



ACT EU workplan and key priorities

Expected contribution from MSP AG

Inaugural meeting of the ACT EU Multi-stakeholder Platform Advisory Group
20 March 2024

Presented by Peter Arlett, Head of EMA Data Analytics and Methods Task Force

An agency of the European Union



ACT EU is delivering benefits to clinical trial stakeholders across key areas:



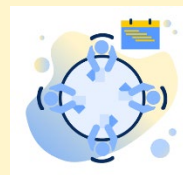
Mapping & governance



Implementation of the Clinical Trials Regulation*



Multinational clinical trials by non-commercial sponsors*



Multi-stakeholder platform*



Good clinical practice modernisation



Clinical trials analytics



Scientific advice*



Clinical Trials methodologies



Clinical trials safety



Clinical trials training curriculum



Clinical trials in public health emergencies*

Over the next 4 years ACT EU aims to

- Establish the **Multi-Stakeholder Platform** (MSP) and its **Advisory Group** as a vehicle for dialogue and collaboration with stakeholders
- Ensure **effective operation** of the clinical trials (CT) regulation
- **Simplify governance** and **align CT approval** with scientific advice
- Support academic sponsors to conduct **impactful clinical trials**
- Establish the place of **novel methodologies**
- Enable **decentralised approaches**
- Training: create an **educational “ecosystem”** (leveraging existing initiatives)
- **Align internationally** (including Good Clinical Practice, GCP)
- **Optimise the use of data** about clinical trials for better research and decision-making
- Enable CTs in **public health emergencies (PHEs)**

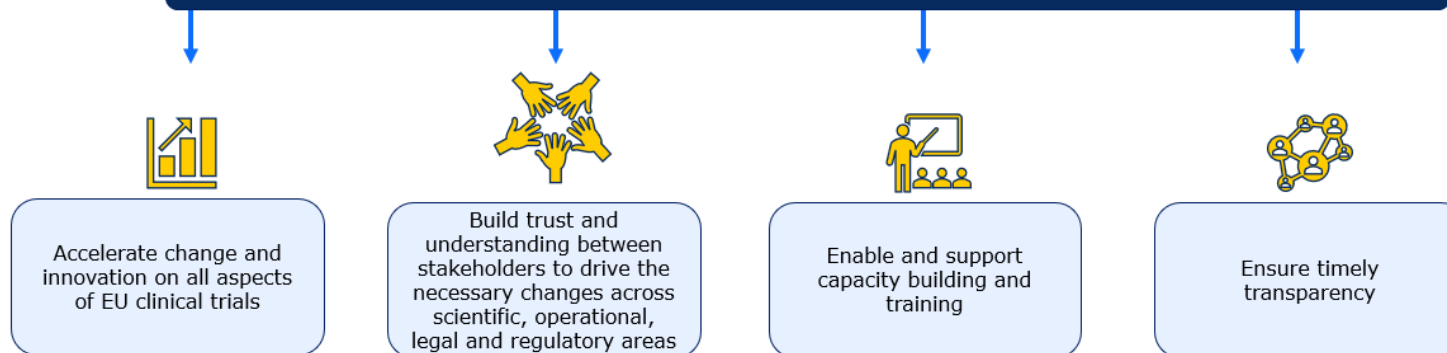


How stakeholders are involved

Multi-stakeholder platform



Key objectives



How stakeholders are involved

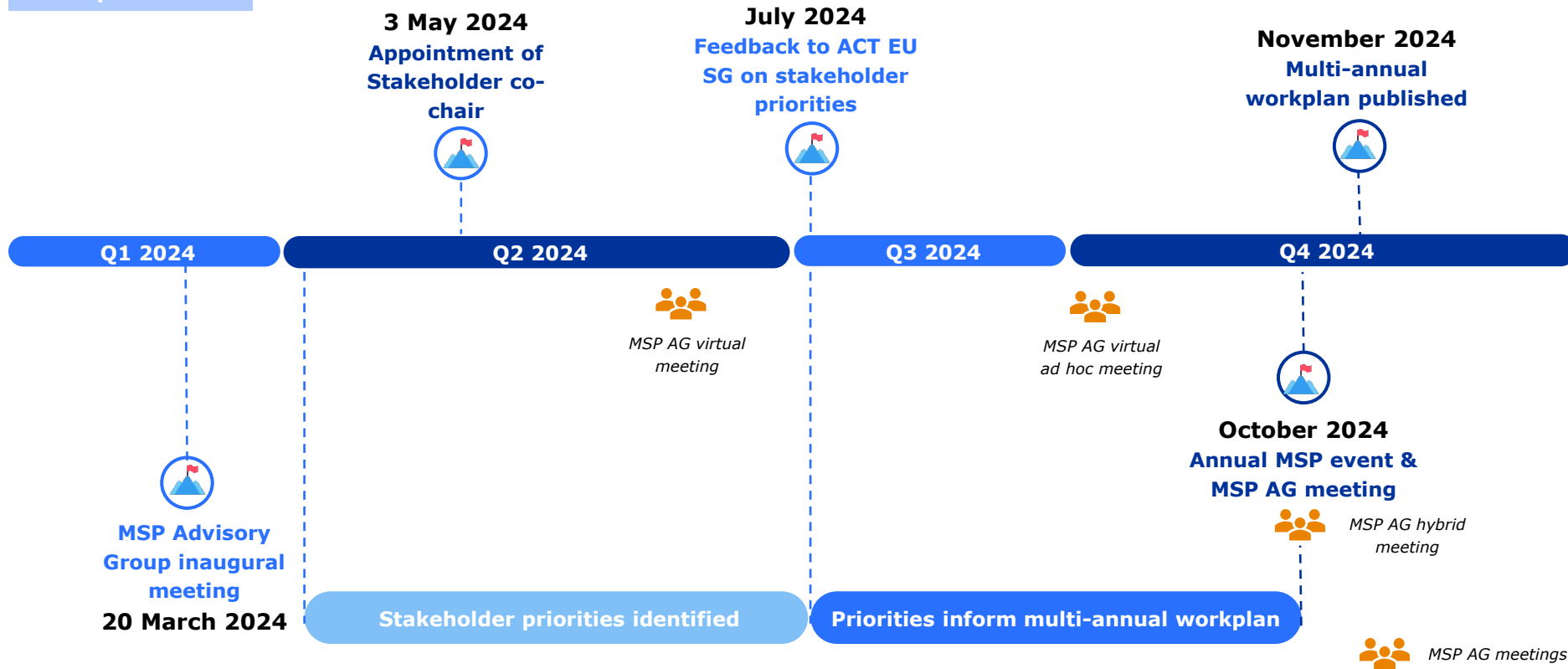
- Providing the ACT EU Steering Group with their views and strategic advice on the [ACT EU multi-annual workplan](#)
- Identifying stakeholder needs, concerns, challenges and priorities, and communicating these to the ACT EU regulatory partners
- Advising ACT EU regulatory partners on stakeholder engagement and communication
- Keeping their respective stakeholder group informed of the output from ACT EU MSP initiatives and overall ACT EU activities
- Reviewing and agreeing on the mandate, workplan and any governance-related documents of the advisory group

