EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MS Preparedness for the use of CTIS

EC-DG SANTE/HMA-CTFG/EMA joint training on the Clinical Trials Regulation (EU) 536/2014
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Define your MS organization model in the context of the new CTR

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- Which organizations in your MSs are going to have access to the system?

Your Ministry of Health?

Your Agency?

Your Ethics Committees?

Other Committees?

Other organizations? e.g. Inspectorate

MS Organizations, which need access to the system from day 1 have to be registered in the EMA **Organization Management System** (**OMS)** before CTIS goes live. If organizations change after go live, these can be further updated

Define the CTIS workload distribution within your MS Organization Model

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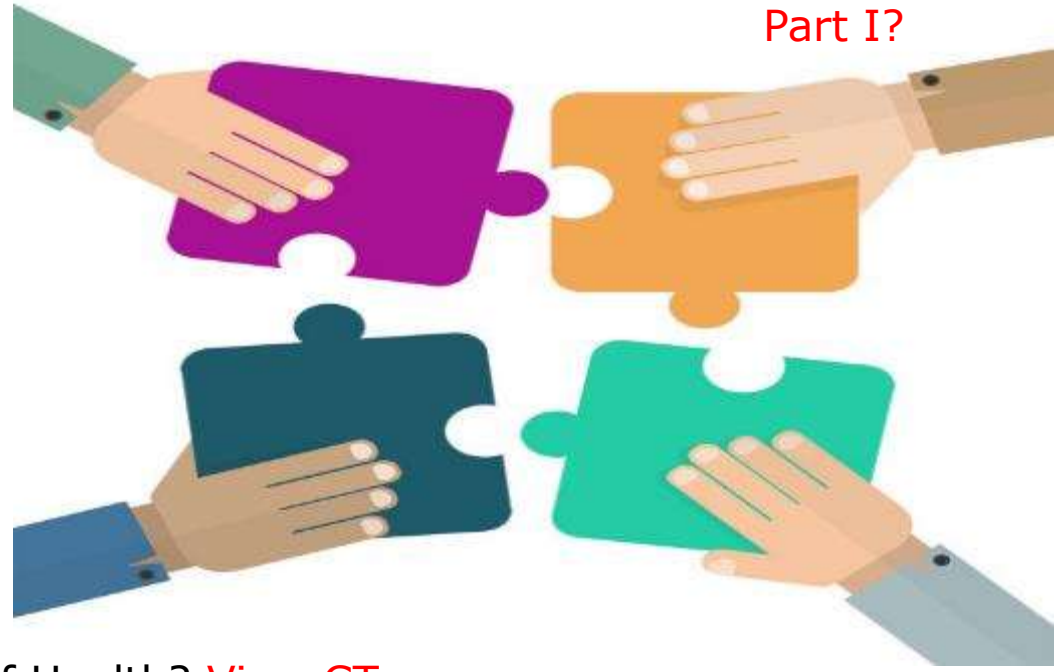
Your Agency? Validate the CTA?, Assess Part I?, Supervise?

- your Ethics Committees? Assess Part II?, provide considerations to Part I?



Your Ministry of Health? View CT Information?

Other organizations? Inspections?

Define the MS roles to be assigned to each organization within your MS model

CTIS-Permissions and Roles

A flexible system that can be adapted in the near future

Permissions
example

Mix and match

Roles
example

Business Roles
(validator, assessor, supervisor etc.)

- **Administrators**
- **Coordinator (only for MS WS)**
- Viewer
- Preparer
- Submitter

Roles will be created by grouping respective permissions

Assign roles to people

Registered user profile

*Each user can be assigned **one or more roles** to allow him/her to execute relevant actions in the system*

Define the MS roles to be assigned to each organization within your MS model

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Member State Admin

- Manage role assignment:
  - Assign role
  - Amend role
  - Revoke role
  - Approve users role requests
- Allocate scope/trials to users
- View users roles

*National organisation administrators

***NOA(s)**

Viewer

- Viewer Part I full rights
- Viewer Part I restricted rights
- Viewer Part II
- BI Report viewer

Preparer *

- Validator preparer full rights (Part I & II)
- Validator Preparer rest. rights (Part I exc. Q-IMPD & II)
- Validator preparer Part II
- Assessor Part I preparer full rights
- Assessor Part II preparer
- Supervisor preparer
- Inspector preparer
- BI Report preparer
- ASR assessor

