ACT EU workplan

2025 - 2026

VERSION 3 – December 2024

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Contents

Introduction

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

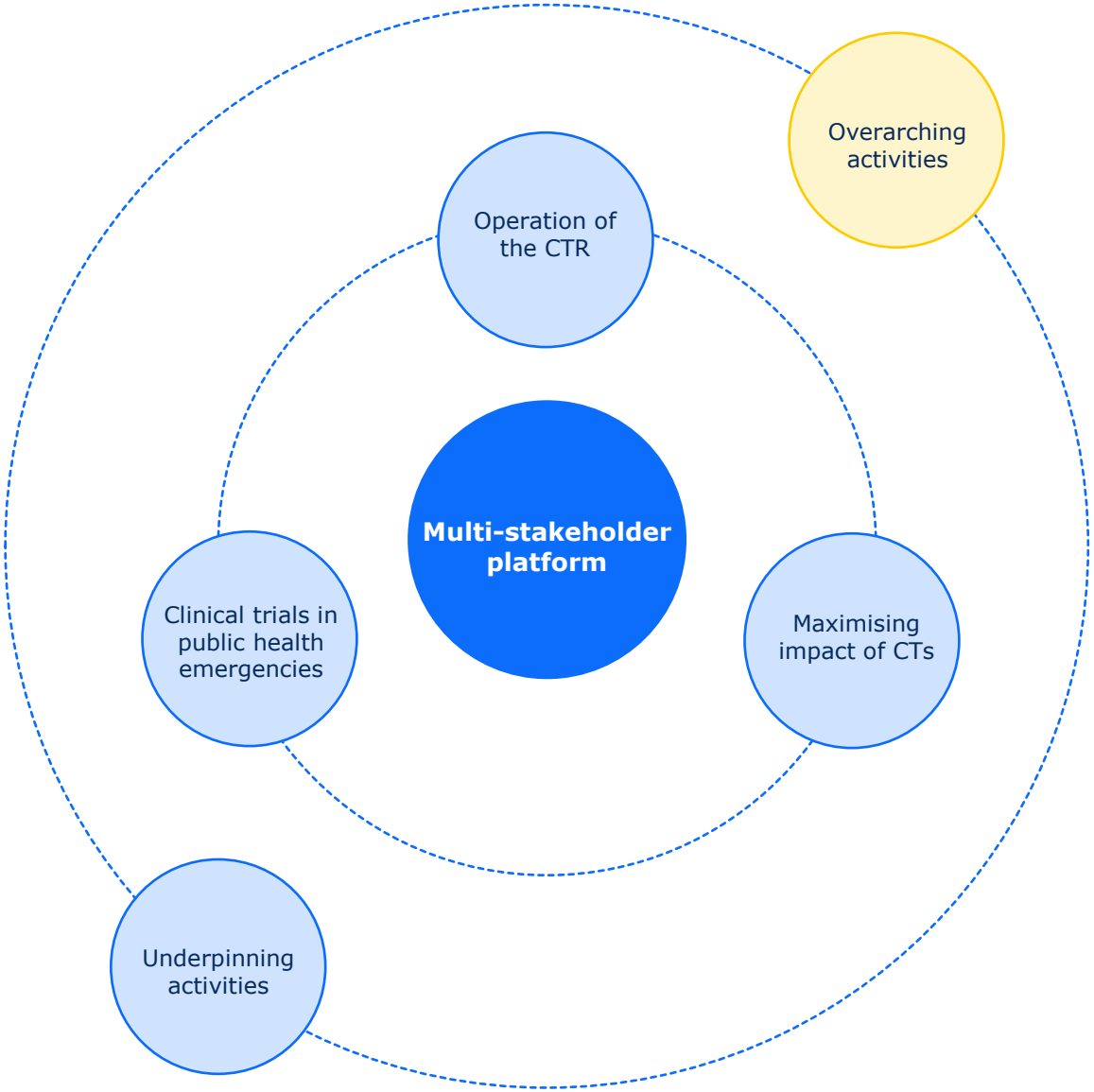
The vision is to have better, faster and optimised clinical trials, benefitting patients and healthcare in Europe.

