Collaborative Biostatistics in Academia

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Department of Biostatistics and Bioinformatics

Outline

- Why I chose to be a collaborative biostatistician
- Duke BERD Collaborative Unit
- The Collaborative Process
- Training the Clinical and Translational Science Workforce

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About Me

- PhD in Statistics from North Carolina State University
- Developed methodology in functional data analysis with applications to Neuroimaging
- My primary motivation for developing methodology is driven by the application
- I love statistics, science, medicine, and being a mentor

Personal Goals

- Conduct impactful research
- Develop methodology as needed
- Mentor junior statisticians
- Teach
- Promote diversity in STEM

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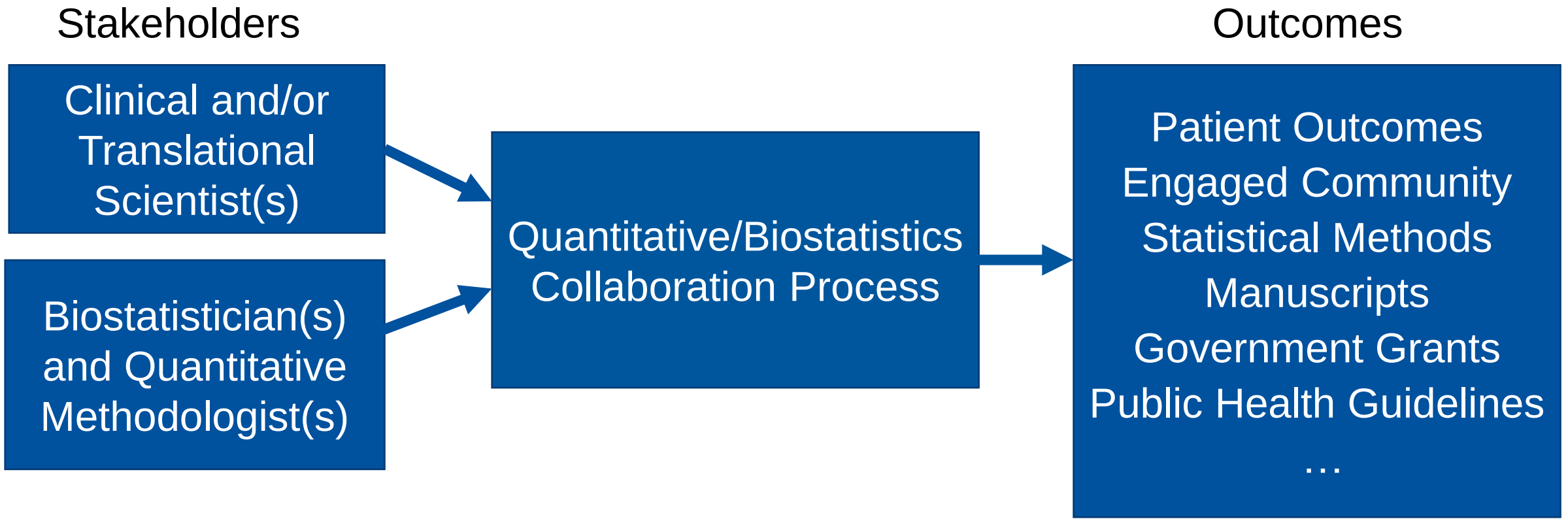
Team Science: Data Driven Research



Goal: Develop models to improve access and this process at the international level.

Quantitative and Qualitative Units at Duke

DHVI
DUKE HUMAN VACCINE INSTITUTE

Duke
GLOBAL HEALTH
INSTITUTE

Duke Center for Health Informatics
Duke University School of Medicine

Department of Population Health Sciences
Duke University School of Medicine

Duke
SOCIAL SCIENCE
RESEARCH INSTITUTE

Duke Department of Biostatistics & Bioinformatics
Duke University School of Medicine

Duke
AI HEALTH

Duke
Statistical Science

Duke Aging Center
Duke University School of Medicine

And many more!

Duke B&B - CTSI BERD Core

Formal Mission:

To work with interdisciplinary network of clinical and translational investigators conducting research at Duke by providing expertise in study design, implementation of quantitative methodology, and interpretation of results.

Functional Roles:

1. Serve as a coordinating center for all quantitative and qualitative methodologists on campus.
2. Build Biostatistics Collaborative resources when they are not otherwise available at Duke.

