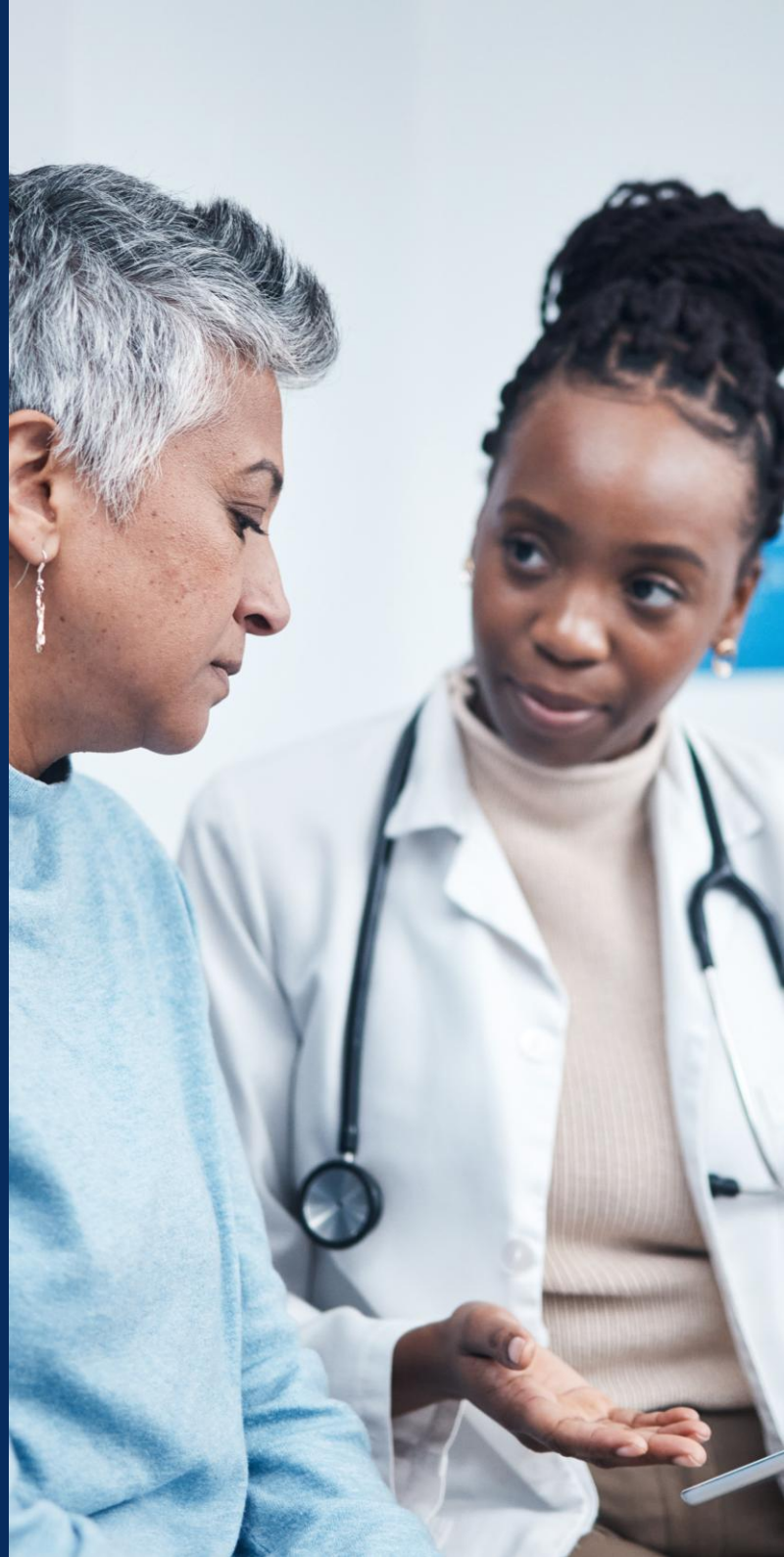
ACT EU workplan

2026 - 2027

VERSION 4 – May 2026

ACTEU@ema.europa.eu



Our Vision

Better, faster, smarter clinical trials.

Our Goal

Increased attractiveness of the EU
500 more multi-national trials authorised by 2030.

Faster access to treatment, 66% of trials start recruitment in under 200 days from application submission.

…while protecting clinical trials participants and generating robust data for public health...

Our Objectives

- Engage stakeholders, patients
- Strengthen EU competitiveness
- Enable innovation
- Facilitate inclusive clinical trials
- Foster excellent scientific and regulatory advice
- Clarify EU position at international level
- Provide capacity building, training

Contents

Introduction

The Accelerating Clinical Trials in the European Union (ACT EU) initiative is a collaboration between the European Commission (EC), The Heads of Agencies (HMA) and the European Medicines Agency (EMA). It supports clinical trials through regulatory, technological and process innovation.

The vision is to have better, faster and smarter clinical trials, benefitting patients and healthcare in the European Union. The ACT EU multi-stakeholder platform is central to the work and enables stakeholders the opportunity to provide feedback on priorities that are considered as part of the revision of the workplan.

The 4th HMA-EC-EMA ACT EU workplan was adopted in May 2026 and covers activities for 2026 and 2027, together with an overview of the achievements from 2025.

