CTIS: state of play and training

FAMHP

Microsoft Teams

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State of play

CTIS Sponsor Handbook

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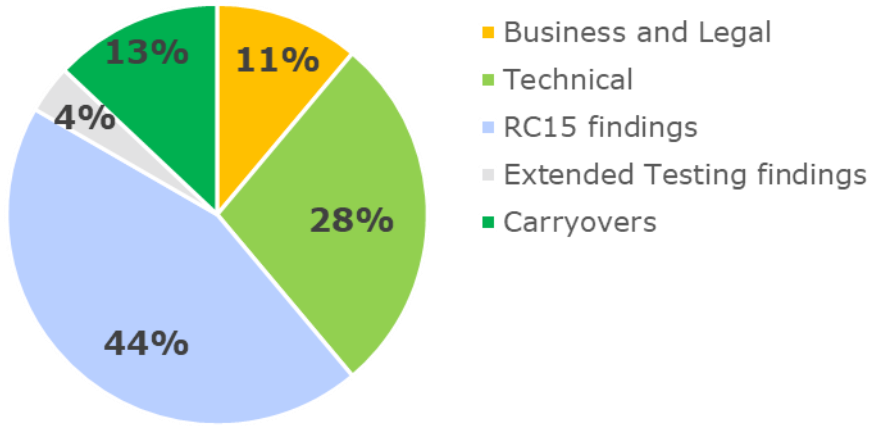
State of play

Sprint 33-34 – Scope and preliminary results:

- Originally planned SP33 and SP34 merged into a longer development Sprint
- Start on July 12th and sprint validation by EMA to be completed on September 27th
- Full scope consisting 47 items plus 7 carryovers from previous sprints (6 Business and Legal items, 15 Technical items, 24 findings from Readiness Confirmation 15, 2 Extended Testing findings, and 7 Carryover items from previous sprints)
- Current testing results & link to origin:

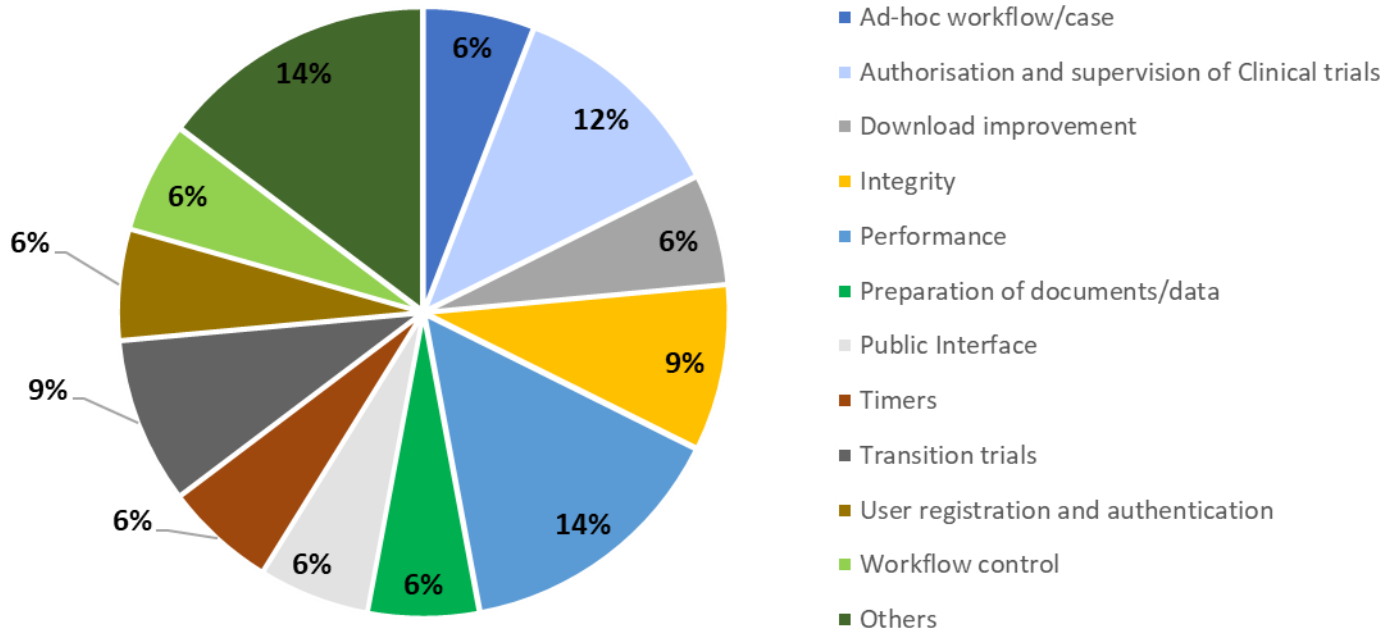
Scope	Delivered
Business and Legal MVP	5/6
Technical MVP	15/15
RC15 findings	23/24
Ext. Testing findings	2/2
Carryovers	5/7



