

PP08

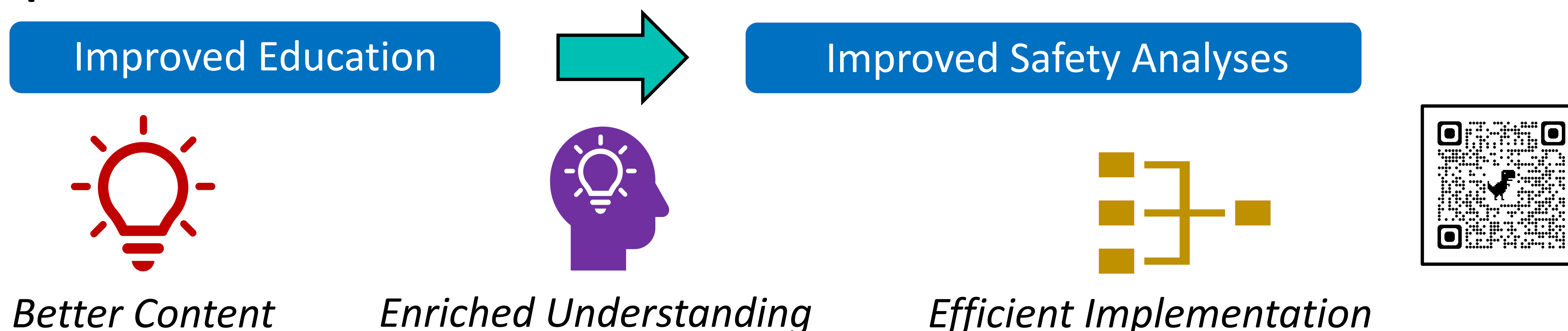
An Introduction to the Safety Analytics Education Project