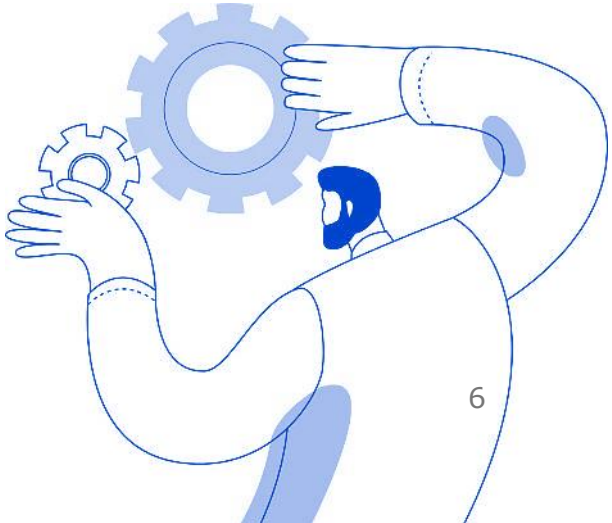
In this new version, the workplan reflects the closure of the priority action on safety that has delivered the operational model to strengthen the exchange of information within the network on safety matters, as well as the priority action on GCP modernisation that has delivered training and change management activities around the newly adopted ICH E6 R3.

The workplan is based on the revised ACT EU objectives endorsed by the ACT EU governance to reflect the needs of the clinical trials environment in the EU.

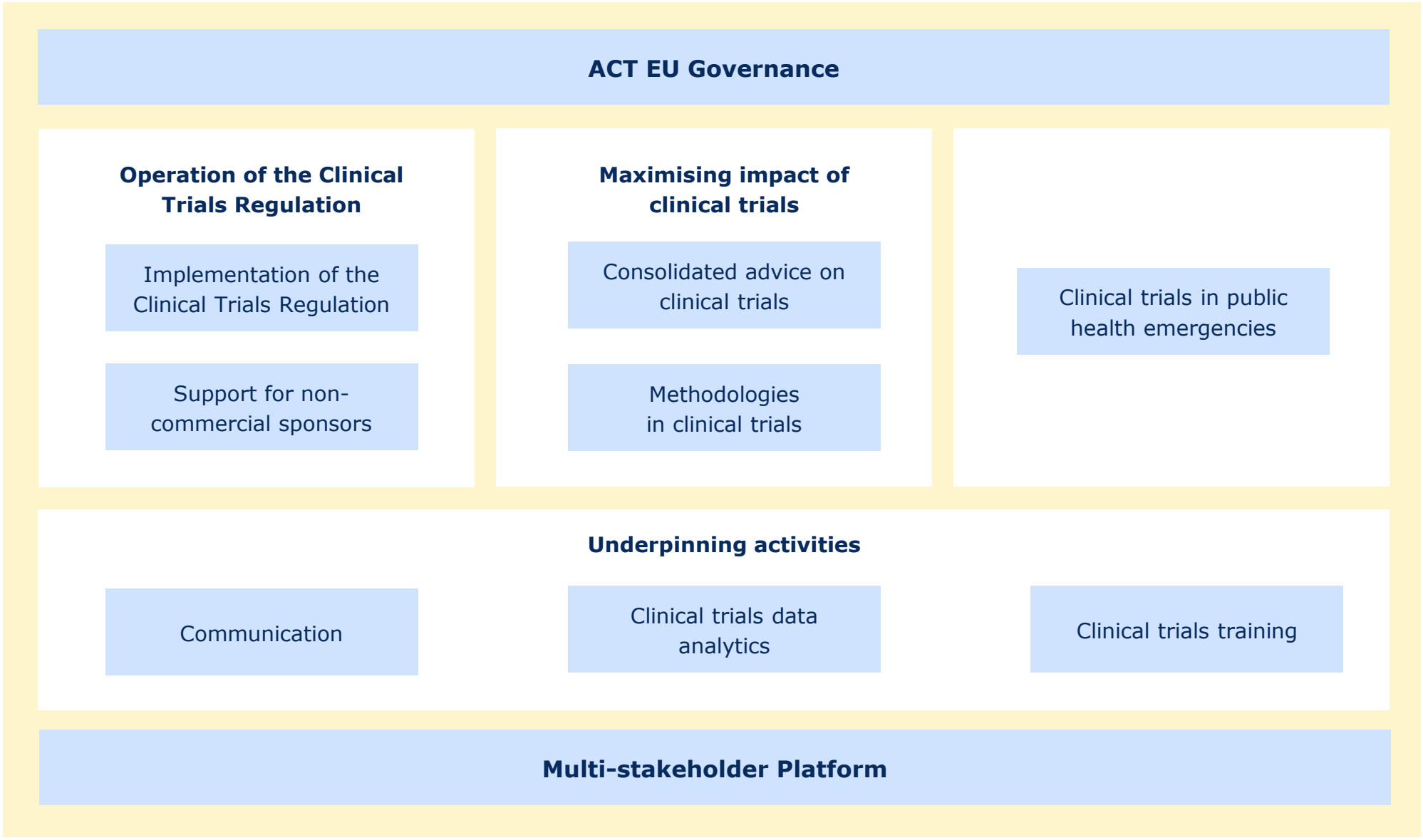
The workplan also considers the EC proposed Biotech Act which impacts the Clinical Trials Regulation (CTR), the EC Life Science Strategy and its Clinical Research Investment Plan and builds synergies with the EU4health initiatives, as well as Innovative Health Initiatives (IHI) funded projects.

