As of GoLive on 31st of January 2022, the Clinical Trials Information System (CTIS) becomes the single-entry portal for submitting clinical trials information in the EU, supporting the day-to-day business processes of authorities and sponsors throughout the life-cycle of a clinical trial.

To get started with CTIS, sponsors must decide their user management approach and complete registrations. A transition period applies: see Guidance.

Select your user management approach

Organisation-centric

The organisation-centric approach serves the needs of organisations that run multiple clinical trials on a regular basis.

Trial-centric

The trial-centric approach serves the needs of small organisations and academic sponsors, which may initiate trials on an *ad hoc* basis.

If you use other EMA applications (e.g. Eudralink, SPOR, IRIS, EudraVigilance, EudraCT) you already have an EMA Account.

Do you have an EMA account? — No / Yes

Do you have an EMA account? — Yes / No

Go to EMA Account Management and click on "Create a new EMA account"

Register for an EMA account

Go to EMA Account Management and click on "Create a new EMA account"

Register for an EMA account

Have you registered a Sponsor Administrator? — No / Yes

Log in to SPOR portal with your EMA account.

Can you find your organisation in SPOR? — No / Yes

Can you find your organisation in SPOR? — Yes / No

Log in to SPOR portal with your EMA account.

If you cannot find your organisation, request creation of a new one.

Register your organisation in OMS

Register your site(s) in OMS

If you cannot find your site(s), request creation of a new one.

Request the first Sponsor Administrator role for your organisation in EMA Account Management

Register your Sponsor Administrator

Have you completed the CTIS training? — No / Yes

Learn more about product registration here

Have you completed the CTIS training? — Yes / No

Take EMA's online CTIS training

Ensure the medicinal products related to the clinical trial are registered in xEVMPD

Take EMA's online CTIS training

READY TO SUBMIT YOUR TRIAL(S)

For more information please consult the CTIS sponsor handbook