

Sandbox: preparation of CTR implementation at FAMHP

FAMHP

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Hans VINCKE

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Actions building up to the sandbox

Sandbox

Testing of the MS Organisation models in CTIS Sandbox

Future plans in CTIS Sandbox

Impressions CTIS Sandbox



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Actions building up to the sandbox

- CTIS Modular Training Programme Module 07 'Management of registered users and role matrix': user management principles, roles hierarchy, categories of permissions and roles, mapping permissions to roles → performing actions in CTIS
- Survey on MS Organisations that will have a role in CTIS: NCA's, Ethics Committees, other organisations, estimated number of users, organisation details for registration in OMS



Actions building up to the sandbox

- **Development of 'user personas' based on feedback gathered from Member State users: a description of typical user groups which can be used to decide which user roles within CTIS should be assigned to individuals**
- **Development of Member State Organisation models in a series of workshops organised from May to October based on survey results: assigning MS Admin role to an organisation, identifying business processes and the necessary role(s) for each organisation, identifying user groups and their respective role(s) within each organisation**



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- **Training environment, made available progressively to different groups of future CTIS users starting from 15 October 2021**
- **Assisting future CTIS users and their organisations in exploring user configuration and the steps needed to submit and authorise a clinical trial application, as well as to supervise a clinical trial after its authorisation until the submission of summary of results**



Sandbox

Phased rollout, structured in 3 waves:

- Wave 1 (15 October 2021): Member State Master Trainers and their related users
- Wave 2 (Mid-November 2021): Sponsor Master trainers and their related users (Batch 1), other sponsor representatives who need environment access for organisation planning and user training (Batch 2)
- Wave 3 (timing TBD): additional Member State and sponsor end-users on the basis of need and urgency
 - information captured through a survey providing self-assessment and expressing interest in sandbox access
 - respondents contacted directly by EMA in December 2021
 - survey may reopen in 2022



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Testing of the MS Organisation models in CTIS Sandbox

- Demo by EMA of the Belgian model in a workshop with all Member States following a script to handle clinical trial applications in the Sandbox
- Member States Master Trainers given access to Sandbox
 - Master Trainer within organisation with MS Admin account: 1 dummy Sponsor account, 1 MS Admin account, several blank accounts to configure, 1 MS API account
 - Master Trainer from other organisation: blank accounts to configure
 - Master Trainers asked to configure their MS Organisation model in the Sandbox making use of available accounts



Testing of the MS Organisation models in CTIS Sandbox

- Several testing workshops organised by EMA
 - 2-3 Member States per workshop (Belgium and Germany)
 - entire day of testing (18/11/2021)
 - involvement of both NCA en EC Master Trainers
 - EMA taking up the role of sponsor
 - application types prepared by EMA: initial applications (part I & II), substantial modifications (part I & II), addition of a Member State
 - evaluation phases: RMS selection, validation, assessment (part I & II), decision
 - multinational applications, RMS role alternating
 - work management tips given by EMA
 - second session planned in January



Testing of the MS Organisation models in CTIS Sandbox

- Testing on our own (NCA and EC Master Trainers) on Member State level, making use of dummy sponsor account
- Testing on fixed time slots on the request of Sponsor Master Trainers
 - 1 session with mononational applications and 1 session with multinational applications with colleagues from NL
 - demo of our MS Organisation model to R&D division colleagues
 - interesting because feels more real and natural than controlling the sponsor account yourself, allows to discover items from the Sponsor perspective



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Future plans in CTIS Sandbox

- Continuous requests from Sponsor Master Trainers to test in CTIS Sandbox
 - no more testing on fixed time slots because very time consuming
 - sponsors indicate desired scenario to be tested
 - applications handled during the week if feasible
- Dedicated training of FAMHP colleagues in January to put into practice the knowledge acquired during training modules and to get accustomed to our MS organisation model



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Impressions CTIS Sandbox

- **Very useful tool**
 - to test configuration of your organisation
 - to bring trainings more to life
 - to test workflow management, especially when going from one step to another if more or other people involved and how to keep the overview
 - to simulate a specific situation
- **Feels quite intuitive after making use of the training material delivered in the modular training program**



Contact

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A large, stylized graphic of a human eye in the background. The eye is composed of a light blue iris with a white pupil and a grey sclera. The eyelids are represented by grey, curved shapes at the top and bottom. A blue horizontal bar is positioned across the middle of the eye, containing the text.

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our concern