How to Prepare for CTIS: a User Perspective

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DIA

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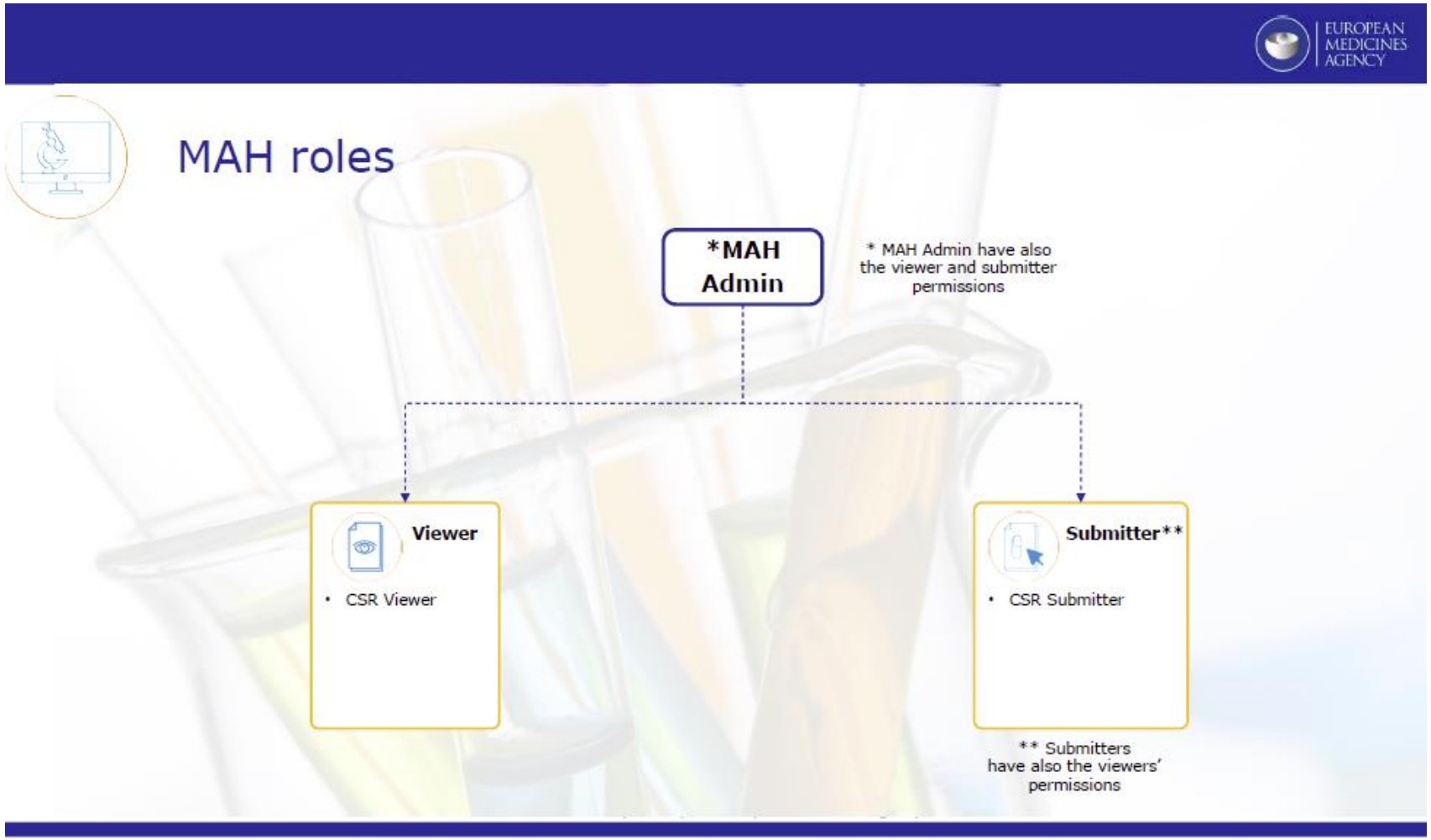
User Management

