ACT EU workplan

2023 - 2026

VERSION 2 – November 2023

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Contents

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.

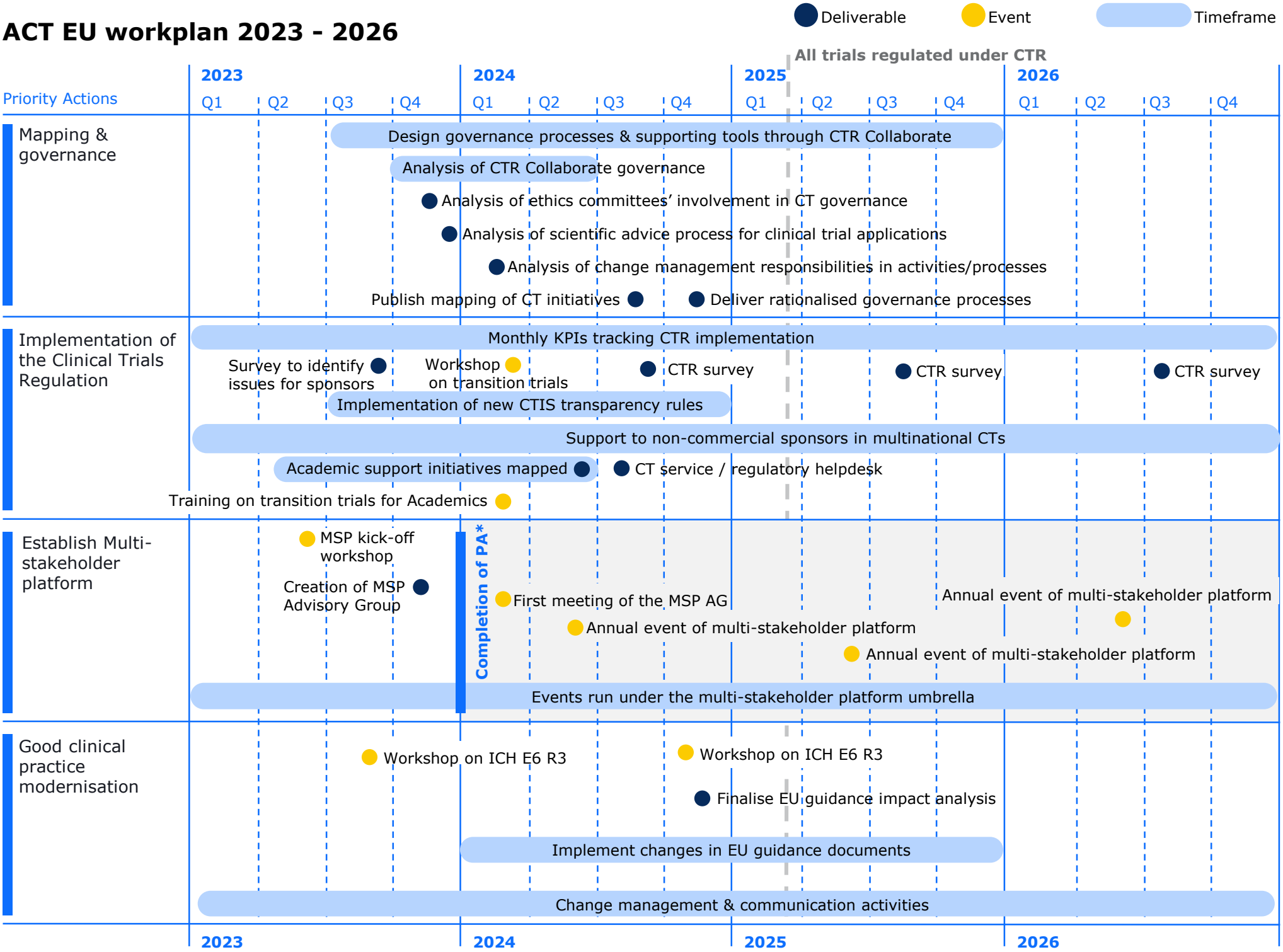
The result will be better, more impactful clinical trials, benefitting patients and healthcare in Europe.

