Safety Analytics

Analyses & Displays for Hepatotoxicity

Project Leads:
Melvin Munsaka & Terry Walsh

Deliverable:
Two white papers for Stage 1 and Stage 2

Proposed Project End Date:
Q1 2026

Project 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. Note that the Stage 1 white paper has been completed.

Project Status:
Green

Project Accepting New Members:
Yes (especially MDs who are experts in DILI assessment)

Key Achievements This Quarter:

- Stage 2 white paper draft moving along well
- Stage 1 white paper Hepatotox R package created on GitHub
- Validation resource for Hepatotox R package identified

Deliverables & Targets Planned for the Next Quarter:

- Finalise Stage 2 white paper
- Finalise R Package Hepatotox tool for Stage 1 white paper
- Embark on Hepatotox R package for Stage 2 white paper

Estimands in Safety Analytics

Project Leads:
Andreas Sashegyi & Michael Colopy

Deliverable:
Series of training modules & white paper

Proposed Project End Date:
Q3 2026

Project 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 ensure information is presented 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.

Project Status:
Green

Project Accepting New Members: No (by exception only)

Key Achievements This Quarter:

- Continued progress on self-study materials by all four sub-teams, addressing the four key topic areas identified
- Draft slide decks available for three of the sub-teams; content staging nearly complete for the fourth
- Poster presentation of the team's work at the 2025 EFSPI regulatory statistics workshop (September)

Deliverables & Targets Planned for the Next Quarter:

- Self-study materials in peri-final form for all four sub-teams
- Begin video and webinar preparations

Project Lead:
Christopher Smith

Deliverable:
Specification document

Key Achievements This Quarter:

Determined path forward

Proposed Project End Date:
Q3 2026

Interactive Analyses and Displays for Laboratory Data

Project 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.

Project Status:
Green

Deliverables & Targets Planned for the Next Quarter:

Will seek to blend the activities of this group with the Safety Education group and produce education material focused on introducing new clinical scientists to working with interactive lab displays.

Project Accepting New Members: Yes

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

Project Leads:
Mac Gordon & Peg Fletcher

Proposed Project End Date:
Q4 2026

Project 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.

Deliverable:
White paper

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

- Industry survey draft created and out for review
- Draft list of definitions created
- Analytics sub-team membership finalised and moving forward

Deliverables & Targets Planned for the Next Quarter:

- Industry survey delivered in Q4 with results received
- Definition list finalised
- Final sub-team (pre-clinical signals/risk communication) to be formed

Safety Analytics Education

Project Leads:
William Palo & Christopher Smith

Proposed Project End Date:
Ongoing

Project Scope:

Develop and deliver education relevant to clinical trial safety analyses, with a focus on Phase II to III.

Deliverable:
1) Enhance the Safety Analytics Education website
2) Deliver webinars on safety content

Project Status:
Green

Project Accepting New Members: Yes

Key Achievements This Quarter:

Finalised scope for hepatotoxicity webinar and weekly LinkedIn posts

Deliverables & Targets Planned for the Next Quarter:

- Present the hepatotoxicity webinar.
- Initiate weekly LinkedIn posts to highlight the safety library