EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The EU Clinical Trial Information System public portal

23 September 2024

MULTI-STAKEHOLDER WORKSHOP - Innovation and Access in Rare Cancers

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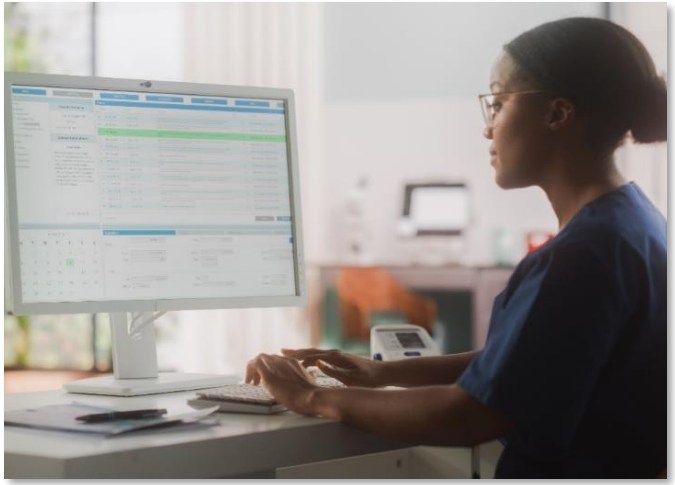
Transparency in European clinical trials

Publication of clinical trials information is important:

- to enable trust
- to identify the right clinical development pathway
- to avoid unnecessary duplication of trials
- to inform on methods and results
- to ensure that patients have access to clinical trials information of their interest



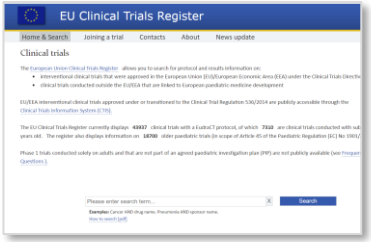
Transparency is a legal requirement for trials conducted in EU/EEA under the Clinical Trial Directive 2001/20 and the Clinical Trials Regulation 536/2014

1 The EU Clinical Trial Information System public portal

Transparency is enabled through public portals

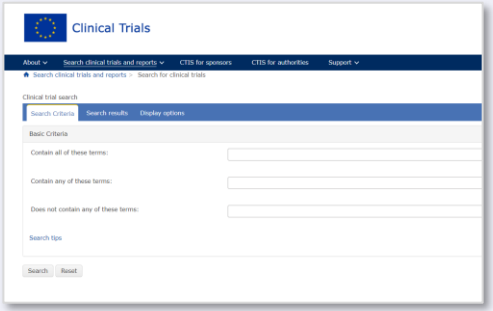
CT Directive 2001/20 + Paediatric Reg 1901/2006

All trials authorised in EU/EEA between May 2004 and 31 Jan 2023 are published on the EU Clinical Trials Register. Most with results.



All trials authorised in EU/EEA since 31 Jan 2022 are published on the CTIS public portal. Most of these trials are currently ongoing.

CT Regulation 536/2014



Clinical trial documents are now published
+
more information is made public
(e.g. clinical trial investigator's sites)

The Clinical Trial Information System publication rules

Article 81(4) of Regulation (EU) No. 536/2014: legal basis for the establishment a publicly accessible EU clinical trials database, while protecting commercially confidential information (CCI), personal data (PD) and confidential information on the assessment conducted by MSs

- The CTIS publication rules recently underwent a simplification process, as a result of a public consultation
- The revised CTIS transparency rules now foresee an earlier publication of key documents of interest, which increases the public engagement and trust while allowing a faster preparation of application dossier by sponsors (including Academia)
- For most of the trials, publication of data and documents occurs at the time of Member State decision on the application, and publication of results at the time of their submission
- Specificities are in place for early development trials on adults (e.g. Phase I, first in humans), that mainly foresee their publication to occur 30 months after end of trial in EU/EEA

The CTIS public portal: what you can search for and how

Information you can view on each clinical trial includes:

- Trial identifiers (EU clinical trial number, protocol code, title, any other ID)
- therapeutic intent and objectives
- Endpoints and trial design
- Participants inclusion and exclusion criteria
- Trial locations, Sponsor(s) and contact information
- Start and end dates and recruitment timelines

You can also view the following trial **documents**:

- Protocol and protocol synopsis
- Summary of the products characteristics, when applicable
- Recruitment arrangements, Subject information and informed consent form
- Summary of results, layperson summary and Clinical Study Report, when posted