State of play

Sprint 33-34 – Scope and preliminary results:

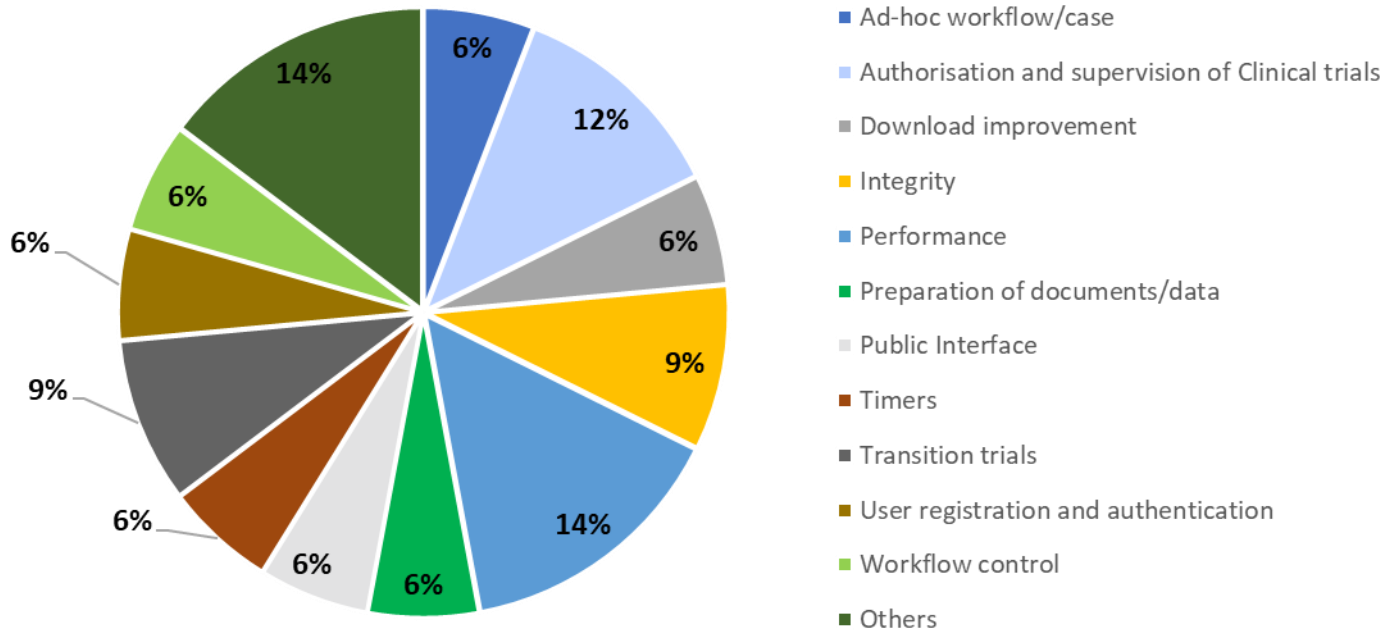
- Main application area improvements



State of play

Sprint 35 – Scope:

- Start of development on September 20th, finalized at the end of October
- Main application area improvements:



CTIS Sponsor Handbook

- to provide clinical trial sponsors with the information they need to get ready to use CTIS
- guidance and links to reference material on key topics related to sponsor preparedness
- set of prioritised topics has been defined
- first version developed with targeted contribution from sponsors for prioritisation and content → published on EMA corporate website on 29/07/2021 https://www.ema.europa.eu/en/documents/other/clinical-trial-information-system-ctis-sponsor-handbook_en.pdf
- Living document to be updated with more topics and information