ACT EU aims to increase the attractiveness of the EU for clinical trials and speed up access to treatment.

The document is informed by consultations of stakeholders and experts.

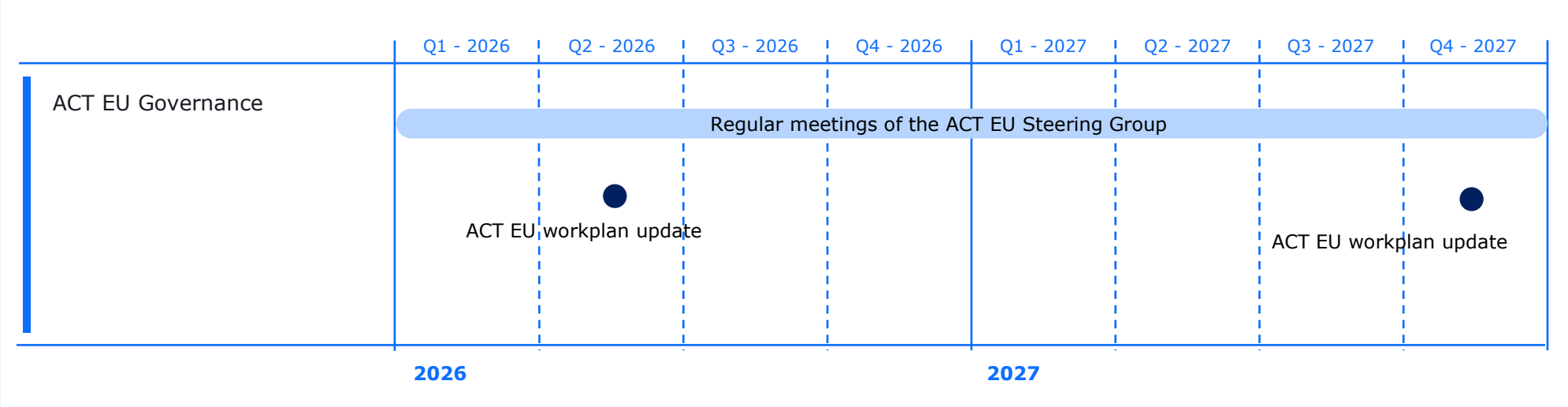


ACT EU Programme Structure



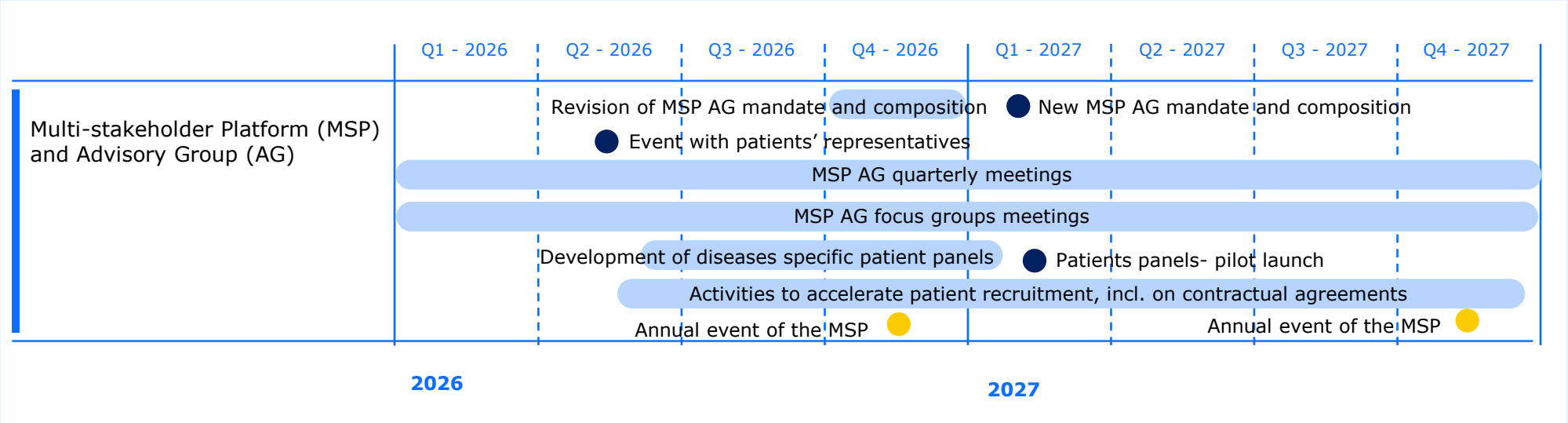
Workplan

FUNCTIONAL AREA OVERVIEW



Event Deliverable Timeframe

FUNCTIONAL AREA OVERVIEW



Event Deliverable Timeframe

ACT EU Governance

The ACT EU Governance includes the ACT EU Steering Group that meets on regular basis and is composed of representatives of the European Commission, HMA and EMA.

