EMA
EUROPEAN MEDICINES AGENCY

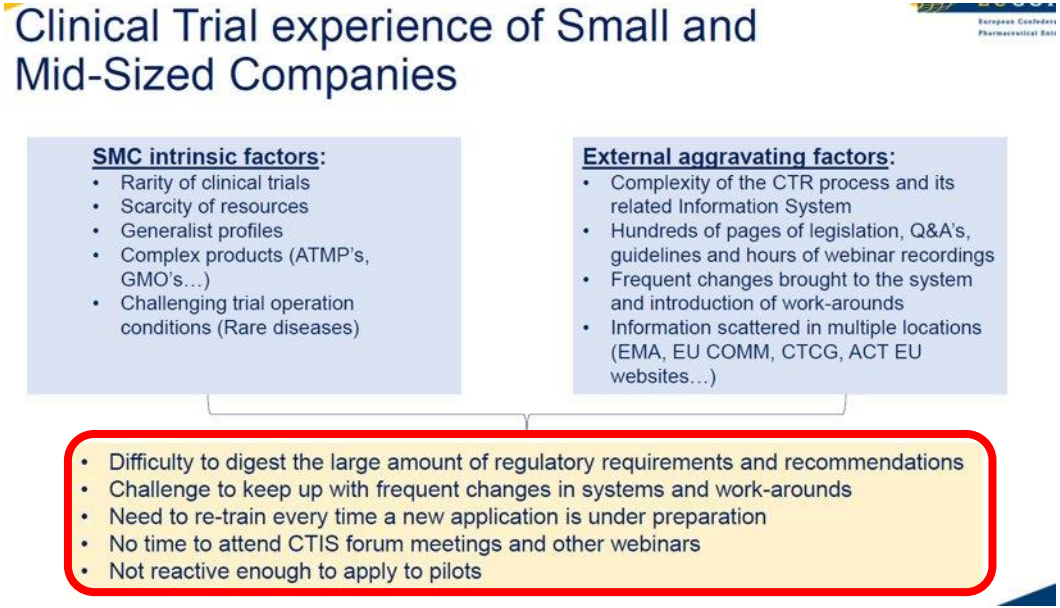
Simplification and redesign of CTR/CTIS training material for Sponsors and Member States

Feedback from stakeholders

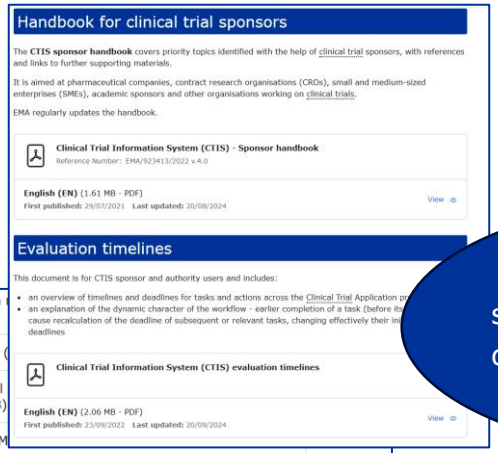
STK feedback about the need to revise the existing material raised via different channels, including EMA Change Management Survey, ACT EU Survey on CTR Implementation and ACT EU Meetings:

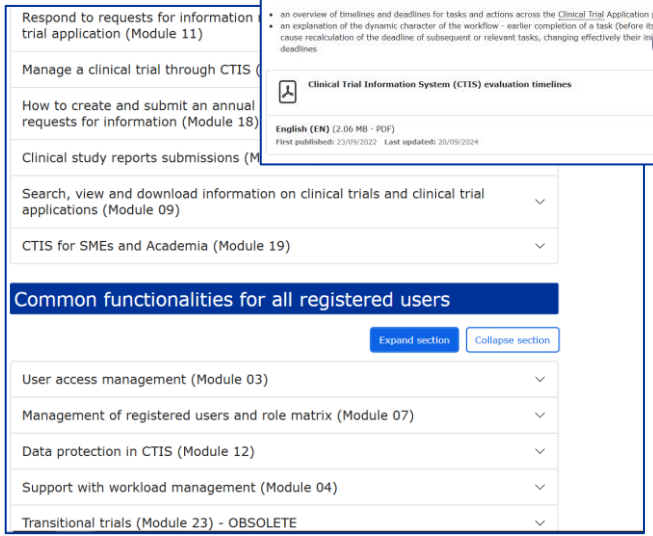
→ challenges experienced when trying to find the information or training of new hires

