ACT EU status update

MSP AG meeting

17.09.2026

PA on Clinical Trials in Public Health Emergencies (PHE)

Guidance on a simplified application package during a PHE - update

- Guidance for sponsors outlining the minimum requirements for a simplified clinical trial application in a PHE
- Goal is to allow for faster submission of application dossier in a PHE
- Easier to conduct multinational clinical trials
- Use is optional

- **CTCG and MedEthicsEU** consulted and overview per Member State developed
- **MSP AG** consulted (24 May-27 June) – 3 comments received, mainly clarifications

Appendix 1: Part I simplified requirements

- Components of Part I application dossier remain the same in a PHE as for standard clinical trial applications, following Annex I of the CTR
- Simplifications regarding requirements for submission of Part I national translations

Member State	**Cover Letter**	**Protocol**	**Protocol synopsis** accessible in public portal (providing trial details for potential trial participants)	**Patient-facing documents (protocol)** on primary and secondary endpoints (where MSs require **translations, submit these in Part II** [2])	**Labelling –** IMP administered by qualified health personnel	**Labelling –** IMP administered by trial participant	**Structured data in EU Application form (CTIS)**
Croatia	en	en	hr	hr	en	hr	en
Cyprus	en	en	en	el[a]	en	en[b] , (el)	en
Czech Republic	en	en	cs	cs	en	cs	en
Denmark	en	en	en	en	en	en[b]	en

Appendix 2: Part II simplified requirements

- Minimum requirements
  - Subject Information Sheet(s)/Informed Consent form(s);
  - Recruitment material targeting trial participants (advertisement), when applicable;
  - PHE simplified Site Suitability form for each participating site (Appendix 3);
  - Principal investigators' CV and Declaration of Interest;
  - Proof of insurance.
- Language simplifications
- Sponsors encouraged to include as much detailed information as possible in the protocol or in the Subject Information Sheet / Informed Consent Form to meet the requirements of CTR Annex 1 and enable Ethics Committee assessment of Part II elements

Appendix 2: Part II simplified requirements

Member State	***Recruitment arrangements*** Additional document required besides information in protocol and advertisement /participant recruitment material	***Compliance with national requirements on data protection*** Additional document required besides information in protocol and ICF on GDPR/national applicable legislation compliance	***Compliance with use of biological samples*** Additional document required besides information in protocol and ICF on applicable rules for collection, storage and future use of biological samples	***Financial and other arrangements - Compensation to trial participants*** Additional document required besides information in ICF on trial participant compensation	***Financial and other arrangements - Site compensation*** Additional document required besides information in simplified site suitability form on site compensation	***Suitability of the facilities*** Additional document or other template required instead of simplified template site suitability form (see Appendix 3)	***Language requirements*** All Part II documents required in national language
Latvia	no	no	no	no	no	no	no
Lithuania	no	no	no	no	no	no	no
Luxembourg	no	no	yes (6)	no	no	no	no
The Netherlands	no	yes	no	no	no	yes	no

Appendix 3: PHE Site Suitability Form

- PHE-customised, simplified from EudraLex Volume 10 clinical trial guidelines
- Compliance statement instead of detailed information, description of financing (not replacing the site contract)
- One form per participating site

This template may be used by Sponsors of clinical trials as part of the application dossier during a Public Health Emergency.

A separate document should be completed and submitted for each site.

EU CT number	
Title of clinical trial	
Name of site, city	
If applicable[1], unique identification number of the site	
Name & department of principal investigator	
Estimated number of trial participants possible to include at the site	
Description of the funding of the clinical trial and, if applicable, the compensation offered to the investigator/clinical trial site per participant who completes all study visits, from [eg. Screening visit to xxxx] (The sponsor will sign a site clinical trial agreement following the applicable country practice/legislation, before the start of the study at the site)	xxxx currency
Additional Information due to country-specific requirements	

With my authorisation/signature, I declare that, considering the nature and use of the investigational medicinal product, the clinical site has the required and appropriate facilities and equipment to be able to conduct the clinical trial and has suitable arrangements in place to ensure that all investigators and other individuals involved in conducting the trial have the suitable qualifications, expertise and training in relation to their role in the clinical trial. Therefore, the clinical site is suitable to conduct the above clinical trial, in compliance with Regulation (EU) No 536/2014.

Issued by (signature – could be electronic):
Name: Click here to enter text. Position:
Click here to enter text.
On behalf of the site/organisation[2]
Date: Click here to enter a date.

[1] Only applicable in those countries where sites are identified with a unique identification number.

[2] Name of the head of the department/institution for the clinical trial site or by some other responsible person, in line with applicable rules in the Member State Concerned.

Guidance on conduct of CTs during PHE - update

- Guidance is addressed to sponsors and other involved stakeholders to explain the Regulatory flexibility that can be applied in CTs in case of PHE.
- The guidance applies to:
  - Clinical trials initiated in response to the PHE, to evaluate preventive or therapeutic interventions relevant to the emergency itself as well as clinical trials initiated during a PHE that are not related to the emergency; and
  - Clinical trials ongoing at the time of the PHE that will continue.
- Overarching principle

A PHE necessitates prompt action to adapt the conduct of clinical trials. Justifiable regulatory flexibilities should prioritise the rights, safety and well-being of trial participants, while safeguarding data integrity and robustness, including the reliability of statistical inference and the interpretability of conclusions, and should be counterbalanced against the foreseeable or expected public health benefits of earlier access to clinical trial results and the continuation of ongoing studies. Measures introduced to address PHE-related challenges may increase uncertainty or bias and should therefore be justified.

