CTIS: state of play

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EMA strategy to prepare future users of CTIS, including academic sponsors

FAMHP

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Hans VINCKE

famhp
federal agency for medicines and health products

.be

CTIS: state of play

- **Go-live on 31 January 2022, delivery of CTIS on track**
- **Current focus on bug-fixing in order to have a stable system at go-live**
- **EMA close to finalising 2022 plan**
- **EMA close to finalising communication strategy**
- **Member States asked to deliver national public holidays to allow for calculation of timetables**

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Newsletter CTIS highlights key in staying up-to-date (Issue 5 on 18/10/2021, Issue 6 on 13/12/2021)

CTIS information events:

- **CTIS virtual information day (26/10/2021)**
  - → presentations on CTR and on preparing for CTIS from perspective of future CTIS users
  - → short demo of CTIS Sponsor and Authority Workspaces
  - → video recording made available
- **Webinar for SMEs & academia on CTR and CTIS (29/11/2021)**
  - → SMEs registered with EMA & academia contact points
  - → video recordings made available on EMA website and youtube channel

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Training environment (CTIS Sandbox)

CTIS Training and support webpages:

- **New training and support page summarising activities ongoing under CTIS training and support programme and containing key reference documents supporting preparation for future use of CTIS such as Sponsor Handbook**
- **Dedicated online modular training programme page to provide easy access to CTIS online training modules for users**
- **Update of Clinical Trials Regulation page planned in Q4 2021 to ensure it includes most relevant information as go-live approaches**
- **Creation of a dedicated page on CTIS planned, giving an overview of the system**

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SME & academia support:

- **Module 19 of online modular training programme 'CTIS for SMEs and academia' published**

  → quick guide (short introduction to CTIS) and a series of step-by-step guides describing CTIS processes in a simple and concise way (User access management and user administration; CTIS workload functionalities for the sponsor workspace; Search, view and download a CT and a CTA in the sponsor workspace; Create, submit and withdraw a clinical trial application and nonsubstantial modifications; Create and submit an RFI response, including changes to an existing application; How to manage a clinical trial; Submit an ASR and how to respond to related RFIs)

  → training on this module to Member State Master Trainers
  → central in SME & academia webinar on 29/11/2021

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Events on related EMA systems:

- **Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities webinar (21/10/2021)**
  - → **targeted at industry users**
  - → **recording to be made available**
- **Extended EudraVigilance medicinal product dictionary (XEVMPD) training (08/11/2021 & 14/12/2021)**
  - → **organised in liaison with DIA**
  - → **focus on how to use XEVMPD in accordance with the CT-3 detailed guideline on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use**
  - → **importance of XEVMPD to support submission of clinical trial information in CTIS**
  - → **information on past and coming events**

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Events on related EMA systems:

- **EudraVigilance & Signal Management Virtual Information Day (24/11/2021)**

  → update on some key elements and activities that will impact EudraVigilance and its stakeholders in the coming years

  → information on the impact of CTR on safety reporting and discuss new Annual Safety Report (ASR) submission processes in CTIS

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CTIS user personas:

- **Assist organisations and individuals who will use CTIS in future**
- **Visual models describing different types of users in CTIS**
- **Define who will do what in CTIS in different kinds of organisations, including sponsor and Member State organisations**
- **Show the possible CTIS user roles each Persona may be given to perform their tasks in CTIS**
- **Sponsor user personas and Member State user personas**

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Principles for sponsor organisation modelling for CTIS:

- First version published
- Document to assist sponsors in their preparations for CTIS go-live
- To outline some examples of how sponsors can manage CTIS access, responsibilities and user roles for different types of clinical trials and in different organisational environments
- Types of trials covered include simple arrangements where sponsors work with a small number of CROs, to more complex co-sponsorship arrangements (academic trial type also included)

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Registration reminder to sponsors by EMA:

- **Registrations open for CTIS Sponsor Administrators**
- **Users reminded preparatory steps to be taken before it is possible to use CTIS**
- **All users without EMA account to register for EMA account**
- **Registration of organisation in OMS (if not yet done) by visiting OMS webpage**

  → EMA account with SPOR user role required to register an organisation in OMS
- **Sponsors opting for the organisation-centric approach to register their first Sponsor Admin in EMA Account Management**

  → requestor to upload completed and signed copy of 'Affiliation Template Letter' as proof of the authority to represent that organisation

  → if no document attached while requesting the role, request to be denied by the system