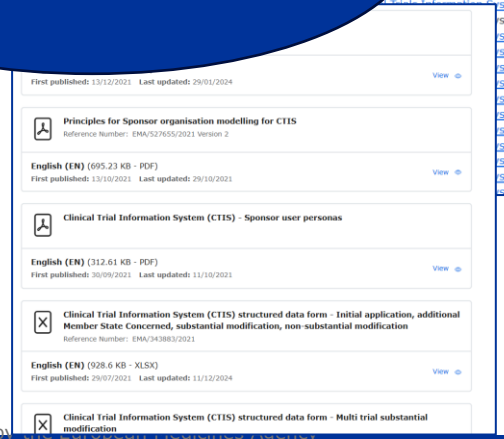
- Too many sources of information
- Complexity of materials and navigation
- Lack of time to attend the various events organised

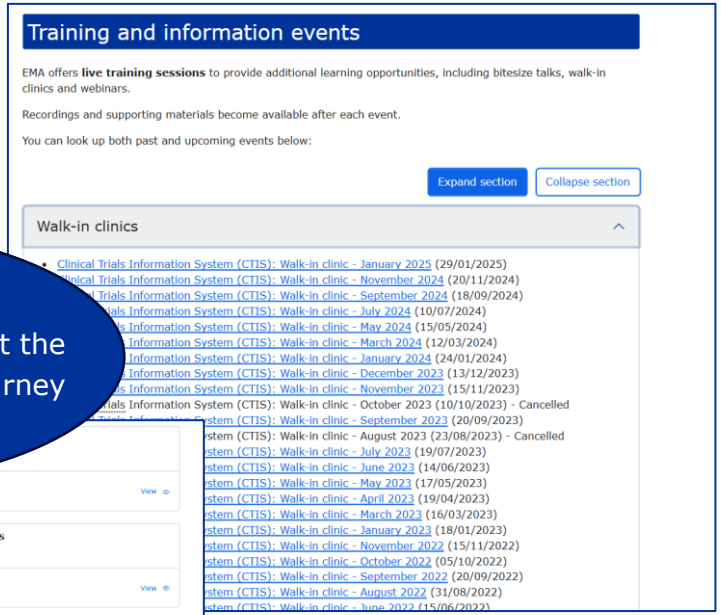


Concepts are scattered throughout more than 200 different documents









Training material was initially structured in modules to reflect the different stages of the user journey

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 clinical trial application
Target audience(s)	• Sponsors
Topics covered	• Phases and associated timelines for the evaluation of a clinical trial application • What a request for information (RFI) is and the different types of RFIs that can be sent by a concerned Member State during the evaluation of a clinical trial application • How to search and view an RFI during the evaluation of a clinical trial application • How to create and submit an RFI response, including changes to an existing application • Roles and permissions involved in the management of an RFI

Learning materials	• e-learning course (use Chrome browser)
	• 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
	• Instructor's guide: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11
	• FAQs: How to respond to Requests for Information received during the evaluation of a Clinical Trial Application - CTIS Training Programme - Module 11
	• Supporting materials:
	  ◦ How to respond to Requests for Information received during the evaluation of a CTA - CTIS Training Programme - Module 11
	• Videos:
	  ◦ How to access and view an RFI in CTIS
	  ◦ How to change a Clinical Trial Application as part of an RFI response
	  ◦ How to respond to RFI considerations and submit an RFI response