Webinar 8 April 2026

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

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

8 April 2026, 10:00 -11.30 (CET/CEST)

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 draft guidance on the conduct of clinical trials during public health emergencies — **5 min**
Romee Reijsenbach 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 the conduct of clinical trials
Informed consent; safety monitoring & reporting; trial monitoring — **10 min**
Gabriele Schwarz (BfArM)

Investigational product management; transfer of patients to other sites — **10 min**
Sarah T'Kindt (AFMPS FAGG)

Q&A — **20 min**

11:25 Launch of the public consultation

How to submit your comments — **5 min**
Giacomo Capone (EMA) and Camelia Mihaescu (EMA)

Registered 528 - Attendees 443

Stakeholder group	count
NCAs	115
Other	76
Commercial sponsors	58
CROs	47
HCPs	46
Ethics Committees	35
Non-Commercial Sponsors (Including Academia)	35
Investigators	16
Patient Organizations	6

European Commission | EMA | HMA Heads of Medicines Agencies

Comments received during the public consultation

- **5 March-30 April 2026 Public consultation**

46

- Industry
- CROs
- Universities
- NCAs
- Ethics Committee
- Health Authorities
- Experts

>600

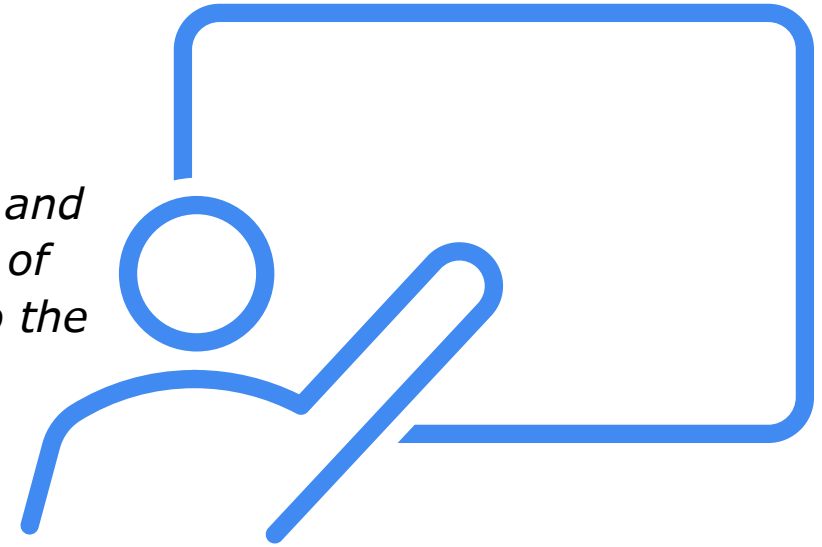
- Around **60** General Comments
- Around **70** on S1 (Introduction)
- **200** on S2 and S3 (Initiating CTs; changes to ongoing CTs)
- Around **300** on S4-S8 (adaptation to key aspects of the conduct of CTs; trial related procedures; methodological aspects; GCP inspections)

Guidance on conduct of CTs during PHE - overview

- The guidance is complementary to other guidance documents being developed under the ACT EU priority action on CTs during PHE
- First consolidated guidance document specifically addressing how to run clinical trials in a public health emergency – building on lessons learnt
- Based on the HMA/EMA/EC COVID-19 guidance (Feb 2022), grounded in existing frameworks: CTR (EU 536/2014), ICH E6(R3), ICH E8(R1), ICH E19

What does the guidance cover?

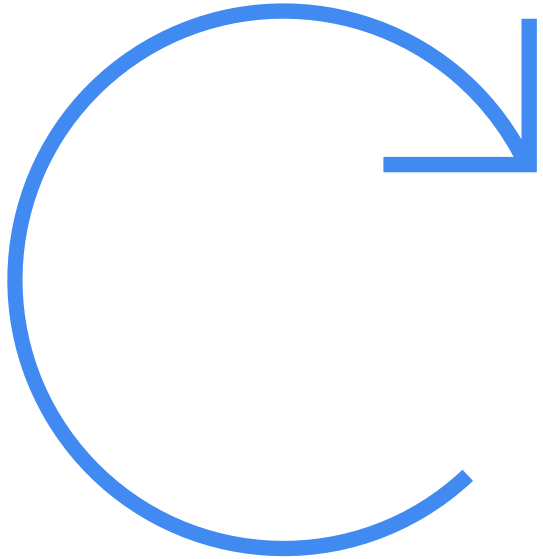
1. General considerations
2. Initiating clinical trials
3. Changes to ongoing clinical trials
4. Adaptations to key aspects of the conduct of clinical trials *(Informed consent; Safety monitoring, safety data collection and reporting; Investigational product management; Distribution of IVD and MD used for testing for medical conditions related to the PHE; Trial management; Trial documentation)*
5. Methodological aspects
6. GCP inspections
7. Communication



What are the main changes after the consultation?

Changes discussed and already implemented after the public consultation include:

- Expedited timelines was added
- Use of USM for aspects related to the PHE as applicable under Art. 54
- Transfer of trial participants
- Section on methodological aspects expanded based on several comments

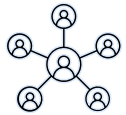


Revision of the draft guidance to be finalised

CT in PHE – Track 2 and 3

September: presenting to CTCG, GCP IWG and MSP AG to be informed on document revision after stakeholder consultation

September: sharing the final draft with CTCG, MedEthicsEU and GCP IWG – for final critical comments (2 weeks-time)



September: informing other relevant groups, as applicable, such as: MWP, HERA, BE READY

October/November: final document ready to be shared with ACT EU Steering Group (October) and CTAG (December) for final endorsement

Webinars and training in Q1 2027

Thank you

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