



ACT EU update

MSP advisory group meeting
18 June 2026

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Now published: ACT EU workplan for 2026-2027



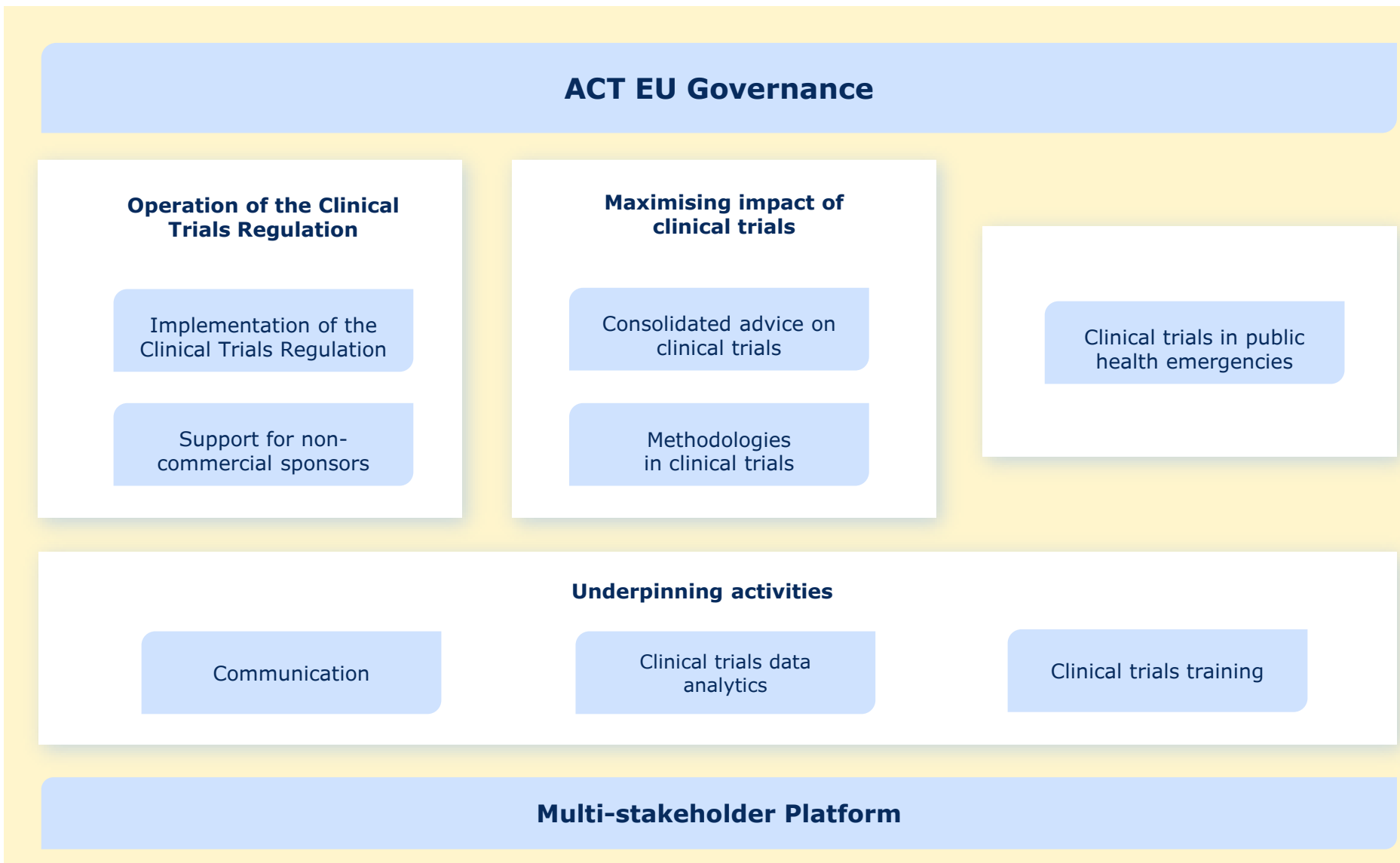
Our Vision

Better, faster, smarter clinical trials.

Our Objectives

- Engage stakeholders, patients
- Strengthen EU competitiveness
- Enable innovation
- Facilitate inclusive clinical trials
- Foster excellent scientific and regulatory advice
- Clarify EU position at international level
- Provide capacity building, training

ACT EU Programme Structure



ACT EU events overview

Events	2026/2027
Quarterly meetings of the MSP AG	2026: 20 March, 18 June, 17 September, 22 October (annual) F2F 2027: three quarterly meetings + annual meeting in Q4
Webinar – Guidance on conduct of clinical trials in PHE	8 April 2026
Webinar – Contractual agreements	16 April 2026
Workshop on paediatric clinical trials with EnprEMA (F2F)	12 May 2026
Workshop on AI and data forum with NDSG (F2F)	12/13 November 2026
ACT EU annual matrix meeting (F2F in IE)	17/18 November 2026
Workshop on multiplicity and platform trials (F2F)	27 November 2026
Workshop on fostering clinical research by NCS	Q4 2026
Workshop on risk-based approaches	Q1 2027
Workshop on activities on PHE	Q1 2027
Workshop on AI use in clinical trials	Q2 2027

