



ACT EU Multistakeholder platform concept paper consultation and kick-off meeting

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An agency of the European Union



Introduction



- Initiative launched on 13 January 2022 with the aim of **developing the EU as a competitive centre for innovative clinical research.**
- Objective also reflected in the in the **Clinical Trial Regulation**, whose aim is to **establish high standards of public transparency and safety for clinical trial participants.**

Introduction



- Amongst other priorities, ACT EU recognises that for the clinical trial environment to evolve with advances in regulation, methodologies, technology and science, there is a **need for multi-stakeholder discussions** to drive and support change.
- Priority Action 3: **establish a multi-stakeholder platform, including patients, after stakeholder analysis.**

Multi-stakeholder platform proposal



To enable clinical trial transformation, bring together key stakeholders, in a neutral forum, for regular, efficient, balanced discussions – putting patients at the centre.



Encompass all aspects of clinical trials including design, conduct, statistical analysis, proposal of revision of regulation(s), transparency of data and patient engagement.



Enabling innovative approaches through multi-stakeholder collaboration.



Enable and support pilots of improvement.



Enhancing trust and understanding between stakeholders and enabling equal, co-creation of change.

Disseminate outcomes.



Multi-stakeholder platform proposal

Key players identified (final composition subject to public consultation feedback)

patients/health
care providers

regulators/
inspectorates

academia/
researchers

health technology
assessment bodies

ethicists

payers/policy
makers

clinical trial investigators/sponsors/
clinical research organisations



ACT EU Steering Group

ACT EU MSP plenary meetings main activities:

- Identification and prioritisation of workplan topics
- Presentation of the workplan topics and call for *ad hoc* topic groups volunteers
- Discussion of proposals and pilot projects for clinical trial improvement
- Progress report to ACT EU SG



Ad hoc topic groups main activities

- Coordinate meetings, work and pilots
- Record work and decisions
- Draft proposals
- Present updates/proposals to MSP plenaries

- Initial workplan priority topics subject to public consultation feedback and linked to ACT EU objectives.
- Ad hoc topic groups formed by experts in the specific field analysed.
- The outcomes/proposals from ad hoc topics group are agreed at MSP level and endorsed by ACT EU SG.

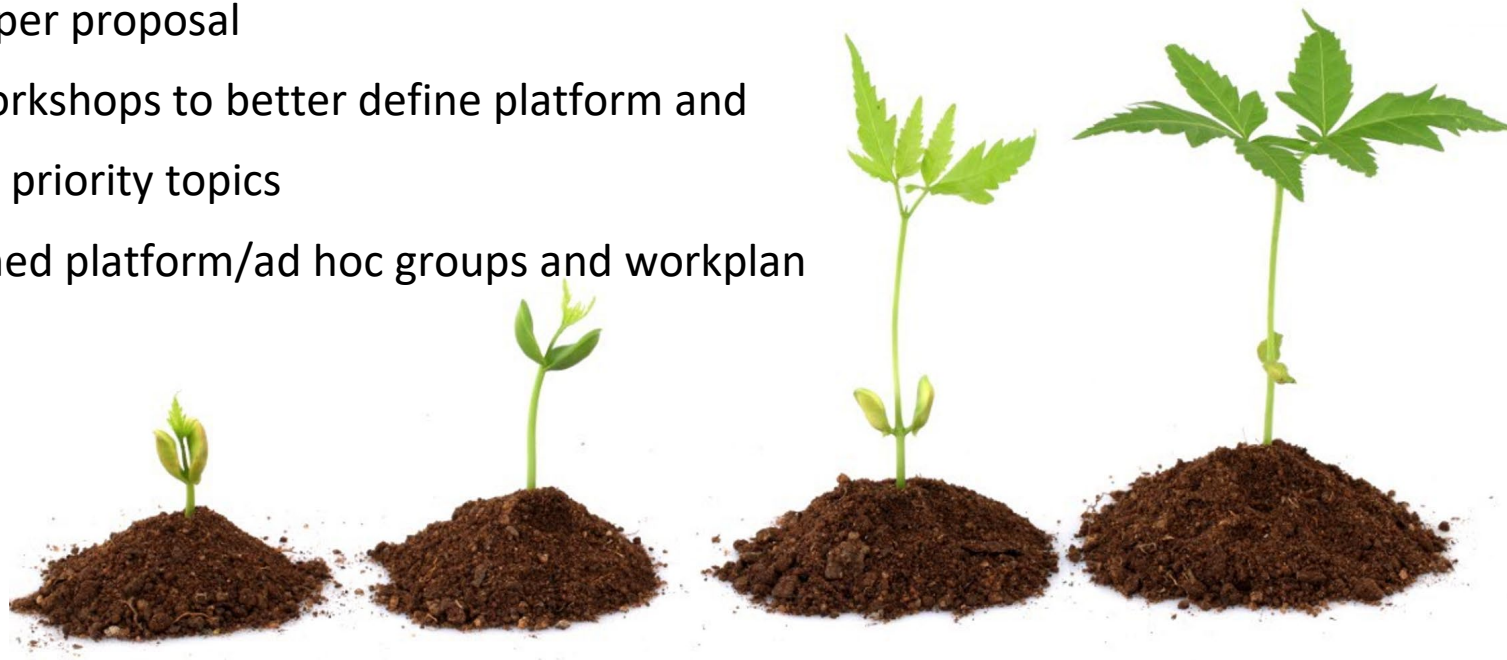
Multi-stakeholder platform proposal


February 2023: launch of a 4 weeks [public consultation](#) to obtain feedback on:

- Interest in being part of the platform
- Priority topics for initial discussion
- MSP concept paper proposal

2023-2024: MSP workshops to better define platform and start discussions on priority topics

2025: well established platform/ad hoc groups and workplan



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- ACT EU seeks to deliver the **clinical trial innovation**.
 - **Dialogue** and **collaboration** across stakeholders is the only way to bring EU clinical trials towards the future.
 - The **multi-stakeholder platform** represents the main forum where all stakeholders are enabled to share each other's **perspectives** and develop **proposals for improvement** on several aspects of clinical trials.

Additional information available on [ACT EU webpage](#).

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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