Update on Accelerating Clinical Trials in the EU (ACT EU) and the Multi-stakeholder platform

2-3 July 2024
Joint PCPWP – HCPWP meeting

Presented by
Ana Zanoletty, Head of Clinical Trials Transformation, EMA
Denis Lacombe, Chief Executive Officer, EORTC

Accelerating Clinical Trials in the EU (ACT EU)

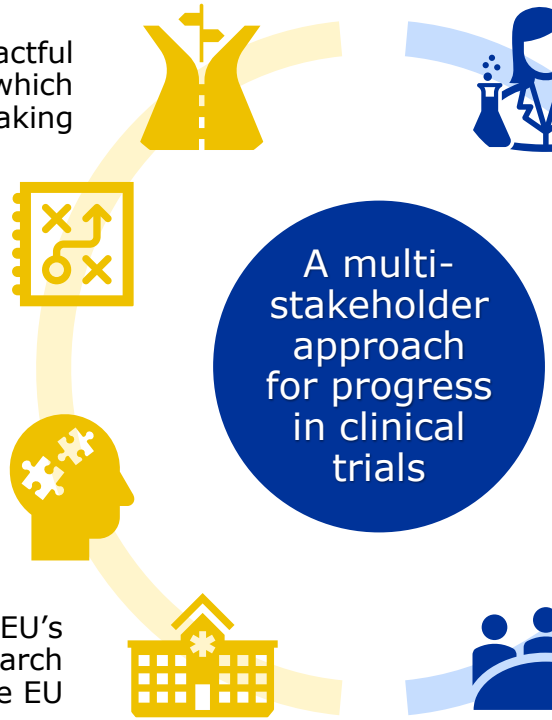
Challenges

Need for more impactful multi-state trials which drive decision-making

Need for an overarching strategy to bring stakeholders together

Multiple actors requiring clear roles and responsibilities

Need to leverage the EU's strong healthcare and research infrastructure in the EU



ACT EU vision

EU as an attractive region for clinical research

Enabling **larger and more impactful CTs**, with seamless coordination among regulators and stakeholders

Smart CTs through **regulatory, technological and process innovation**

Empowering, engaging and supporting **stakeholders**

ACT EU Priority actions 2023-2026

ACT EU is a joint initiative by the European Commission, Heads of Medicines Agencies and EMA, 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

Support to non-commercial sponsors

Action plan in progress

- NEW - Interactive map of national initiatives on the ACT EU website (*signposting*), with input from NCAs
- CTR-CTIS support for large multinational clinical trials
- Optimisation of regulatory helpdesk
- Involvement of academia in the MSP Advisory Group

Objectives

- Higher number of non-commercial multinational clinical trials
- Non-commercial clinical trials generating **high quality scientific evidence**
- **Benefit for EU citizen's health** through optimized therapies and access to innovative medicines

Consolidated advice pilots

1. SAWP/CTCG scientific advice pilot
2. Pre-CTA regulatory/ administrative pilot

Improved quality of applications; improved EU environment for clinical trials

Consolidated advice for sponsors clarifying the landscape

Increased network coordination & efficiency

Launched 10 June 2024

2 applications already received

In line with ACT EU's vision, aiming to benefit patients and healthcare in the region.

How the MSP works

Multi-stakeholder platform (MSP)

Multi-stakeholder workshops

Engagement tools
(consultations, surveys…)

+

MSP Advisory Group
Stakeholder representatives

Patients, industry, HCP, academia, funders, ethics committees, providing:

- strategic advice
- steer on engagement of stakeholders

Key objectives

- Accelerate change and innovation in EU clinical trials
- Build trust and understanding between stakeholders to drive change across scientific, operational, legal and regulatory areas
- Enable and support capacity building and training
- Ensure timely transparency

Which stakeholders are involved

MSP Advisory Group
Permanent stakeholder organisations

Patients/consumers

CANCER PATIENTS EUROPE
EATG European AIDS Treatment Group
eYPAGnet
EPF European Patients Forum
EURORDIS RARE DISEASES EUROPE

Healthcare professionals

ean european academy of neurology
EHA EUROPEAN HEMATOLOGY ASSOCIATION
ESOP European Society of Oncology Pharmacy
ESC European Society of Cardiology

Academics

ecrin eatris
TEDDY NETWORK
EORTC European Organisation for Research and Treatment of Cancer

Industry

ACRO ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS
EuropaBio The European Association for Bioindustries
EUCOPE European Confederation of Pharmaceutical Entrepreneurs AISBL
efpia

Funders

innovative health initiative
KWF Dutch Cancer Society

Ethics committees

ccmo Centrale Commissie Mensgebonden Onderzoek
Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland e.V.

ACT EU partners

MSP latest updates

- MSP Advisory group:
  - Full list of members (permanent, ad-hoc) published on the ACT EU website
  - Regulatory co-chair: María Jesús Lamas, Director of Spanish Agency of Medicines and Medical Products
  - Stakeholder co-chair appointed (May 2024): Denis Lacombe, CEO of EORTC
- Upcoming meetings:
  - MSP AG meeting on 4 July
  - MSP AG meeting on 27 September
  - MSP AG annual F2F meeting on 22 October

What ACT EU means for patients and HCPs

ACT EU:

- **Empowers patients through all stages of clinical research**, with early access to new treatments
- Addresses health needs by **facilitating innovation** in CT methods, data insights and large multinational trials
- Builds engagement with all stakeholders to improve EU as a **global centre for clinical trials**

The new CTIS public portal and the CTR:

- Make it easier to **find** and potentially join **clinical trials**
- Provide clinical trial **results in lay language**
- Enable **medical innovation** and **supports patient safety**

We look forward to further collaboration and knowledge-sharing with patient groups on clinical trials transformation and patient engagement.

How to stay informed

Subscribe to the CT Highlights newsletter and CTIS Newsflash

Previous issues here

Follow the ACT EU website for updates

Contact the ACT EU mailbox