ACT EU deliverables* overview

Deliverables	2026/2027
Regulatory helpdesk 15-month report	25 February 2026
Roadmap of guidance documents MWP/CTCG/HTA CG	2 March 2026
Pilot on consolidated advice - interim analysis report	10 March 2026
Webinar for NCS: France and Portugal	28 January and 21 April 2026
ACT EU workplan 2026/2027	7 May 2026
Video on clinical trial and KPIs	20 May 2026
Pilot on consolidated advice – learning from the pilots, final report	Q4 2026
RFI document update	Q4 2026
Revision of MSP AG composition and mandate	Q4 2026

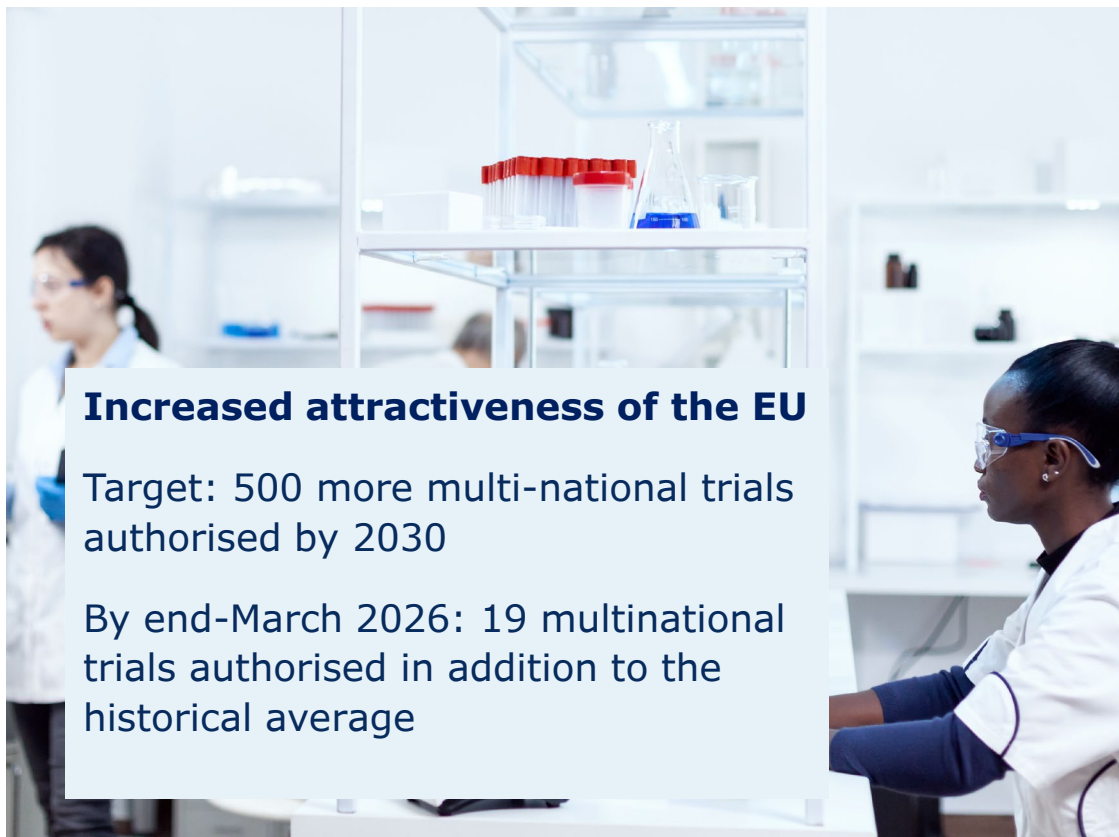
*The table above refers to publicly available documents

ACT EU deliverables* overview

Deliverables	2026/2027
Simplified package and language requirements for CTA in PHE	Q4 2026
Guidance of conduct of clinical trials in PHE	Q4 2026
Recommendation on expedited assessment in PHE	Q4 2026
Paper on publicly available CT data	Q3 2026
Paper on research priorities paper	Q3 2026
Signposting of existing trainings on clinical trials	Q4 2026
Launch of patients panels	Q1 2027
Follow up report on the use of regulatory helpdesk	Q1 2027
Paper on underrepresented population in CT	Q1 2027

*The table above refers to publicly available documents

Progress against 2030 EU clinical trial targets



Increased attractiveness of the EU

Target: 500 more multi-national trials authorised by 2030

By end-March 2026: 19 multinational trials authorised in addition to the historical average



Faster access to treatment

Target: 66% of trials recruit participants within 200 days from application submission by 2030

