The HMA-EMA joint big data steering group workplan

ACT EU workplan

2023 - 2026

VERSION 2 – November 2023
ACTEU@ema.europa.eu
Introduction

Workplan
The HMA-EC-EMA Accelerating Clinical Trials in the EU (ACT EU) workplan

Topic description

Annexes
Priority actions of ACT EU
Introduction

The Accelerating Clinical Trials in the European Union (ACT EU) initiative will support smarter clinical trials through regulatory, technological and process innovation.

Our vision is to strengthen the EU as a region that supports clinical trial development and enables collaboration and innovation at all stages of the clinical research lifecycle.

Seamless coordination among stakeholders, regulators and ethics committees will support more cross-border collaboration.

The result will be better, more impactful clinical trials, benefitting patients and healthcare in Europe.

The 2nd HMA-EC-EMA ACT EU workplan was adopted in November 2023 and covers activities until 2026.

This document introduces each topic and outlines key deliverables. The plan was informed by stakeholder and expert consultation. The document is structured in line with the priority actions of the ACT EU programme (see Annex I).
Workplan
**ACT EU workplan 2023 - 2026**

### Priority Actions

#### Mapping & governance

**2023**
- Q1: Design governance processes & supporting tools through CTR Collaborate
- Q2: Analysis of CTR Collaborate governance
- Q3: Analysis of ethics committees’ involvement in CT governance
- Q4: Analysis of scientific advice process for clinical trial applications
- Q1: Publish mapping of CT initiatives
- Q2: Deliver rationalised governance processes

#### Implementation of the Clinical Trials Regulation

**2023**
- Q1: Survey to identify issues for sponsors
- Q2: Workshop on transition trials
- Q3: Implementation of new CTIS transparency rules
- Q4: Workshop on ICH E6 R3

**2024**
- Q1: Monthly KPIs tracking CTR implementation
- Q2: CTR survey
- Q3: CTR survey
- Q4: CTR survey

**2025**
- Q1: CTR survey
- Q2: CTR survey
- Q3: CTR survey
- Q4: CTR survey

**2026**
- Q1: CTR survey
- Q2: CTR survey
- Q3: CTR survey
- Q4: CTR survey

#### Establish Multi-stakeholder platform

- **2023**
  - Q1: MSP kick-off workshop
  - Q2: Creation of MSP Advisory Group

- **2024**
  - Q1: First meeting of the MSP AG
  - Q2: Annual event of multi-stakeholder platform

- **2025**
  - Q1: Annual event of multi-stakeholder platform
  - Q2: Annual event of multi-stakeholder platform

- **2026**
  - Q1: Annual event of multi-stakeholder platform
  - Q2: Annual event of multi-stakeholder platform

#### Good clinical practice modernisation

- **2023**
  - Q1: Workshop on ICH E6 R3

- **2024**
  - Q1: Workshop on ICH E6 R3
  - Q2: Finalise EU guidance impact analysis

- **2025**
  - Q1: Finalise EU guidance impact analysis
  - Q2: Finalise EU guidance impact analysis
  - Q3: Finalise EU guidance impact analysis
  - Q4: Finalise EU guidance impact analysis

- **2026**
  - Q1: Finalise EU guidance impact analysis
  - Q2: Finalise EU guidance impact analysis
  - Q3: Finalise EU guidance impact analysis
  - Q4: Finalise EU guidance impact analysis

---

**Event Timeframe**

*All trials regulated under CTR*

- **2023**
  - Q1: Academic support initiatives mapped
  - Q2: CT service / regulatory helpdesk

- **2024**
  - Q1: Training on transition trials for Academics

- **2025**
  - Q1: Support to non-commercial sponsors in multinational CTs

- **2026**
  - Q1: Change management & communication activities
  - Q2: Change management & communication activities
  - Q3: Change management & communication activities
  - Q4: Change management & communication activities
Define safety assessors' curriculum

Review of IT functionalities for safety

All trials regulated under CTR

Clinical trials safety

Clinical trials training curriculum

Clinical trials in public health emergencies

Priority Actions

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

2023 2024 2025 2026

Building and maintaining SAFE CT Pharmacovigilance Network

Building collaboration between CT & post-marketing PhV

Define safety assessors' curriculum

SAFE CT assessors' event

SAFE CT workshop

SAFE CT final assessors' meeting

SAFE CT workshop

Review of IT functionalities for safety

Training Strategy

SAFE CT workshop

SAFE CT final assessors' meeting

Publish revised Training Strategy

Stakeholder engagement to strengthen educational ecosystem

Gap analysis (EU regulators)

Gap analysis (Academia)

Gap analysis (SME)

Gap analysis (MRECs)