CTIS Sponsor Handbook

- Content in version 1: 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

- Intended to be used by the users of the CTIS sponsor secure domain

- Wide group of addressees of the handbook includes pharmaceutical companies, contract research organisations (CROs), small and medium-sized enterprises (SMEs), academic sponsors and other organisations working on clinical trials

- Aim to get a new version (V2) of the CTIS Sponsor Handbook published after 3 months from the publication of V1 (around mid/end of October)

CTIS Training Environment (« CTIS sandbox »)

Purpose of the CTIS Training environment :

Provide users and their organisations with the possibility to **explore CTIS both before and after go-live date, to familiarise themselves with CTIS functionalities** in real life, and to **interact with a copy of the system** with mock Clinical Trials.

Approach with controlled and open access :

Given the complexity of CTIS, the training environment approach follows the principle that **access is enabled to users who are already trained on the system**, through the CTIS Training Programme.

Following this principle, **access is first provided to Master Trainers,** who can leverage their access to **support the preparedness of the users in their organisation.**

CTIS Training Environment (« CTIS sandbox »)

Planning

15th October –Training environment live for Member State Master Trainers: generic accounts and access links are distributed to MS Master Trainers.

Mid-November –Training environment live for Sponsor Master Trainers: generic accounts and access links are distributed to Sponsor Master Trainers.

There may be a limited possibility for Sponsor Master Trainers to interact with MS Master Trainers to enable following a full process of CTIS.

EMA is also considering to provide access to nominative accounts for sponsors and MS end users by end of 2021 (existing EMA IAM profile)

CTIS training material

Training and supporting materials are available from the European Medicines Agency (EMA) on how to use the Clinical Trials Information System (CTIS) ahead of its planned launch in January 2022.

Training module **catalogue completeness: 83%** - 20 out of the 24 modules are completed.

The **revision** of training materials **started in Q3**.

The development of two new modules has been planned for Q4.

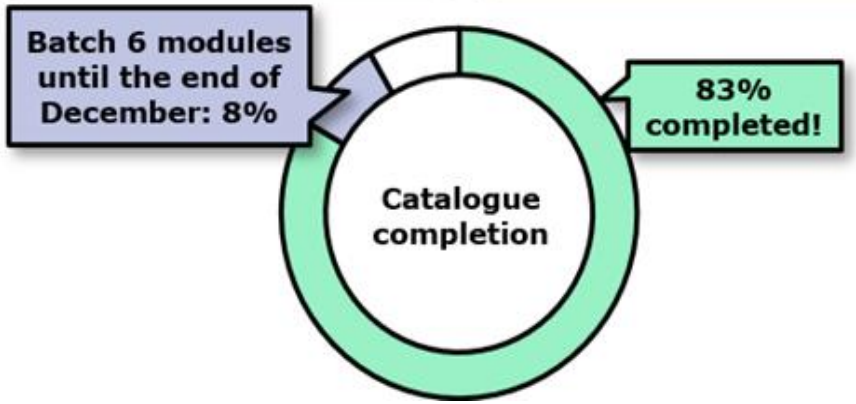
- Manage Union Controls (European Commission).
- Introduction to CTIS for Public Users.

The scope and planning for the revision of the CTIS training catalogue tailored for Q4.

- The revision of training modules in Q4 is sequenced based on the implementation date for the functionalities that will be fixed before go-live and the need for engagement with CTIS content specific experts.
- Post-go live implementations have been set aside for a second wave of revisions.