The CTIS public portal: what you can search for and how

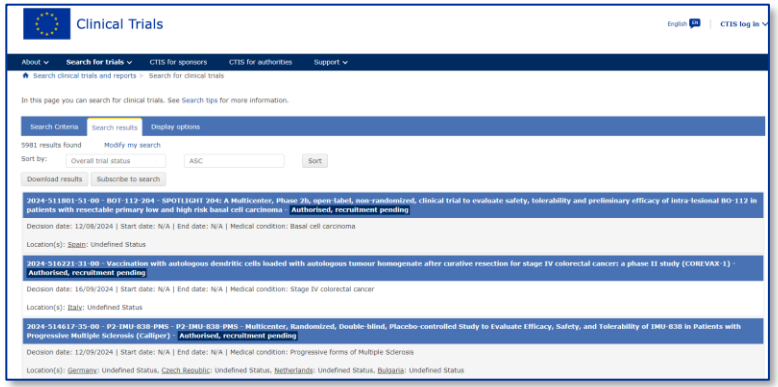
Clinical Trial information can be retrieved through:

- Basic Search
- Advanced Search

Operator	Description
+	Acts as the AND operator.
|	Acts as the OR operator.
*	When used at the end of a term, signifies a prefix query.
"	Wraps several terms into a phrase (for example, "wind rises").
(,)	Wrap a clause for precedence (for example, wind + (rises | rising)).
~n	When used after a term (for example, wnid~3), sets fuzziness. When used after a phrase, sets slop.
-	Negates the term.

Once retrieved:

- More fields can be displayed through the 'Display Option' functionality
- Search results can be downloaded through 'Download Search results'
- You can subscribe to search results through RSS feed

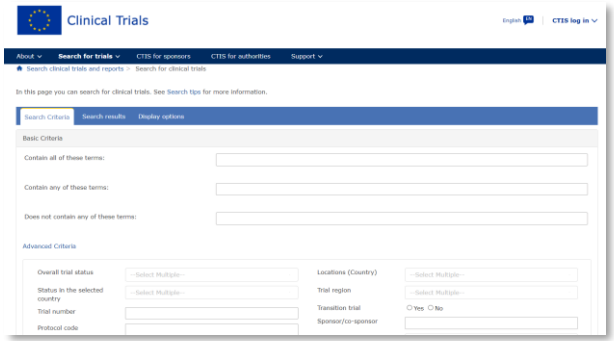


Single trial information and documents can be downloaded

Demo on the CTIS public portal

Additional features just implemented, following consultation with HCPs and patients:

- Advanced Search, to allow users to perform more detailed searches (e.g. trial status per member state)
- Download specific Clinical Trial published information
- Download the results of a performed search
- RSS-feed, to allow users to subscribe to alerts on trials' updates
- Major Improvements of the portal user interface



Information on 6000+ clinical trials is public with 500+ more trials to be published each month

Any further questions can be done to Service Desk Support

Any questions?

Further information

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Back up slides

Principles of revised CTIS transparency rules

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- Clinical trials are made publicly available as per timelines based on their development phase (trial category) and population age
- For most of the trials publication of data and documents occurs at the time of Member State decision on the application
- Summary of results and of Clinical Study Reports are published upon submission to CTIS

Category	Trial type	Publication rules
Category 1 Pharmaceutical development clinical trials	Phase I, Phase 0, Bioequivalence, similarity trials for biosimilars, equivalence trials	On adults: most info (structured data/docs) is published 30 months after EU/EEA End of Trial On paediatrics: structured data published at decision date, documents published at submission of results
Category 2 Therapeutic exploratory & confirmatory clinical trials	Phase I and phase II integrated, Phase II, Phase II and phase III integrated, Phase III clinical trials	All info published upon decision date, except for details on product dosage of integrated phase I and II (published 30 months after EoT)
Category 3 Therapeutic use clinical trials	Phase III and phase IV integrated, phase IV trials	All info published upon decision date

Reference documentation for sponsors

- Revised transparency rules
- Quick guide for users
- Guidance document on how to approach the protection of personal data and commercially confidential information (CCI) while using CTIS and its Annex I
- Q&A on the protection of CCI and Personal Data while using CTIS
- List of CTIS application fields and documents (with publication details)
- List of CTIS notifications fields and documents (with publication details)
- CTIS Bitesize talk on the transparency rules