





#### 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

### 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\*





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



## **Engagement** tools

(consultations, surveys...)



# **(4)**

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

#### Strategic input into ACT EU workplan







2024 Identifying stakeholder needs, concerns, challenges and priorities **July 2024** 3 May 2024 November 2024 Feedback to ACT EU **Appointment of** Multi-annual SG on stakeholder Stakeholder coworkplan published priorities chair Q2 2024 **Q3 2024** 04 2024 Q1 2024 MSP AG virtual MSP AG virtual meeting ad hoc meeting October 2024 **Annual MSP event & MSP AG meeting** MSP AG hvbrid **MSP Advisory** meeting **Group inaugural** meeting **Priorities inform multi-annual workplan** 20 March 2024 Stakeholder priorities identified MSP AG meetings

#### **Operational** input into ACT EU events







2024

#### 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

msp-agsecretariat@ema.europa.eu

**ACT EU website** 

Clinical trials in human medicines | European Medicines Agency (europa.eu)

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands **Telephone** +31 (0)88 781 6000

**Send us a question** Go to www.ema.europa.eu/contact

Follow us on **Weeks**