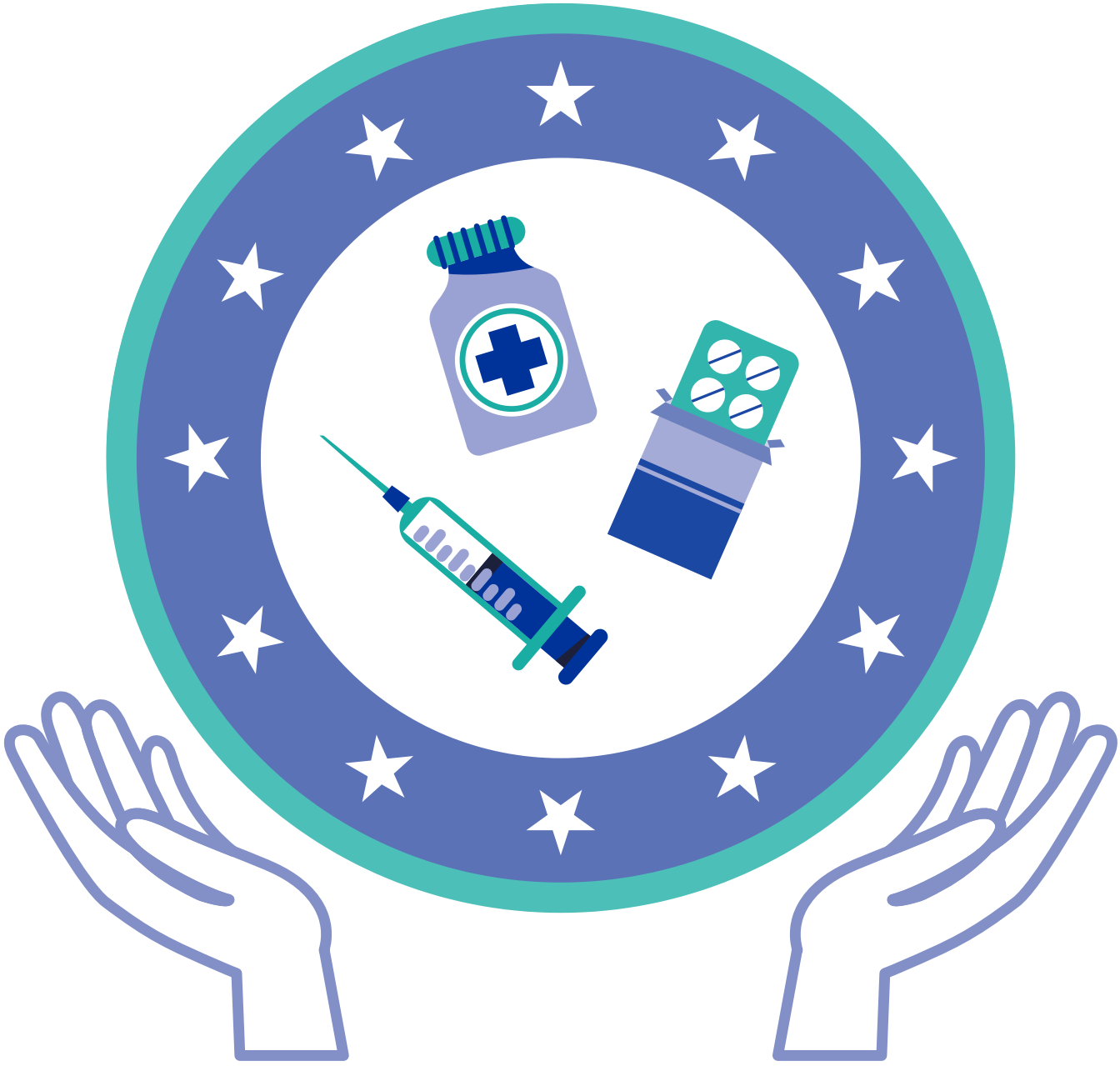
About this website

This website supports the running of clinical trials for human medicines in the European Union (EU) and European Economic Area (EEA).



