

Redesign of the CTIS Training material for sponsor users

CTIS Bitesize Talk

9 July 2025



A few housekeeping rules

Questions were collected in advance on www.sli.do
With event code **#bt9jul**



Tips for optimal screen viewing

- ❖ Make use of the instructions under the **Live broadcast** section on the event page and connect directly to the **EMA's Vimeo channel 1** *for the full-screen experience*
- ❖ Have a **stable internet connection**

Agenda

- Background, vision and objectives
- The CTIS Sponsor Handbook
- Reference webpage for Sponsors
- Reference materials for submitting & conducting a clinical trial in EU/EEA

The experts for this event are:

Moderator: Maria Teresa Calandri



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Background, vision and objectives

Simplification of the CTIS Sponsor Support material and related EMA webpages available to sponsor users

The specific objectives and deliverables of the project were:



1

Enhance Navigation and Accessibility: Organise content in a way that makes it easily accessible and user-friendly for all users by providing a structured and intuitive guide to all available resources.

2

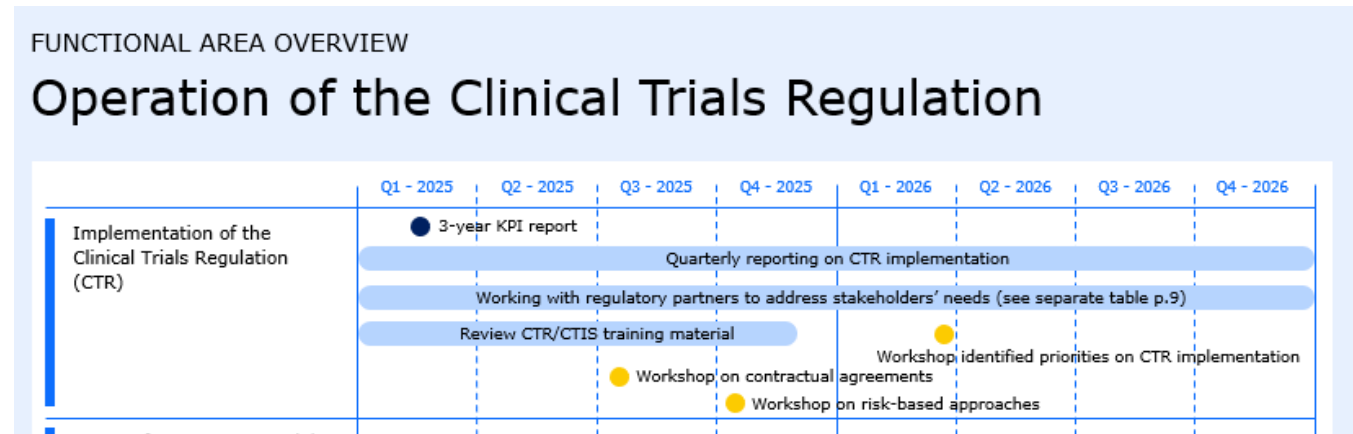
Streamline Materials and Increase Efficiency: Simplify CTIS support materials by consolidating and centralising all materials/documents to eliminate unnecessary duplication and ensure consistency.

3

Relevant signposting on training and support sources (EMA, COM & CTCG): develop a high-level table of contents or overview of all available materials (guidance documents, Q&A and How to's).

Background, vision and objectives

- Sponsors' feedback about the need to revise the existing material raised via different channels, including EMA Change Management Survey, ACT EU Survey on CTR Implementation, & ACT EU Meetings
- Goal: from several fragmented documents and multiple entry points to a single reference document, user-friendly and easy to navigate
- Delivered in accordance with the ACT EU workplan



The training contents for sponsors are now all included in the Sponsor Handbook

- The new version of the Sponsor handbook includes all the sponsor training modules, **now superseded**, as well as further **clarifications** on specific topics and **external links**

Sponsor workspace

Expand section Collapse section

Create, submit and withdraw a clinical trial (Module 10)	▼
Respond to requests for information received during the evaluation of a clinical trial application (Module 11)	▼
Manage a clinical trial through CTIS (Module 05)	▼
How to create and submit an annual safety report and respond to related requests for information (Module 18)	▼
Clinical study reports submissions (Module 13)	▼
Search, view and download information on clinical trials and clinical trial applications (Module 09)	▼
CTIS for SMEs and Academia (Module 19)	▼