22 BERD MoUs Across SoM

Hospital Medicine

Duke Health Technology Solutions (DHTS)

Department of Pharmacy

Duke Population Health Management Office (PHMO)

Department of Dermatology

Duke Center for Human Systems Immunology (CHSI)

Duke Global Health Institute (DGHI)

Division of Gastroenterology

Duke General Internal Medicine (DGIM)

Department of Neurosurgery

Department of Obstetrics and Gynecology

Department of Orthopaedic Surgery

Department of Pediatrics

Duke Center for Childhood Obesity Research (DCCOR)

Psychology & Neuroscience Department

Department of Radiology

Transplant Center

Duke AI Health

Department of Neurology

Division of Pulmonary, Allergy, and Critical Care Medicine

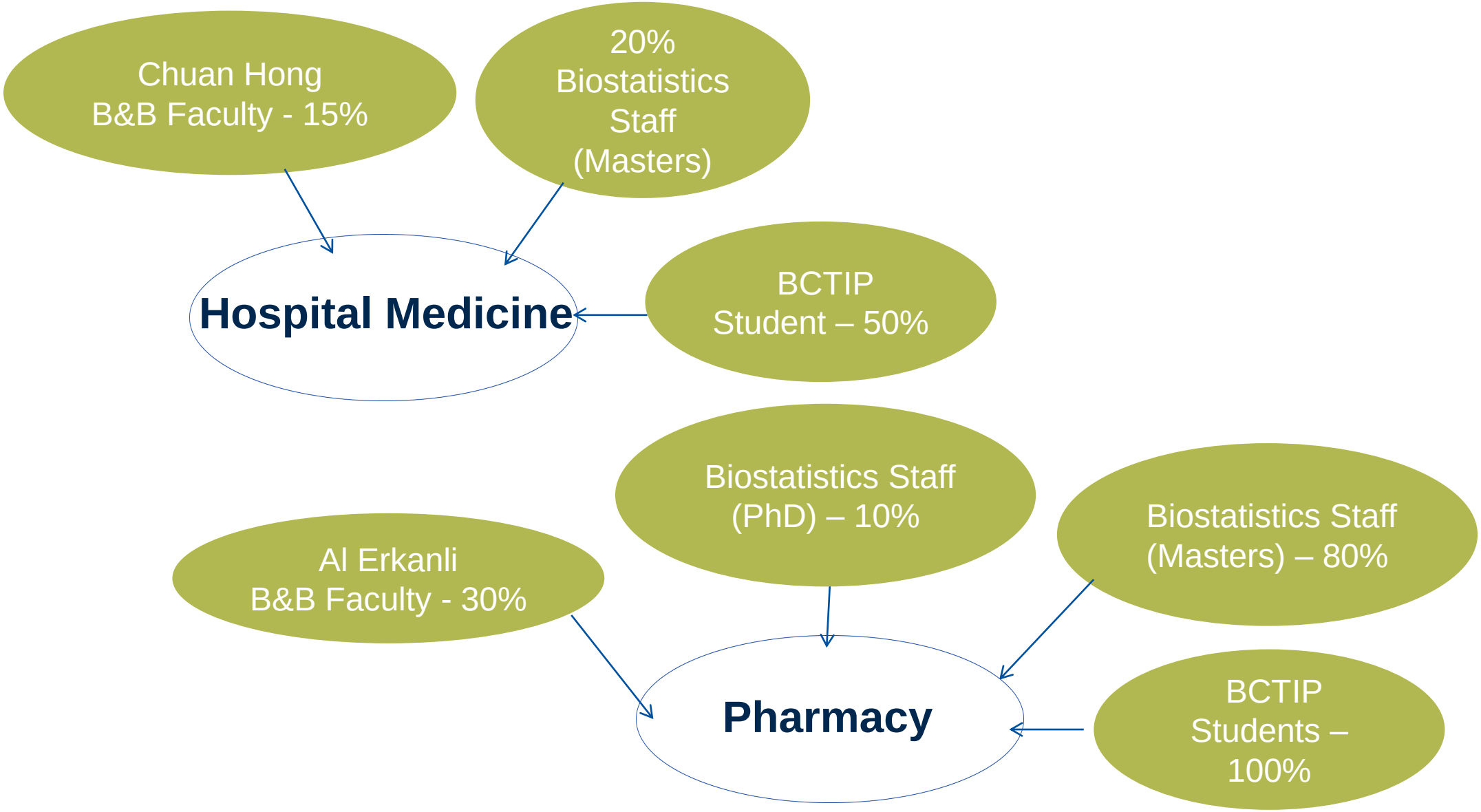
Head and Neck Surgery & Communication Sciences

Division of Hematology

Duke Clinical Translational Science Institute
BERD Core

A team of faculty and staff biostatisticians and affiliated methodologists with diverse and extensive experience conducting a broad range of research projects.