The ACT EU Steering Group steers the vision and mission of the initiative and oversees the development of the clinical trial environment and the deliverables of the programme.

The ACT EU Steering Group has a decision-making role and reports to the EMA Management Board and HMA.

Delivered in 2025:

Q1-Q4 2025	Regular meetings of the ACT EU Steering Group throughout the year.
Q4 2025	Annual meeting of the ACT EU Matrix group including EMA, Member States (HMA) and European Commission.

ACT EU Multi-stakeholder Platform and its Advisory group (AG)

The ACT EU Multi-stakeholder Platform (MSP) and its Advisory Group (AG) are established and operational. The group mandate and composition will be reviewed during 2026 in line with the mandate.

The MSP 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.

Focus groups have been created to discuss the following topics of interest with stakeholders: 1) revision of CTIS/CTR training material, 2) risk-based approaches in clinical trials, 3) training needs for academia and small and medium-sized enterprises (SMEs). The possibility to establish disease specific patient pannels is also being considered.

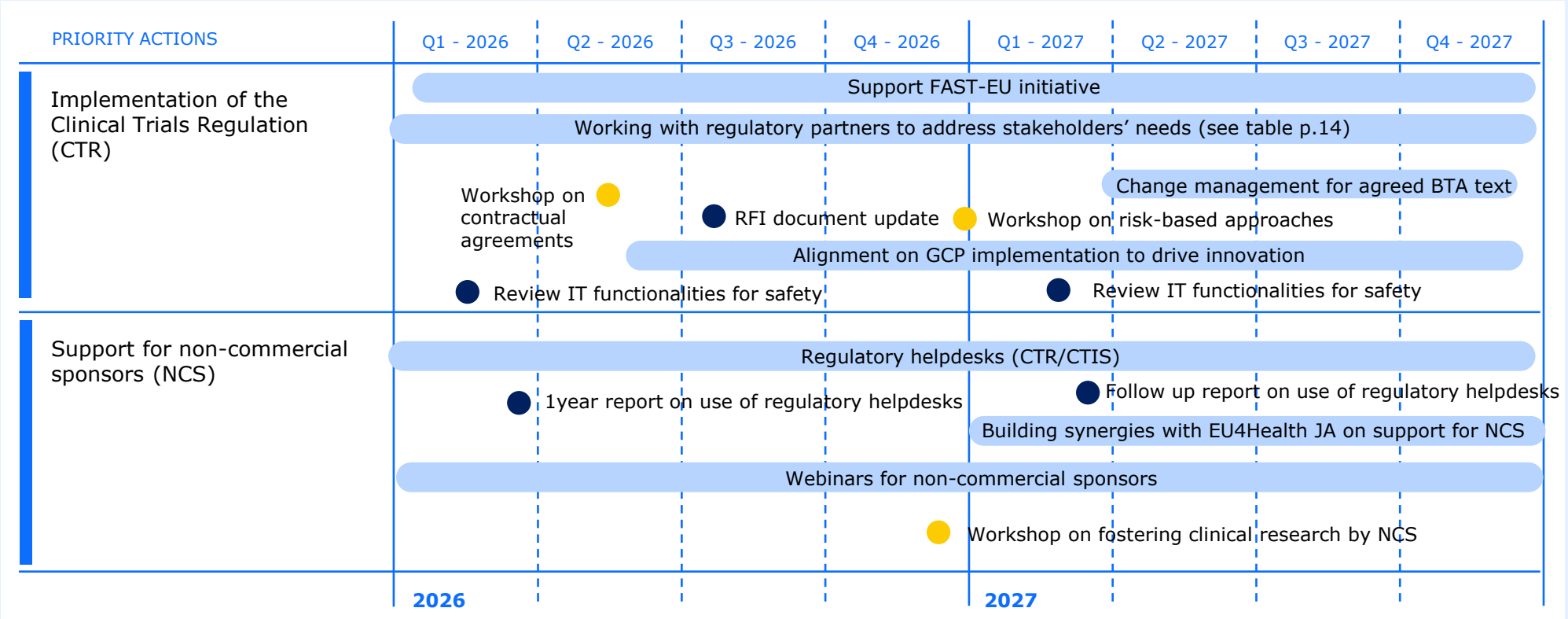
In 2026 a new focus group on management of serious breaches has been created with the aim to streamline the process for reporting and assessment of serious breaches in the EU.

Delivered in 2025:

Q1-Q4 2025	Regular meetings of the MSP AG throughout the year.
Q2-Q4 2025	Establishment via the MSP AG of focus groups on 1) revision of CTIS/CTR training material, 2) risk-based approaches in clinical trials, 3) training needs for academia and SME. Consultation on the update of the paper on the use of auxiliary medicinal products.
Q4 2025	Annual meeting of the ACT EU MSP.

