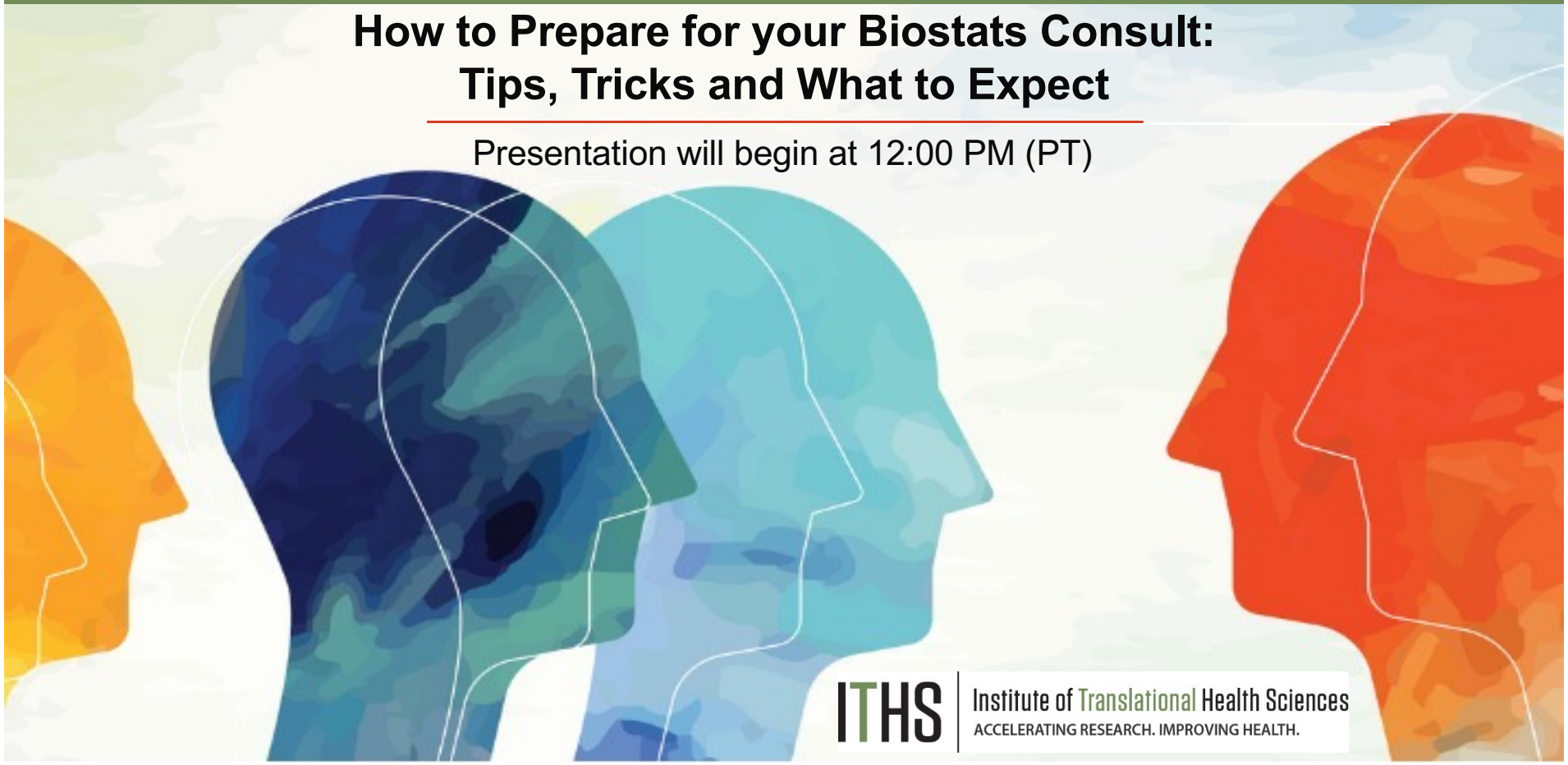
Career Development Series 2023

How to Prepare for your Biostats Consult: Tips, Tricks and What to Expect

Presentation will begin at 12:00 PM (PT)

