



ACT EU

Simplification and redesign of  
CTR/CTIS training material for  
Sponsors and Member States

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# Feedback from stakeholders

STK 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 PA10 survey on clinical trial

training needs for academics and SMEs, & ACT EU Meetings):

→ challenges experienced when trying to find the information or training of new hires

- Too many sources of information
- Complexity of materials and navigation
- Lack of time to attend the various events organised
- Searching CTR/CTIS training material on the EMA website is challenging. Need for improving the search engine efficiency.
- The volume of training material is too large and not manageable by organisations with limited resources. Need for simplification and streamlining of the training material.

## EUCOPE Feedback

### Clinical Trial experience of Small and Mid-Sized Companies



#### SMC intrinsic factors:

- Rarity of clinical trials
- Scarcity of resources
- Generalist profiles
- Complex products (ATMP's, GMO's...)
- Challenging trial operation conditions (Rare diseases)

#### External aggravating factors:

- Complexity of the CTR process and its related Information System
- Hundreds of pages of legislation, Q&A's, guidelines and hours of webinar recordings
- Frequent changes brought to the system and introduction of work-arounds
- Information scattered in multiple locations (EMA, EU COMM, CTG, ACT EU websites...)

- Difficulty to digest the large amount of regulatory requirements and recommendations
- Challenge to keep up with frequent changes in systems and work-arounds
- Need to re-train every time a new application is under preparation
- No time to attend CTIS forum meetings and other webinars
- Not reactive enough to apply to pilots




# Concepts are scattered throughout more than 200 different documents

Handbook for clinical trial sponsors

The **CTIS sponsor handbook** covers priority topics identified with the help of [clinical trial](#) sponsors, with references and links to further supporting materials.

It 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/923413/2022 v4.0

**English (EN)** (1.61 MB - PDF)  
First published: 29/07/2021 Last updated: 20/08/2024

Training and information events

EMA offers **live training sessions** to provide additional learning opportunities, including bitesize talks, walk-in clinics and webinars.

Recordings and supporting materials become available after each event.

You can look up both past and upcoming events below:

[Expand section](#) [Collapse section](#)

Respond to requests for information received during the trial application (Module 11)

Manage a clinical trial through CTIS (Module 05)

How to create and submit an annual safety report and requests for information (Module 18)

Clinical study reports submissions (Module 13)

Search, view and download information on clinical trials and applications (Module 09)

CTIS for SMEs and Academia (Module 19)

**Common functionalities for all registered users**

[Expand section](#) [Collapse section](#)

User access management (Module 03)

Management of registered users and role matrix (Module 07)

Data protection in CTIS (Module 12)


Support with workload management (Module 04)

Transitional trials (Module 23) - OBSOLETE

**Evaluation timelines**

This document is for CTIS sponsor and authority users.


- an overview of timelines and deadlines for trial applications
- an explanation of the dynamic character of the timelines and the cause recalculation of the deadline of subsequent submissions

 **Clinical Trial Information System (CTIS) - Evaluation timelines**  
Reference Number: EMA/343883/2021


**English (EN)** (2.06 MB - PDF)  
First published: 23/09/2022 Last updated: 20/09/2024

**Clinical Trial Information System (CTIS) - Sponsor user personas**

**English (EN)** (312.61 KB - PDF)  
First published: 30/09/2021 Last updated: 11/10/2021

 **Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, substantial modification, non-substantial modification**  
Reference Number: EMA/343883/2021

**English (EN)** (928.6 KB - XLSX)  
First published: 29/07/2021 Last updated: 11/12/2024

 **Clinical Trial Information System (CTIS) structured data form - Multi trial substantial modification**

Good to know:  
training material was initially structured in modules to reflect the different stages of the user journey

Walk-in clinic (CTIS): Walk-in clinic - January 2025 (29/01/2025)

Walk-in clinic (CTIS): Walk-in clinic - November 2024 (20/11/2024)

Walk-in clinic (CTIS): Walk-in clinic - September 2024 (18/09/2024)

Walk-in clinic (CTIS): Walk-in clinic - July 2024 (10/07/2024)

Walk-in clinic (CTIS): Walk-in clinic - May 2024 (15/05/2024)

Walk-in clinic (CTIS): Walk-in clinic - March 2024 (12/03/2024)

Walk-in clinic (CTIS): Walk-in clinic - January 2024 (24/01/2024)

Walk-in clinic (CTIS): Walk-in clinic - December 2023 (13/12/2023)

Walk-in clinic (CTIS): Walk-in clinic - November 2023 (15/11/2023)

Walk-in clinic (CTIS): Walk-in clinic - October 2023 (10/10/2023) - Cancelled

Walk-in clinic (CTIS): Walk-in clinic - September 2023 (20/09/2023)

Walk-in clinic (CTIS): Walk-in clinic - August 2023 (23/08/2023) - Cancelled

Walk-in clinic (CTIS): Walk-in clinic - July 2023 (19/07/2023)

Walk-in clinic (CTIS): Walk-in clinic - June 2023 (14/06/2023)