- 24+ staff Biostatisticians (PhDs and Masters)
- Affiliated experts in qualitative analysis and bioinformatics
- 60+ faculty in the Biostatistics and Bioinformatics Department
- 25+ collaborative teams throughout Duke


Chuan Hong
B&B Faculty - 15%
20%
Biostatistics
Staff
(Masters)
Hospital Medicine
BCTIP
Student – 50%
Biostatistics Staff
(PhD) – 10%
Biostatistics Staff
(Masters) – 80%
Al Erkanli
B&B Faculty - 30%
Pharmacy
BCTIP
Students –
100%

Some Previous Research Questions

- Are patients being given too many stress tests when they come in with chest pain?
- Can we predict the risk of adverse drug events (such as anaphylaxis) before a doctor prescribes the medication?
- Can we evaluate Depression and PTSD in child soldiers in Nepal?
- Is operating time increased when residents perform the surgery?

Can Biostatisticians do it all?

Cross Disciplinary Methods Teams

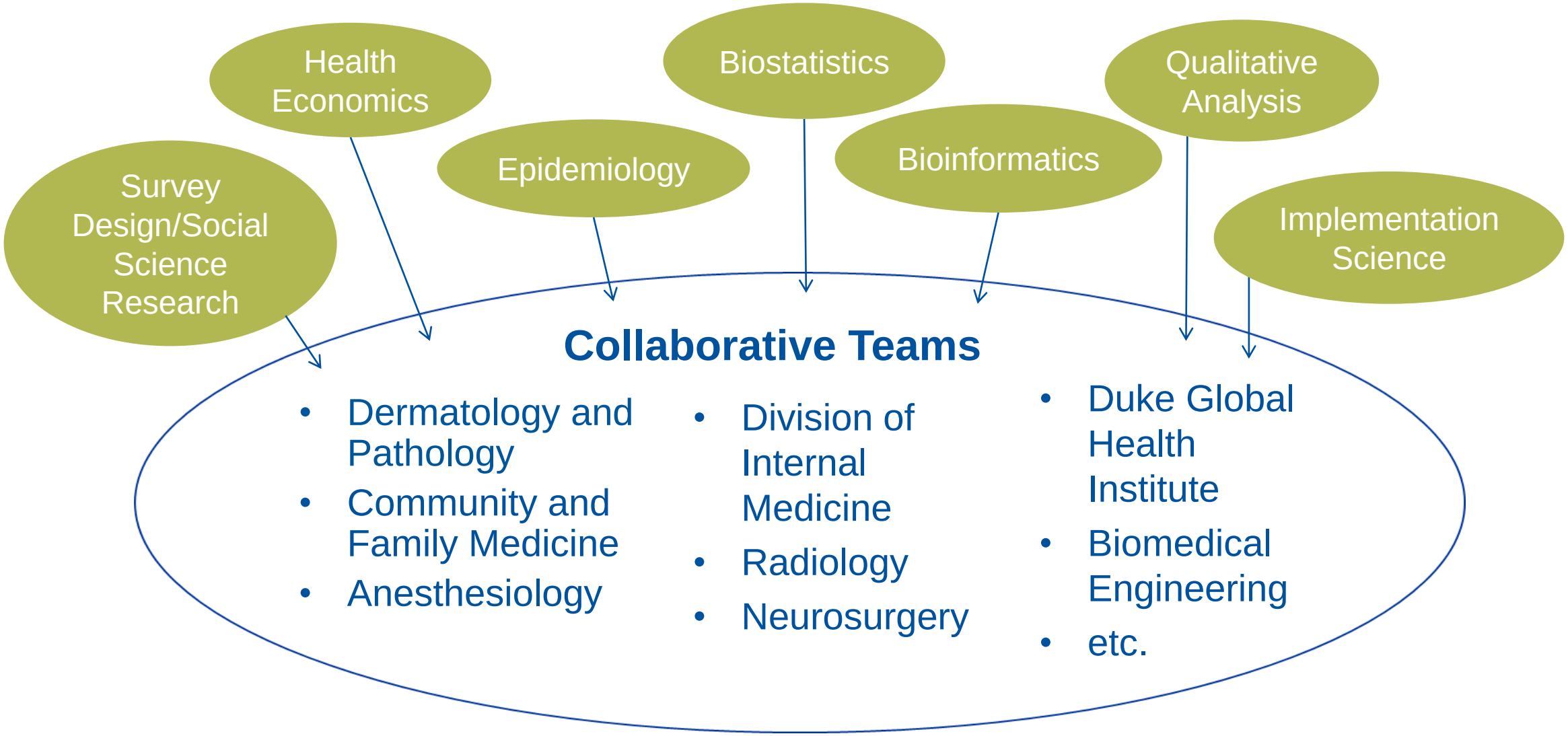
Don’t replicate resources – build connections

- Should the biostatistician learn to do RNA-Seq analysis or focus group analysis or should they work with an expert?

Cross Disciplinary Methods Teams

- Biostatisticians can learn the intuition behind methods by working alongside the informatician/qualitative researcher.