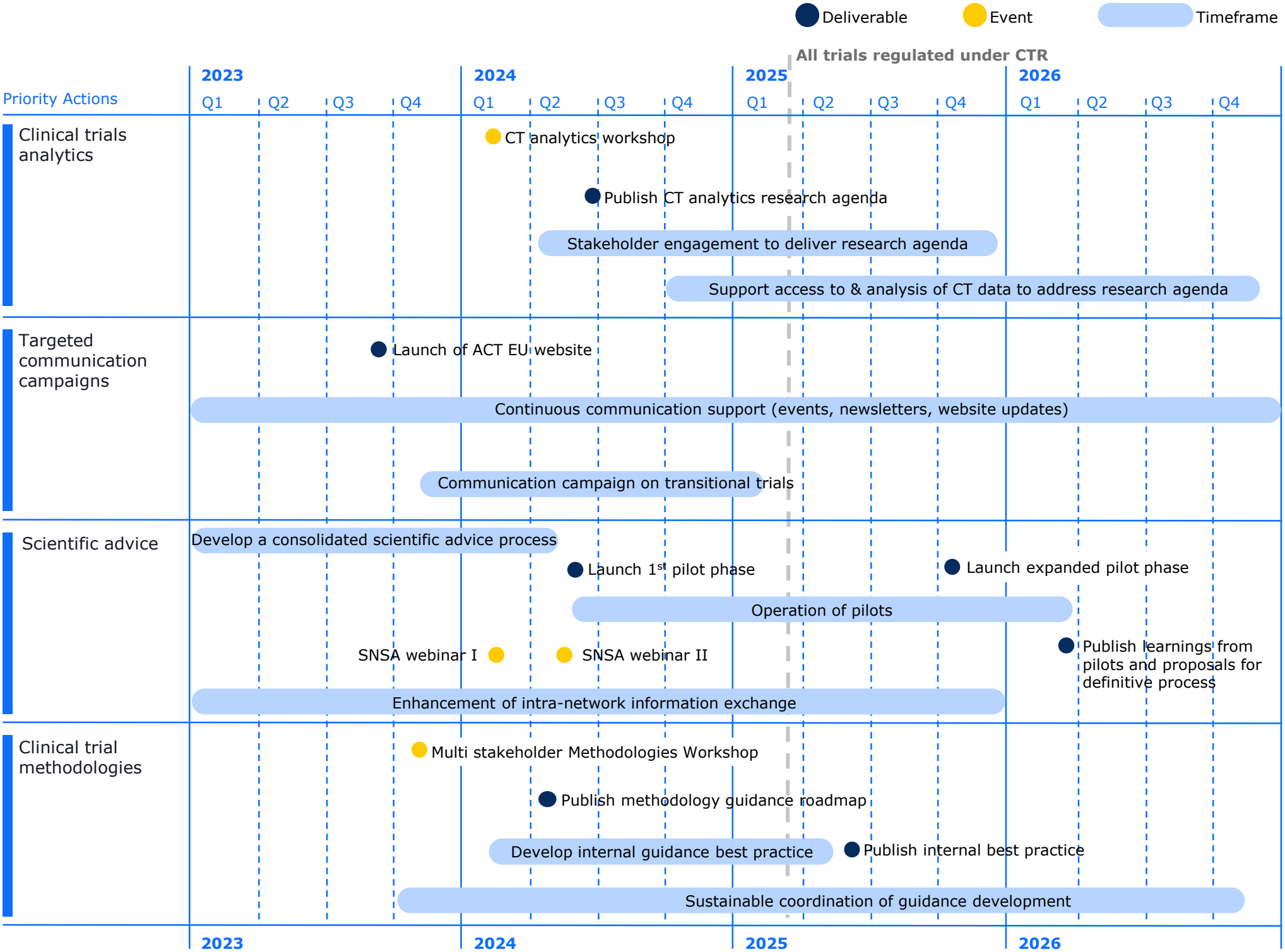
The 2nd HMA-EC-EMA ACT EU workplan was adopted in November 2023 and covers activities until 2026.

