MS Preparedness for the use of the EU Portal

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CTR: Member States Organisation

It should be left to the Member State concerned to determine:

The **appropriate body or bodies** to be **involved** in the **assessment** of the application to conduct a clinical trial

To **organise the involvement of ethics committees** within the timelines for the authorisation of that clinical trial as set out in this Regulation.

Such decisions are a matter of <u>internal organisation for each Member State</u>.

Application Assessment: Member States Organisation

Multiple European countries

Several and diferente MSs organisations

Different:

- ✓ Number of bodies involved in the assessment Applications;
- ✓ Involved bodies with different responsabilities in the assessment;
- ✓ MSs with: 1 central Ethic commitee or several Ethics Commites

One single tool: EU Portal

SAME OBJECTIVE
Implementation

REGULATIONS

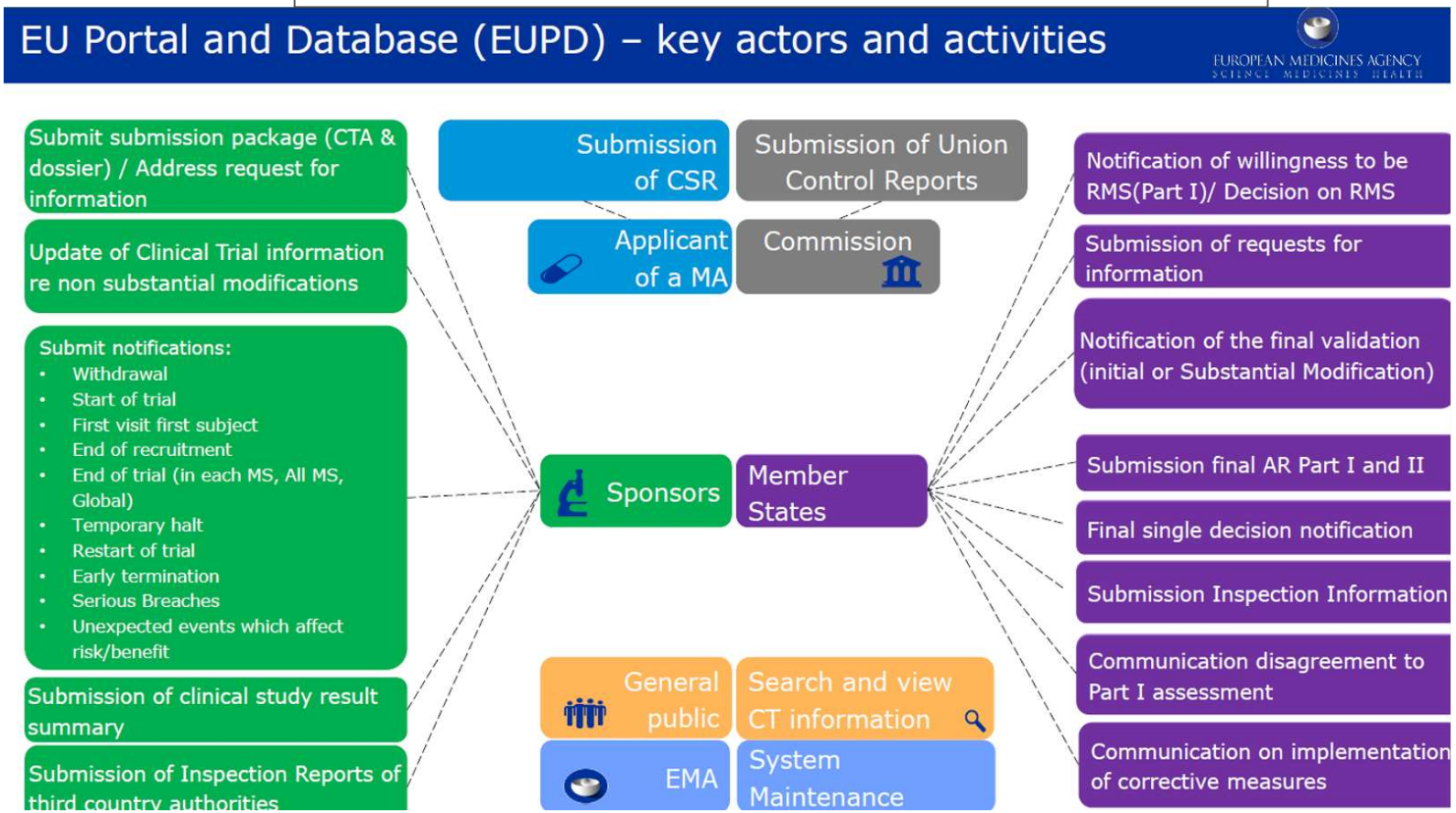
REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
(Text with EEA relevance)

An Enormous Challenge for MSs

EU PORTAL

The system will support the **day-to-day business processes** of Member States and Sponsors throughout the life-cycle of a clinical trial in a user-friendly way.

