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Clinical Trials Information System (CTIS) Training - Information note

The way clinical trials are conducted in the EU will undergo a major change when the Clinical Trial Regulation (Regulation (EU) No 536/2014) comes into application. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU, via a Clinical Trials Information System (CTIS). CTIS will contain the centralised EU portal and database for clinical trials foreseen by the Regulation and will be used by clinical trial sponsors as a single entry point in the EU to obtain approval for clinical trials based on applications and for monitoring clinical trials during their life cycle, including the submission of summary of results.

The system is currently under development and will have collaboration and communication tools, workflow and document management capabilities. It will include a user management tool to enable access for sponsors, Member States and the European Commission via dedicated workspaces. It will also provide the general public with access to clinical trials information. CTIS will centralise the submission process for clinical trial applications and the assessment and authorisation by Member States in a single unique platform. It will facilitate day-to-day business processes of Member States and sponsors of clinical trials throughout the lifecycle of a clinical trial harmonising submission and maintenance of trial applications, assessment and supervision of trials and promoting patient safety and transparency.

The Clinical Trials Regulation, Regulation (EU) No 536/2014, will become applicable as CTIS goes live, which is anticipated in December 2021. Once launched, CTIS will be immediately available for authorities and clinical trial sponsors, while a three-year phased transition period from the current Directive 2001/20/EC to the Regulation will apply.

The European Medicines Agency has developed a training strategy to provide the CTIS users with the skills, capabilities and knowledge needed to successfully adopt CTIS. A strong online presence of training modules is foreseen for all user groups to ensure equal access for all. Quick guides, FAQ sheets, e-learnings, infographics and short videos will be gradually available as of January 2021 in the EMA website.

As a complement to the online self-paced training that forms the fundamental part of the training programme and that will be made available in 2021, two main training strategies have been developed, one for Member States from the European Union and one for Sponsors.

For Member States (MS), a network of Master Trainers has been formed in 2020 representing the National Competent Authorities and the Ethics Committees. The MS Master Trainers will take responsibility for dissemination of training by organising training sessions within their organisations for the CTIS end-users. The MS Master Trainers participated in onboarding sessions (October 2020), a

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kick-off session (November 2020) and the first training session (Group A: 07Dec20, Group B: 15Dec20). Second and third training session for group A and B will take place on January 21st and 25th of 2021, and on March 3rd and 8th of 2021 respectively.

For sponsors, three main programme streams have been envisaged considering the high volume of end-users representing commercial industry sponsors, SMEs and non-commercial sponsors including academia.

The first stream is a **sponsor Master Trainers** concept similar to the train-the-trainer approach now in place for Member State users. This aims to provide training in the functionalities of CTIS for all CTIS roles available for sponsors. It is primarily intended for commercial pharmaceutical industry sponsors and Contract Research Organisations (CROs), that are likely to submit several clinical trial applications and have several CTIS users in various organisation models. The programme is offered by EMA with the organisational support of DIA. The first call for interest for this training has been circulated the 19th of January of 2021. Due date for application: **February 16th of 2021**. For additional information please contact emaevents@diaglobal.org

A second stream will disseminate knowledge to **Small to Medium Enterprises (SMEs) and non-commercial sponsors** (e.g. academic sponsors) adjusted to the needs. This will be done through compact and tailored materials about key CTIS functionalities and dedicated training events. The first training event will be organised by the EMA, free of charge. The webinar is divided into two days, **(22nd of February and 4th of March)**. The first call for interest for this training has been published the 19th of January of 2021 in EMA events page. Due date for application: **29th January 2021**. Additional information available in EMA events page (https://www.ema.europa.eu/en/search/search/ema_editorial_content/ema_event?sort=field_ema_computed_date_field&order=desc)

The third stream will cater to the **end-users** from all sponsor groups to provide training in their role-specific functionalities (e.g. administrator, preparer, submitter). This stream will be initiated closer to CTIS Go-live in Q4 of 2021.

Additionally, to have a better understanding of the needs from the different sponsor organizations, we have developed a **survey to collect information from commercial industry sponsors, SMEs and non-commercial sponsors** interested in the CTIS training programme. The survey is open for completion until **8 February 2021** at **12 CET** to obtain input on clinical trials sponsors (end-user organisations) interest for CTIS sponsor training events. Link to survey – best experience in Chrome browser https://ec.europa.eu/eusurvey/runner/CTIS_Pre_trainingSponsorSurvey2020

For more information, please contact CT.Communication@ema.europa.eu.