Presented by William Palo, AbbVie and Christopher Smith, FDA

Abstract

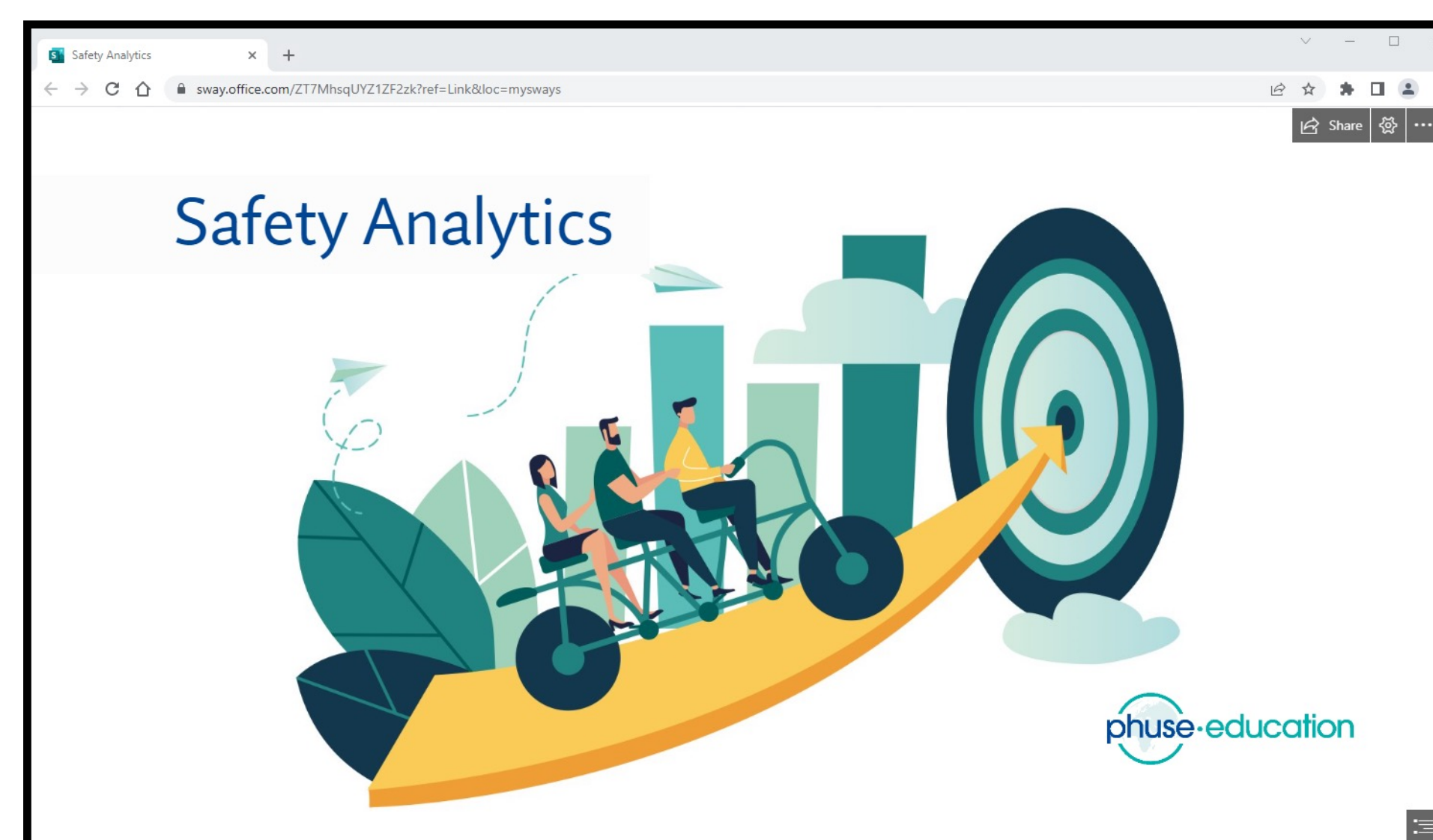
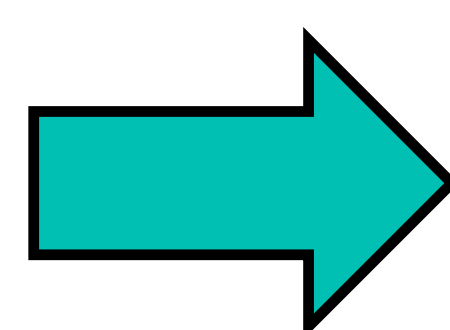
Planning and interpreting clinical trial safety analyses demands scientific expertise that is often missing in educational curricula. The safety analytics field is dynamic and evolving, requiring continual learning. All the roles (e.g., medical, statistics, communications) that collaborate on ongoing safety reviews, clinical study reports, and integrated submission documents can improve their planning, content, execution, and communication of clinical trial safety analyses. To this end, the Safety Analytics Education project was formed to develop and deliver educational content relevant to clinical trial safety analyses with a focus on Phase 2-3.

Our Impact

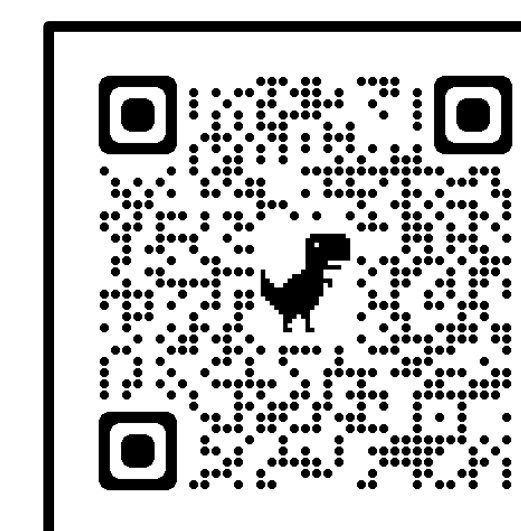


Deliverable: Safety Library

One Stop Shopping for
Safety Education



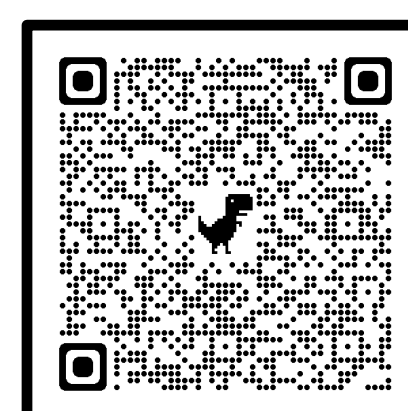
<https://sway.office.com/ZT7MhsgUYZ1ZF2zk?ref=Link&loc=mysways>



