EMA
EUROPEAN MEDICINES AGENCY

EMA ACT-EU (Accelerate Clinical Trials in EU)

ERICA ERN Research Conference

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ACT-EU

What is ACT EU?

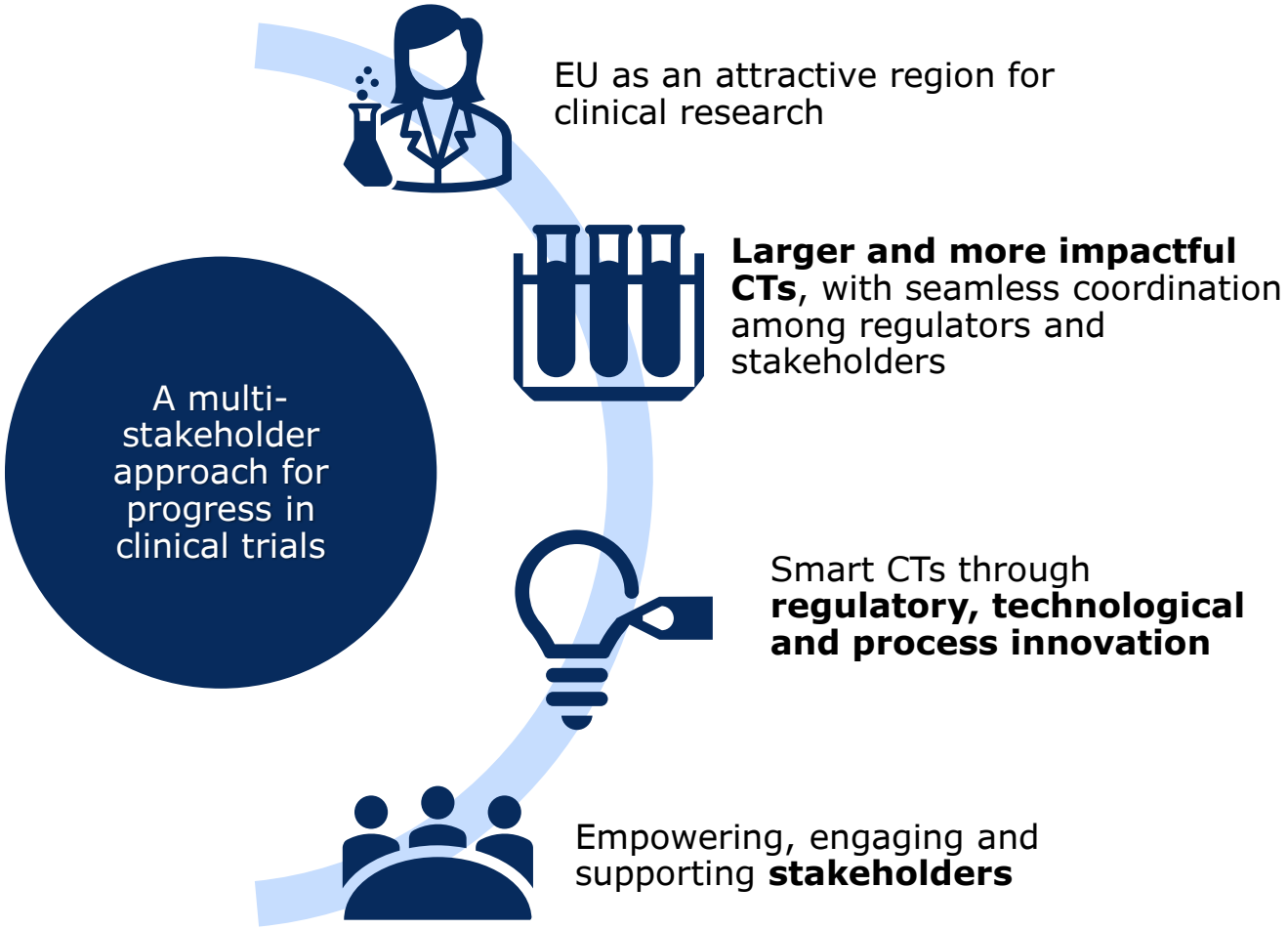
A joint initiative by the European Commission, Heads of Medicines Agencies and EMA.

