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SCIENCE MEDICINES HEALTH

Access and user management, roles and permissions

SME and academia Clinical Trials Information System (CTIS) webinar 29/11/21

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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.

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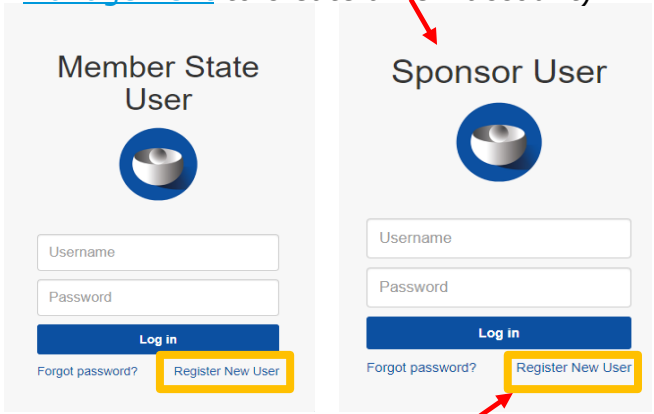
Access Management: Self-registration

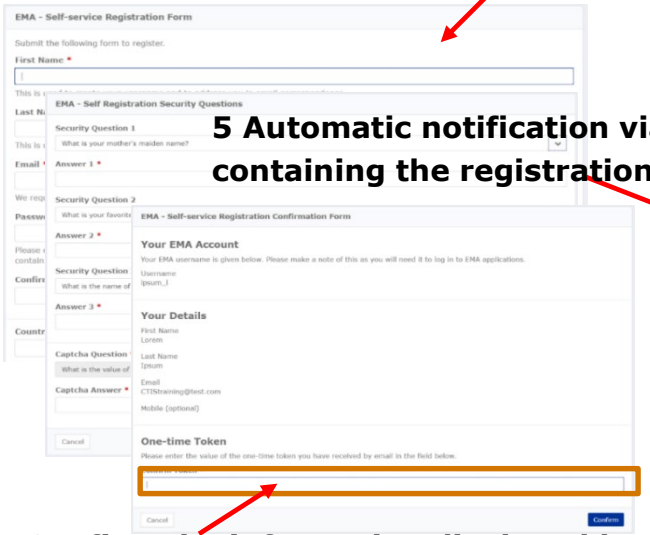
All users must self-register in the EMA Account Management System to **get** their **user credentials** to access to CTIS (refer to training module 03).

1. **Select the sponsor workspace in the CTIS welcome page** (alternatively go to [EMA Account Management] to create a new account)



2. **Select the option 'Register New User**

3. **Complete the self-service Registration Form**



5 Automatic notification via email containing the registration information

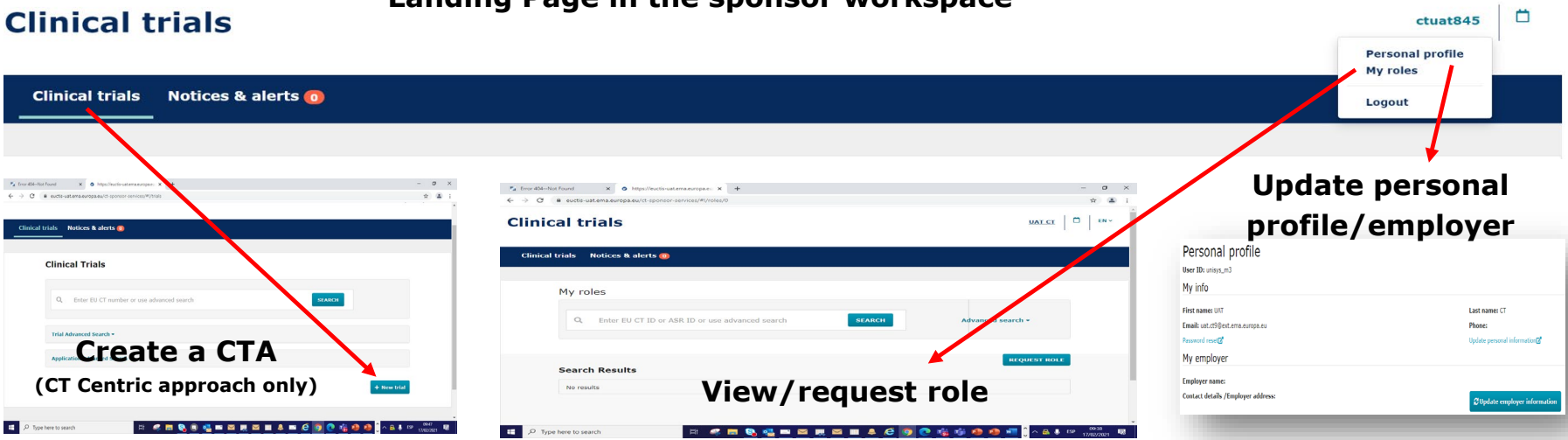
4. **Confirm the information displayed by entering the one-time-token sent via e-mail**