Seamless coordination between stakeholders, regulators and ethics committees strengthens cross-border collaboration. The ACT EU multi-stakeholder platform is central to this.

The 3rd HMA-EC-EMA ACT EU workplan was adopted in December 2024 and covers activities for 2025 and 2026, together with an overview of the achievements from the previous year. Workshops reflected in the workplan will be organised in collaboration with the European Medicines Regulatory Network (EMRN).

The document was informed by stakeholder and expert consultations and reflects the revised structure of the ACT EU programme based on the evolution of activities over time.

ACT EU structure



Overarching activities:

- ACT EU governance
- Multi-stakeholder Platform

Operation of the Clinical Trials Regulation:

- Implementation of the Clinical Trials Regulation
- Support for non-commercial sponsors
- Clinical trials safety

Maximising impact of clinical trials – design and conduct of excellent clinical trials:

- Good clinical practice modernisation
- Consolidated advice on clinical trials
- Clinical trials methodologies

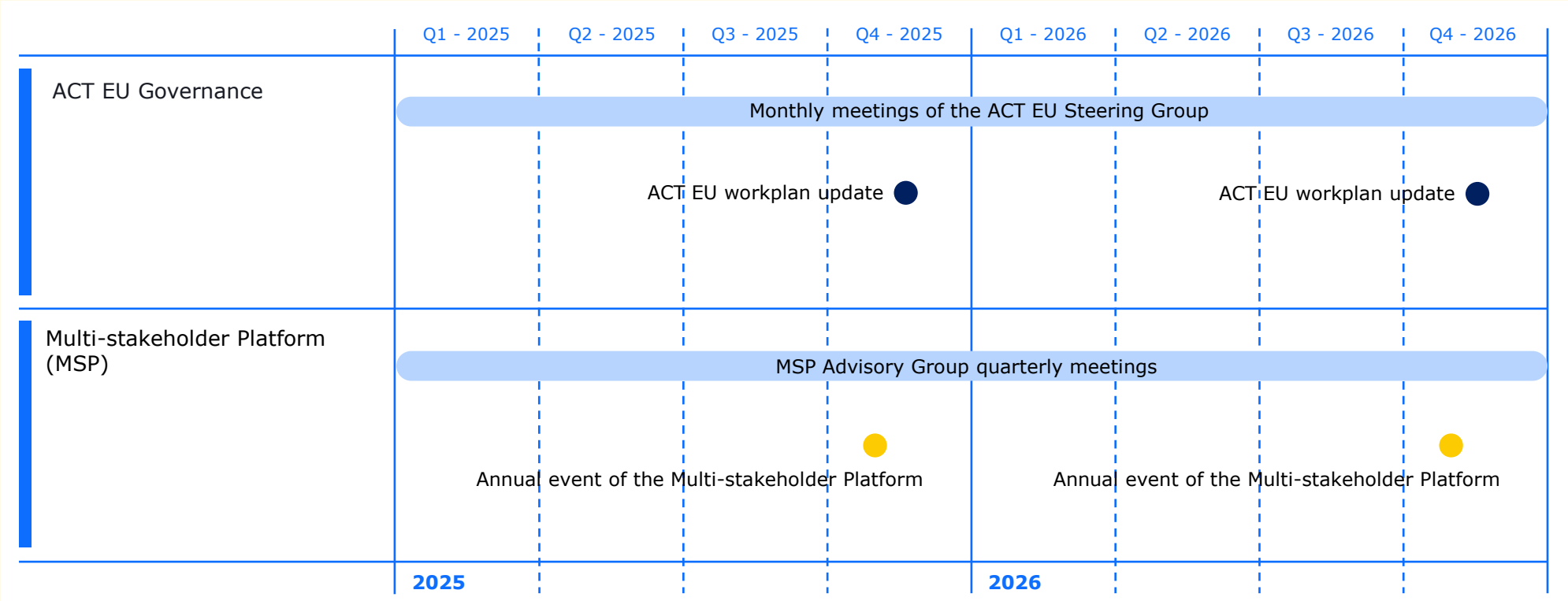
Underpinning activities:

- Communication
- Clinical trials analytics
- Clinical trials training

Workplan

FUNCTIONAL AREA OVERVIEW

Overarching activities



ACT EU Governance and Multi-stakeholder Platform

The ACT EU Governance includes the ACT EU Steering Group that meets on monthly basis underpinned by programme management delivered by representatives of the Commission, HMA and EMA.