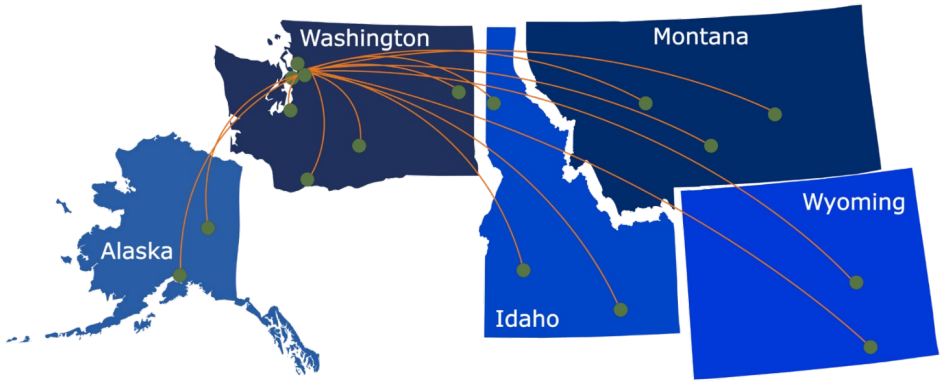


ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

UNIVERSITY of WASHINGTON

FRED HUTCH
CURES START HERE®

Seattle Children's®
HOSPITAL · RESEARCH · FOUNDATION



What We Offer:

1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2. **Community Engagement:** Members can connect with regional and community based practice networks

3. **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4. **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact ITHS

Director of Research Development

- Project Consultation
- Strategic Direction
- Resources and Networking

Melissa D. Vaught, Ph.D.
ithsnav@uw.edu
206.616.3875

Scientific Success Committee

- Clinical Trials Consulting
- Guidance on Study Design, Approach and Implementation
- Feedback on Design and Feasibility

https://www.iths.org/investigators/services/clinical-trials-consulting/

Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2023

How to Prepare for your Biostats Consult: Tips, Tricks and What to Expect

Presented by:

Greta M. Linse, MS
Interim Director – Statistical Consulting and Research Services
Montana State University

Anna Faino, MS
Manager, Biostatisticians
Biostatistics Epidemiology and Analytics for Research (BEAR) Core
Seattle Children's Research Institute

Susanne May, PhD
Professor of Biostatistics at the University of Washington (UW) and Director of the UW Clinical Trials Center

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Learning Objectives

At the end of the session, participants will be able to:

1. List at least two study/research characteristics that a (bio)statistician will need to know about for any consultation
2. Identify two tasks that may need to be completed before an initial consultation
3. Describe the collaborative nature of the scientist-statistician relationship

10 Things to Know…

https://globalhealth.duke.edu/news/10-things-know-about-working-statistician

1. Involve a (bio)statistician as early as possible.
2. A (bio)statistician knows more than just data analysis.
3. Good study design and analysis is a team effort.
4. Budgeting properly for data management can save you time, money and headaches.
5. A predefined analysis plan will ensure analysis goes smoothly.

10 Things to Know…

https://globalhealth.duke.edu/news/10-things-know-about-working-statistician

6. Allow for adequate time to process data and conduct analysis.
7. Think about clinical significance, not just statistical significance.
8. Interpreting and reporting results requires everyone's input.
9. A (bio)statistician can help you pay attention to reporting standards.
10. Know what you (maybe) don't know.

…. we added to the points in the article

Involve a (bio)statistician as early as possible.

It's never too early to involve a biostatistician!

- In an ideal world, a statistician would get involved when **research questions (RQ)** are being formulated.
  - **We can help transform RQ into testable hypotheses!**
- This should be months before a grant submission date!

But why?

- Unless there is an established protocol, determining the appropriate statistical model and methods can take time
- Power analysis is typically not as easy as plug-and-chug
- Statisticians have to coordinate their efforts with other projects underway
- Short lead times lead to rushed results
- Not properly planning or coordinating before data is collected can lead to data that does not answer the RQ
- Vague hypotheses can lead to data/methods that are unable to address the aims or answer the RQ

A (bio)statistician knows more than just data analysis.

- We work with researchers in many fields, so while we might not be an expert in your field, we know data and problems that arise from certain types of data.

- A statistician will have expertise in:
  - Study planning
  - Study design
  - Data collection
  - Data management

- We might be able to help you find (additional) collaborators as well!

