EMA
EUROPEAN MEDICINES AGENCY

Change of sponsor in CTIS

CTIS Bitesize Talk

5 March 2025

A few housekeeping rules

Questions were collected in advance on
www.sli.do
With event code **#bt5mar**

Tips for optimal screen viewing

- Make use of the instructions under the **Live broadcast** section on the event page and connect directly to the **EMA's Vimeo channel 1** *for the full-screen experience*
- Have a stable internet connection

Agenda

- Useful information about publication of events
- Change of Sponsor (via SM)
- Update of Sponsor details (via non-SM)
- Useful Publications
- CTCG Guide for Change of Trial Sponsor
- Q&A

The experts for this event are:

Moderator: Maria Teresa Calandri

Ornela Ademi
Change Manager

Drosos Charalampos
CTIS Business Process Officer

Marianne Lunzer
CTCG Chair

Laura Lavín de Juan
Head of Service of Clinical Trails Division

Lydia Itúrbide Picazo
Technical Consultant of Clinical Trials Division

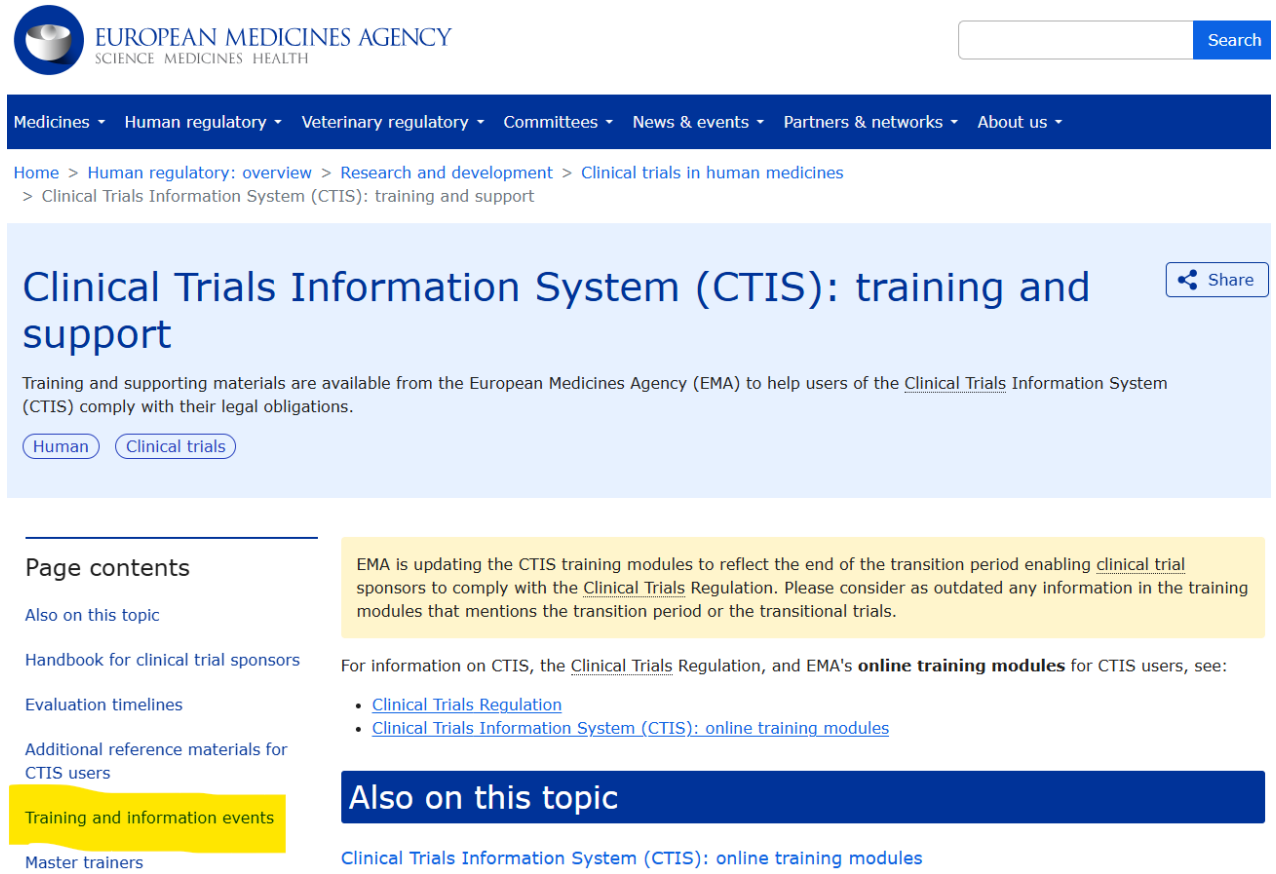
Post event materials

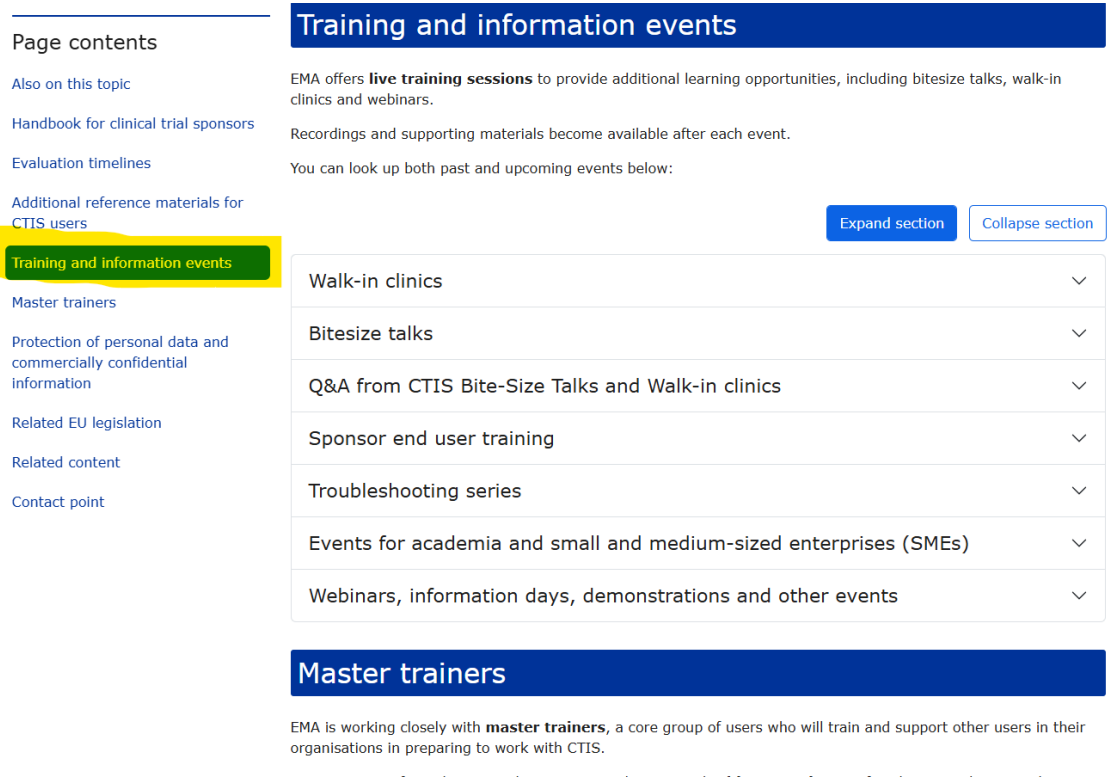
CTIS Bitesize talk

Presented by Ademi Ornela

Where to find post event material?

