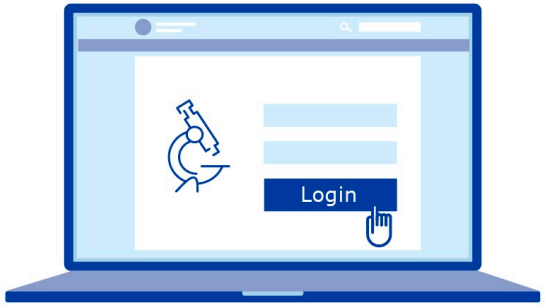
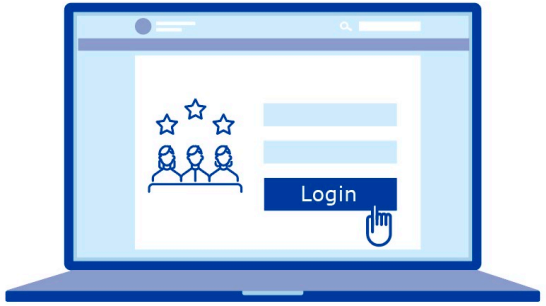
CTIS will be the **single entry point** for submitting clinical trial information in the EU and the European Economic Area (EEA). CTIS contains:

A **public website** where anyone can search for information on clinical trials



A **Sponsor workspace** where clinical trial sponsors and the organisations that work with them can apply for and manage a clinical trial in up to 30 EU/EEA countries



An **Authority workspace** for EU Member States, EEA countries and the European Commission to assess, authorise and oversee clinical trials

Open access

Secure access

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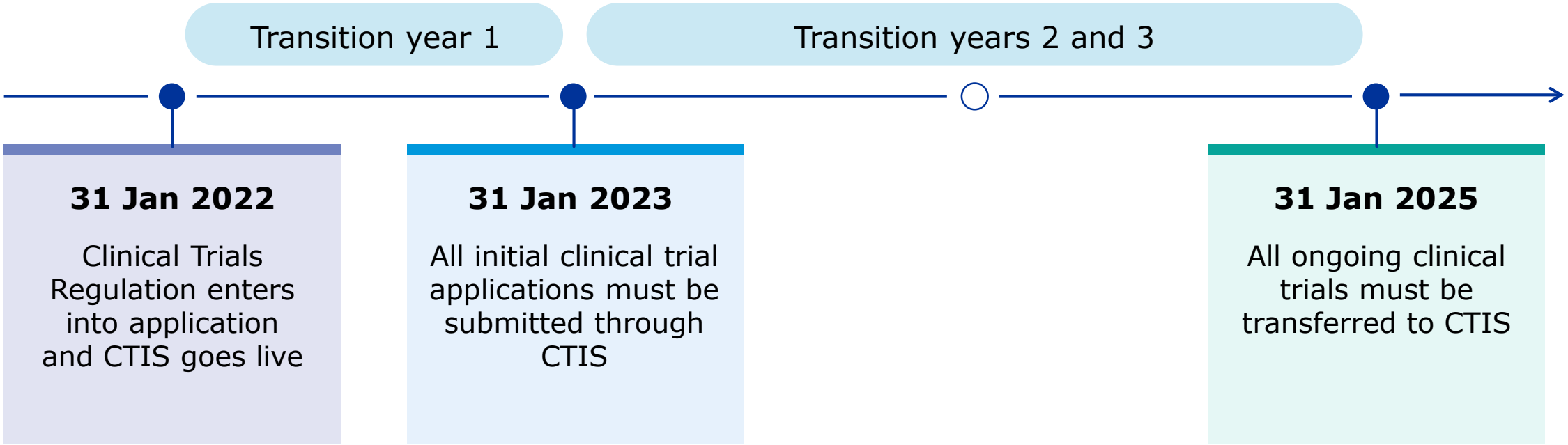
The Clinical Trials Regulation foresees a **3-year transition period** to CTIS:



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How clinical trials are processed in CTIS

- Clinical trial sponsors who want to gain approval to run a clinical trial in one or more EU/EEA countries **submit a single clinical trial application** form and supporting dossier through CTIS.

- The submission of the single clinical trial application **includes the public registration** of the trial.

- National regulators of EU/EEA Member States assess the clinical trial application. If they authorise the application, the trial can begin.

- CTIS **supports the day-to-day business processes** of EU Member States, EEA countries and sponsors throughout the **lifecycle of a clinical trial**. It will provide regulatory oversight of trials and tools for supervision and monitoring.

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How to prepare for CTIS

- Sponsors can consult the CTIS Sponsor Handbook for guidance on how to prepare for CTIS.
- The CTIS online training programme is another key resource.
- The guide to the CTIS training material catalogue on the CTIS training programme page provides an overview of the training catalogue.

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How to register for CTIS

1. Ensure you **have an EMA account**
   - You already have an EMA account if you use EMA systems like Eudravigilance or the substances, products, organisations and referentials database (SPOR)
   - If you do not already have an account, register via EMA Account Management

2. Choose your **user management approach** (organisation vs trial centric)
   - Organisation-centric allows for the management of users by an administrator at the organisation level rather than at the level of an individual trial. It is intended for organisations that will run several trials in CTIS

3. For the organisation-centric approach, ensure your **organisation is registered in OMS** and **register your first High-Level Administrator** via EMA Account Management

4. Ensure your **product is registered** in XEVMPD

View the 'Getting started with CTIS quick guide' here.

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Useful links

- Information on CTIS: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation
- CTIS training and support: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support
- Online modular training on CTIS functionalities: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-ctis-online-modular-training-programme
- CTIS Sponsor Handbook: https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#handbook-for-clinical-trial-sponsors-section
- CTIS Newsletter: https://www.ema.europa.eu/en/news-events/publications/newsletters#clinical-trials-information-system-(ctis)-highlights-section
- For information on the Clinical Trials Regulation: EudraLex - Volume 10 - Clinical trials guidelines | Public Health (europa.eu) and Draft - Questions and Answers Document - Regulation (EU) 536/2014 – Version 4.1 (September 2021)

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