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SCIENCE MEDICINES HEALTH

Clinical Trial Information System (CTIS)
Bitesize talk
User access and Role management

Virtual Event
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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.

Access Management: Self-registration

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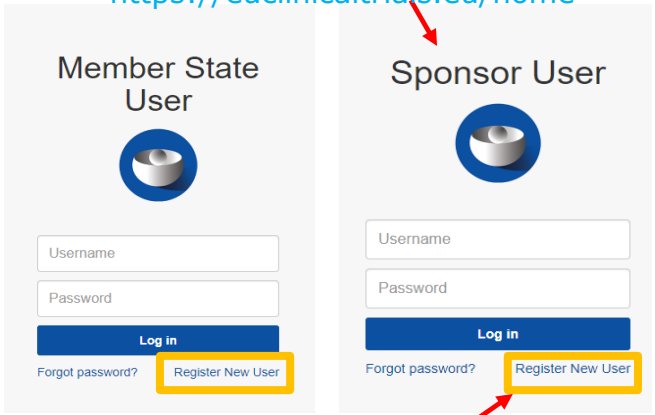
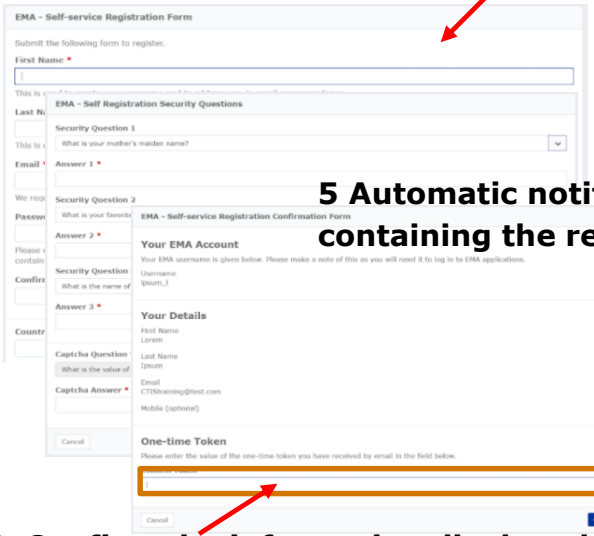
All users must self-register in the EMA Account Management System to **get** their **user credentials** to access to CTIS (refer to training module 03).

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



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

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



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

5. **Automatic notification via email containing the registration information**

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

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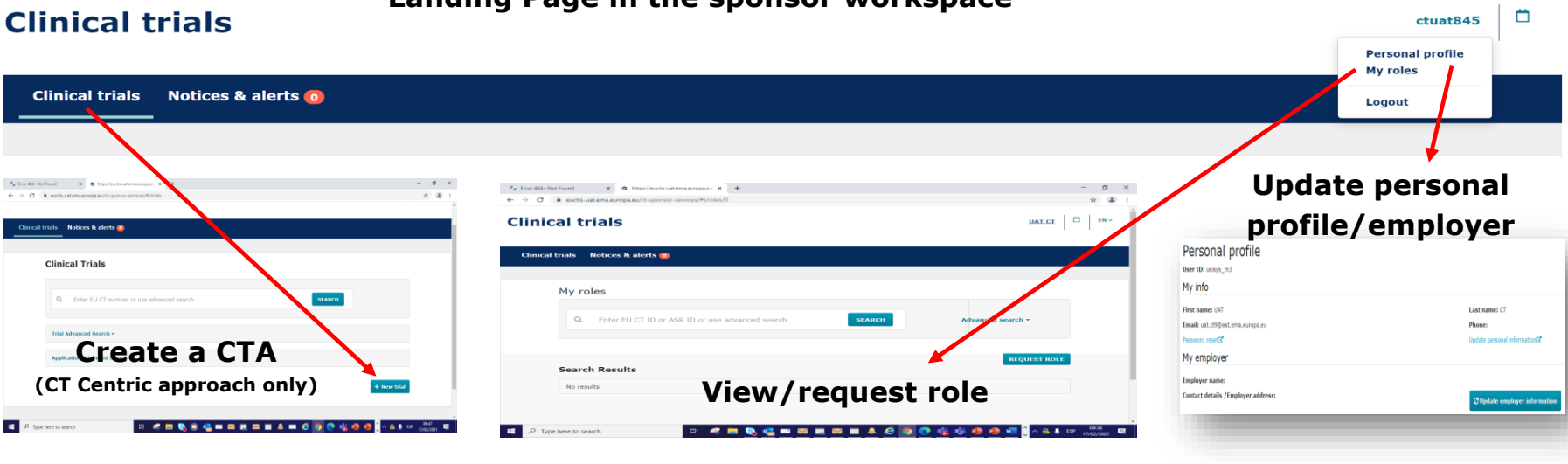
Users will receive with their log-in credentials a **default role** that will allow them to access CTIS and perform a limited number of activities.

