HMA
Heads of Medicines Agencies

European Commission

EMA
EUROPEAN MEDICINES AGENCY

ACT EU multi-annual
Workplan 2022-2026

The EC-HMA-EMA initiative Accelerating Clinical Trials in the EU (ACT EU) was launched on 13 January 2022 and outlines ten priority actions to transform clinical trials in Europe (Annex 1). The ACT EU 2022 – 2026 multi-annual workplan was adopted in August 2022 and introduces each of the priority actions and outlines their key deliverables. The workplan is anchored in the recommendations of the European Medicines Regulatory Network (EMRN) strategy to 2025 and the European Commission's Pharmaceutical Strategy for Europe. The plan builds on the entry into application of the Clinical Trials Regulation (Regulation (EU) No 536/2014) and the activities already underway in the European regulatory network to support clinical trials. The workplan highlights key focus areas to further facilitate innovation in clinical trials, stakeholder engagement and regulatory network collaboration.

This workplan is structured in line with the ten priority actions for ACT EU.

Content:

ACT EU PRIORITY ACTION DESCRIPTIONS

PA 1: Mapping & governance

The European clinical trials regulatory landscape is complex, with various expert groups working in different areas, from issuing guidance, to providing scientific advice, to approving clinical trials which generate evidence for new drugs or treatment strategies; a common framework to clarify roles and responsibilities to the Network and its stakeholders is lacking.

This priority action will create a mapping of existing initiatives within the EMRN and ethics infrastructure to develop a governance rationalisation strategy, which will coordinate and rationalise the work done by different clinical trials expert groups and working parties. The process will be performed in a stepwise approach, with a first phase focusing on the core governance bodies: the Clinical Trials Coordination and Advisory Group (CTAG), Clinical Trials Coordination Group (CTCG), Commission Expert Group on Clinical Trials (CTEG) and Good Clinical Practice Inspectors Working Group (GCP IWG). The remainder of the Network groups will be addressed in a second phase. The outcome of this exercise will be reflected in a regulatory network responsibility assignment (RACI) matrix.

Q4 2022 Mapping of Network CT activities
Q4 2022 Deliver RACI matrix for core governance groups
Q4 2022 Develop RACI matrix for the extended Network groups

PA 2: Successful implementation of CTR

The Clinical Trials Regulation (CTR) entered into application on 31 January 2022 and provides a significant opportunity for the transformation of the EU clinical trials environment by supporting the conduct of large clinical trials in multiple European Member States, to the benefit of medical innovation and patients.

This priority action will oversee activities to ensure the successful implementation of the CTR such as tracking the performance of the European clinical trials environment, raising awareness of training, and quickly addressing issues encountered with the implementation of the CTR. Further development of a scheme to promote larger, multinational trials specifically in the academic setting, will also be central to the work of this priority action.

Q2 2022 Launch monthly KPIs tracking the CTR
Q3 2022 Survey to identify issues for sponsors
Q4 2022 Launch process to prioritise and resolve sponsor issues
Q1 2023 Launch scheme to support large multinational CTs, with particular attention to academic sponsors
Q1 2024 Launch one-stop shop to support academic sponsors

PA 3: Multi-stakeholder platform

The success of clinical trials relies on a multitude of stakeholders, including those designing, regulating, performing and participating in clinical trials. These stakeholders exist at both the European and Member State level, with little opportunity for regular dialogue between all stakeholders at EU level. There is a need for a unifying platform involving all stakeholders to support a more holistic discussion across the clinical research landscape. Such dialogue will facilitate the evolution of the clinical trials environment by helping to identify key advances in clinical trial methods, technology and science, and by finding practical solutions to enable and drive change.

Driven by the need to build consensus for change between stakeholders, a multi-stakeholder platform (MSP) will be developed as part of ACT EU.

Q3 2022 Concept paper for multi-stakeholder input into MSP design

Q2 2023 Kick-off multi-stakeholder platform
Q3 2023 Events run under the multi-stakeholder umbrella

PA 4: Good Clinical Practice modernisation

The renovation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2) guideline on "Good Clinical Practice" (GCP) aims to address the application of GCP principles to the increasingly diverse range of clinical trial types and data sources. Additionally, it will provide flexibility when appropriate to facilitate the use of technological innovations in clinical trials.

