EMA information webinar 29th July 2021
‘How sponsor organisations can prepare for CTIS’

The SME perspective

EUCOPE

w/ Trine B. Moulvad, VP and Head of Regulatory, Patient Safety and Medical Writing, Zealand Pharma

Member of EUCOPE’s CTR focus group as well as other EUCOPE working groups
Part of the Steering Committee of Zealand Pharma’s CTR implementation team

Introductory comments

How are SMEs different?

- High dependence on external resources and partnerships
- Core operational CT functions fully or partly outsourced
- Few or no affiliates (for translations, local CTA submissions)
- Tight budgets
- Limited bandwidth to engage in ‘extracurricular’ training activities

Agenda – SME CTIS preparation and challenges

1. EMA training efforts

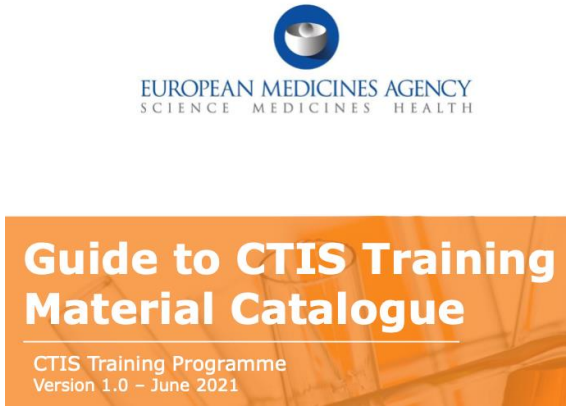
2. In-house vs CRO/vendor roles and responsibilities

3. Training: where are we and where do we need to get to?

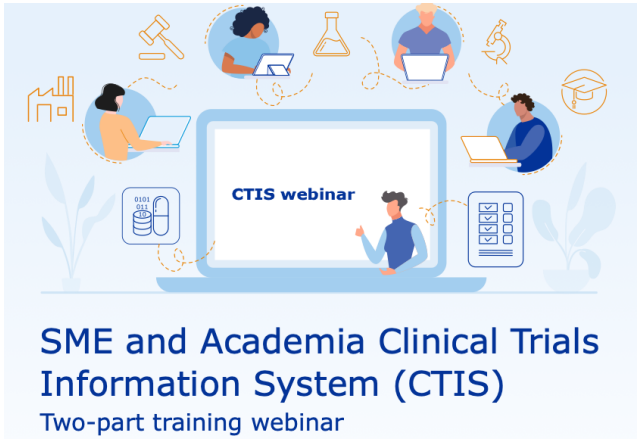
4. EUCOPE take-home messages

1. EMA Training efforts

✓ A variety of helpful information to get started is available



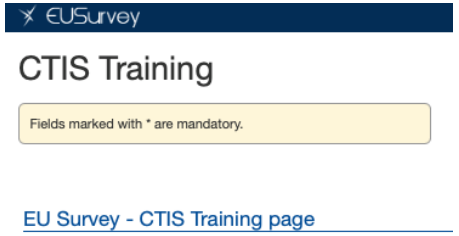
23 Modules, specifically Module 19 for SME & Academia



