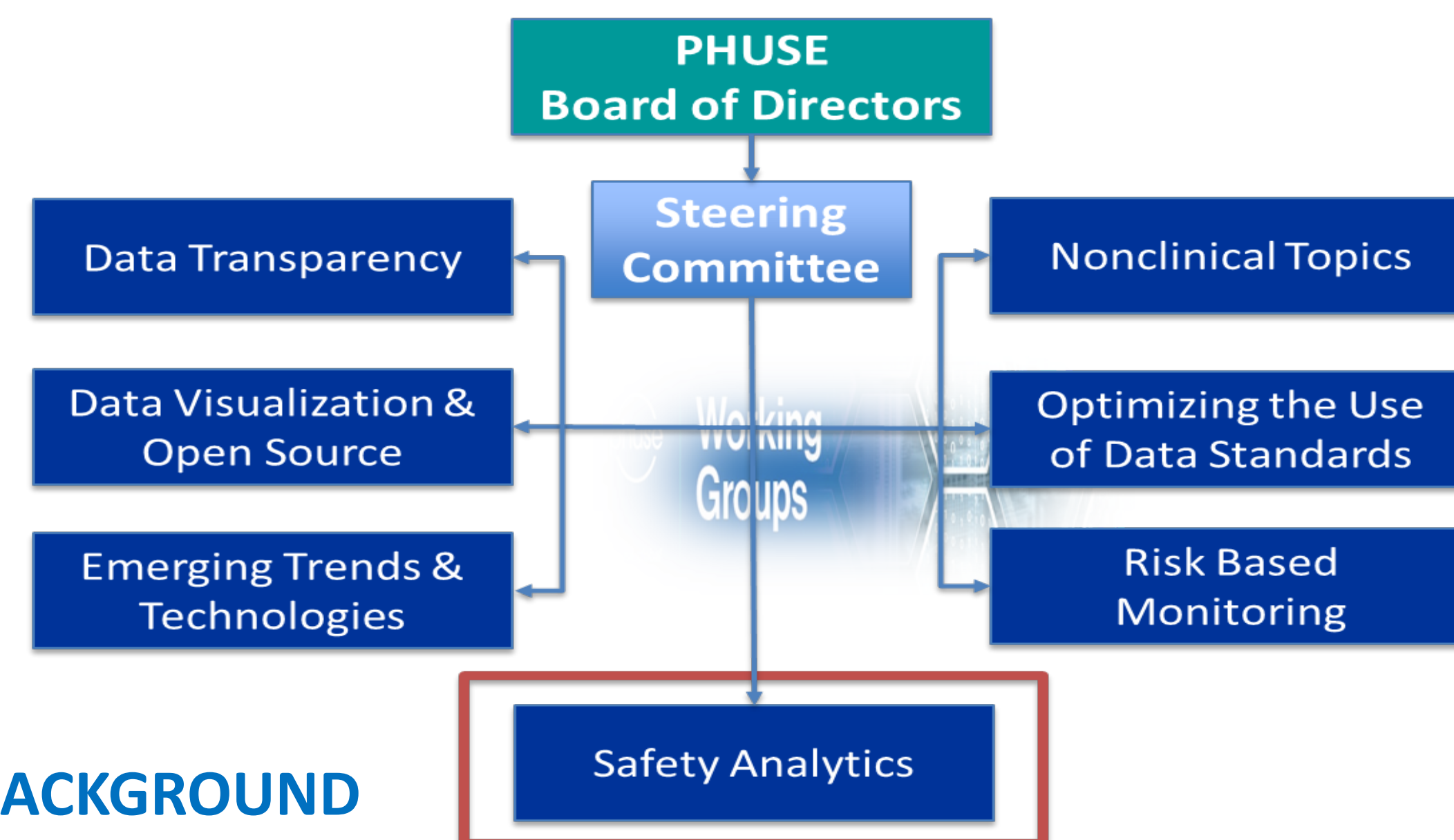