The focal point of this priority action will be to support the implementation of ICH E6(R3), with a multi-stakeholder event geared at the delivery of a responsive guideline which accounts for stakeholders' perspectives and advances in technology and clinical trial design. Further to the guideline consultation process the priority action will focus on developing a communication and change management strategy to support a smooth adoption and implementation of the revised guideline, in addition to updating the relevant EU guidelines impacted by the change.

Q1 2023 Multi-stakeholder workshop on ICH E6 GCP
Q3 2023 Implement changes in EU guidance documents
Q4 2023 Communications and change management strategy

PA 5: Clinical trials data analytics

Over the years the EMRN has collected a wealth of data about clinical trials. These data describing clinical trials are currently difficult to access, process and interpret due to the existence of multiple data sources.

Informed by advanced analytics capable of identifying complex trends within these data, this priority action will seek to maximise their value for all European citizens.

A publicly accessible EU clinical trials dashboard will be developed. The work of this priority action will also involve engagement with researchers, policymakers, and funders on topics of common interest, supporting evidence-based decision-making to improve public health.

Q4 2022 EU clinical trials data analytics strategy
Q1 2023 Start developing EU clinical trials dashboard
Q2 2023 Workshop to identify topics of common interest

PA 6: Targeted communication campaign

This priority action will plan and launch a targeted communication campaign to engage all enablers of clinical trials, including data protection experts, academia, small and medium-sized enterprises (SMEs), funders, Health Technology Assessment (HTA) bodies and healthcare professionals. In 2022 and 2023 this action will address communication needs and remind sponsors of training to support the application of the CTR and the mandatory use of the Clinical Trials Information System (CTIS), in line with a transition period.

Additionally, the group will support communication needs across all priority actions, including communication of ACT EU events, publication of the Clinical Trials Highlights newsletter, and creating a dedicated online space for ACT EU content.

Q2 2022 Launch clinical trials newsletter
Q3 2022 Communication campaign
Q2 2023 Dedicated website for ACT EU
Q1 2024 Launch enhanced website linking to the multi-stakeholder platform

PA 7: Scientific advice

The provision of scientific advice on clinical trials in the EU is carried out by different actors who interact with sponsors at different stages of product development.

This environment can be complex to navigate for sponsors, especially academic or SMEs sponsors that may have less experience of regulatory processes.

Priority action 7 brings together the key actors in clinical trials scientific advice in the EU, with the aim of critically analysing the existing landscape in line with stakeholder needs. A consolidated process will be developed to efficiently manage scientific advice cases and enhance coordination across relevant stakeholders. The project will include a number of pilot phases before delivering the final product, which will ultimately facilitate the development of safe and effective medicines for the benefit of patients.

Q3 2022 Enhance intra-network information exchange
Q1 2023-Q4 2024 Develop a consolidated scientific advice process:
- Survey stakeholders
- Communicate consolidated scientific advice pilot
- Operate a first pilot phase

Q3 2024 Assess opportunities from the Pharmaceutical Strategy
Q4 2025 Operate expanded pilot phase
Q4 2025 Optimise and expand consolidated advice process

PA 8: Methodologies

New and innovative clinical trial designs and methodologies provide opportunities and challenges for the EU clinical trials environment. Complex trial designs such as umbrella trials and basket trials or master protocols require advanced biostatistical and data analytical understanding. Recruitment of patients may also change with the use of new technologies to identify eligible study participants and new ways to capture data during clinical trials.

The work of this priority action therefore focuses on facilitating the development and publication of key methodologies guidance and strengthening the links between innovation and scientific advice. Guidance on complex clinical trials has already been delivered, and towards the end of 2022 guidance on decentralised clinical trials will also be issued.

Guidance on the interface between Regulation (EU) 536/2014 on clinical trials for medicinal products for human use (CTR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) has also been published in 2022.

Priority action 8 will ensure collaboration between all relevant working parties and groups across the EU to identify areas of shared expertise and priority, align workplans and create synergies depending on the identified topic of the guidance. This collaboration together with the input from relevant stakeholders will accelerate the development of future guidance.

