



# Introduction and Welcome



# Agenda

Finding your way to a friendly statistician

- Division of Biostatistics
- Biostatistics Collaboration Center (BCC)
- Quantitative Data Sciences Core (QDSC)
- Northwestern University Data Analysis and Coordinating Center (NUDACC)
- General Information

**Division of Biostatistics**  
Department of Preventive Medicine

# Division of Biostatistics - DPM

## Academic Home

The Division of Biostatistics engages in statistical methods development and application, research design and statistical computing for health science research.

- ~20 biostatistics faculty
- ~20 statistical analyst / biostatistician / data manager staff
  
- Clinical research
- Basic science
- Health services
- Population health

# What We Do

Many areas of expertise, including:

- Bayesian Methods
- Big Data
- Bioinformatics
- Causal Inference
- Clinical Trials
- Database Design
- Genomics
- Longitudinal Data
- Machine learning
- Missing Data
- Reproducibility
- Statistical genetics
- Survival Analysis

Many types of software, including:



East Software



# Division of Biostatistics

## Overview

The Division of Biostatistics engages in statistical methods development and application, research design and statistical computing for health science research.

### *Division of Biostatistics faculty accomplishments*

- High impact collaborative and statistical methodology publications
- Grant funding as PI, MPI and Co-I
- Highly accessed open source software
- American Statistical Association fellows and leaders
- Award winning biostatistics instructors
- Dissertation committee chairs
- Internationally and nationally recognized biostatisticians
- Study section members
- Journal editorial positions

# Division of Biostatistics

## Overview

The Division of Biostatistics engages in statistical methods development and application, research design and statistical computing for health science research.

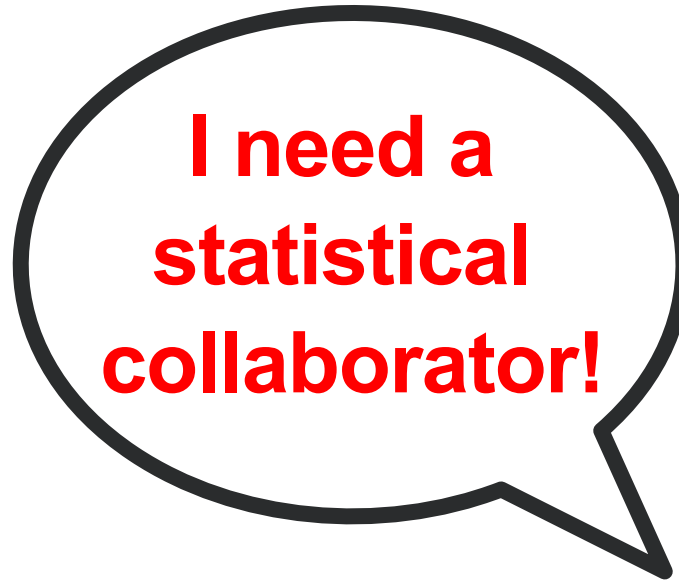
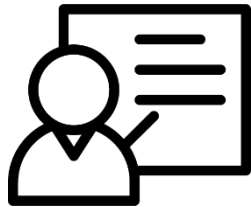
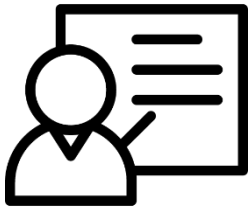
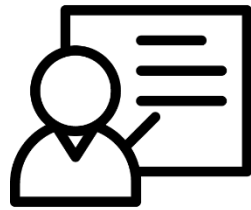
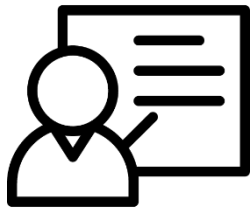
### ***Division of Biostatistics staff accomplishments***

- Masters degrees in statistics/biostatistics or data fields
- Programming prowess
  - R, SAS, Stata, SQL, Python, Shell scripting
- Reproducible research experts
  - RMarkdown, Git, StatTag
- Database set up and quality assurance pipelines
  - REDCap
- Lead authors, conference presenters
- Classroom instructors and award winning TAs



