



Shaping the Next Generation of Clinical Trialists:

*Perspectives on Opportunities,
Challenges, and Innovations in Training
the Clinical Trials Workforce*

Society for Clinical Trials Annual Meeting
Invited Session #2
May 18, 2026

Today's Session

- Introduction/motivation
- Panelist introductions
 - Various sectors and career stages
 - Perspectives from people who have been “trainees” and “trainers”
- Q & A

Motivation for This Session

- Clinical trials environments require skills and knowledge often not covered in formal education/training programs
- Dynamic, interdisciplinary research environments, which require cross-functional knowledge
- **Key Question:** How do we best prepare trainees for careers in this field and design useful opportunities to learn the many facets of clinical trials?

Quick Audience Poll #1

- Which best describes your primary discipline/area of focus?
 - Clinical
 - Biostatistics/statistics or epidemiology
 - Data science, informatics, or another quantitative science
 - Operations or project management

Quick Audience Poll #2

- Which sector do you work in?
 - Academia
 - Industry
 - Government/regulatory

Quick Audience Poll #3

- Who considers themselves to be on the “trainer” side of this discussion?
- “Trainee” side?
- Or maybe both sides?

Megan McCabe

Assistant Professor, Biostatistics

University of Alabama at Birmingham



My Career Path

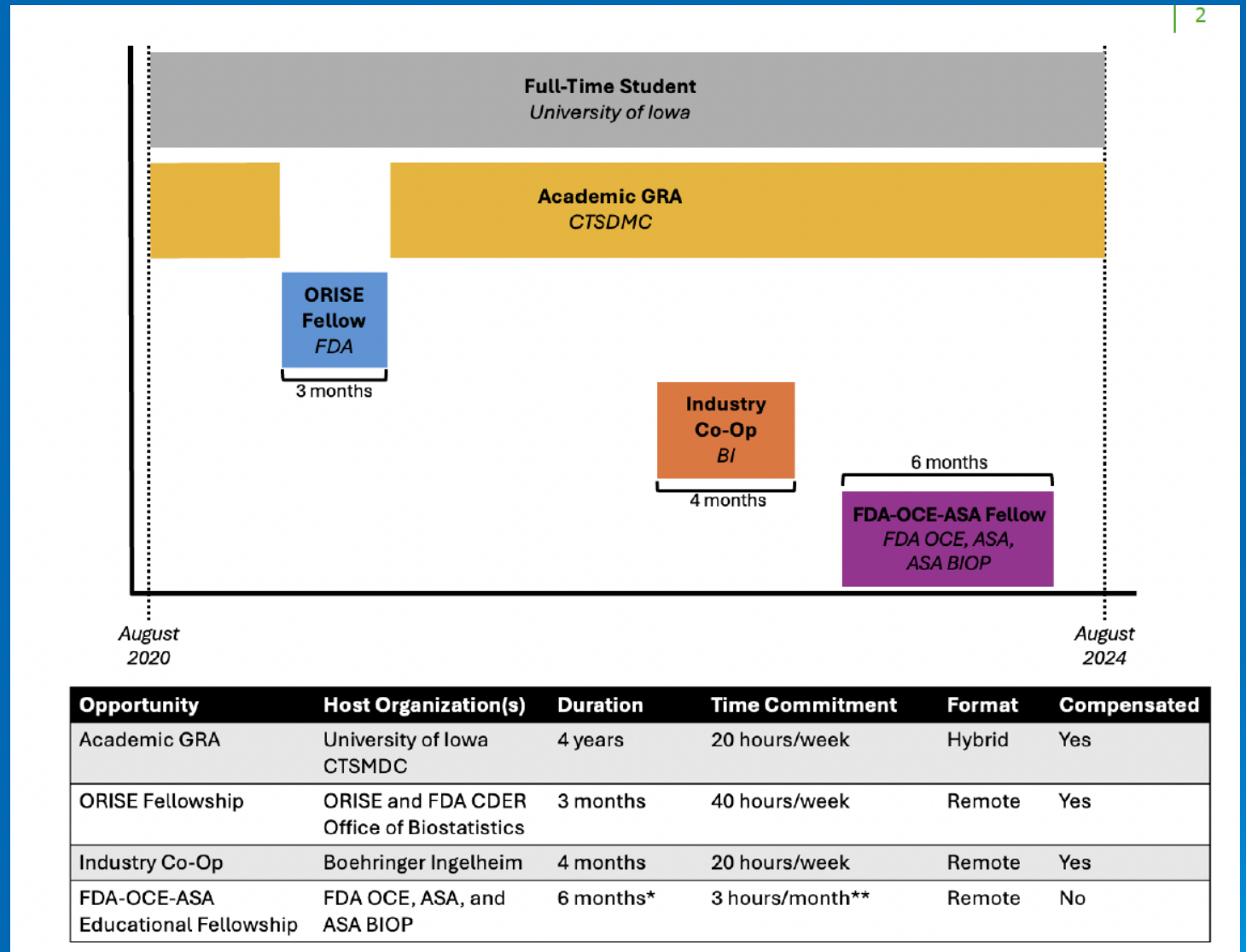


Clinical Trials Statistical and Data Management Center



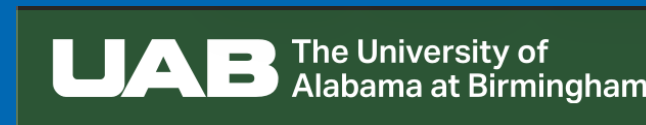
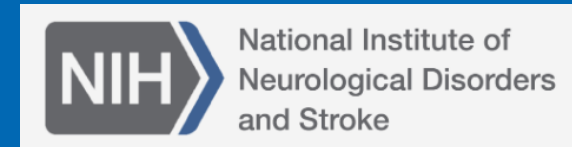
Training Opportunities – During PhD

- Graduate Research Assistant – CTSDMC, University of Iowa
- ORISE Fellow – FDA, CDER, Office of Biostatistics
- Co-op – Boehringer Ingelheim
- Fellow – FDA-OCE-ASA Oncology Educational Fellowship



Training Opportunities – As Junior Faculty

- Biostatistics Trainee – NINDS Clinical Trials Methodology Course (CTMC)
- Mentored Biostatistics Faculty – Advanced Research Institute (ARI) in Mental Health & Aging Research
- Clinical Trialist Development Program (CTDP) – UAB Academic Research Organization for Clinical Trials (ARO-CT)
- Early Career Workshop Series – ENAR
- StatsForward Leadership Fellow - ASA



Anna Snavelly

*Associate Professor, Biostatistics
and Data Science, Public Health
Sciences*

Wake Forest University



Career Path



HARVARD
UNIVERSITY



LINEBERGER
COMPREHENSIVE
CANCER CENTER

PDstat, LLC



Wake Forest University