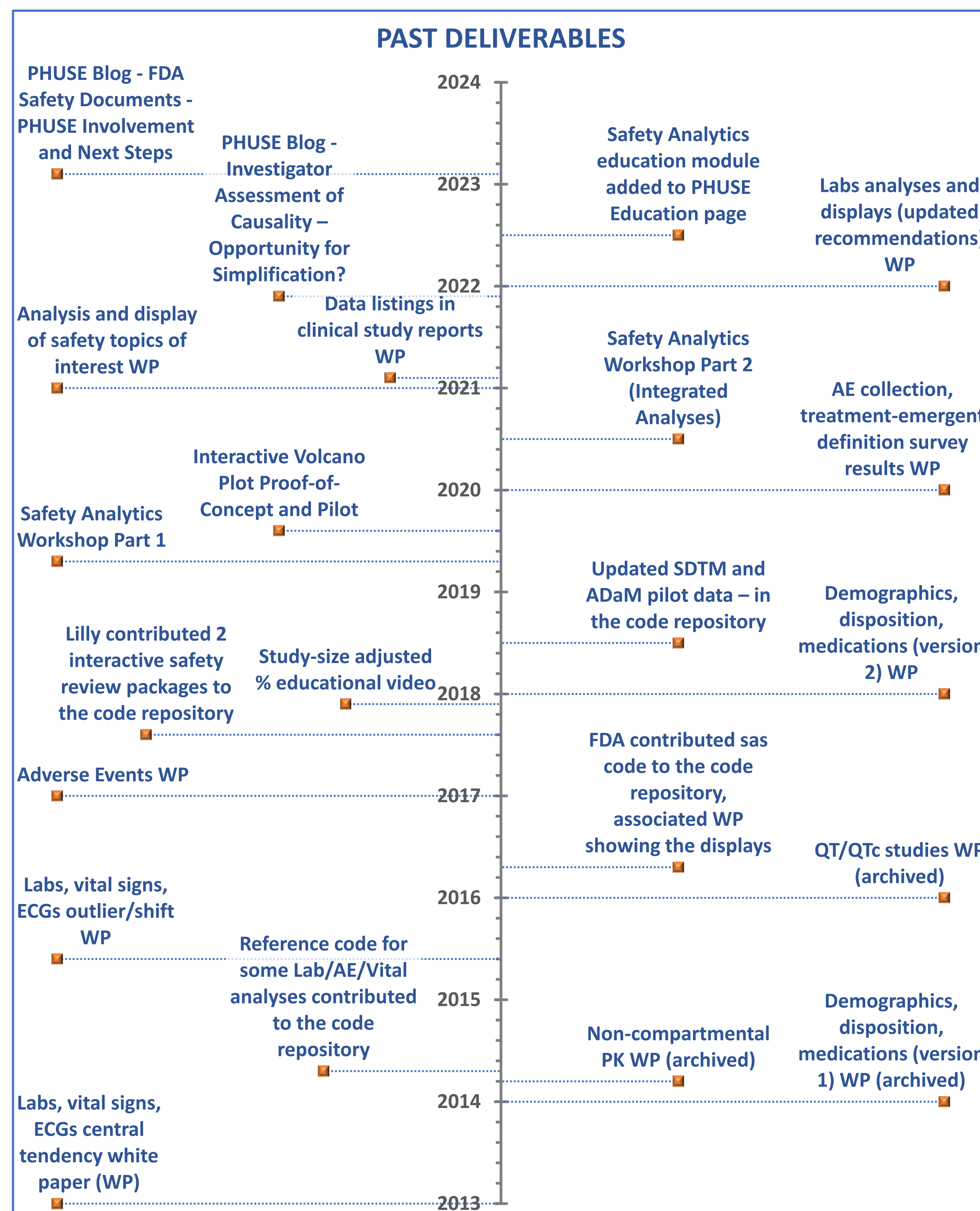


