Rare Disease/Small Population Data Sharing

Project Scope

The goal of this project is to develop a resource for individuals who are anonymising or supporting/facilitating the sharing of rare disease or low population data. The aim is to produce a white paper which provides guidance, recommendations and methodologies for the handling of data from rare diseases/small populations. Although this project may not result in a "perfect" document, the aim is to have something that will be a foundation for future work.

Part of the challenge for this project is determining the scope. Since there isn't currently a document like the one being proposed, we are aiming to potentially cover a number of topics:

- Defining what is meant by rare disease and low population datasets
- The risks associated with sharing such data, and how the context of data use impacts risk
- Anonymisation and data utility considerations given the size of such datasets
- The concept of data sensitivity as a component requiring specific consideration for these datasets
- How the sharing of genetic information impacts the risk, given that many rare diseases often have a genetic component
- Considerations for presenting summary data in publications based on rare disease or low population datasets
- Patient perspectives on sharing
- Gap analysis of the current literature

One of the key components is whether we will be splitting the document into two different sub-documents, one focussing on controlled access datasets and the other on publicly accessible ones. We are currently working on the assumption that this will be a single document, and will re-evaluate as the project evolves. A secondary goal will be supporting facilitation of other organisations developing their own guidance documentation on rare disease/small population data collection.

Problem Statement

Sharing of rare disease and low population datasets poses unique challenges. There is not currently a consolidated source of information to document and further the understanding of these challenges in order to support the sharing of this specialised data. This Working Group is aiming to develop documentation that will support those working in these areas of clinical/medical research. This will allow those researchers and others interested to understand the unique risks associated with this data and to develop standardised methods to share this data in a manner which protects privacy, while at the same time affording data utility.

Problem Impact

This project will impact the industry by providing a comprehensive, cross-regulatory document that will act as a go-to resource for individuals working to anonymise and share rare disease or low population datasets. By providing recommendations on areas that are currently lacking in guidance, this project will be able to help lead rare disease/small population research to the level that other areas of medicine have already attained. The hope is that this document will not only make research more efficient but also give patients and their families a sense of security by understanding how their data is being handled.

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Objectives & Deliverables	Timelines
White Paper Draft	Q4 2023/ Q1 2024

CURRENT STATUS **Q1 2024**

- Team working on the draft of the White Paper