If you are a user of an EMA applications (e.g. SPOR etc) you can use your existing EMA account.

Access Management: CTIS default role

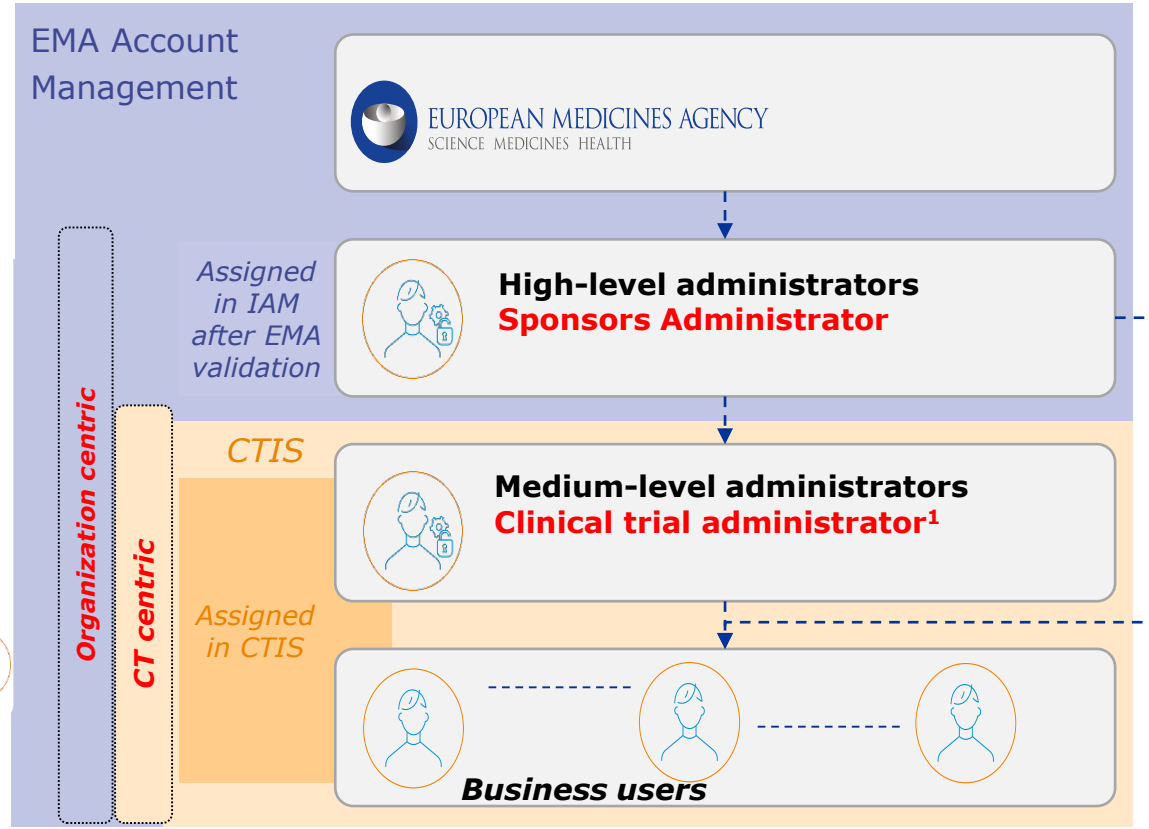
- Users will receive with their log in credentials a **default role** that will allow them to access CTIS and perform a limited number of activities.

