



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Trial-centric and organisation-centric approach in CTIS

When to use what

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

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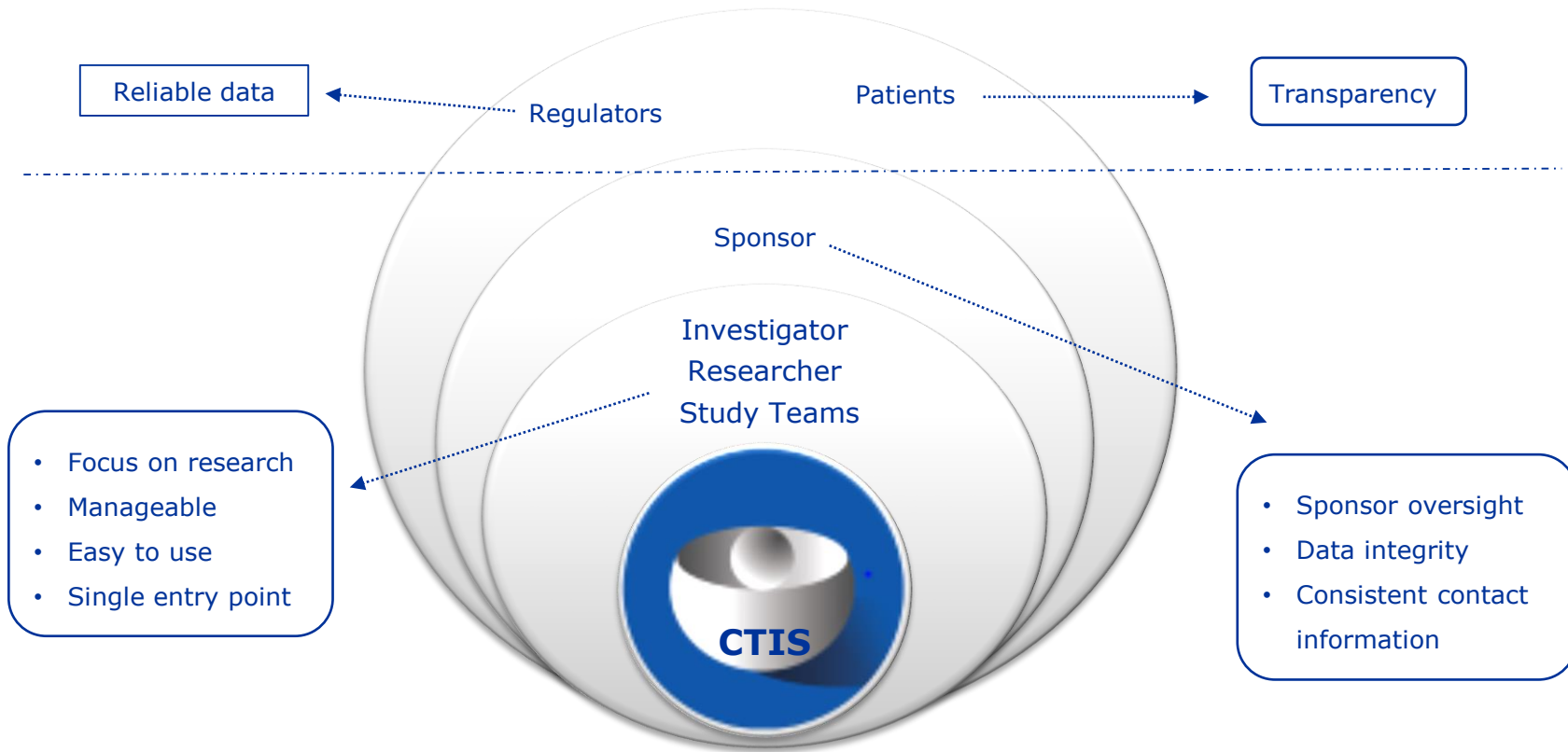




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What makes academic environment special?

- Limited Ressources
 - Staff
 - Finance
- Different organisational Structures
- Different Levels of Experience
- Different Levels of Professionalisation



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.



