Safety Analytics

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Analyses & Displays for Hepatotoxicity

Scope

This project team will create two white papers with recommendations for analyses and displays associated with hepatotoxicity, with a focus on Phase II to IV clinical trials and integrated submission documents as follows:

- Stage 1 White Paper: Set of analyses/outputs with reasonable medical probability to rule out potential DILI
- Stage 2 White Paper (potential DILI has not been ruled out): Additional analyses/outputs that need to be generated to characterise the potential DILI issue and assess causality
- Value Added: Open-source software, Hepatotox tool, for production of outputs/analyses in Stage 1 and 2 white papers

Q4 2026

Proposed End Date

Stage 2 white paper & updated Hepatotox tool

Deliverable Type

Melvin Munsaka & Terry Walsh

Leads

- All key content for Stage 2 white paper finalised
- Added updates to the Hepatotox tool prototype
- Presented at the PHUSE US Connect
- Recruited some new members

Key Achievements This Quarter:

- Finalise Stage 2 draft white paper – Q2
- Route for PHUSE leadership review, public review, and publish – Q3
- Updated Hepatotox tool – Q3
- Wrap up project in Q4

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green
Aceepting New Members – especially hepatologists

- Draft Stage 2 white paper in progress

Project Status

Estimands in Safety Analytics

Scope

- Develop a user-friendly, one-stop education portal on the topic of safety estimands.
- Encompass and reference the learnings and recommendations of external groups working on safety estimands – work in a complementary and comprehensive fashion, and present information in a digestible, fit-for-application manner.
- Develop an education series with the goals of (1) substantially increasing the comfort level of safety scientists when articulating appropriate safety estimands (2) increasing their use in practice and (3) increasing the breadth of estimators routinely used in safety analytics.

Q4 2026

Proposed End Date

Series of training modules & webinars

Deliverable Type

- Added a fifth module to the overall project scope (estimand considerations for aggregated safety analyses)
- Completed four of the five modules and submitted for clinical review
- Started on the introductory slide deck/video to orient the learner to the content

Key Achievements This Quarter:

- All five modules completed and reviewed; speaker notes completed for each module
- Introductory slide deck/video completed
- Scheduling for webinars initiated

Deliverables & Targets Planned for the Next Quarter:

Andreas Sashegyi & Michael Colopy

Leads

Project Status: Green

- Project on track

Project Status

Interactive Analyses and Displays for Laboratory Data

Scope

This project aims to bring together stakeholders from pharma, academia and regulatory bodies with diverse backgrounds, such as statisticians, clinicians, medical experts and programmers. The goal is to collaborate on a deliverable concerning the use of interactive displays in the assessment of laboratory data during Phase II to III clinical trials. The deliverable will be a specification document providing platform-agnostic recommendations to stakeholders about the features and options that should be considered for interactive displays of laboratory data. This project's scope will encompass considerations for interactive visualisations used in ongoing safety monitoring, regulatory submissions and publications.

Q4 2026

Proposed End Date

Specification document

Deliverable Type

Christopher Smith

Lead

Set in motion plan to release a LinkedIn blog post, a PHUSE webinar and a safety clinician survey

Key Achievements This Quarter:

Release survey and start collecting data

Deliverables & Targets Planned for the Next Quarter:

Project Status: Green

- No concerns at the moment

Project Status

Process for Aggregate Assessment of Clinical Trial AE Data (PrOACTS)

Scope

- Define the challenges and processes needed for aggregate AE assessment and identification of safety signals within early development programmes
- Research types of analytics that may be appropriate to implement, and the challenges they bring
- Bring clarity to 'significance' in safety without statistical connotation. Define important terms (medically important, clinically relevant, etc.)
- Delineate potential pitfalls with small sample sizes, limited important events and uncertain background rates
- Understand current organisational trends regarding safety assessment practices through the collection of focused survey results.

Q4 2027

Proposed End Date

White paper

Deliverable Type

Mac Gordon & Peg Fletcher

Leads

Key Achievements This Quarter:

- Survey requests circulated among PHUSE, ASA Biopharm and personal contacts; of 22 company representatives who agreed, 18 have responded to date (67%)
- Definitions team has a draft of over 50% of terms identified; interdisciplinary review has started
- Prepared for LinkedIn blog post and PHUSE webinar
- Prepared for the US Connect
- Topline initial survey responses presented at the US Connect

Deliverables & Targets Planned for the Next Quarter:

- Finalise the table of contents for the white paper and have authoring underway
- Collate the survey results to be used in the white paper and distribute the results to the team. Perform follow-up analyses as needed on the underlying data
- Understand key points from the analysis subteam for further evaluation and inclusion in the white paper

Project Status

Project Status: Green

- No concerns at the moment

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Safety Analytics Education

Scope

Planning and interpreting clinical trial safety analyses demands scientific expertise that is often missing in educational curricula. The safety analytics field is dynamic and evolving, requiring continual learning. All the roles (for example, medical, statistics, writers) that collaborate on ongoing safety reviews, clinical study reports and integrated submission documents can improve their planning, content, execution and communication of clinical trial safety analyses.

Ongoing

Proposed End Date

- Enhance the Safety Analytics Education website
- Webinar series

Deliverable Type

- Delivered session at the US Connect on the PHUSE Safety Library and open Q&A on safety analysis questions
- Initiated an article with PSI and the ASA Safety Working Group to highlight open-source tools available for interactive graphics

Key Achievements This Quarter:

- Initiate transition of the PHUSE Safety Library to the PHUSE website
- Finalise details for trailblazer webinar series (have included PSI and ASA colleagues in discussion)
- Publish article on open-source tools (format TBD but likely a LinkedIn article)

Deliverables & Targets Planned for the Next Quarter:

Christopher Smith & William Palo

Leads

Project Status: Green
Accepting New Members – *Looking for members with interest in sharing their knowledge and facilitating communications such as webinars and LinkedIn.*

- No concerns at the moment

Project Status

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