04 May 2020

This webinar has reached full capacity and registration is now closed. Thank you for your interest. Please note that a recording of the webinar will be available after the event on EUtube (https://www.youtube.com/user/eutube).

Webinar conference organised on 15 May about the Guidance on the management of clinical trials during the COVID-19 pandemic

*The latest revision (v3) of the Guidance on the management of clinical trials during the COVID-19 pandemic was published on 28 April 2020. This version contains key changes based also on the feedback from different stakeholders' groups (patients' organisations, academia and industry) before and during the drafting process. Six experts with support of DG SANTE B4 clinical trials team will hold the seminar, which will take place on **15 May from 15.00 to 17.00** (CET). The purpose of the webinar is to provide stakeholders with an overview of the most important elements of this Guidance and additional clarification where needed.*

Mr. Andrzej Rys, DG SANTE Director for Health systems, medical products and innovation, will open the webinar. The webinar will then give the floor to experts (in order of appearance) Ms. Ann-Marie Janson Lang (MPA) and Ms. Elke Stahl (BfArM) co-chairs of the Clinical Trials Facilitation and Coordination Group (HMA), Ms. Lisbeth Bregnhøj (DKMA, TBC) from GCP-IWG (EMA), Mr. Fergus Sweeney, head of the Clinical Studies and Manufacturing Taskforce (EMA) and Mr. Olivier Le Blaye (ANSM) from GCP-IWG (EMA). DG SANTE will be represented by Ms. Agnès Mathieu, Ms. Edit Szepessy and Mr. Kristof Bonnarens. Attendees will be able to request additional clarifications during the meeting by using the chat function. The webinar will be recorded and available for off line vision afterwards on EUtube (https://www.youtube.com/user/eutube).

Provisional agenda of the webinar:

Webinar conference: Guidance on the management of clinical trials during the COVID-19 pandemic

Friday 15 May at 15.00 CET, Brussels time

DG SANTE will host a webinar conference jointly with EMA and the Clinical Trials Coordination and Facilitation Group of HMA following this **agenda**[1]:

Agenda:

15.00 – 15.15	• **Introduction and welcome** → DG SANTE (European Commission)
15.15 – 15.25	• **Introduction to the guidance/process** → DG SANTE (European Commission)
15.25 – 15.35	• **Initiation of new trials** → CTFG (HMA)
15.35 – 15.45	• **Changes to ongoing trials** → CTFG (HMA)
15.45 – 15.55	• **Communication with authorities** → CTFG (HMA), DG SANTE (European Commission)
15.55 – 16.05	• **Informed consent** → GCP-IWG (EMA)
16.05 – 16.15	• **IMP distribution** → EMA
16.15 – 16.25	• **Monitoring** → GCP-IWG (EMA)

[1] The exact timing of each topic will be adjusted depending on the amount and complexity of questions received before the webinar

16.25 – 17.00 • **Q&A and conclusions**

Practical information to participate in this webinar

Registration is now closed as the webinar has reached full capacity. A recording of the webinar will be available after the event on EUtube (https://www.youtube.com/user/eutube). Thank you for your understanding.

Link to the webinar conference will be sent to registered participants a few days before 15 May.

We are looking forward to welcoming you online.

On behalf of the Speakers,

European Commission
Health and Food Safety Directorate General
Unit B4: Medical products: quality, safety, innovation