FUNCTIONAL AREA OVERVIEW

Operation of the Clinical Trials Regulation



Event Deliverable Timeframe

Additional initiatives and activities to strengthen EU competitiveness

Issue reported	Responsible bodies
Continue activities on RFI and strengthening RMS role	CTCG (CTR Collaborate), MedEthicsEU, CTAG
Harmonisation on CTA part II requirements and use of common templates	CTAG, MedEthicsEU
Building synergies with existing initiatives	EU4health initiatives, Life Science Strategy, IHI READI, IHI Realise-D, etc..
CTIS functionalities	CTIS Programme - Clinical trials in human medicines | European Medicines Agency (EMA)
Interplay CTR/IVDR/MDR	COMBINE Programme - Combined studies - 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:

- Working with the ACT EU regulatory partners, as defined in the overview table, to jointly address main issues on CTR implementation.
- Providing technical support for legislative work, as appropriate.
- Aligning with EU4Health initiatives focused on supporting capacity building for CTR implementation.
- Aligning on GCP implementation to drive innovation.
- Addressing topics of interest such as contractual agreements and risk-based approaches in clinical trials.
- Reviewing IT functionalities related to safety in clinical trials.

Delivered in 2025:

Q1 2025	Successful transition of clinical trials to CTR requirements.
Q1-Q4 2025	Publication of quarterly metrics reports.
Q3 2025	Publication of 3-year analysis report.
Q3 2025	Publication of revised CTR/CTIS training material (CTIS master sponsor handbook).
Q3 2025	Publication of document on most frequently raised RFI part I and part II.

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, as well as on supporting non-commercial sponsors throughout the conduct of these trials.

Particularly relevant for multinational clinical trials, the action plan consists of:

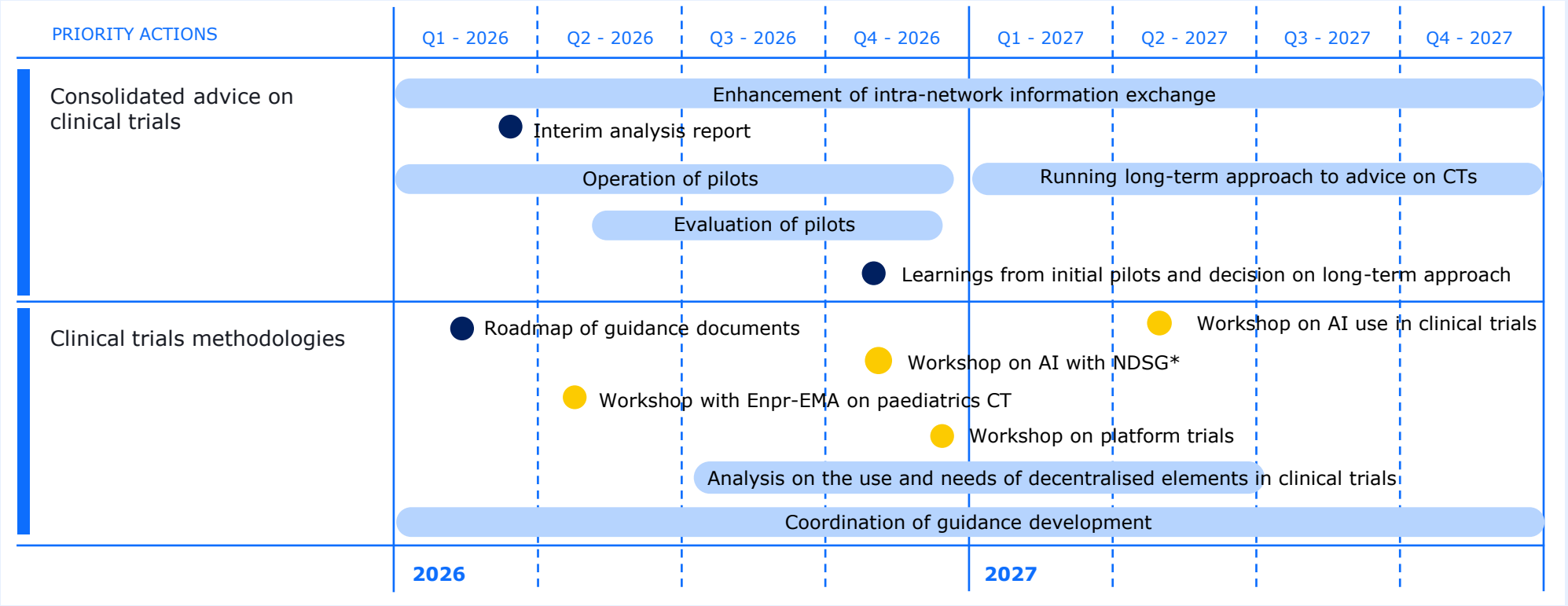
- Maintaining a regulatory helpdesk for enquiries related to CTIS/CTR in collaboration with EU NCAs.
- Organising national webinars to raise awareness of regulatory support available to NCS at national and EU level, including ACT EU.
- Aligning with EU4Health initiatives focused on support for NCS.
- Organising dedicated stakeholder workshops, in liaison with the MSP AG, to address prioritised topics.

Delivered in 2025:

Q1-Q4 2025	Regular updates of the interactive map on the ACT EU website with an overview of national initiatives to support NCS.
Q1-Q4 2025	Regular updates of network initiatives on the ACT EU website to support NCS.
Q1-Q4 2025	Maintenance of CTIS/CTR regulatory helpdesk, in liaison with Member States, to provide support for CTIS/CTR related queries.
Q2-Q4 2025	Organisation of regular webinars to increase awareness of ACT EU and the CTR/CTIS regulatory helpdesk.
Q4 2025	Publication of the 6-month report since the launch of the CTR/CTIS regulatory helpdesk.

