Quality and Reusability of Real World Data

Project Scope
Within this project we will make a list of available data sources and pros and cons. We will discuss what documents and requirements we need to show the FDA in the pre-alignment meeting and we will try to point to or create an outline and/or requirements for those documents. If possible, we will align with the FDA on this.

Problem Statement
Real-world data sources have been used for many years in the pharmaceutical industry. They are useful for validating research questions and protocol set-up, patient and centre selection, post-registry safety follow-up and market access. However, the use for regulatory submissions is new. For this, the requirements are more stringent and we need a robust process to assess quality, accuracy, appropriateness of the data and compliance to regulatory requirements. How are we going to set ourselves up for success? We shall focus on: • selecting the appropriate data source • ensuring the data sources are accurate and traceable • how we assess the quality of the data These are all questions that we will start to answer in this project.

Problem Impact
A number of (real-world evidence parts of) submissions have been rejected because of a lack of power or representativeness. The FDA indicates that aligning with them before the start of a study is key to assessing whether the approach and source we are using is acceptable. Then, we need to have good funding for our assumptions. If we do not have this, we need to restart our design.

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Objectives & Deliverables	Timelines
Project kick off	Q2 2023
List of documents and requirements validating the right data source	Q4 2023
Pre alignment meeting with regulatory agencies	Q4 2023

CURRENT STATUS **Q1 2024**

- Draft blog.
- Planned white paper including the achievements thus far
- Vendor engagement list and plans