Trial-centric and organisation-centric approach in CTIS

When to use what

SME and academia Clinical Trials Information System (CTIS) two-part training webinar

Presented by Andrea Seidel-Glätzer on 22 February 2021
Head of Project Management, Coordination Centre for clinical Trials at the University Hospital Heidelberg
Reproduction and/or distribution of the content of these training materials for non-commercial or commercial purposes is authorised, provided the European Medicines Agency is acknowledged as the source of the materials.

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.
Investigator-Initiated Trails in CTIS - Expectations

- Reliable data
- Regulators
- Patients
- Transparency

- Sponsor
- Investigator
- Researcher
- Study Teams

- Focus on research
- Manageable
- Easy to use
- Single entry point

- Sponsor oversight
- Data integrity
- Consistent contact information

Trial-centric and organisation-centric approach in CTIS
What makes academic environment special?

- Limited Ressources
  - Staff
  - Finance
- Different organisational Structures
- Different Levels of Experience
- Different Levels of Professionalisation
User management approaches:

There are **two user management approaches** in CTIS. They have been designed to cater for the needs of different organisations. **They are automatically applied by the system** based on the **existing data stored in CTIS**.

**Organisation-centric approach**

- Supposed to be used by **sponsors with a larger number of trials**
- A **high-level administrator** validated by EMA is required
- Management of the users by the administrator is done at **organisation level**
- Users become **affiliated** to the **organisation** of the **high-level administrator**
- Users **need** to be assigned a **role** by the administrator to perform any action.

**Trial-centric approach**

- available for **sponsors with only a small number of trials**
- **No** sponsor **administrator** validated by EMA is required
- Users become the **CT Admin** of a trial by **submitting a CTA**
- Management of **business roles** by the **CT Admin** is done at **trial level**.
Organisation-centric approach I

This approach is intended to serve the needs of organisations with large number of users, Clinical trial applications and/or Clinical Trials.

High-level administrator role
Sponsor Admin

Medium-level administrator role
CT Admin

Business roles
Part I Preparer
Part II Preparer etc.

Validates roles
Assigns roles

Sponsor
Sponsor Admin

CT Admin
Study group A

CT Admin
Study group B

Business Roles

CT Admin
Investigator Z

Business Roles

Organisation-centric approach I

Trial-centric and organisation-centric approach in CTIS
Organisation-centric approach II

Positive

• Creates the **opportunity for management of access and roles** across trials within one organization (Sponsor Oversight)

• Improves **security**

• **Prevent duplication** of sponsor organization details

Negative

• Requires a **formal registration** process through IAM

• **Administrative burden** for Institution/Organisation

Trial-centric and organisation-centric approach in CTIS
This approach is intended to serve the needs of small organisations, and non-commercial sponsors, with a smaller number of users, CTAs and/or CTs.
Trial-centric approach II

Positive

- Allows a faster CTA process in case of a first initial application
- Easy to start
- Independent Study Teams

Negative

- Can lead more easily to duplicate sponsor organization details
- Becomes less convenient if an organisation applies for/runs multiple trials
- No standards for information about organisations (Data quality and integrity)
- Everybody can create a trial for an institution
Considerations

- Decision for an approach will be based on the **structure of the Organisation**
- Institutions **decision boards** should decide which approach they want to follow
- Keep in mind, that decision process might **take time**

**Organisation-centric approach is highly recommended**
How to get started...

**Organisation-centric approach**

- **define** and assign **Sponsor Admin**
- **register** organisation (as soon as possible)
- define **organisational workflows**
- **roll-out new structures**
- define **training need**

**Trial-centric approach**

- **roll-out decision** for approach
- ensure **consistent and stringent** data throughout the organization
- **study teams identify training need**
EMA CTIS training programme Module 07 – Management of registered users and role matrix

Click [here](#) for online training materials related to this module.
Any questions?

Further information

CT.Sponsortraining@ema.europa.eu

Official address  Domenico Scarlattilaan 6  •  1083 HS Amsterdam  •  The Netherlands
Telephone  +31 (0)88 781 6000
Send us a question  Go to www.ema.europa.eu/contact

Follow us on  @EMA_News