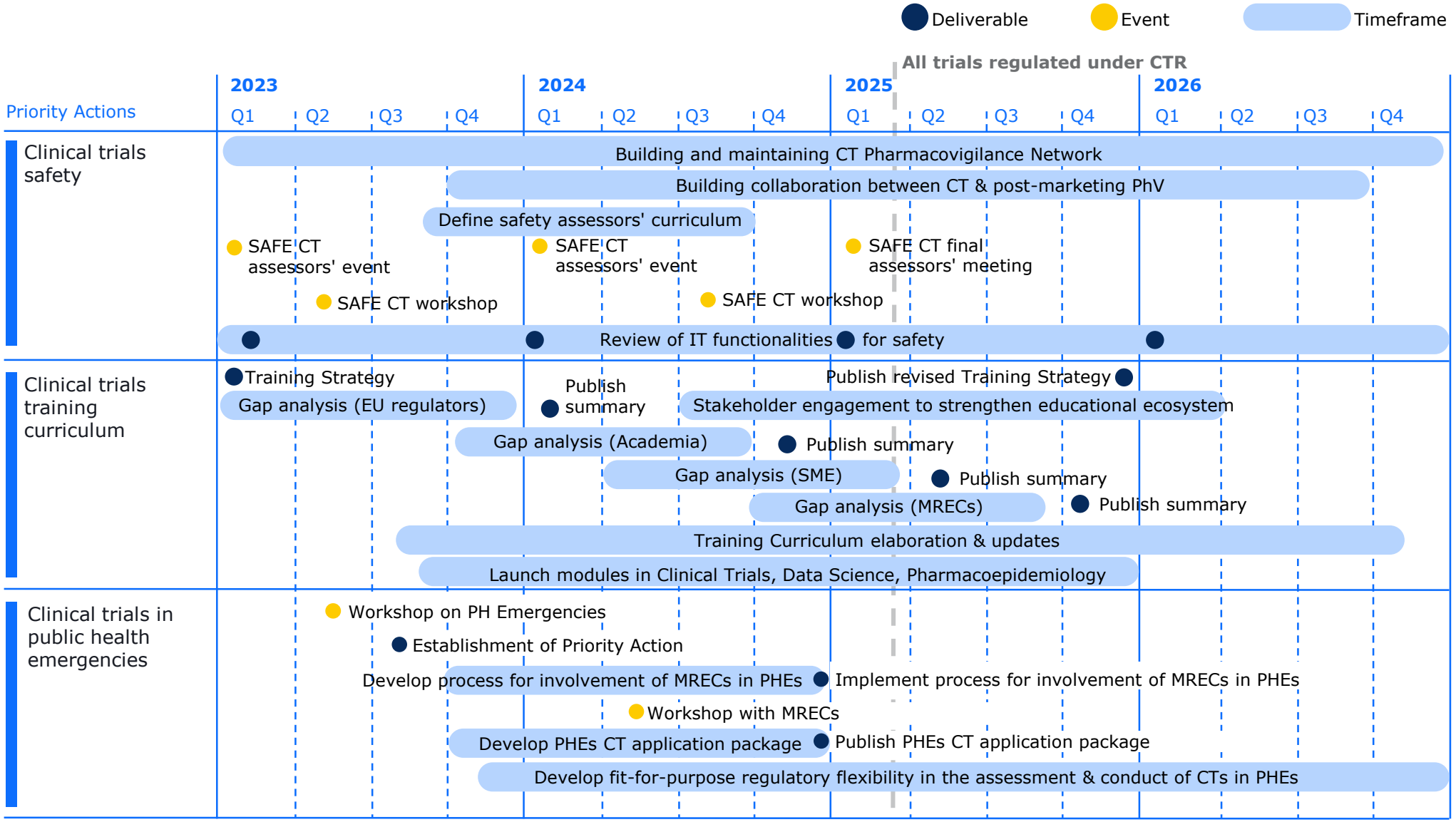
This document introduces each topic and outlines key deliverables. The plan was informed by stakeholder and expert consultation. The document is structured in line with the priority actions of the ACT EU programme (see Annex I).

Workplan

ACT EU workplan 2023 - 2026




Deliverable
Event
Timeframe
All trials regulated under CTR
Priority Actions
2023
2024
2025
2026
Q1
Q2
Q3
Q4
Clinical trials analytics
CT analytics workshop
Publish CT analytics research agenda
Stakeholder engagement to deliver research agenda
Support access to & analysis of CT data to address research agenda
Targeted communication campaigns
Launch of ACT EU website
Continuous communication support (events, newsletters, website updates)
Communication campaign on transitional trials
Scientific advice
Develop a consolidated scientific advice process
Launch 1st pilot phase
Launch expanded pilot phase
Operation of pilots
SNSA webinar I
SNSA webinar II
Publish learnings from pilots and proposals for definitive process
Enhancement of intra-network information exchange
Clinical trial methodologies
Multi stakeholder Methodologies Workshop
Publish methodology guidance roadmap
Develop internal guidance best practice
Publish internal best practice
Sustainable coordination of guidance development