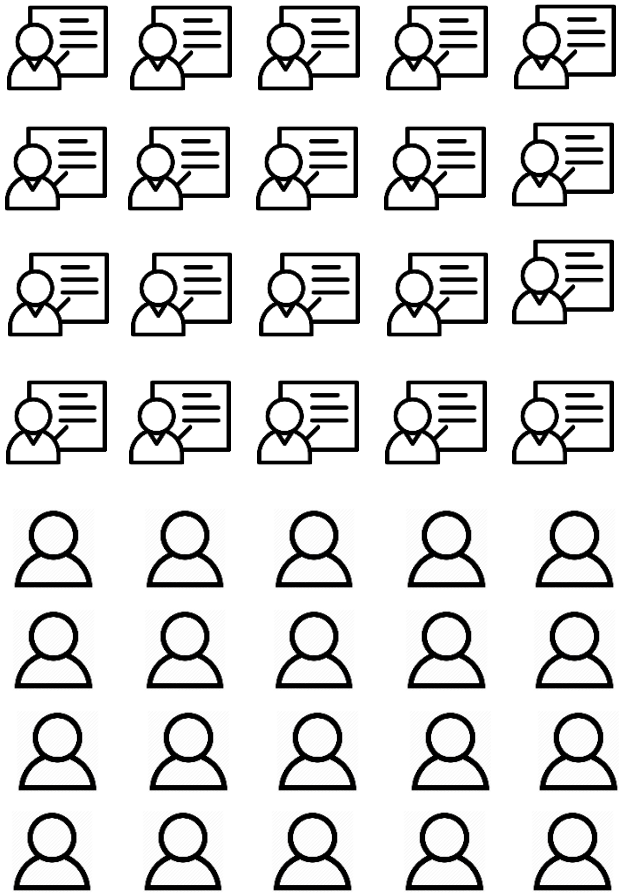
# Division of Biostatistics

Once upon a time...a long, long time ago (about 15 years ago at NU)

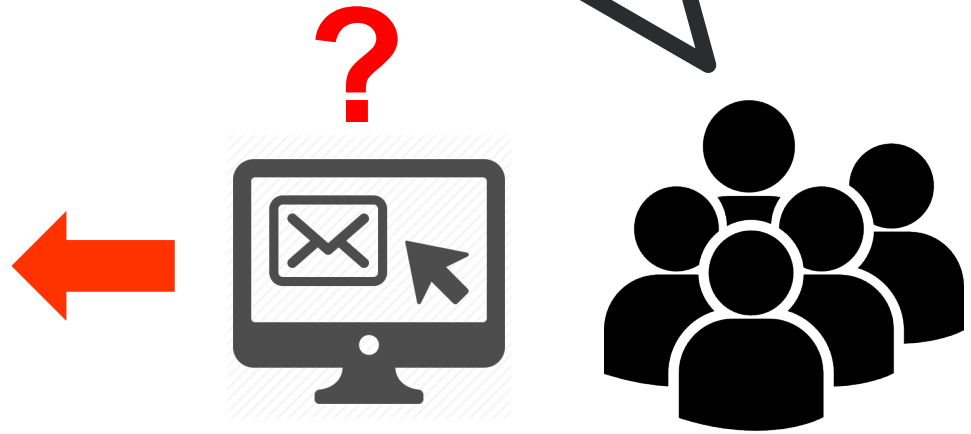


# Division of Biostatistics

Today in 2019....



**I am looking for a statistical collaborator. I anticipate more data than ever before, and it is complex!**



# Biostatistics Resources

## Overview



### Biostatistics Collaboration Center (BCC)

- Supports **non-cancer** research at NU
- Provides investigators an initial 1-2 hour consultation

### Biostatistics Research Core (BRC)

- Supports **Lurie Children's Hospital** affiliates
- **Stanley Manne Research Institute** at Lurie Children's

### Quantitative Data Sciences Core (QDSC)

- Supports all **cancer-related** research at NU
- Provides free support to all Cancer Center members subsidized by RHLCCC
- Grant

### Northwestern University Data Analysis and Coordinating Center (NUDACC)

- Supports prospective, multicenter research
- Spans the full life cycle of research
- Grant

# **Biostatistics Collaboration Center (BCC)**

# BCC: Biostatistics Collaboration Center

What do we do?

*Mission:* to support investigators in the conduct of high-quality, innovative health-related research by providing expertise in biostatistics, statistical programming, and data management.

## Annual Numbers

- Help submit ~90 grant proposals per year, > \$250M
- Work with ~200 different principal investigators and their teams
- More than 250 different research projects across FSM, Northwestern Medicine, McCormick, School of Communication, Lurie Children's, Abilitylab and more ...
- *All non-Cancer related projects*

# BCC: Biostatistics Collaboration Center

How do we do it?

Every **Northwestern affiliated investigator** is provided an initial 1-hour consultation, subsidized by **FSM Office for Research**.

Who is eligible?

- ✓ (Research) Asst/Assoc/Full Professor
- ✓ Graduate Student
- ✓ Fellow/Postdoc
- ✓ Research Coordinator
- ✓ Nurse
- ✓ Resident
- ✓ Anyone NU affiliated with a (non-cancer) research question

What happens in an initial consultation?

We learn about your project

You learn about what we might be able to do

How often can I go back for an initial consultation?

1 per project (e.g., grant submission, manuscript)

# BCC: Biostatistics Collaboration Center

How do we do it?

Grant writing is supported by FSM at **no cost to the investigator**, with the goal of establishing successful collaborations.