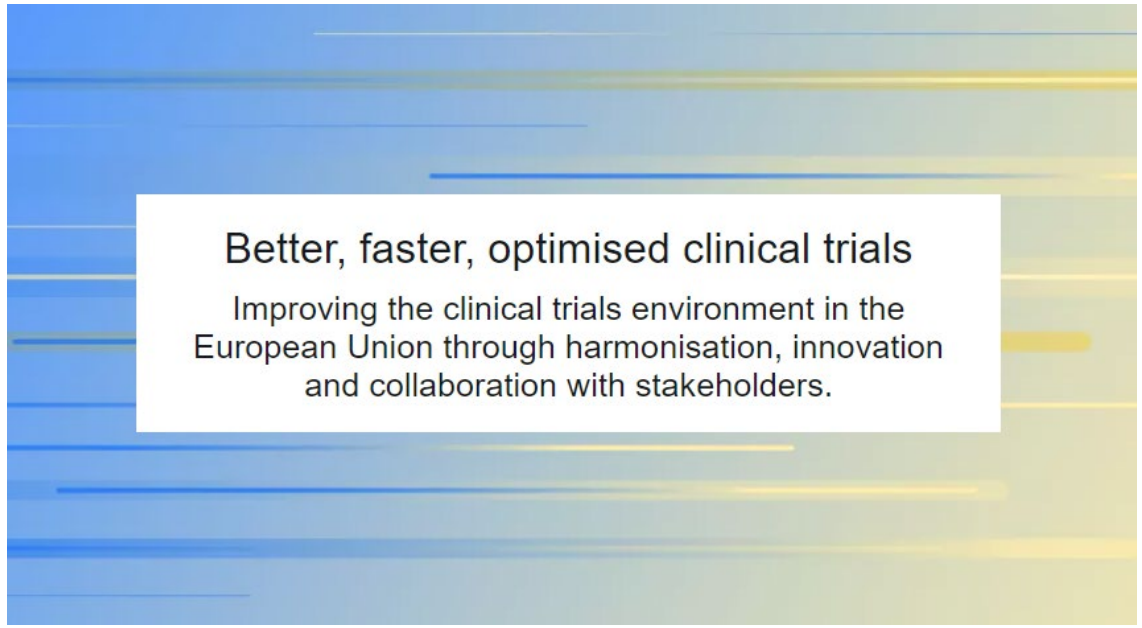
Aiming to deliver on clinical trial innovation recommendations of:

- the European medicines agencies network strategy and
- the European Commission's Pharmaceutical strategy for Europe

The three partners run the initiative together, via the ACT EU steering group.