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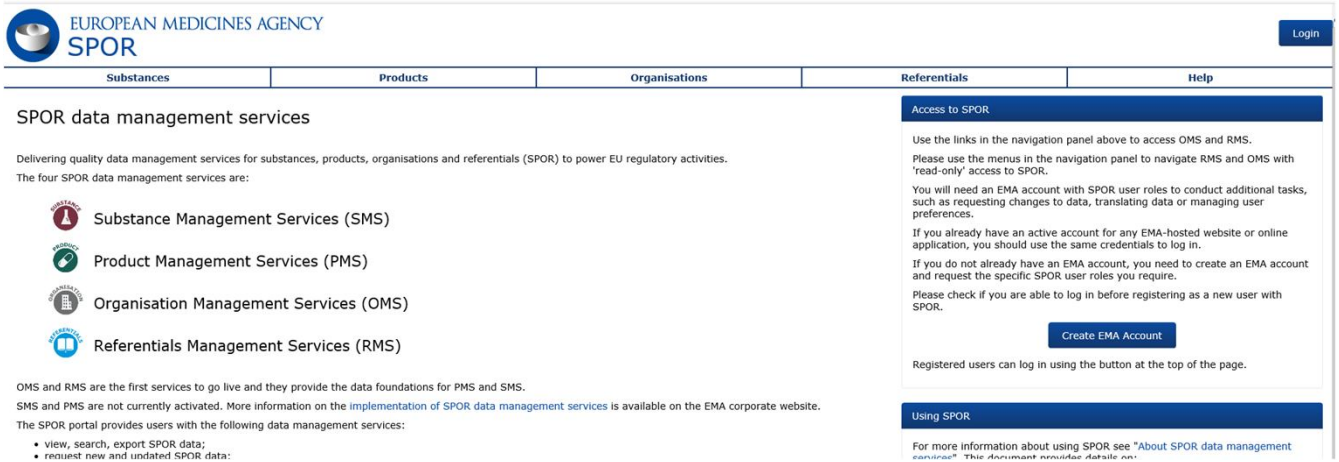
Registration of an organisation in OMS:

- **If organisation already registered in OMS, not needed to complete this step**
- **If organisation not registered in OMS yet, sponsors need to go to the EMA's Substance, product, organisation and referential (SPOR) portal and log in with their EMA account: https://spor.ema.europa.eu/sporwi/**



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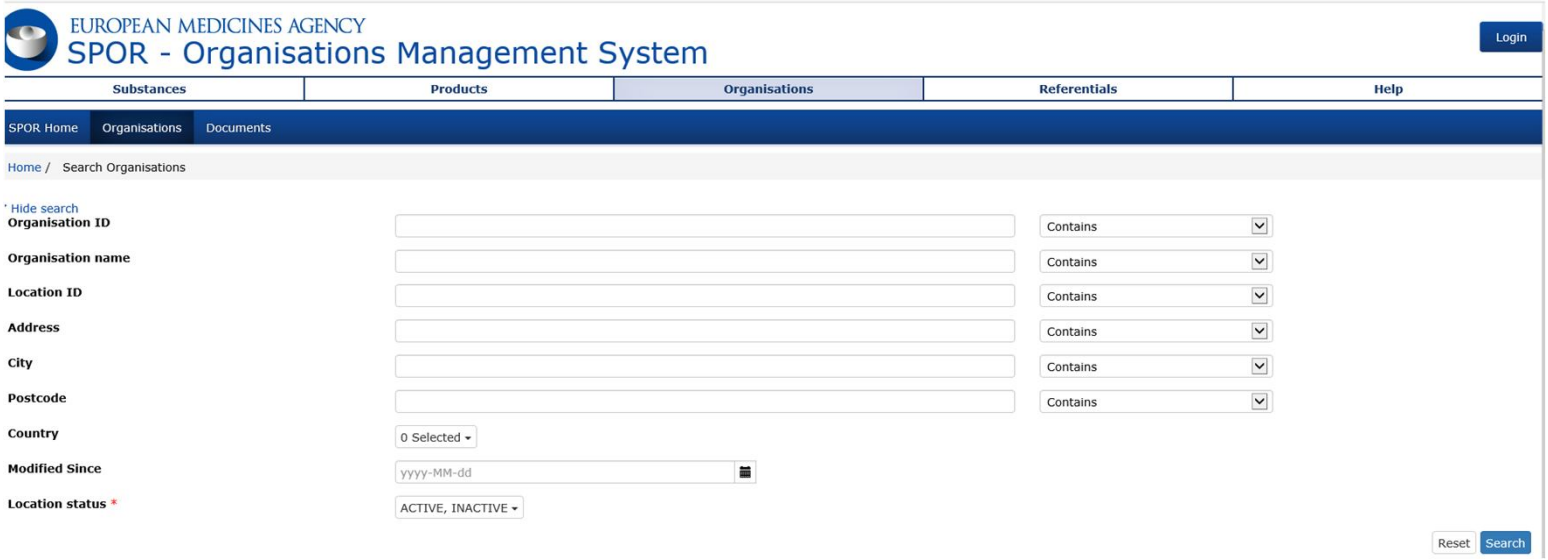
Registration of an organisation in OMS:

- **Before submitting a request to register an organisation via OMS, user must search the available records for their organisation by clicking on the Organisations tab**



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Registration of an organisation in OMS:

- **if organisation cannot be found by name and country, creation of a new organisation to be requested from the search page or from the View Organisation / Location Details page (supporting documents to be submitted allowing EMA Data Stewards to validate the request)**

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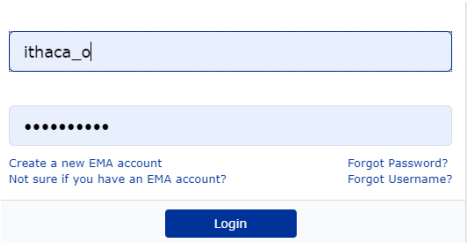
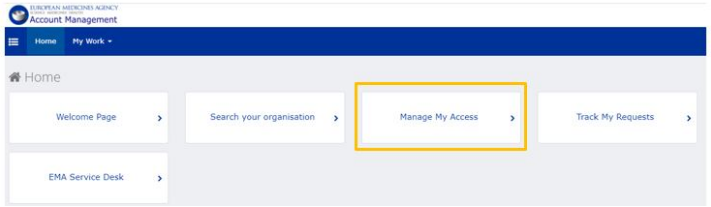
Sponsor Admin registration (register through the EMA Account Management Portal dashboard and wait for EMA approval after submitting the request):

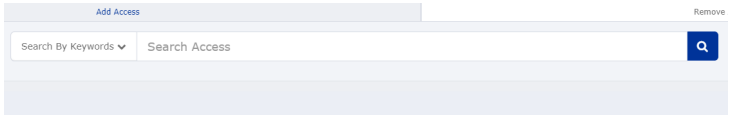
1. Log in to EMA Account Management



2. Click on “Manage My Access”



3. Search to find the “Sponsor Administrator” role, Use “CTIS” as a keyword



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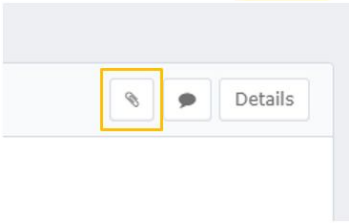
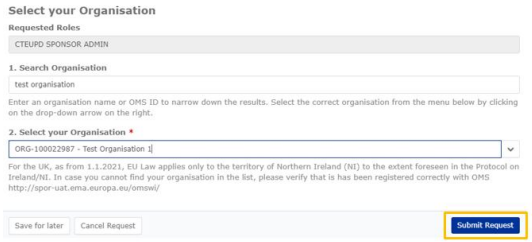
Sponsor Admin registration (register through the EMA Account Management Portal dashboard and wait for EMA approval after submitting the request):

4. Select the “Sponsor Administrator” role and click on “Next” button

5. Attach the affiliation letter and click “Submit”



6. Search functionality to find the sponsor organization, click on the “Submit Request” button



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Organisation-Centric approach vs CT-Centric approach:

- **If a user creates a new CTA for a sponsor organisation that does not have a registered sponsor administrator, that user will become the CT admin of that specific trial (CT-Centric approach)**

- **If a user tries to create a CTA for an organisation that has a Sponsor Admin, the user must first be assigned specific roles by the Sponsor Admin (Organisation-Centric approach)**

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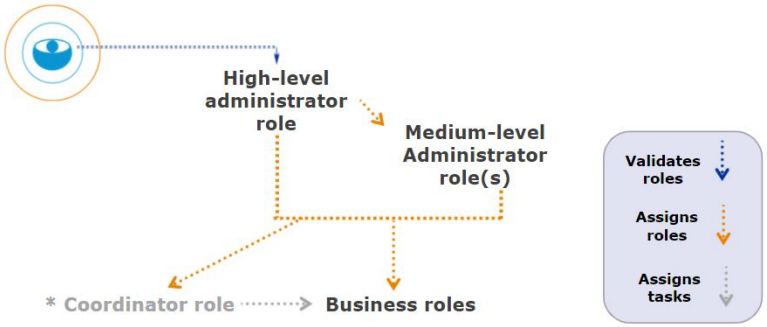
Organisation-Centric approach:

- **High-level administrator (sponsor Admin) validated by EMA required**
- **When roles and permissions assigned by the Admin to a user, that user becomes affiliated to the organisation of the high-level administrator**
- **Users need to be assigned a role by the administrator to perform any action**
- **Intended to serve the needs of big organisations, as it allows to manage a large number of users, CTAs and/or CTs**



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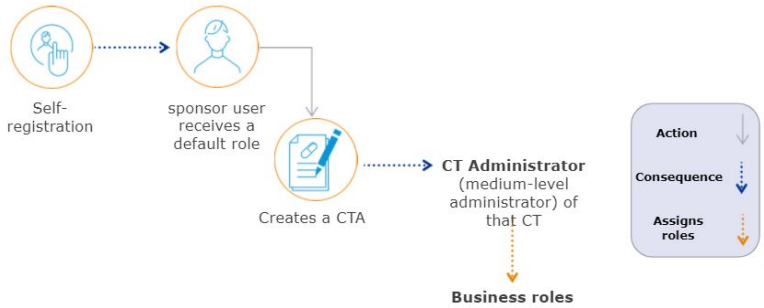
CT-Centric approach:

- **No sponsor Admin validated by EMA required**
- **Users directly become the CT Admin of a CT by creating a CTA without intermediate steps and role assignment**
- **Management of business roles to other users by the CT Admin is done at trial level**
- **Intended to serve the needs of small organisations, and especially non-commercial sponsors, as it allows to manage a smaller number of users, CTAs and/or CTs**



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Structured data fields guidance:

- **Guidance published on data fields clinical trial sponsors need to fill in CTIS when submitting a clinical trial application and managing a clinical trial**
- **3 excel files (Initial application, additional Member State Concerned, substantial modification, non-substantial modification; Multi trial substantial modification; Notifications)**

  → details on type of data to be entered in each field (text, numeric, radio button, document upload)

  → whether fields are mandatory, optional, conditionally required or read only

  → accepted document upload formats for document upload fields

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Sponsor handbook:

- **First version published end of July**
- **Key document for sponsors including a compilation of guidance, technical information and references to assist sponsors in preparing for and using CTIS**
- **Second version published on 02/12/2021**

  → updates to the sections on the OMS registration process, product management in CTIS, the transition from the Clinical Trials Directive to the Clinical Trials Regulation and SUSAR reporting, and the addition of new sections on data fields and document specifications and the training environment