+ **specific topics** furtherly clarified



+ **external links** to legislation, CTIS videos & bitesize talks



The CTIS Sponsor Handbook (v 6.0)

- Official EMA user guidance for sponsors using the CTIS platform, fully replacing the former ‘Sponsor Modules’
- Intended for pharma, SMEs, academics, CROs
- Operational, instructional — not legal/scientific guidance
- Supports all phases of clinical trial lifecycle
 1. Pre-submission steps
 2. Apply for a CT authorisation
 3. Evaluation Phase
 4. Conduct a clinical trial
 5. End of the Clinical Trial & submit results
- It has a dedicated ‘CTIS training and support’ section



9 July 2025
EMA/186412/2021
Clinical Trials Transformation

Sponsor’s handbook on the use of CTIS workspace
Clinical Trial Information System (CTIS) user guidance on the sponsor’s workspace

Version 6.0



Sponsor Handbook: actions and timeline



Analysis of all Sponsor's training material
February 2025



Drafting the handbook through including the **content of** all the former **sponsor modules**
March - April 2025



Review of the comments received **and finalisation of** Sponsor Handbook
May-Jun 2025



Publication of the Sponsor Handbook **9**
Jul 2025

The Handbook's Navigation & Learning tools

- **Clickable Table of Contents**

Interactive navigation to quickly access specific sections of the trial lifecycle and system functionalities.

- **Step-by-Step Procedural Guides**

Detailed walkthroughs for tasks such as submitting applications, responding to RFIs, and managing user roles.

- **Embedded Video Tutorials and Events' Recordings**

Links to EMA-hosted videos demonstrating CTIS functionalities, including user access, application submission, and safety reporting.

- **Links to external resources & Annexes**

Includes links to external resources like EudraLex and CTCTG guidelines, as well as a list of acronyms and regulatory definitions

Clickable Table of Contents

- Located at the beginning
- Allows jumping to any section
- Follows the flow of clinical trial phases
- Best used for navigation, not overview

Clickable table of contents

6. CTIS training & support

Pre-submission steps

- 1.1. Access to EMA applications (CTIS, OMS, EV, XEVMPD)
- 1.2. Sponsor and other organisation(s) registration in OMS
- 1.3. Sponsor registration in EudraVigilance (EV)
- 1.4. Medicinal product registration in XEVMPD
- 1.5. CTIS User Management: Organisation centric vs trial centric
- 1.6. User roles in CTIS ('role matrix')
- 1.7. Role(s) assignment and how to request a certain role

Apply for a CT authorisation

- 2.1. CTIS Publication rules
- 2.2. Clinical Trial (CT) application data fields and documents
- 2.3. Create and submit an Initial CT application (IN)
- 2.4. Fill in specific IN sections (e.g. product section)
- 2.5. Partial submission of an IN
- 2.6. Search, view and download a CT
- 2.7. Withdraw a submitted IN and resubmit it

Evaluation phase

- 3.1. Evaluation steps, outcome and timetable
- 3.2. Notices and alerts
- 3.3. Respond to a Request for Information (RFI)

Conduct a clinical trial

- 4.1. Notify on CT events (e.g. CT start, start of recruitment)
- 4.2. Create and submit an Additional Member State appl. (AM)
- 4.3. Create and submit a Substantial Modification appl. (SM)
- 4.4. SM to change the sponsor
- 4.5. Withdraw a submitted SM or AM and resubmit it
- 4.6. Evaluation of an AM
- 4.7. Evaluation of an SM
- 4.7. Create and submit a Non-Substantial Modification (NSM)
- 4.8. Notify on Unexpected event, Urgent safety measure, Serious breach and Third-Country Inspectorate Inspection
- 4.9. Respond to an RFI raised during an ad hoc assessment
- 4.10. Respond to an RFI raised on a corrective measure
- 4.11. Suspected Unexpected Serious Adverse Reaction (SUSAR)
- 4.12. Submit an Annual Safety Report (ASR) and respond to ASR RFI

End the CT & submit results

- 5.1. Notify the CT end and submit results
- 5.2. Submit interim results, summary of results and layperson summary
- 5.3. Submit the Clinical Study Report (CSR) and update it