- One Biostatistician may have more expertise with image analysis and another with causal inference.


Health Economics
Biostatistics
Qualitative Analysis
Survey Design/Social Science Research
Epidemiology
Bioinformatics
Implementation Science
Collaborative Teams
• Dermatology and Pathology
• Community and Family Medicine
• Anesthesiology
• Division of Internal Medicine
• Radiology
• Neurosurgery
• Duke Global Health Institute
• Biomedical Engineering
• etc.

We Collaborate at Every Step of the Scientific Process

Observation / Pattern

- We brainstorm with investigators

Scientific question

- Hypotheses
- Study design / Data collection
- Analysis
- Results / Conclusions

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The 12 Phases of the Biostatistics Collaboration Process:

Initial Collaboration Phases

1	The investigator ensures that the question has scientific relevance, poses it to the biostatistician, and provides clinical background information.
2	The biostatistician brainstorms with the study team about the question being posed, the primary outcomes, possible data available, and discusses feasibility.
3	The investigator sends background materials (e.g. study objective, preliminary hypotheses; relevant publications; list of relevant variables) so the statistician can become familiar with the scientific background and literature.
4	As the collaboration progresses (via meetings/correspondence with the biostatistician), the nature of the project, study design, objectives, and hypotheses are clarified. Expectations of the collaborative roles and authorship are discussed.

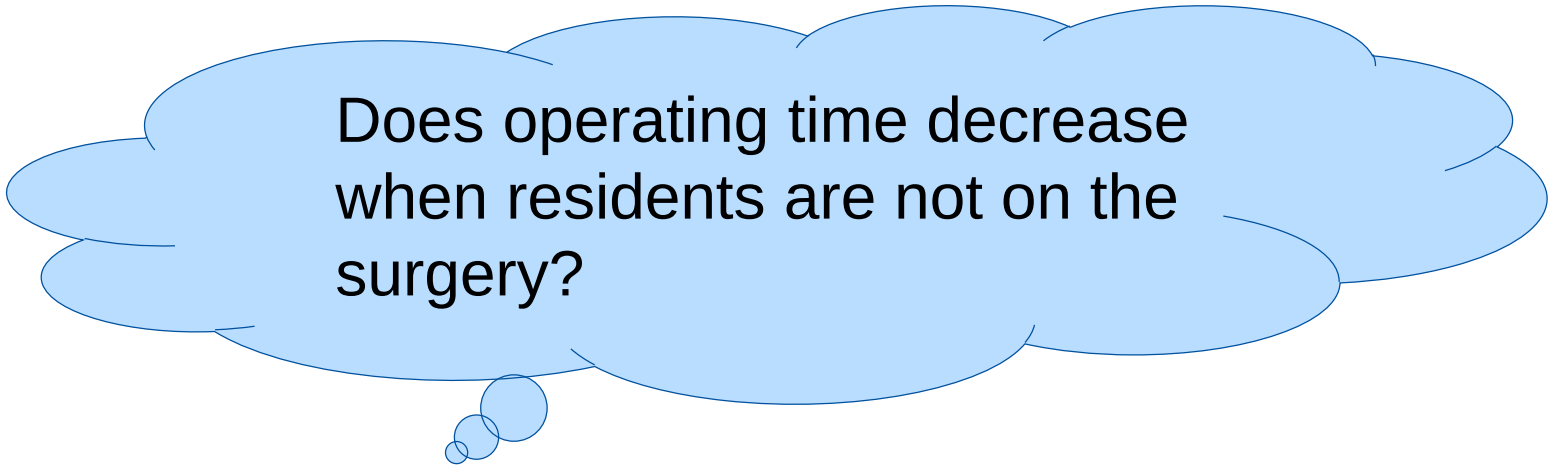
Statistical Analysis and Dissemination Phases

5	Expertise and advice on randomization, data collection, database design, and data provenance are provided.
6	A statistical analysis plan (SAP) is created, discussed, and agreed upon, derived variables are defined, and data consistency checks are specified.
7	The statistician and investigator meet/correspond regularly to ensure that the project is progressing and to keep the team updated.
8	Data collection is finalized, an analysis dataset with derived variables is created, and final data consistency checks are implemented.
9	Analyses per SAP are conducted, properly documented, and a statistical report is provided which includes interpretations of all results.
10	Results are discussed with the investigator. Additional data requests may be addressed – but the main hypotheses are expected to remain unchanged.
11	When a project results in a publication, the statistician writes the statistical methods section, and critically reviews the entire manuscript to ensure correct reporting and interpretation of results. For typical projects, biostatisticians will be included as co-authors.
12	Throughout the entire collaboration, the Biostatistician maintains documentation of all analyses to allow for full reproducibility of their work and extend the original knowledge base. At study conclusion, documentation is organized for potential dissemination.

