

Good Transparency Practices



Project Scope

Define a set of best practices for data transparency and create a Good Transparency Practices guidance. The best practices will aim to ensure anonymised data is compliant with the legal requirements as defined by Regulators, as well as preserves as much data utility as possible. If possible, Regulators such as the European Medicines Agency (EMA) and Health Canada will be consulted to ensure that the guidance created by the working group reflects their current standards. The planned document will have a similar format as the Good Clinical Practices guidance created by the International Conference on Harmonisation (ICH). The Good Transparency Practices document will include: an introduction, a glossary of terms, a set of principles, and subsections dedicated to different parties involved in the anonymisation process (such as the trial sponsor and the entity performing the anonymisation) describing their responsibilities and providing guidance. Additional sections may be added as needed.

Problem Statement

Transparency initiatives allow public scrutiny and research in the application of new knowledge based on clinical data. Current GxP guidelines do not apply to transparency as it represents a different flow of data in which anonymisation is carried out on a copy of the regulated data.

Problem Impact

Good Transparency Practices (GTP) would provide a means to achieving accountability and traceability while providing reasonable assurance that privacy requirements are being upheld.

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Objectives & Deliverables	Timelines
Good Transparency Practices guidance document	Q2 2023

CURRENT STATUS Q1 2024

- Publication of White Paper
- Project close