Q4 2022 Decentralised clinical trials (DCT) workshop
Q4 2022 Publication of DCT recommendation paper
Q4 2022 Complex clinical trials Q&A workshop
Q4 2023 Publication of methodology guidance roadmap
Q1 2024 Support to guideline developments
Q1 2025 ICH E9 (R1) Estimands fully implemented

PA 9: Clinical trial safety

This priority action will support the successful establishment of clinical trial safety monitoring, where Member States will work together to improve trial safety by means of a coordinated work-sharing assessment. The work is directly connected with the activities of the EU4Health Joint Action Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials (SAFE CT). The overall goals of the Joint Action are improving the quality of safety data in clinical trials and marketing authorisation, reinforcing Member States surveillance expertise and capacity, and harmonising and facilitating clinical trials in EU/EEA.

To support these activities the priority action will focus on training for safety assessors, with the development of a curriculum to harmonise expertise. To further increase safety assessors' expertise a mentorship programme will be established.

To ensure a smooth transition to the mandatory submission of clinical trial applications under the CTR, a process for collaboration within the Network will be created, including the creation or alignment of safety procedures for emerging safety issues potentially impacting clinical trials. To track the implementation of the CTR in each Member State, key performance indicators for safety will be developed.

Q3 2022	Launch the mentorship programme & assessors training
Q4 2022	Safe CT KPIs identified
Q1 2023	Review of IT functionalities for safety (yearly evaluation)
Q3 2023	Process established for Network safety coordination
Q3 2024	Safety assessors' curriculum defined