Landing Page in the sponsor workspace



In order **to perform additional actions CT related**, users need to be assigned with **business roles** by the user administrators.

User management hierarchy



Administrator of roles

a) IAM

- *Other Sponsor Admin roles*

b) CTIS

- *Assign new role/CT access*
- *Amend role/CT access*
- *Revoke role/CT access*
- *Approve/reject user requests for a role (only applicable to sponsor users)*

Business roles

- *Role allocated to perform CT related activities in the system*

1 These roles have also mapped the permissions of business roles: able to perform CT actions in CTIS on top of user administration

User Management: Organisation centric vs trial-centric approach (1/3)

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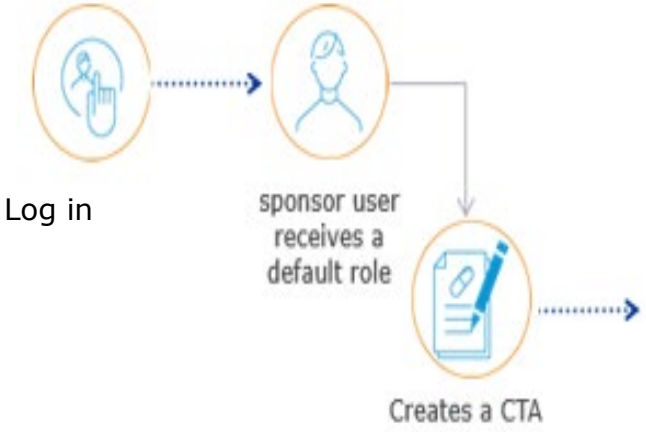
*These approaches **are automatically applied by the system** based on the **existing sponsor administration registration data** in the EMA account management system*



Select Sponsor Organisation

System automatically checks if the sponsor organisation selected for the CTA has registered a sponsor administrator

Yes- Organisation Centric
The user cannot proceed to create the CTA unless has been assigned with the CT Admin role by the sponsor administrator of the organization selected

No- CT Centric
The user can proceed and create the CTA

User becomes CT Administrator for this CTA

EMA encourage sponsors to follow the Organization centric approach:

1. Ensure your sponsors organization is registered in OMS (SPOR) portal
2. Register your sponsor Admin in the EMA account management system (Training module 07 - https://youtu.be/SWvMeCnBhz0- Registration open since 1st September 2021

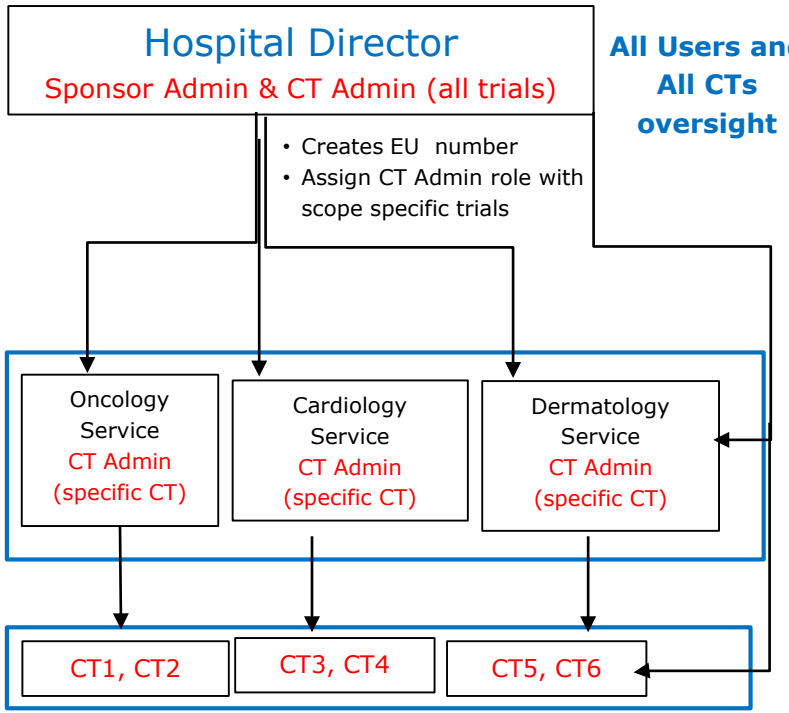
User Management: Organisation centric vs trial-centric approach (2/3)

