ACT EU workplan and key priorities
Expected contribution from MSP AG

Information session for *ad hoc* representatives of the ACT EU Multi-stakeholder Platform Advisory Group
11 April 2024

Presented by Ana Zanoletty, Head of EMA Clinical Trials Transformation workstream

ACT EU Priority actions 2023-2026

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*

* *Priorities agreed by ACT EU Steering Group*

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

Multi-stakeholder workshops

Engagement tools

(consultations, surveys…)

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MSP Advisory Group
Stakeholder representatives

Key objectives

- Accelerate change and innovation on all aspects of EU clinical trials
- Build trust and understanding between stakeholders to drive the necessary changes across scientific, operational, legal and regulatory areas
- Enable and support capacity building and training
- Ensure timely transparency

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

Process for involvement of ad hoc representatives

During the drafting of the MSP Advisory Group meeting agenda, each relevant priority action coordinator, in agreement with the relevant co-lead, is responsible for flagging the need to involve ad hoc representatives in the discussions.

The proposals are discussed with the co-chairs who can also provide additional input.

The secretariat follows up with the relevant ad hoc representatives identified during the nomination process. This is done 4 weeks in advance to allow ad hoc representatives to participate in the relevant meeting.

The ad hoc members will receive the MSP AG meeting agenda and minutes once these are available (i.e. upon publication).

Strategic input into ACT EU workplan

2024 Establishment phase

Identifying stakeholder needs, concerns, challenges and priorities

Q1 2024

MSP Advisory Group inaugural meeting
20 March 2024

Q2 2024

3 May 2024
Appointment of Stakeholder co-chair

Information session
11 April 2024

MSP AG virtual meeting

Stakeholder priorities identified

Q3 2024

July 2024
Feedback to ACT EU SG on stakeholder priorities

MSP AG virtual ad hoc meeting

Priorities inform multi-annual workplan

Q4 2024

November 2024
Multi-annual workplan published

October 2024
Annual MSP event & MSP AG meeting

Opportunity for all MSP AG reps to meet

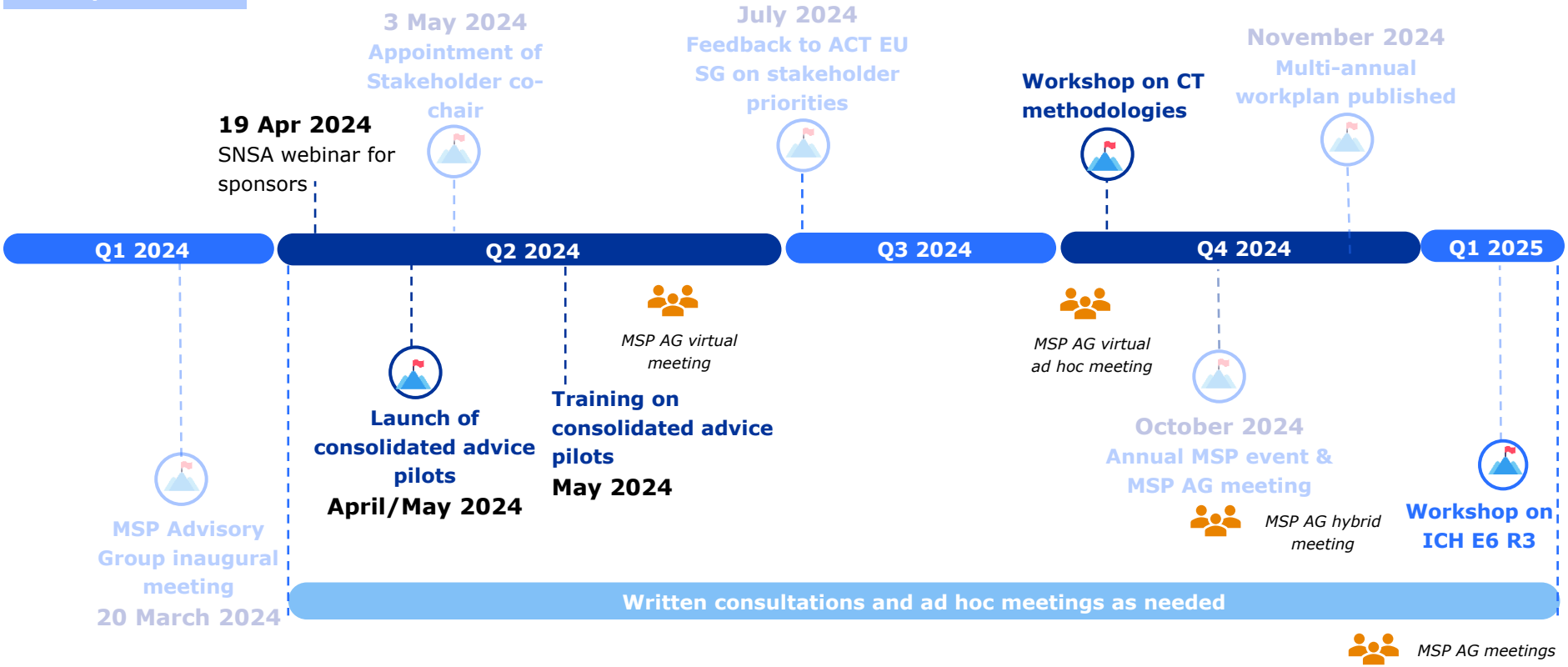
MSP AG hybrid meeting

MSP AG meetings

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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