



Clinical Trials Information System Webinar:

Second Year of Transition

4 July 2023, 13:00 – 17:30 CEST

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 is mandatory for sponsors to submit all initial clinical trial applications via CTIS.

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

- reflection on the implementation of the Clinical Trials Regulation;
- reflection on Transitional Trials and Ethics Committee assessment procedures;
- update on the current status of CTIS.

Questions will be asked via [Slido](#) in advance, between 1-17 June 2023.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trials Information System Webinar: Second Year of Transition

Chaired by Marianne Lunzer and Peter Arlett

Welcome and Opening Remarks

13:00 – 13:05	Welcome and introduction	5'
13:05 – 13:20	Opening Remarks	15'

Session 1: Clinical Trials Regulation Implementation

13:20 – 13:30	CTR Implementation	10'
13:30 – 14:00	Member States' Experience and Perspective on Transitional Trials	30'
14:00 – 14:30	Sponsors' Experience and Perspective on Transitional Trials	30'
14:30 – 15:20	Questions & Answers – Panel discussion	50'

Coffee Break 20'

Session 2: CTIS Governance, Stabilisation and Planning

15:40 – 16:10	Member States' Best Practices for Transitional Trials	30'
16:10 – 16:30	CTIS Looking Forward	20'
16:30 – 17:20	Questions & Answers – Panel discussion	50'

Closing Remarks

17:20 – 17:30	Wrap-up and Closing Remarks	10'
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