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SCIENCE MEDICINES HEALTH

Overview of CTIS guidance and training available for sponsors

Webinar for SMEs and Academia on the Clinical Trials Regulation and the Clinical Trials Information System 29 November 2021

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CTIS Programme

An agency of the European Union

The European Medicines Agency developed this training material to enhance public access to information on the Clinical Trial Information System (CTIS). This material describes a preliminary version of CTIS and may therefore not entirely describe the system as it is at the time of use of this material. The Agency does not warrant or accept any liability in relation to the use (in part or in whole) or the interpretation of the information contained in this training material by third parties.

CTIS – where to start looking…..

Available on
www.ema.europa.eu

URL

QR code:

[CTIS Sponsor Handbook for clinical trial sponsors]
Summary information, links, references

[Training - 20 Online training modules] and more to come
e-learning, FAQs, videoclips, quick guides, step-by-step guides
Essential: [Guide to CTIS training material catalogue]
Coming soon: Joint Controllership Arrangement (in Module 12: Data protection)

[Events: Training and information]
Recordings of previous events; see also [EMA general events page]

[Information: CTIS Highlights Newsletters]

CTIS Sponsor Handbook –a Very Good Starting Point

Collection of **guidance and links** to reference material on key topics related to sponsor preparedness

Cooperation between EMA and sponsor associations

Living document – 1st version 29 July 2021, 2nd version Nov/Dec 2021

Published on EMA corporate website

Comments and proposals welcome (link embedded in Handbook)

CTIS Sponsor Handbook – facilitating preparations

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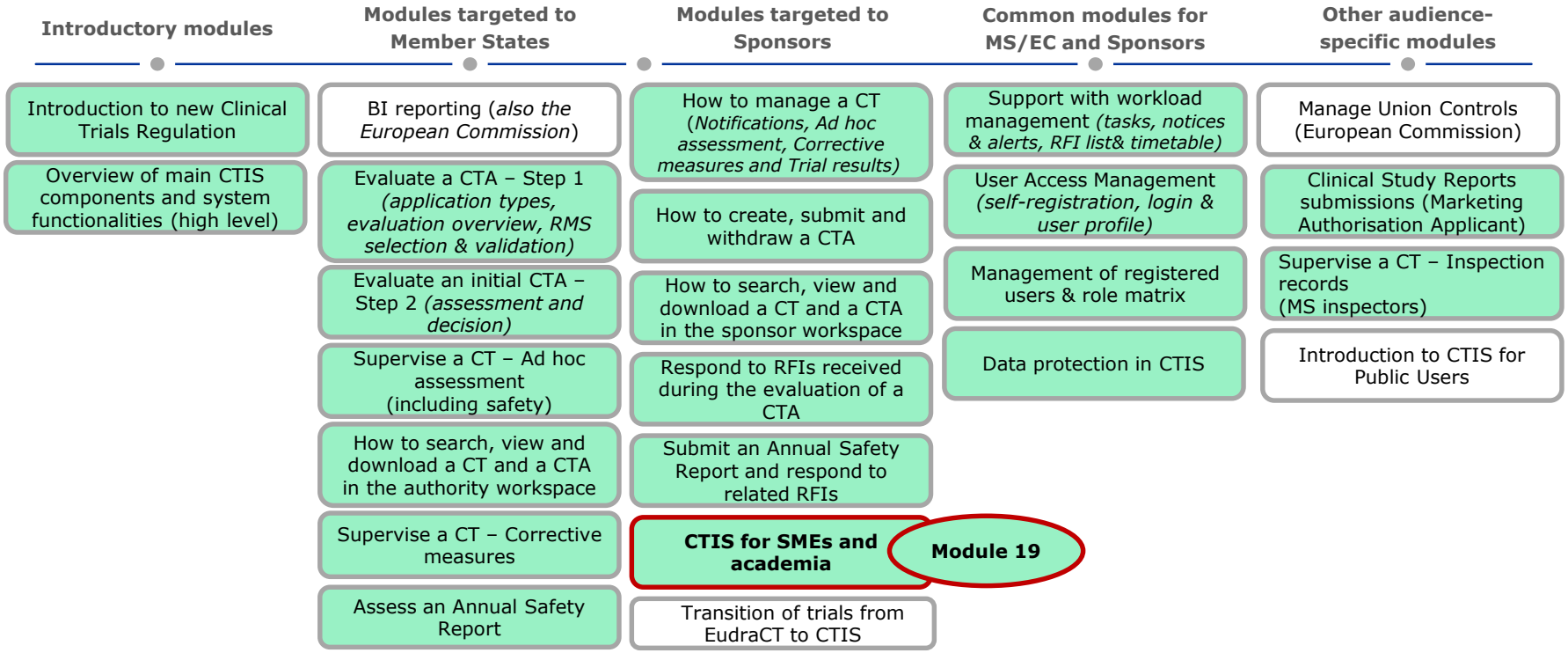
- What CTIS is and what it does
- Registrations: Users, Organisations, Organisation Administrators, Products
- Management of users and organisations in CTIS
- Transition of a trial from Directive to CTR – what to think about