- **Two critical components to draft before any collaboration are the study design and timeline**
  - But be willing to make adjustments if needed!

Good study design and analysis is a team effort.

A complex project might require a large team of statisticians with specialized skills such as:

- Data management
- Survey design
- Survey analysis
- Analysis of complex designs
  - Cluster randomized trials
  - Stepped wedge or other complex longitudinal designs
- Epidemiology
- Psychometrics
- And more!

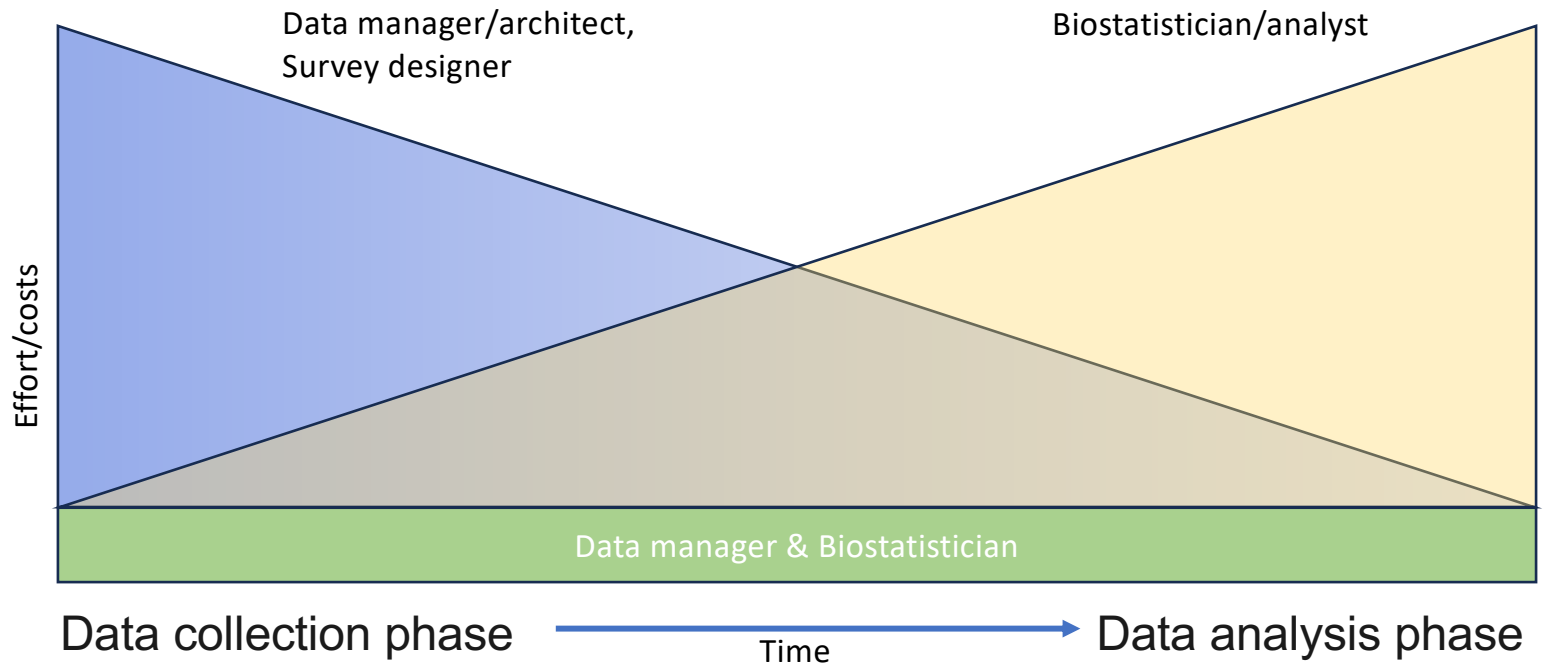
How much will this all cost?!?

- Be prepared to budget for the appropriate biostatistician or team of statisticians
- An appropriate budget for data management and statistical analysis with flexibility for unforeseen costs will save money in the long run

When do we talk about the budget?