- Study design
- Sample size calculations/power
- Data analysis plans
- Developing (testable) specific aims
- BCC faculty/staff typically included as Co-I/Biostatistician with appropriate % effort to conduct the proposed work.
- Available to all investigators to full-time FSM faculty at the level of instructor or higher.
- We spend > 450 hours/year writing grants. The largest portion of our time is spent working on them when they are funded.

# BCC: Biostatistics Collaboration Center

How do we do it?

For projects that require biostatistics expertise but are limited in scope and do not require a biostatistician funded at % effort, the BCC supports a re-charge/fee-for-service model.

- Hourly rates are \$125-\$150 per hour.
- NIH cost study approved
- Some projects may qualify for NUCATS Tier 1 vouchers to offset costs. <https://www.nucats.northwestern.edu/funding/pilot-funding/nucats-voucher-and-pilot-programs.html>



# BCC: Biostatistics Collaboration Center

How do we do it?

The BCC also partners with the Shirley Ryan Abilitylab and the Stanley Manne Research Institute at the Ann & Robert H. Lurie Children's Hospital to provide additional expertise to those investigators.

- Abilitylab investigators should submit a request to the BCC.
- Lurie Children's investigators should submit a request to the BRC (Biostatistics Resource Core)  
<https://www.luriechildrens.org/en/research/research-areas/clinical-research/biostatistics-research-core/>



# BCC: Biostatistics Collaboration Center

How do you find us?



Northwestern University Feinberg School of Medicine  
Biostatistics Collaboration Center

## BCC Appointment Request

Please complete the request form so that the BCC may match you with appropriate expertise. You will receive a confirmation email upon successful submission, and we will contact you shortly thereafter to arrange an initial consultation.

If your request is for cancer-related research, please submit to the RHLCCC's QDSC intake form [here](#). If you are an LCH investigator, please submit your appointment request to the BRC [here](#).

**Please note that the initial consultation of 1-2 hours is free of charge and subsidized by the Feinberg School of Medicine.** During that meeting we will determine the appropriate course of collaboration, and whether or not any fees will apply.

During periods of high demand for biostatistics collaboration, we may be unable to assist with requests for collaboration within 4 weeks of a deadline.

More information, including guidelines for obtaining the most from your initial consultation, is available [here](#).

---

**Request Date**  M-D-Y

**Project Deadline**   M-D-Y  
\* must provide value  
Due to high volume, please note that the deadline should be no less than four weeks from the project request time.

**Principal Investigator First Name**   
\* must provide value  
Please enter PI first name only. If you are not the PI on this study, you will be able to enter your name later.

**Principal Investigator Last Name**   
\* must provide value  
Please enter PI last name only. If you are not the PI on this study, you will be able to enter your name later.

**Principal Investigator Title**   
\* must provide value

**Principal Investigator NetID**

**Principal Investigator E-mail Address**

# BCC Collaboration: HANDS

A Multi-Center Clinical Trial to Evaluate the Effectiveness of Intermittent Hypoxia Therapy in Individuals with Spinal Cord Injury



**William Rymer, MD, PhD** partnered with the BCC to develop a multi-site clinical trial for innovative treatment of spinal cord injury (SCI)

**Masha Kocherginsky, PhD,** helped write the grant proposal. She developed clinical trial design and analysis plan, calculated sample size, and leads the Statistics and Data Coordination Core



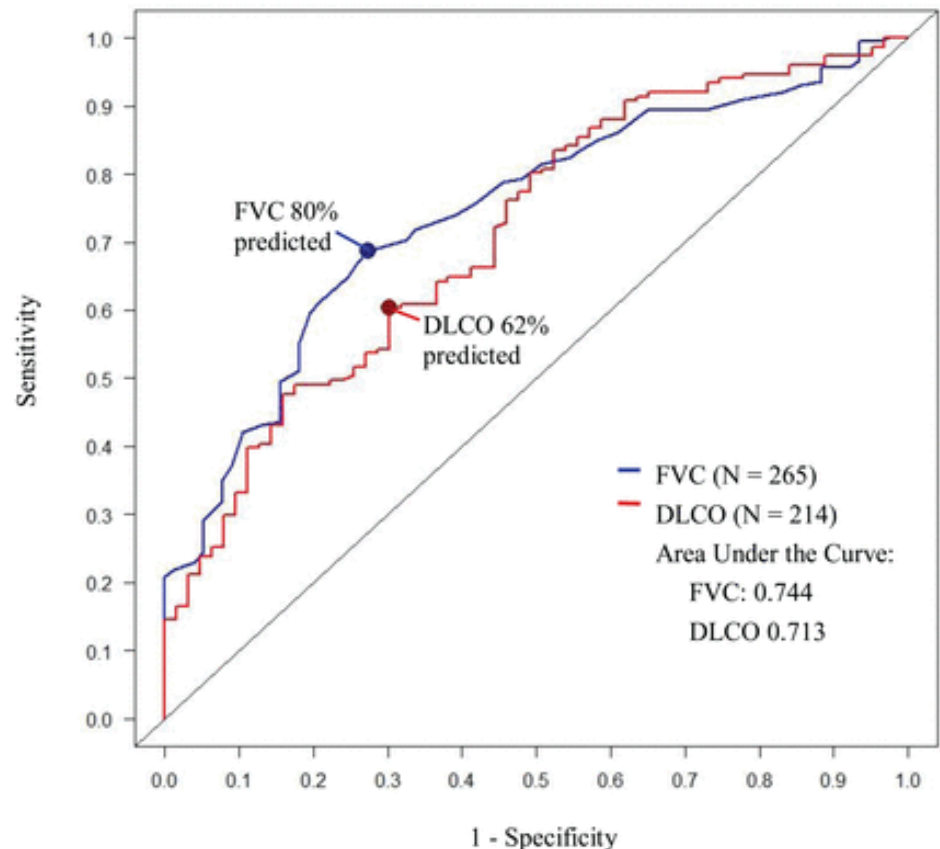
**Elizabeth (Lib) Gray, MS** worked with HANDS team to design the CRF's, developed the REDCap database, implemented the randomization in REDCap, developed ongoing quality reports