[Clinical Trials Information System (CTIS): training and support | European Medicines Agency (EMA)](#)





CTIS Walk in clinics

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Training and information events

EMA offers **live training sessions** to provide additional learning opportunities, including bitesize talks, walk-in clinics and webinars.

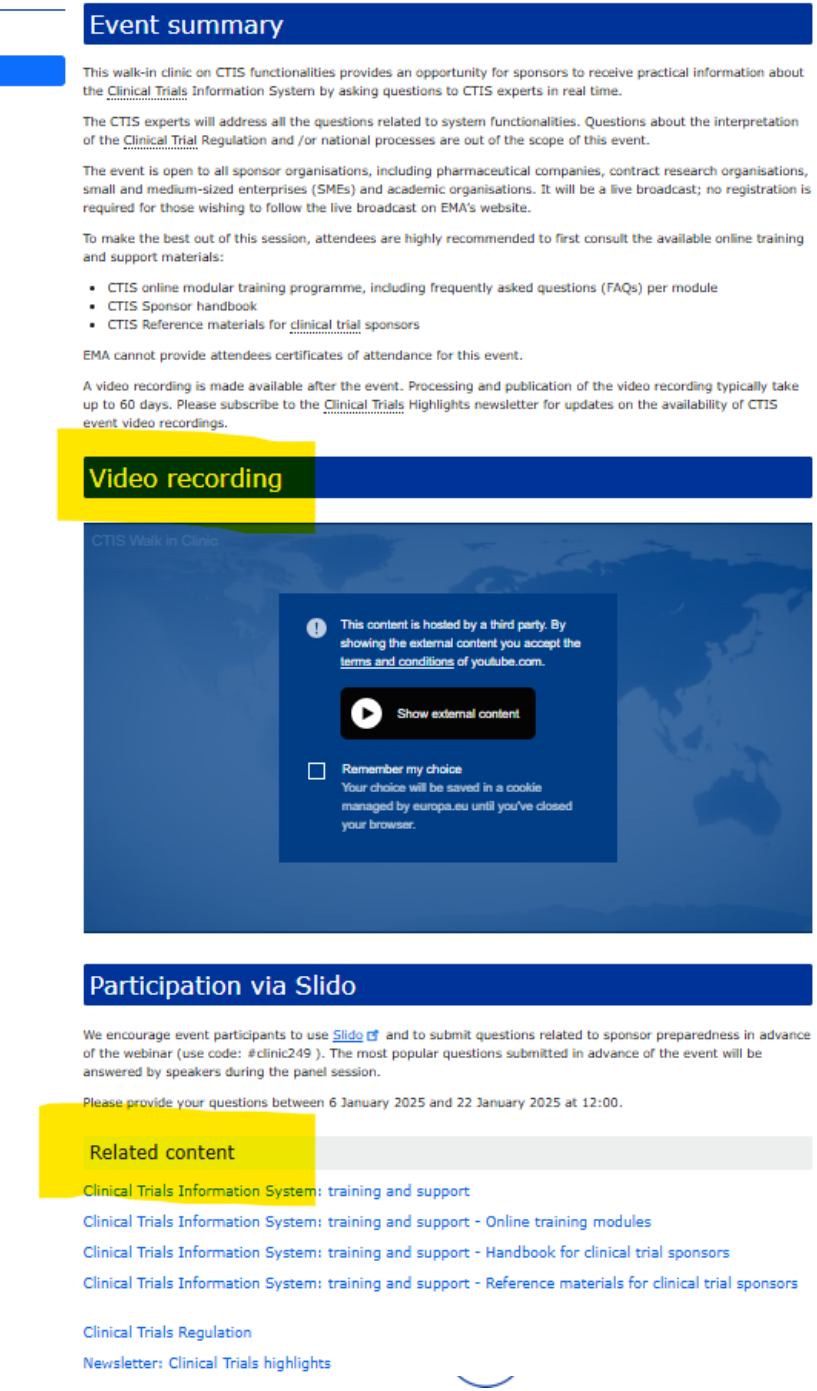
Recordings and supporting materials become available after each event.

You can look up both past and upcoming events below:

Expand section | Collapse section

Walk-in clinics

- Clinical Trials Information System (CTIS): Walk-in clinic - January 2025 (29/01/2025)
- Clinical Trials Information System (CTIS): Walk-in clinic - November 2024 (20/11/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - September 2024 (18/09/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - July 2024 (10/07/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - May 2024 (15/05/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - March 2024 (12/03/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - January 2024 (24/01/2024)
- Clinical Trials Information System (CTIS): Walk-in clinic - December 2023 (13/12/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - November 2023 (15/11/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - October 2023 (10/10/2023) - Cancelled
- Clinical Trials Information System (CTIS): Walk-in clinic - September 2023 (20/09/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - August 2023 (23/08/2023) - Cancelled
- Clinical Trials Information System (CTIS): Walk-in clinic - July 2023 (19/07/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - June 2023 (14/06/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - May 2023 (17/05/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - April 2023 (19/04/2023)
- Clinical Trials Information System (CTIS): Walk-in clinic - March 2023 (16/03/2023)



Page contents

Event summary

Video recording

Participation via Slido

Related content

Event summary

This walk-in clinic on CTIS functionalities provides an opportunity for sponsors to receive practical information about the Clinical Trials Information System by asking questions to CTIS experts in real time.

The CTIS experts will address all the questions related to system functionalities. Questions about the interpretation of the Clinical Trial Regulation and /or national processes are out of the scope of this event.

The event is open to all sponsor organisations, including pharmaceutical companies, contract research organisations, small and medium-sized enterprises (SMEs) and academic organisations. It will be a live broadcast; no registration is required for those wishing to follow the live broadcast on EMA's website.