By end-March 2026: 40.5% of trials meet this timeline

Quarterly progress reports published on the ACT EU website



Updates on ACT EU activities

Multi-stakeholder Platform Advisory Group

Contractual agreements

- Webinar held on 16 April, 430 participants
- Closely aligned with KPI on speed of access to treatment
- [Agenda](#), [presentations](#) and [report](#): national and EU level experiences on clinical site agreements between sponsors and trial sites
- Analysis of preliminary feedback shows interest on sharing knowledge and experience in the different Member States
- Next steps are being defined, engaging with stakeholders

Serious breaches

- Bring under the ACT EU Programme the focus group on management of serious breaches to streamline the process for reporting of serious breaches

Implementation of the Clinical Trials Regulation

- Draft guidance on risk-based approaches being revised and updates expected in Q3 2026.
- Preparations for workshop on risk-based approaches to be hold on Q1 2027

Support for non-commercial sponsors (NCS)

- 5th webinar to support academic network organised with INFARMED PT (previously organised with IE, AT, BE and FR)
- They represent a good opportunity to explain regulatory options available at National and European level to support the conduct of multinational CT by NCS and hear from sponsors about major obstacles encountered
- CTIS data driven strategy for a more structured approach to support non-commercial sponsors is being developed, annual event planned for Q4
- 15-month [report](#) on the support delivered through the helpdesk for NCS has been published

Consolidated advice

Current status of the procedures:

- Pre-CTA → 28 applications received; 23 concluded, 2 rejected and 3 ongoing
- SAWP/CTCG → 18 applications received; 13 concluded and 5 ongoing

- Considerations around Pre-CTA to become permanent offer in Q4 2026:
- SAWP/CTCG to continue as pilot

- Interim analysis published in March [Consolidated advice pilots interim report March 2026](#)

Clinical trials methodologies

EnprEMA-ACT EU workshop on paediatric clinical trials (12 May)

- [Agenda](#) and [presentations](#): strengthen collaboration between PDCO/CTCG, meaningful inclusion of children and families' perspectives in trial design
- 500 Participants (hybrid event)
- Report to be published
- Follow up activities being considered by ACT EU & EnprEMA with focus on patient engagement, access to data and platform trials

AI and Data Forum organised by NDSG (12/13 November)

- Dedicated session to discuss use cases on the use of AI in clinical development, call for topics end June/beginning of July, further discussion expected at the September AG meeting

Workshop on multiplicity and platform trials (27 November)



Public Health Emergencies (PHE)

Simplified clinical trial application package in PHEs

- Guidance on part I and part II requirements in a PHE
- Appendix 1 - Part I simplified requirements for national language translations
- Appendix 2 - Part II simplified requirements
- Appendix 3 - PHE simplified Site and Facilities Suitability template
- Prepared with input from Member States through CTCG and MedEthicsEU consultations
- Critical comments by **24 June**

Public Health Emergencies - timelines

Simplified clinical trial application package in PHEs

- Documents sent to the MSP AG for critical comments by 24 June
- September: feedback to CTCG, MedEthicsEU and MSP AG on the comments received
- Seek endorsement by ACT EU Steering Group and CTAG in Q4

Guidance on conduct of clinical trials in PHEs

- Currently updating guidance based on public consultation (>600 comments)
- September: feedback to the different groups involved, including MSP AG, on the comments received
- Seek endorsement by ACT EU Steering Group and CTAG in Q4

Publication of both deliverables in **Q4 2026** with joint communication



Communication

- Communications on the publication of the revised [ACT EU workplan](#)
- News announcement on International CT day on the publication of first quarterly [report](#) monitoring progress against 2030 targets
- Video campaign “Explaining clinical trials”
 - [Explaining Clinical Trials \(Short version\)](#)
 - [Explaining Clinical Trials \(Long version\)](#)
- Activities around communication campaign to raise awareness on the importance of **timely** submission of **high-quality data** in CTIS

Clinical trials analytics

- Interactive dashboard for the European Medicines Regulatory Network (EMRN): access CTIS data and produce analysis reports
- Continuous training of network data experts in Power BI
- Revamp of ACT EU KPI quarterly report also to address new submetrics on impactfulness of clinical trials
- Ongoing discussions/investigation on metrics for women and children health in clinical trials in line with ACT EU objectives to increase inclusivity



Clinical trials training

- Monthly focus group meetings → EU regulators, academia and SME stakeholders' members
- Strategy being developed for mapping and signposting of clinical trials trainings on the ACT EU website
- List of criteria for appraising trainings being tested
- Collaboration with WHO training group
- ACT EU website features to enable signposting being explored

Change management in support of ACT EU

Supporting timely workplan delivery and facilitating stakeholder adoption



Stakeholder centric approach

- Increase **effectiveness, adoption and long-term success**
- Collect needs and monitor adoption (surveys, feedback loops) assisted by tailored communications and events



Learning and knowledge exchange

- **Sustain momentum** through continuous learning, pilots and best practice exchange



BTA readiness (2027 onwards)

- Building on experience gathered from CTR/CTIS (1.0) implementation
- Support network readiness with consistent messaging, **early MS engagement** and alignment

Thank you

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