Virtual training/webinars

We need to allocate time & resources

Newsletter published quarterly key updates



Feedback platform

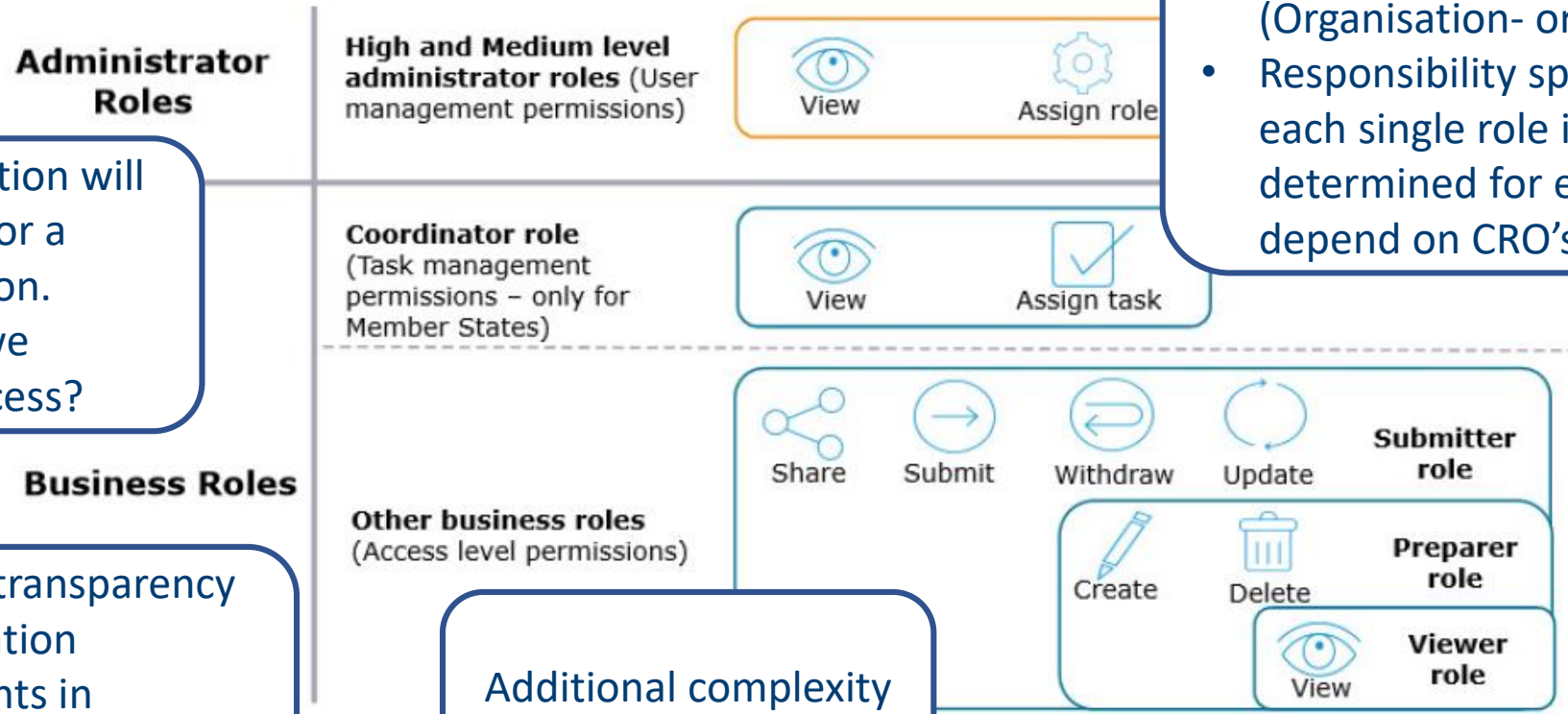
2. In-house vs CRO/vendor roles and responsibilities

SMEs are dependent on CRO capabilities/processes and **need to engage NOW with key CROs** for co-preparation

Decisions to be made:

- User management approach (Organisation- or trial-centric?)
- Responsibility split Sponsor/CRO on each single role in the system to be determined for each trial – and will depend on CRO's capabilities

User administration will be a huge task for a small organisation. Where should we anchor this process?



Managing transparency and translation requirements in collaboration with CROs – who does what?

Additional complexity with >1 vendor pr trial

Figure reference: FAQs Management of roles and Permissions, CTIS Training Programme – Module 7, Version 1.2– June 2021

What we need to do has impact

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

WORKLOAD: in-/external resources

It takes **time to become an expert**

Development of new ways of working and collaborating with CROs

Plan for frontloading redactions and translations requires time and resources

COSTS ↑

Internal staff

External support and services e.g. redaction and translation

Expected **increase in CRO costs**

RISKS ↑

Trust & accuracy: e.g. information can be made public by mistake
Cost/benefit as to the (im-)maturity of system and processes – **when is the best time to start using CTIS**?

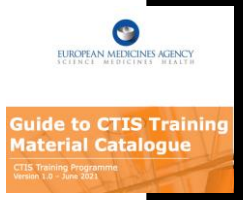
3: Training and system readiness

To prepare we need to make our way into the CTIS “black box” using EMA’s various training materials

Companies need to prepare NOW

Excellent online training modules @CTIS training site ☺

Information about CTIS is complex



No sandbox means we don’t know what we don’t know

Comprehensive CTIS Training material catalogue

SMEs have limited in-house resources to dedicate to preparing for CTIS

4. EUCOPE take-home messages

- Comprehensive training materials are available –we **need to start preparing NOW**
- Practising in the system is key to our preparation – so we need access to a sandbox environment ASAP
- Managing roles and responsibilities in collaboration with CROs will be complex so co-preparation is a must
- A training module with CROs together with SMEs (and academia) would make sense

Thank you