CTIS User Personas

CTIS Training Programme

Document Objectives

- This document maps out CTIS User Personas, which are visual models which describe different types of users of CTIS.

CTIS User Personas

What is a CTIS User Persona?

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

CTIS User Personas describe groups of people with similar responsibilities in CTIS who may vary in the details of their job roles or responsibilities. The CTIS User Personas aim for a **'best fit'** in representing broad user groups. Please note that **User Personas are not the same as user roles in CTIS.** Rather, they represent the actual people in sponsor organisations that will have CTIS user roles.

The CTIS User Personas describe typical tasks each Persona may complete in CTIS and possible user roles they could be assigned to complete these tasks, based on user research. It must be noted that **the User Personas only describe expected typical practices in CTIS. Organisations may assign tasks and user roles in any way they wish within CTIS.**

Overview of CTIS User Personas

The following CTIS User Personas have been developed.

Member State National Competent Authorities

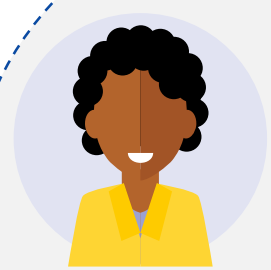
- National Competent Authority Head of Unit
- National Competent Authority Coordinator
- National Competent Authority Assessor
- National Competent Authority Inspector

Member State Ethics Committees

- Ethics Committee Coordinator
- Ethics Committee Assessor

Click on each Persona to see more detail

MS National Competent Authority: Head of Unit



*"I will mostly rely on my team to complete CTIS processes, while I will maintain **oversight of ongoing work** and advise on complex issues as needed."*

Possible user role in CTIS: Viewer Part I full rights, Viewer Part II. Decision Maker-Submitter in some Member States

My background

- Experienced senior manager

My technology knowledge

Frequency of CTIS use: Infrequent, variable

Level of familiarity with technology: Not very familiar

MY USE OF CTIS

My CTIS application usage

- Perform dedicated tasks in CTIS in some Member States, e.g. approving choice as Reporting Member State
- Only use CTIS on ad-hoc basis in others, to view the details of a complex Clinical Trial Applications
- Review metrics and reporting, often with the help of a team member to extract the data

My work environment

- Responsible for managing the Clinical Trial Unit and reporting to NCA leadership
- Many time-consuming responsibilities and tasks delegated to other managers in their team

MS National Competent Authority: Coordinator

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*“I act as the **bridge between NCA Assessors, Sponsors and the Ethics Committee**. I am an experienced Project Manager, familiar with using IT systems. I need to know about all aspects of CTIS.”*

Possible user role in CTIS: Clinical Trial Coordinator, possibly Assessor Part I & Part II Submitter, Validator, Decision Maker-Submitter

My background

- Experienced in project management/communication

My technology knowledge

Frequency of CTIS use: Daily

Level of familiarity with technology: Very familiar

MY USE OF CTIS

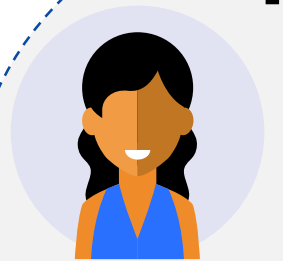
My CTIS application usage

- Select Reporting Member State (in some Member States done by Head of Unit)
- Coordinate responses to applications
- May assign tasks to other users
- Input information from assessors and other users (in some Member States)
- Complete validation (in some Member States)

My work environment

- Office environment
- Close work with NCA assessors
- Ensure timely completion of Clinical Trial assessment and supervision

MS National Competent Authority: Assessor



*I am a **self-directed researcher** responsible for assessing the content of the clinical trial application. I will search CTIS, view documents, and prepare my assessment.*

Possible user role in CTIS (if access is given): Assessor Part I Preparer, may also be Submitter.

My background

- Specialisation in different areas (pre-clinical, clinical etc.)

My technology knowledge

Frequency of CTIS use: Regular

Level of familiarity with technology: Quite familiar

MY USE OF CTIS

My CTIS application usage

- Monitor clinical trial application review deadlines
- Search for applications and documents
- Download and review documents/data
- Prepare assessment report
- Submit assessment (limited to some users e.g. seniors)

My work environment

- Office environment
- Core focus on deadline management, prioritisation and scientific excellence

MS National Competent Authority: Inspector

*I will use CTIS to **prepare inspection reports**, and to **search for data** on inspection sites.*

Possible user role in CTIS (if access is given): Inspector Preparer or Submitter.

My background

- Highly trained in the area of inspections

My technology knowledge

Frequency of CTIS use: Frequent

Level of familiarity with technology: Very familiar

MY USE OF CTIS

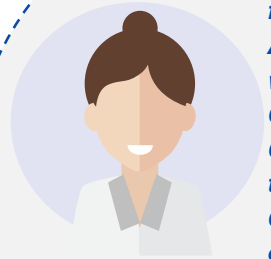
My CTIS application usage

- Search for investigation sites
- View clinical trial applications and protocols
- Download documents
- Work with the Inspections module
- In some Member State, the inspector's work is done by a Coordinator

My work environment

- Works in the office and at inspection sites
- Core activity: preparation for and conducting inspections

MS Ethics Committee: Coordinator



*I **coordinate responses from Ethics Committee Assessors**, communicate with the National Competent Authority Coordinator, and **ensure timely Ethics Committee contributions are made to CTIS**.*

Possible user role in CTIS: National Organisation Administrator, Assessor Part II Submitter

My background

- Experienced administrator

My technology knowledge

Frequency of CTIS use: Daily

Level of familiarity with technology: Familiar

MY USE OF CTIS

My CTIS application usage

- Monitor clinical trial application notifications
- Send documentation to rapporteurs/Ethics Committee members
- Upload Part II assessments to CTIS
- Monitor deadlines

My work environment

- Day-to-day management of Ethics Committee activities and deadlines
- Ensure Ethics Committee Assessors have appropriate documentation
- Upload Ethics Committee assessments to CTIS
- Office environment
- Work with secretaries with different responsibilities

MS Ethics Committee: Assessor

*“I **assess clinical trials for the Ethics Committee** on a voluntary, part-time basis on top of my full-time job.”*

Possible user role in CTIS (if access is given): Assessor Part I Viewer, Assessor Part II Viewer or Preparer

My background

- Senior specialists in medicine, law, ethics, or laypersons

My technology knowledge

Frequency of CTIS use: Not expected to be regular

Level of familiarity with technology: Quite familiar

MY USE OF CTIS

My CTIS application usage

- Variable use & access for Assessors (not yet fully determined for most Ethics Committees)
- If access to CTIS, may review some sections of Part I, for national Ethics Committees may review all sections of Part II and prepare Part II assessment

My work environment

- Review Clinical Trials documents and handles requests based on their area of expertise within their own working environments
- Meet with Ethics Committee on a regular basis to discuss and finalise assessments for entry into CTIS

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands
Telephone +31 (0)88 781 6000
Send a question

www.ema.europa.eu