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SCIENCE MEDICINES HEALTH

EMA training and support for sponsors

Clinical Trials Information System (CTIS) webinar: How sponsor organisations can prepare for CTIS 29 July 2021

Presented by Fia Westerholm
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 Sponsor engagement

Engagement	Info events Collaborative approach
Online Training	Extensive online programme available Sponsor Master Trainer programme
Online Support	EMA CTIS Sponsor Handbook Supportive materials and references
Research community/SME	Targeted SME/academia training module SME/academia further training Q3-4 2021
EMA CTIS info	EMA Info events (recorded & published) EMA CTIS Highlights Newsletters
EMA CTIS Service Desk	At time of GoLive Training helpdesk end 2021

CTIS Training and Support plan 2021-2022

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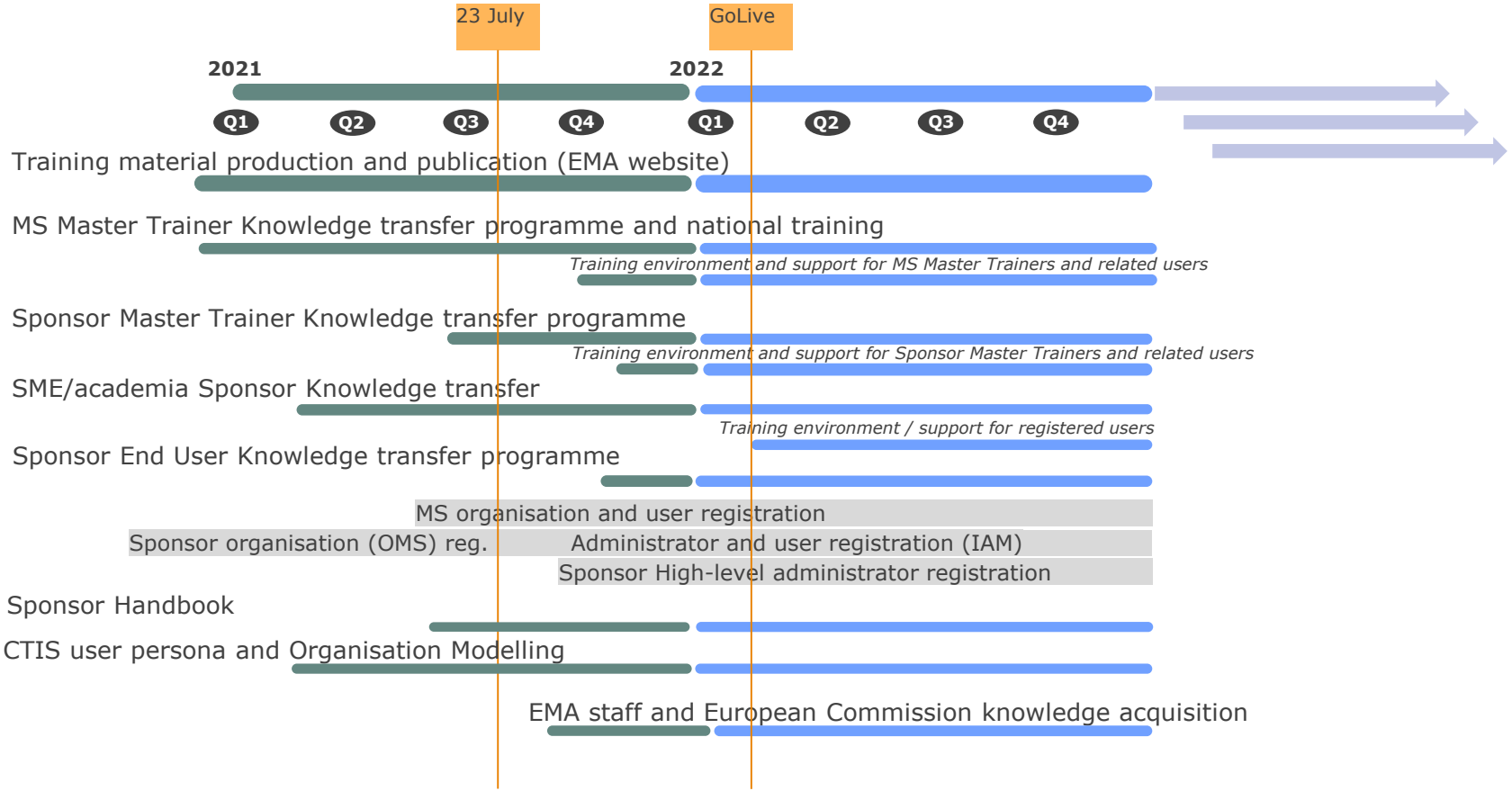

