



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revised CTIS transparency rules and new version of the public portal

Joint PCWP – HCPWP meeting, 2 July 2024

Presented by Francesca Scotti, CTIS Transparency Lead
European Medicines Agency

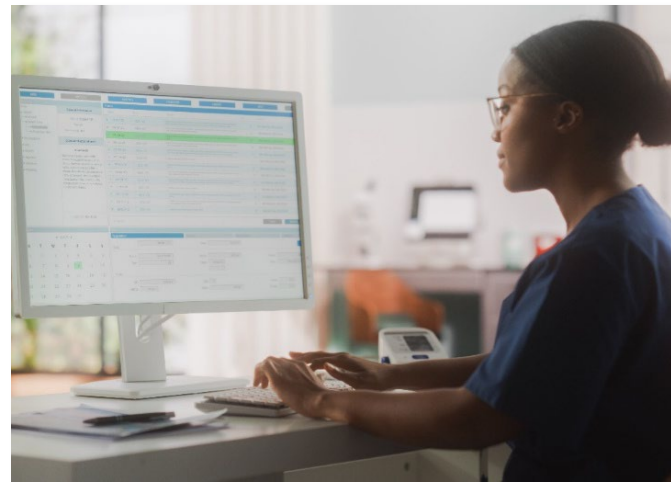
An agency of the European Union



Transparency in 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



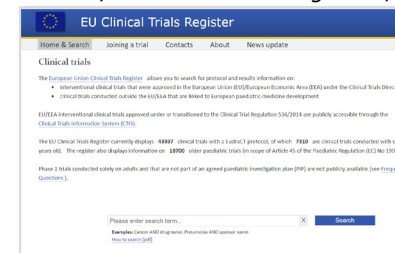
Transparency is a legal requirement for trials conducted in EU/EEA under the Clinical Trial Directive 2001/20 and the Clinical Trials Regulation 536/2014



Transparency is enabled through public portals

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

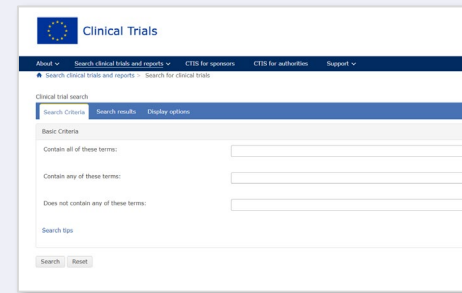
CT Directive 2001/20 + Paediatric Reg 1901/2006