- During the initial consultation, we will ask many questions to determine the effort and size of the team needed.
- We will need time to review the project and estimate costs after the meeting to prepare an estimate and proposed budget.
- You most likely will not leave the initial consultation with an exact number but may be able to give you a ballpark estimate of the costs.

Stages of a (simplified) project from a biostatistician's point of view (post award)



Including data management in your budget can save you time, money and headaches.

- With **new requirements for data sharing going into effect at the NIH**, proper planning of all phases of data management – from survey design to collection to processing to preservation -- is more important than ever.

Including data management in your budget can save you time, money and headaches.

- **Investing in a data manager/architect** can help ensure a statistician spends less time fixing errors and more time on analysis and reporting.
  - Although many statisticians can do well at data management, **data managers are specialized experts** who can make sure survey design and data collection go according to plan (and may be much more efficient doing so).

  - **Data managers and statisticians should work together closely** during the initial stages of the study to make sure not only that all relevant data are collected, but also that study data can validly answer the intended research questions.

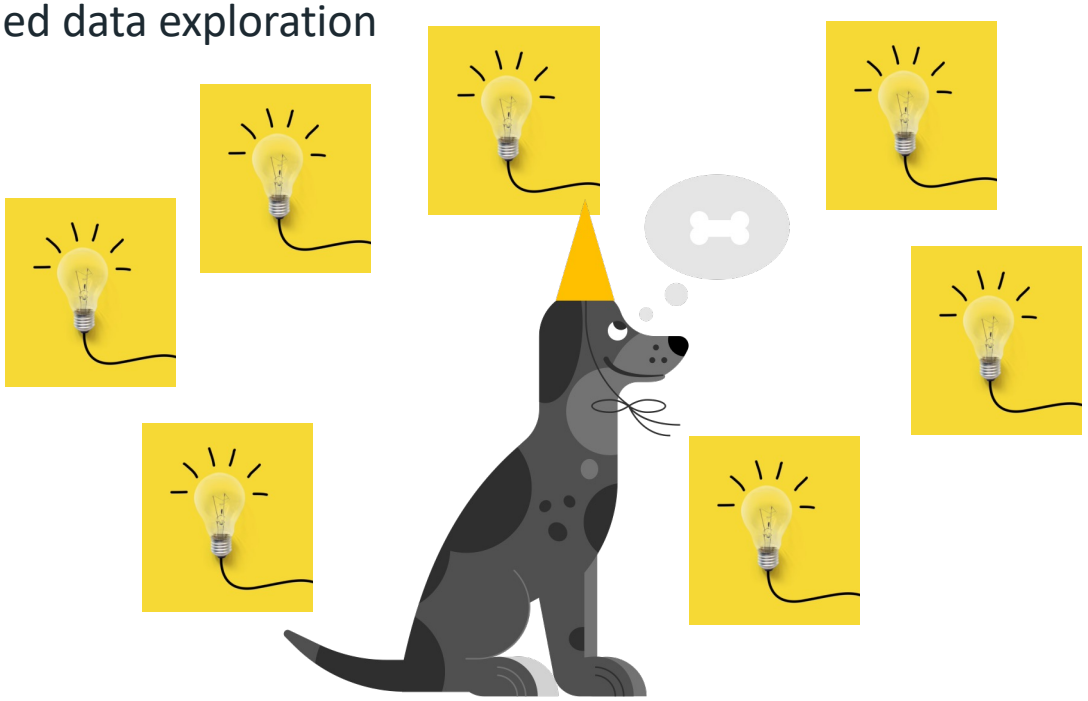
With a maze, the beginning point and the end goal may be the same, though there are several different paths that can be taken. With regards to building your study team with all the necessary expertise, do this at the beginning rather than halfway through the maze.

A predefined analysis plan will ensure analysis goes smoothly.

- A **statistical analysis plan (SAP)** defines the hypotheses and primary and secondary outcomes and how the statistical analysis will be conducted from beginning to end.
  - Having a well-defined SAP can save a lot of time in data analysis and also can be used to draft the methods section of your manuscript.

A predefined analysis plan will ensure analysis goes smoothly.

A well thought out SAP can also help keep an analysis focused and with less unplanned data exploration



A predefined analysis plan will ensure analysis goes smoothly.

A SAP can also contain planned, or “shell” tables and figures for a manuscript.