CTIS training strategy and location of materials

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Training in waves

- Focus now on main CTIS user communities i.e. Member States and Sponsors

Train-the-Trainers approach

- Master trainers within organisation

Online programme for everyone

- Extensive training tools for self-study available on EMA corporate website

End user training

- Complementing (not replacing) the Online programme

https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation/clinical-trials-information-system-ctis-training-programme

CTIS training material catalogue status

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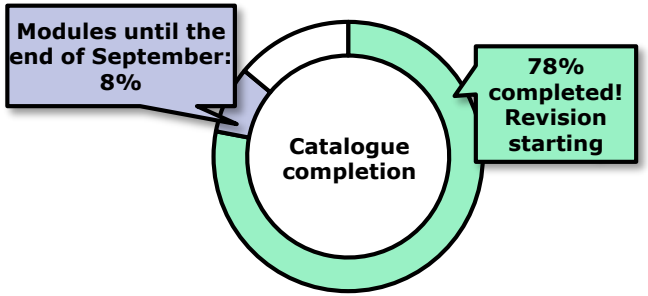
The training catalogue consists of 24 training modules. 18 modules are already published.

Introductory modules	Modules targeted to Member States	Modules targeted to Sponsors	Common modules for MS/EC and Sponsors	Other audience-specific modules
Introduction to new Clinical Trials Regulation	BI reporting (*also the European Commission*)	How to manage a CT (*Notifications, Ad hoc assessment, Corrective measures and Trial results)*	Support with workload management *(tasks, notices & alerts, RFI list& timetable)*	Manage Union Controls *(European Commission)*
Overview of main CTIS components and system functionalities (high level)	Evaluate a CTA – Step 1 *(application types, evaluation overview, RMS selection & validation)*	How to create, submit and withdraw a CTA	User Access Management *(self-registration, login & user profile)*	Clinical Study Reports submissions (Marketing Authorisation Applicant)
	Evaluate an initial CTA – Step 2 *(assessment and decision)*	How to search, view and download a CT and a CTA in the sponsor workspace	Management of registered users & role matrix	Supervise a CT – Inspection records (MS inspectors)
	Supervise a CT – Ad hoc assessment (including safety)	Respond to RFIs received during the evaluation of a CTA	Data protection in CTIS	Introduction to CTIS for Public Users
	How to search, view and download a CT and a CTA in the authority workspace	Submit an Annual Safety Report and respond to related RFIs		
	Supervise a CT – Corrective measures	CTIS for SMEs and academia		
	Assess an Annual Safety Report	Transition of trials from EudraCT to CTIS		



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.