- 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

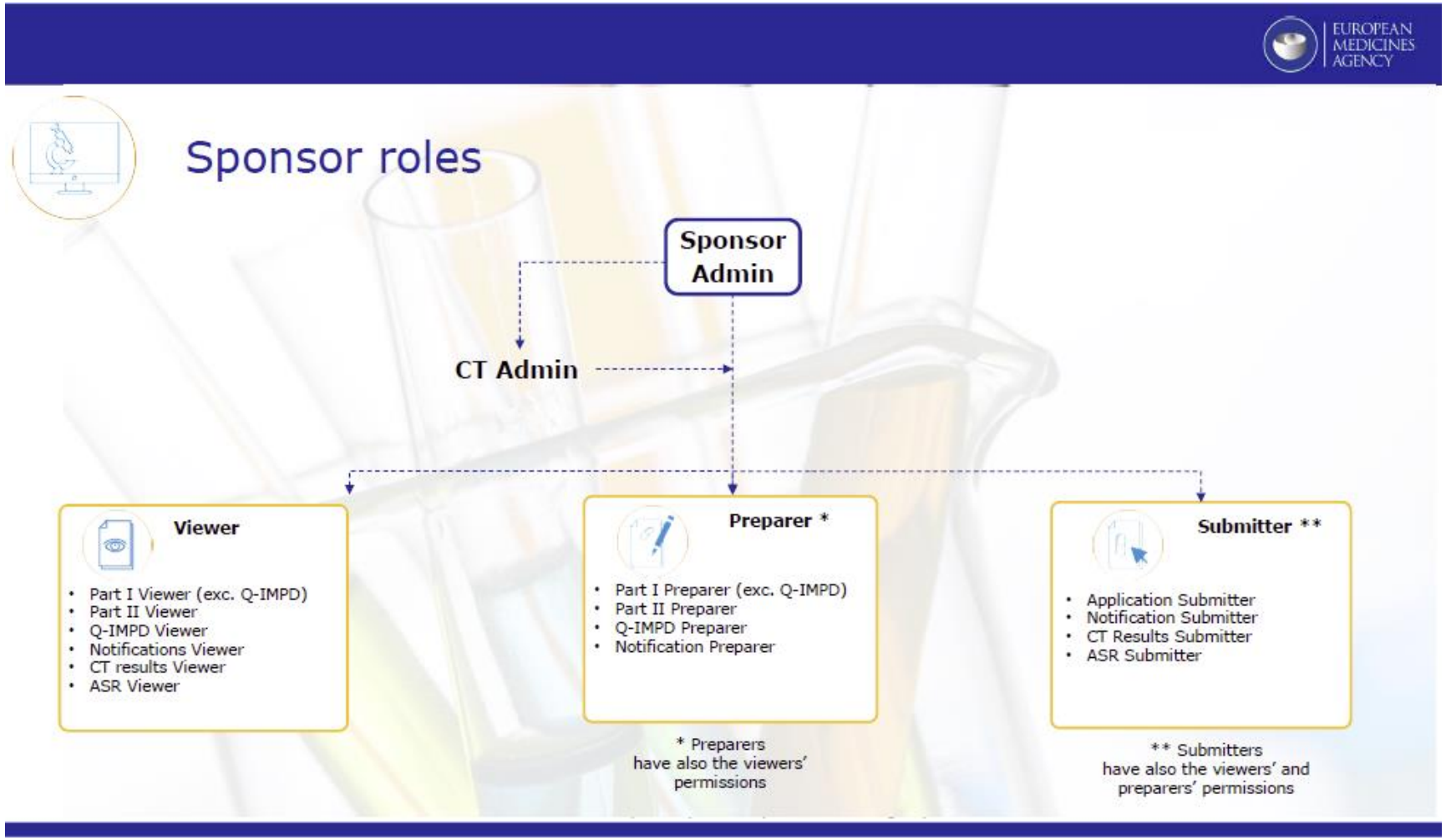
User Management



User Management

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

User Management

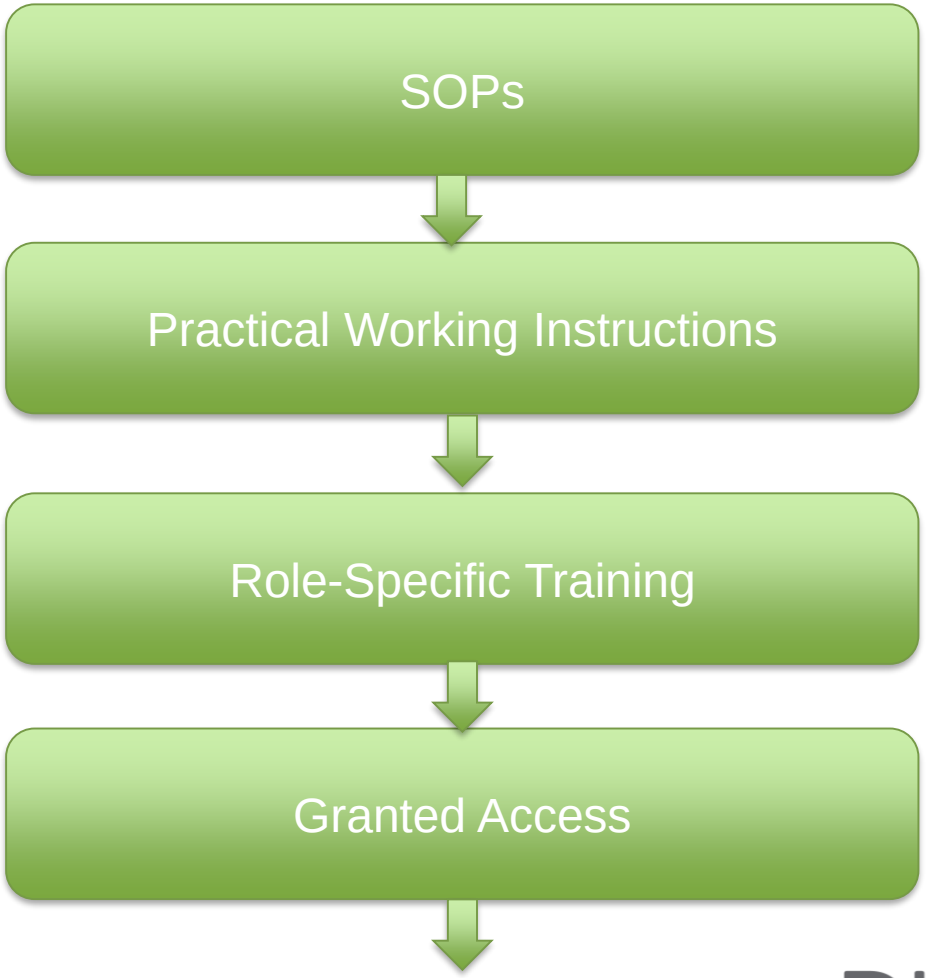


User Management

- 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

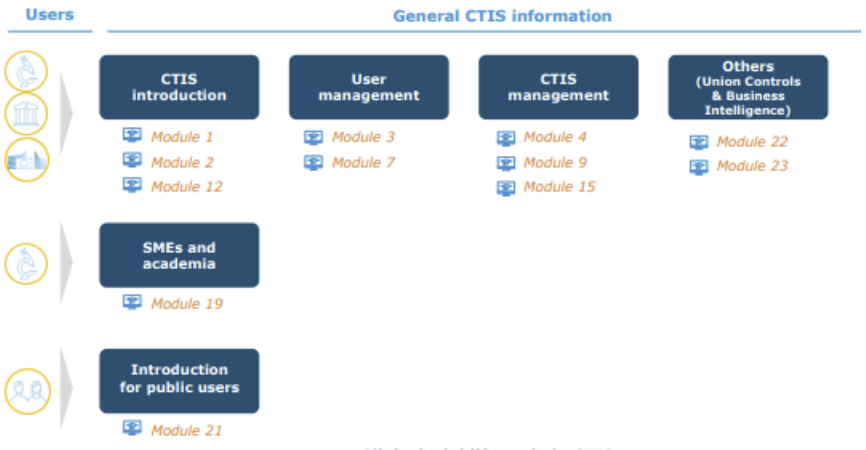
Procedures

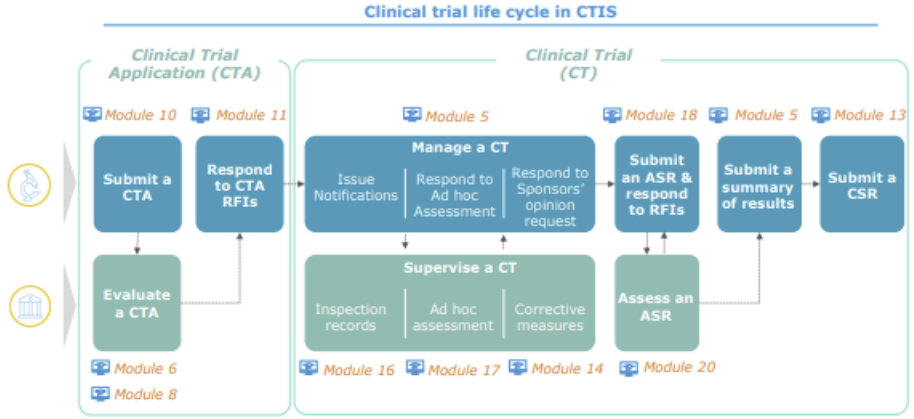
- Procedures already in place ?
- Needing updates ?
- New procedures needed ?
- Up-to-date procedures required
  - Either new or updated
- Change management



Training

- **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)
-





User personas

- 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

EUROPEAN MEDICINES AGENCY

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

Notices and alerts & RFI’s

- 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 loose 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
- Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 4.1 (September 2021)
- User Personas