Submitter **

- Validator submitter full rights (Part I and II)
- Validator Part II submitter
- Assessor Part I submitter full rights
- Assessor part II submitter
- Decision-maker submitter
- Decision Maker-Supervisor Submitter
- Supervisor submitter
- Inspector submitter
- ASR Decision Maker-Submitter

Coordinator

- CT Coordinator

***** Preparers have also the viewers' permissions

****** Submitters have also the viewers' and preparers' permissions

Define the roles to be assigned to each organization within your model

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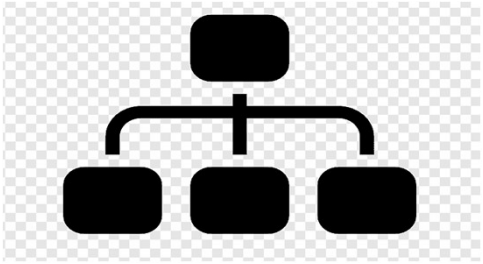
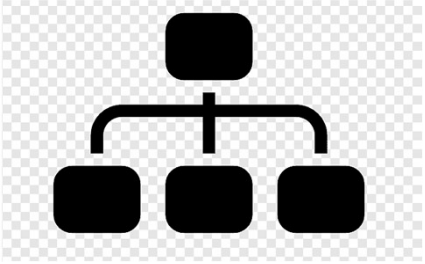
Agency
Validate the CTA?,
Assess Part I?,
Supervise?



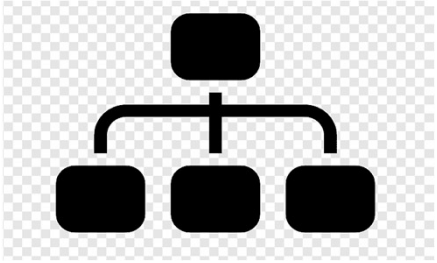
MS Administrator
National Organization Admin
Validator Part I and II
Assesssor Part I preparer FR
Assessor Part I submitter FR
Decisions Maker
Supervisor preparer
Supervisort submitter
Viewer Part I
Viewer Part II
Viewer Part I RR

Ethics C. ?
Assess Part II?, provide considerations to Part I?



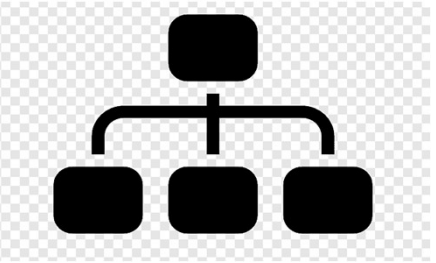
National Organization Admin
Validator Part II
Assesssor Part I preparer RR
Viewer Part I RR
Viewer Part II

Inspectorate?
Inspections?



Inspector preparer
Inspector submitter
Viewer Part I
Viewer Part II
Viewer Part I R

Ministry of Health?
View CT Information?



Viewer Part I
Viewer Part II
Viewer Part I R

Define the roles to be assigned to each organization: Administrator roles

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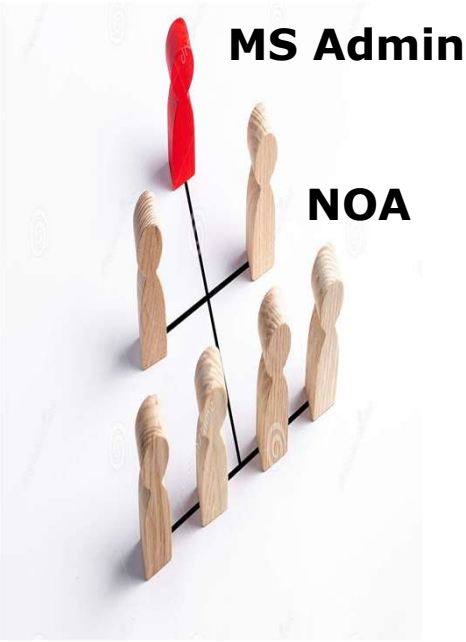
- Each MS should have one MS Administrator with at least one back-up
- Which organizations and who within those organizations will have an **administrator role** in the system (i.e. responsible to administer users (assign/amend/revoke roles)?
  - To which organization will the **MS administrator** belong?
    - to your Agency, to your Ministry of Health?.
    - Do you plan to have MS administrators back-ups?.
    - Have you identified the user with the MS administrator role?
  - Will each of your MS organizations have a **National Organization Administrator (NOA)** so those NOAs can manage user roles within that organization? e.g. A NOA is assigned per Ethics Committee (EC) and those NOAs will manage the users within those ECs.
- Ensure the MS Administrators are registered and **validated in IAM** in advance to the go-live of CTIS