Complex system to adress all CTR requirements



Member States

How to prepare my team for this new challenge?

Communication Plan between diferente bodies

Working with the EU Portal

WHO accesses WHAT /WHO takes responsability on specific actions

Cooperation: Responsibilities and Rules

How the feedback is taking into consideration in the EU Portal?

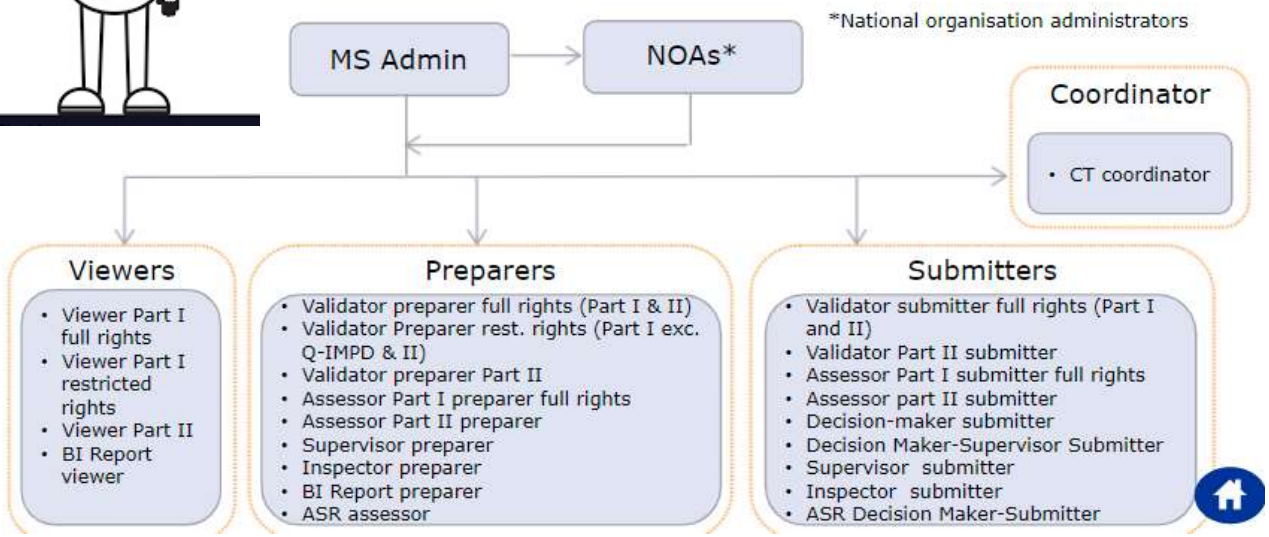
Who is responsible to update the EU Portal?

PART I Coordinated assessment Internal Involvement of different bodies (i.e NCA +EC)	PART II National Evaluation Ethics Committee
• **Benefits vs. risks** for subjects, including relevance of CT, reliability and robustness of data • **Manufacturing and importation for** IMP • **Labelling requirements** • **Investigator's Brochure**	• **Informed consent**, subject **recruitment, data protection** • **Reward/compensation** investigators/subjects • **Suitability of investigators and of trial sites** • **Damage compensation** • Collection/storage/**use of biological samples**

How to establish my Organizational Structure?

- **How to proceed?**

- **How to select the right roles and permissions?**



Working with EU PORTAL - How to achieve success?

❑ ORGANISE

Communication /Cooperation: established rules

- ✓ MSs
- ✓ Ethics Commitee´s

❑ **Plan** how you want to work with EU Portal:

- ✓ Size team
- ✓ Nº CTAs/year
- ✓ Internal/external employees
- ✓ Workflow control

❑ Organise your team **in advance**;

❑ **Choose the right people** for the **right role**. Experience with:

- ✓ CTR knowledge
- ✓ EudraCT, EUCTR, DWH…
- ✓ **VHP assessment (!)**

How to establish my Organizational Structure?