	Organisation centric	CT centric
Positive	• Creates the **opportunity for centralised management of access and roles** across trials within one organization (Sponsor Oversight) • Improves **security** • **Prevents duplication** of sponsor organization details	• Allows a **faster CTA process** in case of a first initial application • Has **less burdensome** as registration in IAM is not required
Negative	• Requires a **formal registration** process through IAM • Creates **administrative burden** for Institution/Organisation	• **Anyone** can create a trial for the same sponsor organisation running independently • Becomes **less convenient** if an organisation applies for/runs **multiple trials due to lack of** centralised oversight • **Creates no standards** for information about organisations: **data quality and integrity (duplicates)**

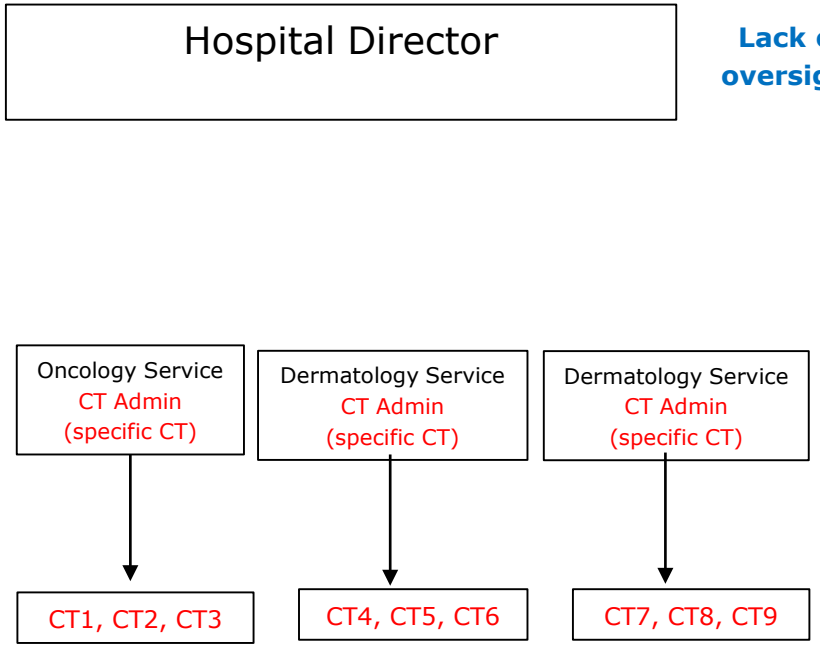
User Management: Organisation centric vs trial-centric approach (3/3)