To make the best out of this session, attendees are highly recommended to first consult the available online training and support materials:

- CTIS online modular training programme, including frequently asked questions (FAQs) per module
- CTIS Sponsor handbook
- CTIS Reference materials for clinical trial sponsors

EMA cannot provide attendees certificates of attendance for this event.

A video recording is made available after the event. Processing and publication of the video recording typically take up to 60 days. Please subscribe to the Clinical Trials Highlights newsletter for updates on the availability of CTIS event video recordings.

Video recording

CTIS Walk in Clinic

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Remember my choice

Your choice will be saved in a cookie managed by europa.eu until you've closed your browser.

Participation via Slido

We encourage event participants to use Slido and to submit questions related to sponsor preparedness in advance of the webinar (use code: #clinic249). The most popular questions submitted in advance of the event will be answered by speakers during the panel session.

Please provide your questions between 6 January 2025 and 22 January 2025 at 12:00.

Related content

Clinical Trials Information System: training and support

Clinical Trials Information System: training and support - Online training modules

Clinical Trials Information System: training and support - Handbook for clinical trial sponsors

Clinical Trials Information System: training and support - Reference materials for clinical trial sponsors

Clinical Trials Regulation

Newsletter: Clinical Trials highlights

CTIS Bitesize talks

Page contents

- Also on this topic
- Handbook for clinical trial sponsors
- Evaluation timelines
- Additional reference materials for CTIS users
- Training and information events
- Master trainers
- Protection of personal data and commercially confidential information
- Related EU legislation
- Related content
- Contact point

- Clinical Trials Information System (CTIS): Walk-in clinic - June 2022 (15/06/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic (02/06/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic - May 2022 (19/05/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic - 5 May 2022 (05/05/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic - April 2022 (22/04/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic (04/04/2022)
- Clinical Trials Information System (CTIS): Walk-in clinic - March 2022 (28/03/2022)

Bitesize talks

Clinical Trials Information System (CTIS) bitesize talk: Change of sponsor in CTIS (05/03/2025)

Clinical Trials Information System (CTIS) bitesize talk: End of transition period and notifications including serious breach (16/10/2024)

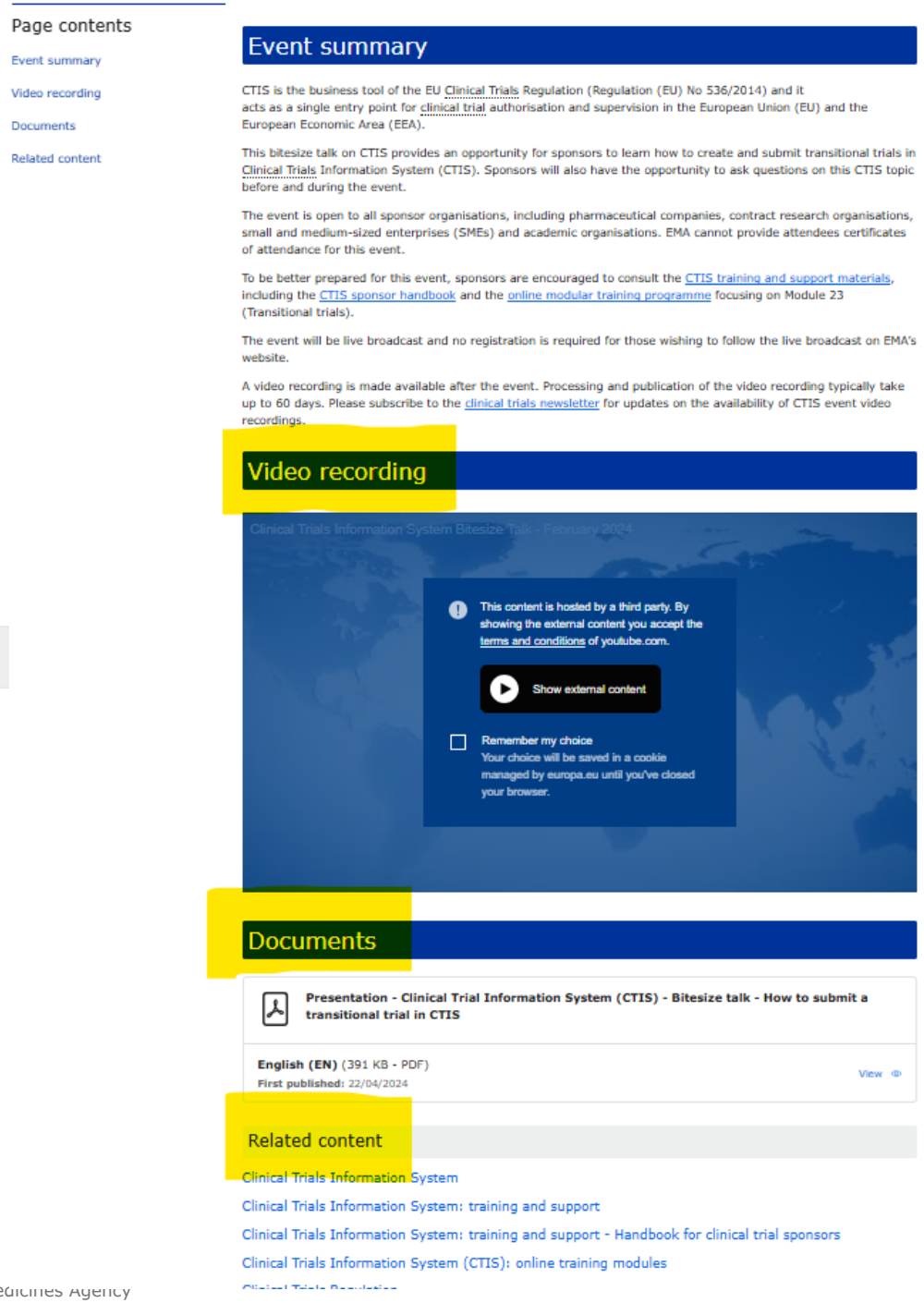
Clinical Trials Information System (CTIS) bitesize talk: Revised transparency rules and the new CTIS public portal (20/06/2024)

CTIS Bitesize Talk: Alternate IMPD-Q and new guidance AxMP (24/04/2024)