ACT EU vision





Priority actions 2023-2026

Mapping & governance

Implementation of the Clinical Trials Regulation

Support to non-commercial sponsors

Multi-stakeholder platform

Good clinical practice modernisation

Clinical trials analytics

Consolidated advice on clinical trials

Clinical Trials methodologies

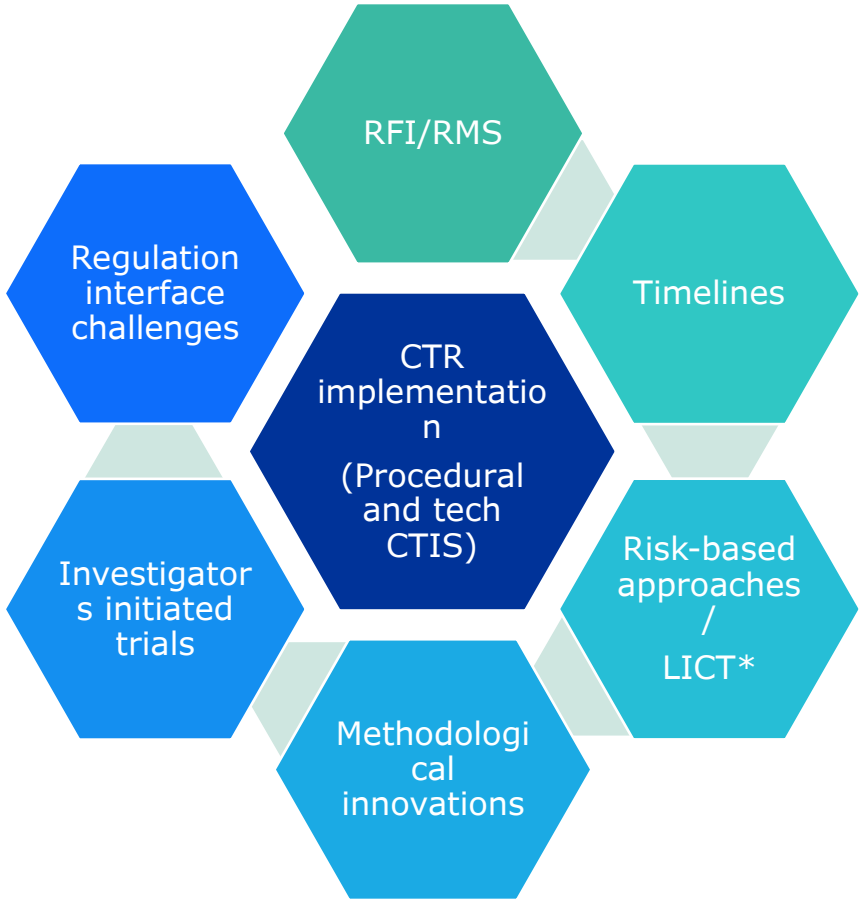
Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

Revised ACT EU workplan to be finalised based on stakeholders' feedback

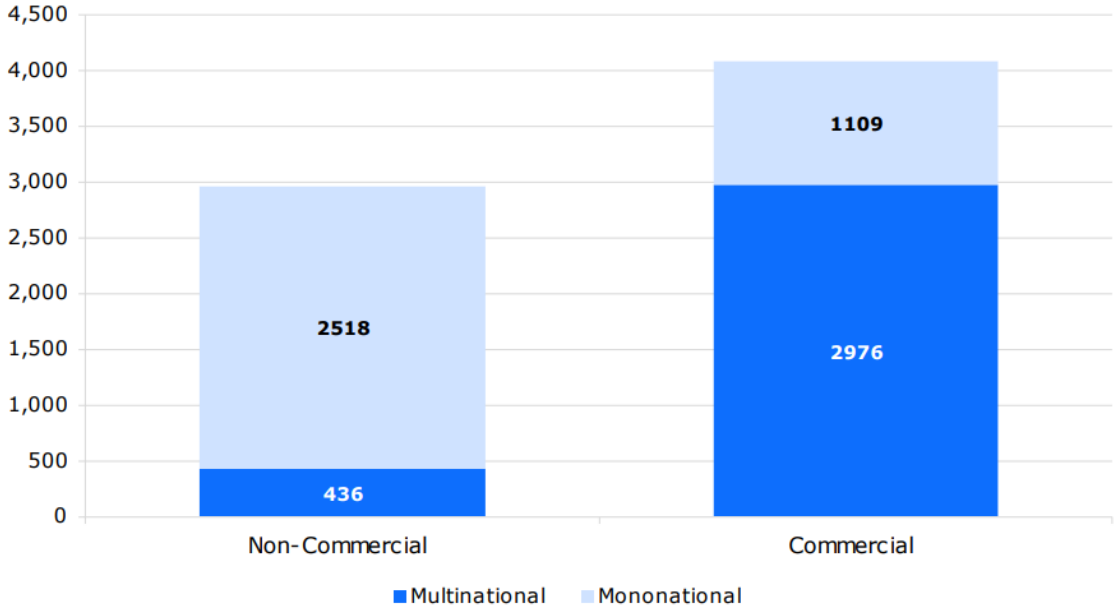
Issues reported by stakeholders



- Main issues reported by stakeholders driving the revision of the ACT EU workplan 2025-2026
- The implementation of the Clinical Trials Regulation remains the top priority to be addressed
- Focus of activities for ACT EU in conjunction with the Regulatory partners (CTAG, CTCG (CTR Collaborate), MedEthicsEU, COMBINE).

