

Clinical Trials Facilitation and Coordination Group - CTFG

CTFG Meeting with Stakeholders October 28 2019

hosted by the Swedish Medical Products Agency, Uppsala, Sweden

The European Heads of Medicines Agencies Clinical Trials Facilitation and Coordination Group (CTFG) invites stakeholders (via representative organisations) to a meeting on clinical trials. The one-day meeting will be hosted by the Swedish Medical Products Agency in Uppsala, Sweden.

The aim of the meeting will be to exchange on topics of interest concerning clinical trials including

- Interplay between legislation on in vitro diagnostics (IVDs) and clinical trials
- Follow-up of CTFG's Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials
- · Burning issues and horizon scanning

The meeting will focus on issues related to the regulatory requirements for IVDs in clinical trials of medicinal products. The meeting will provide an opportunity for regulatory bodies as well as commercial and non-commercial sponsor organisations to discuss potential hurdles together.

The meeting will also address the follow-up of CTFG's Recommendation Paper on the <u>Initiation and Conduct of Complex Clinical Trials</u> (CTFG/HMA website under Key documents list, Guidances,) with a panel discussion including representatives from commercial and non-commercial sponsor organisations as well as representatives from ethics committees and patients' organisations.

A horizon scanning session will allow an exchange on burning issues related to clinical trials in EU/EEA. Participants are welcome to propose topics for this session with their registration.

CTFG invites stakeholders' organisations to inform their members and possibly identify among them a few members/stakeholders with specific interest in the field of clinical trials to participate in this meeting. Registrations is open until **September 28, 2019**.

For more information on the meeting, kindly contact the CTFG secretariat: m.sarra@aifa.gov.it.

Depending on availability, participation might be restricted to up to two participants per organisation. The meeting is free of charge. Please be informed that CTFG will not be able to reimburse any travel or accommodation expenses.

Kind regards,

Dr. Ann Marie Janson Lang and Dr. Elke Stahl (Co-Chairs, CTFG)