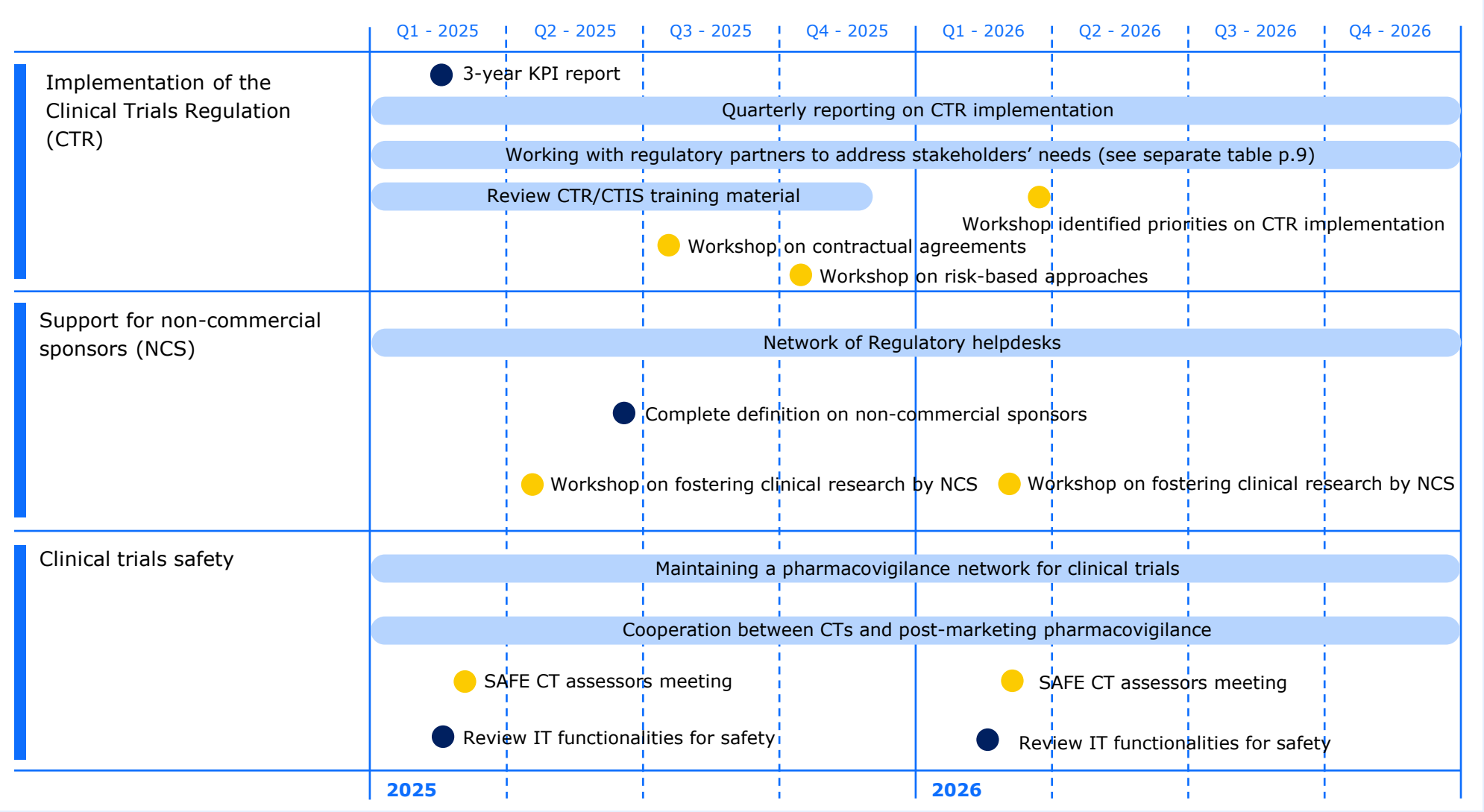
The ACT EU Multi-stakeholder Platform (MSP) and its Advisory Group have been created. The Multi-stakeholder Platform meets yearly with a public meeting, while the advisory group meets on quarterly basis. Via this forum, stakeholders can discuss their needs and priorities and communicate these to the ACT EU regulatory partners.

