

Population Health Research Institute



PHRI Statistics and CANNeCTIN

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Working with Statisticians

Collaboration

- Collaboration rather than service
- Meeting of two experts, who may not always speak the same language
- Each needs to learn some of the other's language for communicate to occur
- Statistician needs to understand the research question
- Researcher needs to understand how the statistical methodology can answer their question

Ultimate Goal of Statistical Consultation

- More efficient study design is chosen
- Ensure that the study hypothesis is completely and accurately tested by the statistical tests used

“Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can be made precise”
JW Tukey

Early Involvement is Key

- When protocol is in early draft
- Work with senior level PHRI statistician
- Operationalize the hypotheses
- Consider means of reducing variability e.g. repeated measurements
- Covariate adjustment
- Randomization type

Statistical Consult

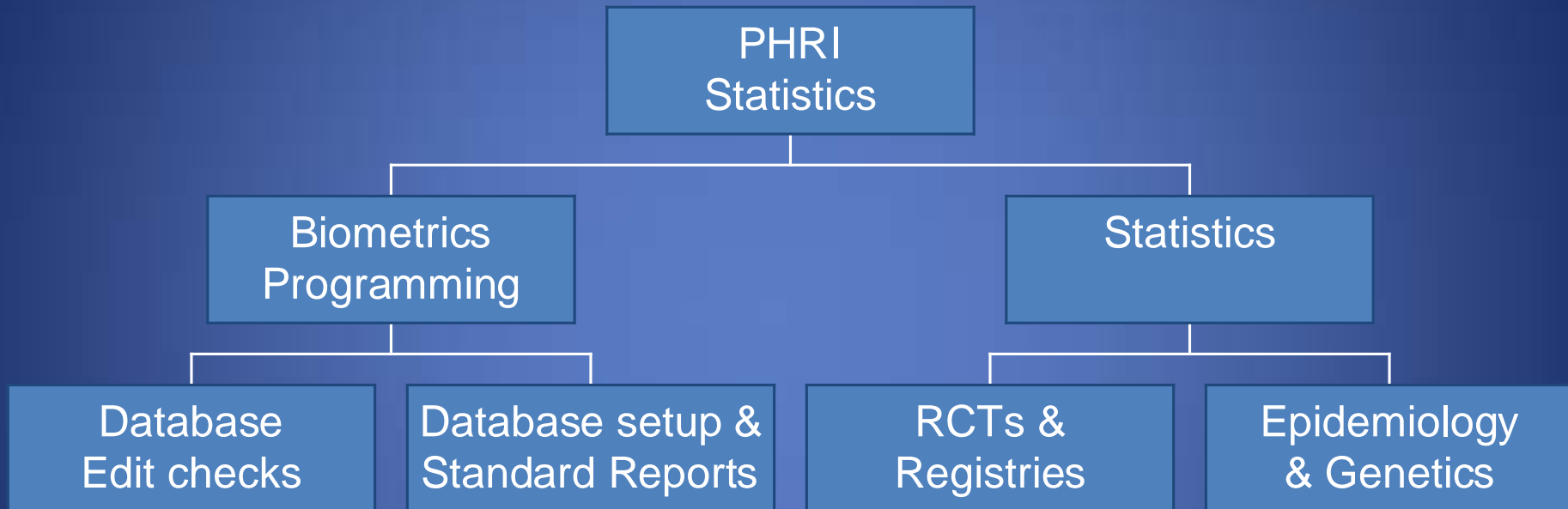
- Multiple testing issues (>2 outcomes, treatments, time points)
- Plan for missing data
- Sample size
 - Robustness of event rate estimates
 - Non-compliance
 - Lost to follow-up
- Interim monitoring plan

Requirement for Stats Section

Question	Section
Who are the Participants	Baseline characteristics
Did they follow the Protocol?	Compliance, assessments done, follow-up complete
Is the intervention Safe?	Adverse events, reasons for stopping, hypothesis?
Did the intervention Work?	Primary outcome, key secondary outcomes
Other questions	Mechanistic, Risk-benefit, subgroups, etc.

Role of Statisticians throughout the Trial

PHRI Statistics Group



Statistics: Initiation of RCT

- Statistician:
 - Prepare Randomization or Packaging List (PHRI Request Form)
 - Review the Case Report Forms !!!!!
- Biometrics Programmers:
 - Study database setup in iDataFax
 - Edit check programs to ensure completeness and accuracy of data (e.g. legal ranges, complete answers)
 - Activity occurs at the request of the Project Manager

Statistics: Conduct of Trial

- Biometrics Programmer:
 - Create standardized reports for recruitment and data quality
 - Set up data transfers
- Statistician: Other study specific reports including:
 - Baseline characteristics
 - Compliance
 - Outcome rates
 - Safety

Statistics: Near the Trial End

- Statistician will work with researchers to develop the Statistical Analysis Plan
 - Exact definitions
 - Key analyses
 - Subgroups
 - Any new analysis (or outcomes) not already in the protocol

Statistics: End of Trial

- Statistician will perform final analysis
- Graphics
- Draft statistical methods section for publications
- Help answer reviewer questions during process of publication
- Provide tables of unblinded treatment allocations to study team for distribution

Practical Details

- Be prepared for questions from the statistician
- Conference calls work best, rather than e-mail
- Please define medical terminology
- Provide advanced notice of requirements and set reasonable deadlines
- Let us know if there are issues

We look forward to
working with you!