EU CTR Implementation

Project Scope

The EU Clinical Trial Regulation (CTR) has sweeping new requirements for the publication of clinical trial documents of trials conducted in the European Union. Documents will be subject to publication earlier in clinical development than before, and documents like the Investigator's Brochure will be routinely published for the first time.

The EU CTR has important implications for the planning of trials in the EU and for how sponsors prepare clinical trial documents. Stakeholders include any sponsor conducting an EU trial, including pharmaceutical and biotechnology companies and academic institutions. The initial deliverable for this project may build on a poster previously prepared by this Working Group outlining avenues of data disclosure.

Types of document to be published under the EU CTR, their possible timelines for publication, the deferral mechanism for protecting confidential commercial information (CCI), which documents can be redacted for CCI and which cannot, and protection of personal protected data.

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Objectives & Deliverables	Timelines
Poster	Q32021

CURRENT STATUS **Q3/42021**

Project on hold until Q1 2022. Will meet again in March 2022 (and likely monthly thereafter) to discuss any learnings from pilots and initial trials going through the Regulation. Will also discuss more concrete next steps at that time, including how best to summarise learnings and when to aim for deliverables.

Resources

CSS 2021 Poster – Overview of Transparency Requirements for EU Clinical Trials Regulation 536/2014

Additional Content

- Initial Submission/During and After Trial
- 3-year Transition Plan to Regulation

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