ABSTRACT The PHUSE Safety Analytics Working Group, a cross-disciplinary collaboration, is working to improve the content and implementation of clinical trial safety analyses for medical research, leading to better data interpretations and increased efficiency in clinical drug development and review processes. The Working Group has produced multiple deliverables (e.g., Conference Poster and Presentation, White Paper, Publication and Blog) over the past 10 years and has multiple ongoing projects. This presentation will provide an overview of the Working Group and its associated project teams, share a list of the teams' progress, key deliverables for awareness and a summary of ongoing projects. We encourage feedback and we are accepting additional volunteers.



BACKGROUND

- ❑ FDA/PHUSE collaboration started 2012
- ❑ Platform for academia, regulators, industry, and technology providers to address computational science needs in support of regulatory review
- ❑ Supported by PHUSE, the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER)
- ❑ Resources that improve preparation and analysis of regulatory data and associated documentation



ONGOING PROJECTS



Adverse Event Collection Recommendations

- Leads: Aimee Basile, Mary Nilsson
- Presented the Investigator-determined Causality Issue during April PHUSE Webinar Wednesday
- This project team will create a white paper with recommendations for adverse event collection instructions, with a focus on Phase 2-4 clinical trials.

Analysis & Displays for Hepatotoxicity

- Leads: Terry Walsh, Melvin Munsaka
- This project team is creating a white paper with recommendations for analyses and displays associated with hepatotoxicity, with a focus on Phase 2-4 clinical trials and integrated submission documents

Analysis & Displays for Laboratory Data

- Leads: Wei Wang, Charles Beasley
- Created a white paper with updated recommendations for analyses and displays for laboratory data, with a focus on Phase 2-4 clinical trials and integrated submission documents.

Listings for Clinical Study Reports

- Leads: Mercy Navarro, Nancy Brucken
- Published white paper Dec 2021
- CDISC US Interchange 2021 oral presentation
- PHUSE US Connect poster 2022
- PharmaSUG paper 2022
- Published viewpoint article to Pharmaceutical Statistics Jan 2023

Treatment Emergent Definition Recommendations

- Leads: Bill Palo, Mary Nilsson
- This project team created a survey to elicit thoughts on how treatment emergence should be defined
- This project team will create a white paper with recommendations on treatment emergent definitions

Safety Analytics Education

- Lead: Bill Palo
- This project team developed a repository of fundamental safety references that we've found helpful in our careers
- Audience: Someone new to patient safety analyses in clinical trials, Cross-functional colleagues

NEW: Adverse Event Groupings in Safety (AEGiS)

- Leads: Mac Gordon, Peg Fletcher
- This project team will create a white paper with recommendations on choosing across existing AE groupings (e.g., FDA Medical Query, Standardized MedDRA Query) versus creating a custom grouping.
- Develop efficient standardized processes and analyses that can leverage new technologies

NEW: Comments on FDA's Safety Tables and Figures Integrated Guide

- Leads: Mary Nilsson, Greg Ball, Mac Gordon
- Consolidate comments on the FDA Standard Safety Tables and Figures Integrated Guide from PHUSE community
- PHUSE Blog - FDA Safety Documents - PHUSE Involvement and Next Steps Jan 2023

POTENTIAL FUTURE PROJECTS

- Estimands for safety
- Specifications for interactive safety review tools
- Plain language summaries
- Adverse event analyses and displays (version 2)
- Vital signs analyses and displays (version 2)
- ECG analyses and displays (version 2)
- Disposition collection recommendations
- Improving lab data quality
- Defining gender-specific MedDRA preferred terms
- Safety population definition recommendation
- Preparing for the FDA Type C meeting on integrated safety plans
- Notable criteria, narratives
- Combining studies for integrated analyses
- Analysis of genomic and biomarkers
- Writing statistical results for safety
- Analyses and displays of adjudicated data
- Safety in rare diseases
- Analyses for clinpharm studies
- Safety update recommendations

CONCLUSION

As you can see, the Safety Analytics Working Group project teams have accomplished a considerable amount over the past years, but we still have more work to do. Additional volunteers for the current project teams are welcome, and the Working Group also encourages proposals for new projects that fit under the Safety Analytics umbrella.

REFERENCES

PHUSE Working Groups and Deliverables.

<https://www.phuse.global/>

ACKNOWLEDGMENTS

We would like to express thanks to the Safety Analytics Working Group leads and all members.

For more information or join PHUSE Safety Analytics Working Group? Scan the QR code!