Publish summary

Launch modules in Clinical Trials, Data Science, Pharmacoepidemiology

Training Curriculum elaboration & updates

Clinical trials training curriculum

Clinical trials in public health emergencies

Workshop on PH Emergencies

Establishment of Priority Action

Develop process for involvement of MRECs in PHEs

Implement process for involvement of MRECs in PHEs

Develop PHEs CT application package

Publish PHEs CT application package

Develop fit-for-purpose regulatory flexibility in the assessment & conduct of CTs in PHEs

List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT</td>
<td>Clinical Trial</td>
</tr>
<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use</td>
</tr>
<tr>
<td>CTR</td>
<td>Clinical Trial Regulation</td>
</tr>
<tr>
<td>SNSA</td>
<td>Simultaneous National Scientific Advice</td>
</tr>
<tr>
<td>KPI</td>
<td>Key Performance Indicator</td>
</tr>
<tr>
<td>PhV</td>
<td>Pharmacovigilance</td>
</tr>
<tr>
<td>CTIS</td>
<td>Clinical Trial Information System</td>
</tr>
<tr>
<td>MRECs</td>
<td>Medical Research Ethics Committees</td>
</tr>
<tr>
<td>MSP</td>
<td>Multi-stakeholders Platform</td>
</tr>
<tr>
<td>PHEs</td>
<td>Public Health Emergencies</td>
</tr>
<tr>
<td>AG</td>
<td>Advisory Group</td>
</tr>
</tbody>
</table>
Priority actions
Mapping & governance

The ACT EU programme will map existing clinical trial activities and develop a governance rationalisation strategy.

This aims to clarify the roles and responsibilities of the various expert groups working within the European medicines regulatory network.

The **Clinical Trials Regulation (CTR) Collaborate** initiative aims to optimise Member State and NCA/Ethics collaboration regarding clinical trials authorisation under the CTR. Anchoring the initiative to ACT EU will enable prioritisation of CTR related activities under the programme.

Governance use cases based on the CTR Collaborate initiative will be developed to support the creation of a governance rationalisation strategy.

**Key milestones:**

| Q4 2023 | Ethic committees’ involvement in CT governance & scientific advice process for CTA analysis |
| Q1 2024 | Change management responsibilities in activities/processes analysis |
| Q3 2024 | Publish mapping of CT initiatives |
| Q4 2024 | Deliver rationalised governance processes |
| 2023-2025 | Design governance processes & supporting tools through CTR Collaborate |
The ACT EU programme aims to oversee the successful and timely implementation of the Clinical Trials Regulation (CTR) and its implementing acts. This includes aspects such as:

• tracking the performance of the European clinical trials environment through monthly KPI reporting;
• reducing administrative burden while ensuring high levels of transparency;
• regularly consulting sponsors on their experience with the implementation of the CTR and the use of the Clinical Trials Information System (CTIS).

Key milestones:

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3 2023</td>
<td>CTR survey to identify issues for sponsors</td>
</tr>
<tr>
<td>Q1 2024</td>
<td>Workshop on transitional trials</td>
</tr>
<tr>
<td>Q3 2024</td>
<td>CTR survey to identify issues for sponsors</td>
</tr>
<tr>
<td>Q4 2024</td>
<td>Implementation of new CTIS transparency rules</td>
</tr>
<tr>
<td>Q3 2025</td>
<td>CTR survey to identify issues for sponsors</td>
</tr>
<tr>
<td>2022-2026</td>
<td>Monthly KPIs tracking of CTR implementation (recurrent activity)</td>
</tr>
</tbody>
</table>
Multinational clinical trials by non-commercial sponsors

The aim of the programme is to understand the bottlenecks that prevent non-commercial sponsors from planning and initiating multinational clinical trials and subsequently to set a valid action plan for non-commercial sponsors, through for example, specific regulatory support and access to scientific advice, resulting in:

- higher number of non-commercial CTs conducted in more than one EU/EEA Member State;
- high quality scientific evidence generated by non-commercial clinical trials;
- a benefit for EU citizen’s health through optimised therapies and access to innovative medicines.

<table>
<thead>
<tr>
<th>Key milestones:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Q1 2024</strong></td>
</tr>
<tr>
<td><strong>Q2 2024</strong></td>
</tr>
<tr>
<td><strong>Q3 2024</strong></td>
</tr>
<tr>
<td><strong>2023-2026</strong></td>
</tr>
</tbody>
</table>
The programme will establish a Multi-stakeholder platform (MSP), to function as a unifying vehicle for clinical trial stakeholders and regulators, to voice their views and collaborate to improve the clinical trials environment for European patients and citizens.

The MSP will enable dialogue with regulators through:

1. the creation of a MSP Advisory Group;
2. multi-stakeholder events;
3. consultations, surveys, and other tools to gather stakeholders’ feedback.

