

PHUSE Deliverables Related to Safety Analytics

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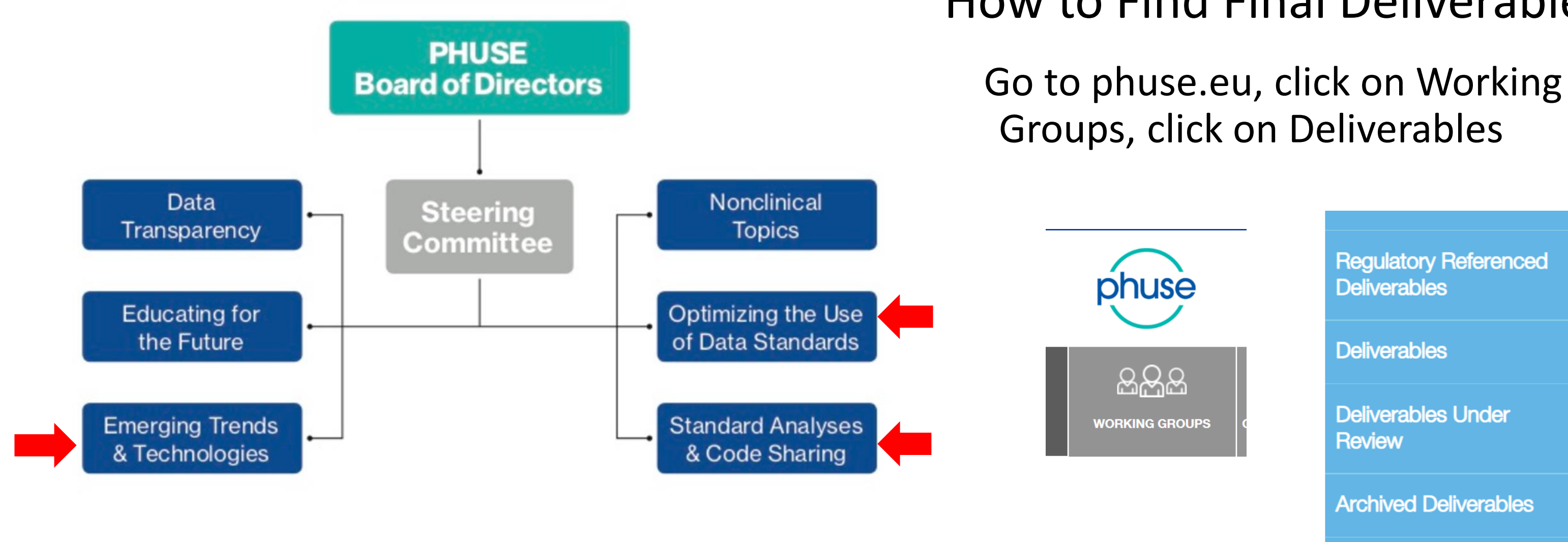
ABSTRACT

Since the beginning of the FDA/PHUSE collaboration in 2012, numerous deliverables by multiple PHUSE project teams have been finalized related to safety analytics. For example, the Analysis and Display White Papers project team authored 4 safety-related white papers providing recommendations for analyses, tables, figures, and listings (laboratory measurements, vital signs, electrocardiograms, adverse events, medications, disposition), and conducted an associated educational workshop on the material. As another example, the Interactive Analyses for Submissions project team conducted a proof-of concept and pilot, which led to the inclusion of an interactive display on adverse event data in a submission. This poster will provide a summary of the final deliverables related to safety analytics, and a summary of ongoing work and planned work. We encourage researchers to leverage existing deliverables, and we welcome additional volunteers to assist in ongoing and planned work.

