Sub-Course Abbreviations
**BDC:** Biostatistics and design considerations
**AGQ:** Asking good questions
**TLC:** Trial logistical considerations
**RR:** Responsible research

## AGENDA

While we are not requiring 16 hour days, we want the course participants to make as much progress on fully developing protocols during this 3.5 day period. We are recommending working dinners on Monday and Wednesday within the small groups. In addition, course faculty will be available for one-on-one meetings with trainees within their small groups, and/or with trainees from other small groups.

## Sunday August 7

* 5:30 pm Faculty meeting – Huron Ballroom
* 6:00 pm Networking Reception – Terrace Ballroom
* 7:00 Welcome Dinner – Welcome to Residential Course: **Will Meurer**

Introduction of Foundations/Associations (Alzheimer’s Association, **Jennifer Howard**; American Academy of Neurology, **Deborah Hall**, **Alberto Ramos**; American Association of Neuromuscular & Electrodiagnostic Medicine, **Anthony Chiodo**)

* 8:00 **Keynote presentation** – Clinical trials in the CNS space: **Michael Krams**

## Monday August 8

* 7:30-8:00 Registration and breakfast – Terrace Ballroom
* 8:00-8:15 Introduction to Course : **Will Meurer**
* 8:15-9:00 Overview of clinical trials: **Chris Coffey**
* 9:00-9:45 How to do transformative clinical trials: **Jeffrey Saver**
* 9:45-10:00 Break
* 10:00-10:45 Selecting Outcome Measures for Neuroscience Trials: **Jeremy Shefner**
* 10:45-12:15 BREAKOUT Small Group Meeting 1 *(see room locations on page 5)*
* 12:15-1:00 Lunch – Terrace Ballroom
* 1:00-1:45 Biomarkers: **Merit Cudkowicz**
* 1:45-2:30: High yield points for protocols / manuals of procedures: ensuring reproducible research : **Dixie Ecklund, Marianne Kearney**
* 2:30-3:00 Break
* 3:00-3:45 Learn phase designs 1 – Dose Finding: **Jason Connor**
* 3:45-4:30 Learn phase designs 2 – Futility Designs: **Valerie Durkalski- Mauldin**
* 4:30-5:15 INDs/IDEs – Perspectives of Sponsor Investigators : **Pooja Khatri, Robert Silbergleit**
* Evening Small Group work and/or dinner with your small group *(List of area restaurants available)*

## Tuesday August 9

* 7:30-8:00 Networking and breakfast – Terrace Ballroom
* 8:00-8:05 Introduction to Day 2: **Will Meurer**
* 8:05-8:50 Clinical Trials in Rare Diseases: **Erika Augustine**
* 8:50-9:15 What does an IRB do?: **Roger Lewis**
* 9:15-10:00 DSMBs and the clinical monitoring of trials/role of medical safety monitor: **Roger Lewis /Robin Conwit**
* 10:00-10:15 Break – **GROUP PHOTO –** Terrace Patio
* 10:15-10:45 Enrolling representative populations: recruitment of disadvantaged and historically under-represented groups in research: **Adrianne Haggins**
* 10:45-11:30 Multiplicity: Incentives and risks of fooling oneself: **Michelle Detry**
* 11:30-12:15:BREAKOUT Small Group Meeting 2 *(see room locations on page 5)*
* 12:15-1:00 Lunch – Terrace Ballroom
* 1:00-1:45 Recruitment and retention: **Josh Grill**
* 1:45-2:30 Developing a statistical plan/objectives pertaining to “safety” : **Jordan Elm**
* 2:30-3:00 Break
* 3:00-5:00 Faculty Office Hours or protocol writing time *(see page 5 for details)*
* 6:30-8:00 **American Academy of Neurology Sponsored** Group Dinner

Professional Autobiographies of Clinical Trialists: **Merit Cudkowicz, Dietrich Haubenberger, Pooja Khatri**

## Wednesday August 10

* 7:30-8:00 Networking and breakfast – Terrace Ballroom
* 8:00-8:15 Introduction to Day 3: **Will Meurer**
* 8:15-9:00 Your Date at the PROM: Patient Reported Outcome Measures : **Brett Kissela** **/ Laurie Gutmann**
* 9:00-10:00 A (Brief) Introduction to Adaptive Designs and Clinical Trial Simulation: **Kert Viele**
* 10:00 10:15 Break
* 10:15-11:00 Using preclinical data to inform human trials: Scientific premise and safety : **Dietrich Haubenberger / Wendy Galpern**
* 11:00-11:30 Stopping rules for clinical trials : **Ken Cheung**
* 11:30-12:15BREAKOUT Small Group Meeting 3 *(see room locations on page 5)*
* 12:15-1:00 Lunch – Terrace Ballroom
* 1:00-1:45 Career development mechanisms at NINDS: **Stephen Korn**
* 2:00-5:00 Faculty Office Hours or protocol writing time *(see page 5 for details)*
* 5:00-6:00 Clinical Trials Knowledge Contest: **CTMC course directors**
* Dinner on your own (meet with people outside the course or other faculty/trainees) *(Please review list of area restaurants)*