Support to non-commercial sponsors

The graph below shows the number of clinical trials authorised since 31 January 2022, split into mono national/ multi-national and per sponsor type

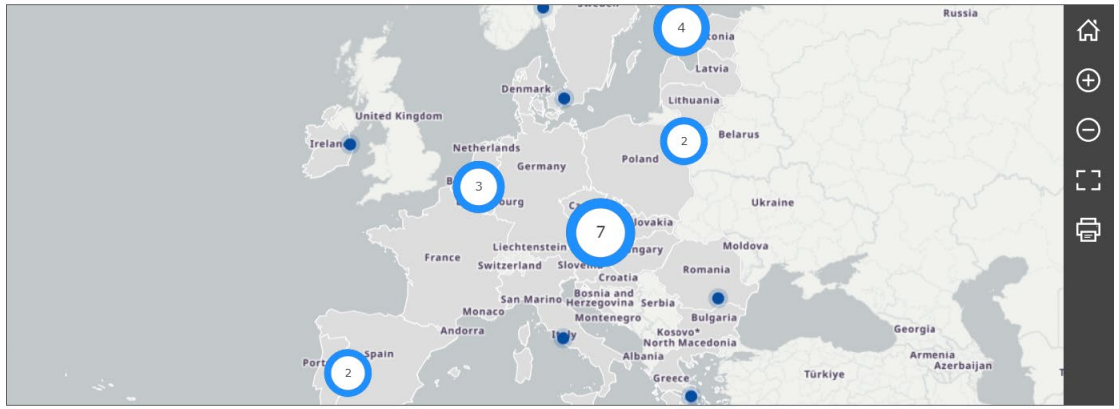


Source: [Monitoring the clinical trial environment October 2024]

- Interactive map showing [existing initiatives] at national level and other stakeholders initiatives published in June 2024:
  - Updated regularly with feedback from Member States, as soon as new information becomes available
  - Other useful initiatives (Enpr-EMA/ECRIN) also linked
- Launch of a helpdesk for non-commercial sponsors: dedicated support on CTR/CTIS use with involvement of NCAs
  - Fast track for resolution of issues raised by non-commercial sponsors, mostly on CTIS
- Next steps:
  - Stakeholders feedback on the re-organisation of the training material on CTIS/CTR