Guide to CTIS Training Material Catalogue: EMA website

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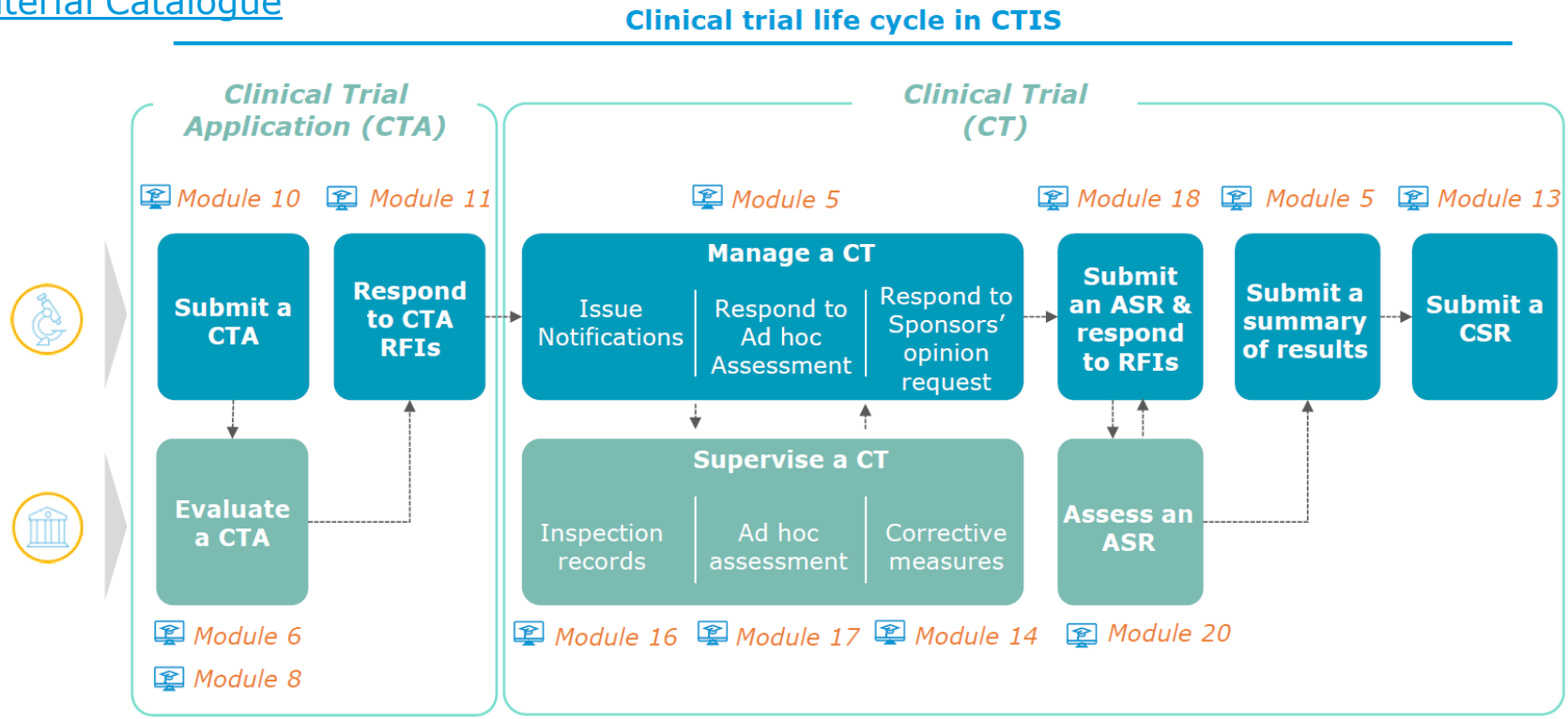
Lifecycle of Clinical Trial with reference to Training modules: see the Guide to CTIS Training Material Catalogue



Question to the audience:

Have you already studied CTIS using the

CTIS Online training material

that is available on EMA webpage?"

Access to CTIS training environment and support

Prior self-study/ training is essential

Access in waves:

- Wave 1 - MS Master Trainers and related MS end users
  MID-END OCTOBER 2021
- Wave 2 – Sponsor Master Trainers and related sponsor users
  NOVEMBER 2021
- Wave 3 – other CTIS users
  TBC

A dedicated CTIS training helpdesk will be set up

Member States also in position to support

CTIS Sponsor Handbook – to facilitate sponsor CTIS preparations

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 end July/early August 2021

To be published on EMA corporate website

Comments and proposals welcome (link embedded in Handbook)

The CTIS Sponsor Handbook V1 – content

What CTIS is and what it does

Getting access to CTIS (registrations)

Management of users and organisations in CTIS

Product management

Transition from Directive to Clinical Trial Regulation

Data, documentation and processes

Safety reporting obligations

Data transparency

Support

Other references

Acronyms and Glossaries

Questions and Answers - options

Current (See CTIS Sponsor Handbook for links):

- 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 with colleagues/within organisation/published materials before placing the question
- Questions and answers on the CTR are available in EudraLex - Volume 10 - Clinical trials guidelines
- EMA events page

Any questions?

Further information

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