Walk-in clinic (CTIS): Walk-in clinic - May 2023 (17/05/2023)

Walk-in clinic (CTIS): Walk-in clinic - April 2023 (19/04/2023)

Walk-in clinic (CTIS): Walk-in clinic - March 2023 (16/03/2023)

Walk-in clinic (CTIS): Walk-in clinic - January 2023 (18/01/2023)

Walk-in clinic (CTIS): Walk-in clinic - November 2022 (15/11/2022)

Walk-in clinic (CTIS): Walk-in clinic - October 2022 (05/10/2022)


Walk-in clinic (CTIS): Walk-in clinic - September 2022 (20/09/2022)









Walk-in clinic (CTIS): Walk-in clinic - August 2022 (31/08/2022)

Walk-in clinic (CTIS): Walk-in clinic - June 2022 (15/06/2022)

Classified as public by the European Medicines Agency

# Several explanatory documents for every module

Respond to requests for information received during the evaluation of a clinical trial application (Module 11) 

Module 11	Respond to requests for information received during the evaluation of a <u>clinical trial</u> application
Target audience(s)	<ul style="list-style-type: none"><li>• Sponsors</li></ul>
Topics covered	<ul style="list-style-type: none"><li>• Phases and associated timelines for the evaluation of a <u>clinical trial</u> application</li><li>• What a request for information (RFI) is and the different types of RFIs that can be sent by a <u>concerned Member State</u> during the evaluation of a <u>clinical trial</u> application</li><li>• How to search and view an RFI during the evaluation of a <u>clinical trial</u> application</li><li>• How to create and submit an RFI response, including changes to an existing application</li><li>• Roles and permissions involved in the management of an RFI</li></ul>
Learning materials	<ul style="list-style-type: none"><li>• <a href="#">e-learning course</a> (use Chrome browser)</li><li>• <a href="#">Step-by-step guide: How to respond to requests for information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11</a></li><li>•   <a href="#">Instructor's guide: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11</a></li><li>•   <a href="#">FAQs: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11</a></li><li>• Supporting materials:<ul style="list-style-type: none"><li>◦  <a href="#">How to respond to Requests for Information received during the evaluation of a CTA - CTIS Training Programme - Module 11</a></li></ul></li><li>• Videos:<ul style="list-style-type: none"><li>◦ <a href="#">How to access and view an RFI in CTIS</a> </li><li>◦ <a href="#">How to change a Clinical Trial Application as part of an RFI response</a> </li><li>◦ <a href="#">How to respond to RFI considerations and submit an RFI response</a> </li></ul></li></ul>

- E-learning
- Step by step guide
- FAQ
- Instructor guide
- Video
- Supporting material, etc.

Each one with limited content,  
[example](#)



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# 'As is' analysis from a user's perspective

- There is **no unique document** that includes all instructions needed to submit, conduct and complete a trial through CTIS
- Resources are scattered throughout **more than 200 different docs/videos (incl. recordings of CTIS related events)/e-learning**s
- Similar **content is repeated** among different documents
- **Poor searchability**: concepts within docs are not easy to find
- There is **no** doc reflecting all necessary **steps to take, in chronological order**
- The reference document that sponsors use is the **CTIS Sponsor handbook**
- Two different entry points on EMA corporate website, further info published on CTIS public website and on ACT EU website, and several other webpages on CTIS on EMA website that are **long and verbose**

Users' feedback & [Targeted consultation on the implementation of the ClinicalTrialsRegulation \(EU\)No 536/2014 - summary report](#)



# Revision as per ACT EU workplan 2025-2026

- Revision of training materials included in the endorsed ACT EU workplan 2025-2026
- Our scope for today's meeting: revision of sponsor's material available **in the EMA website**

## FUNCTIONAL AREA OVERVIEW

### Operation of the Clinical Trials Regulation



# Vision and Objectives

Simplification of the current CTR/CTIS Support material and related EMA webpages available to stakeholders, based on collected feedback.