Landing Page in the sponsor workspace



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

Demo - user access and profile management

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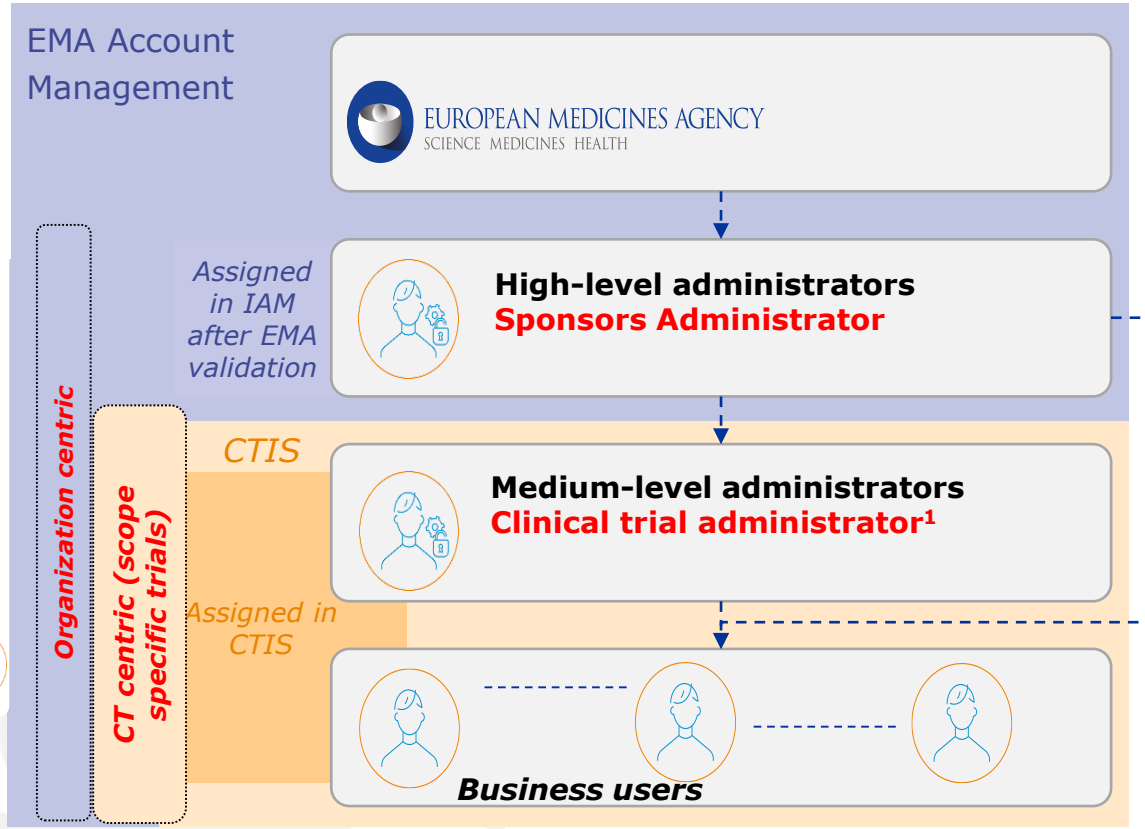
EMA CTIS training programme Module 03 – User access management and role matrix

Click here for online training materials related to this module.

User management hierarchy



Administrator of roles

a) EMA Account Management (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*

Role scope

- All trials
- Specific trials

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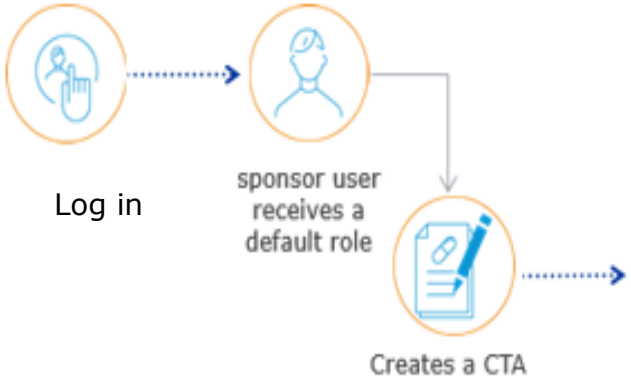
*These approaches **are automatically applied by the system** based on the **existing sponsor administration registration data** in the EMA account management system*