Step 1

Investigator(s) develops project idea:

- Question/hypothesis is clearly articulated
- Outcomes and Metrics are clearly defined and data sources defined



Step 1

Investigator submits a request for statistical collaboration.

Overview

Biostatistics, Epidemiology, and Research Design (BERD) Methods Core is a team of faculty and staff methodologists across several departments with diverse and extensive experience conducting a broad range of research projects.

COLLABORATION REQUEST FORM

Mission

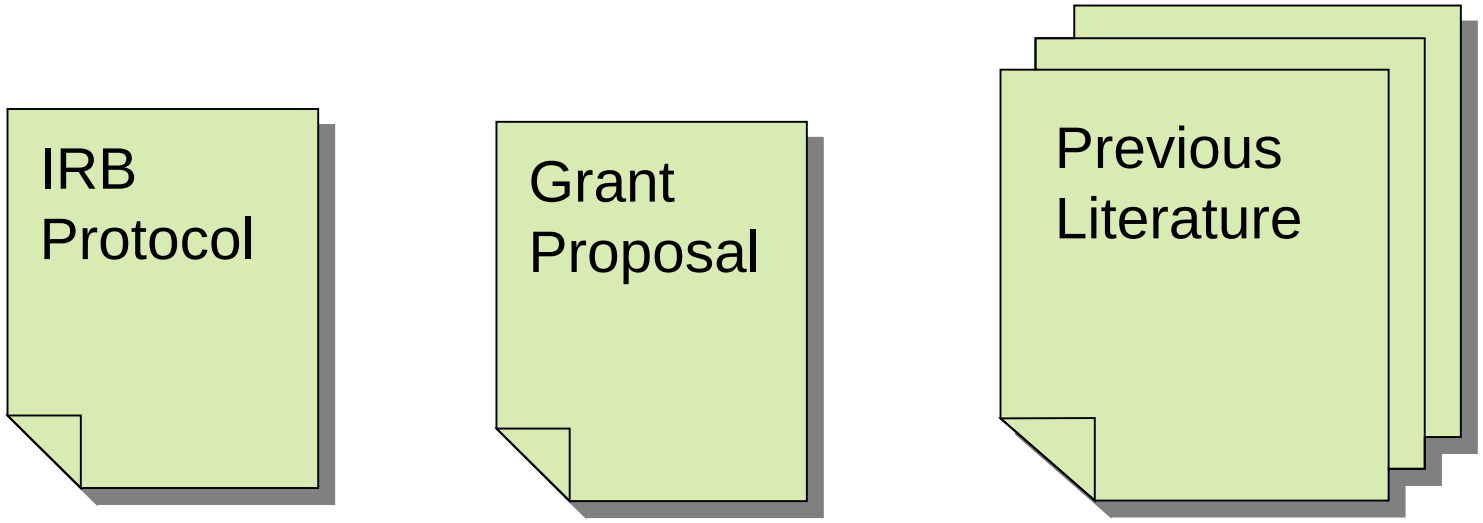
To work with an interdisciplinary network of clinical investigators conducting research at Duke by providing expertise in study design, implementation of statistical methodology, and interpretation of results.

Step 2

An initial meeting with the investigator is scheduled.