# BCC Collaboration: Less harmful detection of disease

Showalter et al. *The Journal of Rheumatology* (2018)

- Can pulmonary function tests (FVC and DLCO) be used to diagnose lung disease without radiation exposure?
- Investigators partnered with **David Aaby, MS**, and **Julia Lee, PhD** to develop an analysis plan and use registry data at NU
- AUCs of 0.74 and 0.71
- AUC guidelines:
  - 0.70–0.90 considered “moderately accurate,”
  - > 0.90 considered “highly accurate”

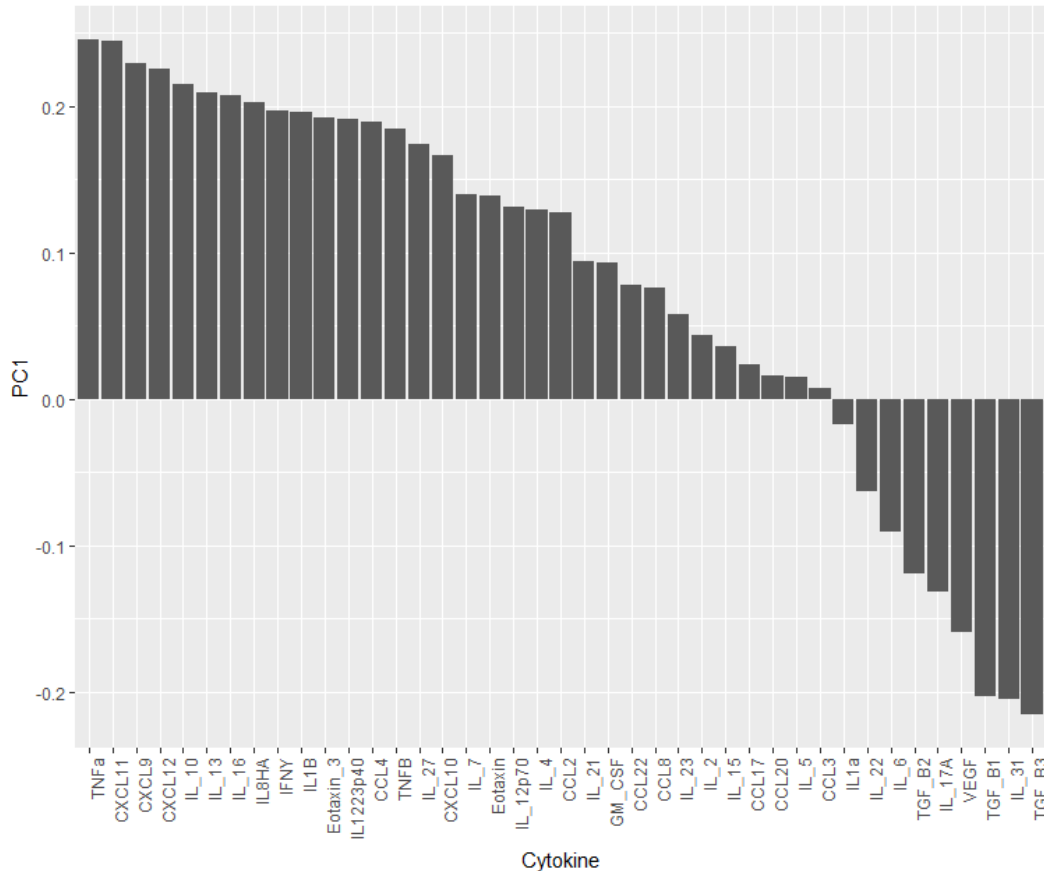


**Figure 1.** Receiver-operating characteristic curves for % predicted forced vital capacity (FVC) and DLCO, demonstrating the performance of varying FVC and DLCO % predicted cutpoints for associated radiographic interstitial lung disease in systemic sclerosis.

