



# Advancing the Implementation of Safety Methodologies

**PSI Conference 2026**

Naomi Givens, Dooti Roy, Matthias Trampisch,  
Florence Le Maulf  
& the Benefit Risk SIG Safety Implementation Working Group



# Consolidation of Brainstorming

## 2025 Focus



### Successful adoption - considerations beyond the science

- How to get new methodology and process improvements adopted in companies
- Best practice for 'getting to yes', including senior stakeholder management, engaging developers and end-users
- Successful adoption pathways

### Aggregate safety process - how to operationalise?

- Share experiences of and develop guidance for the implementation of aggregate safety review and reporting to FDA

# Consolidation of Brainstorming

## 2026 Progress



### Successful adoption of new methodology

- How to get new methodology and new tools adopted

### Quantitative Evolution of Drug Safety: Adapting Inventions to Innovations

- Successful adoption pathways

### Aggregate safety process - how to operationalise?

- Share experiences of and develop guidance for the implementation of aggregate safety review and reporting to FDA

# Consolidation of Brainstorming

## 2026 Progress



### Successful Adoption

- How to get new methodology and new

**Quantitative Evolution of Drug Safety: Adapting Inventions to Innovations**

- Successful adoption pathways

### Aggregating Data

**Beyond Individual Cases: Operationalizing FDA IND Safety Reporting for Anticipated Serious Adverse Events**

# Consolidation of Brainstorming

## Beyond 2025



### Operationalising ISS reporting

- Share experiences of ISS reporting, develop an ISS template

### Background rate generation - benefits and pitfalls

- Partner with Epidemiology colleagues to educate on contextualisation of data to get to a suitable background rate
- Promote the use of the statistician skillset to generate operating characteristics and sensitivity analyses

### Use of tools/ visualisations - for us and our colleagues

- Share tools companies have developed and encourage release of them as open-source packages
- Share experience of 'interactive' tool being used in a submission

### Safety estimands

- Efficacy estimands are well established and should also be applied to key safety endpoints but is it happening?
- Share knowledge/experiences

### Safety speak

- Can we speak a common language across disciplines, Safety, Epi and Biostats? How can we influence/advocate

# Consolidation of Brainstorming

## 2026 Progress

### Operationalising ISS reporting

- Share experiences of ISS reporting

### Pooling, Grouping, Adjusting: A Statistician's Toolkit for Integrated Summary of Safety Development

... toolkit to generate operating characteristics and sensitivity analyses

### Use of tools/ visualisations - for us and our colleagues

- Share tools companies have developed and encourage release of them as open-source packages
- Share experience of 'interactive' tool being used in a submission

### Safety estimands

- Efficacy estimands are well established and should also be applied to key safety endpoints but is it happening?
- Share knowledge/experiences

### Safety speak

- Can we speak a common language across disciplines, Safety, Epi and Biostats? How can we influence/advocate