- Data, documentation and processes
- Safety reporting
- Data Transparency
- Support
- References e.g. Commission Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 4.1 (September 2021)
- Acronyms and Glossaries

CTIS training material catalogue status

The **training catalogue** comprises **24 modules; 20 modules** (green) **have been developed** since March 2020



OnLine materials for all user groups

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A variety of material types are created and published for each training module

Training materials

FAQs
Compilation of responses to frequently asked questions

Quick guides
Presenting key information about specific system functionalities and steps in the system

eLearning materials
including online PPTs and eLearning interactive modules of system functionalities

Audio-visual material
ad hoc for selected modules and functionalities

Instructor guides
How-to guides for Master Trainers to support consistent knowledge dissemination

Infographics
Visual representation of key information

Additional support documents
Ad hoc documentation to support the dissemination of specific content

Step-by-step guide
Document summarising the basic steps of the process.

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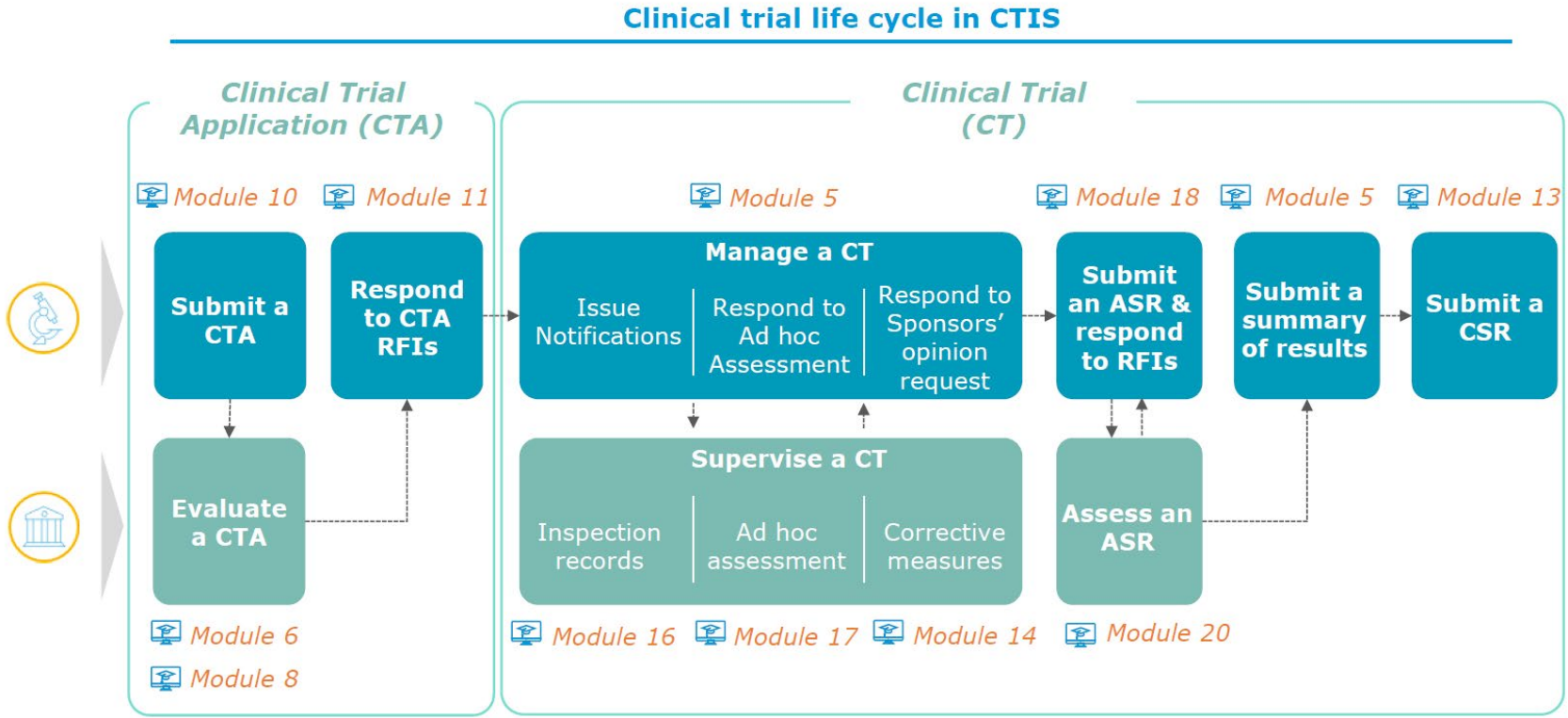
Guide to CTIS Training Material Catalogue – CT Lifecycle linking to Training modules