Define the roles to be assigned to each organization: Bussiness roles

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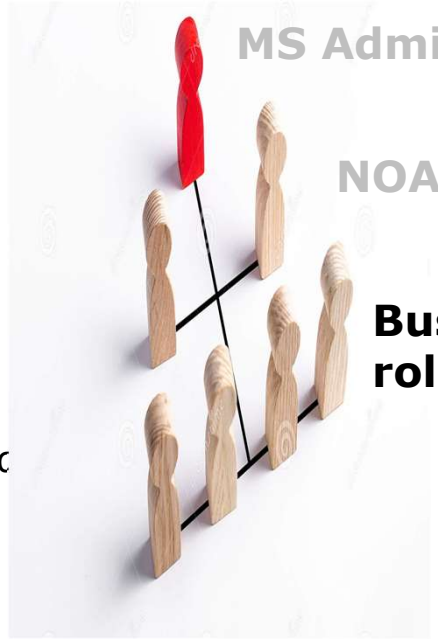
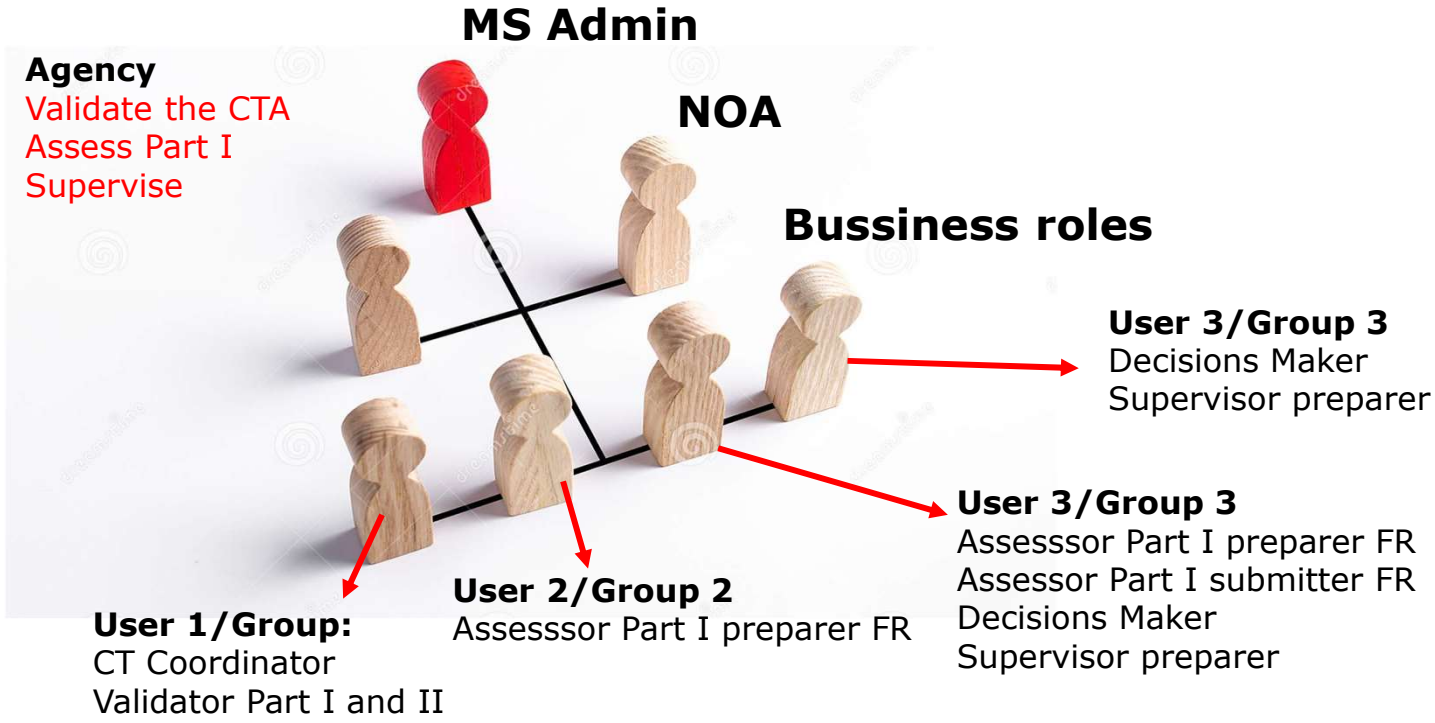
- Who are the users/group of users within those organizations that will have **business roles** in the system?
  - Analyse, per organization, which user/group of users are going to be responsible to perform the different CT activities possible in the system e.g. who is going validate in the system? and to assess? and to decide on the trial? etc.
  - Per activity, identify if the organization user will have **preparer** responsibilities (linked to preparer role and soft tasks) or **submitter** ones (linked to submitter roles and hard tasks)?
  - Are some of these users/group of users expected to perform more than one activity in the system? e.g. "validation and decision making" or "validation and assessment or…" etc.



