CLINICAL TRIALS INFORMATION SYSTEM

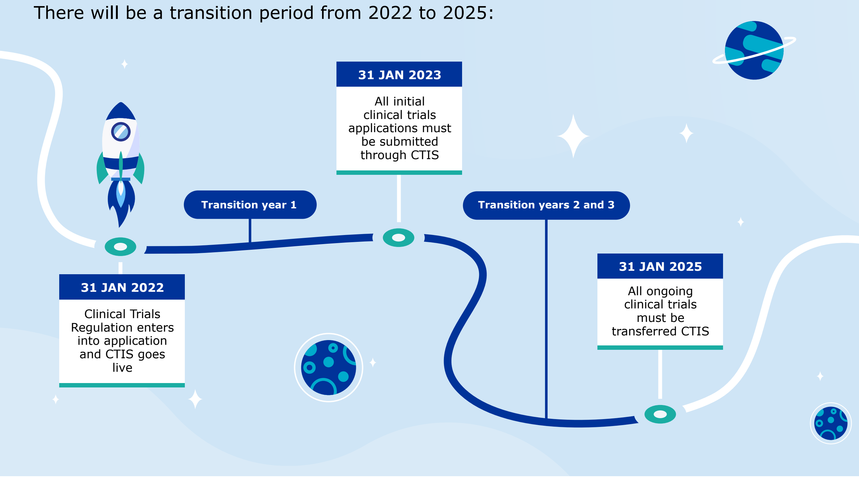
Key Information for Sponsors on CTIS

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:



Getting started with CTIS

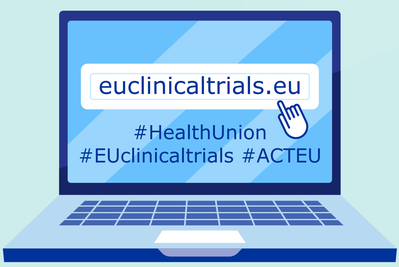
To get started with CTIS, sponsors must decide their user management approach and complete registrations:

1. Select your user management approach: the best user management approach for you in CTIS depends 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 — LEARN MORE

Online modular training on CTIS functionalities — LEARN MORE

Guide to CTIS training catalogue — LEARN MORE

CTIS Sponsor Handbook — LEARN MORE

CTIS Newsletter — LEARN MORE

Information on the Clinical Trials Regulation — LEARN MORE