FUNCTIONAL AREA OVERVIEW

Design and conduct of excellent clinical trials



*Network Data Steering Group

Event Deliverable Timeframe

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 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 pilot, coordinated by CTCG, covers pre-CTA advice on regulatory aspects.

The two pilots will continue to gather experience, and results will be further analysed in 2026 together with a decision on the long-term approach for clinical trials advice.

Delivered in 2025:

Q1-Q4 2025	Throughout the year, the two pilots on SAWP/CTCG interaction and pre-CTA were maintained, with a total of 32 applications received in 2025.
Q1-Q4 2025	3 reviews of pre-CTA advice and 2 reviews of SAWP/CTCG applications. Each review included 5 applications for which assessment has been concluded.
Q2 2025	Update of guidance documents for sponsors/applicants on the pilot initiative.

Clinical trials methodologies

The priority action is focused on methodological aspects of clinical trials.

The objectives of the work are to:

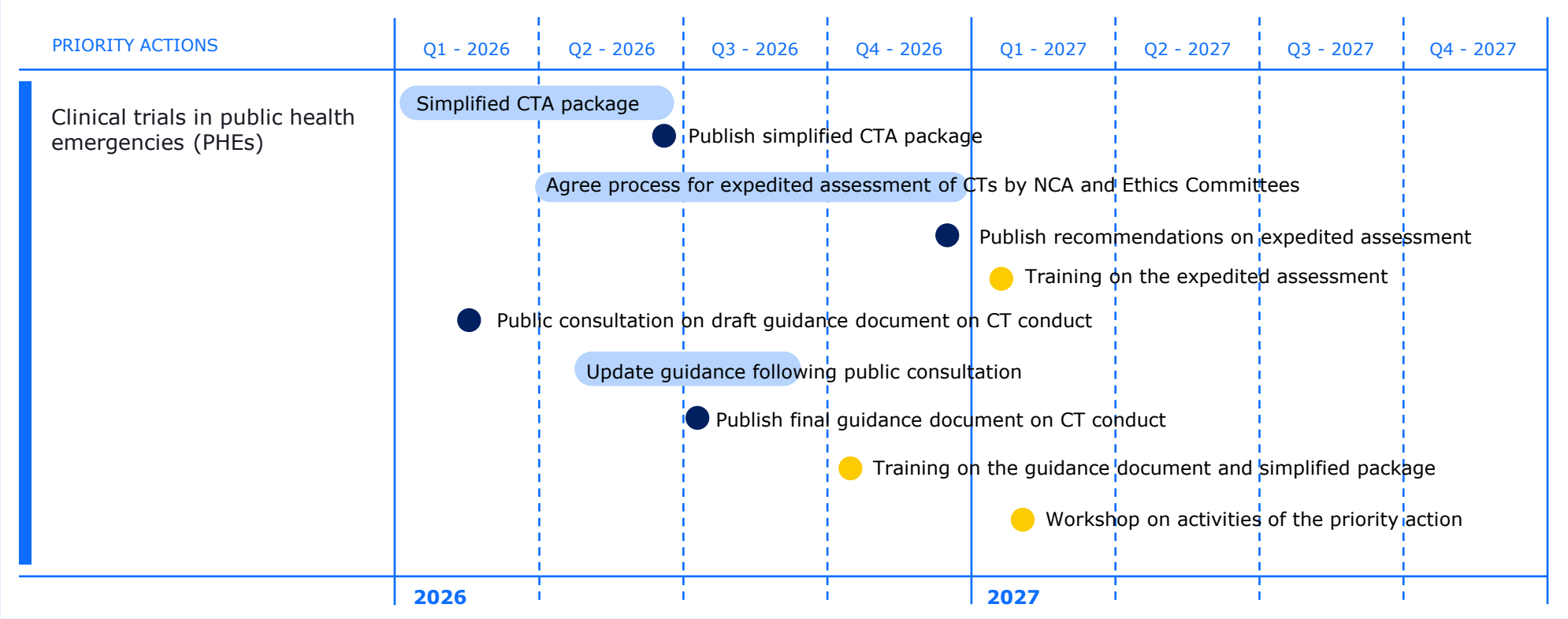
- Promote the use of the best practice on guidance development, resulting in high impact guidance documents implemented in practice.
- Bring together key decision makers during the clinical trial life cycle (including MWP, CTCG, HTA Coordination Group) via coordination of guidance development.
- Provide an overview of future guidance documents developed within the network, in line with the workplans of the relevant groups.
- Contribute to the NDSG workshop on the use of AI.
- Organise dedicated workshops on topics of interest such as paediatric clinical trials and platform trials.

Delivered in 2025:

Q1-Q4 2025	Regular meetings to coordinate methodology guidance (MWP/CTCG/HTA CG).
Q1 2025	Signposting of existing methodology guidance documents on clinical trials.
Q2 2025	Finalisation of the best practice on guidance development.
Q2 2025	Workshop on Bayesian statistics.
Q3 2025	Workshop for assessors on clinical trials in paediatric populations.
Q4 2025	Workshop on external controls in clinical trials.