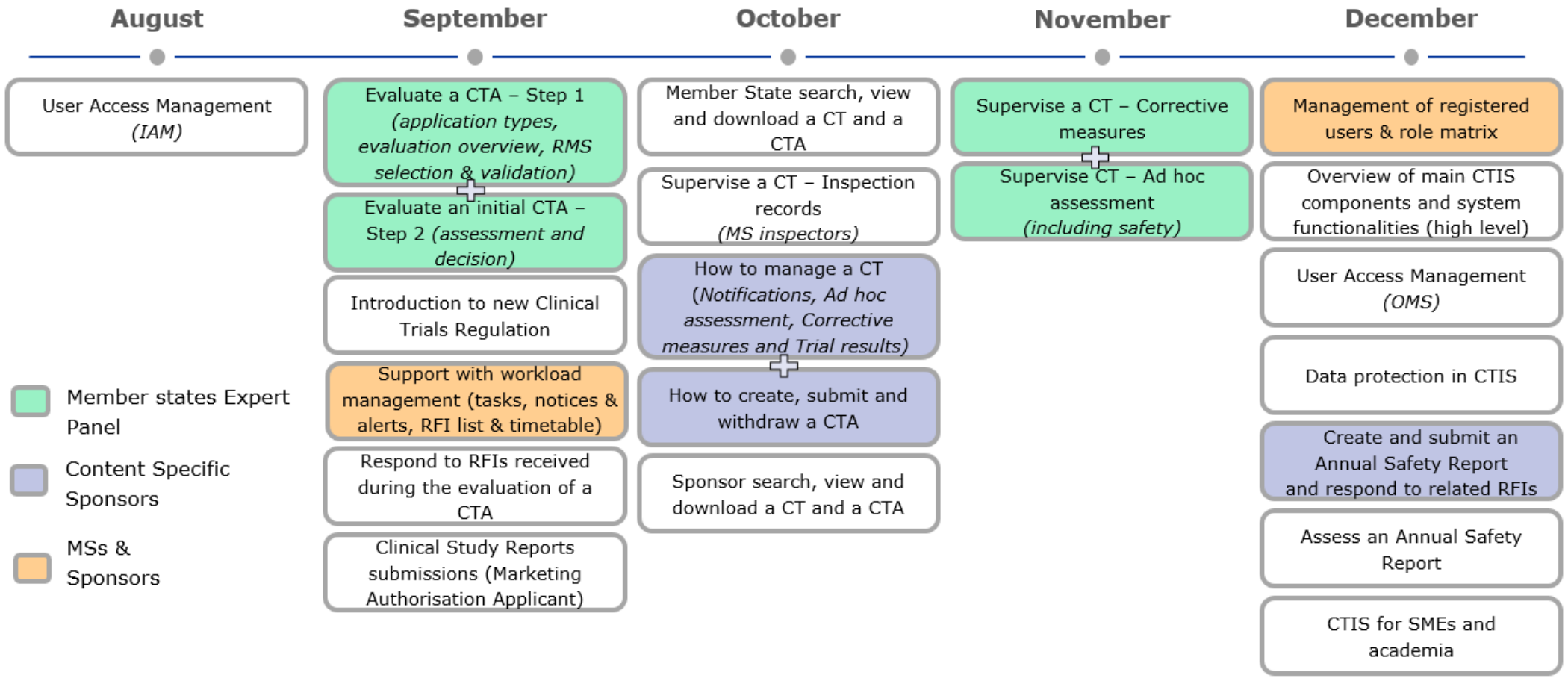
CTIS training modules

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		



CTIS training modules

Indication when revision for each module will be finalised tentatively in Q4



CTIS Training page on EMA's corporate website

- EMA's training modules are available on:

URL to CTIS training page on EMA website

Online material on other EMA websites

Organisation Management Service (OMS):

- https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/organisation-management-service-oms
- single source of validated organisation data that can be used as a reference to support EU regulatory activities and business processes
- stores master data comprising organisation name and location address for organisations such as marketing authorisation holders, sponsors, regulatory authorities and manufacturers
- data mastered with unique identities (ID), labelled in the OMS as 'Organisation_ID' and 'Location_ID'
- important to have your organisation registered in OMS prior to CTR go-live
- 03/02/2021 webinar targeted at industry users: Introduction to OMS services and activities https://www.youtube.com/watch?v=fxMpsgDnWZY

