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New CTIS transparency rules: from policy to reality

ACT EU MSP annual meeting, 22 October 2024

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European Medicines Agency

The Clinical Trial Information System publication rules

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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 conducted in 2023

The Revised transparency rules now foresee an **earlier** publication of **key** documents of interest, which brings the following benefits:

- increases the public engagement and trust
- allows a faster preparation of application dossier by sponsors (including SMEs and Academia)

- ✓ Patients and HCPs can access key data and documents as early as possible in the clinical trial lifecycle
- ✓ Increased awareness on possible treatment options
- ✓ Clinical trial information is easier to find and to consult
- ✓ Simplified publication rules reduced the burden to CTIS users and help to promote conduct of clinical research in the EU

Launch of new CTIS Public Portal on 18 June 2024

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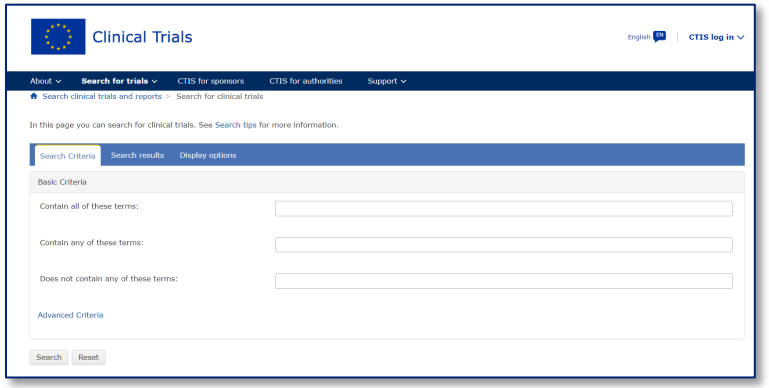
- The Revised CTIS transparency rules became applicable on 18 June 2024 with the launch of a new version of CTIS public portal
- Applications submitted as of 18 June follow the revised rules. For those submitted before, only structured data were published ('historical' trials)
- **Over 6,500 trials are public**, of which over **2,600 with documents.** Overall, more than 64,300 documents are now publicly available



Reference documents: Quick guide for users &

all materials published on "Transparency in CTIS" - ACT EU website

What you can search for

Information you can view on each clinical trial includes:

- Trial identifiers (EU CT number, protocol code, title etc)
- Therapeutic intent, objectives, endpoints and trial design
- Participants inclusion and exclusion criteria
- Trial locations and contact details of principal investigator
- Sponsor(s) contact information
- Start and end dates and recruitment timelines
- Safety notifications and corrective measures

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

Patients and HCPs feedback in July 2024

"The website should be **more patient-friendly and intuitive**, as it seems targeted at industry and authorities rather than patients and the public"

"**A lot of information is there but hidden**", the following is difficult to find:

- Recruitment status for each trial
- Trial title and code and full trial information
- a summary of the intervention and objective of trial
- All inclusion/exclusion criteria
- information about who to contact to get enrolled
- Documents (e.g. protocol, informed consent form)

The Advanced search should include **search per 'recruitment status'** per Member state

The **search results list** should be more readable, it should be downloadable, and it should be easier to extract information about studies involving children

A **lay language explanation** of each field should be provided, as well as webpages with an explanation of the content of the site and how to search

The search function should be thesaurus related and there should be an accessible API

Not yet!

Additional features delivered on 20 September 2024

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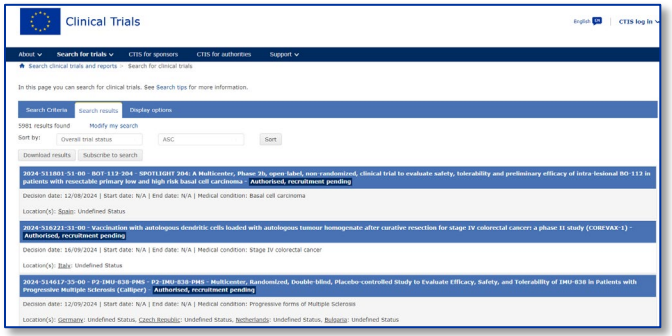
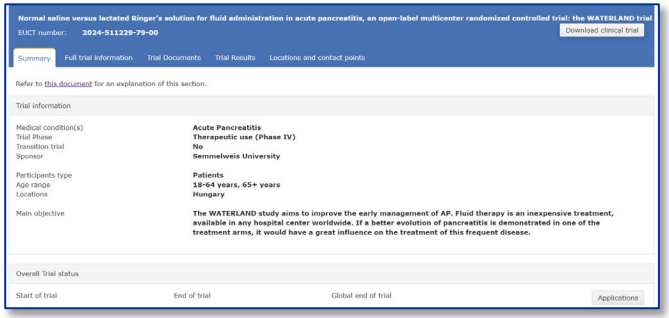
- Advanced Search, users can now perform more detailed searches (e.g. CT status per Member state)
- Download specific CT information
- Download results of a performed search (granular information on participants' age is now also included in the 'Display options' and in the 'Download clinical trials' file)
- RSS-feed, users can subscribe to alerts on updates
- Major user interface improvements (clearer list of search results, recruitment status displayed in all sections, ad hoc sections on docs & on locations and contact points
- Each trial's section now includes 'explanatory documents' in lay language and pages 'what you can search for' and 'search tips and guidance' provide tips to users, including contact points of patients representatives and HCPs





Thank you for your attention

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