



Clinical Trials Information System (CTIS) webinar: 6 months of CTIS and looking forward

1 July 2022, 09:30 – 13:30 CET

VIRTUAL MEETING

Background and objectives

The way clinical trials are conducted in the European Union/EEA underwent a major change when the Clinical Trials Regulation (Regulation (EU) No 536/2014) came into application on 31 January 2022. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU, via a Clinical Trials Information System (CTIS), which contains the centralised EU portal and database for clinical trials foreseen by the Regulation.

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

EMA is organising this open event to:

- Inform stakeholders of system usage metrics
- Listen to stakeholders' experience and reflections on using CTIS
- Discuss user support feedback and training environment

Clinical Trials Information System (CTIS) Webinar: 6 months of CTIS and looking forward

Chaired by Pieter Vankeerberghen (EMA)

Introduction

09:15 – 09:30	Joining and technical checks	15'
09:30 – 09:35	Welcome and introduction <i>Pieter Vankeerberghen (EMA)</i>	5'

Session 1: CTIS status and updates

09:35 – 09:45	System Metrics <i>Laura Pioppo (EMA)</i>	10'
09:45 – 09:55	CTIS 2023 Roadmap <i>Pieter Vankeerberghen (EMA)</i>	10'

Session 2: CTR and Transition period

09:55 – 10:10	CTR and transition period <i>Kristof Bonnarens (European Commission)</i>	15'
10:15 – 10:30	Q&A – Sessions 1 and 2 <i>Pieter Vankeerberghen (EMA)</i> <i>Kristof Bonnarens (EC)</i> <i>Laura Pioppo (EMA)</i>	15'
10:30 – 10:40	Break	10'

Session 3: Member States Experience and reflections

10:40 – 10:55	Netherlands – presentation <i>Monique Al (NL)</i>	15'
10:55 – 11:10	Finland – presentation <i>Outi Konttinen (FI)</i>	15'

11:10 – 11:25	Austria – presentation <i>Stefan Strasser (AT)</i>	15'
11:25 – 11:40	France - presentation <i>Sophie Accadebled (FR)</i>	15'

Session 4: Sponsor experience and reflection

11:40 – 11:55	Sponsor – presentation <i>Gaby di Matteo (Sponsor)</i>	15'
11:55 – 12:25	Q&A – session 3 & 4 <i>MS and Sponsor Panel</i>	30'
12:25 – 12:40	Break	15'

Session 5: Training and communication

12:40 – 12:50	User support feedback <i>Thale Patrick-Brown (Sponsor)</i>	10'
12:50 – 13:00	CTIS Training environment and Communication <i>Noemie Manent (EMA)</i>	10'
13:00 – 13:15	ACT EU <i>Ana Zanoletty (EMA)</i>	15'
13:15 – 13:25	Q&A <i>Panel</i>	10'
13:25 – 13:30	Wrap up and closing remarks <i>Noemie Manent (EMA)</i>	5'