# BCC Collaboration: Data Reduction

Collaboration with Lurie Children's investigators, Drs. Alonso and Chapin, via the BRC

Waterfall Plot for PC1 Loadings



- 40% of pediatric liver failure cases have no identifiable etiology
- **Drs. Alfonso and Chapin** (Lurie Children's) partnered with **Nina Srdanovic, MS** and **Lauren Balmert, PhD** via the **BRC** to investigate the role of cytokines
- 41 cytokines on 20 patients
- Principal components analysis used for data reduction

*Abstract presented at Am Assoc for the Study of Liver Diseases, manuscript preparation in progress*

# RHLCCC Quantitative Data Sciences Core (QDSC)

# QDSC: Quantitative Data Sciences Core

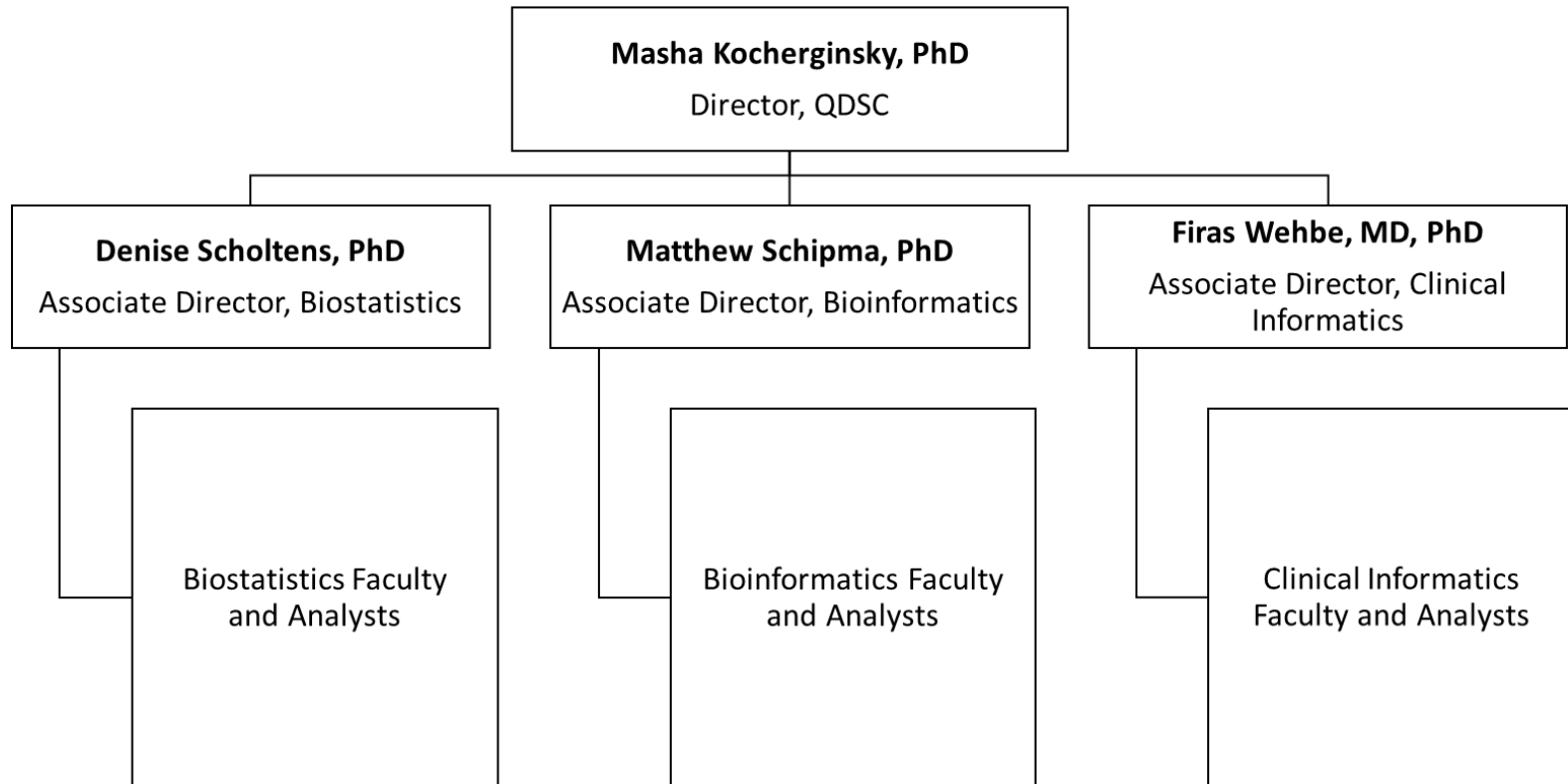
Collaborative biostatistics for cancer research

