



Creating Preliminary Data: Observational Studies

Bellal Joseph, MD, FACS

Professor & Chief of Trauma and Acute Care Surgery

The University of Arizona, Tucson, AZ



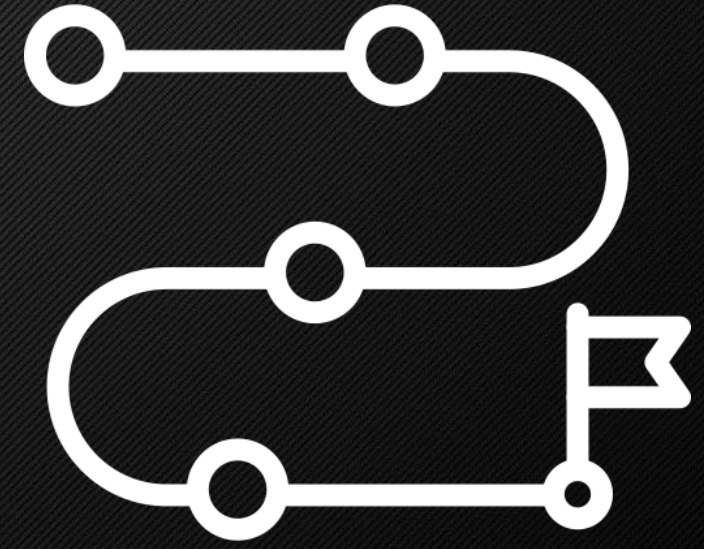
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Disclosures

No Disclosures

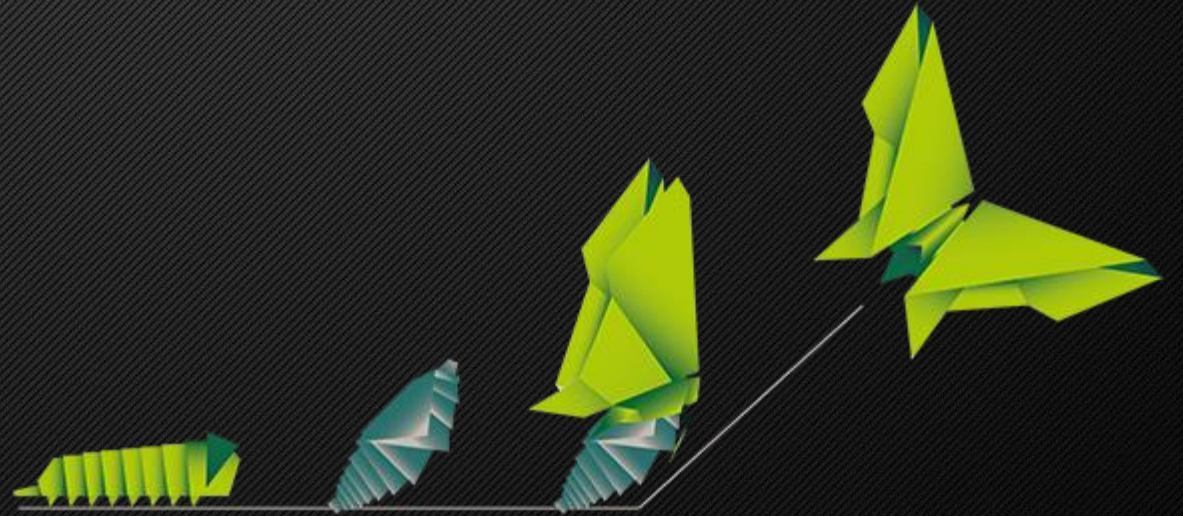
Outline

- What is prelim data?
- How to get prelim data? (our experience)
- Take home messages



What is Prelim Data

- Data generated **prior to conducting full scale studies**
- Why do we need it?
 - Evaluate **feasibility**
 - Test overall approach
 - Provide **proof of concept**



Generating a Research Question

- Daily clinical experience
 - Encounter many **uncertainties**
 - **Insufficient** evidence
 - **Controversial** management approach
 - **Poor** outcomes
 - **Challenge** dogmas



The Right Research Question

- Ask the right research question
- The right form of the question
 - **P**: Patient population
 - **I**: Intervention/exposure
 - **C**: Comparator
 - **O**: Outcomes



Literature Review



- Conduct a **thorough literature review**
- Evaluate **quality of available evidence**
- Does the literature answer your question?
- Identify a **knowledge gap (if any)**



How To Get Started

- Have a clear idea of the **overarching research question**
- Consult **senior researchers**
- Search for **collaborative opportunities**
- **Network**: Find other scientists working on the same topic



Conducting an Observational Study



Observational Study

- What is an **observational study**?
 - Passive observation
 - **No intervention** by investigator
 - Establish **association**
 - **Support** overarching research goal



Why Observational ?