Interactive map

National initiatives for non-commercial sponsors



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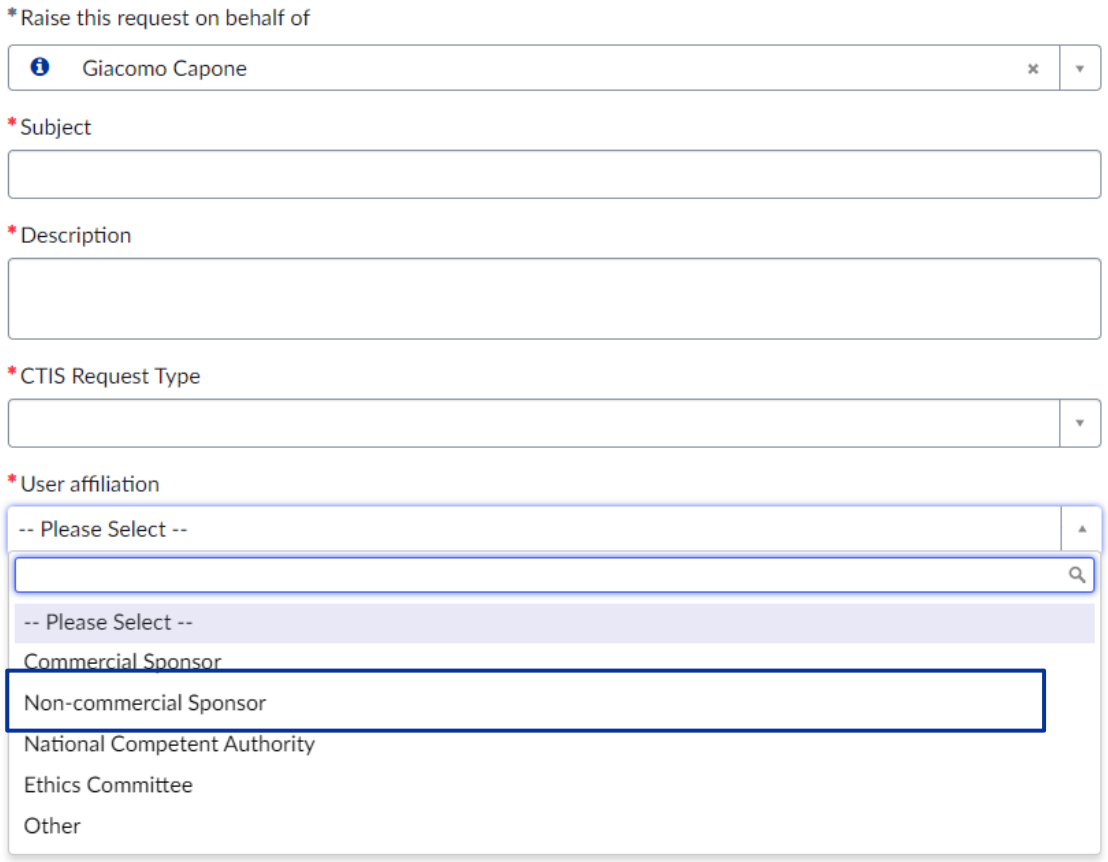
This map compiles information on support initiatives at national level and may not be exhaustive. If you are aware of information that should be added to this overview, please contact us.

Contact >

Initiatives in Italy

Support mechanisms for non-commercial clinical trials		Level		
		National	EU Level (Multinational)	Global
Dedicated webpage				
Training courses				
Scientific advice				
Helpdesk, regulatory, CTIS and ethics support	▪ General webpage on clinical trials ▪ FAQs ▪ Dedicated mailboxes for support on CTs, including non-commercial CTs: reg.eu.sperimentazioni@aifa.gov.it for all CT related questions and CTR@aifa.gov.it for practical questions related to CTs in CTIS ▪ Webpage of the National coordinating committee for ethics committees, with guidance and FAQs	X	X	X
Other services by National Competent Authority	**NCA fee reduction or waiver** As per the Ministerial Decree of 30 November 2021, no fees are requested for the submission of the Clinical Trial Application (full fee waiver).	X	X	X

Regulatory helpdesk for non-commercial sponsors



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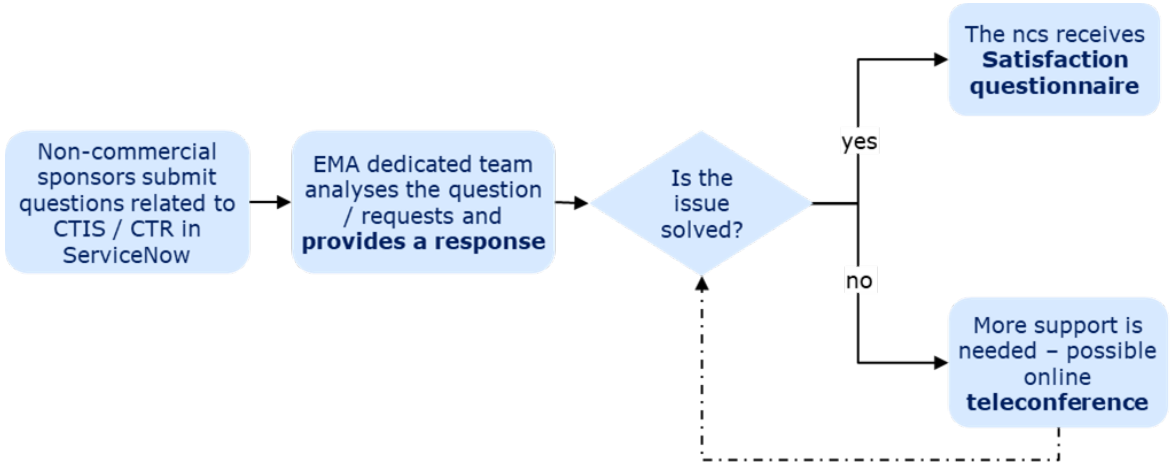