*Mission:* provide state-of-the-art integrated data science support to Robert H. Lurie Cancer Center (RHLCC) members engaged in basic, translational, population, and clinical research in all programs

- QDSC has faculty and MS-level analysts in
  - Biostatistics
  - Bioinformatics
  - Clinical Informatics
- Collaboration within QDSC
  - Biostatistics – Bioinformatics: study design and analysis
  - Biostatistics/Bioinformatics – Clinical Informatics: data collection, storage and database design

# QDSC: Quantitative Data Sciences Core

## QDSC structure





# QDSC: Quantitative Data Sciences Core

## Biostatistics Sub-Core

- Clinical trial design and analysis
  - Development of Investigator Initiated clinical trials
  - Phase I and II clinical trials
  - Standard and innovative clinical trial designs
- Grant development
  - research study design – from basic science to population studies
  - experimental design and planning
  - power and sample size calculations
  - development of statistical analysis plans
- Statistical data analysis
  - wide variety of statistical analysis methods
- Manuscript writing

# QDSC: Quantitative Data Sciences Core

## What we work on

- Since August 2018:
  - 134 new projects
  - 39 projects involved development of new or analysis of on-going clinical trials
  - 42 projects involve study planning, experimental design or power calculations
- Recently funded major collaborative grants:
  - Brain SPORE
  - U54 Study of HIV-Associated Cancers in Nigeria
  - NU IMPACT
  - Cancer Prevention Clinical Trials Network

# QDSC: Quantitative Data Sciences Core

## Operations

- QDSC is supported by the NCI Cancer Center Support Grant (CCSG) and the Robert H. Lurie Cancer Center
- LCC members are eligible for QDSC support at no cost, for projects without designated funding
- Grant development: expectation that a faculty statistician and a statistical analyst are included with appropriate % effort
- We also work with other cancer researchers, including medical and graduate students, residents and fellows.
  - Such projects require participation of an LCC member, including presence at the initial meeting

# QDSC: Quantitative Data Sciences Core

## Requesting Support

- Project tracking system for QDSC (*all sub-cores*)
  - REDCap-based system
  - Facilitates project management and reporting
- Project requests **must be submitted** for all new projects
- To request QDSC support:
  - Submit Project Description/Appointment Request form
  - You can request a particular QDSC collaborator in the “Comments” field
  - Your project will be routed to a QDSC member
- **Project Description/Appointment Request Form:**
  - <https://redcap.nubic.northwestern.edu/redcap/surveys/?s=7YAAR3YFHJ>

# QDSC: Quantitative Data Sciences Core



## Quantitative Data Science Core

### QDSC Project Description and Appointment Request

Please fill out the below form in order to ensure the best possible collaboration. You will receive a confirmation email upon successful submission of your request and we will contact you shortly for further arrangement. Visit the services page for general guidelines to help you prepare for a consultation with the Quantitative Data Science Core.

Request Date	<input type="text" value="12-11-2018"/> M-D-Y
Project Deadline <small>* must provide value</small>	<input type="text"/> Today M-D-Y
Principal Investigator First Name <small>* must provide value</small>	<input type="text"/> <small>Please enter PI first name only. If you are not the PI on this study, you will be able to enter your name later.</small>
Principal Investigator Last Name <small>* must provide value</small>	<input type="text"/> <small>Please enter PI last name only. If you are not the PI on this study, you will be able to enter your name later.</small>
Principal Investigator NETID <small>* must provide value</small>	<input type="text"/>
Principal Investigator e-mail address <small>* must provide value</small>	<input type="text"/>
Contact e-mail address <small>* must provide value</small>	<input type="text"/> <small>It is QDSC policy to communicate only via institutional e-mail addresses (e.g. northwestern.edu, luriechildrens.org, nm.org, etc.) for Feinberg and its affiliates. Please DO NOT enter a non-institutional e-mail address (e.g. gmail.com, yahoo.com). If you are affiliated with Northwestern and enter a non-institutional address, your request may be delayed.</small>
Principal Investigator Title <small>* must provide value</small>	<input type="text"/>
Institutional Affiliation <small>* must provide value</small>	<input type="checkbox"/> Lurie Children's <input type="checkbox"/> NMHC <input type="checkbox"/> NU <input type="checkbox"/> AbilityLab <input type="checkbox"/> Other
Department/Division	<input type="text"/>
Are you the PI on this project? <small>* must provide value</small>	<input type="radio"/> Yes <input type="radio"/> No
Contact phone number <small>* must provide value</small>	<input type="text"/>

