

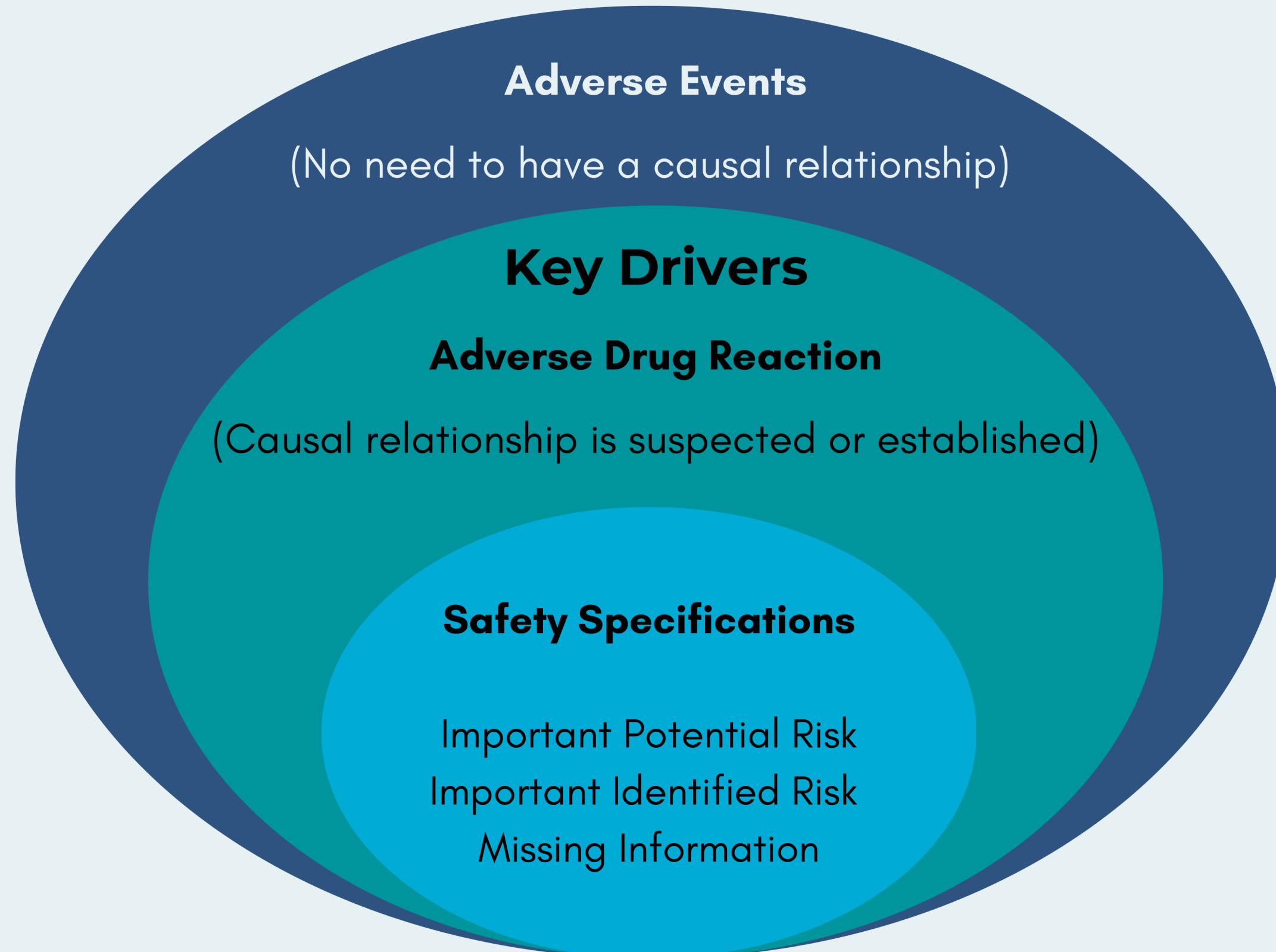


LIFECYCLE OF A RISK

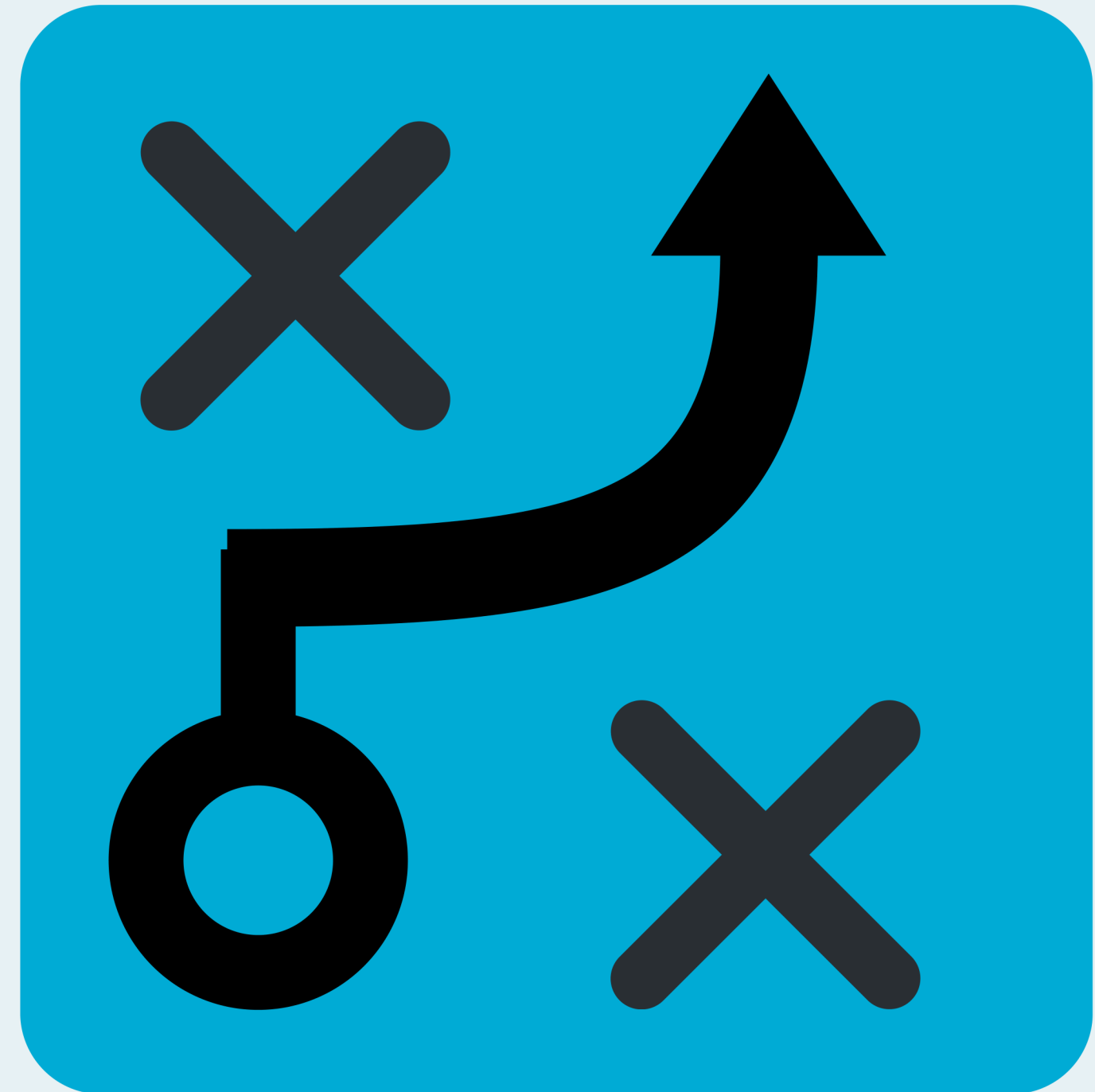
GLASS EIGHT

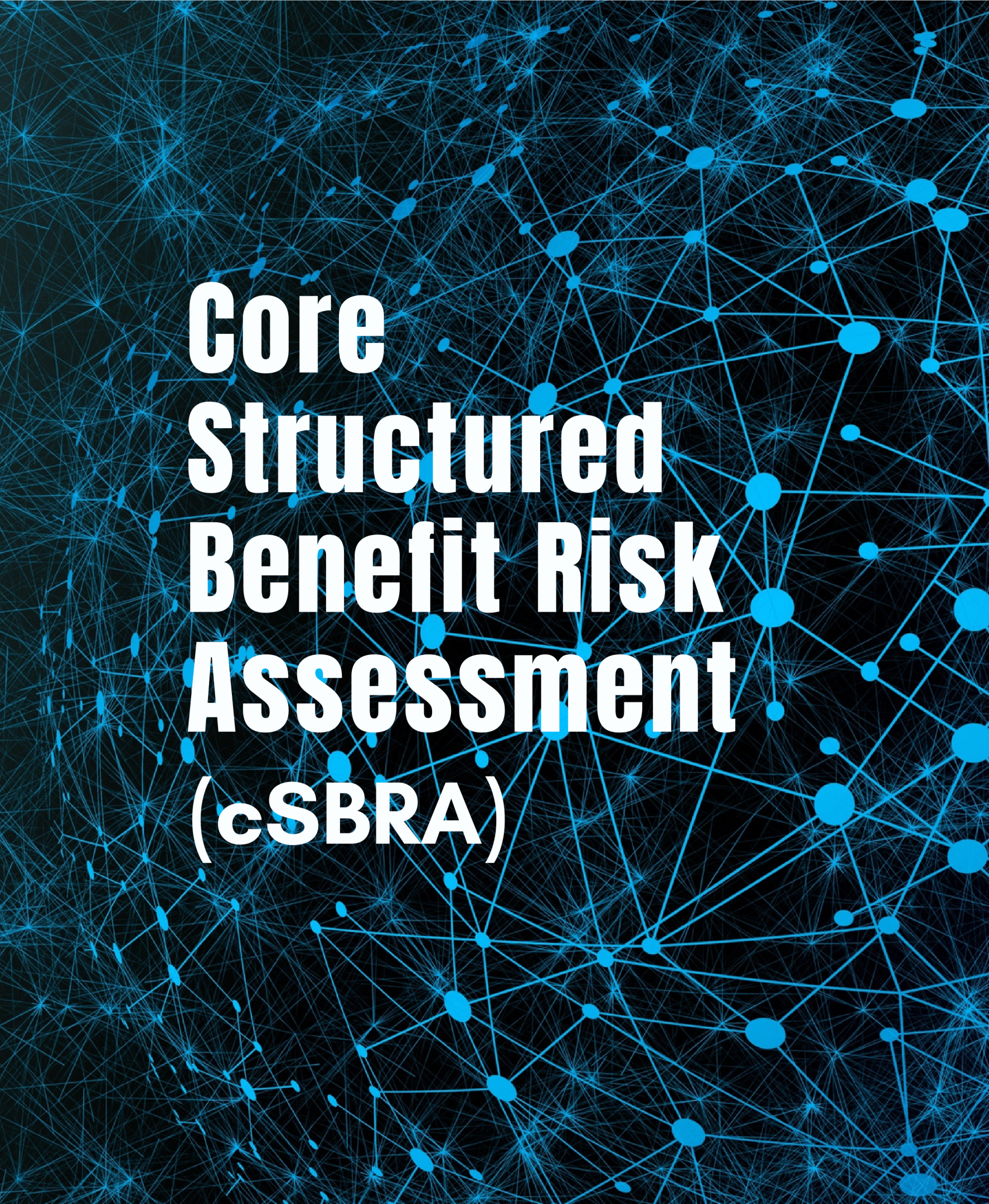


RISK TUNNEL



**Core
Structured
Benefit Risk
Assessment
(cSBRA)**





Core Structured Benefit Risk Assessment (cSBRA)

- A living document/continuous process which involves weighing the benefit vs the risk of a product for a particular indication
- Core – meaning its an internal document (not submitted to the agency but serves as source document for many regulatory documents)
- Prepared at end of phase 2 (EOP2)
- Involves crossfunctional collaboration

Figure 1: FDA's Benefit-Risk Framework

Benefit-Risk Integrated Assessment

Benefit-Risk Dimensions

Dimension	Evidence & Uncertainties	Conclusions & Reasons
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk & Risk Management		

Opportunities for Structured Benefit/Risk Assessment during Drug Development

Assess patient group views on:

1. Analysis of Condition
2. Treatment Option

Share clinical data confidentiality with patient group and seek feedback on:

1. Benefit
2. Risk
3. Risk Management

Provide advisory committee members with in briefing document to frame the meeting

