



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS explained with user personas and organisation models





CTIS User Personas

What is a Persona?

- A visual model that is developed to **represent different stakeholder groups**
- Looks inside user organisations to see '**who does what**'
- Provides **insights** into the different user groups
- Describes groups of users whose **basic tasks and needs are similar**



The CTIS user personas are used to **tailor training and communication** activities and **map CTIS user roles to end-users**.



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

Personas are published on the EMA [CTIS training and support page](#).

Sponsors can use the personas to

- **Create tailored training plans** for different kinds of end-users
- **Map user roles to end users**
- **Enhance storytelling** in trainings





CTIS Sponsor Organisation Modelling

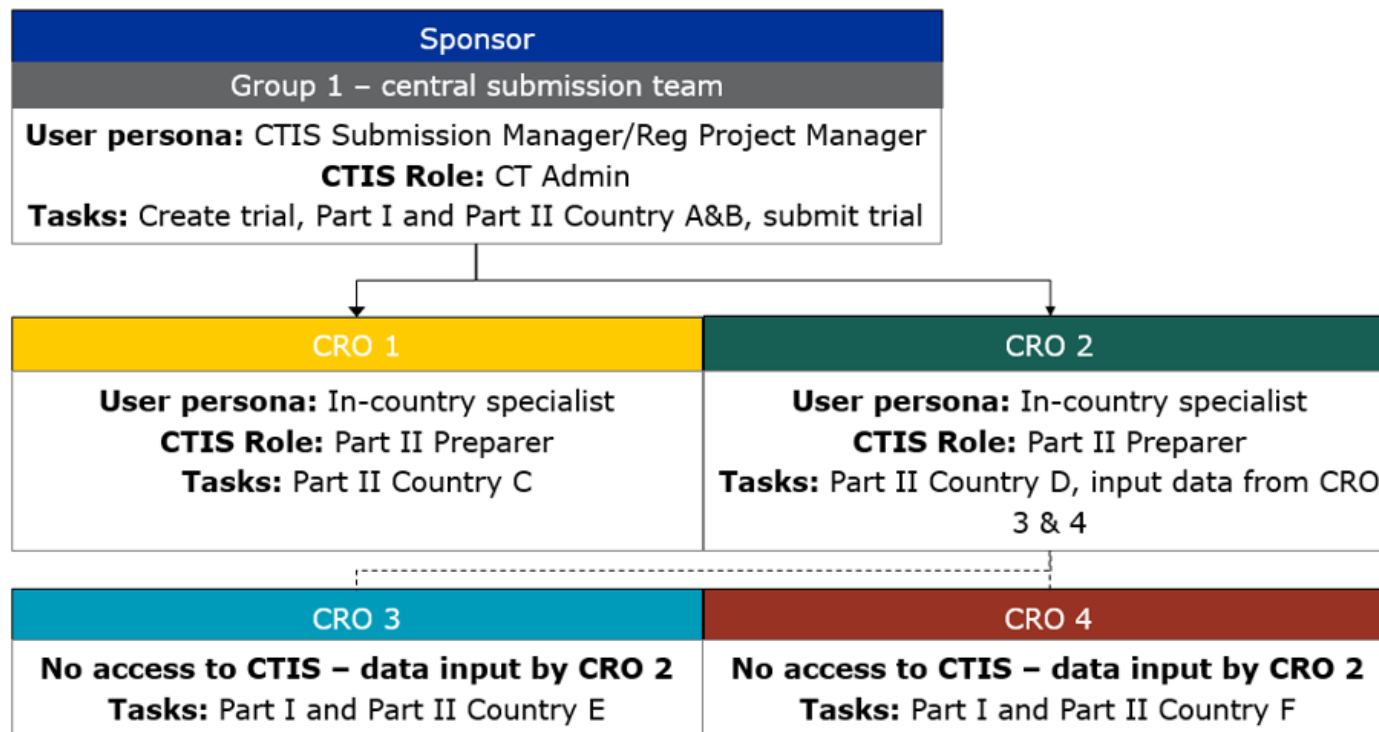
What is Organisation Modelling?

