Outcome of public stakeholder consultation on ACT EU multi-stakeholder platform

Multi-stakeholder platform kick-off meeting
22-23 June 2023

Presented by Giacomo Capone, Data Analytics and Methods Task Force- Clinical Trial Transformation Workstream
European Medicines Agency

Background

- Priority Action 3 aims to establish a multi-stakeholder platform (MSP);
- Concept paper on MSP published on 20 Jan 2023: "Priority Action 3 concept paper: an EU multi-stakeholder platform for improving clinical trials":
  - Objectives, composition, organisational aspects.
- Public consultation on ACT EU multi- stakeholder platform (ACT EU MSP) participation and priorities for discussion (03 Feb 2023- 03 Mar 2023).

20 January 2023
EMA/41656/2023

Accelerating Clinical Trials in the European Union (ACT EU)

Priority Action 3 concept paper: an EU multi-stakeholder platform for improving clinical trials

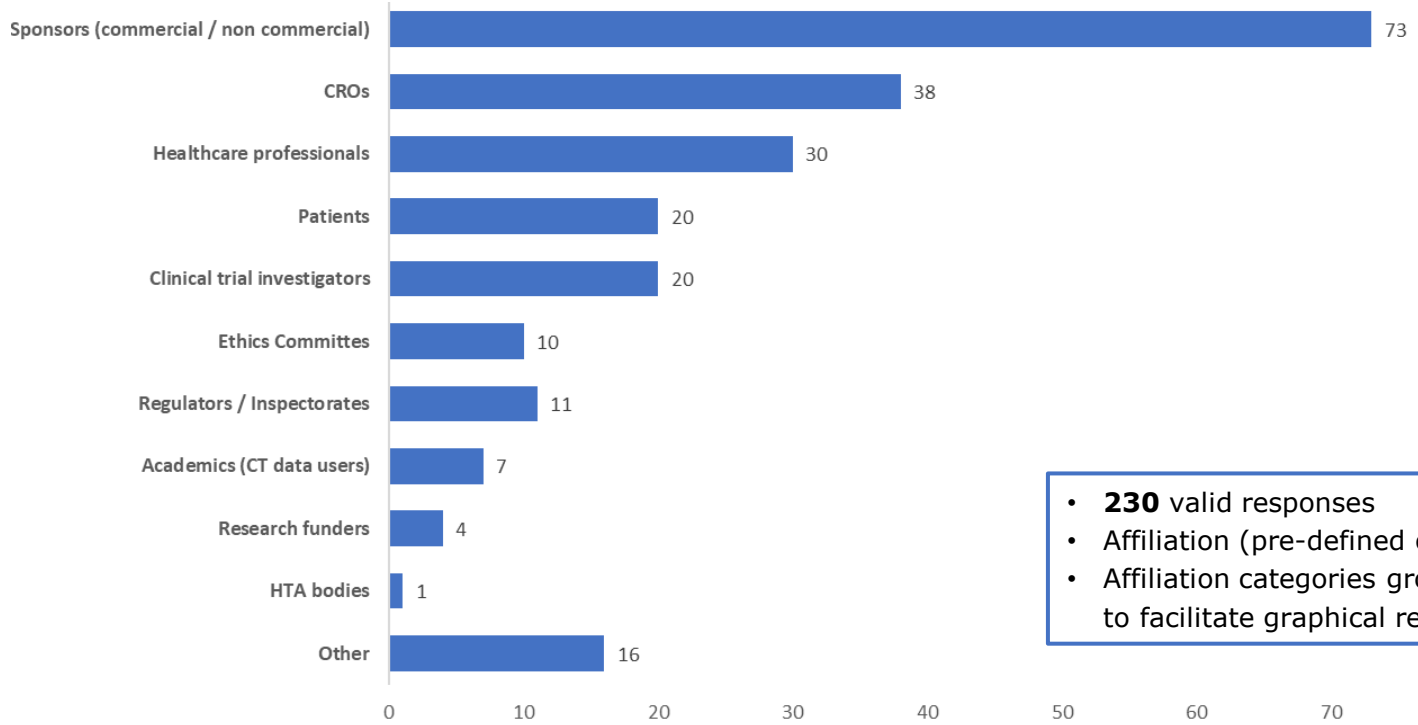
Sent for comments to ACT EU co-leads	June 2022
Sent for comments to ACT EU matrix	18 November 2022
Adopted by ACT EU Steering Group	27 January 2023