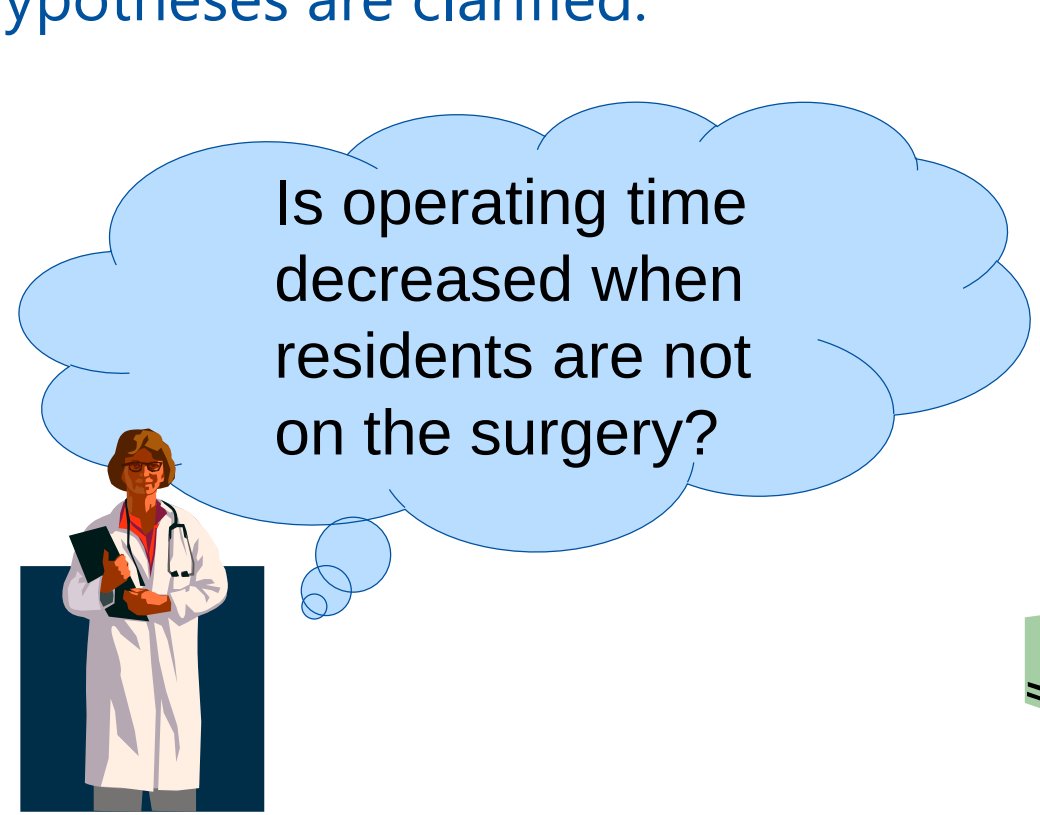
Step 3

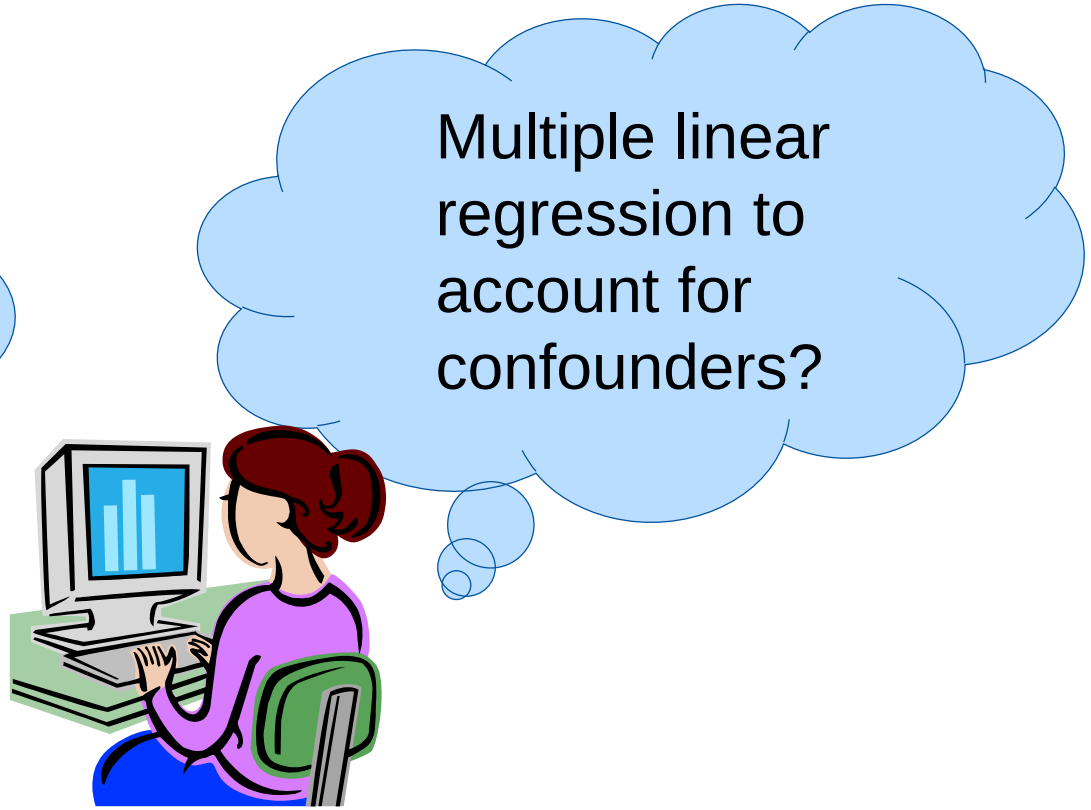
The investigator sends meeting materials (e.g. study objective, preliminary hypotheses, relevant publications, list of relevant variables) that are discussed at the meeting.



Step 4

As the collaboration progresses (via meetings/ correspondence with the biostatisticians), the nature of the project, study design, objectives, and hypotheses are clarified.





Additional Brainstorming

Is the **complication rate** higher for patients who had residents on their service longer than for those patients with only attending's on service?

What data are available?

Additional Brainstorming

What kind of complication rates are you referring to?

