Revised CTIS transparency rules and new version of the public portal

Joint PCWP – HCPWP meeting, 2 July 2024

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European Medicines Agency
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.

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)
Transparency journey in CTIS

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

- **2022**: CTIS goes live
  - CTIS Transparency rules foresee docs publication, including possibility of postponing it (‘deferrals’)

- **May – June 2023**: Public consultation on CTIS Transparency rules
  - 204 responses received by sponsors, HCPs, patients: consensus on the need for simplification and earlier access to key documents

- **5 October 2023**: Revised CTIS transparency rules adopted by the EMA Management Board
  - Include comments from patients repr.

- **18 June 2024**: Launch of a revised CTIS public portal: simpler info + removal of deferrals

Since 18 June over 4,000 trials are public, and approx. 500 additional trials per month will be published.
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

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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