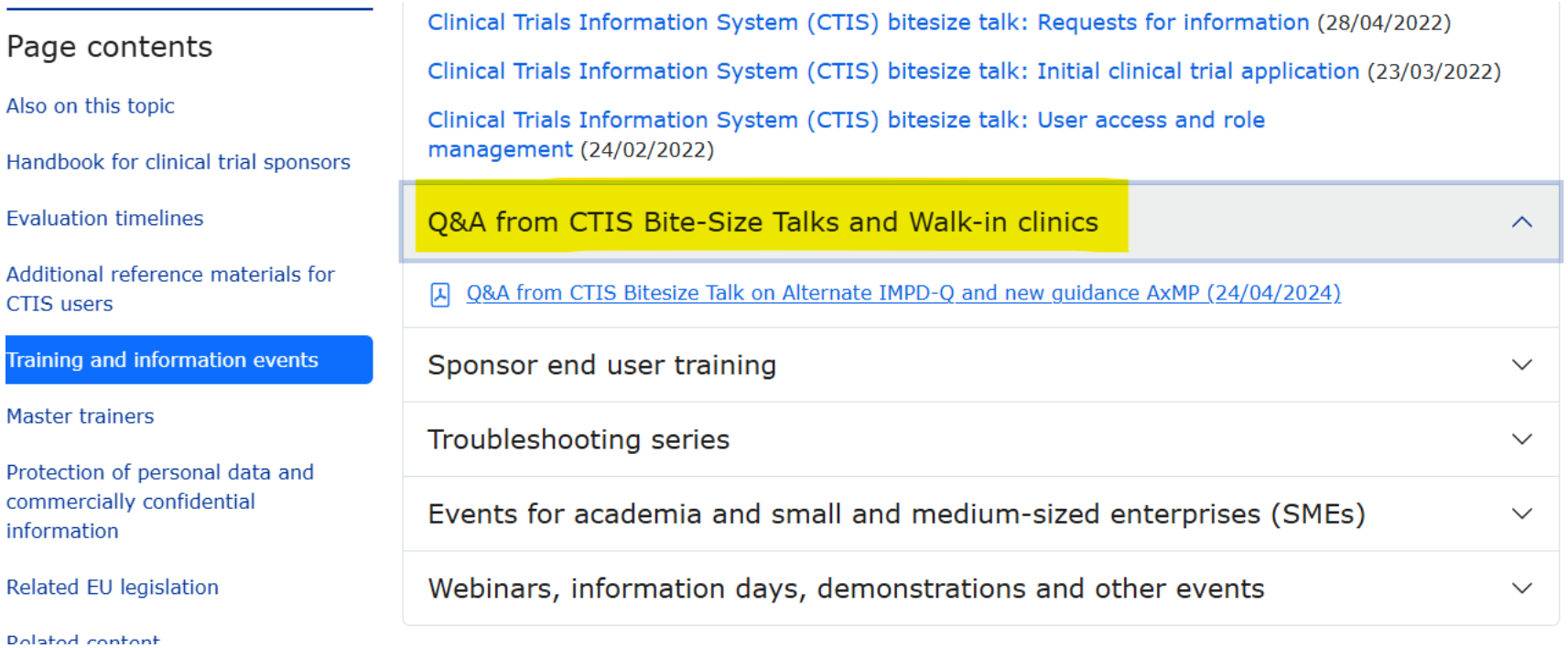
Clinical Trials Information System (CTIS) bitesize talk: How to submit a transitional trial in CTIS (29/02/2024)

Clinical Trials Information System (CTIS) bitesize talk: Training materials, CTIS pre-requisites, and updates on transparency rules (29/11/2023)

Clinical Trials Information System (CTIS) bitesize talk: Part I-only applications and Part II requirements in CTIS (30/08/2023)