EMA

Good Clinical Practice modernisation

- CHMP adoption of final text for principles and Annex I expected in Q4 followed by implementation in the region
- Annex II public consultation started in Q4 2024 for 3 months
- Broadcast workshop planned for 19 and 20 February 2025, to discuss final adopted text
- Impact analysis and change management in relation to the implementation of ICH E6(R3) and interplay with EU guidance
- Coordinate with relevant stakeholders (e.g. GCP IWG, ICH E6(R3)) Expert Working group on relevant training/communication and change management

Support the modernisation of good clinical practice to align with the increasingly diverse range of clinical trial types and data sources

Scientific and regulatory advice

The Accelerating Clinical Trials in the EU (ACT EU) launched two advice pilots 10 June 2024

SAWP-CTCG

Improve the quality of applications for clinical trial and marketing authorisation applications

Questions of scientific nature

Bringing together SAWP/CTCG and follow SAWP timelines

Fee as per current practice

CTCG = Clinical trials coordination group

CTA = Clinical Trial Application

SNSA = Simultaneous National Scientific Advice

Pre-CTA advice

Led by CTCG on questions of administrative/ regulatory aspects

30 days per procedure

Entry point via SNSA

Fees as per lead MS requirements

How stakeholders are involved

Accelerate change and innovation in EU clinical trials

Build trust and understanding between stakeholders to drive change

Enable and support capacity building and training

Ensure timely transparency

The **Multi-stakeholder platform (MSP)** functions as a vehicle for clinical trials stakeholders and regulators to come together, voice their views and collaborate to improve the clinical trials environment for European patients and citizens

https://accelerating-clinical-trials.europa.eu/our-work/multi-stakeholder-platform_en

The MSP will provide the opportunity for stakeholders to exchange views and enable dialogue with regulators through:

1. the creation of an MSP Advisory Group;

2. multi-stakeholder events;