With the establishment of the MSP Advisory Group the MSP will be formally established, closing the activity of this priority action and positioning the MSP as an overarching structure within the ACT EU programme.

Key milestones:

- **Q2 2023**: MSP kick-off workshop
- **Q4 2023**: Creation of MSP Advisory Group
- **Q4 2023**: Completion of priority action
- **Q1 2024**: First meeting of the MSP Advisory Group
- **Q2 2024**: Annual event of the ACT EU multi-stakeholder platform
- **Q2 2025**: Annual event of the ACT EU multi-stakeholder platform
- **Q2 2026**: Annual event of the ACT EU multi-stakeholder platform
- **2023-2026**: Events run under the multi-stakeholder platform umbrella
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 multi-stakeholder events geared at the delivery of a responsive guideline which takes account of stakeholders’ perspectives and advances in technology and clinical trial design. The priority action will also focus on developing a communication and change management strategy to support smooth adoption and implementation of the revised guideline, in addition to updating the relevant EU guidelines impacted by the change.

Key milestones:

- **Q3 2023** Workshop on ICH E6 R3
- **Q4 2024** Second workshop on ICH E6 R3
- **Q4 2024** Finalise EU guidance impact analysis
- **2024-2025** Implement changes in EU guidance documents
- **2023-2026** Change management & communication activities
Clinical trials analytics

Over the years the EMRN has collected a wealth of data about clinical trials. These data are used to support regulatory decision making, but their potential use extends far beyond that scope. Stakeholders may have diverse interests, from locating trials for certain health conditions to monitoring innovation in healthcare and even applying Artificial Intelligence for novel insights. While these data hold immense potential, their current format poses challenges in access and usability.

To understand how best to address these challenges, the priority action will engage with the community of stakeholders to understand their needs and how data about clinical trials could support them. A multi-stakeholder workshop will collect those needs and identify evidence gaps in the EU clinical trials environment. These will be gathered into a clinical trial analytics research agenda which will not only guide regulatory action but may influence future public funding calls. By highlighting research needs and facilitating analysis of clinical trial data, this Priority Action will help address key challenges in the EU clinical trials environment.

Key milestones:

<table>
<thead>
<tr>
<th>Year Range</th>
<th>Activity Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 2024</td>
<td>Clinical trials analytics workshop</td>
</tr>
<tr>
<td>Q2 2024</td>
<td>Publish CT analytics research agenda</td>
</tr>
<tr>
<td>2024-2025</td>
<td>Stakeholder engagement to deliver research agenda</td>
</tr>
<tr>
<td>2024-2026</td>
<td>Support access to &amp; analysis of CT data to address research agenda</td>
</tr>
</tbody>
</table>
The programme aims to reinforce scientific advice coordination between clinical trial approval and clinical trial design in the EU medicines regulatory network.

This priority action 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.

Key milestones:

- **Q1 2024**: SNSA I webinar
- **Q2 2024**: SNSA II webinar
- **Q2 2024**: Launch 1st pilot phase
- **2023-2024**: Develop a consolidated scientific advice process
- **Q4 2025**: Launch expanded pilot phase
- **Q1 2026**: Publish learnings from pilots and proposals for definitive process
- **2023-2025**: Enhancement of intra-network information exchange
- **2024-2026**: Operation of pilots
Clinical trial methodologies

ACT EU aims to facilitate aligned clinical trial guidance development across the EU network resulting in high impact guidance documents implemented in practice. To reach this goal, the objectives of the work will be to:

1. Ensure mutual awareness of the guidance landscape across EU expert groups.
2. Ensure involvement of all relevant stakeholders at the right time to facilitate alignment, consolidation and implementation of methodology guidance.
3. Involve clinical trial authorisation by Member States and down-stream decision makers.
4. Help stakeholders navigate the EU clinical trial guidance landscape.
5. Ensure capture and sharing of lessons learned.

Key milestones:

- **Q4 2023**: Clinical trial methodologies multi-stakeholder workshop
- **Q2 2024**: Publish methodology guidance roadmap
- **Q2 2025**: Publish internal guidance best practice
- **2024-2025**: Develop internal guidance best practice
- **2023-2026**: Sustainable coordination of guidance development
Clinical trials safety

The programme aims to further strengthen clinical trials safety monitoring in the EU, by building and maintaining a clinical trials pharmacovigilance network and enabling collaboration between clinical trial & post-marketing pharmacovigilance.

This will see Member States working together to improve trial safety through coordinated work-sharing assessment, facilitated by the EU4Health Joint Action 12.

To support these activities, ACT EU will focus on training for safety assessors, with the development of a curriculum to strengthen expertise, including addressing adverse event reporting in line with ICH E19 and the CTR.