Delivered in 2024:

Q2-Q3 2024	Mapping of Governance for clinical trials Closure of the priority action 1 on mapping and governance
Q2 2024	Creation of MSP and its Advisory Group (MSP AG) The objective of priority action 3 to establish the MSP has been achieved, and the priority action can be considered closed

FUNCTIONAL AREA OVERVIEW

Operation of the Clinical Trials Regulation



Network initiatives and activities

To address the most important issues reported by stakeholders on the CTR implementation

Issue reported	Responsible bodies
Preparation of requests for information (RFI)	CTCG (CTR Collaborate), MedEthicsEU (part II of CTA), CTAG
Strengthening the role of the reporting Member States (RMS)	CTAG, CTCG, NCA and Ethics Committees
Harmonisation on CTA part II requirements	CTAG, MedEthicsEU, CTCG
Use of common templates in CTA	MedEthicsEU, CTAG
Translation aspects (CTA documents/RFI)	MedEthicsEU, CTAG, CTCG
Risk based approach and Low Interventional Clinical Trials	CTAG, CTCG, MedEthicsEU
Patients' involvement in clinical trials	CTCG
Interplay CTR/IVDR/MDR	COMBINE Programme - Combined studies - European Commission
CTIS functionalities	CTIS Programme - Clinical trials in human medicines | European Medicines Agency (EMA)
Additional relevant initiatives	
Strengthening funding mechanisms	European Commission

Implementation of the Clinical Trials Regulation

The priority action is focused on the implementation of the Clinical Trials Regulation (CTR).

This includes aspects such as:

- Tracking the performance of the European clinical trials environment though regular reporting.
- Re-organisation of existing training material and guidance documents on CTR/CTIS, to facilitate access to users and content update to align with latest developments.
- Working with the ACT EU regulatory partners, as defined in the overview table, to jointly address main issues on CTR implementation.
- Organisation of dedicated workshops, in liaison with the MSP AG to address issues raised by stakeholders.

Delivered in 2024:

Q2 2024	Implementation of CTIS revised transparency rules
Q1-Q4 2024	Increasing transition of clinical trials to CTR, via CTIS
Q3 2024	Yearly survey to sponsors with corresponding published report
Q1-Q4 2024	Publication of monthly KPI reports

Support for non-commercial sponsors

The priority action is focused on understanding the bottlenecks that prevent non-commercial sponsors (NCS) from planning and initiating clinical trials.

This is particularly relevant for multinational clinical trials, and subsequently, the aim is to establish an action plan with clear measures in place, which consists of:

- Creating and maintaining a network of regulatory helpdesks, building on national activities, including extra support for questions related to CTIS/CTR.
- Finalising a definition of non-commercial sponsors.
- Organise dedicated workshops, in liaison with the MSP AG, to address prioritised topics.

Delivered in 2024:

Q2-Q3 2024	Publication of national initiatives at MS level to support NCS
Q2-Q3 2024	Publication of network initiatives (i.e. ECRIN, Enpr-EMA) to support NCS
Q3 2024	Provision of extra support for CTIS related questions

Clinical trials safety

The priority action is focused on strengthening clinical trials safety monitoring in the EU, by maintaining a clinical trials pharmacovigilance network.

This includes regular dialogue via the safety assessors' roundtables and enabling collaboration between clinical trial and post-marketing pharmacovigilance.

This activity enables Member States to work together to improve trial safety through coordinated work-sharing assessment. The EU4Health Joint Action 12 (SAFE CT), which is focused on capacity building and training, facilitates this activity.