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

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

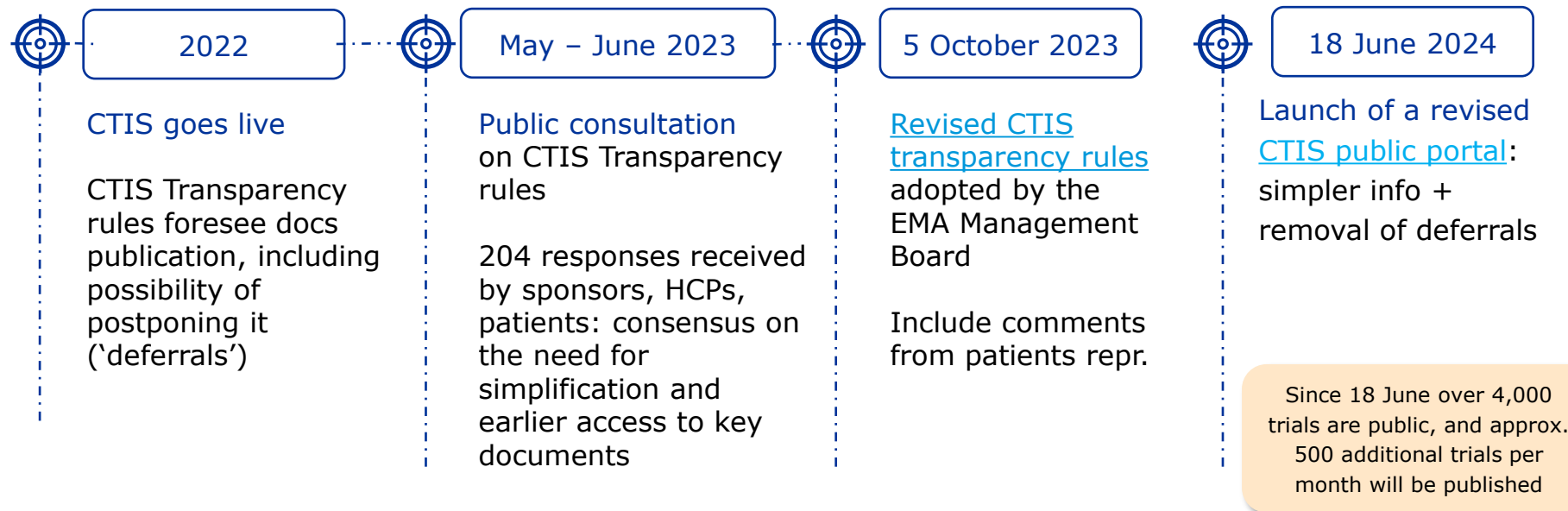
CT Regulation 536/2014





Transparency journey in CTIS

Transparency is a pillar of the Clinical Trials Regulation, delivered through the searchable Clinical Trial Information System (CTIS) public website



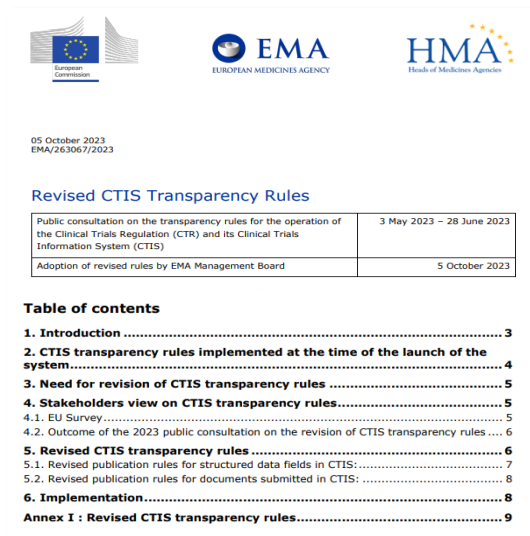
Revised CTIS transparency rules: key changes

Main differences with previous rules:

- Publication focused on key documents of interest
- Documents are published earlier in time, due to the removal of deferral functionality
- Use of redaction as the method to protect Commercially Confidential Information (CCI)

As of 18 June 2024 (see [quick user guide](#)):

- All trials' applications submitted on or after 18 June follow the [revised rules](#)
- All trials submitted before 18 June ('historical' trials) have their structured data published



Benefits of the revised CTIS transparency rules

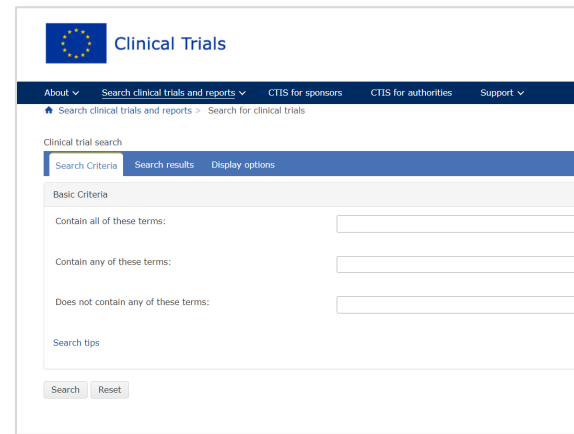
- ✓ Patients and HCPs can **access key data and documents as early as possible in the clinical trial lifecycle**, before the start of the trial
- ✓ Clinical trial information is easier to find and to consult
- ✓ Awareness on possible treatment options is increased and could facilitate recruitment
- ✓ Simplified publication rules reduce the burden to CTIS users and help to promote conduct of clinical research in the EU



Demo on the CTIS public portal

Additional features implemented in the upcoming months:

- Advanced Search, to allow users to perform more detailed searches (e.g. per member state, with/without results)
- 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
- Minor Improvements of the portal user interface



The screenshot shows the 'Clinical Trials' search interface. At the top, there is a navigation bar with links: 'About', 'Search clinical trials and reports', 'CTIS for sponsors', 'CTIS for authorities', and 'Support'. Below this is a search bar with the text 'Search clinical trials and reports > Search for clinical trials'. The main section is titled 'Clinical trial search' and has three tabs: 'Search Criteria' (selected), 'Search results', and 'Display options'. Under 'Search Criteria', there are three input fields: 'Contain all of these terms:', 'Contain any of these terms:', and 'Does not contain any of these terms:'. Below these fields is a 'Search tips' link. At the bottom, there are 'Search' and 'Reset' buttons.

Public event held on 20 June 2024: [CTIS Bitesize Talk: Revised transparency rules and the new CTIS public portal](#)



Any questions?

Further information

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