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.

Sponsors & Contract Research Organisations (CROs)

- CTIS Submission Manager
- Regulatory Project Manager
- In-Country Specialist

SMEs & Academia

- Study Coordinator
- Clinical Trial Submission Specialist
- Study Nurse*
- Safety Specialist

*Academia only

Click on each Persona to see more detail

Sponsors & CROs: CTIS Submission Manager

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*I am a CTIS **system expert** that ensures the **smooth running of CTIS processes**. I work closely with the Regulatory Project Manager to ensure accurate and timely input of information in CTIS.*

Possible user role in CTIS: CT Admin, Sponsor Admin

My background

- Mix of backgrounds (clinical trials, regulatory, administrative)

My technology knowledge

Frequency of CTIS use: Daily

Level of familiarity with technology: Very familiar

MY USE OF CTIS

My CTIS application usage

- Day-to-day management of CTIS
- Review of notices, alerts, submission deadlines
- May input clinical trial application data
- May verify the information input to CTIS by others
- User role administration (if not done by the IT team)

My work environment

- Office environment, often as part of a small CTIS team, supporting other users
- Close work with the regulatory team

Sponsors & CROs: Regulatory Project Manager

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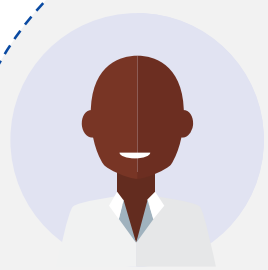

*I **coordinate the regulatory submission** for a clinical trial, including liaising with In-Country Specialists, the CTIS Submission Manager and other stakeholders.*

Possible user role in CTIS: Part I & II preparer/Application Submitter, Notification Submitter, Clinical Trials Results Submitter, ASR Submitter

My background

- Scientific background with regulatory experience

My technology knowledge

Frequency of CTIS use: Very regular

Level of familiarity with technology: Very familiar

MY USE OF CTIS

My CTIS application usage

- **In some organisations**, take an **active role in CTIS**: prepare part I, may input part II data, submit the application, monitor notices & alerts and input safety information
- **In other organisations**, only keep **overview of CTIS tasks** which are completed by the CTIS Submission Manager/CRO, also keep responsibility for transparency/deferrals

My work environment

- Office environment
- External coordination (if work in sponsor, coordinate with CROs, or if work in CRO, coordinate with sponsor)
- Internal coordination with e.g. CTIS submission manager, in-country specialists

Sponsors & CROs: In-Country Specialist

I work with the in-country team to provide data that will be submitted through CTIS. ***I may not have direct access to CTIS****.*

Possible user role in CTIS (if access if given): Part II Preparer, Notification Preparer

My background

- Scientific background, in-country expertise

My technology knowledge

Frequency of CTIS use: May not be regular

Level of familiarity with technology: Very familiar

MY USE OF CTIS

My CTIS application usage

- Provide Part II data for submission to CTIS
- If access to CTIS, prepare Part II documents, input notification dates
- May assist in Organisation Management System (OMS) registration for clinical trial sites

My work environment

- Office environment
- Part of an in-country team
- Close work with the clinical trial sites
- Coordinate with CTIS Submission Manager/Regulatory Project Manager

SMEs & Academia: Study Coordinator

> *I **run small clinical trials**, including patient-facing tasks. I **may complete regulatory submissions**.*

Possible user role in CTIS: CT Admin

My background

- Diverse professional background
- Possible experience as nurse, physiotherapist or lab technician

My technology knowledge

Frequency of CTIS use: At the beginning of the trial and for entering notifications/modifications

Level of familiarity with technology: Familiar

MY USE OF CTIS

My CTIS application usage

- Prepare and submit trial documents
- Review notices and alerts
- Review Requests for Information (RFIs) and submit RFI responses
- Submit of trial notifications and results

My work environment

- Office environment in a university or SME, or academic hospital
- Varied tasks: manage patients, stakeholders and regulatory submission
- May work individually or with other study coordinators

SMEs & Academia: Clinical Trial Submission Specialist

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*"I **work with clinical research teams** to **prepare the Clinical Trial Application and** ensure it is submitted on time. I work closely with clinical trial sites, Clinical Trial Project Managers, NCAs and Ethic Committees."*

Possible user role in CTIS: CT Admin, Sponsor Admin

My background

- Mix of backgrounds
- Possible former clinical research associate now clinical trials submission specialist

My technology knowledge

Frequency of CTIS use: Daily

Level of familiarity with technology: Familiar

MY USE OF CTIS

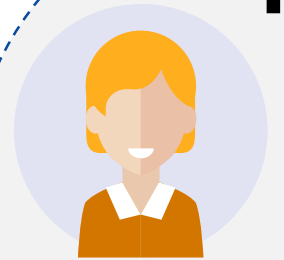
My CTIS application usage

- Prepare and submit the clinical trial application
- Review notices and alerts
- Review Requests for Information (RFIs) and submit RFI responses
- Submit trial notifications and results

My work environment

- Office environment in a university or SME, or academic hospital
- Usually juggling deadlines for various ongoing clinical trials

Academia: Study Nurse



*I **support the day-to-day conduct** of clinical trials. In **smaller clinical trials**, I may complete regulatory submission.*

Possible user role in CTIS:
CT Admin

My background

- Background in nursing
- Possibly a lot of experience or freshly graduated from university

My technology knowledge

Frequency of CTIS use: Infrequent

Level of familiarity with technology: Not familiar

MY USE OF CTIS

My CTIS application usage

- In smaller trials:
  - Prepare and submit clinical trial application
  - Review notices and alerts
  - Review Requests for Information (RFIs) and submit RFI responses
  - Submit trial notifications and results

My work environment

- Busy hospital environment
- Varied tasks: patient care, paperwork and correspondence with patients, sponsors and colleagues

SMEs & Academia: Safety Specialist

*I am responsible for **submitting safety reports**. I may not have access to CTIS. If I do, I will prepare and may submit ASRs.*

Possible user role in CTIS (if access is given): ASR Submitter

My background

- Mix of junior and senior profiles with scientific or medical backgrounds

My technology knowledge

Frequency of CTIS use: Infrequent

Level of familiarity with technology: Familiar

MY USE OF CTIS

My CTIS application usage

- If access to CTIS: submit annual safety reports (ASRs) and other safety related information
- Another persona may submit to CTIS on his/her behalf (Study Coordinator, Submissions Specialist, or administrator/safety secretary)

My work environment

- Office environment (operational, medical or safety unit, or part of regulatory department)
- Management of deadlines, preparation of safety reports, internal & external communication

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

www.ema.europa.eu