Maybe logistic regression?

- What is the event rate?

Step 5

Expertise and advice on randomization, data collection, database design, and data provenances is provided.

Step 6

- Study data are shared using a secure method (e.g., REDCap or Duke Box)
  - Key Personnel on IRB
- A statistical analysis plan (SAP) is created by the biostatistician, discussed, and agreed upon by the investigator (*signed*).

Statistical Analysis Plan

Primary Objective:

Secondary Objective:

Primary Outcome:

Secondary Outcome:

Data Collection:

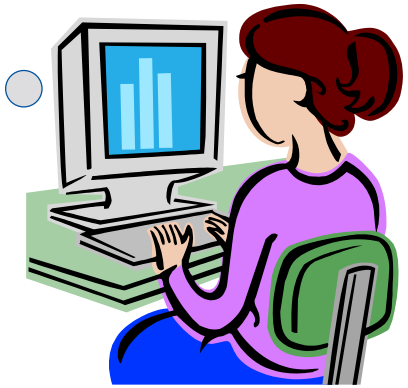
Statistical Methods:

Step 7

The statistician and investigator meet/correspond regularly to keep the team up-to-date.

Are these outliers or is it a mistake in the data collection?

Let me ask the medical student to check, we may not be collecting that variable properly.



Step 8

Once data collection has been finalized, an analysis dataset with derived variables is created and data consistency checks are implemented.

Patient_ID	Age	Gender	Race	PI	BMI	Complication
1	42	Male	Caucasian	<20%	20.67	1
2	50	Female	African American	<20%	25.72	1
3	88	Male	Caucasian	>20%	25.16	1
4	58	Male	Caucasian	>20%	22.91	0
5	47	Female	African American	<20%	26.96	0
6	61	Female	Caucasian	>20%	29.41	0
7	58	Female	Caucasian	<20%	28.84	1
8	59	Male	Caucasian	>20%	35.13	1

Step 9

Analyses per SAP are conducted, properly documented, and a statistical report is provided.

(Reproducible Research)

Step 10

Results are discussed with the investigator. Additional data requests may be addressed but the main hypotheses are expected to remain unchanged.

- Biostatisticians will avoid fishing at all costs!

Step 11

- The biostatistician writes the statistical methods section, and critically reviews the entire manuscript to ensure correct reporting and interpretation of results.
- Biostatisticians are included as co-authors

Step 12: Ensuring Reproducibility

- Throughout the entire collaboration, the Biostatistician maintains documentation of all analyses.
- Guidelines around this documentation process ensure reproducibility of their work.
- At study conclusion, documentation is organized for potential dissemination.

The Impact of BERD Collaborations

- COVID-19
- Cancer
- Hunger
- Transplant
- HIV
- Diabetes
- Fertility
- …

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Training the Clinical and Translational Workforce

Training the Clinical and Translational Workforce

Statistical Literacy for Medical Investigators

- Formal education has limits
- Time is limited
- Research can be overwhelming

Just In Time Learning

Dr. Tina Davenport – BERD Education Coordinator
Dr. Steve Grambow – BERD Education Mentor

- Short modules on highly relevant topics
- Designed to be used with interactive workshops focused on case studies
- https://biostat.duke.edu/berd-methods-core/training-series

Collaborative Biostatisticians

- Responsible for ensuring that the design and analytic methods are sound and sufficiently rigorous for accurate inferences and/or predictions.

- Works closely with clinical and/or translational collaborators to ensure results are interpreted appropriately to inform clinical practice and decision-making that will ultimately affect patient care or health outcomes.