On this page

Status update: Implementation of the Clinical Trials Regulation

On 31 January 2023, the clinical trial information system (CTIS) (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support) will become the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data which includes a public searchable database (https://euclinicaltrials.eu/search-clinical-trials-reports/) for healthcare professionals, patients, and the public.

The system was launched on 31 January 2022 (https://www.ema.europa.eu/en/news/regulatory-harmonisation-clinical-trials-eu-clinical-trials-regulation-enter-application-new), starting the clock for the one-year transition time (https://euclinicaltrials.eu/about-this-website/#transition-period) for all sponsors of clinical trials. During the transition period clinical trial sponsors can still choose whether to submit an initial clinical trial application in line with the Clinical Trials Directive (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A02001L0020-20090807) or under the Clinical Trials Regulation (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation), via CTIS. On 31 January 2023, the use of CTIS will become mandatory.

CTIS is the information system supporting the implementation of the Clinical Trials Regulation (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation), which changes the way that applications for authorisation of clinical trials in the EU are submitted, how the clinical trials are authorised and supervised. The provisions of the Clinical Trial Regulation bring extensive changes in practices by all stakeholders and require effective change management.

Some users have experienced problems with the system. EMA is working closely with Member States, the European Commission, and stakeholders to improve the CTIS user experience for core CTIS processes by the time the use of the system becomes mandatory for all new applications. The Agency has invested additional resources to achieve this goal.

EMA is working closely with national competent authorities in the Member State and the European Commission to facilitate the change to the new system for sponsors and other stakeholders. Training material (https://euclinicaltrials.eu/training/) is available to help sponsors submit information on their clinical trials data, including their applications for authorisation of a clinical trial; the material is updated regularly to reflect information needs. EMA is running regular training webinars (https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support#training-and-information-events-section) with sponsors to explain the system and listen to and address concerns.

More information:

Clinical Trials Regulation	**(https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation)**
Clinical Trials Information System	**(https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-support)**

Introduction

A clinical trial is a study performed to investigate the safety or efficacy of a medicine. For medicines intended for human use, these studies are carried out in people who volunteer.

Clinical trials in the EU and EEA are governed by the Clinical Trials Regulation (Regulation (EU) No 536/2014) which came into application on 31 January 2022. It is part of a broad initiative to transform the EU/EEA clinical trials environment in support of large clinical trials in multiple European countries, to the benefit of medical innovation and patients.

The regulation of clinical trials aims to ensure that the rights, safety and well-being of clinical trial participants are protected and the results of clinical trials are reliable and informative.

- Clinical trial sponsors (usually researchers or companies that oversee a clinical trial and collect and analyse the data) can use this website to apply for permission to run a clinical trial anywhere in the EU/EEA including in multiple countries, provide updates to national regulators about a trial, and submit trial results.
- EU/EEA national regulators can use it to process clinical trial applications collaboratively, request further information, authorise or refuse a trial and oversee an authorised trial.
- Anybody can use it to view information on clinical trials in the EU and EEA from 31 January 2022.

Clinical trial sponsors and EU/EEA national regulators work in the Clinical Trials Information System, the system underpinning this website.

The EU Member States and EEA countries, the European Commission and EMA launched the Clinical Trials Information System on 31 January 2022. On the same day, EMA launched this website. EMA maintains this website in collaboration with the EU Member States and EEA countries, and the European Commission.

For more information on the regulation of clinical trials in human medicines, see:

Clinical trials in human medicines	**(https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines)**

Secure workspaces

This website supports the business processes of clinical trial sponsors and national regulators throughout the lifecycle of a clinical trial, via the secure Sponsor workspace and Authority workspace Users need to log into these secure workspaces.

Clinical trial sponsors can apply for authorisation to run a clinical trial in up to 30 EEA countries via a single application in this website. They can also carry out tasks including liaising with national regulators while a trial is ongoing and recording the results of the trial.