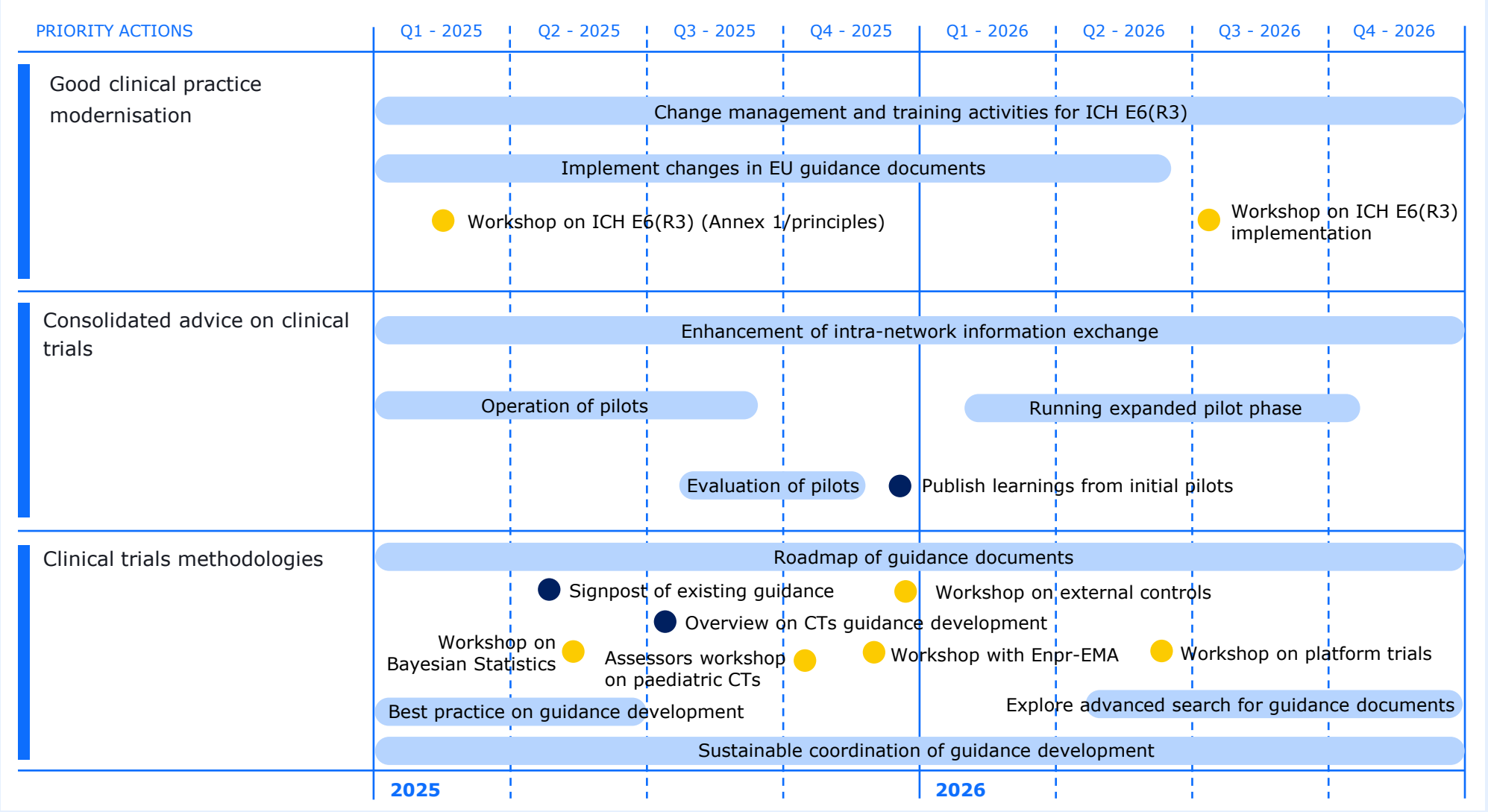
In addition, a training curriculum for safety assessors has been developed.