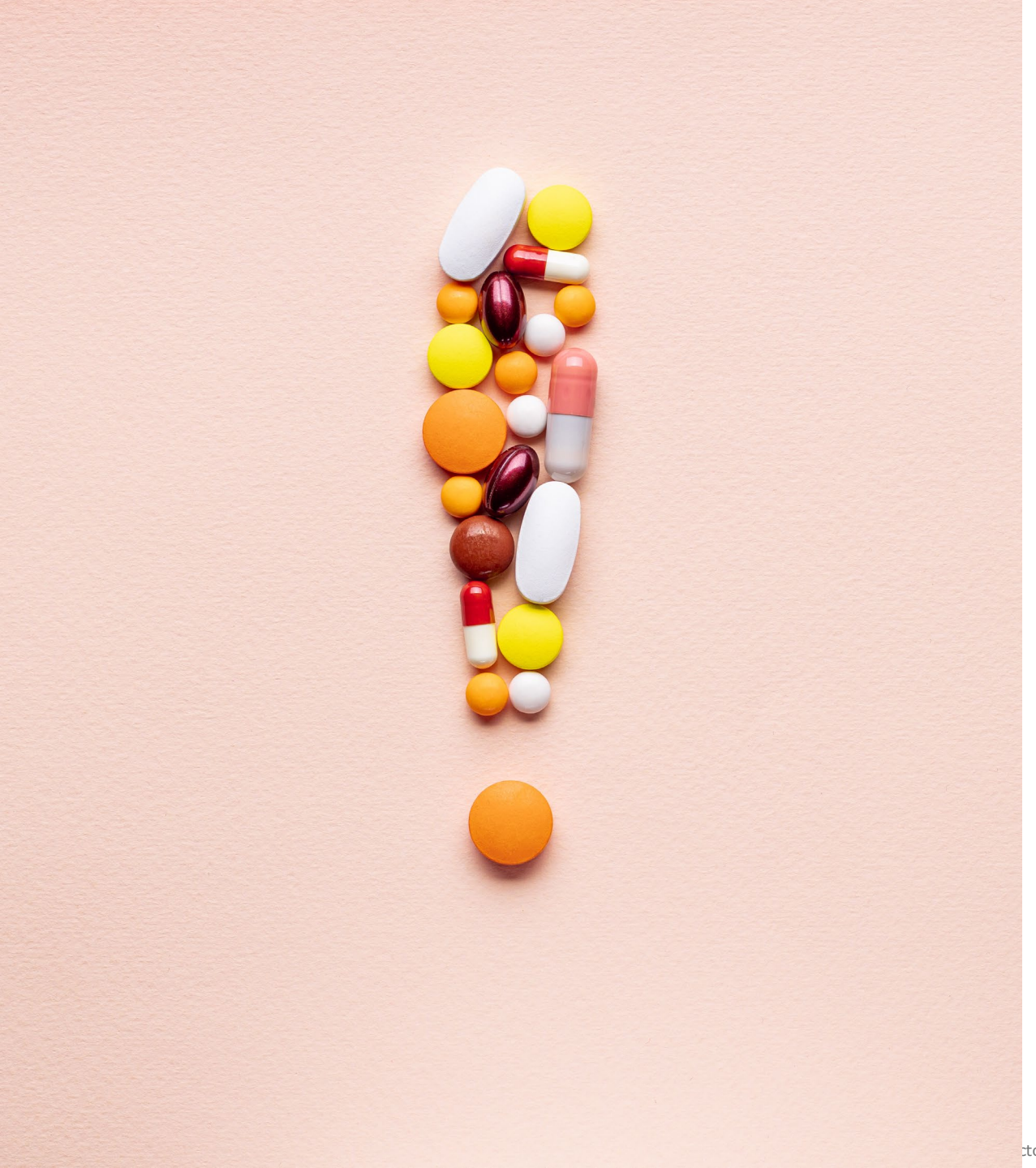
3. consultations, surveys, and other tools to gather stakeholders' feedback

Upcoming events

ACT EU workshop on ICH E6 R3:

- Efficiency Guideline 6 (E6) as the global regulatory guideline for Good Clinical Practice, the ACT EU Priority Action – GCP Modernisation is conducting a Workshop on ICH E6 R3 on **19 and 20 February 2025.**

  The workshop aims to engage all stakeholders of ICH E6 R3, including but not limited to **patients, healthcare professionals, including investigators, regulators, service provider, ethics committee members industry and academia.**



Better, faster, optimised clinical trials

- A single clinical trial application covering up to 30 EU/EEA countries
- Streamlined process for the authorisation and supervision of clinical trials with increased transparency
- Creating a stronger EU network to facilitate operational aspects in relation to clinical trials, with dedicated support to non-commercial sponsors
- Continuous dialogue with stakeholders via the MSP

Working with EMA

Open call to establish a list of external experts

- Call remains open for the period of 2024-2029 for:
  - Expert panels on medical devices and in vitro diagnostic medical devices
  - Pool of patient, consumer, and healthcare professional experts to provide expertise to EMA
- For more details, please visit: Call for expression of interest for medical device and in-vitro diagnostics medical devices experts (EXPAMED) and patient, consumer and healthcare professional experts (P&HCP)
- Any queries related to the procedure (Q&A) should be addressed to Expertselection@ema.europa.eu

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Thank you

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