National regulators can work together using this website on the assessment and authorisation of a clinical trial in several countries.

They can also use this website together with other systems to work together on clinical trial oversight, including monitoring and assessing safety-related data in the context of a clinical trial.

CTIS for sponsors

Clinical trial sponsors and other organisations involved in running clinical trials can apply to run a trial and can manage an ongoing trial in up to 30 countries in the European Union and European Economic Area via the Clinical Trials Information System (CTIS).

Explore (../ctis-for-sponsors/)

CTIS for authorities

Regulatory authorities, such as national competent authorities and ethics committees of EU Member States and European Economic Area countries can participate in the assessment, authorisation or oversight of a trial.

Explore (../ctis-for-authorities/)

Searching for clinical trials

This website contains limited information on individual clinical trials entered since its launch on 31 January 2022.

It will gradually contain more information as clinical trial sponsors and EU/EEA regulators use it to initiate and oversee clinical trials in the EU and EEA.

For information on individual clinical trials initiated before 31 January 2022 see:

European Union Clinical Trials Register. (https://www.clinicaltrialsregister.eu/ctr-search/search)

To find detailed information on clinical trials granted or refused permission in the EU and EEA via the Clinical Trial Information System, this website has a search function.

You can view information on individual clinical trials as soon as it becomes available, such as the EU clinical trial number, name and address of the trial sponsor, start and end dates of participant recruitment and of the trial itself.

Further information, including the identity of the investigational medicine and details of the trial design, is also made available via this website, but its publication may be deferred to protect legitimate economic interests.

Find out more and search for clinical trials(../search-clinical-trials-reports/)

Training and support

Training and supporting materials are available from EMA on how to use the Clinical Trials Information System, and a dedicated user support service is available:

Training(../training/)

User support service(../support-info/)

Legal framework

The Clinical Trials Information System, the system underpinning this website, serves to implement EU pharmaceutical law in the The goal of the Regulation is to create a favourable environment for conducting clinical trials in the EU, to ensure the EU remains an attractive region for clinical research, with the highest standards of safety for participants and transparency of information.

It does this by harmonising the submission, assessment and supervision processes for clinical trials supported by this website. Before the launch of this website, sponsors had to submit clinical trial applications separately to national competent authorities and ethics committees in each country to gain regulatory approval to run a clinical trial.

The EU Member States and EEA countries, the European Commission and EMA launched the Clinical Trials Information System on 31 January 2022. On the same day, EMA launched this website. EMA maintains this website in collaboration with the EU Member States and EEA countries, and the European Commission.

The assessment, authorisation and supervision of clinical trials are the responsibilities of EU Member States and EEA countries.

Transition period

Under the Clinical Trials Regulation, EU Member States and EEA countries will carry out their legal responsibilities to assess and oversee clinical trials using the Clinical Trials Information System from its launch on 31 January 2022.

- Clinical trial sponsors can choose whether to apply to start a clinical trial via the Clinical Trials Information System or under the Clinical Trials Directive until 31 January 2023.
- From 31 January 2023 onwards, clinical trial sponsors will need to apply to start a clinical trial via the Clinical Trials Information System.
- By 31 January 2025, any ongoing trials approved under the Clinical Trials Directive will fall under the Regulation and information about them will need to be transferred to the Clinical Trials Information System.

For more information:

EMA: Clinical trials in human medicines	**(https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials-human-medicines)**
EMA: Clinical Trials Regulation	**(https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation)**
European Commission, EudraLex - Volume 10: Clinical trials guidelines	**(https://ec.europa.eu/health/documents/eudralex/vol-10_en)**

EMA news and events

Find EMA news and events related to clinical trials in the EU and the EEA.

News and events related to clinical trials in the EU	**(https://www.ema.europa.eu/en/search/search/field_ema_web_topics%253Aname_field/Clinical trials?sort=field_ema_computed_date_field&order=desc)**