Delivered in 2024:

Q1 2024	Organisation of SAFE CT workshop
Q1-Q4 2024	Establishment of roundtable for safety assessors, maintaining a clinical trials pharmacovigilance network
Q4 2024	Delivery of the training curriculum for safety assessors

FUNCTIONAL AREA OVERVIEW

Design and conduct of excellent clinical trials



Good clinical practice modernisation

The renovation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 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 provides flexibility, when appropriate, to facilitate the use of technological innovations in clinical trials.

The priority action is focused on supporting the implementation of ICH E6(R3), also via dedicated workshops in liaison with the MSP and its advisory group.

The activities of the priority action include 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.

Delivered in 2024:

Q1-4 2024 Activities at ICH level on E6 (R3) revision

Consolidated advice on clinical trials

The priority action is focused on bringing together key actors in clinical trials in the EU. Pilot initiatives are in place to facilitate the dialogue between regulators and sponsors/applicants prior to submission of applications.

One pilot aims at reinforcing the scientific advice coordination between clinical trial approval and clinical trial design in a collaboration between SAWP/CTCG.

A second initiative, coordinated by CTCG, covers pre-CTA advice on regulatory aspects.

An analysis of the pilot initiatives, followed by a publication of the learnings will take place in 2025. Subsequent proposals for definitive processes will be considered, to facilitate the development of safe and effective medicines for the benefit of patients.

Delivered in 2024:

Q2 2024	Launch of consolidated pilots on clinical trials: SWAP/CTCG and pre-CTA (CTCG)
Q2 2024	Publication of guidance documents for sponsors/applicants on the pilot initiatives
Q3 2024	Evaluation of the first two iterations of pre-CTA consolidated advice (10 pre-CTA procedures)

Clinical trials methodologies

The priority action is focused on facilitating activities on methodological aspects for clinical trials.

To reach this goal, the objectives of the work are:

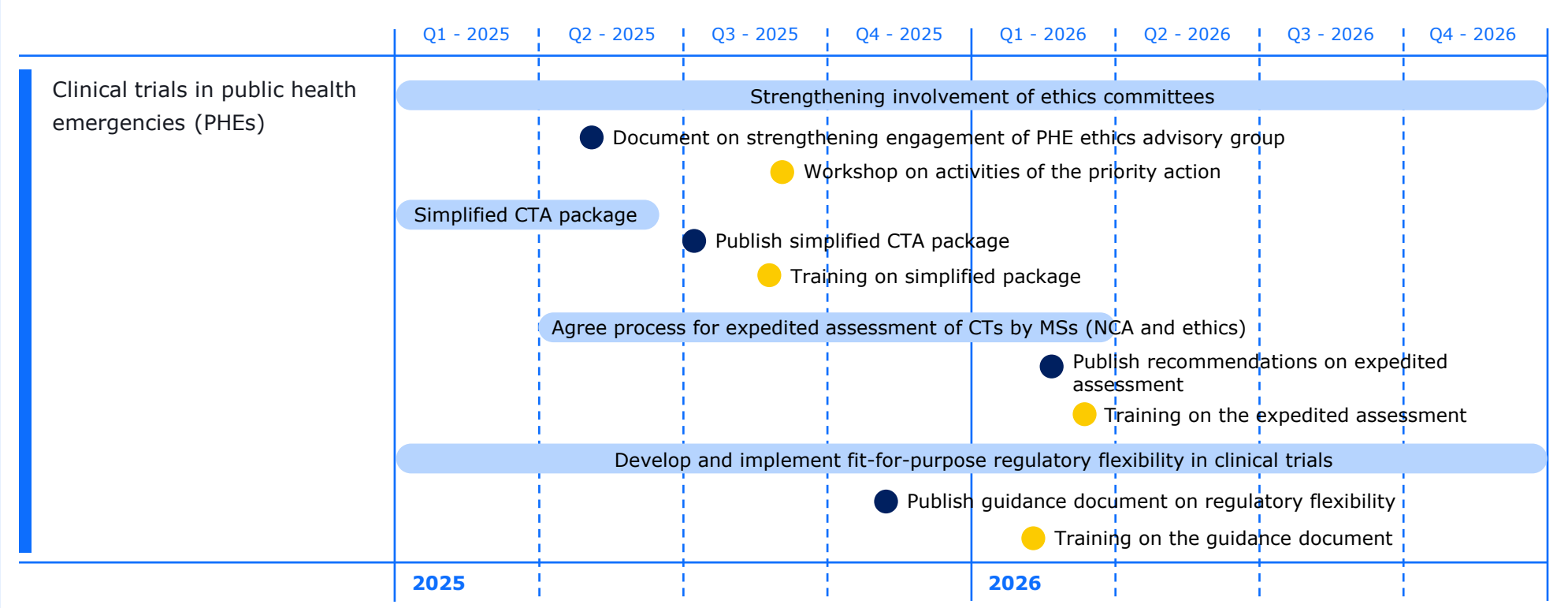
- Ensure aligned clinical trial guidance development across the EU network resulting in high impact guidance documents implemented in practice.
- Bring together key decision makers during the clinical trial life cycle (including MWP, CTCG, HTA) via sustainable coordination of guidance development.
- Help stakeholders navigate the EU clinical trial guidance landscape, by developing a signposting of existing MWP/CTCG/HTA guidance documents and an advanced search tool. In addition, an overview of future guidance documents in line with corresponding workplans of the relevant groups will be generated.
- Organise dedicated workshops on topics of interest, also in liaison with the MSP AG.