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 have been tackled, including:

- Strengthening collaboration across National Competent Authorities and Medical Research Ethics Committees in the assessment of clinical trials in PHEs liaising with the EMA Emergency Task Force (ETF), to foster alignment and discussion across Member States.

The activities of the priority action continue to focus on:

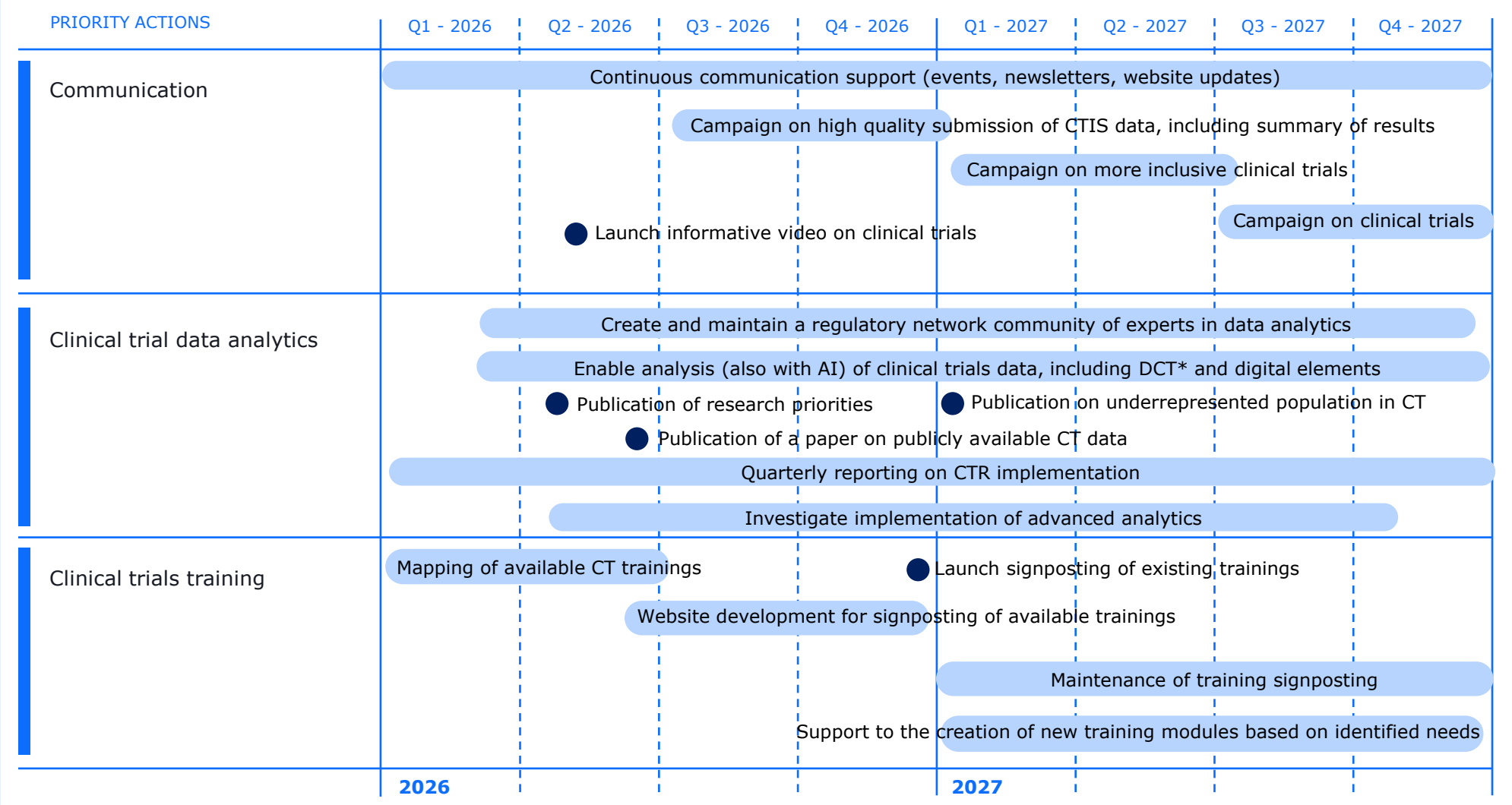
- Defining a simplified package for submission of applications, including language requirements for clinical trials in PHEs.
- Enabling regulatory flexibilities in the conduct of clinical trials, based on the experience gained during COVID-19 pandemic.
- Developing a process for expedited assessment during PHEs.

Delivered in 2025:

Q1 2025	Define and set up the process for collaboration between the PHE Ethics Advisory Group and the EMA ETF.
Q1-Q4 2025	Ongoing activities to define content of simplified package and language requirements.
Q3 2025	Internal consultation within the EMRN on the regulatory flexibility guidance in the conduct of clinical trials during public health emergencies.

FUNCTIONAL AREA OVERVIEW

Underpinning activities



* Clinical Trials with Decentralised elements

Event Deliverable Timeframe

Communication

The priority action is on communication support to the programme and to the network on clinical trials related topics. It also supports regular dissemination of newsletters and information about events organised under ACT EU.

