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

- Target Population
  - Screened Population
    - Eligibility and Consent
  - Study Population
    - Randomization
    - Treatment Group 1 Patients
      - Treatment and Follow-Up
        - Outcomes Ascertained
        - Data Analysis: Comparison of Outcomes
    - Treatment Group 2 Patients
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