Define the users/ group of users profile per organization

- Define the Job profile of a user/group of users by assigning one or a combination of roles
- Administrator assign roles to user in CTIS in accordance with the defined Job profile



Ensure CTIS users are self-registered in EMA Account Management System

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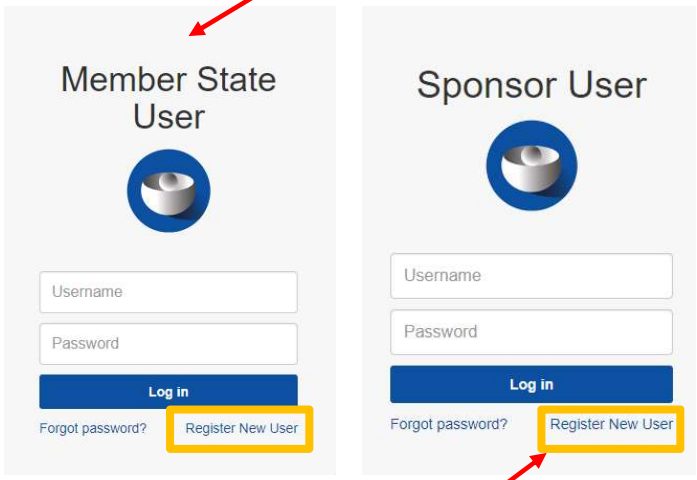
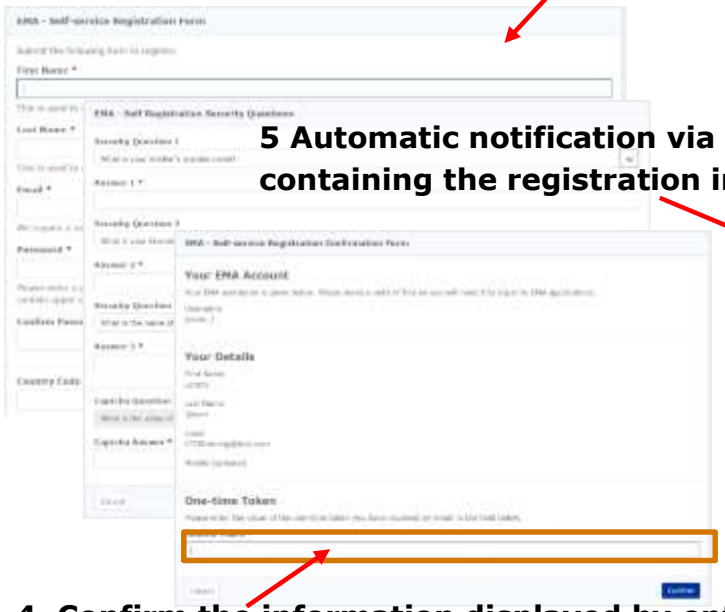
All users must self-register in the EMA Account Management System to get access to CTIS.

1. Select the MS workspace in the CTIS welcome page



2. Select the option 'Register New User

3. Complete the self-service Registration Form



5 Automatic notification via email containing the registration information

4. Confirm the information displayed by entering the one-time-token sent via e-mail

MS Preparedness: EMA support

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- The EU Commission through their CTEG group has provided EMA with one contact point per MS to understand the different MS organization models and how EMA can help to work with the system
- A survey has been circulated to these MS contact points to collect the following information:
  - Estimated numbers of organizations (NCAs/Ethics Committees/Other Organization) that will use CTIS
  - Details of those specific organization, so they can be registered in the EMA Organization Management System (OMS) by the OMS team
  - Estimated number of users that are expected to use CTIS within these organizations
  - Indicate in which organization will be based the MS Admin, who needs to be validated by EMA
- Organise in Q2 some workshops to identify MS organization models
- Identify, as appropriate, additional training material (on top of what is already planned) to help using the system for the administration of users as well as oversight and management of workload for each of the identified MS organization models.

Any questions?

Further information

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