- 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**



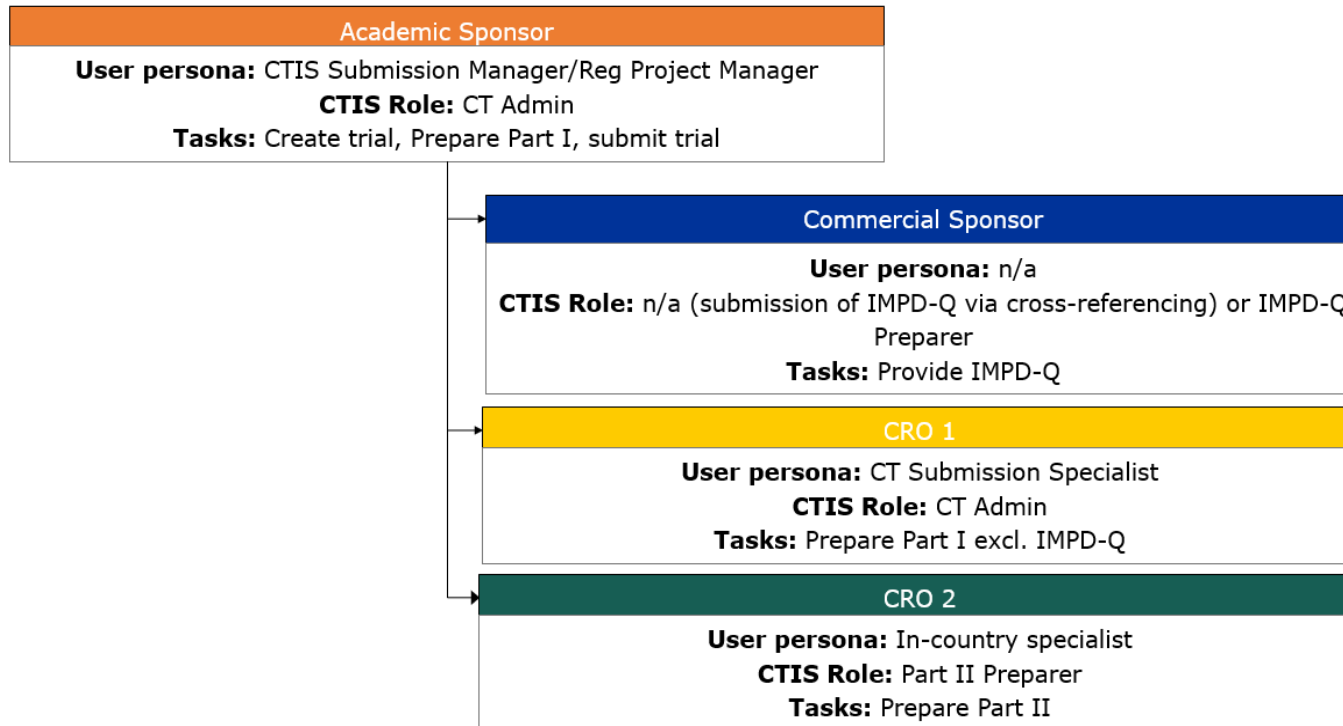
'Principles for sponsor organisation models for CTIS' document published on the EMA website.

Example Organisation Model





Example Organisation Model - Academia





Key principles for organisation modelling

- **Access to CTIS**

- Give all partners (e.g. CROs/co-sponsors) access or delegate CTIS submission to only some?

- **Centralised vs decentralised approach**

- Small group/one person responsible for CTIS submission or each expert adds their contribution?

- **Data sharing**

- Know what each role can view. E.g. Part II Viewers can view all countries, CT Admins can view IMPD-Q



Any questions?

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