RWD Guideline for Programming and Analysis Processes

Project Scope

The project will bring together statistical programmers across pharma to collaborate and provide their input to create an RWE Guideline/White Paper for the industry.

Problem Statement

Many pharma and biotech companies have invested resources to develop their own company-specific real-world data policies. All these fragmented efforts deserve a wider platform to unite and come up with generalised cross-industry guidelines via further development and expert input. Focus should be given on refinement and conciseness. This might have the potential to shape the industry going forward.

Problem Impact

Over the last few years the prevalence of real-world data being recognised as a component of a successful drug development programme has significantly increased. Reviewers, approvers and the healthcare industry in general expect sponsors to provide evidence from these sources. The traditional clinical trial being the only method for drug development is no longer enough, and successful leveraging of these broader data sources – e.g. EHRs, registries, payer data, wearables – is now seen as integral in development programmes.

The proposed guideline/white paper seeks to guide statistical programmers in the approaches to take for studies where RWD is involved. It is an end-to-end resource which provides users with guidance on data sourcing, utilisation, transformation, standardisation and submission whilst educating users on the value of real-world evidence. It also emphasises how engagement and collaboration with functional stakeholders, namely data science, stats, epidemiology, DM and clinical programming can have a greater impact in those areas.

Successful operation of this guideline/white paper could increase efficiency, cost-effectiveness and collaboration amongst peers and stakeholders.

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Objectives & Deliverables	Timelines
Project kick-off	Q3 2023
Production of guideline/white paper on real-world data	Q1 2024

CURRENT STATUS Q1 2024

- Project kicked off
- Sub-topics selected
- Sub-team with team lead formed
- Each sub-team do their own meeting and report in the bi-weekly project meetings