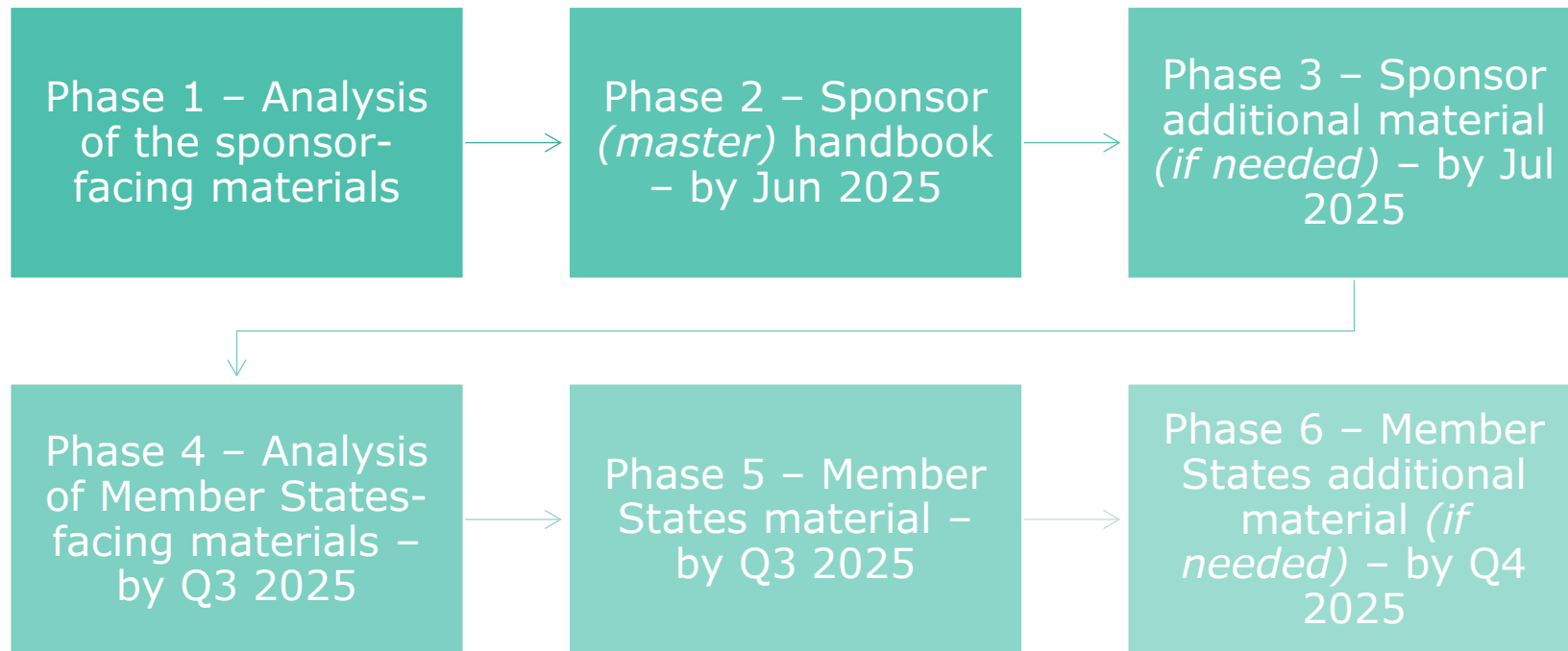
The specific objectives and deliverables are:



- 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 CTR/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).



# Overall process



***Focal points*** are involved and consulted from the beginning, and will also validate and review the final material

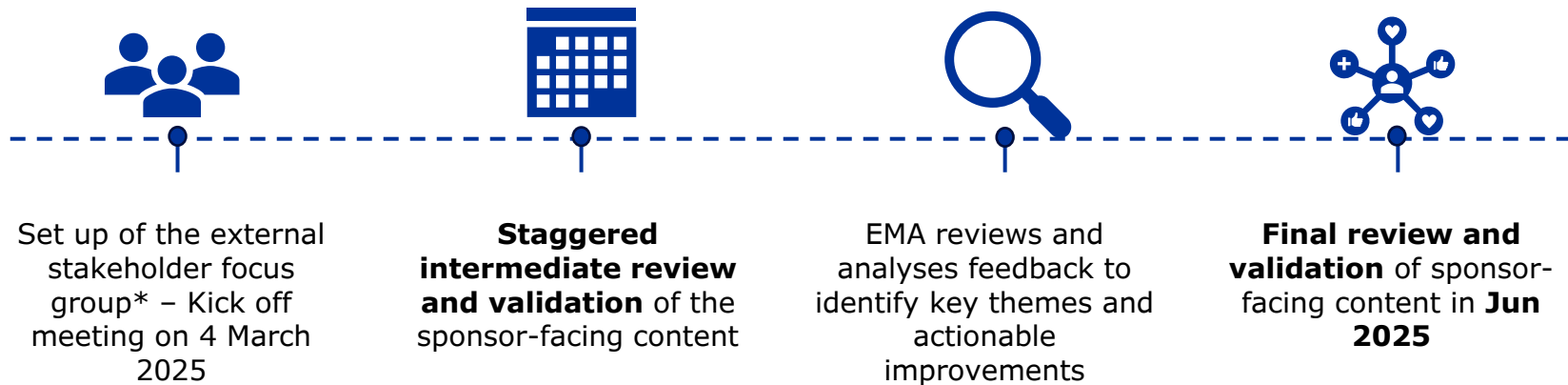


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# Next steps for the Sponsor Handbook



\*Focus groups has representatives from Member States, patients, commercial and non-commercial sponsors



# Conclusion & Acknowledgements

- **Your feedback matters:** This work is built on the invaluable input from stakeholders, gathered through surveys, meetings, and consultations.
- **Delivering on our objectives:** The redesign simplifies and streamlines CTR/CTIS training materials, making them more accessible, focused, and user-friendly.
- **Stronger together:** This initiative is a collaborative effort between the EMA, Member States, the European Commission, and focus groups representing diverse stakeholders.
- **What's next:** Together, we are committed to delivering targeted training and tailored Q&A resources that will empower faster, more efficient clinical trials across Europe.





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