How to Prepare for CTIS: a User Perspective

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<th>Type of Financial Interest within last 12 months</th>
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<td>☐ Grants/Research Funding</td>
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Content

1. User Management
2. Procedures
3. Training
4. User personas
5. Notices and alerts & RFI’s
6. Useful links
▲ Sponsor registration

▲ 2 roles to be requested in EMA Account Management portal

• “High-level Administrator” aka Sponsor Admin
• Marketing Authorisation Holder (MAH)
  • Registration process currently under development and to be confirmed in a very near future
User Management

MAH roles

*MAH Admin

* MAH Admin have also the viewer and submitter permissions.

Viewer

• CSR Viewer

Submitter**

** Submitters have also the viewers’ permissions.
User Management

- Sponsor registration
- Request **CTIS High Level Administrator** role
- Assign user roles according to your organisation and operating model
User Management

Sponsor roles

CT Admin

Sponsor Admin

Viewer
- Part I Viewer (exc. Q-IMPD)
- Part II Viewer
- Q-IMPD Viewer
- Notifications Viewer
- CT results Viewer
- ASR Viewer

Preparer *
- Part I Preparer (exc. Q-IMPD)
- Part II Preparer
- Q-IMPD Preparer
- Notification Preparer
* Preparers have also the viewers’ permissions

Submitter **
- Application Submitter
- Notification Submitter
- CT Results Submitter
- ASR Submitter
** Submitters have also the viewers’ and preparers’ permissions
Ensure strong user administration process

- Who grants/revokes access?
- How is it documented?
- All or specific trials?

The more granularity, the stronger the user management process must be
Procedures

- Procedures already in place?
- Needing updates?
- New procedures needed?
- Up-to-date procedures required
  - Either new or updated
- Change management

- SOPs
- Practical Working Instructions
- Role-Specific Training
- Granted Access
Train users before they access the system
Ensure appropriate training for each role
Document users’ training
Master Trainer programme and online training material (cf. Fia Westerholm)
Structures and organisation of trials can vary widely among sponsors (including academia)

Creation of User Personas to provide each organisation examples that will help users identify the most approaching model

EMA published this User Personas Modelling

• Thank you Sarah Scales for managing these models and making them available so rapidly
User personas

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
Do not underestimate the monitoring of notifications and RFI’s

- Needs a proactive check from Sponsors (and MS) (no emails sent)

RFI maximum response time = 12 days

- We cannot afford to lose one day of response time

Strong process to be in place, but also avoiding permanent check of the notifications system
Last but not least

- **EMA Sponsor Handbook**
- **EMA Online Training Modules**
- **EudraLex - Volume 10 - Clinical trials guidelines**
- **User Personas**