Select Sponsor Organisation

System automatically checks if the sponsor organisation selected for the clinical trial application has registered a sponsor administrator

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

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

User becomes CT Administrator for this CTA

EMA encourages sponsors to follow the Organization-centric approach:

1. Ensure your sponsor organisation 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)

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	Organisation centric	Trial 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 • **Less burdensome process,** as registration in EMA Account Management (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)

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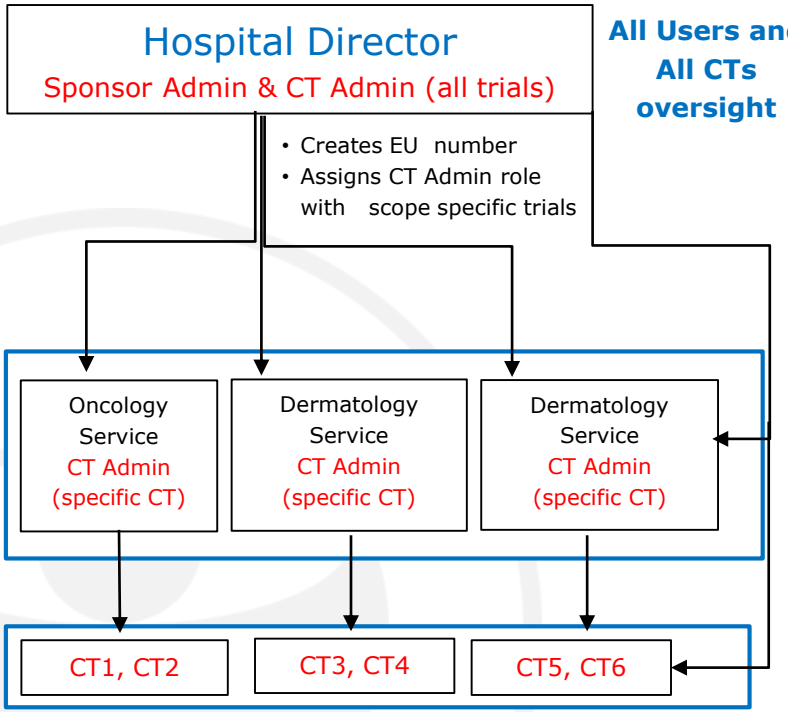
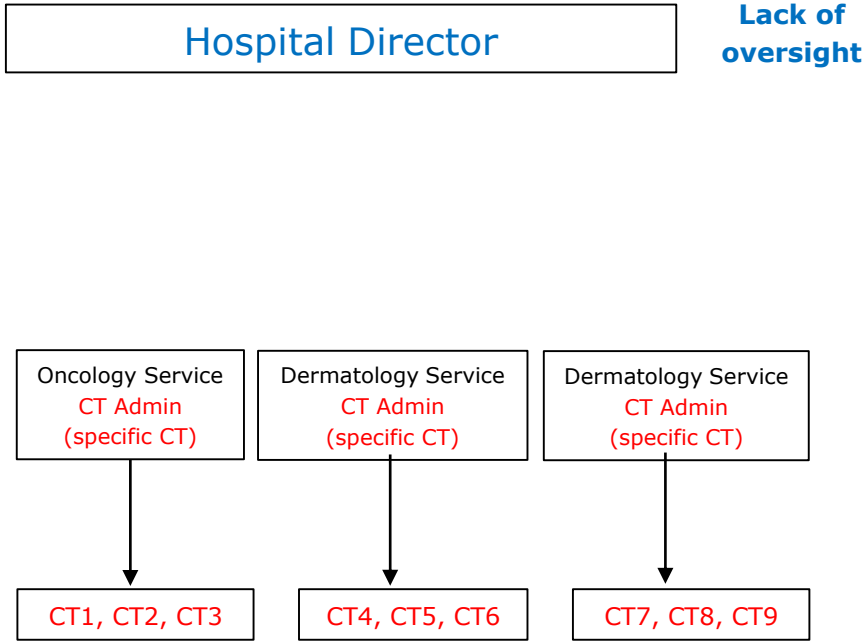
Example of academic sponsor

