



CTIS Webinar: Last Year of Transition

25 March 2024, 13:00 – 17:30 CEST

VIRTUAL MEETING

Background and objectives

The Clinical Trials Information System (CTIS) was launched on 31 January 2022, starting the clock for the three-year transition period from the Clinical Trials Directive to the Clinical Trials Regulation. Since 31 January 2023, it has been mandatory for sponsors to submit all initial clinical trial applications via CTIS. In less than a year, from 31 January 2025 onwards, sponsors will need to comply with their obligations under the CTR and its Delegated Acts for all clinical trials conducted in the EU/EEA.

The European Medicines Agency (EMA) is organising this virtual event to provide:

- reflection on the implementation of the Clinical Trials Regulation;
- reflection on transitional trials and their management in CTIS;
- update on the current status of CTIS.

This event is open to all sponsor organisations, including pharmaceutical companies, contract research organisations, small and medium-sized enterprises (SMEs), and academic organisations.

Questions will be asked via Slido in advance, between 4-18 March 2024.

CTIS Webinar: Last Year of Transition

Chaired by Marianne Lunzer and Noemie Manent

Introduction

12:30 – 13:00	Joining and technical checks	30'
13:00 – 13:05	Welcome and Introduction <i>Marianne Lunzer (AGES / CTCG chair)</i> <i>Noemie Manent (EMA)</i>	5'
13:05 – 13:20	Opening Remarks <i>Emer Cooke (EMA)</i> <i>Björn Eriksson (MPA)</i>	15'

Session 1: Clinical Trials Regulation Implementation

13:20 – 13:30	CTR Implementation <i>Linda Abdelall (EC)</i>	10'
13:30 – 13:50	CTIS Metrics and looking forward <i>Noemie Manent (EMA)</i>	20'
13:50 – 14:20	Best practices for transitional trials and their management in CTIS <i>Monique Al (CCMO)</i>	30'
14:20 – 14:55	Questions & Answers – Panel discussion	35'

Coffee Break

14:55 – 15:15	Coffee break	20'
----------------------	---------------------	------------

Session 2: Experience in Transitional Trials

15:15 – 15:55	Member States' Perspective <i>Lene Petersen (DKMA)</i> <i>Stefan Strasser (AGES)</i>	40'
15:55 – 16:35	Sponsors' Perspective <i>Barbara Lanthaler (Medical University of Innsbruck)</i> <i>Martin O'Kane (NOVARTIS)</i>	40'
16:35 – 17:20	Questions & Answers – Panel discussion	45'

Closing Remarks

17:20 – 17:30	Wrap-up and Closing Remarks <i>Marianne Lunzer (AGES / CTCG chair)</i> <i>Noemie Manent (EMA)</i>	10'
----------------------	--	------------