Title of Project <small>* must provide value</small>	<input type="text"/>
Brief description of project (e.g. objectives, methods, data) <small>* must provide value</small>	<input type="text"/>
Is this study already associated with an IRB protocol? If so please enter the protocol number which starts with "STU###" <small>Optional</small>	<input type="text"/>
Has this study already been assigned a Cancer Center protocol? If so please enter that protocol ID if you have it. <small>Optional</small>	<input type="text"/>
Type of Collaborative Service Requested (Check all that apply)	<input type="checkbox"/> Grant writing <input type="checkbox"/> Analysis review/result interpretation <input type="checkbox"/> Data analysis <input type="checkbox"/> Data monitoring/quality control <input type="checkbox"/> Database setup <input type="checkbox"/> Experimental design <input type="checkbox"/> Clinical trial design <input type="checkbox"/> Form design <input type="checkbox"/> Manuscript preparation <input type="checkbox"/> Abstract/poster/presentation <input type="checkbox"/> Randomization <input type="checkbox"/> Respond to reviewers' comments <input type="checkbox"/> Sample size determination/power calculation <input type="checkbox"/> Survey design <input type="checkbox"/> Obtain clinical data <input type="checkbox"/> Obtain clinical samples <input type="checkbox"/> Bioinformatics support <input type="checkbox"/> Research website
How did you hear about us?	<input type="text"/>
Have you worked with the QDSC before?	<input type="radio"/> Yes <input type="radio"/> No
Comments	<input type="text"/>

# QDSC Collaboration: Predicting Lymphedema in Breast Cancer

Development and Validation of a Nomogram to Predict Lymphedema After Axillary Surgery and Radiation Therapy in Women With Breast Cancer From the NCIC CTG MA.20 Randomized Trial (Int J. Rad Onc, 2019)



**Jonathan Strauss, MD**

Associate Professor of  
Radiation Oncology  
Vice Chair for Education

- Dr. Strauss sought to develop a risk calculator for occurrence of lymphedema in breast cancer patients undergoing radiation treatment
- Used data from randomized Phase III clinical trial (MA.20) and identified 3 main risk factors:
  - BMI, extent of axillary surgery, nodal irradiation
- Statistical methods included:
  - Logistic regression, multiple imputation, bootstrap
- External validation using external cohort (NM patients):
  - Concordance Index 0.71



**Fred Rademaker, PhD**  
Professor Emeritus, Biostatistics



**Irene Helenowski, PhD**  
Senior Biostatistician

# QDSC Collaboration: Surgery in Cervical Cancer

Minimally Invasive Surgery Leads to Worse Survival for Cervical Cancer Patients (NEJM, 2018)



**Shohreh Shahabi, MD**

The John and Ruth Brewer  
Professor of Gynecology  
and Cancer Research

- Minimally invasive surgery for early stage cervical cancer
  - an alternative to open surgery for radical hysterectomy
  - adopted before high-quality evidence regarding its effect on survival was available.
- Dr. Shahabi partnered with QDSC to examine the effect of minimally invasive surgery on all-cause mortality using NCDB database
- Found the risk of death within 4 years was 9.1 percent in MIS as compared to 5.3 percent in the open surgery group (HR=1.65)
- High-profile publication in NEJM, with Drs. Shahabi and Kocherginsky as senior co-authors



**Masha Kocherginsky, PhD**  
Professor of Preventive Medicine  
(Biostatistics)

# Northwestern University Data Coordinating Center (NUDACC)



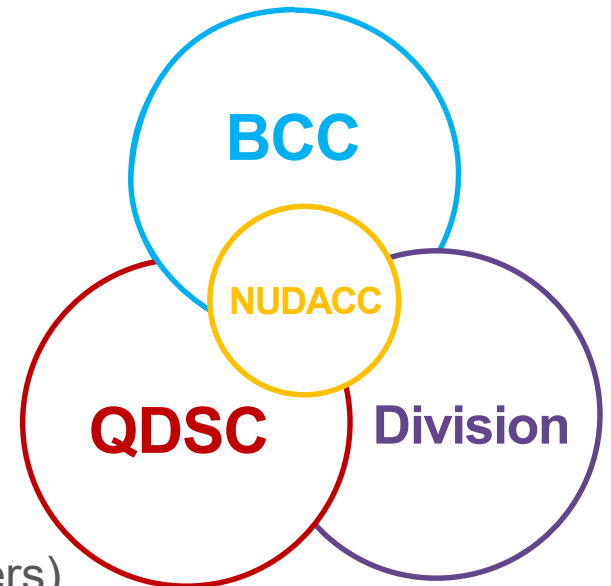
# NUDACC: Northwestern University Data Analysis and Coordinating Center

## Our Mission

*Mission:* to harmonize all components of the clinical research study life cycle through interdisciplinary collaboration and leadership within Northwestern University Feinberg School of Medicine and across our partner institutions.

How do we accomplish this?