Organisation Centric



Trial Centric

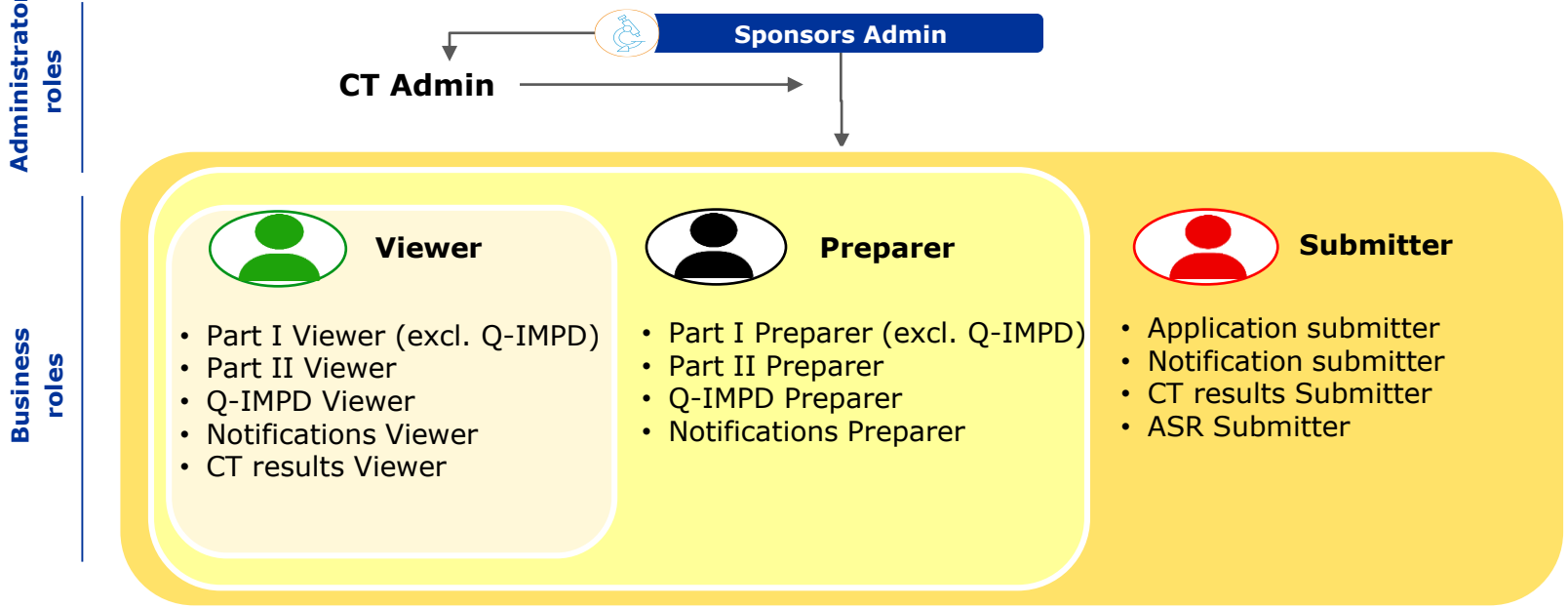


EMA CTIS training programme Module 07 – Management of registered users and role matrix

Click here for online training materials related to this module.

Sponsor roles and permissions

There are in 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 needs to be assigned on top in order to be able to submit ASR as well.**
- **The user profile can be built by the combination of one or several roles.**

Role Scope

- When assigning a role in CTIS, the administrator has to indicate the scope of that role.
- There are two types of “role scope”:
  - “All trials”: this means that a user will have the assigned role for all the trials under the umbrella of the sponsor organization
  - “Specific trials”: in this case the administrator when assigning the role and selecting this scope will need to provide the CT EU number. This means that the user will have the assigned role only for the trial under the role scope.

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.

Demo – Role based access in CTIS

EMA CTIS training programme Module 07 – Management of registered users and role matrix

Click here for online training materials related to this module.

CTIS user personas

- Personas are visual models that **represent different users**
- They look inside user organisations to see **'who does what'** related to CTIS
- They provides **insights** into the different user groups, e.g. typical tasks in CTIS.

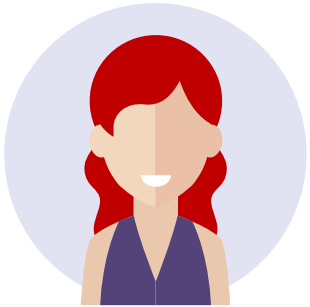
The CTIS user personas **describe typical users** in sponsor organisations and provide **suggested user roles**.

