SPF SANTÉ PUBLIQUE, SÉCURITÉ DE LA CHAÎNE ALIMENTAIRE ET ENVIRONNEMENT
DG Soins de Santé - College

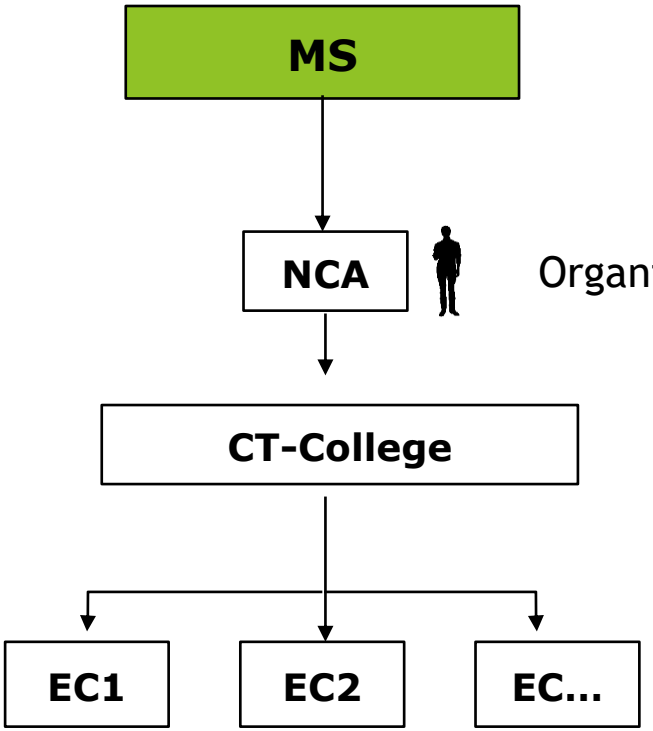
DGGS

CTR Information Session for Sponsors

J. Frgacic

15/12/2021

Belgian organization model for CTIS



Organisation with the MS Admin role

Main roles:
Assessor preparer Part I RR
Assessor preparer Part II

ECs and CT-College training

- ECs can evaluate only the dossiers they are assigned to
- Preparer roles for part I and II allow the ECs to perform actions within CTIS
  - ✓ Consult the validated dossier (except for the quality part)
  - ✓ raise considerations
  - ✓ prepare an AR
- the Sponsor Master Trainers have expressed their interest to interact directly with MS MT in order to collaborate in the context of training activities in CTIS Sandbox for the approval of the Clinical Trial applications that they will submit on behalf of their fictive Sponsor organisations. (mock CTAs)

ECs and CT-College training

Sessions	Modules' titles	Corresponding EMA Module number
Session 1	High level overview of CTIS workspaces and common system functionalities	2
	User access management	3
	Management of registered users and role matrix	7
	Belgian organization model	NA
Session 2	Evaluate a clinical trial application : selection of RMS and validation of the CTA	6
	Evaluate a clinical trial application : assessment and decision making	8
	Search, view and download a clinical trial and a clinical trial application	15
Session 3	Support with workload management	4
	Introduction to training with mock CTAs	NA
Session 4	Data protection in CTIS	12
	Supervise a clinical trial : corrective measures	14
	Supervise a clinical trial : ad hoc assessment	17
	Public Portal	22

CTIS – signed documents

For submissions in CTIS, signed CVs and signed Suitability Statements must be provided. As those documents generally have a handwritten signature, they will need to be redacted as the use of CTIS implies their publication.

Will the evaluating EC have access to the actual signed documents?

-> Yes, please see the following slides

CTIS – signed documents

Suitability of the facilities

Study1_BE_site suitability form_UZ Leuven_ORG-100006001_24-11-2021_redacted

English · Suitability of the clinical trial sites facilities (for publication) · **System version 1.00**
Submission date 06/12/2021
· **Version 1** · 01/12/2021

Study1_BE_site suitability form_UZ Leuven_ORG-100006001_24-11-2021

English · Suitability of the clinical trial sites facilities (not for publication) · **System version 1.00**
Submission date 06/12/2021
· **Version 1** · 01/12/2021

CTIS - signed documents

Suitability of the investigator

Investigator CV *:

Study1_BE_CV PI UZ Leuven_24-11-2021_redacted

English · Investigator CV (for publication) · **System version 1.00**
Submission date 06/12/2021
· **Version 1** · 01/12/2021

Study1_BE_CV PI UZ Leuven_24-11-2021

English · Investigator CV (not for publication) · **System version 1.00**
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Questions?