Content of the public consultation

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

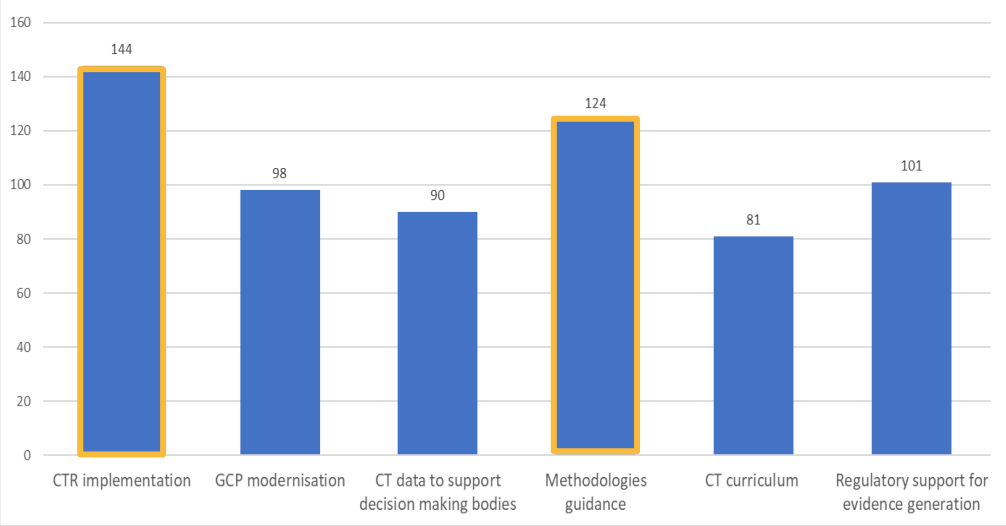
- **Affiliation** (pre-defined options).
- **Identify priorities** for discussion based on ACT EU objectives (6 options).
- Possibility to add new priority topics (open question).
- Comments on the **concept paper** (open question).
- Expression of **interest** to take part in the MSP.

Responses grouped by affiliation



- **230** valid responses
- Affiliation (pre-defined options).
- Affiliation categories grouped and/or abbreviated to facilitate graphical representation.

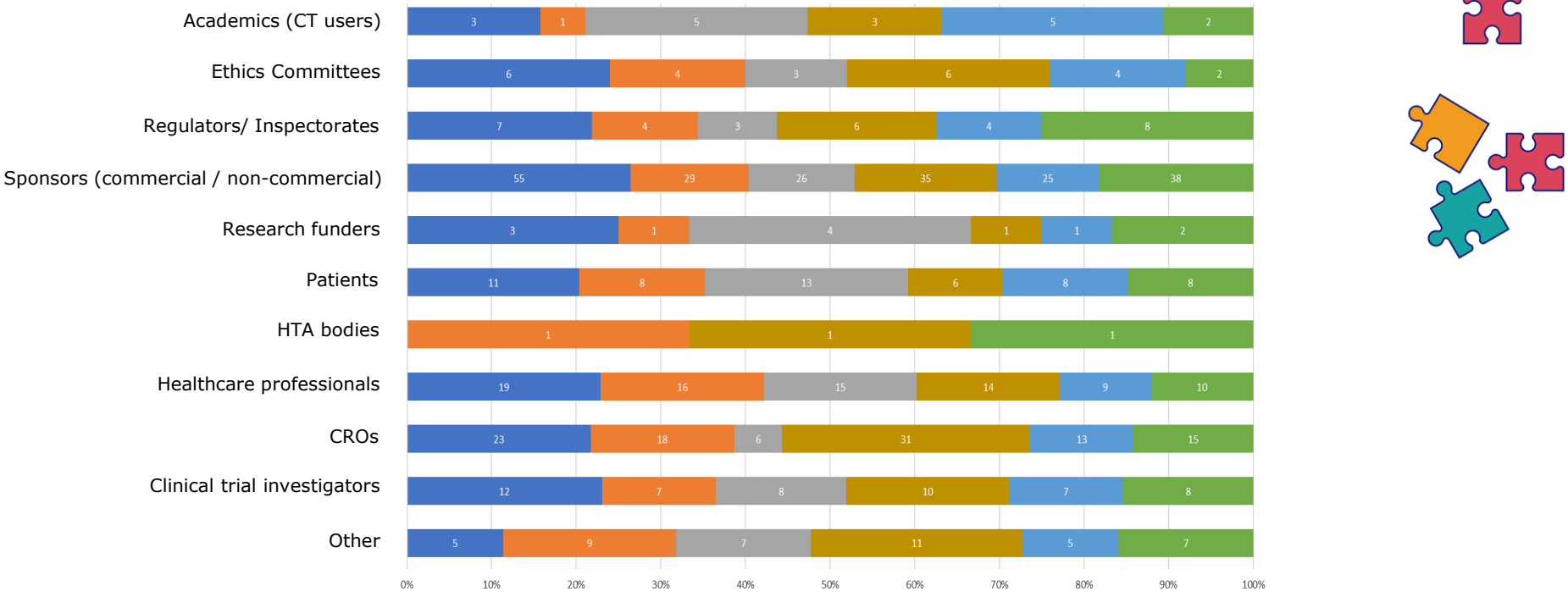
Most selected topics based on ACT EU priority actions



