

## **CTFG Meeting with Stakeholders October 24<sup>th</sup> 2018 BfArM, Bonn, Germany**

The European Heads of Medicines Agencies Clinical Trial Facilitation Group (CTFG) invites stakeholders (via representative organisations) to a meeting on clinical trials. The one-day meeting will be hosted by BfArM, Bonn, Germany.

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

- Implementation and challenges of the Clinical Trial Regulation EU 536/2014 in the EU/EEA
- Innovative (complex) trial design, and
- Burning issues and horizon scanning.

All stakeholders need to be ready when the EU Regulation on Clinical Trials 536/2014 (CTR), applies, at the time the essential Clinical Trial IT System (EUPD, CTIS) goes live, even if this IT development might be in focus at the moment. The CTFG is supporting the upcoming new regulation by improving the preparation of all stakeholders with different activities such as the drafting of guidance or best practice documents, support for European multinational (Voluntary Harmonisation Procedure, Annual Safety Report Work-sharing) and national (pilot) projects to improve cooperation and harmonization of procedures. The CTFG is also involved in the compilation and dissemination of relevant information. This meeting will be an opportunity to share information and discuss topics related to the new approach to the management of clinical trials.

A follow up will be given to the discussions at CTFG's Stakeholder Workshop on complex clinical trial design at AIFA in March.

The session on burning issues and horizon scanning should be an exchange with all stakeholders on short term and upcoming challenges to be addressed directly if possible and especially feed into follow up exchanges between clinical trial regulatory bodies and stakeholders.

CTFG invites stakeholders' organizations 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 are open until 5<sup>th</sup> October 2018. Please register by filling the attached form (Annex I) and sending the registration to the CTFG secretariat: [m.sarra@aifa.gov.it](mailto:m.sarra@aifa.gov.it)

Depending on availability, participation might be restricted to up to 2 participants per organization or Company. Please be informed that CTFG will not be able to reimburse travel or accommodation expenses.

Kind regards,

Dr. Elke Stahl and Dr. Ann Marie Janson Lang  
(CoChairs CTFG)