Q&A



Revision and redesign of the CTIS/CTR training ongoing

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SCIENCE MEDICINES HEALTH

Thank you

Ornela.ademi@ema.europa.eu

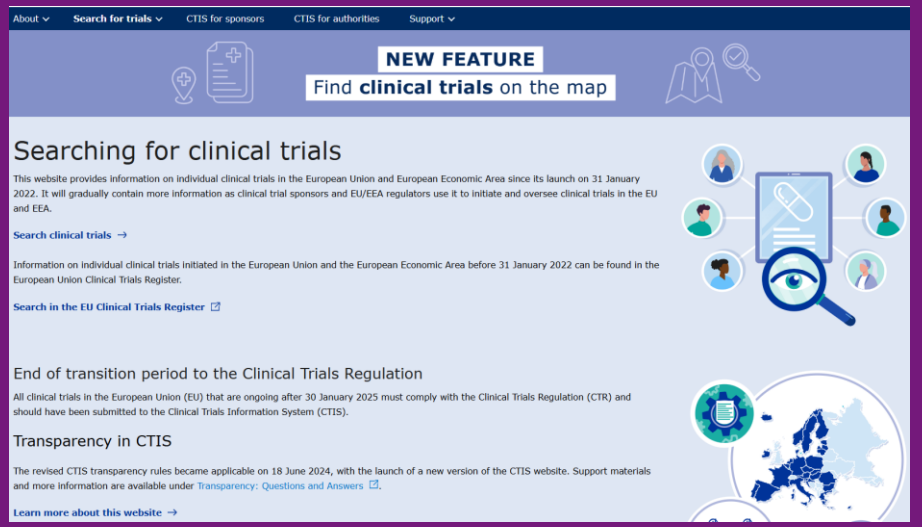
Follow us

Change of Sponsor in CTIS

CTIS Bitesize talk

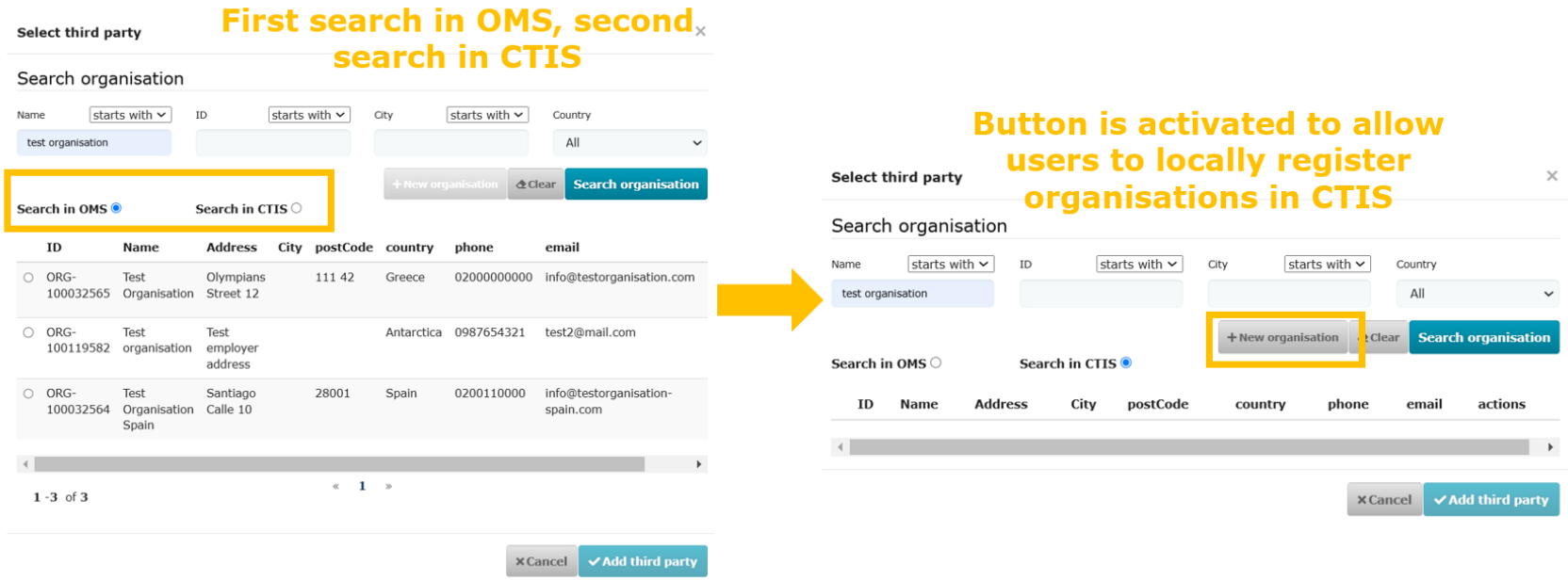
Presented by Drosos Charalampos

CTIS Homepage
https://euclinicaltrials.eu/



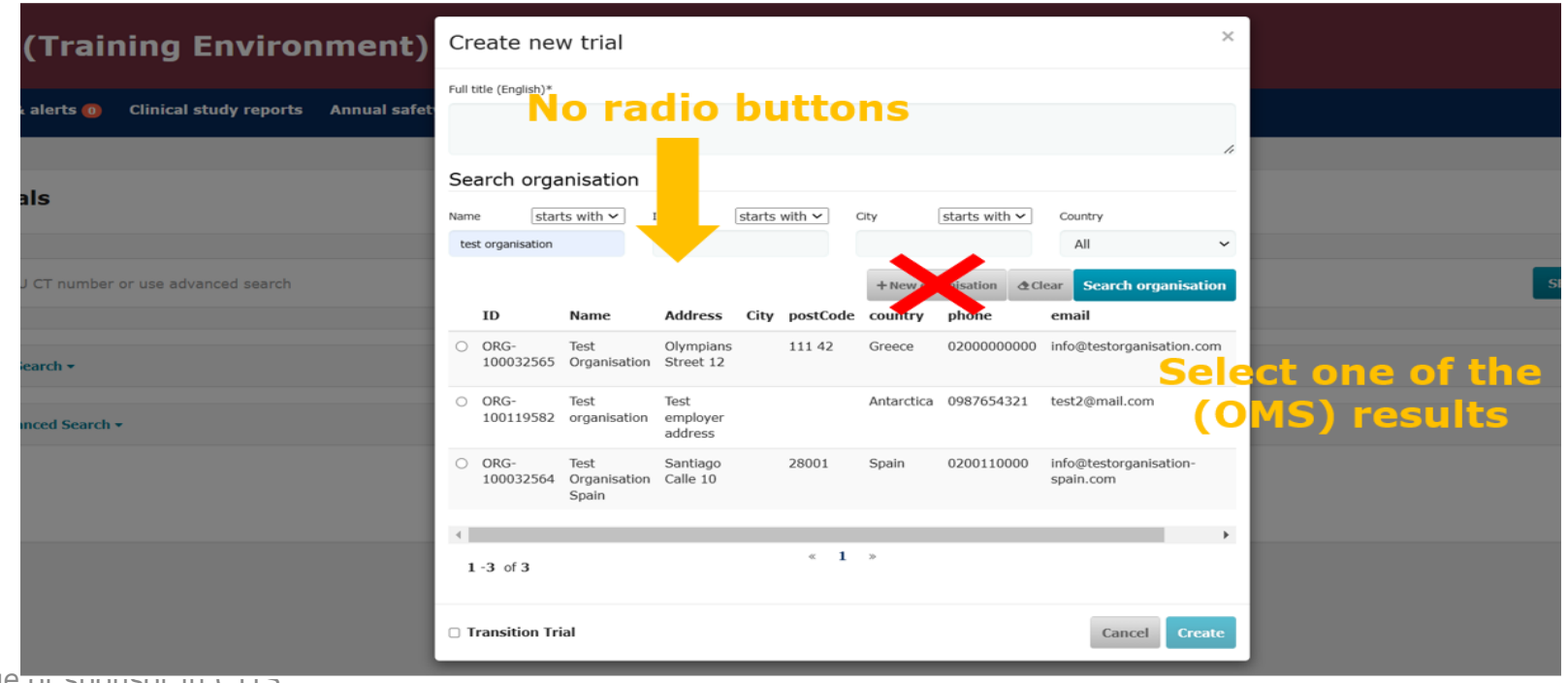
Introduction (1)

- In CTIS, users need to populate organisation related data in different sections. The search functionality, by default, retrieves data maintained in OMS.
- For certain areas (listed below), if users cannot find the desired organisation among the (OMS) results, they can use the respective radio button, to search for organisations locally registered in CTIS. If the desired organisation cannot be found among the results of the second search, users can use the activated 'Add organisation' button, to locally register their organisation in CTIS.
  - Part I Sponsor section – Third party organisations
  - Part II – Trial sites
  - Serious Breach Notifications – Details of the site where the serious breach occurred
  - Third Country Inspectorate Inspection – Third country inspection site
  - MS Inspections – Inspected site