## Thursday August 11

* 7:30-8:00 Networking and breakfast– Terrace Ballroom
* 8:00-8:15 Introduction to Day 4: **Will Meurer**
* 8:15-9:00 Metrics, Progress Reports and Next Steps: **Small group faculty**
* 9:00-9:45 BREAKOUT Small Group Meeting 4 *(see room locations on page 5)*
* 9:45-10:00 Break
* 10:00-10:45 Creating an Effective Clinical Trial Budget: **Valerie Stevenson**
* 10:45-11:30 Clinical Trial Networks: NeuroNEXT, StrokeNET, NETT/SIREN: **Bill Barsan, Chris Coffey, Robin Conwit, Pooja Khatri**
* 11:30-12:15 Course evaluations / Small group awards
* 12:15 Adjourn didactic sessions – Boxed lunches in Terrace Ballroom
* 1:00 Additional potential office hours for those still in Ann Arbor / additional protocol writing time

## Breakout Meeting Schedules and Locations

In each small group meeting, the trainees will report to their peers and small group leaders regarding their current status.

Breakout meeting 1: Describe current status of protocol and areas for improvement while in Ann Arbor

Breakout meeting 2: Describe status of plan for IND/IDE, “safety” and human subjects protection and areas for development

Breakout meeting 3: Describe plan for recruitment, retention and enrollment and areas for development

Breakout meeting 4: Provide updated design and specific aims to the larger group along with next steps after the course

## Faculty Office Hours

Faculty and other clinical trial experts outside your small group will have 30 minute blocks of time to meet with trainees or groups of trainees regarding their projects. For example, you might want to meet with a stroke faculty member outside of your small group. Alternatively, you may want to meet with the research staff from NETT/NeuroNEXT/StrokeNET regarding recruitment. Use the SignUpGenius links below to sign up online for time slots with available residential course faculty. Faculty bios and contact information are available in the directory on the course website <https://nett.umich.edu/training/ctmc/ctmc-directory>

## Clinical Trial Simulation Track / Labs (applicable to Group 7 only)

In addition to a more advanced clinical trial protocol, the projects in this group will develop a concept for an adaptive clinical trial, and a working simulation. The working simulations and design report will be the primary responsibility of the collaborating biostatisticians from Utah and Vanderbilt.

**Monday, August 8**

* Follow residential course agenda above

**Tuesday, August 9**

* 7:30-8:00 Networking and breakfast – Terrace Ballroom
* 8:00-8:15 Introduction to Day 4: **Will Meurer** – Terrace Ballroom
* 8:15-9:00 Biostatisticians attend simulation programming lab (Dahlmann West Boardroom). Clinicians follow residential course agenda above.
* 10:00-10:15 Break – **GROUP PHOTO** – Terrace Patio
* 10:15-11:30 Biostatisticians attend simulation programming lab (Dahlmann West Boardroom). Clinicians follow residential course agenda above.
* 11:30 BREAKOUT Meeting: Reconvene biostatisticians and clinicians to report on progress and next steps.
* 12:15-1:00 Lunch – Terrace Ballroom
* 1:00-2:30 Biostatisticians attend simulation programming lab. Clinicians follow residential course agenda above.
* 2:30-3:00 Break
* 3:00-5:00 Biostatisticians attend simulation programming lab. Clinicians meet with other faculty to hone clinical aspects of protocol.
* 6:30-8:00 **American Academy of Neurology Sponsored** Group Dinner

**Wednesday, August 10**

* 7:30 – 8:00 Follow residential course agenda above
* 1:00-1:45 Small group meeting to report current status and next steps (Dahlman West Boardroom)
* 1:45-5:00 Simulations with access to course faculty for questions and advice

**Thursday, August 11**

* Follow residential course agenda above

## Faculty List

## Course Directors

Chris Coffey, PhD: Professor of Biostatistics, University of Iowa
Robin Conwit, MD: Program Director, Office of Clinical Research, National Institute of Neurological Disorders and Stroke

Laurie Gutmann, MD: Professor, Vice Chair of Clinical Research, Department of Neurology, University of Iowa
Roger Lewis, MD, PhD: Professor of Emergency Medicine, Harbor-UCLA Medical Center
William Meurer, MD, MS: Associate Professor of Emergency Medicine and Neurology, University of Michigan

## Core Faculty (Small group leaders)

Erika Augustine, MD, MS: Assistant Professor of Neurology and Pediatrics, University of Rochester

Kristine Broglio, MS: Statistical Scientist, Berry Consultants, LLC

Ken Cheung, PhD: Professor of Biostatistics, Columbia University

Jason Connor, PhD: Statistical Scientist, Berry Consultants, LLC

Michelle Detry, PhD: Statistical Scientist, Berry Consultants, LLC

Valerie Durkalski-Mauldin, PhD, MPH: Professor of Biostatistics, Medical University of South Carolina