Strategic input into ACT EU workplan



2024
Establishment
phase

Identifying stakeholder needs, concerns, challenges and priorities

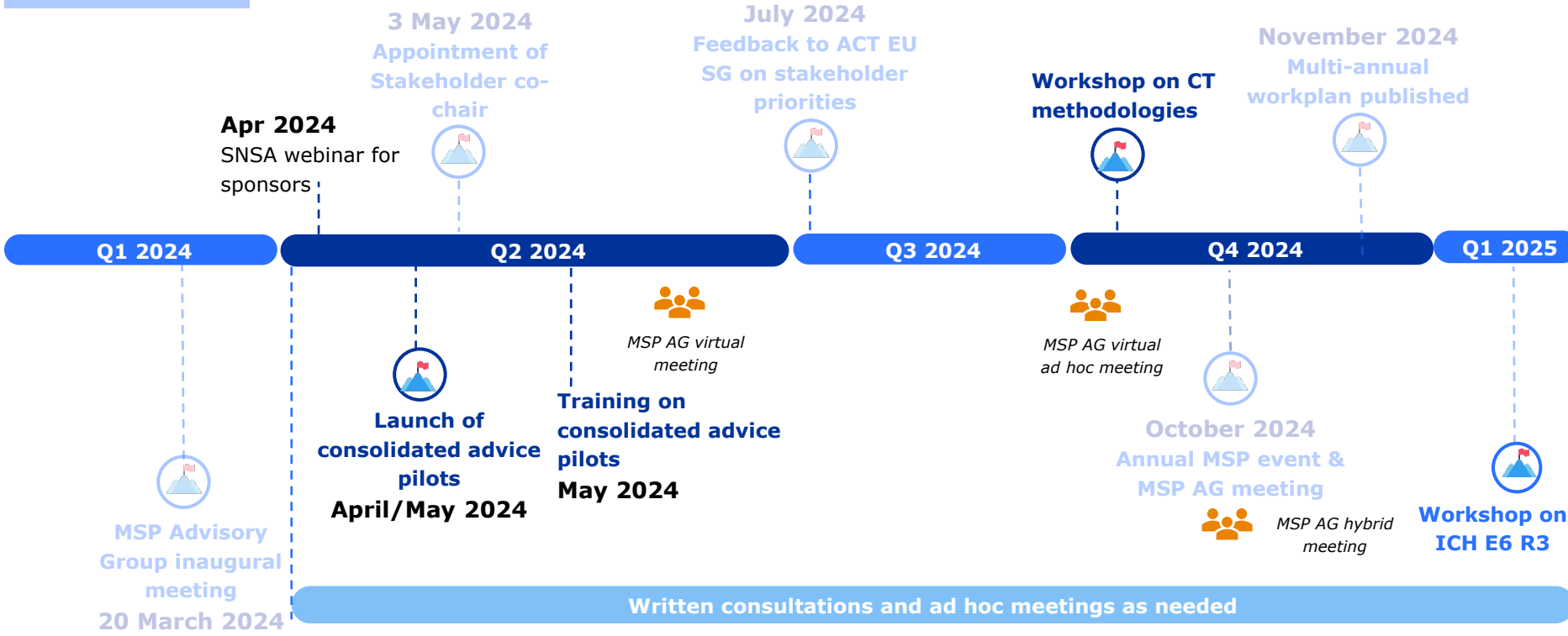


Operational input into ACT EU events



2024
Establishment
phase

Advising ACT EU regulatory partners on stakeholder engagement and communication



Let's discuss

How can we ensure comprehensive identification of stakeholder priorities and needs, and integration into the work of ACT EU?

How can we ensure widespread sharing of information?

What are the essential ingredients for ensuring the success of the MSP AG?

Any questions?

Further information

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[ACT EU website](#)

[Clinical trials in human medicines | European Medicines Agency \(europa.eu\)](#)

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