- Study Design and Development
- Data Coordinating
- Statistical Analyses
  - Cross cutting with Division, BCC, QDSC
- Grant writing
  1. Independent U grant submissions as PI
  2. Companion R submissions (clinical + data centers)
  3. MPI / Co-I on R grants with substantial team effort



# NUDACC: Northwestern University Data Analysis and Coordinating Center

Research Life Cycle Support

## *Study Design and Development*

- Prospective clinical or observational research study design
- Sample size and power
- Randomization procedure development
- **Recruitment and feasibility studies**
- **Protocol and Manual of Operations development**
- **Data Management Plan development**
- **Data and Safety Monitoring Plan development**

## *Data Coordinating*

- **Data collection tool development, e.g. CRFs**
- **Database construction and maintenance**
- **Programming of automated range, logic and consistency checks**
- **Data query management and resolution**
- **De-identification and data security**
- **Regulatory and ethics committee reporting including Data and Safety Monitoring Board (DSMB) reporting**

## *Statistical Analyses*

- Statistical analysis plan development
- Interim statistical analyses
- Final statistical analyses
- Manuscript development and dissemination of findings
- Ancillary study development
- Methodologic innovation

# When do I come to NUDACC?

- Is your study a multi-site, prospective, human research study?
- Are you submitting a large R, U or P to NIH?
- Do you intend to allocate substantial effort and resources in data management, ongoing quality assurance and regulatory reporting?
- Will your study require a single IRB?
- Will you need to develop case report forms?
- If you start to answer YES to a few of these, you may want to reach out to NUDACC.

**What we can do for you and when**

# General Biostatistics Advice

## When should you find us?

- Hundreds of grants submitted/year, many of them are January 5, June 5, and October 5.
- For example, the BCC submits a grant about every 4 days if you average out over the year. But what that really means is 20+ grant submissions per cycle.
- Come early (6 or more weeks!), and involve biostatisticians in the writing and development process.
- We are logical thinkers, good reviewers, and have seen a lot of specific aims.
- For grant requests submitted within days of a deadline, the BCC and QDSC can provide a Letter of Support detailing availability. It's unlikely we will be available to make substantive contributions.

# Biostatistics Guidelines: Authorship & Ethics

We follow the *International Committee of Medical Journal Editors'* authorship guidelines.

- One criterion for authorship: “Substantial contributions to [. . . ] the **acquisition, analysis, or interpretation of data**”
- “individuals who meet the first [above] criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.”
- Payment does not replace authorship (or vice versa)

We also adhere to the *American Statistical Association's Ethical Guidelines for Statistical Practice*

- Good statistical practice is fundamentally based on transparent assumptions, reproducible results, and valid interpretations.

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

<https://www.amstat.org/ASA/Your-Career/Ethical-Guidelines-for-Statistical-Practice.aspx?hkey=85085cd1-5dfc-4fb9-b526-e3c6d45abc0d>

# Contact Information

- Biostatistics Collaboration Center (BCC)

- Website: <http://www.feinberg.northwestern.edu/sites/bcc/index.html>
- Email: [bcc@northwestern.edu](mailto:bcc@northwestern.edu)
- Phone: 312.503.2288

Non-cancer

- Quantitative Data Sciences Core (QDSC)

- Website: <https://www.cancer.northwestern.edu/research/shared-resources/quantitative-data-sciences.html>
- Email: [qdsc\\_rhlccc@northwestern.edu](mailto:qdsc_rhlccc@northwestern.edu)
- Phone: 312.503.2288

Cancer

- Biostatistics Research Core (BRC)

- Website: <https://www.luriechildrens.org/en/research/research-areas/clinical-research/biostatistics-research-core/>
- Email: [merreed@luriechildrens.org](mailto:merreed@luriechildrens.org)
- Phone: 773.755.6328

Lurie Children's

- Northwestern University Data Analysis and Coordinating Center (NUDACC)

- Website: <https://www.feinberg.northwestern.edu/sites/nudacc/>
- Email: [nudacc@northwestern.edu](mailto:nudacc@northwestern.edu)

Data Coordinating

**Your feedback is important to us!  
(And helps us plan future lectures)**



# Statistically Speaking: Upcoming Lectures

We hope to see you again!

- Tuesday, November 19 **Protocol Development and Review from a Biostatistical Perspective**  
**Jody Ciolino, PhD**, Associate Professor, Division of Biostatistics,  
Department of Preventive Medicine
- Wednesday, January 15 **To p or not to p: reflections on recent p-value statements**  
**Mary Kwasny, ScD**, Professor, Division of Biostatistics, Department of  
Preventive Medicine
- Wednesday, March 18 **Biostat Basics: Some Practical Things to Know**  
**Nina Srdanovic, MS**, Statistical Analyst, Division of Biostatistics,  
Department of Preventive Medicine
- Monday, May 11 **Logistic Regression: Odds & Ends**  
**Lauren Balmert, PhD**, Assistant Professor, Division of Biostatistics,  
Department of Preventive Medicine

***All lectures will be held from Noon to 1 pm in Baldwin Auditorium,  
Robert H. Lurie Medical Research Center, 303 E. Superior St.***

<http://www.feinberg.northwestern.edu/sites/bcc/education/lecture/2019.html>