Key Information for Sponsors on CTIS

The Clinical Trials Regulation (CTR) ensures consistent rules for clinical trials throughout Europe and harmonises assessment and supervision via the Clinical Trials Information System (CTIS).

euclinicaltrials.eu

Transition period

There will be a transition period from 2022 to 2025:

- **31 JAN 2023**: All initial clinical trial applications must be submitted through CTIS.
- **31 JAN 2025**: All ongoing clinical trials must be transferred to CTIS.

To get started with CTIS, sponsors must decide their user management approach and complete registrations:

1. Select your user management approach: the best approach will depend on how many trials your organisation expects to run.
2. Ensure you have an EMA account: username and account details for CTIS are provided via EMA Account Management.
3. Register your organisation/trial sites in OMS.
4. Ensure your medicinal products are registered in xEVMPD.

Find more information about getting started with CTIS in the Getting started quick guide.

CTIS Go-Live

Go to euclinicaltrials.eu to learn more and to access the CTIS secure Sponsor workspace.

Key links for clinical trials sponsors

- CTIS training and support
- Online modular training on CTIS functionalities
- Guide to CTIS training catalogue
- CTIS Sponsor Handbook
- CTIS Newsletter
- Information on the Clinical Trials Regulation