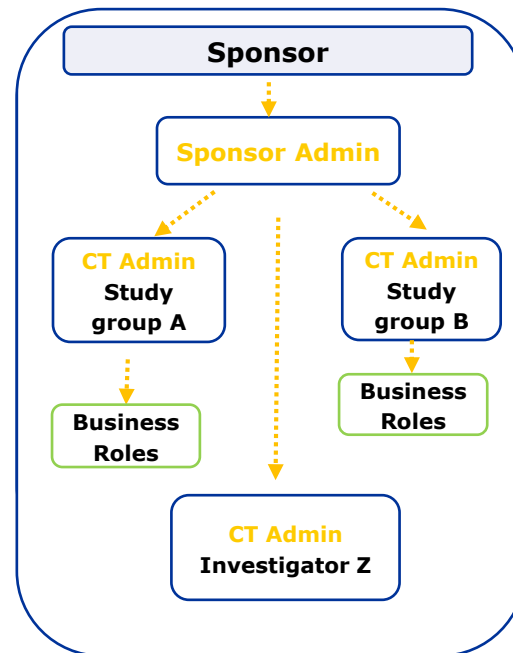
This approach is intended to serve the needs of **organisations with large number of users, Clinical trial applications and/or Clinical Trials.**



High-level administrator role
Sponsor Admin

Medium-level administrator role
CT Admin

Business roles
Part I Preparer
Part II Preparer
etc.



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

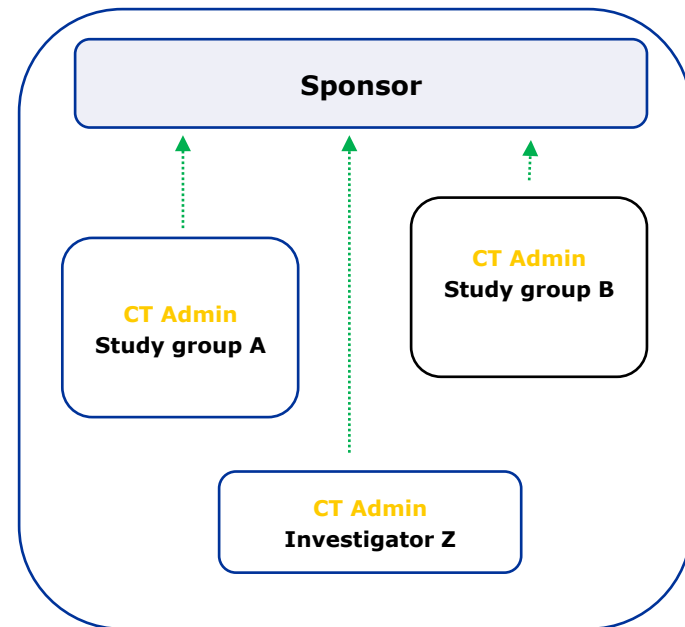
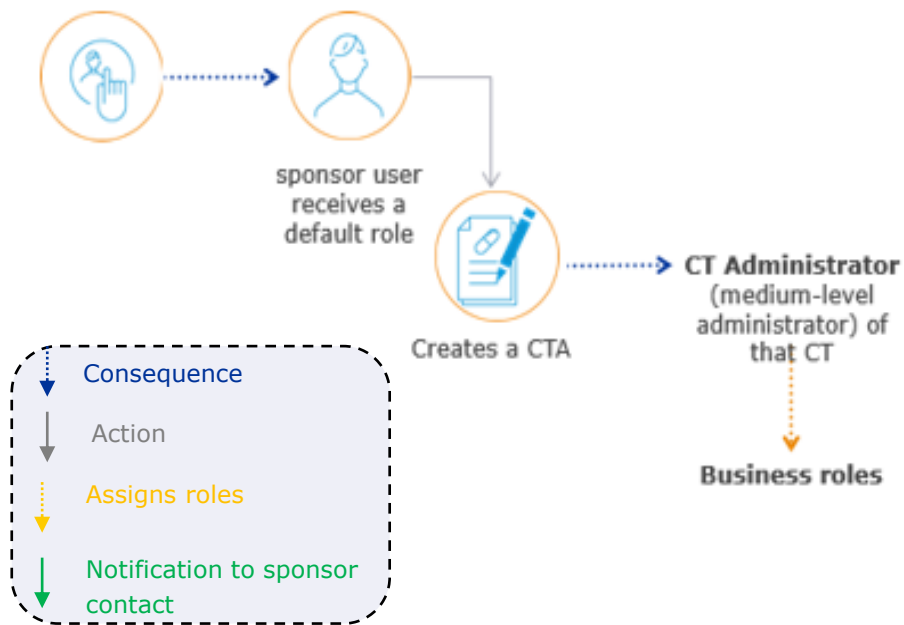


- Requires a **formal registration** process through IAM
- **Administrative burden** for Institution/Organisation

Trial-centric approach I



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**.



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



- 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

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

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