



CTIS Event on 20 January 2023: Readiness for Mandatory CTR use from 31 January 2023

20 January 2023, 10:00 – 13:00 CET

Background and objectives

Clinical Trials Information system (CTIS) was launched on 31 January 2022, starting the clock for the one-year transition time for all sponsors of clinical trials. During the first year of the transition period, clinical trial sponsors can choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive or under the Clinical Trials Regulation, via CTIS. The last date for sponsors to submit under the Clinical Trials Directive is 30 January 2023.

Starting from 31 January 2023, the use of CTIS will be mandatory for all initial clinical trial applications in the EU. For trials authorised under the Clinical Trial Directive, sponsors can continue to submit substantial amendments following the principles of the Clinical Trial Directive until the end of the transition period on 30 January 2025. The European Medicines Agency (EMA) is organising this open event to provide:

- reflection on the implementation of the Clinical Trials Regulation;
- update on the current status of CTIS;
- outlook on 2023/2024 CTIS planning.

Questions will be asked via [Slido](#) in advance, between 6-13 January 2023.

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Chaired by Marianne Lunzer (AGES / CTCG chair) and Peter Arlett (EMA)

Welcome and Opening Remarks

10:00 – 10:05	Welcome and introduction <i>Marianne Lunzer (AGES / CTCG chair)</i> <i>Peter Arlett (EMA)</i>	5'
10:05 – 10:20	Opening Remarks <i>Björn Eriksson (MPA)</i> <i>Emer Cooke (EMA)</i>	15'

Session 1: Clinical Trials Regulation Implementation

10:20 – 10:30	CTR Implementation and KPIs <i>Laura Pioppo (EMA)</i>	10'
10:30 – 10:40	Member States' Experience and Perspective <i>Maria Elgaard Sørensen (DKMA)</i>	10'
10:40 – 11:10	Sponsors' Experience and Perspective <i>Karina Griffiths (EFPIA / Pfizer)</i> <i>Andrea Seidel-Glätzer (ECRIN / Universitätsklinik Heidelberg)</i>	30'
11:10 – 11:25	Questions & Answers	15'

Session 2: CTIS Governance, Update and Planning

11:25 – 11:45	CTIS Status Update <i>Ana Rodriguez (EMA)</i>	20'
11:45 – 12:00	CTIS Planning 2023 / 2024 <i>Petri Paakkonen (EMA)</i>	15'
12:00 – 12:15	Questions & Answers	15'
12:15 – 12:25	Helpdesk support and how to report a priority issue <i>Anna Herks Vitezova (EMA)</i>	10'
12:25 – 12:35	Training and Change Management Activities <i>Noemie Manent (EMA)</i>	10'
12:35 – 12:50	Questions & Answers	15'

Closing Remarks

12:50 – 13:00	Wrap-up and Closing Remarks <i>Marianne Lunzer (AGES / CTCG chair)</i> <i>Peter Arlett (EMA)</i>	10'
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