Figure 1: 

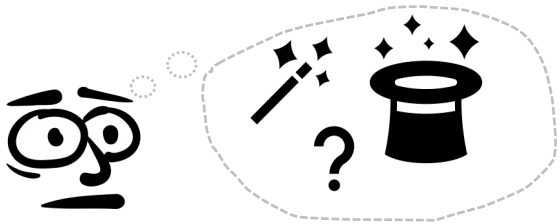
Table 1: 

Figure 2: 

Etc.

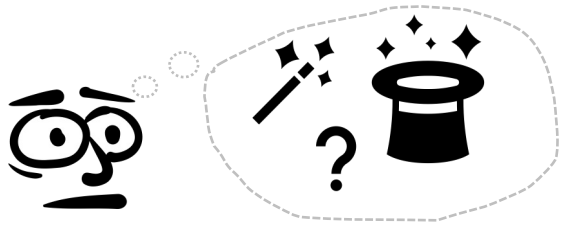
Allow for adequate time to process data and conduct analysis.

- Data processing and analysis are never as simple as plugging data into code and outputting numbers.
  - There is no magical “black box” for statisticians, and while some types of analyses may be simpler than others, they still take time.



Allow for adequate time to process data and conduct analysis.

- Data processing and analysis are never as simple as plugging data into code and outputting numbers.
  - There is no magical “black box” for statisticians, and while some types of analyses may be simpler than others, they still take time.



- Writing and checking analysis code, making modifications after checking statistical assumptions, and producing publication-quality statistical tables and figures all **take time and should not be rushed**.
  - When work is rushed, mistakes will inevitably be made.

Allow for adequate time to process data and conduct analysis.

- Statisticians are almost always working on several different projects at once, and this needs to be factored into analysis timelines.

Think about clinical significance, not just statistical significance.

Examples

- Differences in age of half a year?
- Prolonging life by 3 months?
- Large data sets
- Minimally clinically important differences (if applicable)
- What (statistically significant) difference would convince you / your colleagues to change practice?

Think about clinical significance, not just statistical significance.

Study	SBP Diff	95% CI	P value
A	27.16	-14.14, 68.46	0.1974
B	0.27	-0.14, 0.68	0.1974
C	27.16	6.51, 47.81	0.0099
D	0.27	0.06, 0.47	0.0099

- Interpreting non-significance
- Studies A and B are both “nonsignificant”
  - Only study B ruled out clinically important differences
  - The results of study A might reasonably have been obtained if the treatment truly lowered SBP by as much as 68 mm Hg

Think about clinical significance, not just statistical significance.

Study	SBP Diff	95% CI	P value
A	27.16	-14.14, 68.46	0.1974
B	0.27	-0.14, 0.68	0.1974
C	27.16	6.51, 47.81	0.0099
D	0.27	0.06, 0.47	0.0099

- Interpreting significance
- Studies C and D are both statistically significant results
  - Only study C demonstrated clinically important differences
  - The results of study D are only frequently obtained if the treatment truly lowered SBP by 0.47 mm Hg or less

Interpreting and reporting results requires everyone's input.

Examples

- Clinical trial with clearly non-significant results.
  - Company wanted in the abstract "remains an attractive option" based on exploratory post-hoc analysis findings.
- Wrongly interpreting odds ratios as probabilities.
- Non-statistician colleague slightly changed statistical language – grant submission consequence.