Look at the reality of your Member State

EU Portal user administration allows you to:

- Organise your team according to your needs;
- Provide diferent roles/permissions;
- **Combine roles** for the same user – **Establish an User Profile**

How are you going to start working with EU Portal?

Conservative Approach

Only few employees will work with the system, assuming the role of "**Superuser"/CTA National coordinator**

\+ Employees full trained and experienced with the system (VHP like);
\+ Higher workflow control;
\+ Less opportunity to make mistakes;

\- Need to establish a set of employees for these functions;

More complex Approach

Establish different roles for several employees that will act in collaboration and acess to different parts of the system – **network of employees**

\+ A network of employees working with the system;
\- Different employees working with a system with less experience/Less training;
\- Less workflow control;
\- Increased opportunity to make mistakes;

Conservative Approach

Coordinators (Validators) will check the dossier – Will assign the CT. The assignement may take into account:

- ❑ Previous trials with the same product;
- ❑ If the MS will act as RMS
- ❑ Others

Coordinators/Super-user role

Requirements:

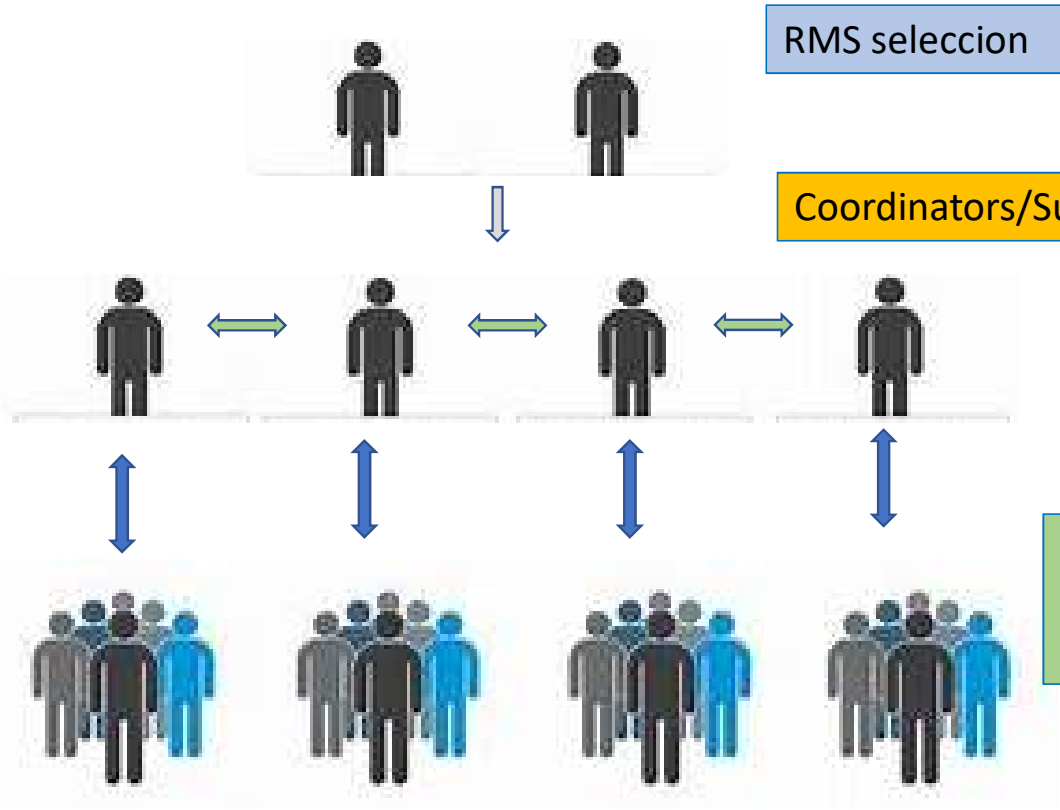
- Previous CTR knowledge /experience;
- CTIS Experts/intensive training

Activities:

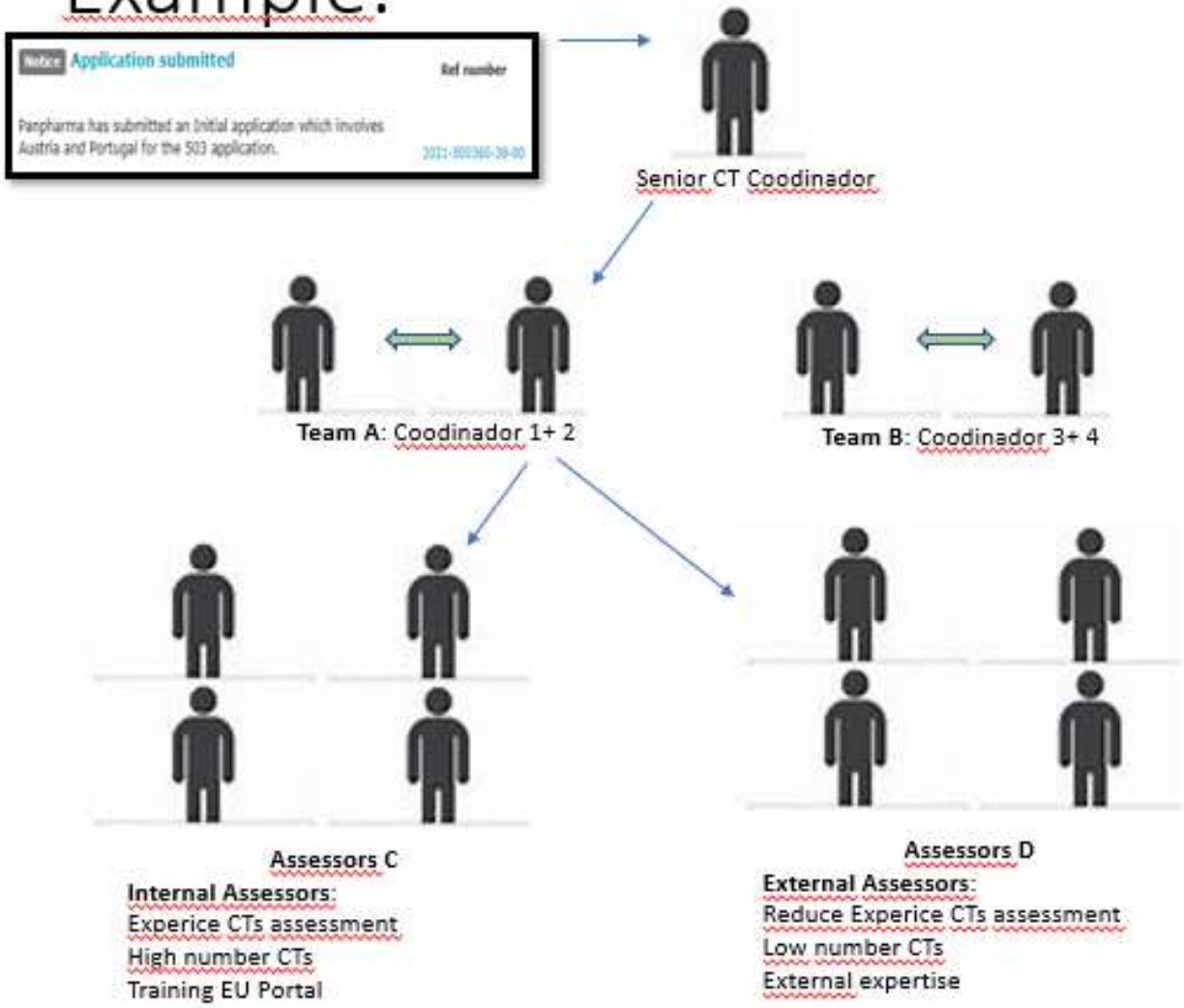
- ❑ Perform all steps of the worflow in the system;
- ❑ Liason with assessors and other experts
- ❑ Communication with Sponsors

Follow all lifecycle of a specific CTA (Initial submission, Substantial modifications, notifications, …)

Excellent experience with VHP Procedure



Example:



Head CT Unit / Senior CTs Coodinador

- **RMS selection**
- **Assign New CT to a Team Coordinators**

Role:

- **Decision/Maker Submitter**
- **Coordinator**

Coordinadors TEAM - Work in pairs (Backup)

- Trial Validation
- Assign Trial Assessors Team
- Update EU Portal /Comunication with Assessors

Role:

- **Validator submitter full rights**
- **Assessor Submitter Full rights**
- **Coordinator**
- **Decision/Maker Submitter**
- **Supervisor submitter**

Assessors:

Role- Assessors C:

- Assessor Preparer Full rights

Role - Assessors D:

- Viewer part I full rights

Coordinators will liaise with assessors

More complex Approach

Several employees working with the system and assuming diferente roles and permissions.

