SME and Academia Clinical Trials Information System (CTIS)

Two-part training webinar

Day 1: 22 February 2021, 13:15 – 17:00 (CET)
Day 2: 4 March 2021, 13:15 – 17:00 (CET)

Background and objectives

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. CTIS 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 for clinical trial sponsors, while a three-year phased transition period from the current Directive 2001/20/EC to the Regulation will apply.

To facilitate preparedness for use of CTIS users, the European Medicines Agency has developed a training programme for future CTIS users and comprehensive online training material will be made available gradually in 2021 on the EMA website. For Micro, Small to Medium Enterprises (SMEs) and academia, EMA is organising a targeted webinar to provide training on CTIS and its functionalities. The webinar is divided into two parts (Day 1 and Day 2) and participants are advised to attend both. This two-part event is free of charge. A two-step process to registration applies.

SME and Academia Clinical Trials Information System (CTIS) – Two-part training webinar

Day 1: 22 February 2021

Chaired by Ana Rodriguez (EMA) and Stéphanie Kromar (EORTC)

Introduction

13:15 – 13:30	**Joining and technical checks** Barbara Zajec (EMA)	**15'**
13:30 – 13:35	**Welcome** Fergus Sweeney (EMA)	**5'**

Session 1

13:35 – 13:40	**Introduction to the Clinical Trial Regulation (Regulation (EU) No 536/2014, CTR)** Agnes Mathieu-Mendes (EC)	**5'**
13:40 – 13:45	**CTIS Benefits** Fergus Sweeney (EMA)	**5'**
13:45 – 13:55	**Clinical Trials Regulation – what is changing in practice** Stéphanie Kromar (EORTC)	**10'**
13:55 – 14:10	**Overview of Clinical Trials Information System (CTIS) with focus on CTIS sponsor workspace** Laura Pioppo (EMA)	**15'**
14:10 – 14:25	**User Access Management – how to register users** Ana Rodriguez (EMA)	**15'**
14:25 – 14:55	**Trial-centric and organisation-centric approach in CTIS – when to use what** Andrea Seidel-Glaetzer (ECRIN)	**30'**
14:55 – 15:25	**Sponsor User Management** Stéphanie Kromar (EORTC)	**30'**
15:25 – 15:35	**Break**	**10'**

Session 2

15:35 – 16:05	**Sponsor roles and permission in CTIS** • Sponsor admininistrator • CT Administrator • Other sponsor business roles Ana Rodriguez (EMA)	**30'**
16:05 – 16:55	**Panel discussion and Q&A** **Panel Members:** Ana Rodriguez (EMA) Andrea Seidel-Glaetzer (ECRIN) Ann Marie Janson Lang (SE; Clinical Trials Facilitation Group) Edit Szepessy (EC) Fátima Simões (PT; Clinical Trials Facilitation Group) Laura Pioppo (EMA) Stéphanie Kromar (EORTC)	**50'**
16:55 – 17:00	**Availability and location of CTIS training materials** **Closing remarks** Fia Westerholm (EMA) Barbara Zajec (EMA)	**5'**

SME and Academia Clinical Trials Information System (CTIS) – Two-part training webinar

Day 2: 4 March 2021

Chaired by Fia Westerholm (EMA) and Stéphanie Kromar (EORTC)

Introduction

13:15 – 13:30	**Joining and technical checks** Barbara Zajec (EMA)	**15'**
13:30 – 13:40	**Welcome and session overview** Pieter Vankeerberghen (EMA)	**10'**

Session 1

13:40 – 13:45	**Recap of Day 1** Fia Westerholm (EMA)	**5'**
13:45 – 13:50	**Introduction to the Clinical Trial Regulation (Regulation (EU) No 536/2014, CTR)** Agnes Mathieu-Mendes (EC)	**5'**
13:50 – 14:25	**Submission of an initial Clinical Trial Application in CTIS – structure, data and documents of an initial application dossier** Laura Pioppo (EMA)	**35'**
14:25 – 15:00	**Update of an initial application through other applications** • Substantial modifications with scope Part I only, Part II only or Part I and II • Addition of a new Member State Concerned **Use of responses to Requests for Information (RFI) applicable across applications** **Non-substantial modifications** Laura Pioppo (EMA)	**35'**
15:00 – 15:20	**Panel discussion and Q&A** **Panel Members:** Fátima Simões (PT; Clinical Trials Facilitation Group) Andrea Seidel-Glaetzer (ECRIN) Fia Westerholm (EMA) Kristof Bonnarens (EC) Laura Pioppo (EMA) Pieter Vankeerberghen (EMA) Stéphanie Kromar (EORTC)	**20'**

15:20 – 15:30	**Break**	10’

Session 2

15:30 – 15:45	**Sponsor activities during the life-cycle of a clinical trial** • Submission of notifications Stéphanie Kromar (EORTC)	15’
15:45 – 15:55	**Submission of trial results and layperson summary** Andrea Seidel-Glaetzer (ECRIN)	10’
15:55 – 16:10	**Transparency – publication of clinical trial information contained in CTIS** Laura Pioppo (EMA)	15’
16:10 – 16:20	**Break**	10’

Session 3

16:20 – 16:35	**Work-planning and management tools** Stéphanie Kromar (EORTC)	15’
16:35 – 16:55	**Panel discussion and Q&A** **Panel Members:** Fátima Simões (PT; Clinical Trials Facilitation Group) Andrea Seidel-Glaetzer (ECRIN) Fia Westerholm (EMA) Kristof Bonnarens (EC) Laura Pioppo (EMA) Pieter Vankeerberghen (EMA) Stéphanie Kromar (EORTC)	20’
16:55 – 17:00	**Availability and location of CTIS training materials** **Closing remarks** Fia Westerholm (EMA) Barbara Zajec (EMA)	5’