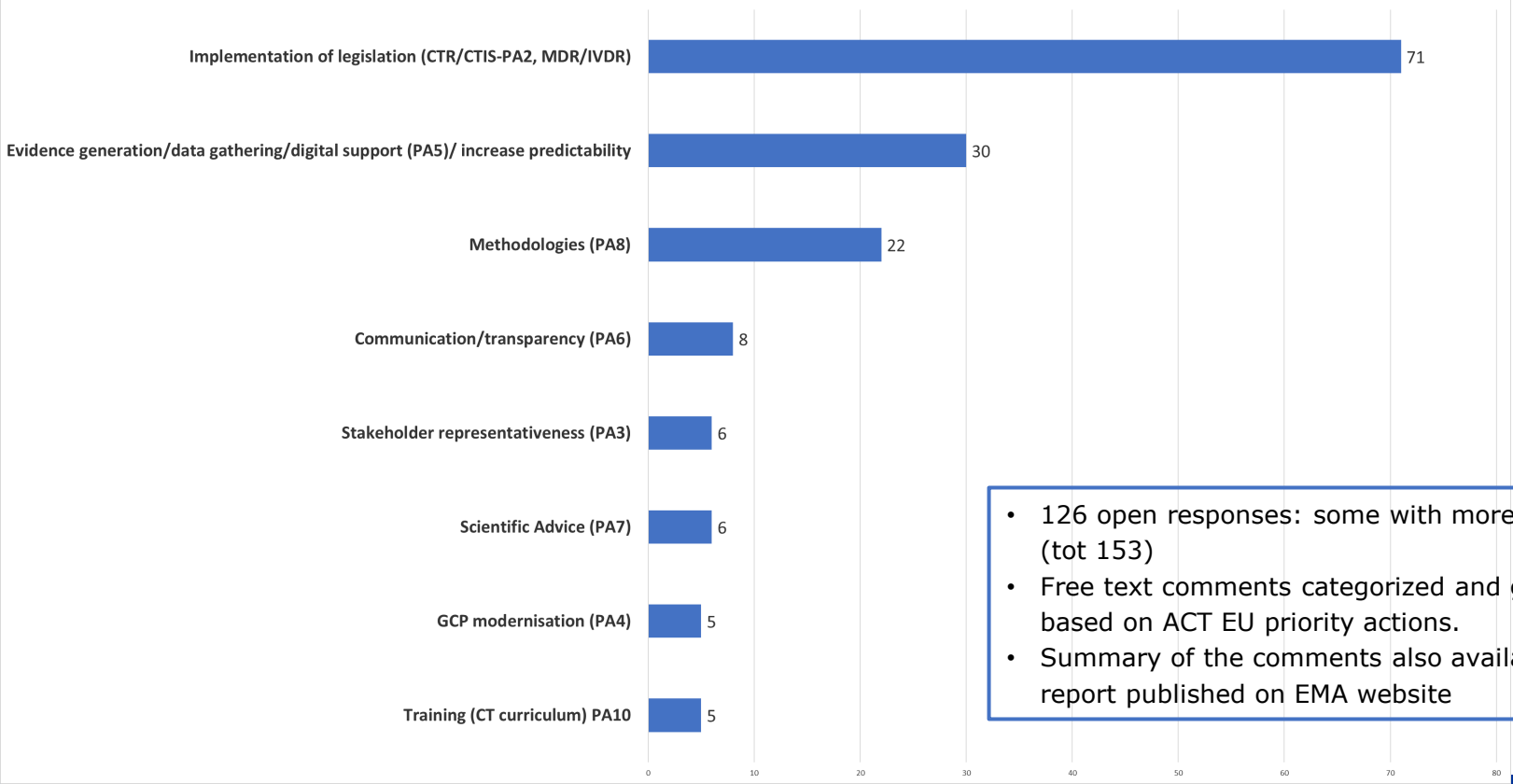
6 pre-defined options

- The successful and timely implementation of the Clinical Trials Regulation (CTR) and its implementing acts.
- Good Clinical Practices (GCP) modernisation informed by the revision of ICH guidance.
- The analysis of clinical trial data to support policymaking, funding on research outputs, and to support evidence-based decision making.
- Need for methodologies guidance such as on Machine Learning/Artificial Intelligence impacted CTs, decentralised CTs and In Vitro Diagnostics Regulation/CTR interface.
- Clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs.
- Regulatory support structures for evidence generation and enabling innovation.

Most selected topics per affiliation group

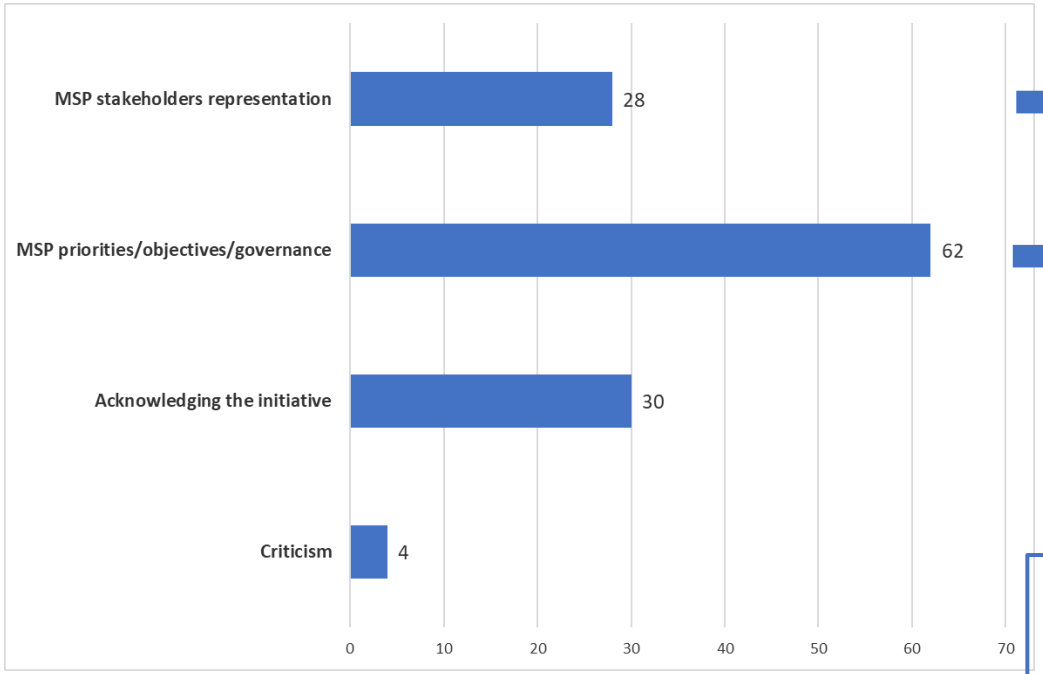


Additional priority topics (open question)



- 126 open responses: some with more than 1 topic (tot 153)
- Free text comments categorized and grouped based on ACT EU priority actions.
- Summary of the comments also available in the report published on EMA website

Comments on MSP concept paper (open question)