Deliverable: Webinars

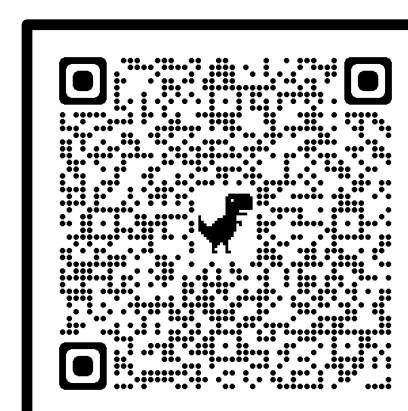
Interdisciplinary Safety Evaluation
for Learning and Decision Making

5-part series in partnership with DIA and ASA



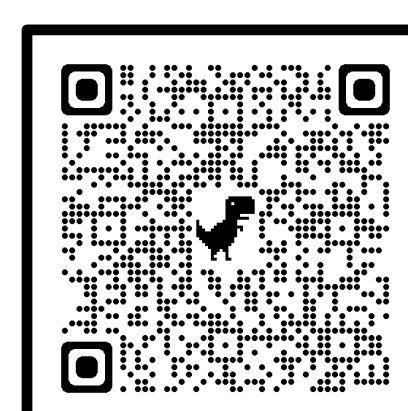
Integrated Safety Analyses in Drug
Marketing Applications:
Avoiding Common Mistakes

Partnership with FDA SBIA



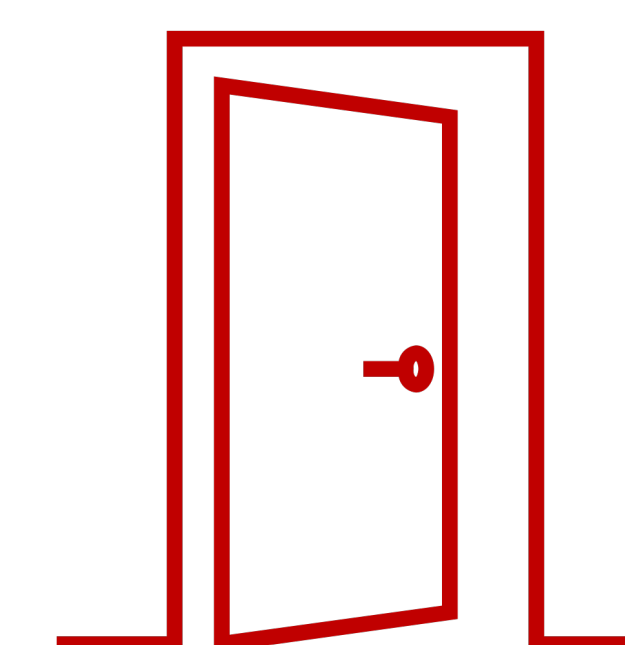
Statistical Considerations for
Premarketing Risk Assessment

Partnership with FDA SBIA

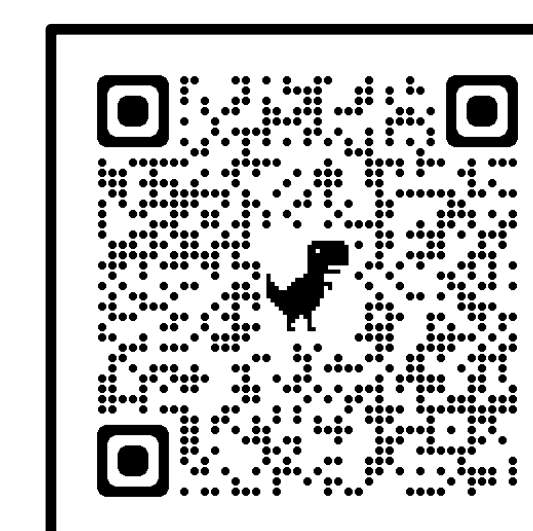
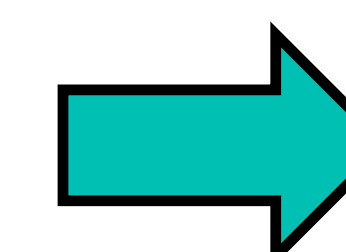


Future webinars in continued
partnership with FDA SBIA

Additional ideas?
You're welcome to join us!



Check out the useful
FDA SBIA content!



See additional PHUSE
education material!

