

Safety Analytics Education



Project Scope		
Development and delivery of education relevant to clinical trial safety analyses, with a focus on Phase 2-3.		
Problem Statement		
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.		
Problem Impact		
Improving Safety Analytics Education will lead to better content, implementation, and understanding of clinical trial safety analyses. Additionally, when stakeholders are educated, less time is needed for aligning on analysis plans and data interpretations.		
Members of the Safety Analytics Education project team have been active in delivering and promoting educational content for a while:		
<ul style="list-style-type: none">• Leading Safety Analytics workshops at the PHUSE CSS• Presenting at the Duke Margolis-FDA workshop on advancing premarket safety analytics• Partnering with the PHUSE Education team to create and maintain a Safety Analytics Education website• Hosting a webinar series on Interdisciplinary Safety Evaluation for Decision-Making		
The Education project team will provide a dedicated channel for future efforts and enhance the standing of PHUSE in the safety analytics space.		
Project Leads	Emails	
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<div>CURRENT STATUS Q1 2024</div> <ul style="list-style-type: none">• Contributed presentation to the 7 March SBIA webinar: “Integrated Safety Analyses in Drug Marketing Applications: Avoiding Common Mistakes”.		
Objectives & Deliverables		Timelines
Enhance the existing Safety Analytics Education website		Ongoing
Deliver webinars on safety content		Ongoing
Education Resources:		
Education Page		
Reimagining a Safety Submission – Vision of Interactive Safety Reviews		
Aggregate Safety Assessment Planning-Community Forum		
Safety Analytics Workshop 2020		
Safety Analytics Workshop 2019		
Webinar series on Interdisciplinary Safety Evaluation for Decision-Making		