Real World Evidence Project

Project Scope

The increasing interest in including results based on Real-world Data as part of regulated clinical trial submissions and similar research initiatives is testing how current regulatory and good practice requirements can incorporate these results into submissions. Whilst specific projects have successfully addressed these issues, Real World Evidence guidelines or points for consideration are not yet formalised. PHUSE members are involved in the management and analysis of these data, and best practices for dealing with Real World Evidence data that would assist members in this space. The project has three goals:

1. Focus on Real World Evidence issues.
2. Develop a White Paper presentation focused on establishing the range of areas that need to be considered/impact on the use of Real World Evidence in support of regulated clinical trial submissions. This would be focused on identifying issues such as data sources, Real World Evidence technologies, data privacy and related issues, standards etc. impacting on Real World Evidence use. (e.g. see PHUSE SDE London May 2019 presentations).
3. Identify and prioritise future Real World Evidence projects/sub-projects.

Project Leads	Email
Berber Snoeijer (ClinLine)	b.snoeijer@clinline.eu
David Hood (Axtria)	David.Hood@Axtria.com
Katie Warren (PHUSE Project Assistant)	katie@phuse.global

Objectives & Deliverables	Timelines
White Paper which establishes a range of areas that need to be considered/impact the use of Real World Evidence	Q2 2022
Community Forum: The Role of the Statistician and Statistical Programmer in Real-world Data Analysis.	Q3 2022
Community Forum: Challenges in Real World Data Ingestion and Standardization	Q4 2022

Published Deliverables	Date
Basic Considerations for the use of Real World Evidence (RWE) in Support of Regulated Clinical Trial Submissions: Version 1.0	16-Jul-2020

CURRENT STATUS **Q3/4 2022**

- White Paper in final stages
- Hosted a PHUSE Community Forum: The Role of the Statistician and Statistical Programmer in Real-world Data Analysis
- Starting to plan second Community Forum for Q4 2022