PHUSE New Project Request Template

PHUSE collaborations are organised into a number of Working Groups, each with a broad topic area. Each Working Group has specific projects designed to achieve a set of specific objectives.

Working Groups include volunteers from major stakeholders such as academia, the pharmaceutical industry, the biologics industry, the device industry, contract research organisations, core laboratory organisations, technology vendors, SDOs and interested regulatory agencies. Participation is open to anyone who wants to contribute.

The process New Project Requests follow can be found at www.phuse.global/useful-information. They are reviewed on a monthly basis by the PHUSE Working Groups Steering Committee using the criteria described, to ensure all projects meet the needs of our community, as well as our objectives of addressing unmet computational science needs in support of health product development and regulatory review.

1. Project Title:

Communication of version metadata for Open Source Languages

2. Working Group:

☐ Data Transparency
☐ Data Visualisation and Open Source Technology
☐ Emerging Trends & Technologies
☐ Nonclinical Topics
☐ Optimizing the Use of Data Standards
☐ Real World Evidence
☐ Risk Based Quality Management
☐ Safety Analytics
☐ Other

Please state.

3. Problem Statement:

Historically, when using proprietary statistical programming languages, communicating the version metadata of the statistical procedures/functions used to generate analysis has been done within the SAP with a general statement as to software and version that was used. With the growing popularity of open source statistical programming languages it is necessary that metadata is provided on each package that is used as a more general statement is no longer appropriate.

4. Problem Impact:

This project will develop a template (or add to an existing template e.g. SDSP, ADRG, etc… depending on the discussions within the team) so that the metadata relating to the version of the statistical packages/procedures used can be consistently (aligned with documented health authority expectations) completed by sponsors in a single template.

5. Project Scope:

Submission of evidence to health authorities of metadata relating to the version as part of a submission of clinical studies for review.

6. Project Deliverable(s) and Timeline(s):

A white paper describing both the content to be provided and the justification for the content, as well as a template (or addition to an existing template - tbc) for the provision of the described content. Additionally a sample completed template should also be created to support the consistent population of the template.

7. Tools Required/Planned to be Developed:

N/A

8. Project Lead(s):

Lovemore Gavaka (Novo Nordisk), Joel Laxamana (Roche-Genentech)

9. Project Requestor(s):

Chris Price, Mike Stackhouse, Michael Rimler

10. Stakeholders:

FDA

11. Email Address:

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