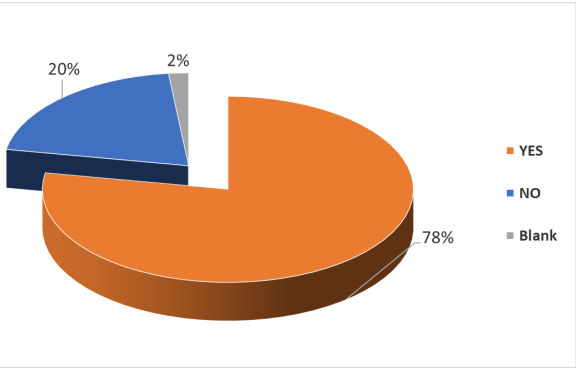


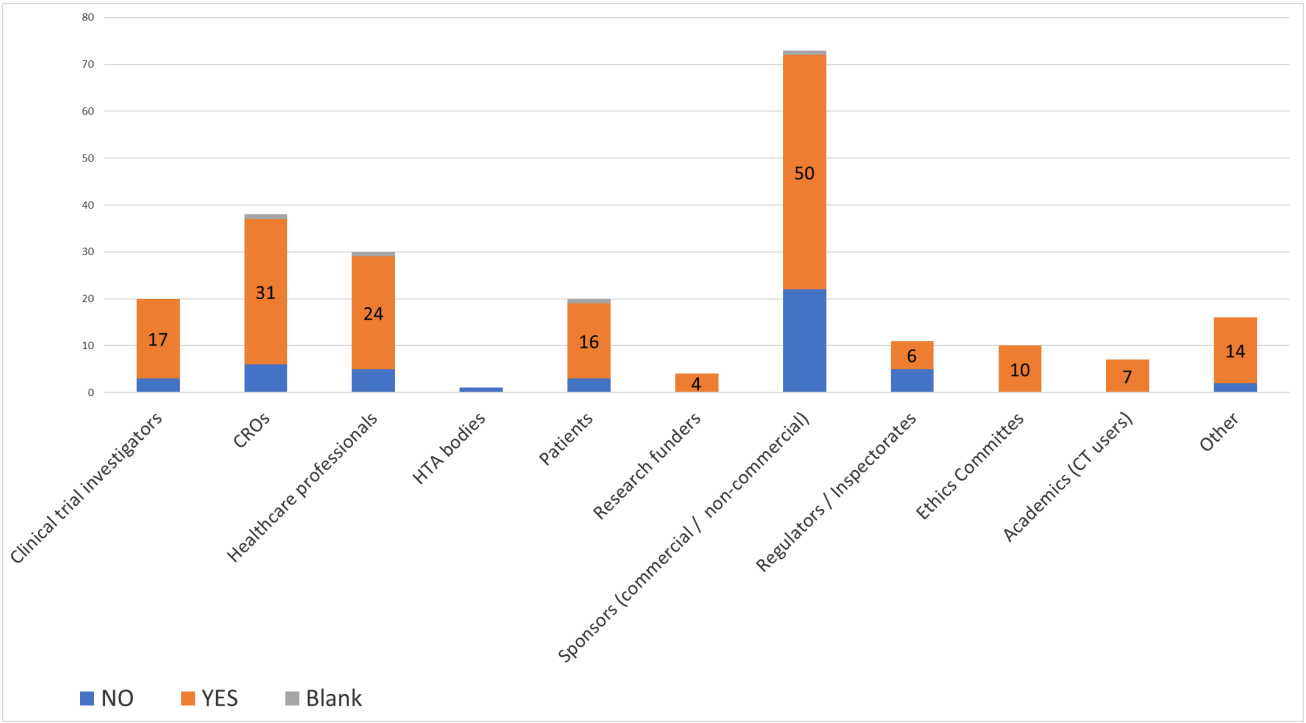
Ensure adequate representation of key groups including patients, clinicians, national and international authorities, and ethics committees in the platform.

- innovative technology/digital health;
- rare diseases, paediatrics, oncology;
- harmonisation of requirements of EU and non-EU initiatives and national support;
- patient equity and acceleration of diagnosis

- 102 responses: some with more than 1 topic (tot 124)
- Free text comments categorized and grouped

Interest in being part of the MSP





Any questions?

Further information

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