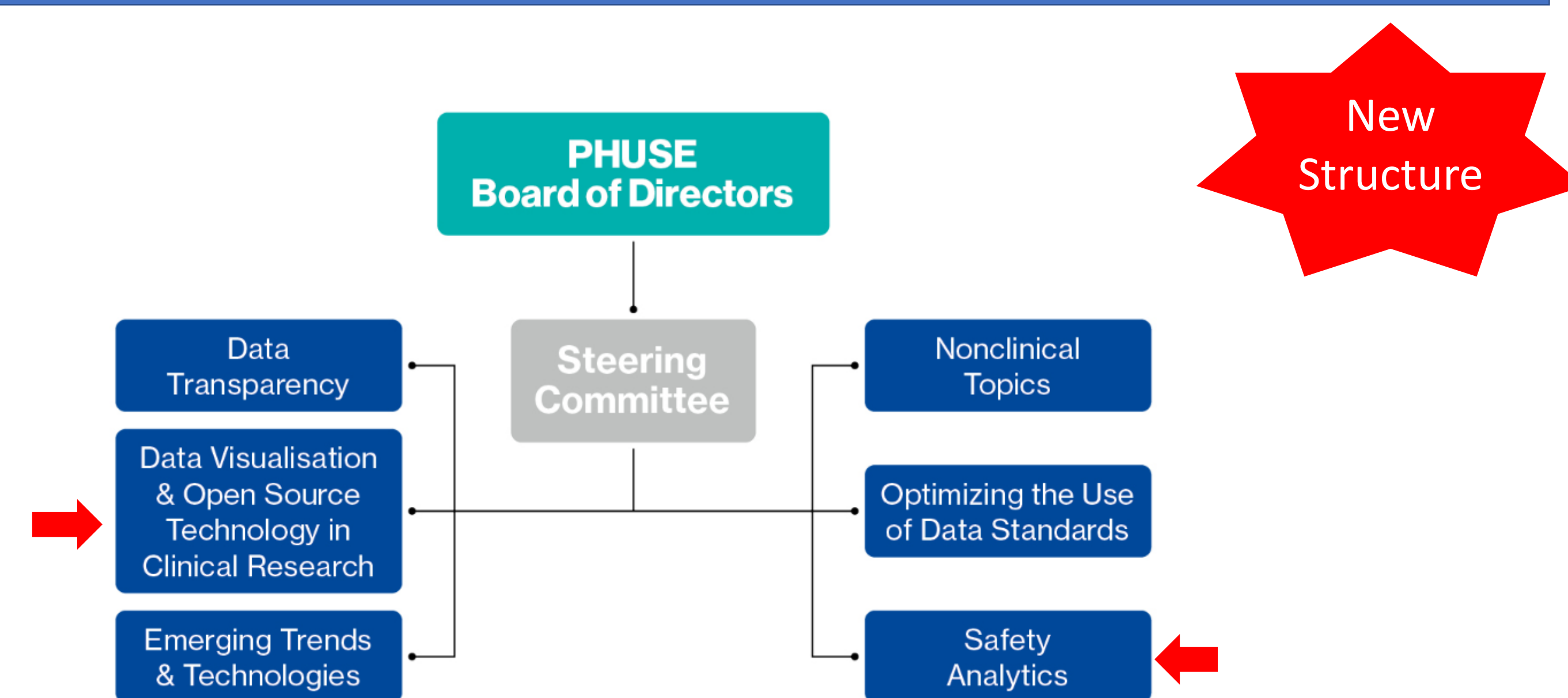
Final Deliverables

How to Find Final Deliverables

Go to phuse.eu, click on Working Groups, click on Deliverables



Ongoing/Planned Deliverables



- 2013 Labs, vitals, ECGs central tendency white paper
- 2014 Demographics, disposition, medications (version 1) white paper (archived)
- 2014 Non-compartmental PK white paper (archived)
- 2014 Reference code for some white paper analyses contributed to Code Repository
- 2015 Labs, vitals, ECGs outliers/shifts white paper
- 2016 QT/QTc studies white paper (archived)
- 2016-7 FDA contributed sas code to Code Repository, associated white paper showing the displays
- 2017 Adverse event white paper
- 2017 Lilly contributed 2 interactive safety review packages to Code Repository
- 2017 Study-size adjusted percentage educational video
- 2018 Updated SDTM and ADaM pilot data – in Code Repository
- 2018 Demographics, disposition, medications (version 2) white paper
- 2019 Safety analytics workshop Part 1
- 2019 Interactive volcano plot for adverse events in a submission proof-of-concept and pilot completed
- 2020 Output tips and considerations white paper
- 2020 AE collection, treatment-emergent definition survey results white paper
- 2020 Safety analytics workshop Part 2

- Safety topics of interest white paper
- Sharing interactive safety review package in a submission proof-of-concept
- Listings for clinical study reports white paper
- Analyses and displays for lab data white paper
- Analyses and displays associated with hepatotoxicity white paper
- Adverse event collection recommendations
- Treatment emergent definition recommendations
- Safety analytics education resource site
- Interactive volcano/forest Plot code
- Possible EU layperson summary collaboration



WE NEED YOU TO:

- **SOCIALIZE THE FINAL DELIVERABLES**
- **VOLUNTEER TO WORK ON FUTURE DELIVERABLES**

- Use the recommendations!
- Forward to any standards groups within your organization
- Include links to white papers in Statistical Analysis Plans
- **ADVERTISE!**
- **VOLUNTEER!**