Public consultation on ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion

Fields marked with * are mandatory.

Background information

The Accelerating Clinical Trials in the EU (ACT EU) is an EC-HMA-EMA initiative that was launched on 13 January 2022 with the aim of further developing the EU as a competitive centre for innovative clinical research. This objective was also reflected in the Clinical Trials Regulation, which aims to establish high standards of public transparency and safety for clinical trials participants.

The success of clinical trials relies on a multitude of stakeholders and therefore regular dialogue between all parties involved can help to identify key advances in clinical trial methods, technology and science or roadblocks, and by finding practical solutions to enable and drive change. ACT EU outlines a set of 10 priority actions (ACT EU 2022-2026 workplan), with a key action being the establishment of a multi-stakeholder platform (MSP).
The ACT EU MSP is expected to be the main forum where stakeholders can discuss all aspects related to clinical trials and develop a better understanding of each other's perspectives. The platform is intended to meet regularly and discuss topics according to an established workplan. It is foreseen that the MSP will be supported by ad hoc topic groups responsible for more technical discussions. The "ACT EU multi-stakeholder platform concept paper" outlines the key objectives and governance aspects of the MSP. It is anticipated that the ACT EU MSP kick-off meeting will take place at the beginning of Q2 2023.

In order to initiate the setting up of the platform and its workplan, a public stakeholder consultation is hereby launched. We would appreciate your feedback and interest in being part of the ACT EU MSP and on the topics you consider high priority for discussion in 2023-2024.

The completion of this survey is expected to take 10-15 minutes and will be available until the 3rd of March 2023 (midnight CET).

In case of queries please contact: ACTEU@ema.europa.eu.

We take this opportunity to thank you in advance for your contribution!

Data protection statement for 'Public consultation on ACT EU multi-stakeholder platform (ACT EU MSP) participation and priorities for discussion'.

By participating in this survey, your submission will be assessed by EMA. However, with exception of question 4, EMA does not collect, process or store your personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format. If in response to question 4 you provide your personal details, you would need to confirm that you have read and understood the data protection statement enclosed below.

Survey

1.Affiliation

- ○ Academics as users of clinical trial data
- ○ Clinical Research Organisations (CRO) and other clinical trial service providers, including consultants
- ○ Clinical trial investigators
- ○ Ethicists and ethics committee members
- ○ Healthcare professionals (HCP) and HCP organisations
- ○ Health technology assessment (HTA) bodies
- ○ Inspectorates
- ○ Patients and patient organisations
- ○ Payers
- ○ Policy makers
- ○ Regulators: medicines approval regulators, clinical trial assessors, safety (Pharmacovigilance in clinical trials) assessors, clinical development advisors, and medical device bodies
- ○ Research funders
- ○ Sponsors, incorporating academia and pharmaceutical companies, notably small and medium-sized enterprises (SMEs)
- ◉ Other

1.1 If "Other" was selected, please specify:

On profit independent drug bulletin

2.In order to deliver its objectives, ACT EU has a series of priority actions. Please select the top 3 topics based on ACT EU priority actions that you deem the MSP should focus on initially. For each of the priority action selected, additional details can be added.

between 1 and 3 choices

- ☑ 1.The successful and timely implementation of the Clinical Trials Regulation (CTR) and its implementing acts.
- ☐ 2.Good Clinical Practices (GCP) modernisation informed by the revision of ICH guidance.
- ☑ 3.The analysis of clinical trial data to support policymaking, funding on research outputs, and to support evidence-based decision making.

- [ ] 4.Need for methodologies guidance such as on Machine Learning/Artificial Intelligence impacted CTs, decentralised CTs and In Vitro Diagnostics Regulation/CTR interface (to strengthen links between innovation and scientific advice fora).
- [x] 5.Clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs (serving as an educational "ecosystem").
- [ ] 6. Regulatory support structures for evidence generation and enabling innovation.

Additional comments on topic 1

500 character(s) maximum

Additional comments on topic 3

500 character(s) maximum

Additional comments on topic 5

500 character(s) maximum

2.1 Taking into consideration the ACT EU and MSP objectives, list any additional priority topic not included in the above selection.

1000 character(s) maximum

Need for methodologies guidance to support meaningful clinical research providing reliable and robust data and results giving insight on the efficacy based on clinical criteria and safety of the medicinal product and its utility for patients.
Need for methodologies guidance to support identification of research bias (to strengthen innovation through clinical meaningful research)
Clinical trials training curriculum modules on drug development for evidence generation and meaningful and reliable clinical research

3. The ACT EU multi-stakeholder platform concept paper outlines the scope, objectives and organisation of the MSP. Please provide any comments you may have on the proposal.

2000 character(s) maximum

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“The experience with the COVID-19 pandemic has clearly demonstrated the need to accelerate change and innovation in the way that clinical trials are designed, regulated and conducted to maximise their efficiency and utility to patient access to treatments.”

We recommend to add following information:
Among lessons learnt from the pandemic, international regulators, including EMA, focused on the support of large randomized controlled clinical trials that are most likely providing robust and reliable evidence required for regulatory decision-making, and evidence that can be used for patient care, including clear and transparent benefit-risk analyses. Regulators also encouraged investigators to make results fully and quickly accessible so that the global research community can benefit from that information https://www.ema.europa.eu/en/news/international-regulators-provide-guiding-principles-covid-19-clinical-trials + https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/guidance-developers-companies/covid-19-guidance-research-development

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“MSF composition”: should also include independent clinical research experts

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Transparency : “MSP agendas, highlights and key outputs are expected to be published in respect of confidentiality”

If the aim is to build mutual trust and improving the EU clinical trials landscape for the benefit of European citizens, FULL TRANSPARENCY is needed. The positions and perspectives of the different participants should be transparent for the general public and those not participating in the process.

4. Would your organisation be interested in joining the MSP?

- ○ Yes (By clicking here you demonstrate your consent to process personal data as explained in the data protection statement which you can read by clicking here. If you do not wish to consent and provide this data, simply click ‘no’ as an answer for this question.)
- ◉ No

Contact

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