List of abbreviations

CT	Clinical Trial	ICH	International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
CTR	Clinical Trial Regulation	SNSA	Simultaneous National Scientific Advice
KPI	Key Performance Indicator	PhV	Pharmacovigilance
CTIS	Clinical Trial Information System	MRECs	Medical Research Ethics Committees
MSP	Multi-stakeholders Platform	PHEs	Public Health Emergencies
AG	Advisory Group		

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

Implementation of the Clinical Trials Regulation

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 though 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:

Q3 2023	CTR survey to identify issues for sponsors
Q1 2024	Workshop on transitional trials
Q3 2024	CTR survey to identify issues for sponsors
Q4 2024	Implementation of new CTIS transparency rules
Q3 2025	CTR survey to identify issues for sponsors
2022-2026	Monthly KPIs tracking of CTR implementation *(recurrent activity)*

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.

Key milestones:

Q1 2024	Training on transitional trials for academic sponsors
Q2 2024	Academic support activities mapped
Q3 2024	Creation of a CT service / regulatory helpdesk
2023-2026	Support to non-commercial sponsors in multinational clinical trials

Multi-stakeholder platform

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

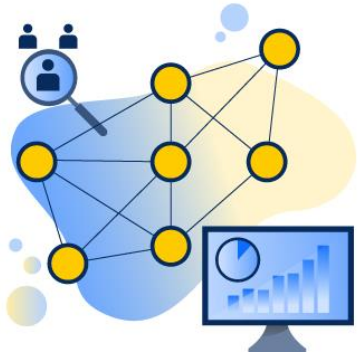
The renovation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2) guideline on "Good Clinical Practice" (GCP) aims to address the application of GCP principles to the increasingly diverse range of clinical trial types and data sources. 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:

Q1 2024	Clinical trials analytics workshop
Q2 2024	Publish CT analytics research agenda
2024-2025	Stakeholder engagement to deliver research agenda
2024-2026	Support access to & analysis of CT data to address research agenda

Scientific advice

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:

Q1 2023	SAFE CT assessors' event
Q2 2023	SAFE CT workshop
Q1 2024	SAFE CT assessors' event
Q3 2024	SAFE CT workshop
2023-2024	Define safety assessors' curriculum
Q1 2025	SAFE CT final assessors' meeting
2023-2026	Building and maintaining CT Pharmacovigilance Network
2023-2026	Building collaboration between CT & post-marketing PhV
2023-2026	Review and update of IT functionalities for safety

Clinical trials curriculum

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:

Q1 2023	Training Strategy
2023	Gap analysis (EU regulators)
Q1 2024	Publish summary
2023-2024	Gap analysis (Academia)
Q4 2024	Publish summary
2024-2025	Gap analysis (SME)
Q2 2025	Publish summary
2024-2025	Gap analysis (MRECs)
Q4 2025	Publish summary
Q4 2025	Publish revised Training Strategy
2023-2025	Launch modules in Clinical Trials, Data Science, Pharmacoepidemiology
2023-2026	Training Curriculum elaboration & updates

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:

Q2 2023	Workshop on PH Emergencies
Q3 2024	Establishment of Priority Action
Q2 2024	Workshop with MRECs
2023-2024	Develop process for involvement of MRECs in PHEs
Q4 2024	Implement process for involvement of MRECs in PHEs
2023-2024	Develop PHEs clinical trial application package
Q4 2024	Publish PHEs clinical trial application package
2023-2026	Develop fit-for-purpose regulatory flexibility in the assessment & conduct of clinical trials in PHEs

Annexes

Priority actions

Mapping & governance

Map existing initiatives and develop a governance rationalisation strategy (aligning different expert groups and working parties in the EMRN and ethics infrastructure).

Implementation of the Clinical Trials Regulation

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.

Multi-stakeholder platform

Establish a multi-stakeholder platform, including patients, after stakeholder analysis.

Good clinical practice modernisation

Implementing the GCP modernisation informed by the development of guidance at ICH.

Clinical trials analytics

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.

Targeted communications

Plan and launch a targeted communication campaigns to engage all enablers (including data protection experts, academia, SMEs, funders, HTA bodies, healthcare professionals).

Scientific advice

Reinforce the coordination between scientific advice on CT approval and CT design and link to the methodologies working party domain.

Clinical trial methodologies

Facilitating aligned clinical trial guidance development across the European network resulting in high impact guidance documents implemented in practice.

Clinical trials safety

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.

Clinical trials training curriculum

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’).

Clinical trials in public health emergencies

Facilitating large and multinational clinical trials in the European Union (EU) to promptly tackle public health emergencies.

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