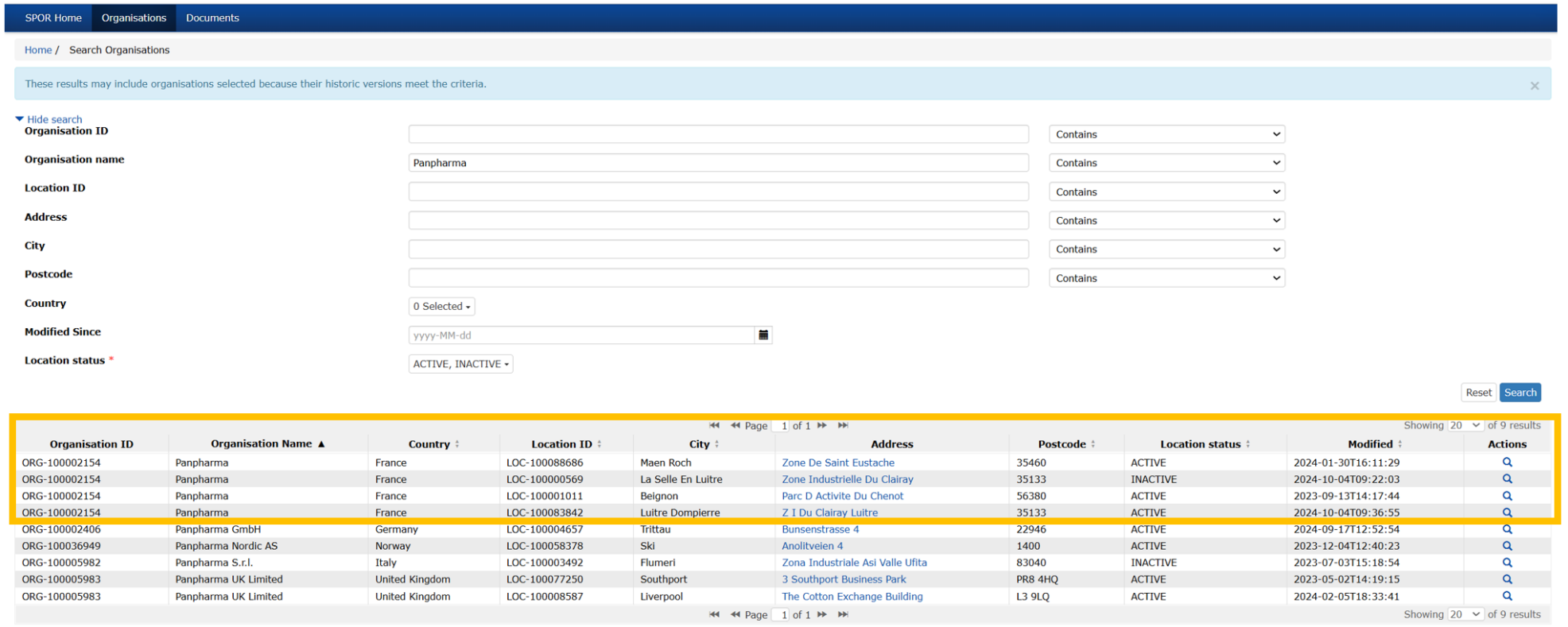
Introduction (2)

- In other working areas (not listed in the previous slide), such as the one that users populate the **Sponsor organisation of a trial**, the radio buttons do not exist. Search retrieves data only from OMS.
- While creating a trial, user needs to select a sponsor organisation (**cannot** be edited during the evaluation of the initial application). Sponsor organisation needs to be selected from the search results (which are retrieved from OMS).
- If users cannot find the desired sponsor organisation among the results of the first (OMS) search (no radio buttons in the search functionality), they **are strongly encouraged to register their organisation in OMS** before the creation of an initial application in CTIS. After the approval of the registration request in OMS, users need to wait up to one day until the organisation is retrievable in CTIS.
- Users are encouraged **NOT to use** the 'Add organisation' button to add the sponsor organisation in their trial.



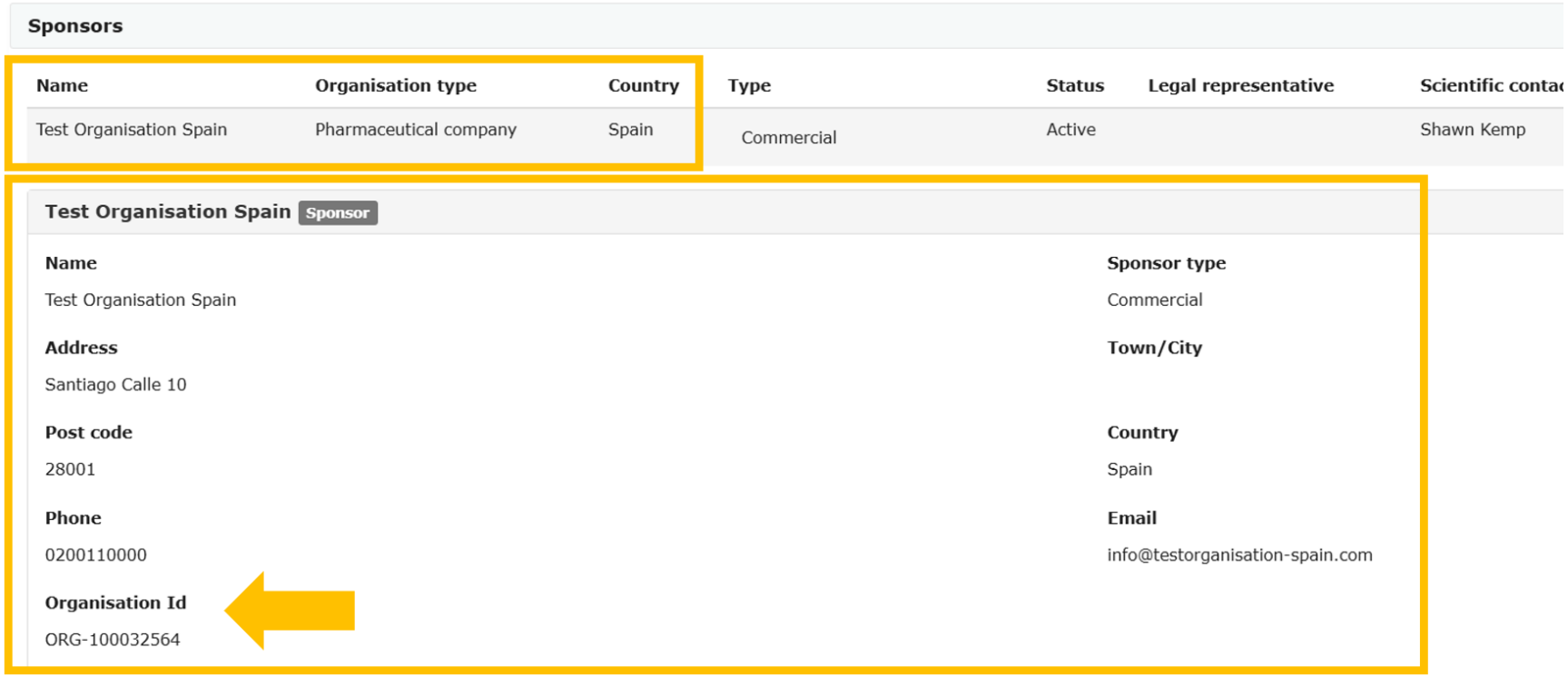
Introduction (3)

- Any organisation successfully registered in OMS has been assigned an ID, the org-ID. Under the org-ID, an organisation might have multiple locations (different branches). Each one of them is assigned a loc-ID.
- In the example below, under the first org-ID, there are four loc-IDs, with different addresses. The three **active** ones will be retrieved in CTIS, after performing the relevant search and one of them can be selected to be the sponsor of the trial.