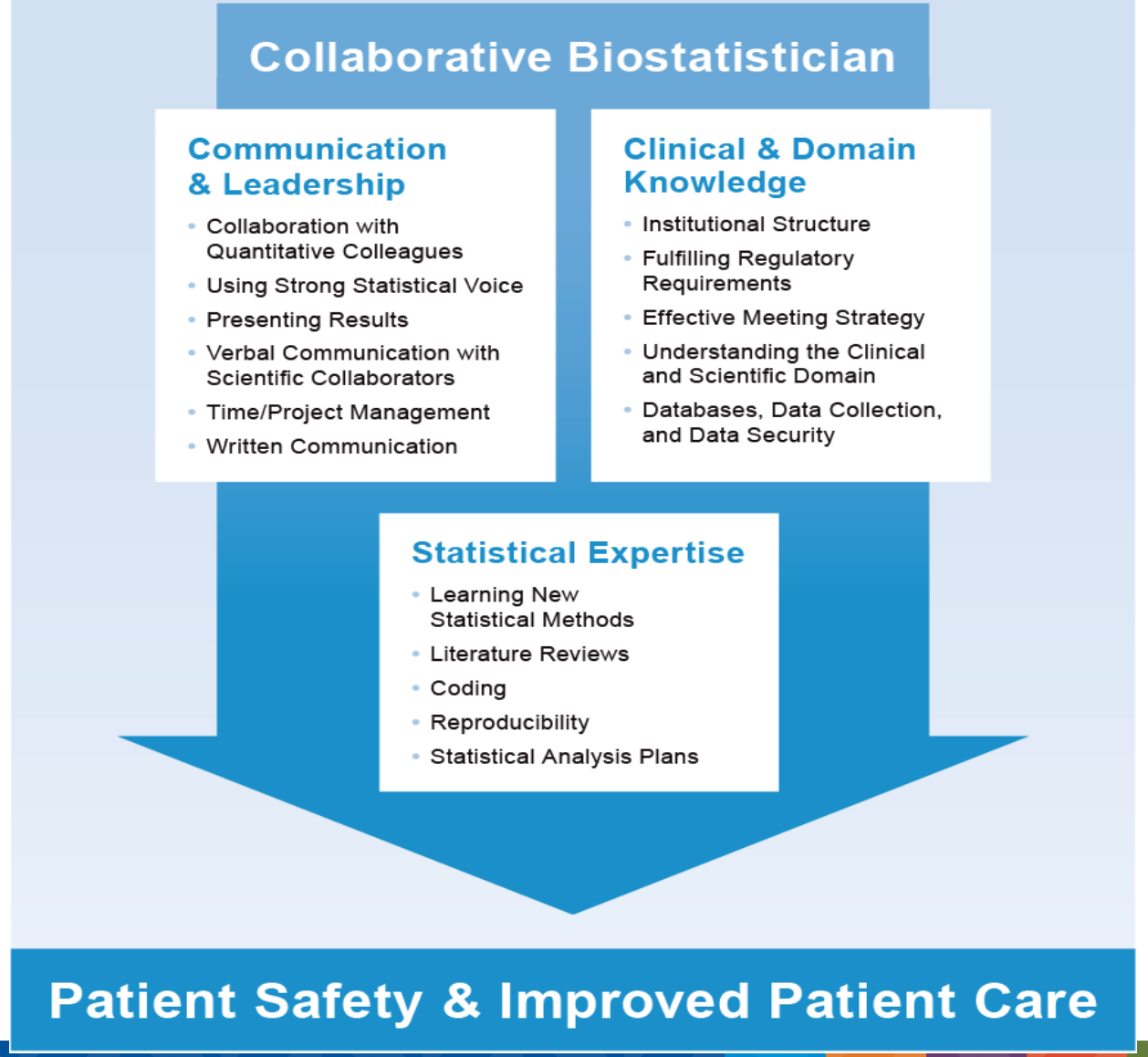
BERD Collaboration Unit: Training

BERD Core Training & Internship Program (BCTIP)

- 10-20 Master of Biostatistics Students per year
- Six weeks of training sessions
- One-three semesters of collaborative biostatistics work
- Structured mentorship program

Tobi H, et al. Towards a curriculum for the consultant biostatistician: Identification of central disciplines. Statistics in Medicine 2001; 20(24): 3921–3929.

Pomann, Gina-Maria, et al. "Methods for training collaborative biostatisticians." *Journal of Clinical and Translational Science*: 1-13.



Clinical Domain Knowledge

- Databases, Data Collection and Data Security
- Fulfilling Regulatory Requirements
- Institutional Structure
- Understanding the Clinical/Scientific Domain

Communication and Leadership

- Written communication
- Time/project management
- Effective meeting strategy
- Verbal communication with scientific collaborators
- Presenting Results
- Using a strong statistical voice
- Collaboration with quantitative colleagues

Statistical Expertise

- Statistical Analysis Plans
- Reproducibility
- Coding
- Literature Reviews
- Learning New Statistical Methods

Welcome to Duke!!

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https://biostat.duke.edu/berd-methods-core

Teach, Implement, and Evaluate (TIE)

Learning New Statistical Methods	Teach: *What CBs should learn*	1. Self-instruction and implementation of new statistical methods as required by ongoing collaborations. 2. The critical review of new methodology to determine appropriateness in ongoing collaborations.
	Implement: *What CBs should do*	1. Practice implementing new methodology based on review of papers and reading materials. a. If available, provide sample code. b. If necessary, review theory behind methodology. 2. Use literature review methodology above to identify potentially relevant papers and methods. a. Read and take notes on all identified papers/methods.
	Evaluate: *What Supervisors should do*	1. Meet with CBs to discuss questions about new methodology and review analysis to confirm accuracy. 2. Meet with CBs to discuss all identified methodologies. 3. Evaluate CBs' ability to describe the pros and cons of each method (including but not limited to assumptions, efficiency, generalizability, etc.).