Online material on other EMA websites

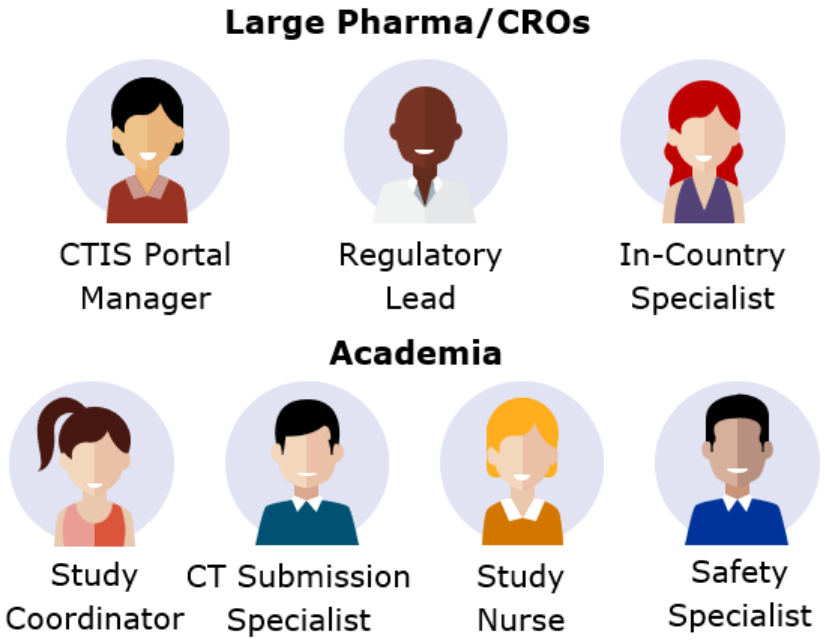
Referentials Management Service (RMS):

- https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/referentials-management-service-rms
- stores referential master data, i.e. lists of terms (controlled vocabularies) to describe the attributes of medicinal products, such as lists of dosage forms, units of measurement and routes of administration
- master data intended to support EU-wide regulatory activities, by enabling stakeholders in the European medicines regulatory network to uniquely identify medicinal products
- data comply with the two ISO IDMP standards for pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO 11239); units of measurement (ISO 11240)
- 04/02/2021 webinar targeted at industry users: Introduction to RMS services and activities https://www.youtube.com/watch?v=70zq7TBO-6A

Other supporting material

User personas:

- 13 user personas for sponsors, target publication date end September



Other supporting material

CTIS sponsor organisation modelling:

- to assist sponsors in their organisational and process preparations for CTIS by clarifying key principles for access to CTIS, user roles and responsibilities in different organisational environments
- to generate knowledge on how sponsors will organise in CTIS by bringing together CTIS and sponsor organisation expertise
- completed in collaboration with sponsor representatives to ensure input of sponsor organisational knowledge
- output of the activity: 4 example sponsor organisation models and 'Principles and good practices for Sponsor organisation models for use of CTIS' document → first version target publication date end September, final version foreseen in October

Other supporting material

CTIS newsletter CTIS highlights:

- Issue 3 published in June & issue 4 in August, next issue foreseen early October

- Sign up by emailing CT.communication@ema.europa.eu

Other supporting material

CTIS information events:

- Planned to help future CTIS users prepare for CTIS Go-Live
- 21 September 2020 event: dynamic demo of sponsor workspace https://www.ema.europa.eu/en/events/ema-clinical-trial-information-system-ctis-webinar-dynamic-demo-sponsor-workspace
- 29 July 2021 event: How sponsor organisations can prepare for CTIS https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-webinar-how-sponsor-organisations-can-prepare-ctis (including documents & video recording)

Other supporting material

CTIS information events:

- 26 October 2021 event: CTIS: the future user perspective
  - Organised in liaison with DIA
  - Audience: MS & sponsor end users
  - Objective: Ensure awareness of CTIS, prepare users for the new way of working with CTIS
  - Over 1hr of Q&A time planned
  - https://www.ema.europa.eu/en/events/clinical-trials-information-system-ctis-virtual-information-day

Other supporting material

CTIS information events targeted at SMEs and academia:

- 22 February 2021 & 04 March 2021 event: two-part training webinar:
  - Day 1 https://www.ema.europa.eu/en/events/sme-academia-clinical-trials-information-system-ctis-two-part-training-webinar-day-1
  - Day 2 https://www.ema.europa.eu/en/events/sme-academia-clinical-trials-information-system-ctis-two-part-training-webinar-day-2

- 29 November 2021 event: Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the Clinical Trials Information System (CTIS) https://www.ema.europa.eu/en/events/webinar-small-medium-sized-enterprises-smes-academia-clinical-trials-regulation-clinical-trials

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