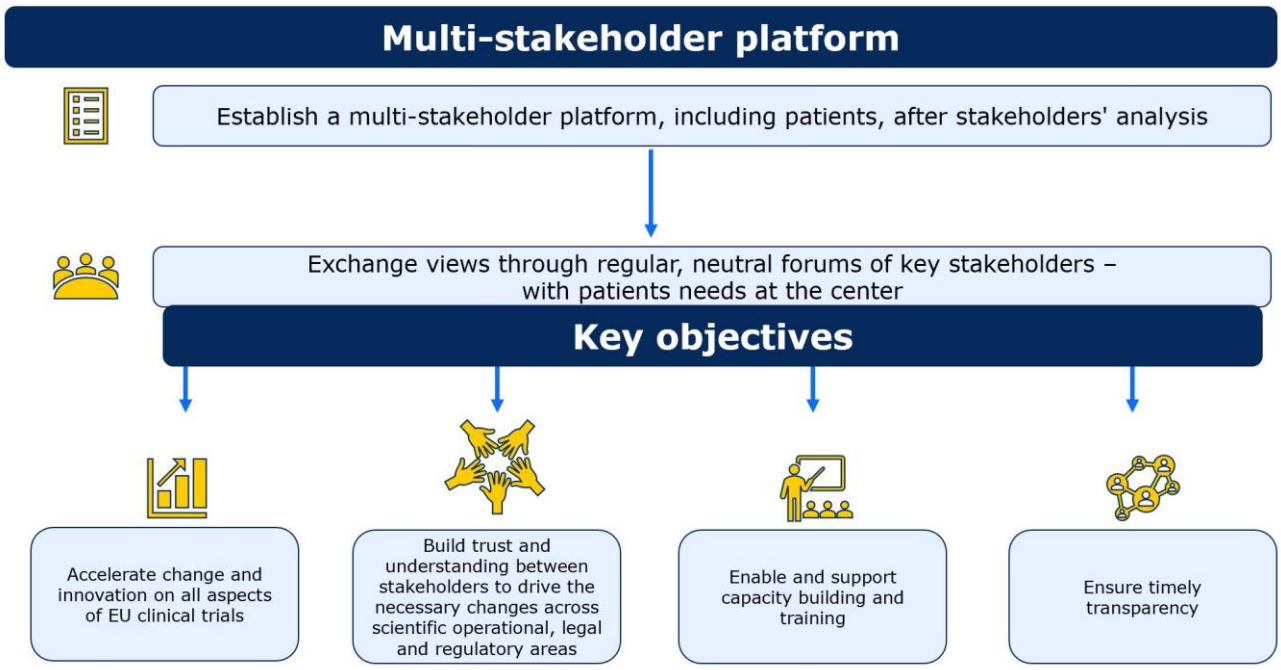

Figure 1: Objectives of the ACT EU multi-stakeholder platform

Configuration of the of the ACT EU multi-stakeholder platform

The ACT EU MSP includes the following elements to enable dialogue and cooperation between stakeholders and regulators:

1. ACT EU multi-stakeholder events;

2. the MSP Advisory Group (MSP AG);

3. other engagement tools for gathering feedback from stakeholders, such as consultations, surveys, reference groups.

1. ACT EU multi-stakeholder events

When organising multi-stakeholder events, stakeholder participation is carefully considered by the ACT EU Priority Actions to ensure adequate representation of all concerned groups.

2. MSP Advisory Group

The MSP AG initially consists of representatives of key stakeholder groups including:

- patients/consumers organisations;

- industry EU trade organisations;
- healthcare professional organisations;
- non-commercial European clinical data and translational research organisations and networks;
- research funders.

Additional extension to other stakeholder groups will be considered based on the experience gathered.

The ACT EU regulatory partners will support the MSP AG, with representation from the ACT EU Priority Actions joining discussions as needed. This will promote dialogue between regulators and stakeholders, while maintaining strong links to the relevant ACT EU initiatives. The inclusion of ACT EU representatives will also enable a continued information flow between the MSP AG and other European regulatory clinical trial structures.

Additionally, acknowledging the important complementary initiatives taking place between ACT EU and ethics bodies, the MSP AG will also include 2 ethics committee representatives.

Based on the topics discussed, *ad hoc* involvement of experts from other groups is foreseen. This allows the participation of other international bodies, Health Technology Assessment (HTA) bodies and payers where relevant.

By ensuring a balanced representation of views and interests from represented stakeholders, the MSP AG enables the development of an understanding of different stakeholder group perspectives and needs, in addition to exchanging on:

- strategic advice regarding the ACT EU workplan (i.e., identification of stakeholder priorities);
- operational advice for ACT EU initiatives (i.e., identification of experts and engagement methodology).

The MSP AG representatives are selected via public call for expression of interest, and all nominations are evaluated by the ACT EU Steering Group (ACT EU SG)[1] against predefined guiding criteria.

The MSP AG meets at least twice a year (and more frequently if needed) normally via virtual/hybrid meetings, in addition to *ad hoc* written consultations.

Each member actively contributes to the work of the MSP AG by:

- providing their views and strategic advice on the activities of the ACT EU workplan;
- identifying stakeholders' needs, concerns, challenges and priorities;
- advising on stakeholder engagement and communication;
- ensuring timely transparency and sharing of positions reached with the group they represent.

The MSP AG has two co-chairpersons responsible for running the MSP AG meeting. One co-chair is a representative of ACT EU and is nominated by the ACT EU SG. The other co-chair representing

[1] ACT EU SG: the group is composed of a chair (provided by the EC) and includes up to five nominated members from the Heads of Medicines Agencies (HMA), two members from the European Commission (EC) and two members from EMA. In addition, membership will include the chairs of the EMA Management Board, Clinical Trials Coordination Group, Committee for Medicinal Products for Human Use (CHMP) and a representative from the Network Portfolio Advisory Group (NPAG).

stakeholders is selected from MSP AG non-commercial representatives following a call for candidates and agreed by the ACT EU SG.

EMA provides a secretariat that is responsible for the organisation of MSP AG meetings. This includes setting up meetings, publishing agendas and meeting highlights and providing feedback on behalf of the MSP AG to the ACT EU SG.

3. Other engagement tools for gathering stakeholders' feedback

To ensure optimal engagement of clinical trials stakeholders, dedicated surveys and public consultations are carried out in line with the ACT EU workplan and following advice from the MSP AG. These activities further reinforce engagement of stakeholders and further offer opportunities to contribute to the discussions.

Conclusion

ACT EU is an initiative with well-defined objectives and priorities, which recognises the importance of ensuing that stakeholders' views are adequately represented in discussions on how to improve the EU clinical trials landscape. The ACT EU MSP provides a framework by which to gather and share these views. The MSP will promote dialogue between the stakeholders and the ACT EU communities, which is key to ensuring clinical trials in the EU continue to offer EU citizens long lasting benefits in terms of access to safe, effective and innovative medicines.