Submitting Real World Data

Project Scope

The scope of the project includes developing collaterals for submission of real-world data through mutual discussion, knowledge and experience sharing by industry colleagues. The collaterals will be developed by undertaking research of existing draft guidance documents on real-world evidence by regulatory bodies, and by analysing members' lessons learnt from completed case studies. The scope of this project will include submission of real-world data obtained from primary and widely used real-world data sources. These may include key electronic health record sources, patient reported outcomes, widely used and accepted claims data sources, and other commonly used observational data. This project will also touch upon the data curation and ingestion processes pertaining to clinical operational as well as submission data. Since real-world data can come from a wide variety of sources, the scope of this project will consider the widely and most commonly used real-world data sources by industry and member companies.

Problem Statement

The pharmaceutical and biotech industry has witnessed incremental use of real-world data in the clinical trial and overall drug development process. As per the latest survey, close to 70% of clinical trials now use some form of real-world data. Based on the message from the FDA at the PHUSE /FDA CSS 2022, real-world evidence will be a primary focus of the FDA in 2023 and 2024. Although there are draft guidance documents from the FDA about submission of real-world data, there is a need to have a more detailed framework and direction to industry regarding submission of real-world data to regulatory bodies. This project aims to focus on developing collaterals which pharma industry, CROs and technology vendors can utilise for submission of real-world data to regulatory bodies.

Problem Impact

This project plans to develop a submission-guidance-specific white paper for different types of real-world data including but not limited to EMR, claims data, patient reported outcomes and other observational data. These collaterals are aimed to assist the industry in making informed decisions while submitting real-world data to regulatory bodies. The project deliverables will be built upon the work completed by the Real World Evidence project and all efforts here will be in coordination with the Real-world Evidence team.

Project Leads	Email
Parag Shiralkar, *Sumptuous Data Sciences*	parag.shiralkar@sumptuous-ds.com
Chris Hurley, *MMS*	chris.hurley@phuse.global
Jeffery Abolafi, *Pinnacle 21*	jabolafia@pinnacle21.com
Nicola Newton, *PHUSE Project Assistant*	nicky@phuse.global

CURRENT STATUS **Q2 2024**

- Conducted knowledge sharing session for HL7-FHIR Introduction.
- Conducted knowledge sharing session by inviting Vulcan project.
- Drafted Blog for '*Feasibility Assessment of HL7-FHIR as a submission standard*'.
- Defined core areas of focus for further tasks and objectives.

Objectives & Deliverables	Timelines
Project kick off	Q2 2023
Decision Tree on how to submit the real-world data	Q4 2023
Checklist for things to consider while submitting real-world data	Q4 2023
Standardised documentation templates if needed	TBD
Overall road map of things leading to each deliverable submitted to the FDA	Q1 2024