FDA

The Clinical Investigators Role
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FDA U.S. FOOD & DRUG ADMINISTRATION

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

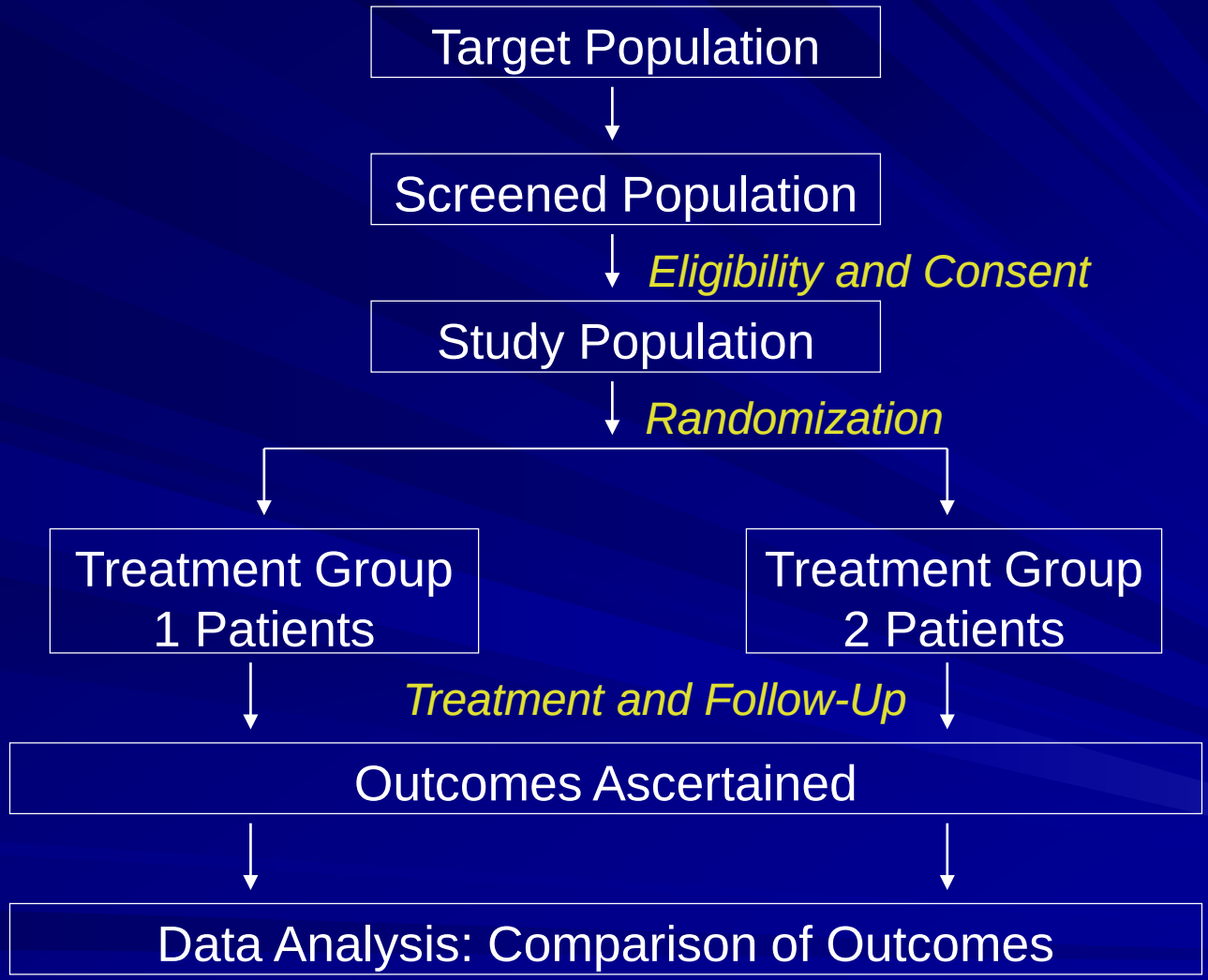
Epidemiology

- Distribution and Determinants of Disease
- Clinical Trials – Phases I-IV

Investigator Responsibilities

- Delegate Carefully
- Supervise Attentively
- Meet Goals
- Follow Protocol
- Know the Design
- Know Your Patients

Clinical Trial Paradigm



Administration

- IRB Submissions
- Regulatory Document Management
- Study Product Dispensing/Accountability
- Assure Data Quality

Patient Interfaces

- Screen and Assess for Eligibility
- Obtain Informed Consent
- History and Physical Examination
- Administer Study Product
- Laboratory Specimen Collection
- Answer Questions

Fundamental Clinical Trial Ethics

- Autonomy
- Beneficence
- Justice
- Minimize Risk

Performance

- Case Report Form (CRF) Completion
- Randomization
- Prescribe Study Product
- AE/SAE Assessment
- AE/SAE Reporting
- Laboratory Specimen Processing and Shipping
- Review of Laboratory Results

Quality Control

- Local Data
- Central Data
- Bias and Error
- Belt and Suspenders

Intellectual Content

- Design
  - Propose
  - Review
- Plan Data Analysis

Safety

- Active Surveillance Every 6-12 Weeks
- Expected Adverse Events
- Serious or Unexpected Adverse Events
- Impact of Design
- Placebo Safest but Not Entirely Safe
- Passive Surveillance

Outcomes

- Ascertain Universally
- Realistic Expectations
- Mean and Dispersion

Rules of the Road

- Navy Priorities
  - 1st – Float – Infrastructure
  - 2nd – Move – Recruit
  - 3rd – Fight – Treat and Evaluate
- Kingship

  Uneasy lies the head that wears a crown