ACT EU Multi-stakeholder platform kick off workshop

22 - 23 June 2023

CTIS transparency aspects

Multi Stakeholder platform 22 June 2023

CTIS transparency

- The legal basis for having a CTIS public domain is **Article 81(4)** of the CTR that requires high levels of transparency, while ensuring protection of personal data and commercial confidential information (CCI) in CTIS;
- CTIS functionalities to enable the publication of data and documents are based on the content of the document: **Appendix, on disclosure rules,** to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014", endorsed by EMA Management Board in 2015;
- Publication of information of clinical trials in the EU/EEA is important to build trust and support clinical research and requires:
  - **Protection of personal data:** it can be achieved with the functionality of having documents 'for publication' and 'not for publication';
  - **Protection of CCI:** based on current rules it can be achieved with the 2 documents version **OR** by using deferrals functionalities in CTIS.

CTIS transparency

- The Appendix on disclosure rules, endorsed in 2015, set the scene for CTIS transparency rules;
- The document covers **principles** on protection of personal data and CCI as well **as technical aspects** on CTIS functionalities;
- An opportunity arises now to:
  - Make the best use of the 18 month experience acquired since the launch of the system, available since 31 January 2022;
  - Build on the close collaboration with the Member States in relation to transparency aspects;
  - Consider the best approach to support clinical research in the European Union, what can make the difference in accessing clinical trials information;
  - Ensure the information that is needed by patients and researchers is available fast and easy to find.
- With this in mind a public consultation on the revision of CTIS transparency rules has been launched, available until 28 June: https://www.ema.europa.eu/en/news-events/open-consultations

CTIS transparency

- The consultation of CTIS transparency rules intends to collect views from system users and stakeholders and stimulate discussions on the best possible approaches to:
  - balance transparency of clinical trials information in CTIS with confidentiality requirements while
  - simplifying the modalities of use of the new system
- Listening to users' feedback there is a need for simplifications;
- The use of deferrals over time has proven to be complex from the technical standpoint. Currently clinical trials with any deferrals are not published in CTIS public domain;
- The outcome of the public consultation will lead to modifications of the existing rules and an update in the system functionalities;
- The Appendix on disclosure will be replaced by a new, concise, document: a concept paper on CTIS transparency rules covering the **technical aspects**;

CTIS transparency aspects

- **Principles** on how to protect personal data and CCI while using CTIS have been elaborated further in published documents:
  - Joint controllership arrangement JCA (for protection of personal data)
  - Interim guidance and its Annex
  - ACT EU Question and answers
  - All these documents have built and expanded on the principles of the Appendix on disclosure rules;
  - Other documents might be produced in the future to refer to the interplay between transparency aspects in CTIS and CSR publication via Policy 0070;

CTIS transparency clarifying the touchpoints

- Policy 0070 and CTIS both provide access to clinical trials information but stem from different legal basis and have different scope;
  - CTIS public website enables the publication of clinical trials data and documents submitted to the Member States concerned as part of clinical trial applications and during the whole trial life cycle, including CSR if applicable;
  - Policy 0070 applies to the publication of CSR provided in a centralised marketing authorisation procedure (MA);
- With current rules CCI can be protect in CTIS with deferrals or redaction of documents;
- It is expected that redaction applied in the documents to protect CCI will decrease over time as CCI is time-dependent;
- The submission and publication of CSRs via CTIS and Policy 0070 have similar milestones (i.e. the end of the MA procedure), work ongoing to avoid overlap

Take home messages

- Publication of clinical trials information is important:
  - to enable trust;
  - to identify the right clinical development pathway;
  - to avoid unnecessary duplication of trials;
  - to ensure that patients have access to clinical trials information of their interest;
- Key information needs to be findable and available in a timely manner
- We can act now to learn from experience and improve the process;
- Survey is still open until 28 June: this is your chance to contribute to the revision of CTIS transparency rules.