- **Inexpensive**
- **Faster** data collection
- **Large** sample size
- Asses **multiple outcomes**
- **Expedited** board review







Observational Study Downsides






- **Lower standard** of evidence
- More prone to **bias and confounding**
- Can demonstrate **association** but not **causality**
- May **overpredict results**



Decide on a Study Design

- Prospective/Retrospective cohort study  → Rare exposure
- Cross sectional study  → Asses prevalence
- Case-control study  → Rare outcomes
- Case series  → Rare conditions

Decide on a Data Source

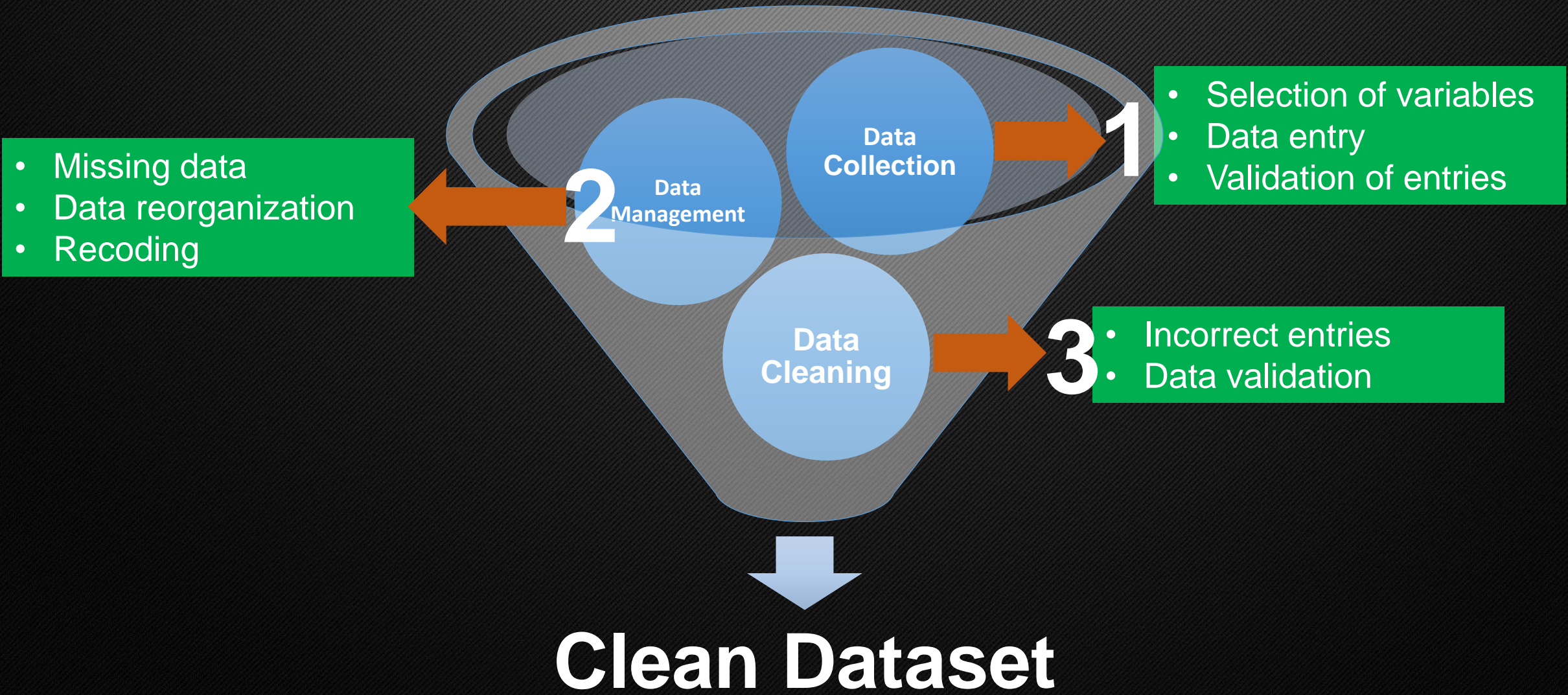
- Chart review  → Granular data
- Biobank  → Molecular data
- Multicenter data  → Generalizable data
- Nationwide databases  → Large sample size
- Quality improvement projects  → Local experience

Getting IRB Approval

- Use deidentified data
- Protect patient confidentiality/welfare
- Ethical conduct of research



Data Management



Data Analysis

- Statistical support
- Univariate/multivariate analysis
- Appropriate statistical methods
 - Regression
 - Propensity scores matching
 - Subanalysis