Main Content

- Pre-submission steps:
 - Access to EMA applications (CTIS, OMS, EV, XEVMPD) and relevant timelines
 - Roles in CTIS + users management (organisation centric vs trial centric)
- Apply for a trial, Evaluation phase, trial conduction and conclusion:
 - Publication rules & application fields and documents
 - Create and submit IN, AM, SM, NSM, Notifications and respond to RFIs, Results submission
 - Timetables
- Training and Support
 - Info & Service Desk



Specific Characteristics

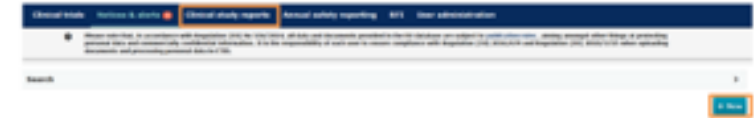
- Clearly divided into main **sections** and numbered **subsections**, with numbered steps and bullet lists
- Required **Sponsor's roles** at the beginning of each step-by-step guide
- Charts and images to visualize concepts
- Uses active voice where possible
- Bold for headings and key terms
- 'Note' and 'Important' call-outs for emphasis
- Cross-Referencing: uses 'see section X.X' and document references (redundant by design for **easy access** from any section)
- Notes from the [List of known issues and workarounds](#)

5.3.2. Create and submit a CSR

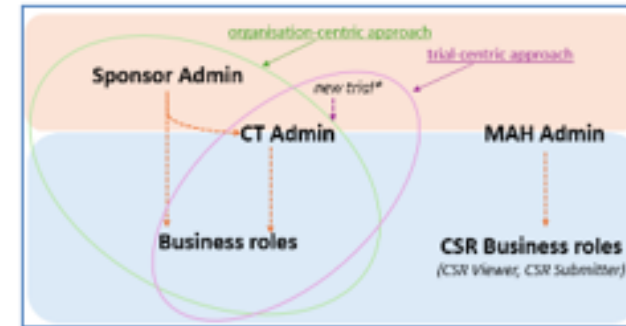
The below process describes how users with **CSR Submitter** and/or **MAH Admin** roles can create a CSR for a clinical trial that has been authorised.

After having accessed the [sponsor workspace](#):

1. From the 'Clinical study reports' tab, click on the '+ New' button displayed on the left of the screen:



2. **Search** for the trial for which you intend to submit the CSR through the advanced search functionality.
3. Select the trial of interest and then click on the **'Confirm'** button at the end of the results page.



Section [2.3.1](#), is on practical matters the users should be aware [2.3.2](#), explains how to remove metadata from any document (regardless of whether will be made publicly available or not). **Bot** **tion performed** through the system, including the preparation SM, NSM, see sections [4.1](#), [4.9](#), [5.2](#), [5.3](#)).

3.3. Respond to a Request for Information (RFI)

Before applying the below instructions, the following resources should be consulted: the [CTIS Key Documents list](#) on 'RFI Response template', and the [CTR Q&A](#) (search for the relevant keywords). For questions, refer to your [MSC\(s\) contact point\(s\)](#).

A CT application RFI is a request for additional information regarding an application that the

Important: any document inadvertently uploaded as first document for those documents placeholders that are 'for publication' will be published. It is the responsibility of the sponsor to ensure that in those documents CCT and personal data are removed and can be published. For example, if an Investigator's Brochure (IB) is uploaded into the RMP section of a category 2 or 3 trial, the IB will be made public if the sponsor does not correct this oversight before the decision on the application.

Note: for category 1 trials, Recruitment arrangements and Subject Information and informed consent form documents are not subject to publication, even if the relevant message in CTIS displays them as

Tips for Effective Use

- Use the handbook as a **daily reference** tool
- Start with the **clickable table of contents**
- Use PDF search to **find terms**
- Understand which is the **regulatory material** for your topic (e.g. CTR Q&A)
- Open videos/bitesize talks in parallel
- Look at section 6. CTIS training and support



EMA webpage for sponsors on CTIS training material

- [Clinical Trials Information System \(CTIS\): training and support](#): **Sponsor Handbook** + any other training material that is also linked in the handbook:
 - docs on protection of personal data and CCI
 - additional reference materials (excels on structured data & docs)
 - training and events
 - Contact us
- For authorities: [Clinical Trials Information System \(CTIS\): online training modules for authorities](#)

Clinical Trials Information System (CTIS): training and support

The European Medicines Agency (EMA) makes training and supporting materials available to help users of the Clinical Trials Information System (CTIS) comply with their legal obligations.