No central coordination

Less control of the workflow

Need to provide training to all users

Higher risk of disharmonisation between users

Different Users assessing the system:

- ❑ Validators preparer
- ❑ Validator submitter
- ❑ Assessors part I Preparer
- ❑ Assessor part I submitter
- ❑ Decision Maker submitter
- ❑ Supervisor Preparer
- ❑ Supervisor Submitter
- ❑ Other roles

User Profile

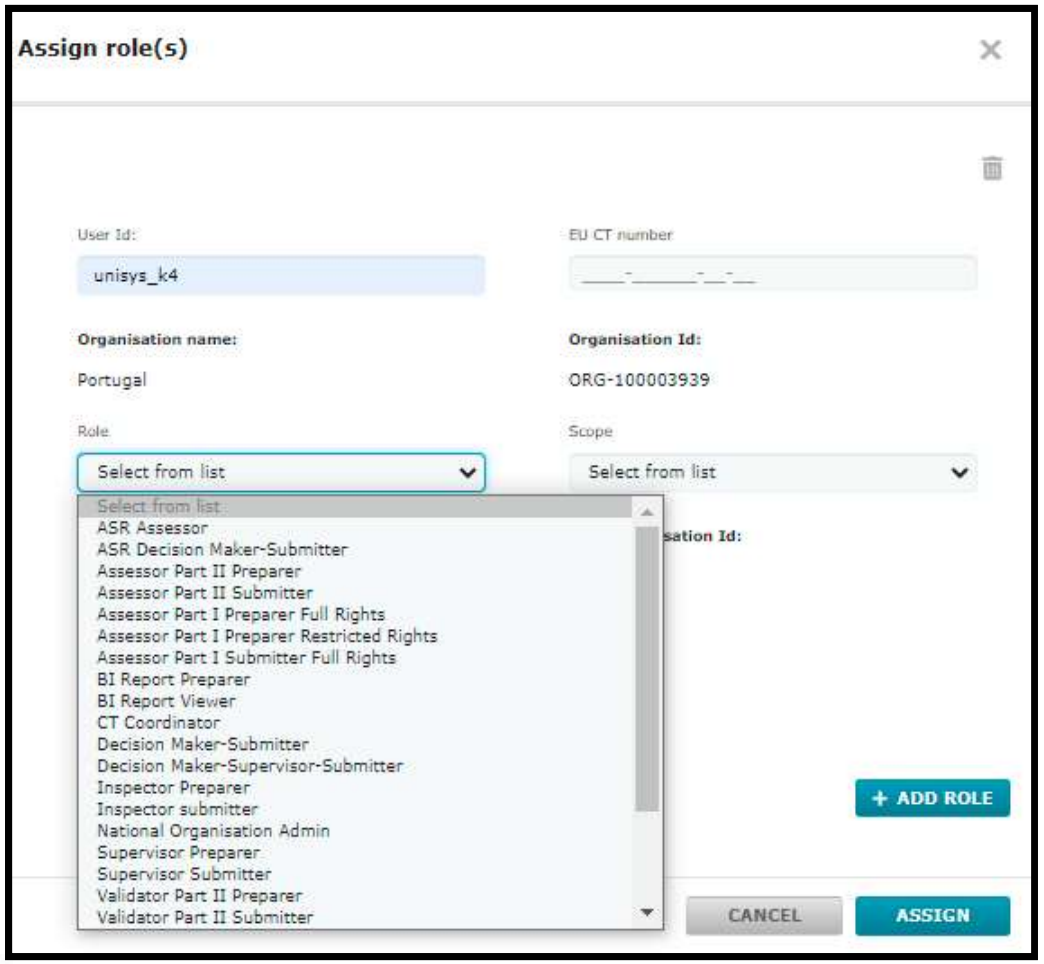
Internal MS organisation

Set up the **User profile** for your employee:
Example:

User Profile 1- Coordinator Part I
Coordinator
Validator full rights submitter
Assessor part I submitter full rights
Decision Maker submitter
Supervisor Submitter

User Profile 2 - Coordinator Part II
Coordinator
Validator part II preparer
Assessor part II submitter

Select the **adequate training modules** for each User Profile according to the user responsibilities