Delivered in 2024:

Q2-Q4 2024	Coordination of guidance between MWP, CTCG and HTA coordination group established
Q2-Q4 2024	Ongoing activities on best practice on guidance development

FUNCTIONAL AREA OVERVIEW

Clinical trials in public health emergencies



Event Deliverable Timeframe

Clinical trials in public health emergencies

The priority action is focused on enabling multinational clinical trials during public health emergencies (PHEs).

Different aspects of the process of clinical trial approval are tackled, including:

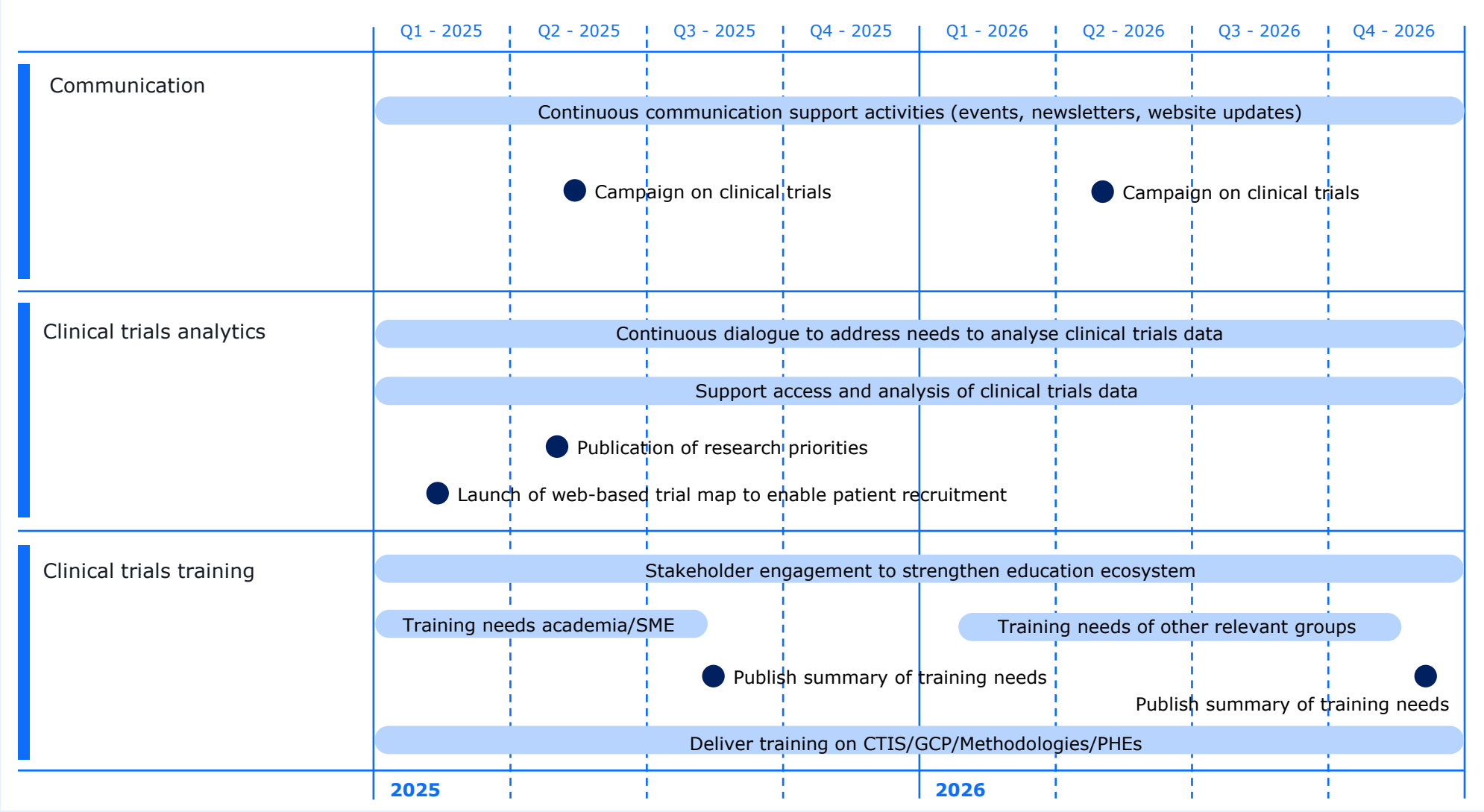
- Strengthen collaboration across National Competent Authorities and Medical Research Ethics Committees in the assessment of clinical trials in PHE and liaise with the EMA Emergency Task Force (ETF), to foster alignment and discussion across Member States. This includes also an analysis on possible benefits of having a central ethics committee during PHE.
- Define a simplified package for submission of applications for clinical trials in PHE and expedited assessments.
- Enable regulatory flexibilities in the assessment and conduct of clinical trials, based on the experience gained during COVID-19 pandemic.