Introduction (4)

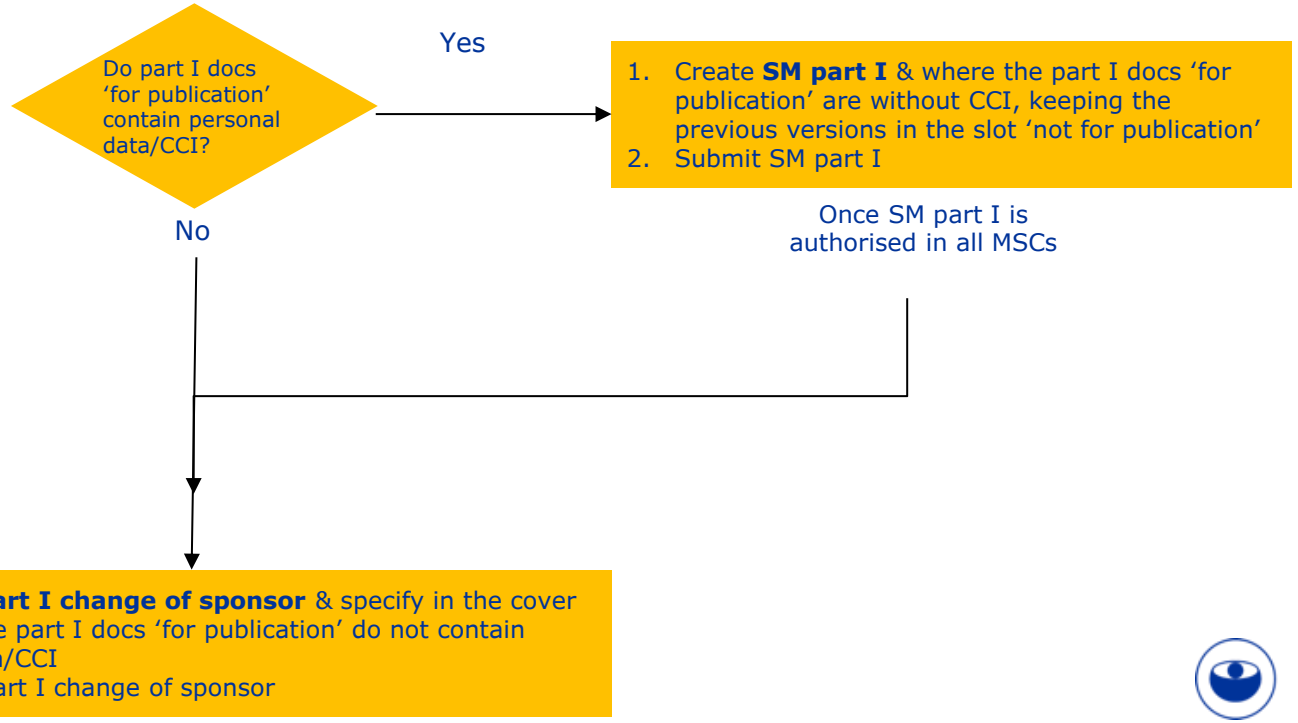
- The selected sponsor data cannot change during the evaluation of the initial application (i.e. with an RFI response).
- After the full authorisation of the initial application **by all MSCs**, and if needed, sponsor user can submit changes on the sponsor.
  - Change on the sponsor and the selected org-ID (change of ownership, acquisition, take-overs from different legal entities). Sponsor notifies authorities of change of sponsor (org-ID) via an SM (Part I – Change of Sponsor type).
  - Change on sponsor details, but not on org-ID (change on the selected location, change of address, change of contact details, or contact points). Sponsor notifies authorities of change of sponsor details via a non-SM (that regards part I).
- Before submitting the changes in CTIS, make sure that those are **already validated in OMS**. Updated data (either new org-ID or new loc-ID) will be retrieved from OMS too.



Change of Sponsor org-ID via SM (1)

- After the authorisation of the initial application by all MSCs, sponsor users submit changes on sponsor org-ID, to transfer the ownership to a different legal entity.
- Such a change can be submitted with a specific type of SM "SM Part I – Change of sponsor".
- Change is in implemented in CTIS only after **all MSCs** authorise this SM.
- **Attention:** Authorisation of that SM type comprises a publication trigger event for Part I documents. Considering the publication rules regarding historical trials, users need to make sure that their relevant dossier parts are fully redacted, before submitting the SM.

For a trial submitted to CTIS before 18 June 2024:



Change of Sponsor org-ID via SM (2)

- **Attention**: Users should not proceed with SM draft/submission if there are pending Requests for Information (RFIs) for Annual Safety Reports (ASRs), Ad hoc assessments, Corrective measures or if there are ongoing evaluations for ASRs or other applications.
- **Attention**: Users should not have any drafts of ASR, application or non-SM during this process.
- Warning messages will appear during the SM creation and submission that need to be considered by users.
- In contrast to other types of SMs, the 'SM Part I – Change of Sponsor' has very limited and pre-defined scope. Only very specific structured data fields and document placeholder can be updated.

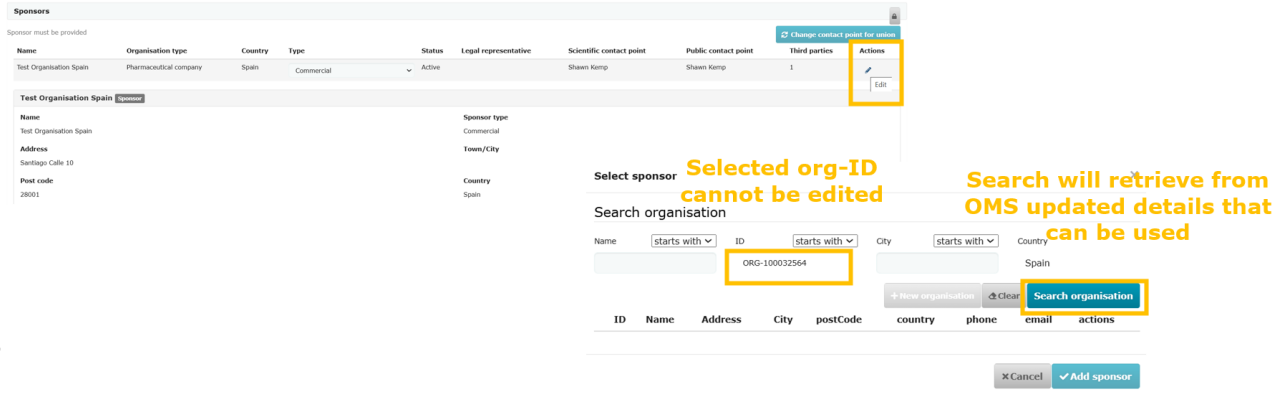
1. FORM page: certain sections have padlock and are editable: 'SM details' and 'proof of payment fee'.
   - Document placeholders: 'Cover letter', 'Modification description', 'Supporting information documents', 'Proof of payment of fee'
   - Structured data: 'Supporting information'
   - The fields 'SM reason' and 'scope' have been pre-populated and cannot be modified
2. Part I page: 'Sponsor' section has a padlock and can be edited: All the structured data fields in this section can be modified, including those dedicated to contact points.