New Users should not work with CTIS without proper training

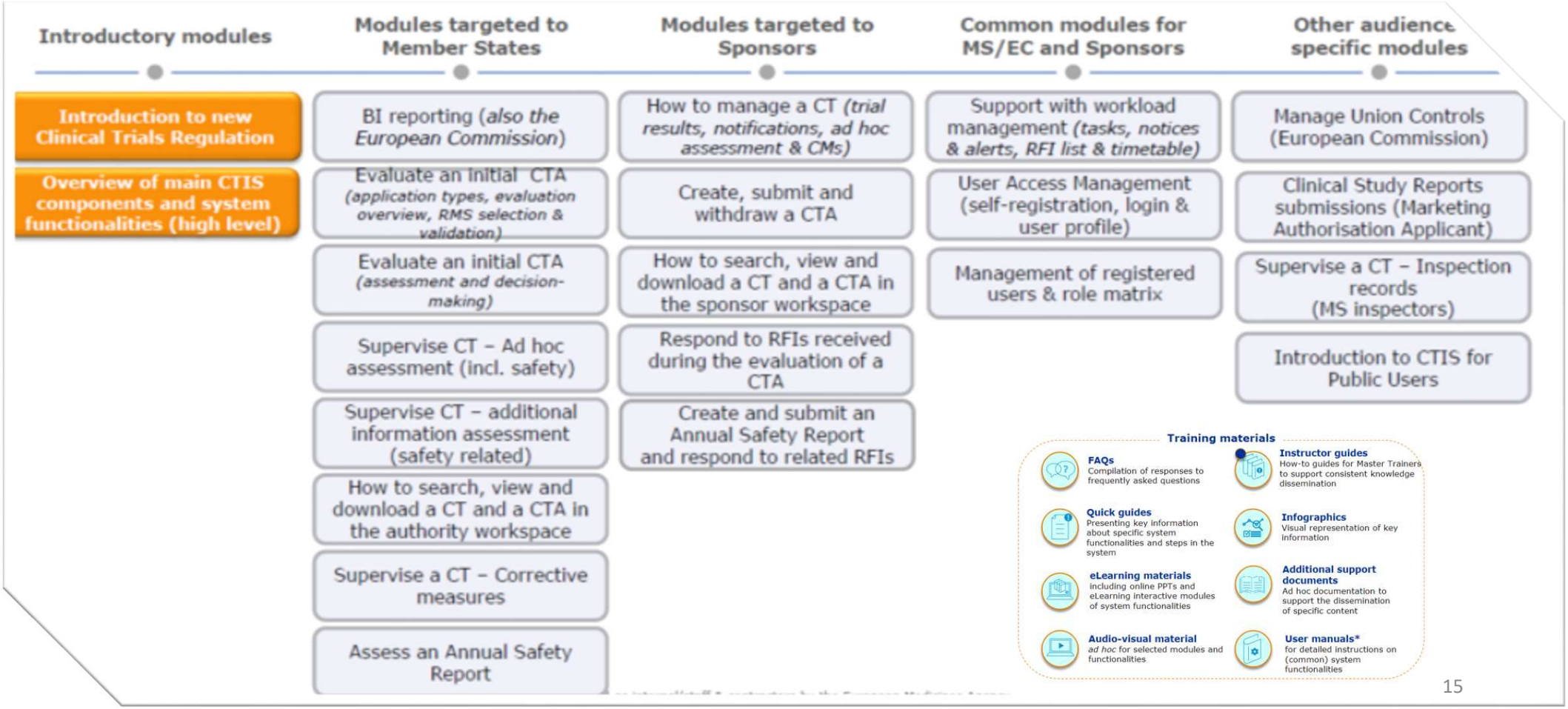
EU Portal: Training Programme

- **TRAINING** is **FUNDAMENTAL** for working with the Portal;
- **EMA** in collaboration with **Member States and Sponsor´s** representatives, is working and developing a **"live" Training Catalogue** for the system;
- **ELearning based** training programme – allow at any time: training new users/remind functionalities;
- **Different types of materials** to address different needs (eLearning, quick guides, clips, FAQs);
- **Modules** -EMA site - **EMA CTIS Training Programme**