Delivered in 2024:

Q2 2023	Work structure defined with 3 dedicated tracks
Q3 2024	Establishment of PHE ethics advisory group
Q4 2024	Workshop with Emergency Task Force

FUNCTIONAL AREA OVERVIEW

Underpinning activities



Event Deliverable Timeframe

Communication

The priority action is focused on the communication aspects related to clinical trials. In addition, it supports regular dissemination of newsletters and information about events organised under ACT EU.

Annual awareness campaigns are planned, with the intention to highlight the importance of clinical trials and their benefits for patients to increase public understanding and promote trust in the research process.

Delivered in 2024:

Q1-4 2024	Training, events, newsletters, communication campaign, regular updates of the ACT EU website

Clinical trials analytics

The priority action is focused on engagement with the community of stakeholders to understand their needs and how data about clinical trials could support them.

The stakeholders' use cases are being collected to inform research priorities which may influence future public funding calls.

A trial map for patients and health care professionals is being developed to facilitate access to clinical trials information in a user-friendly manner. The map will make it easier for patients to identify trials relevant to them.

By highlighting research needs and facilitating access and analysis of clinical trial data, this priority action will inform better research and development of medicines and policy making in the EU.

Delivered in 2024:

Q1 2024	Clinical trials analytics workshop

Clinical trials training

To support high quality clinical trials and enable better knowledge sharing, a training curriculum informed by regulatory experience is being developed.

An overarching strategy and collection of training needs for different stakeholder groups will serve as the basis for the development of curricula.

Engaging with stakeholders, identified via the dedicated training strategy, the curriculum will feed into an educational 'ecosystem' which will benefit from bidirectional exchanges to enable targeted training on clinical trials.

Delivered in 2024:

Q2-Q4 2023	Training gap analysis for regulators
Q1 2024	Publication and dissemination of gap analysis summary/report
Q2-Q4 2024	Ongoing analysis of training needs for academia and SME

European Medicines Agency

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Visit Accelerating clinical trials in the EU