Jordan Elm, PhD: Research Associate Professor of Biostatistics, Medical University of South Carolina

Eric Foster, PhD: Clinical Assistant Professor of Biostatistics, University of Iowa

Wendy Galpern, MD, PhD: Medical Director, Neuroscience Clinical Development Group, Janssen Research and Development

Dietrich Haubenberger, MD: Director, Clinical Trials Unit, National Institute of Neurological Disorders and Stroke
Pooja Khatri, MD: Professor of Neurology, University of Cincinnati
Brett Kissela, MD: Professor and Chair of Neurology and Rehabilitation Medicine, University of Cincinnati

Jeremy Shefner, MD, PhD: Professor and Chair of Neurology, Associate Director, Barrow Neurological Institute

Robert Silbergleit, MD: Professor of Emergency Medicine, University of Michigan

Kert Viele, PhD: Statistical Scientist, Berry Consultants, LLC

Sharon Yeatts, PhD: Research Associate Professor of Biostatistics, Medical University of South Carolina

## Residential Course Faculty

William Barsan, MD: Professor of Emergency Medicine, University of MichiganMerit Cudkowicz, MD, MSc: Professor of Neurology, Massachusetts General Hospital (MGH) / Harvard UniversityDixie Ecklund RN, MSN, MBA: Associate Director, Clinical Trials Statistical & Data Management Center, University of Iowa
Joshua Grill, PhD: Adjunct Associate Professor of Psychiatry and Human Behavior, Associate Director, Alzheimer’s Disease Research Center, UCI

Adrianne Haggins, MD, MS: Clinical Lecturer, Department of Emergency Medicine, University of Michigan

Marianne Kearney: Director of Research Operations, Neurological Clinical Research Institute (NCRI), MGH

Stephen Korn, PhD: Director, Office of Training, Career Development & Workforce Diversity, National Institute of Neurological Disorders and Stroke

Michael Krams, MD, PhD: Global Head of Quantitative Sciences at Janssen Pharmaceuticals, Inc

Jeffrey Saver, MD, FAHA, FAAN, FANA: Professor of Neurology, Senior Associate Vice Chair for Clinical Research, Director, UCLA Comprehensive Stroke Center

Valerie Stevenson, BAS, RRT, CCRP: Administrative Director, Neurological Emergencies Treatment Trials, University of Michigan

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| --- | --- | --- | --- | --- |
| **August 7** | **August 8** | **August 9** | **August 10** | **August 11** |
| □ Keynote Address: Michael Krams | □ Overview of clinical trials – Chris Coffey  | □ Clinical trials in rare diseases – Erika Augustine | □ Patient reported outcome measures – Brett Kissela | □ Metrics, next steps |
|  | □ How to do transformative clinical trials – Jeff Saver | □ IRBs – Roger Lewis | □ Intro to Adaptive Designs – Kert Viele | □ Creating an Effective Clinical Trial Budget – Valerie Stevenson |
|  | □ Selecting outcome measures for neuroscience trials– Jeremy Shefner | □ DSMBs – Robin Conwit/Roger Lewis | □ Using preclinical data – Dietrich Haubenberger/Wendy Galpern | □ Clinical Trials Networks: Multiple presenters |
|  | □ Biomarkers – Merit Cudkowicz | □ Enrolling representative populations – Adrianne Haggins | □ Stopping rules for clinical trials– Ken Cheung | □ Overall residential course evaluation |
|  | □ High yield points for protocols/manuals for procedures – Dixie Ecklund, Marianne Kearney | □ Multiplicity – Michelle Detry | □ Career development at NINDS – Stephen Korn | **PLEASE NOTE**: CME requests must be submitted within 30 days of the residential course. You must  |
|  | □ Learn phase designs 1 – dose finding – Jason Connor | □ Recruitment and retention – Josh Grill | □ Clinical trials knowledge contest | complete an overall course evaluation to request CMEs.  |
|  | □ Learn phase designs 2 – futility designs – Valerie Durkalski-Mauldin | □ Developing a statistical plan/objectives pertaining to safety – Jordan Elm |  | Please submit CME requests to ninds-ctmc-info@umich.edu |
|  | □ IND/IDEs: perspectives of sponsor investigators – Pooja Khatri, Robert Silbergleit | □ Career Development/Professional Autobiographies - Panel |  |  |

**Accreditation Statement:** This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of the American Academy of Neurology Institute and the (name of non-accredited provider). The American Academy of Neurology Institute is accredited by the ACCME to provide continuing medical education for physicians.

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**The Clinical Trials Methodology Course is supported by the NINDS R25 NS088248 and is administered by the University of Michigan, the University of Iowa, and Los Angeles BioMed. Additional support is provided by the American Academy of Neurology.**