EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CTIS personas and sponsor organisation modelling for sponsor preparedness

CTIS July Info Event

Presented by Sarah Scales on 29th July 2021

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.

CTIS User Personas

What is a Persona?

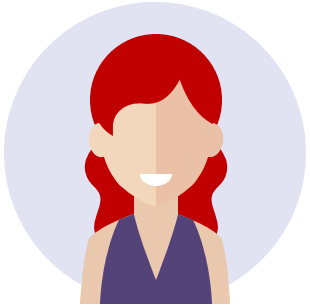
- A visual model that is developed to **represent different stakeholder groups**
- Looks inside user organisations to see **'who does what'**
- Provides **insights** into the different user groups
- Describes groups of users whose **basic tasks and needs are similar**

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

Core personas: 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

Regulatory Project Manager Persona

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Regulatory Project Manager

CTIS user roles:
Part I and II preparer, Application submitter*, Notification Submitter*, CT Results Submitter*, ASR Submitter*

I coordinate the regulatory submission for a clinical trial, including liaising with in-country specialists, the submission manager and other stakeholders, and preparing the clinical trial package for submission to CTIS.

Background

Scientific background, vary in experience level.

CTIS application usage

- In some organisations, I input data into CTIS, prepare part I, submit the application, monitor notices & alerts and input safety information.
- In others, I keep an overview of the above tasks while another person (e.g. submissions manager or a CRO Regulatory Project Manager) performs them. I also decide on transparency/deferrals.

*May also have this role, depending on organisational processes

Personas to be published on the EMA CTIS training page Q2 2021.

Sponsors can use the personas to

- **Create tailored training plans** for different kinds of end-users in your organisation
- **Map user roles to end users** in your organisation
- **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 and good practices for Sponsor organisation models for use of CTIS' document to be published Q3 2021.

Organisation Modelling status

- Sponsor representatives for collaboration identified
- **Current activity:** determine actors in and outside of CTIS for different kinds of trials
- **Next work:** identify user personas and user roles of actors in CTIS, validation

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Any questions?

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