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

Each one with limited content, example

‘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-learnings**
- 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**

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**

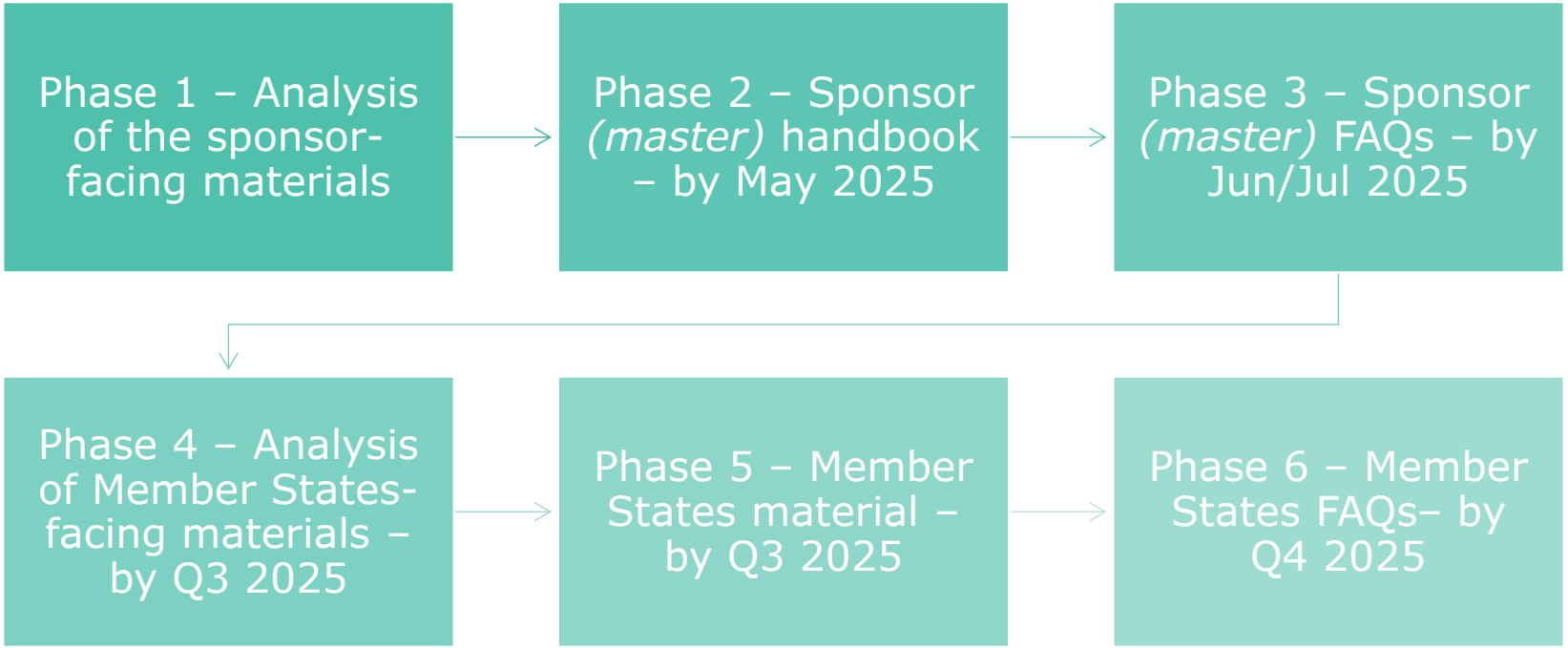
Vision and Objectives

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*

Next steps

Set up of the external stakeholder focus group – Kick off meeting on 4 March 2025

Staggered intermediate review and validation of the sponsor-facing content

You will receive the draft sponsor handbook and a feedback template

EMA reviews and analyses feedback to identify key themes and actionable improvements

Final review and validation of sponsor-facing content in **mid-May**

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Thank you

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