Clinical research campaigns will be addressed by the Priority Action in collaboration with the Working Group of Communication Professionals and MSP AG.

The planned activities include awareness campaigns on:

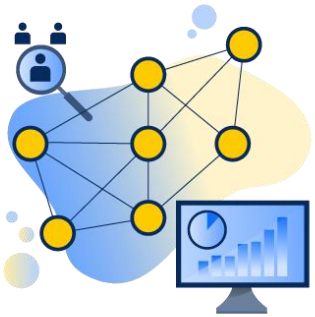
- High quality submission of CTIS data, particularly trial results (also in lay terms), to be delivered in collaboration with the priority action on clinical trials data analytics.
- Awareness and participation in clinical trials, with the aim to have more inclusive clinical trials.

More campaigns may be considered on prioritised focus areas. The aim is to highlight the importance of clinical trials and their benefits for patients to increase public understanding and promote trust in the clinical research process.

Delivered in 2025:

Q1-Q4 2025	Training, events, newsletters, communication campaign, regular updates of the ACT EU website.
Q4 2025	Video to increase awareness on clinical trials prepared (with launch planned in 2026).
Q4 2025	Video on new features of trial map prepared and launched (search enabled in official EU/EEA languages).

Clinical trial data analytics



By highlighting research needs and facilitating access and analysis of data about clinical trials, this priority action informs better research and development of medicines and policymaking in the EU.

The priority action is focused on engagement with the EU regulatory network and stakeholders to understand their needs and how clinical trials data can support them.

Reports to monitor trends of clinical trials in the EU are published on a quarterly basis with key performance indicators measured against targets, looking at attractiveness and speed of clinical trials in the EU.

A trial map for patients and health care professionals has been developed to facilitate access to clinical trials information in a user-friendly manner. The trial map makes it easier for patients to identify trials relevant to them; similar implementation of advanced analytics will continue.

Delivered in 2025:

Q1 2025	Launch of the trial map to facilitate patient recruitment.
Q4 2025	Launch of additional features of trial map and search in EU/EEA languages.

Clinical trials training

This priority action focuses on creating a learner centric eco-system to facilitate access to trainings on clinical research, and particularly interventional studies, of relevance for academia and Small and Medium Enterprises (SME).

Identification of prioritised training areas builds on the stakeholders' feedback following the survey conducted in 2025.

The priority action will identify and appraise existing training resources, ensuring they are context-relevant.

Via signposting, it will ensure access to trainings, based on learners individual needs and monitor the eco-system usefulness, including reach, quality, and impact of training activities.

By doing this the priority action may identify scientific and regulatory gaps. For some of these gaps, it may invite the creation of new modules.

Delivered in 2025:

Q1 2025	Launch of a survey on training needs for academia and SME.
Q3 2025	Publication of a report describing identified training needs for academia and SME.
Q4 2025	Initiating mapping and signposting of existing offerings.

ACT EU objectives

Revised ACT EU objectives

Objective 1

Strengthen EU competitiveness by accelerated clinical research timelines, increased efficiency and enhanced regulatory convergence, in line with the Biotech Act proposal amending the Clinical Trial Regulation and the Clinical Research Investment Plan by:

a. Strong leadership and coordination on clinical trial authorisation and execution.

b. Optimising ethical oversight and further integrate ethics committees into the clinical trial and medicines regulatory lifecycle, to promote the highest level of participant protection and ensure that public trust in clinical trials remains a cornerstone of EU clinical research.

c. Supporting the conduct of large-scale multinational clinical trials with broader geographical scope.

d. Reducing administrative burden, especially for academic and SMEs sponsors and increasing coordinated national implementation.

e. Increasing awareness of the resources available to design, manage and conduct clinical trials, including access to funding and research infrastructures.

Objective 2

Strengthening clinical trials with appropriate **inclusion of under-represented populations** such as children and women (including pregnant and lactating women) to deliver decisional evidence.

This should include clinical trials that answer research questions for **unmet medical needs**, rare diseases as well as vaccines and therapeutics for public health crises and pandemics.

Objective 3

Heighten the impact of European clinical trials through **excellent and coordinated regulatory and scientific advice** to trial authorisation, to support marketing authorisation and access throughout the medicine lifecycle.

Revised ACT EU objectives

Objective 4

Effectively communicate and engage with stakeholders to proactively deliver **inclusive patient-oriented medicines development**, ensuring patients' voices are integrated throughout the clinical trial lifecycle.

Objective 5

Ensure a **clear and unified European position** on clinical trials in strategic matters at the international level.

Objective 6

Support **capacity building** in all aspects of drug development and regulatory science relevant to clinical trials, including through research collaboration, collaboration with European research infrastructures and training with academia.

Objective 7

Enable innovation through responsible integration of AI, digitalisation, regulatory sandboxes and data use across the clinical trials lifecycle.

Support **innovative and decentralised trial designs** to improve feasibility and inclusiveness, while maintaining trial integrity.

Facilitate the **systematic, high-quality use of real-world data** to support regulatory decisions and improve trial efficiency in alignment with EHDS.

European Medicines Agency

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Visit Accelerating clinical trials in the EU