Change of Sponsor org-ID via SM (3)

- Any role with scope for the specific trial (subjected to change of sponsor org-ID) under the old org-ID will remain active during the SM assessment. Those roles will be automatically revoked once the SM is fully authorised (by **all** MSCs).
- Users of the new sponsor will be able to assess the trial only if they are given roles associated to the new sponsor org-ID.
- The (sponsor) Administrator of the new sponsor can assign roles with scope ‘All trials’ before (recommended) or after the SM Part I – Change of Sponsor.
- New sponsor admin can assign roles with scope ‘Specific trial’ (under the new sponsor) to users only after the full authorisation (by all MSCs) of the SM Part I – Change of Sponsor.
- If the new sponsor organisation follows **the CT-centric approach** (no Sponsor Admin has been assigned), the CT Admin role under the new sponsor org-ID will be assigned by EMA. A CT Admin of the trial under the prior sponsor needs to raise a ticket to User Service Desk and ask the CT Admin role assignment to a user of the new sponsor.

Update of Sponsor details via non-SM

- After the authorisation of the initial application by all MSCs, sponsor users can submit changes on sponsor details (not to org-ID).
- Such a change can be submitted with a non-SM that affects Part I (non-SM Part I and non-SM Part I & II). Change is implemented in CTIS after the submission of the non-SM.
- **Attention:** Submission of a non-SM Part I comprises a publication trigger event for Part I documents. Considering the publication rules regarding historical trials, users need to make sure that their relevant dossier parts are fully redacted, before submitting the SM.
- **Attention**: Users should not proceed with non-SM draft/submission if there are pending Requests for Information (RFIs) for Annual Safety Reports (ASRs), Ad hoc assessments, Corrective measures or if there are ongoing evaluations for ASRs or other applications.
- **Attention**: Users should not have any draft of ASR, application or non-SM during this process.
- Warning messages will appear during the non-SM creation and submission that need to be considered by users.
- The functionalities on how to submit a non-SM are applicable in this case too. Sponsor section and the related data can be updated. ORG-ID cannot be edited, but by using the search button, users can retrieve the updated data maintained in CTIS (different name, different address, …) and overwrite the initially populated obsolete sponsor details.



Useful Publications

- Guidelines on how to submit SM Part I – Change of Sponsor: NewsFlash 26/07/2024
- Guidelines on how to submit non-SM to update Sponsor details: NewsFlash 03/05/2024
- OMS Homepage and OMS Document Repository (particularly the document 'E - OMS Change Requests' which includes guidelines on how to submit request to create a new organisation in OMS)
- Quick Guide on how to use OMS (CTIS Training Programme – Module 03)
- Guidelines on how to register organisations locally in CTIS (**not intended** for sponsor organisations)
- Protection of PD and CCI in CTIS and Annex I
- Guide for Change of Trial Sponsor from HMA CTCG website (section Key documents list)

CTCG Guide for Change of Trial Sponsor

CTIS Bitesize talk

Presented by Marianne Lunzer

CTCG Guide for Change of Trial Sponsor – Before Substantial Modification Submission

- Pre-Requisite for sponsor change application: Authorisation of the trial by all MSs
- Transition trials: First SM after Sponsor change SM is first SM post transition (documentation to be completed in line with CTCG guidance)
- Legacy trials (trials submitted before 18 June 2024):
  Check for redacted versions of documents in scope of new transparency rules (if needed: CCI/personal data SM to upload redacted version, indicate limited scope in cover letter; absence of CCI/PD shall be indicated in the cover letter otherwise)
- OMS registration and user administration
- Finalisation of all pending applications before creating the draft SM for sponsor change

CTCG Guide for Change of Trial Sponsor – Assessment

- Validation: Considerations on proof of payment or structured data possible, in the absence of considerations completed in 6 calendar days
- MSs´fee requirements published in annex to Sponsor guide
- After completing validation RMS uploads standard template AR to both FAR sections and finalises conclusion and ideally also decision the same day
- The MSC(s) complete(s) the decision task within a maximum of 5 calendar days.
- There is no expectation that doubts in relation to a sponsor are dealt with during the change of sponsor SM. Instead, these will be addressed after the end of the procedure.

CTCG Guide for Change of Trial Sponsor – After SM Authorisation

- Sponsor performs impact assessment: Change of sponsor legal entity requires other SMs (affect patients' willingness to continue with trial)
- Sponsor submits an SM Part I and/or SM Part II without undue delay when needed according to impact assessment
- Within this subsequent SM application, the sponsor also submits all other documents reflecting only the administrative change of sponsor
- This SM Part I and/or Part II will be handled in a standard SM application procedure as it can also include other scientific changes
- If no SM needed reflection of non-substantial changes in the TMF
- Re-labelling can take place with the next batch release
- A valid contact point should be ensured at all times

CTCG Clinical Trials Coordination Group

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Thank you

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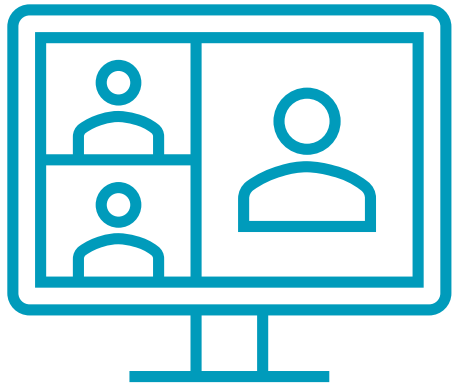
Upcoming CTIS events



- **14 May 2025**, 16:00 - 17:00 CET - CTIS Walk-in Clinic
- **9 July 2025**, 16:30 - 18:00 CET- CTIS Bitesize Talk
- **24 September 2025**, 16:00 - 17:00 CET - CTIS Walk-in Clinic
- **19 November 2025**, 16:30 - 18:00 CET- CTIS Bitesize Talk

For upcoming CTIS events, please consult Clinical Trials Information System: training and support | European Medicines Agency (europa.eu) and EMA events pages

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Thank you for attending today's event

Please provide your feedback for this event in our
Slido survey

Use the passcode: **#bt5mar**