17 June 2026
European Medicines Agency

Clinical Trials Information System Information Day Webinar

Virtual

17 June 2026, 12:30 – 17:30 (CET/CEST)

Since its launch on 31 January 2022, CTIS has undergone significant updates to enhance its functionality and improve user experience. This webinar aims to:

- Provide insights into the current of CTIS and an overview of implemented optimisations.
- Feedback on progress on CTIS and CTCG/CTAG guidance.
- Highlight key support initiatives and tips to help users navigate CTIS effectively, and discuss upcoming developments aimed at enhancing system functionality, user experience, and planned developments.

CTIS Info Day Event Summary

The CTIS Info Day provides a comprehensive update on the Clinical Trials Information System (CTIS), including progress made, upcoming priorities, and key legal and regulatory developments affecting CTIS. The event aims to strengthen understanding of the Clinical Trials Regulation (CTR), promote best practices, and gather stakeholder input to support effective implementation of the CTR and continuous system improvement.

Programme overview

The programme will cover:

- CTIS Roadmap progress, including completed milestones, ongoing work, and upcoming priorities;
- Implementation updates from Member States and sponsors, reflecting CTCG and CTAG perspectives;
- New support materials, such as the Sponsor Handbook and updated Sponsor FAQs;
- Practical aspects of CTIS use, including:
    - ServiceNow support,
    - frequently asked questions,
    - common errors and how to avoid them.

The CTIS Info Day will also highlight targeted support for non-commercial sponsors, share key findings from recent reports, and discuss relevant regulatory developments, including the Biotech Act, the ICH M11 template, and EU pilot initiatives such as Fast EU and combined procedures.

Panel discussions and stakeholder exchanges will focus on what is working well and where challenges remain. Structured feedback collected during the event will inform future improvements, change management activities, and continuous optimisation of CTIS.

Audience

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

Live participation via Slido

Participants are encouraged to submit questions related to CTIS use, implementation, and sponsor preparedness in advance of the webinar through Slido (code:#CTISInfoDay2026). The most popular questions submitted in advance of the event will be answered by speakers during the panel session. Please submit your questions by **8 June 2026**, 12:00 noon.

Post event feedback survey

Attendees are invited to fill out a short feedback survey via Slido that will be available after the event.

No certificates of attendance will be issued for this event.

The event will be broadcast live. A video recording will be made available after the event. Processing and publication of the video recording typically take up to 60 days.

CTIS Information Day Webinar

Chaired by Ana Rodriguez Sanchez Beato (EMA) and Marianne Lunzer (AGES/CTCG)

17 June 2026, 12:30 - 17:30 (CET/CEST)

12:00 Joining and technical checks

12:30 Opening remarks

Peter Arlett (EMA) **10'**

12:40 Updates on CTIS programme

Roadmap – Progress to date and next steps **30'**
Oskia Bueno (EMA)

13:10 Feedback on CTIS Progress from Sponsors

Sponsors perspective **45'**

Commercial Sponsor Perspective *- TBC*
CRO perspectives *– Leona Fitzgerald*
Non-commercial Sponsor Perspective *- TBC*

13:55 CTCG/CTAG guidance

Members State perspective **45'**

Ongoing Pilots:
FAST EU *- TBC*
Combine *- TBC*

Updates from CTCG & CTAG: Sponsor Change and Other (Q&A) *- TBC*
Translations *- TBC*

14:40 Panel discussion

Presenters - Panellists **35'**
Moderators: Pierre Omnes & Ana Rodriguez Sanchez-Beato

15:15 Coffee Break

15:25 Legal and Regulatory Developments

Biotech Act **30'**
Edit Szepessy (European Commission)

ICH M11 **10'**
Mumtaz Sultani (EMA) Noemie Manent (EMA)

16:05 Safety Module

Presenter **10'**
Mumtaz Sultani (EMA)

16:15 Engagement to support users

ServiceNow Overview and CTIS Training environment **15'**
Giovanni Varricchio (EMA), Ornela Ademi (EMA)

ACT EU support to Non-Commercial Sponsors **10'**
Giacomo Capone (EMA)

Pilots on consolidated advice in clinical trials **10'**
Massimiliano Sarra (EMA)

16:50 Panel discussion

Presenters - Panellists **35'**
Moderator: Martin O'Kane (Novartis) and Marianne Lunzer (AGES/CTCG)

17:25 Closing remarks

Presenters - Panellists **5'**
Ana Rodriguez Sanchez-Beato (EMA) and Marianne Lunzer (AGES/CTCG)