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 preserving 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 to 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.

Project 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.

Project 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
Define the full set of requirements for GTP	Q32021
Preparation of components of GTP	Q42021

CURRENT STATUS **Q3/42021**

Group are completing current background research and organising not es to prepare for writing the GTP guidance.

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