School of Medicine



Wake Forest University
School of Medicine

The academic core
of Atrium Health

Current Roles



Wake Forest University
School of Medicine

Department of Biostatistics and Data Science



Wake Forest University
School of Medicine

Department of Emergency Medicine

Wake
Forest



NCORP RESEARCH BASE



mPATH



CHEST PAIN MOUNTAIN



Wake Forest University
School of Medicine

The academic core
of Atrium Health

Training Experiences



An AACR/ASCO Workshop on

Methods in Clinical Cancer Research

July 26-31 | Vail, CO

AACR American Association
for Cancer Research

ASCO AMERICAN SOCIETY OF
CLINICAL ONCOLOGY



Comprehensive Cancer Center

Clinical Trial Boot Camp



New Investigator Workshop



Wake Forest University
School of Medicine

The academic core
of Atrium Health

Heidi Munger Clary

Associate Professor, Neurology

Wake Forest University



From Trainee to Faculty Roles

Heidi M. Munger Clary, MD, MPH, FACNS, FAES, FANA

- Vice Chair of Research, Department of Neurology
- Director, Faculty Research Development
- Associate Professor
- Wake Forest University School of Medicine

Methodology Training → Faculty Leader

- MD/MPH, Northwestern University, 2007
- NINDS Clinical Trials Methodology Course Trainee 2017-2018
- NINDS NeuroNEXT Fellow 2018-2019
- UCSF Implementation Science Certificate Program 2019-2021
 - Course faculty subsequent to completion of certificate
 - Introduction to Implementation Science Theory and Design (2021)
- Director of Career Enhancement, Wake Forest NeuroNEXT 2022-present
- NINDS Clinical Trials Methodology Course Core Faculty, 2023-present

NINDS Clinical Trials Methodology Course

Project: protocol/synopsis development & refinement

grant development/
mock study section

Small groups

webinars

Residential
course
(3 day)

Small
groups

webinars

**Small groups-3 trainees, 1 biostats
faculty, 2 clinical faculty**

Christopher Coffey

*Professor, Biostatistics
Director, Clinical Trials and Statistical
Data Management Center*

University of Iowa



“Fun”damentals of Clinical Trials Training

Christopher S. Coffey

Professor of Biostatistics

Director, Clinical Trials Statistical and Data Management Center

University of Iowa

NeuroNEXT Biostatistics Fellow



CTMC Biostatistics Track



CTMC



Clinical Trials Course – Extra Credit



Letitia Weigand

*Director, Office of Training and
Workforce Development*

NIH, NINDS



NINDS Office of Training and Workforce Development (OTWD)