Module 19 for SME and academia

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Module 19: CTIS for SMEs and academia

Quick guide - Introduction

Step-by-step guide 1: **User** access management and user administration

Step-by-step guide 2: CTIS **workload functionalities** for the sponsor workspace

Step-by-step guide 3: **Search, view and download** a CT and a CTA in the sponsor workspace

Step-by-step guide 4: **Create, submit and withdraw** a clinical trial application and nonsubstantial modifications

Step-by-step guide 5: **Create and submit an RFI response**, including changes to an existing application

Step-by-step guide 6: How to **manage a clinical trial**

Step-by-step guide 7: **Submit an ASR** and how to respond to related RFIs

https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme#sponsor-workspace-section

CTIS training environment and User Support Service

The CTIS training environment is an important component of CTIS Go-Live plan
User Support Service will be available at Go-Live

Purpose of the CTIS Training environment

- Available for users and their organisations for training
  - to explore user configuration & CTIS functionalities before and after go-live date
  - enable MS to explore authority workspace in steps of an application
  - enable sponsors to create an application in sponsor workspace
- Limited interaction using a copy of the system

Controlled access in waves & phases to dedicated workspaces

- For users who are already trained on the system, through the CTIS Training Programme (online self study, Master Trainer or EMA events)
- First access to MS and Sponsor Master Trainers
- Access thereafter based on need and urgency

CTIS User Support Service

- A dedicated support desk is available for CTIS training environment users
- The main service desk opens when CTIS goes live

Stay up to date: CTIS Highlights Newsletter

Access to CTIS training environment (CTIS Sandbox)

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A rollout of the CTIS training environment can be provided in waves and phases to defined CTIS end-user groups based on need and urgency

15 Oct 2021	Wave 1 Member States Master Trainers and related users
Starting 22 Nov 2021	Wave 2 Sponsor Master Trainers and related users Access based on completion of Sponsor Master Trainer programme
Phases, timings tbd	Wave 3 Sponsor users/organisations (if no Master Trainer) in phases Phased access based on self-assessment need and urgency, EMA to evaluate For interested sponsors to perform self-assessment a first survey was conducted in October and may be reopened once wave 3 has started (more information in CTIS Highlights Newsletters)

Questions and Answers - options

- CTIS Sponsor Handbook and linked materials
- Frequently Asked Questions on CTIS functionalities in published training modules
- New/additional questions on CTIS functionalities to EMA by use of the general form
  - Please check in published materials /within organisation/ with colleagues before placing the question
  - This channel will be replaced by CTIS User Support Service at GoLive
- EudraLex - Volume 10 - Clinical trials guidelines
- Commission Draft Questions and Answers Document - Regulation (EU) 536/2014 – Version 4.1 (September 2021)
- EMA events page (search e.g. "CTIS")

CTIS – how to prepare for first use of CTIS

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- Make use of the CTIS Sponsor Handbook
- Take the CTIS training module 19 for SME and academia and other sponsor modules see Guide to CTIS Training Material Catalogue
- Ensure organisation is registered; if needed by placing a "change [of OMS] request" in EMA Organisation Management System (OMS) see Industry Webinar Introduction to OMS services and activities – YouTube; Person needs to have an EMA account (EMA account management)
- Users of the Organisation must register in EMA account management
- 1st Sponsor Administrator registers for the Organisation in EMA account management
  Person needs to have an EMA account (EMA account management)
- Ensure product is registered see Data submission on investigational medicines: guidance for clinical trial sponsors
- Prepare your CTA & collect your supporting documents in accordance with CTR requirements see Commission Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 4.1 (September 2021)
- Keep informed of general developments on CTIS in CTIS Highlights Newsletters

Any questions?

Further information

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