New offering of IFAPP's Continuous Professional Development Programme

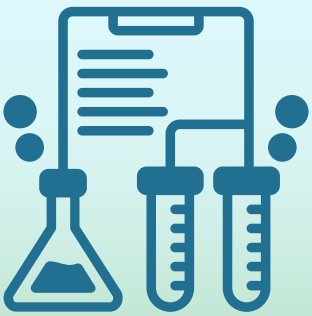
INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

A free virtual training workshop on 01 and 02 March 2023 moderated by Dr Birka Lehmann and Dr Ingrid Klingmann

From 31 January 2023 all clinical trials with medicines must be authorised, handled and reported according to the rules lined out in the Regulation EU No 536/2014 (Clinical Trials Regulation).

The Regulation introduces an authorisation procedure based on a single submission via a single EU portal and data base, an assessment procedure leading to a single decision, rules on the protection of participants and informed consent, and transparency requirements. With this the Regulation will ensure a greater level of harmonisation of the rules for conducting clinical trials throughout the EU.

Therefore, all aspects of clinical trials are following new rules. This includes communication between sponsor, competent authorities and ethics committees. The new EU Database called CTIS (Clinical Trials Information System) is the key element. Sponsors will need to adapt their own systems and procedures to the new requirements in the European Union.



IFAPP offers you a free 2-day virtual training programme that will explain what you need to understand about the new processes, procedures and obligations of parties involved for updating your regulatory knowledge and for the preparation and conduct of your clinical trials in the EU. And the workshop will give you ample opportunities to ask your questions and discuss your concerns with experts in the fields.

Click **here** to register for the Training Workshop on **Wednesday 1 and Thursday 2 March 2023**.

Dr Birka Lehmann MD PhD is a Consultant in Pharmaceutical Medicine and a Board Member/Chair of the Education and Certification Working Group (ECWG) of IFAPP

Dr Ingrid Klingmann MD PhD is President of the PharmaTrain Federation and a member of IFAPP's ECWG

INTRODUCTION TO THE NEW EU CLINICAL TRIALS REGULATION

Audience: People from all around the world who want to understand the principles of the new EU regulatory environment for clinical trials, e.g., sponsors of clinical trials, clinical trial experts, investigators and site staff, regulatory affairs and medical affairs professionals, competent authority and ethics committee members, patient experts

Moderators: Ingrid Klingmann and Birka Lehmann
All session times according to CET

DAY 1 01 March 2023

10:00-10:10	Welcome and introductions
10:10-11:00	Clinical trial aspects that will change under the new EU Clinical Trials Regulation Q&A
11:00-11:45	The new “Single Dossier” in clinical development Q&A
11:45-12:00	**Break**
12:00-13:00	The Coordinated Clinical Trial Authorisation procedure: functioning, timelines and collaboration between competent authorities, ethics committees and the sponsor, also for substantial modifications Q&A
13:00-13:45	**Lunch**
13:45-14:45	The EU’s clinical trial transparency rules from trial authorisation to result reporting – balanced between patients’ needs for transparency and needs for protection of data confidentiality and commercially confidential information Q&A
14:45-15:05	**Break**
15:05-16:05	The Clinical Trials Information System “CTIS” – structure, functioning, requirements, training options Q&A

Moderated discussion: Advantages and hurdles of the new Regulation for sponsors of trials in different phases from within the EU and abroad
Open Forum Discussion with Moderators and Speakers

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DAY 2 02 March 2023

10:00-10:30	Getting access to CTIS within the EMA registration and filing systems Q&A
10:30-11:15	(Re?-)Organisation of responsibilities and oversight for sponsor and vendors required to achieve clinical trial authorisation in an auditable quality environment Q&A
11:15-11:35	**Break**
11:35-12:45	Reporting obligations during and after the clinical trial: study management, pharmacovigilance, technical summary and lay summary of trial results Q&A
12:45-13:45	**Lunch**
13:45-14:10	IMP Management under the Clinical Trials Regulation from definitions to labelling Q&A
14:10-15:00	Clinical trials in vulnerable populations under the Clinical Trials Regulation: minors, pregnant & breastfeeding women, emergency situations, incapacitated patients Q&A
15:00-15:15	**Break**
15:15-16:00	Challenges in the transition period between former Clinical Trials Directive and the new Clinical Trials Regulation Q&A
16:00-16:30	How should I prepare for the Clinical Trials Regulation in my work environment - All I could not ask before Open Forum Discussion with Moderators and Speakers
16:30	Conclusions and Farewell