Tish Weigand, PhD
Director



Lauren Ullrich, PhD
Deputy Director



K. Rezaizadeh, PhD
Program Director



Marguerite Matthews, PhD
Program Director



Elizabeth Sypek, PhD
Program Director



Jenny Kim, PhD
Program Director

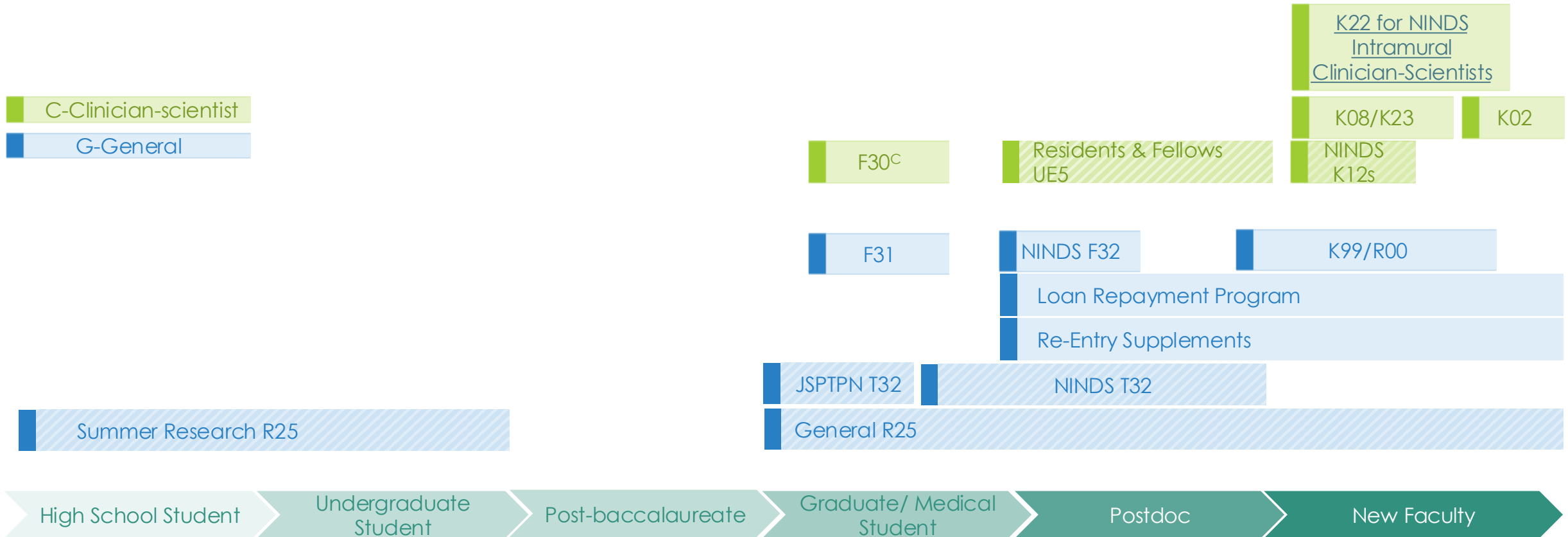


Joshua Sanchez, PhD
*Health Program
Specialist*



Nina Hsu, PhD
Program Director

NINDS Training and Workforce Development Programs (2026)



My Background & Interest in Today's Topic



10 years creating, administering, leading NINDS training and career development programs

3 years in industry – medical affairs

Close collaborator with NINDS Division of Clinical Research – co-authored an editorial in *Neurology* “Training Clinical Scientists: At All Career Stages” (2024)

Speaker and mentor for NINDS Clinical Trials Methodology Course

Leader in NIH-wide Training and Workforce Development space including on a new working group focused on how NIH supports the training of clinical trialists

General interest in modernizing how NINDS supports training the neuroscience workforce (this is a goal in OTWD Strategic Plan)

Specific interest in training clinical trialists – what are the gaps and how can NINDS/NIH help fill them?

Pallavi Mishra-Kalyani

Deputy Director, Division of Biometrics V

FDA, CDER



Career Path

- Current Role:
 - Deputy Director, Division of Biometrics V, CDER, FDA
 - Joined FDA 11 years ago as a reviewer in oncology statistics
- Before FDA:
 1. Undergraduate degree in Econ
 2. Consulting
 3. Epidemiology SM
 4. Biostatistics PhD

Involvement in Training Opportunities

- Lead of FDA-OCE-ASA Oncology Statistics Educational Fellowship program since 2024
 - Yearly cohorts of 20 stats/biostats graduate students and post-doc fellows
 - Focuses on statistical methods and issues in oncology
 - Mostly related to clinical trials in oncology, but also covers some other areas of interest (e.g. RWE)
- FDA clinical fellowship programs

Q & A

What are some of the key skills that should be emphasized in training opportunities?

What gaps exist in traditional training/educational programs?

Many training opportunities are limited in terms of their time. How do we thoughtfully design opportunities so that trainees can efficiently learn the required and most critical skills?

How do trainees ensure that they are making the most of an opportunity?

What are unique features of an opportunity which make it more appealing to trainees?

How should we identify trainees who might be interested in these opportunities? What are effective ways of advertising?

Audience Q & A