CTIS - useful information for non-commercial sponsors

General useful information for sponsors

- Online modular training
- Overview of the different modules of Online Training: Guidance to CTIS training material catalogue
- Module 02 (Online modular training): High-level overview of CTIS workspaces and common system functionalities
- Sponsor handbook
- CTR Q&A published by the European Commission under EudraLex volume 10

One pager and pre-requisites

- Getting started with CTIS - Sponsor quick guide (europa.eu)
- CTIS pre-requisites checklist (see separate document)

Live demo and information on creation of new CTA in CTIS:

- Module 07 (Online Modular training): Management of registered users and role matrix
    - How to create a CT: Clinical Trial centric approach vs organisation centric approach
    - How to request roles and how to assign roles to register users in CTIS

- Module 10 (Online Modular training): Create, submit, and withdraw a clinical trial: e-learning course: initial clinical trial applications (use Chrome browser)
    - e-learning course: other types of clinical trial applications (use Chrome browser)
    - Create, submit and withdraw a clinical trial application and non-substantial modifications:
        - Step-by-step guide -
        - Instructor's guide
        - Frequently asked questions (FAQs)

  Video instructions are available to view the completion of a CTA in CTIS:

- How to submit an initial clinical trial application in CTIS – Fill in the Form and the MSC sections
  How to submit an initial clinical trial application in CTIS Sponsor workspace – Fill in the Part I section

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- How to submit an initial clinical trial application in CTIS – Fill in the trial details of Part I section
- How to submit an initial clinical trial application in CTIS – Fill in the Sponsor details of Part I section
- How to submit an initial clinical trial application in CTIS – Fill in the Product details of Part I section
- How to submit an initial clinical trial application in CTIS – Fill in the Part II section
- How to submit a substantial modification in the CTIS Sponsor workspace
- How to submit an additional Member State concerned application in the CTIS Sponsor workspace

Supporting materials:

- Additional supporting material is available at the EMA webpage CTIS Training and Support

- Bite size talk: Initial clinical trial application (including presentation)

- Module 19 (Online Modular training): CTIS for SMEs and Academia
  - Quick guide - Introduction
  - Step-by-step guide: User administration

Date of the XEVMPD demo

Please monitor the following webpage for online 1 day courses dedicated for non-commercial sponsors Extended EudraVigilance medicinal product dictionary (XEVMPD) training | European Medicines Agency (europa.eu)

Information Transitional trials

- Guidance for the transition of clinical trials published by the European Commission under EudraLex volume 10
- CTCG's best practice guide and cover letter template for sponsors of transitional trials
- Module 23 of the CTIS online training programme
- Bitesize talk: How to submit a transitional trial in CTIS (including presentation)
- Bitesize talk: Transitional trials and additional Member State concerned (MSC) application (including presentation)

Important to remember that sponsor should raise a ticket with the CTIS User Support Service if they cannot find the trial they wish to transition in CTIS when searching by EudraCT number.