Personas are published on the EMA CTIS training and support page.

Core personas: large sponsors and CROs

- Coordinates the preparation of the clinical trial application
- Coordinates responses to RFIs
- May or may not input information directly into CTIS

Regulatory Project Manager



- Provides Part II data for submission to CTIS
- Prepares country-specific material when needed
- May not input information directly into CTIS

In-Country Specialist

- Collects information from others, checks information is complete, submits to CTIS
- Checks for notices and alerts
- May perform user administration

CTIS Submission Manager

Core personas: SME & Academia

- In smaller studies they prepare the clinical trial submission and submit
- Runs the clinical trial, potentially with other study group members

Study Coordinator

- In very small studies, they may prepare the clinical trial application and submit to CTIS
- Assists with the technical running of the clinical study

Study Nurse

- Larger institutions have dedicated staff to assist researchers with CTA preparation and submission
- Manages user administration if organisation-centric approach is taken

CT Submission Specialist

- Present in larger institutions
- ASRs and other safety reporting
- May or may not directly access CTIS

Safety Specialist

Sponsor Organisation Modelling

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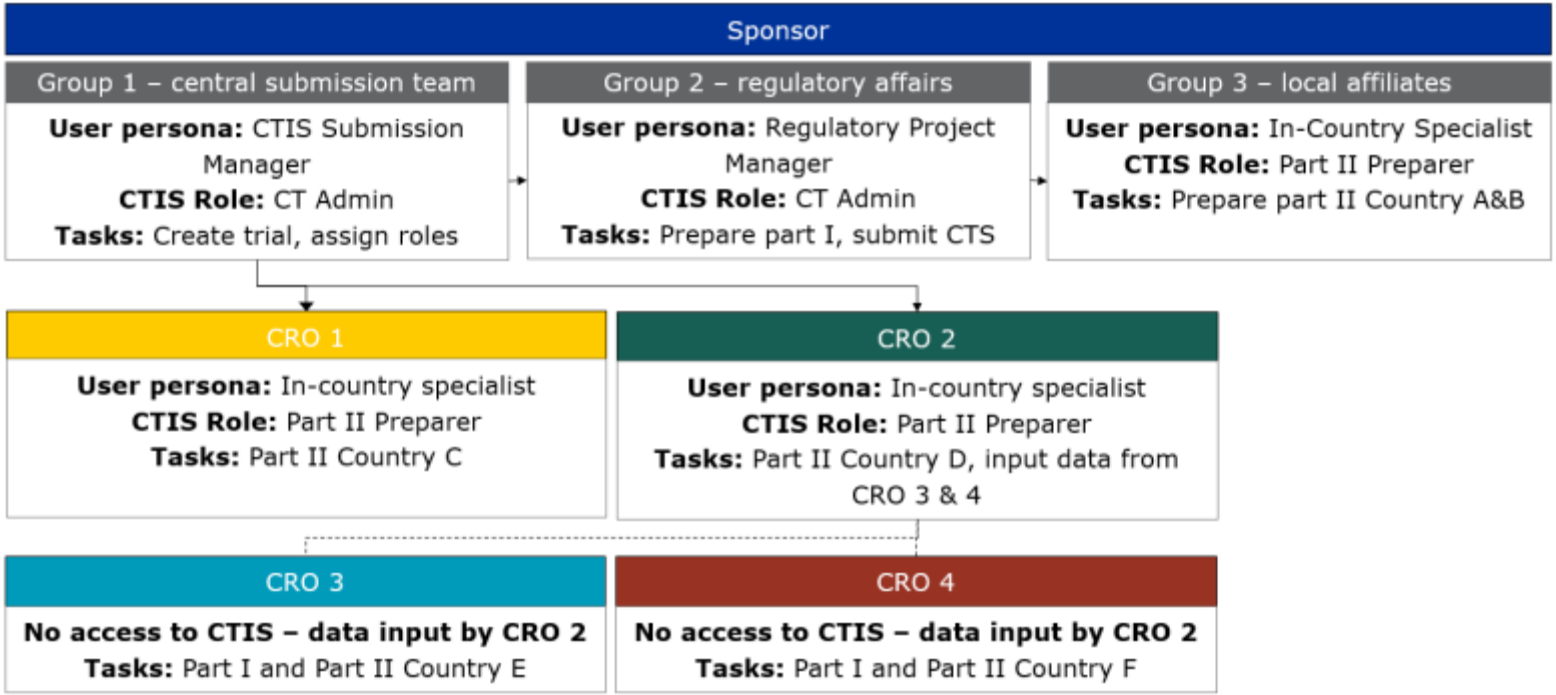
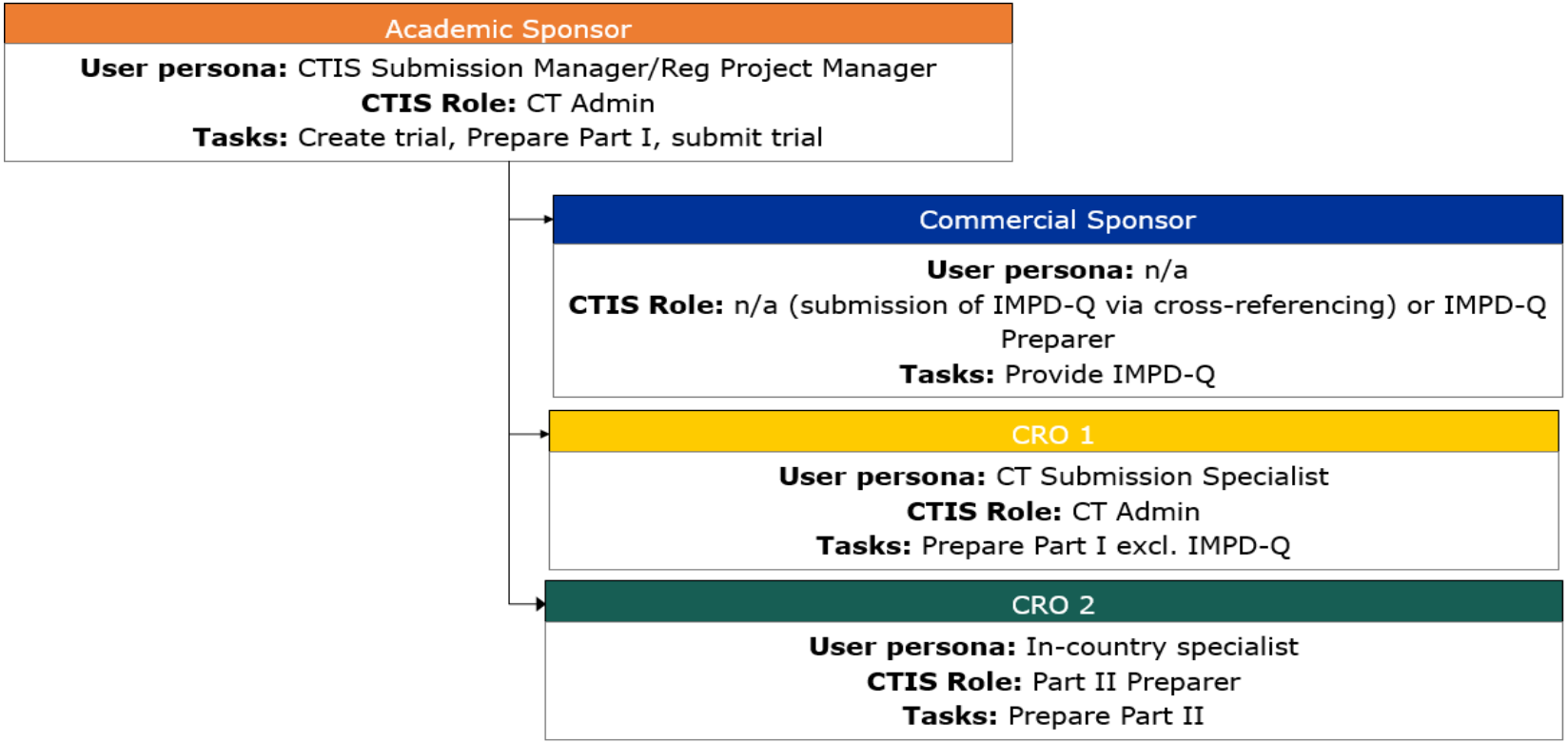
- Assists sponsors in **organisation and process preparation** for CTIS
- Clarifies **key principles for access to CTIS, user roles and responsibilities** in different organisational environments.
- Developed **in collaboration with sponsor representatives**

'Principles for sponsor organisation models for CTIS' document published on the EMA website.

Example Organisation Model – Large sponsor



Example Organisation Model - Academia



Thank you for attending today's CTIS Bitesize talk

Next bitesize talk on 23 March: Initial clinical trial application

Further information

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