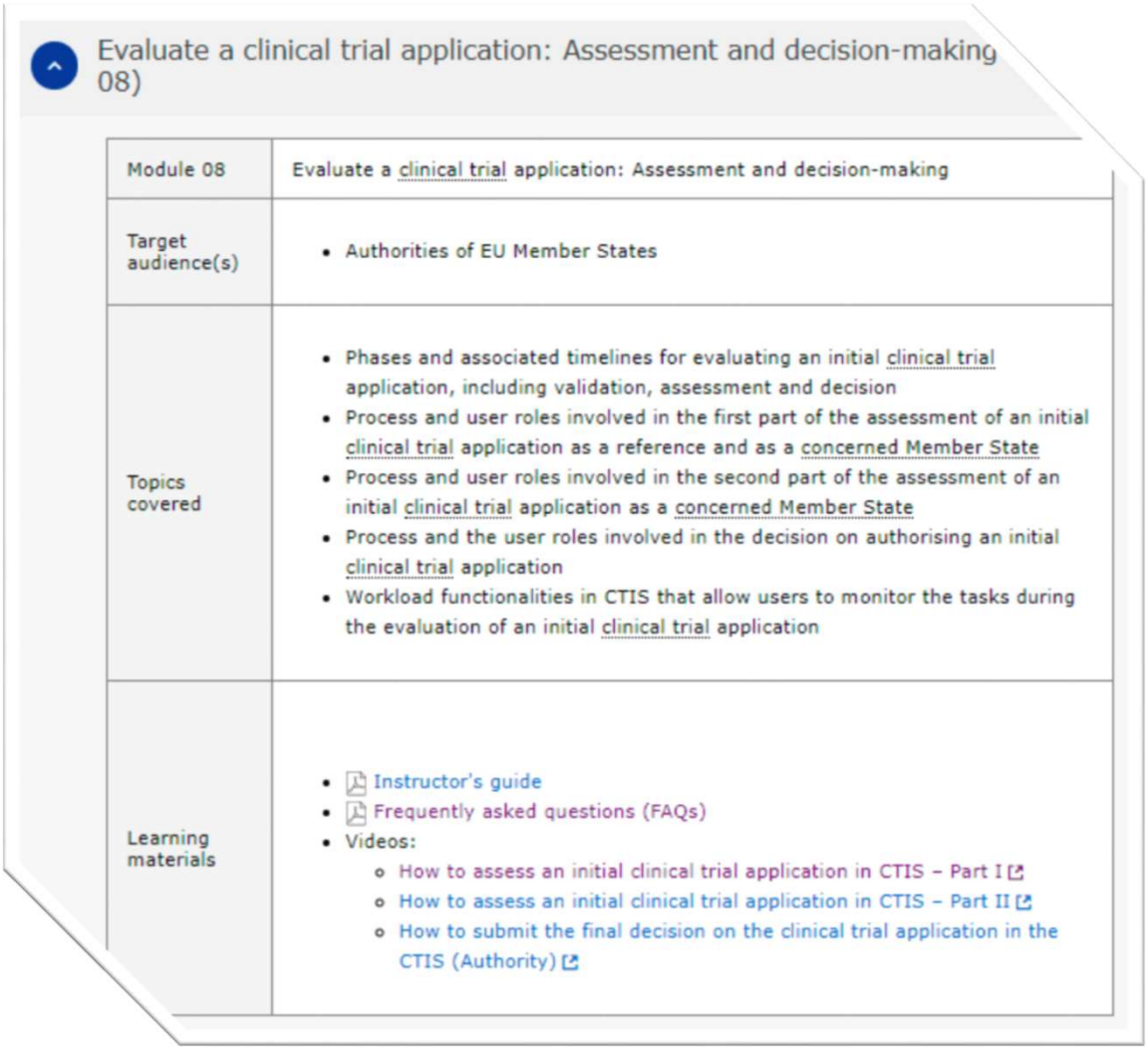
https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trial-regulation/clinical-trials-information-system-ctis-training-programme

EU Portal: Training Programme - Modules

21 Modules



EU Portal: Training Programme



Evaluate a clinical trial application: Assessment and decision-making 08)

Module 08	Evaluate a clinical trial application: Assessment and decision-making
Target audience(s)	• Authorities of EU Member States
Topics covered	• Phases and associated timelines for evaluating an initial clinical trial application, including validation, assessment and decision • Process and user roles involved in the first part of the assessment of an initial clinical trial application as a reference and as a concerned Member State • Process and user roles involved in the second part of the assessment of an initial clinical trial application as a concerned Member State • Process and the user roles involved in the decision on authorising an initial clinical trial application • Workload functionalities in CTIS that allow users to monitor the tasks during the evaluation of an initial clinical trial application

Learning materials	• Instructor's guide
	• Frequently asked questions (FAQs)
	• Videos:
	  ○ How to assess an initial clinical trial application in CTIS – Part I
	  ○ How to assess an initial clinical trial application in CTIS – Part II
	  ○ How to submit the final decision on the clinical trial application in the CTIS (Authority)

Training is the Key to Success

- **Extensive** Training catalogue (21 Modules)
- EMA's training programme is mainly composed of **online training modules**
  - ➢ Design by **module** and **target user group;**
  - ➢ **Each module** contains a brief **summary of the topics** it covers and **learning materials;**
  - ➢ **Learning materials** are accessible **via links;**
- To support **micro, small and medium-sized enterprises** (SMEs) and **non-commercial sponsors** in academia, EMA is organising tailored virtual training sessions.

