



Webinar on draft guidance on the conduct of clinical trials during public health emergencies

8 April 2026, 10:00 – 11:30 (CET/CEST)

Virtual Teams meeting

The Accelerating Clinical Trials in the EU (ACT EU) initiative has published [a draft guidance document outlining how clinical trials should be conducted during public health emergencies \(PHEs\)](#), now open for public consultation until **30 April 2026**.

The guidance is intended for sponsors and all parties involved in the design and conduct of clinical trials in the EU. This is the first guidance on PHEs to reflect the EU's current legislative framework as well as the guidelines from the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) developed following the COVID-19 pandemic.

This webinar aims to:

- Raise awareness of the ongoing public consultation
- Provide an overview of the draft guidance content, including its scope and key recommendations
- Explain how the guidance aligns with the current EU legislative framework and ICH guidelines developed after COVID-19

- Clarify the consultation process, including how to submit comments using the official template
- Address questions from stakeholders regarding both the draft content and the consultation procedure

This webinar is open to members of the public, particularly relevant for patients organisations, commercial, non-commercial sponsors (including academia), health-care professionals, investigators, national competent authorities (NCAs), ethics committees, contract research organisations (CROs) and others.

To participate in the webinar please register [via this link](#). After registration you will receive the meeting link.

You are kindly invited to provide comments or questions on the content of draft guidance in advance via [Slido](#) (use code: #Guidance2026, or scan the QR code listed below).

You will be also able to raise questions during the Q&A sessions.

Please provide your questions by 6 April 2026, EOB.



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Chair: Giacomo Capone (EMA) and Camelia Mihaescu (EMA)

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09:45 **Joining and technical checks**

10:00 **Welcome and opening remarks**

Welcome and introduction **5 min**
Marco Cavaleri (EMA)

10:05 **Clinical trials in public health emergencies**

Overview of the content of the guidance document on the conduct of clinical trials during public health emergencies developed under ACT EU **5 min**
Romee de Haan (EMA)

Initiating Clinical trials **10 min**
Jeroen De Roeck (AFMPS FAGG)

Changes to ongoing clinical trials **10 min**
Jeroen De Roeck (AFMPS FAGG)

Q&A **15 min**

Adaptation of key aspects of clinical trials **20 min**
Gabriele Schwarz (BfArM)

Q&A **15 min**

11:20 **Launch of the public consultation**

How to submit your comments **10 min**
Giacomo Capone (EMA) and Camelia Mihaescu (EMA)