Key milestones:

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2023</td>
<td>Define safety assessors’ curriculum</td>
</tr>
<tr>
<td>2023-2024</td>
<td>SAFE CT assessors’ event</td>
</tr>
<tr>
<td>2023-2026</td>
<td>Building and maintaining CT Pharmacovigilance Network</td>
</tr>
<tr>
<td>2023-2026</td>
<td>Building collaboration between CT &amp; post-marketing PhV</td>
</tr>
<tr>
<td>2023-2026</td>
<td>Review and update of IT functionalities for safety</td>
</tr>
</tbody>
</table>
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 analyses for different stakeholder groups 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.

Key milestones:

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 2023</td>
<td>Training Strategy</td>
</tr>
<tr>
<td>2023</td>
<td>Gap analysis (EU regulators)</td>
</tr>
<tr>
<td>Q1 2024</td>
<td>Publish summary</td>
</tr>
<tr>
<td>2023-2024</td>
<td>Gap analysis (Academia)</td>
</tr>
<tr>
<td>Q4 2024</td>
<td>Publish summary</td>
</tr>
<tr>
<td>2024-2025</td>
<td>Gap analysis (SME)</td>
</tr>
<tr>
<td>Q2 2025</td>
<td>Publish summary</td>
</tr>
<tr>
<td>2024-2025</td>
<td>Gap analysis (MRECs)</td>
</tr>
<tr>
<td>Q4 2025</td>
<td>Publish summary</td>
</tr>
<tr>
<td>Q4 2025</td>
<td>Publish revised Training Strategy</td>
</tr>
<tr>
<td>2023-2025</td>
<td>Launch modules in Clinical Trials, Data Science, Pharmacoepidemiology</td>
</tr>
<tr>
<td>2023-2026</td>
<td>Training Curriculum elaboration &amp; updates</td>
</tr>
</tbody>
</table>
Clinical trials in public health emergencies

The programme will focus on activities enabling multinational clinical trials in the EU during public health emergencies.

Structural challenges and barriers encountered with setting up and promptly starting adequately sized, multinational clinical trials in the context of the COVID-19 pandemic and during the Monkeypox emergency have highlighted the need to define and implement optimised processes.

Different aspects of the process of clinical trial approval will be tackled including increasing collaboration across National Competent Authorities and ethics committees, and the role of the EMA Emergency Task Force in fostering alignment and discussion across Member States.

---

**Key milestones:**

<table>
<thead>
<tr>
<th>Quarter/Year</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2 2023</td>
<td>Workshop on PH Emergencies</td>
</tr>
<tr>
<td>Q3 2024</td>
<td>Establishment of Priority Action</td>
</tr>
<tr>
<td>Q2 2024</td>
<td>Workshop with MRECs</td>
</tr>
<tr>
<td>2023-2024</td>
<td>Develop process for involvement of MRECs in PHEs</td>
</tr>
<tr>
<td>Q4 2024</td>
<td>Implement process for involvement of MRECs in PHEs</td>
</tr>
<tr>
<td>2023-2024</td>
<td>Develop PHEs clinical trial application package</td>
</tr>
<tr>
<td>Q4 2024</td>
<td>Publish PHEs clinical trial application package</td>
</tr>
<tr>
<td>2023-2026</td>
<td>Develop fit-for-purpose regulatory flexibility in the assessment &amp; conduct of clinical trials in PHEs</td>
</tr>
</tbody>
</table>
Annexes
<table>
<thead>
<tr>
<th>Priority actions</th>
<th>Mapping &amp; governance</th>
<th>Implementation of the Clinical Trials Regulation</th>
<th>Multi-stakeholder platform</th>
<th>Good clinical practice modernisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Map existing initiatives and develop a governance rationalisation strategy (aligning different expert groups and working parties in the EMRN and ethics infrastructure).</td>
<td>Successful and timely implementation of the CTR and its implementing acts by developing KPIs and dashboard to track performance of the European clinical trials environment, and the promotion of larger, multinational trials specifically in the academic setting.</td>
<td>Establish a multi-stakeholder platform, including patients, after stakeholder analysis.</td>
<td>Implementing the GCP modernisation informed by the development of guidance at ICH.</td>
</tr>
<tr>
<td>Clinical trials analytics</td>
<td>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.</td>
<td>Plan and launch a targeted communication campaigns to engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals).</td>
<td>Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical trials training curriculum</td>
<td></td>
<td>Clinical trial methodologies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td>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').</td>
<td>Facilitating aligned clinical trial guidance development across the European network resulting in high impact guidance documents implemented in practice.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical trials in public health emergencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Facilitating large and multinational clinical trials in the European Union (EU) to promptly tackle public health emergencies.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>