MASTER TRAINERS NETWORK
Member States

<u>Objetive</u>:Dissemination of knowledge about the EU Portal

- **Core group of users** who will **train and support** other users in **their organisations** in preparing **to work with the sytem**

- Master trainers from the **national competent authorities** and **ethics committees** of each EU Member State

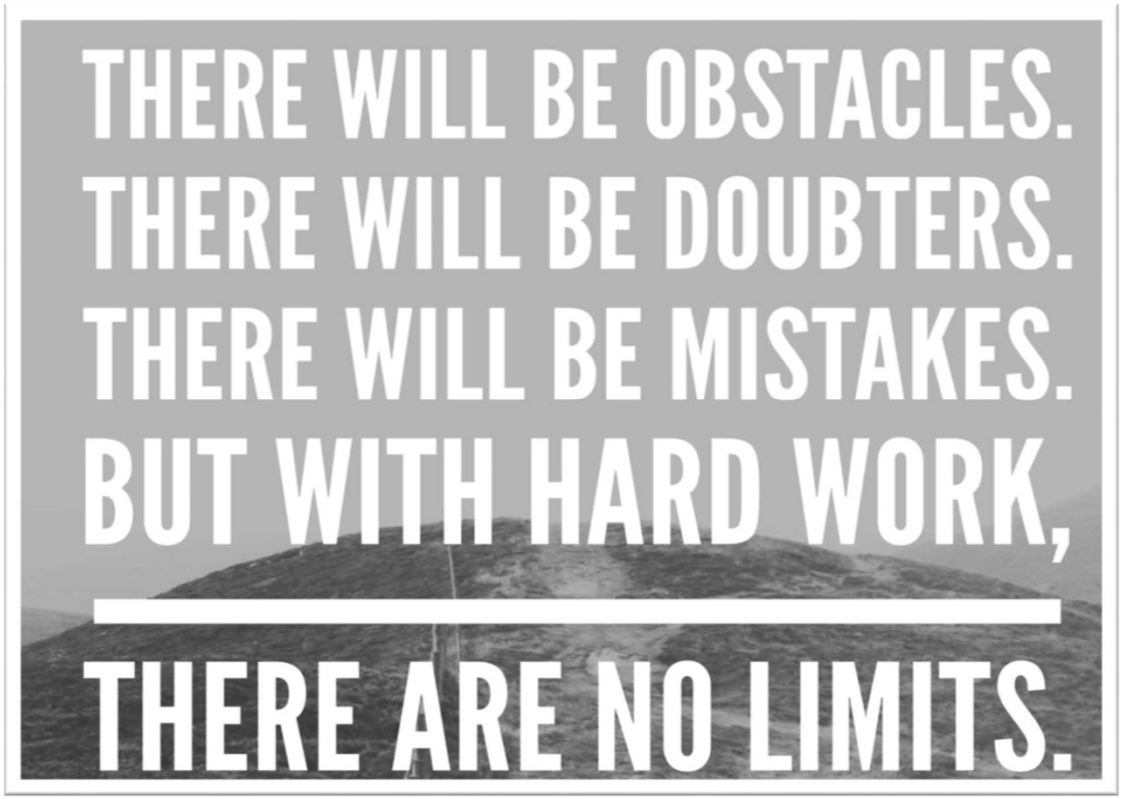
- **Master trainers**, at **National level**, should:
  - Plan a training programme, according to the training provided;
  - Select the target audience for each Module;
  - Ask for feedback on each Module (content /training material);
  - Provide the feedback gathered to the EMA training team - <u>Improve Learning Material</u>

Communication and collaboration between MSs, Sponsors and EMA

New challenges require effective communication between partners

- ❑ MSs, Sponsors, EMA and EC need to communicate and collaborate together;
- ❑ Each MS should establish a functional organization adapted to its reality, allowing the correct use of the EU Portal
- ❑ MSs should also provide support to Academia
  - Periodic training sessions;
- ❑ EMA should establish an effective and quick helpdesk for the EU Portal support;

Questions?



Thank You
For Your Attention

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