Using Prelim Data



- Incorporate findings in **grant application**
- Use data to:
 - Calculate **sample size**
 - Adjust **design**
 - Estimate **cost**
 - Determine **timeframe** for patient recruitment



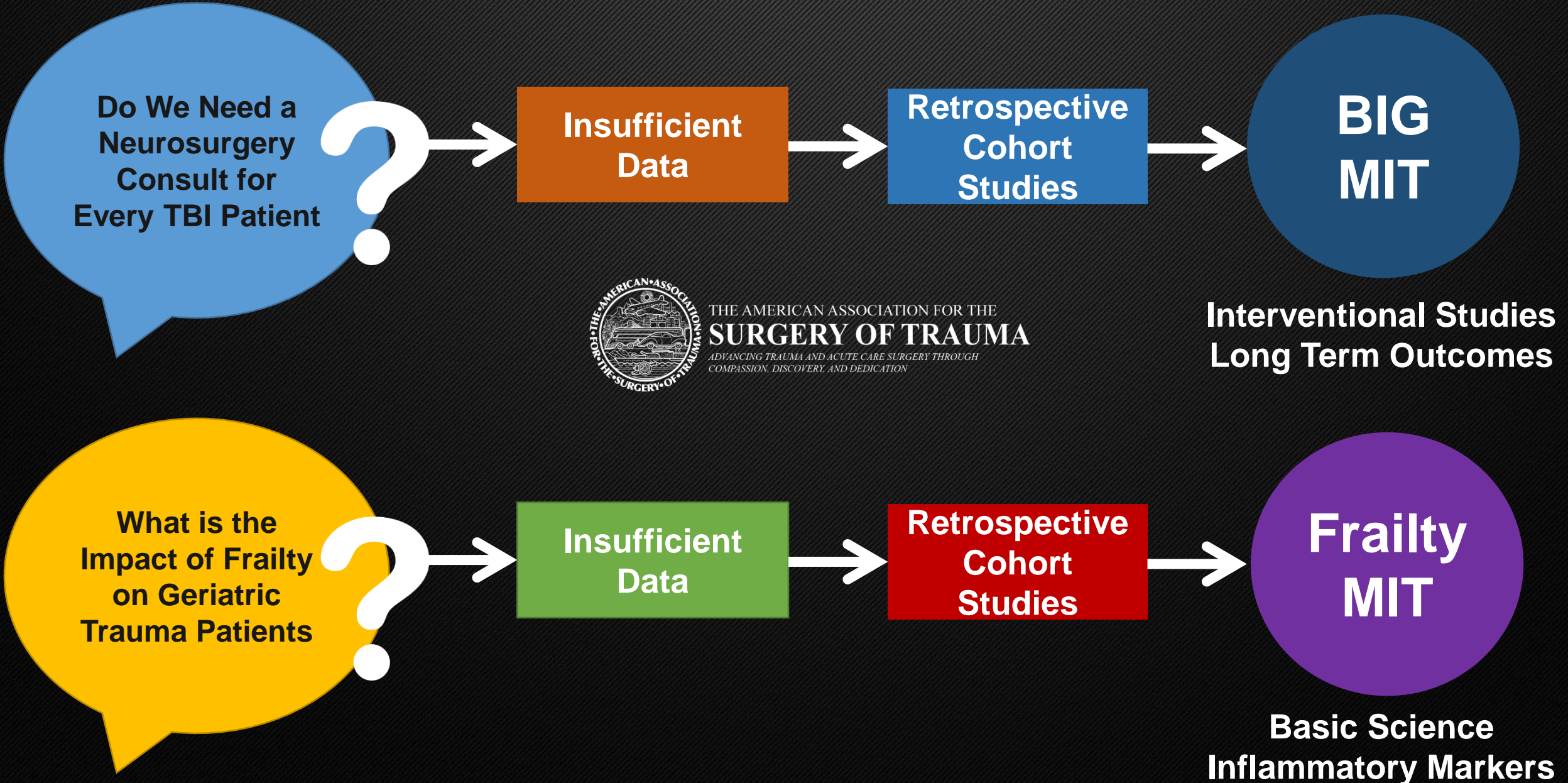
The Brain Injury Guidelines

Frailty



The University of Arizona

Putting It All Together



Interventional Studies
Long Term Outcomes

Basic Science
Inflammatory Markers



Take Home Message

Generate The Right Question

Choose Appropriate Study Design

Use The Right Database

Spend Time On Data Management & Methodology

Prelim Data Integral To Successful Grant Application

Thank You!



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@TopKnife_B



bjoseph@surgery.arizona.edu