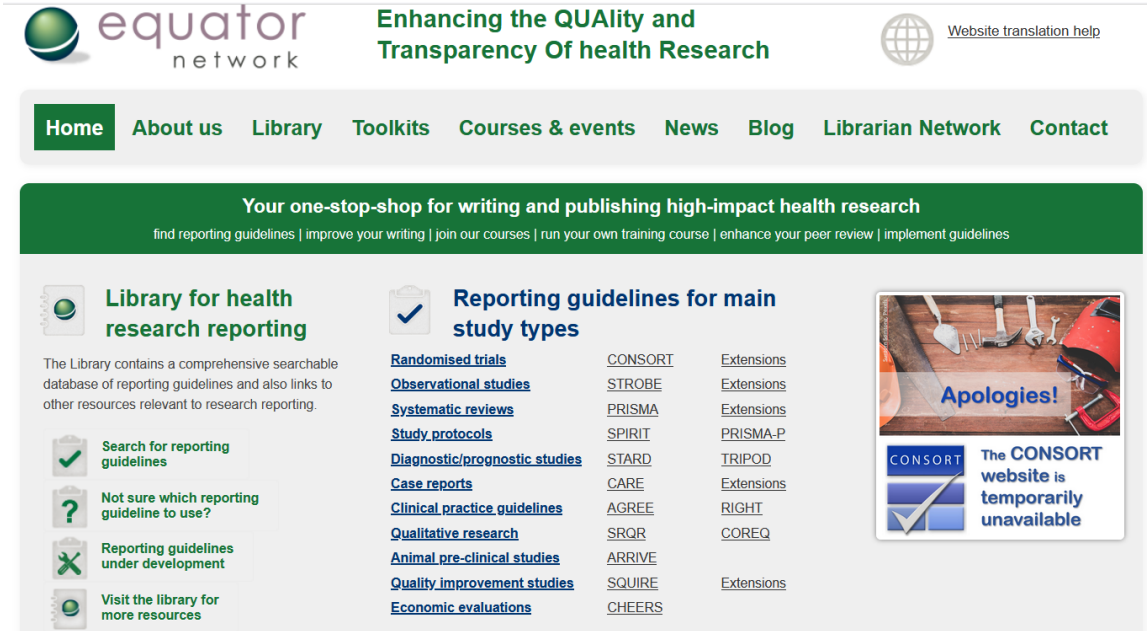
A (bio)statistician can help [with] reporting standards.

April 17, 2018, Wall Street Journal, Irreproducibility crisis

- Policy makers often cite research to justify their rules, but many of those studies wouldn't replicate.
- The chief cause of irreproducibility may be that scientists, whether wittingly or not, are fishing fake statistical significance out of noisy data.
- Suggestions: Preregister research protocols
- Incentives to publish negative results
- Each scientific discipline needs to accept responsibility for its share of the irreproducibility crisis and incorporate strict standards into its procedures.

A (bio)statistician can help [with] reporting standards.

Reporting standards www.equator-network.org



Know what you (maybe) don't know.

- Very important: estimate(s) of variability around your primary outcome/variables.
- It is important for you to understand some basic statistics (e.g. understanding p-values and confidence intervals).
- It is important for the (bio)statistician to understand some of the basics of your area of research.
- Ask questions and be prepared to teach the (bio)statistician about what they don't know.

Recap of Learning Objectives

1. List at least two study/research characteristics that a (bio)statistician will need to know about for any consultation
   → **Study design, timeline, estimate(s) of variability**
2. Identify two tasks that may need to be completed before an initial consultation → **Research question(s) & data (to be) collected**
3. Describe the collaborative nature of the scientist-statistician relationship → **It should be collaborative at all stages!**

Thank You!

Questions ???

ITHS | Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.

Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.

Appendix – Example 1

- Specific Aim 1. To determine whether, among individuals with HIV-associated neurocognitive impairment (HNCI), antiretroviral therapy (ART) applied according to a CNS-targeted strategy (CNS-T) improves neurocognitive outcomes compared to a conventional (non-CNS-targeted) comparison strategy. All patients enrolled will be HIV-infected individuals with cognitive impairment eligible for new ART regimens according to contemporary consensus treatment guidelines.

Appendix – Example 1

- Initial hypothesis: Neurocognitive outcome in the DNS-T arm will be better than in the non-CNS-T arm.
- …
- Later hypothesis: Participants in the CNS-T arm will demonstrate greater improvement in NC functioning than participants in the non-CNS-T arm.

Appendix – Example 2

- The long-term goal is to enhance the understanding of social and cultural pressures among women within the [specific group] Community regarding HIV and to reduce gender disparity in this population. The overall objective is to determine areas of misconception, misunderstanding and fear among these women regarding HIV infection and transmission.

Appendix – Example 2

- Initial hypothesis: Our central hypothesis is that although likely multi-factorial, gender disparity regarding knowledge about (?) HIV in the [specific community] culture contributes to misconceptions regarding HIV prevention and transmission and possibly limits access to healthcare.