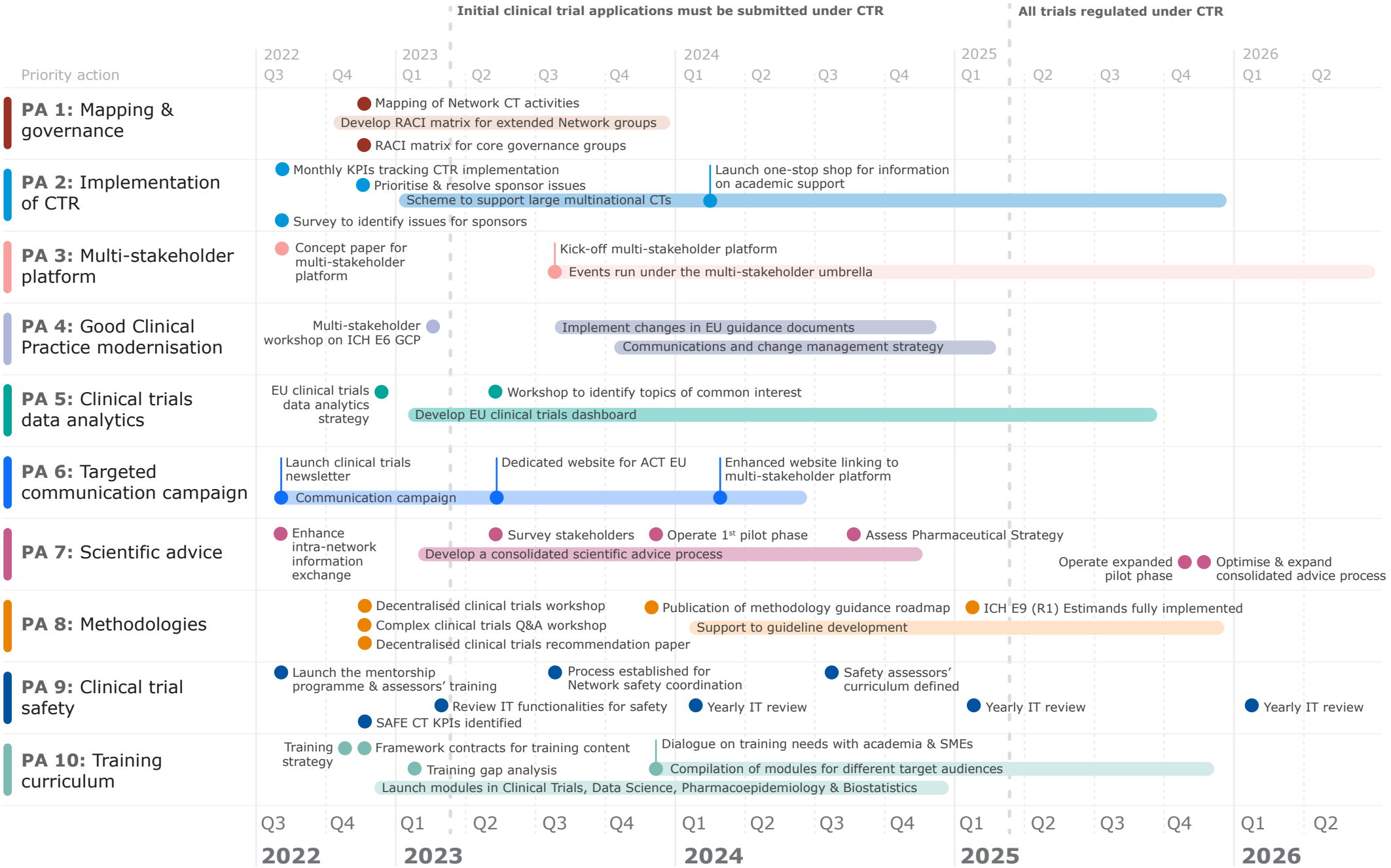
PA 10: Training curriculum

Europe has a world class life sciences sector, and a high level of academic engagement in medicines development. To support high quality medicines development and enable better knowledge sharing, a training curriculum informed by regulatory experience will be provided, with modules on drug development and regulatory science. Engaging with universities and SMEs, the curriculum will serve as an educational 'ecosystem' which will benefit from bidirectional exchanges to enable training on clinical trials. Training provided by actors other than the regulatory network will also feed into this educational 'ecosystem'.

An overarching strategy and gap analysis will serve as the basis for the development of the curriculum. Subsequently a comprehensive compilation of modules covering relevant areas to clinical trials enablement will be rolled out.

Q4 2022	Training strategy
Q4 2022	Framework contracts for training content
Q4 2022	Launch modules in clinical trials, data science pharmacoepidemiology & biostatistics
Q1 2023	Training gap analysis
Q4 2023	Dialogue on training needs with academia and SMEs
Q4 2023	Compilation of modules for different target audiences

ACT EU MULTI-ANNUAL WORKPLAN 2022-2026



ANNEX I : ACT EU PRIORITY ACTIONS

PA 1	Map existing initiatives and develop a governance rationalisation strategy (aligning different expert groups and working parties in the EMRN and ethics infrastructure): successful and timely implementation of the CTR and its implementing acts; develop KPIs and dashboard to track performance of the European clinical trials environment
PA 2	Including the promotion of larger, multinational trials specifically in the academic setting
PA 3	Establish a multi-stakeholder platform, including patients, after stakeholder analysis
PA 4	Implementing the GCP modernisation informed by the development of guidance at ICH
PA 5	Analyse data about clinical trials leveraging academic, non-profit, European, and international initiatives, improving the impact of policymaking and funding on research outputs to support evidence-based decision making
PA 6	Plan and launch a targeted communication campaign to engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals)
PA 7	Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain
PA 8	Develop and publish key methodologies guidance e.g. on AI/ML impacted CTs, complex trials, decentralised CTs and IVDR/CTR interface (to strengthen links between innovation and scientific advice fora)
PA 9	Successfully establish CT safety monitoring and bridge to the EU4Health Joint Action and start its integration into a pre- and post-marketing safety monitoring framework
PA 10	Deliver a clinical trials training curriculum including modules on drug development and regulatory science with links to universities and SMEs (serving as an educational 'ecosystem')

ANNEX II : GLOSSARY

ACT EU	Accelerating Clinical Trials in the EU
CTAG	Clinical Trials Coordination and Advisory Group
CTCG	Clinical Trials Coordination Group
CTEG	Commission Expert Group on Clinical Trials
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation (Regulation (EU) No 536/2014)
DCT	Decentralised clinical trial
EMRN	European Medicines Regulatory Network
GCP	Good Clinical Practice
GCP IWP	GCP Inspectors Working Group
HTA	Health Technology Assessment
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IT	Information Technology
IVDR	*in vitro* diagnostic medical devices
MSP	Multi-stakeholder platform
SAFE CT	Safety Assessment Cooperation and Facilitated Conduct of Clinical Trials
SME	Small and medium-sized enterprise