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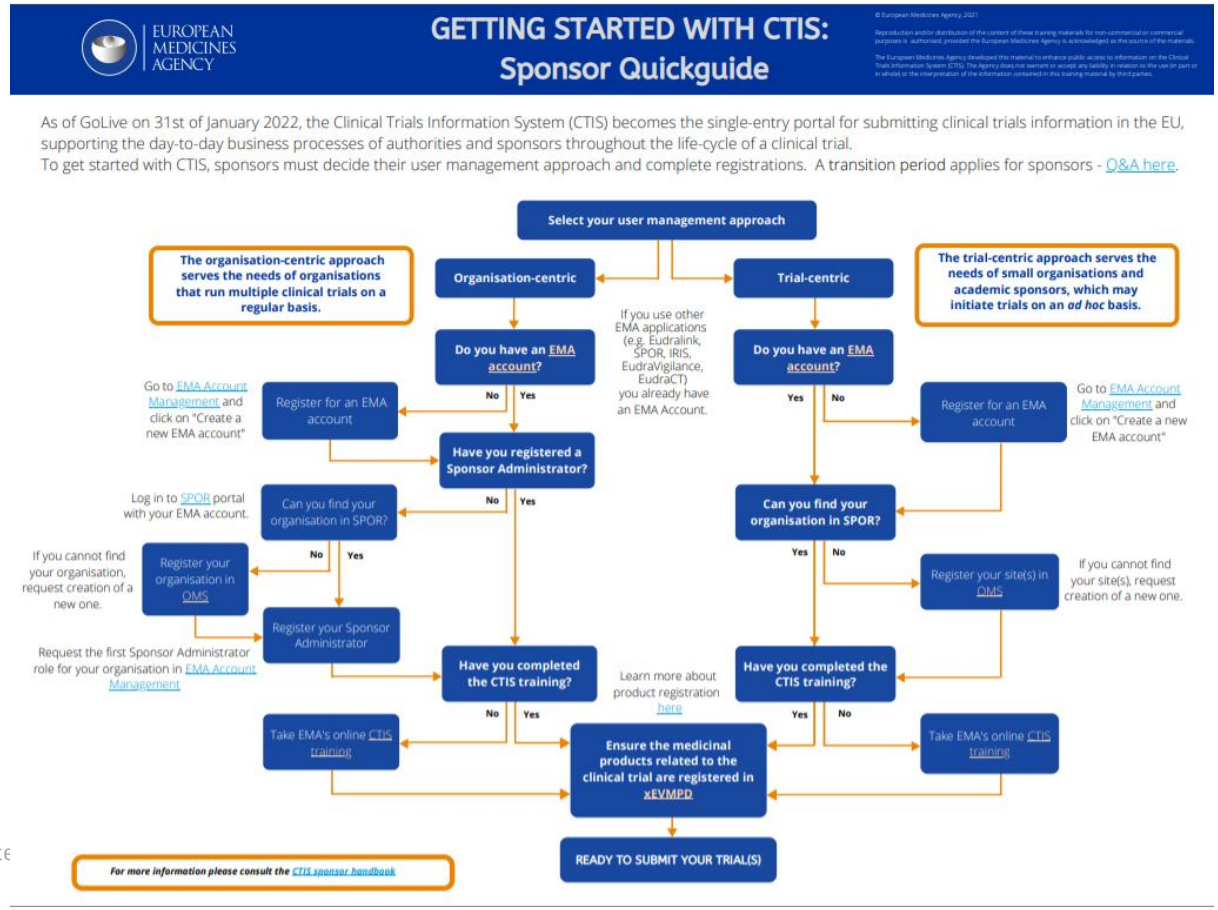
Sponsor quick guide:

- One-pager quickguide for sponsors on getting started with CTIS



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Clinical trials site registration in OMS:

- Clinical trials sites routinely participating in clinical trials advised to register in OMS to facilitate submission of clinical trial applications
- Less relevant for those sites participating in clinical trials only once or very infrequently

XEVMPD guidance on registration of IMPs:

- How to register investigational medicinal products (IMPs) in the Extended EudraVigilance medicinal product dictionary (XEVMPD) for clinical trial sponsors
- IMP must be registered in XEVMPD before clinical trial sponsors can complete a clinical trial application in CTIS
- New webpage created to outline the steps needed to register an IMP in XEVMPD, including detailed guidance documents

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Training material:

- **22 training modules available on CTIS online modular training programme page**
  - **→ Modules 21 'Union Controls in CTIS' and 22 'Introduction to CTIS for public users' added last**
  - **→ More modules under development (transition of clinical trials from Directive to Regulation)**

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Training material:

- **Existing online training modules undergoing revision**

  → creation of new materials to describe specific processes in further detail (Quick guide (OMS) in module 3 explaining how to use OMS when searching an organisation, creating a new organisation or updating an existing organisation)

  → update of existing materials to match current system functionalities

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Training material:

- **New sponsor content in early 2022**
  - **→ how to populate authorised and unauthorised products in clinical trial applications as part of Module 10 (Create, submit and withdraw a clinical trial)**
  - **→ how to submit notifications as part of Module 5 (Manage a clinical trial through CTIS)**

- **New authorities content in early 2022**
  - **→ how to evaluate substantial modifications and additional Member State Concerned (MSC) applications**

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CTIS events 2022:

- **EMA plans to host regular 'CTIS talks'**
  - **→ to include short presentation about a key CTIS functionality area, e.g. user management, initial applications, modifications**
  - **→ provide an opportunity for users to ask questions about this functionality area to CTIS experts**
  - **→ details of CTIS Talks to be provided on EMA events listing**

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Sponsor end user training:

- **Planning of limited number of sponsor end user training courses starting 2022**
- **Focus on explaining and demonstrating CTIS functionalities related to the use of CTIS by sponsors**
- **More information to be published on EMA and DIA websites**

Contact

Federal Agency for Medicines and Health Products – FAMHP

Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS

tel. + 32 2 528 40 00
fax + 32 2 528 40 01
e-mail welcome@fagg-afmps.be

www.famhp.be

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