

Academic and charity sectors' position on proposals for clinical study reports in the Clinical Trials Regulation

Our position:

- **We support transparency for clinical trials registration, outcomes and data as these are important for the development of safe and effective treatments for patients.**
- **We do not support the proposed amendments to produce ICHe3 clinical study reports because of the resources required to produce them, their lack of utility for follow on research and patient confidentiality risks which arise from their publication.**
- **A requirement to produce a Data Sharing Plan offers an alternative means to guarantee transparency of data. Data Sharing Plans will provide greater reassurance to the public, Sponsors and Member States that data will be shared following the end of a clinical trial in an appropriate manner.**

Transparency is important to clinical research, it ensures the robustness of study findings and supports clinical decision making. The current Regulation contains sufficient requirements to ensure that all trials taking place in the EU are registered on the EU portal and that summary results are reported. We support efforts to ensure that discovery and accessibility of data is promoted by the legislation however, we reject the proposal that this should be done via clinical study reports as set out by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICHe3). Instead we propose that a Data Sharing Plan offers the opportunity to ensure Sponsors make their data available in an appropriate manner.

ICHe3 clinical study reports

- ICHe3 clinical study reports are not currently produced following non-commercial trials as their main purpose is to provide information to Regulators for marketing authorisation decisions. We do not believe it is proportionate to require all trials to produce these reports.
- The Medical Research Council and Cancer Research UK trials units have confirmed that it would take 2-3 months of statisticians' time to arrange the data into the format of an ICHe3 report. Currently statisticians in trials units can be working on producing the results or setting up numerous trials at any one time.
- Adding requirements to present the data at the end of a trial in an ICHe3 report would create additional extra work which in turn will hamper academic trials units' ability to set up new trials or to provide additional follow on analysis to trials that have closed.
- It is important that any reporting requirements provide protection for patient confidentiality. Producing accessible clinical study reports in the ICHe3 format would require extensive redaction of patient identifiable information. Redacting information would decrease the utility of the information to researchers wishing to further analyse it. We therefore believe that other mechanisms may be more appropriate for sharing data arising from clinical trials.
- The inflexibility of the ICHe3 Clinical Study Report and its annexes are a major concern to the research community. ICHe3 was originally issued in 1995, predating the EU Clinical Trials Directive, and it has required clarifications to aid interpretation and implementation. Reporting

requirements in the ICHe3 report do not reflect the current documentation used in running clinical trials. Instead, reporting based on the internationally agreed CONSORT statement¹ would fulfil many of the requirements needed for transparent reporting of trial results but avoid creating excessive bureaucracy for academic funders while protecting patient anonymity.

- ICHe3 reports are currently produced as a pdf. This format does not lend itself to being easily accessible for follow on research. We believe that appropriate data release by Sponsors would be the most constructive and useful way of promoting data transparency.

Data Sharing Plans – a transparent mechanism to assure data sharing

- Data Sharing Plans are currently required by many non-commercial funders of research to ensure that investigators make the data from their work available in a timely manner. We believe that a requirement to submit a Data Sharing Plan offers a proportionate alternative to requiring ICHe3 clinical study reports are produced.
- Requiring Sponsors to submit a Data Sharing Plan as part of the clinical trial application process, outlining how and when the and data from the trial will be disclosed will assist with delivering greater transparency to the release of data from clinical trials and provide reassurances to Sponsors as to how the data they produce will subsequently be handled.
- Submission of a Data Sharing Plan by a Sponsor, and approval of that Plan by Member States in the application process, would provide clarity as to how the and data from a clinical trial will be shared and offers a mechanism for Member States and the public to hold Sponsors to account on transparency.
- A Data Sharing Plan would also contain information about the timelines for the Sponsor making the data available. This would allow Member States to approve Sponsors justification for waiting to share data, for example if there are intellectual property protection reasons to not release the data before marketing authorisation is granted.
- The plan would be made publicly available on the EU portal following approval of the clinical trial application and therefore will allow the Sponsor to be held to account.

Requirements for Members States to assess the Sponsor Data Sharing Plan should be included in Article 6 paragraph 1.

Further detail on what should be contained in a Data Sharing Plans would be included in Annex 1 of the Regulation. A possible amendment could be:

DATA SHARING PLAN

A data sharing plan outlining how and when the data from the trial will be made available following the end of the trial.

The plan shall identify the methods and the timelines in which the data shall be made available.

The plan shall outline the reasons for setting the timelines for data release.

The plan should include descriptions of the patient and commercial confidentiality issues associated with the release of data associated with the trial.

¹ <http://www.consort-statement.org/>

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