Example of academic sponsor

Organization Centric

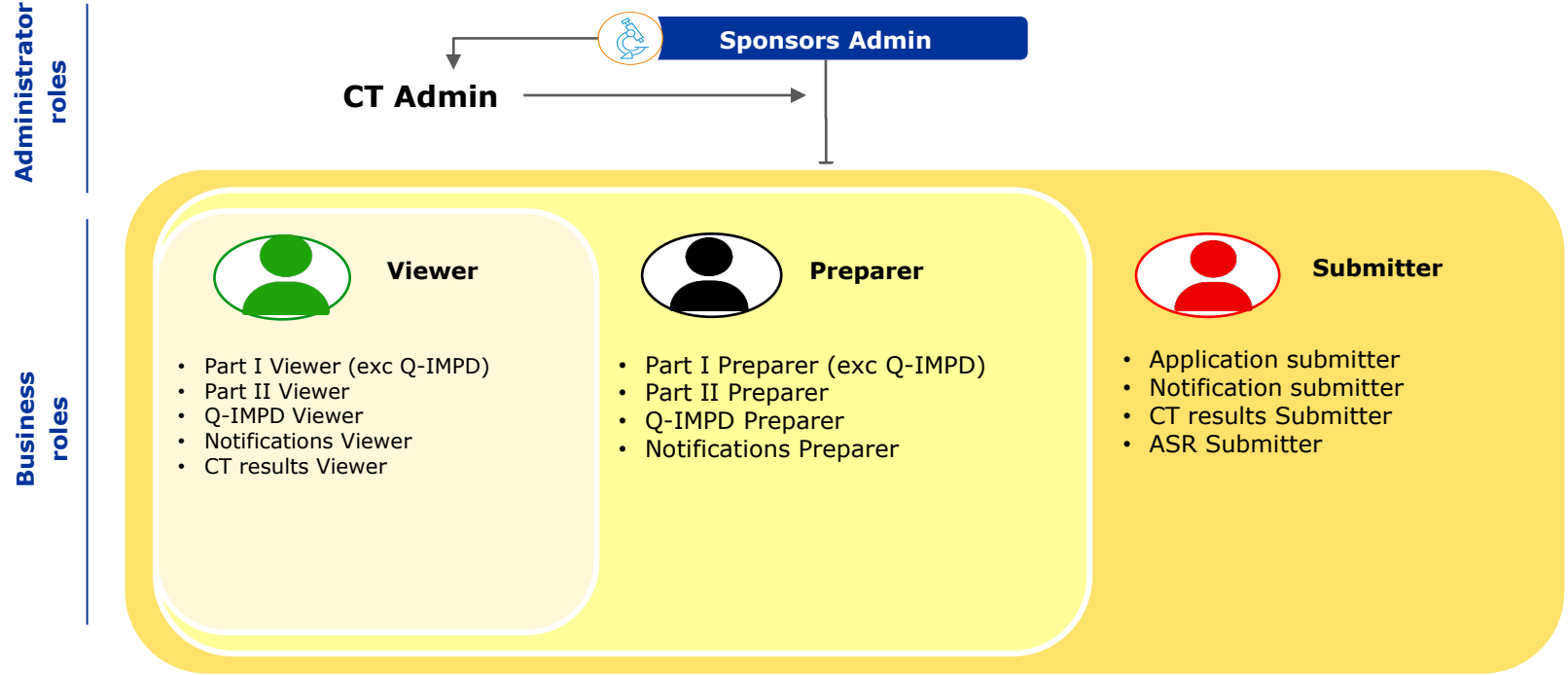


CT Centric



Sponsor roles and permissions

- There is a total 13 sponsor business roles and 2 administrator roles in the sponsor workspace



With only the CT Admin Role it is possible to perform all CTAs business related activities in CTIS. The ASR submitter role need to be assigned on top in order to be able to submit ASR as well

Sponsor workspace: roles and permissions

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CTIS is a **role-based system** that enables users to perform different actions depending on the permissions attached to the roles assigned to them by the administrator roles.

Viewer

View and **download** structured data and documents in different formats.

These roles will not impact the processes as they do not have additional permissions.

Preparer

In addition to the **Viewer permissions**, the Preparer role allows users to **create**, **edit**, **save**, **upload documents, delete** or **cancel** draft items.

Submitter

In addition to the **Viewer** and **Preparer** permissions, the Submitter role allows users to **submit data/documents** from their respective workspace to the EU database and **withdraw** or update the submitted information.

Other permissions

Permission related to user management (assign roles etc.) e.g. Sponsor Administrator

Bear in mind that the roles are embedded in each other, i.e. the 'Preparers' have also the 'Viewers' permissions and the 'Submitters' have both the Viewers' and Preparers' permissions.

Any questions?

Further information

emaevents@diaglobal.org (CTIS sponsor Master Trainer programme)
CT.Sponsortraining@ema.europa.eu (general queries on other (sponsor) training)

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