Human Clinical trials

Page updated on 9 July 2025 to reflect the updated CTIS training materials.

Handbook for clinical trial sponsors

The **CTIS sponsor handbook** is the reference document that clinical trial sponsors should use when applying for a clinical trial authorisation through CTIS. They should also use the handbook when entering any other information in CTIS.

The handbook is aimed at:

- pharmaceutical companies;
- contract research organisations (CROs);
- small and medium-sized enterprises (SMEs);
- academic sponsors;
- and other organisations working on clinical trials.

EMA regularly updates the handbook.

Clinical Trial Information System (CTIS) - Sponsor handbook
Reference Number: EMA/143883/2024 v.5.0

English (EN) (3,54 MB - PDF)
First published: 25/11/2024 Last updated: 25/11/2025

View

Also on this topic

- [Clinical Trials Association](#)
- [Clinical Trials Information System](#)
- [Clinical Trials Information System \(CTIS\): online training modules for authorities](#)

Protection of personal data and commercially confidential information

Information on clinical trials submitted in CTIS is made available on the [CTIS public portal](#), in line with the revised CTIS transparency rules applicable as of June 2024.

Before uploading data and documents to CTIS, sponsors should be fully aware of the publication rules, see:

- [Clinical Trials Information System, CTIS transparency rules](#)

The roles and responsibilities of each party regarding the processing of personal data in CTIS is described by the joint controllership arrangement. For more information, see:

- [Clinical Trials Information System, Processing of personal data](#)

All reference documents on CTIS transparency rules can be found on the Accelerating Clinical Trials in the EU website. For more information, see:

- [Accelerating Clinical Trials in the EU \(ACT-EU\): Implementation of the Clinical Trials Regulation](#)

Additional reference materials for CTIS users

Expand all Collapse all

Public holidays recorded in CTIS

European Union Member State Public Holidays Recorded in CTIS (year: 2025)
Reference Number: EMA/143883/2024

English (EN) (219.03 KB - PDF)
First published: 25/11/2024

View

CTIS structured data and documents

Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, substantial modification, non-substantial modification
Reference Number: EMA/143883/2024

Reference materials for submitting & conducting a clinical trial in EU/EEA

- Regulatory resources:

[EudraLex - Volume 10 - Clinical trials guidelines](#)

[Clinical Trials - Regulation EU No 536/2014](#)

[Clinical Trials Coordination Group \(CTCG\) Key Documents list](#)

[National Competent Authorities \(NCA\) websites](#) on national requirements

- EMA Training and Support page:

[CTIS Sponsor Handbook](#)

[CTIS publication rules](#) and [processing of personal data](#): reference documents

[Additional reference materials](#) for CTIS users

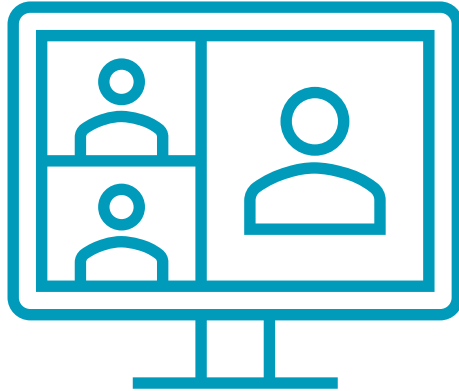
Links can **all** be found in the CTIS Sponsor Handbook

Demo

EMA training & support page,
CTIS Sponsor Handbook



Upcoming CTIS events



- **24 September 2025**, 16:00 - 17:00 CET - CTIS Walk-in Clinic
- **19 November 2025**, 16:30 - 18:00 CET- CTIS Bitesize Talk

For upcoming CTIS events, please consult [Clinical Trials Information System: training and support | European Medicines Agency \(europa.eu\)](#) and [EMA events](#) pages

Thank you for attending today's event

Please provide your feedback for this event in our **Slido**
survey

Use the passcode: **#bt9jul**