



ASENT 2025

Neurotherapeutics Clinical Trials Course

March 10-11, 2025

HYATT REGENCY BETHESDA, MD

APPLICATIONS OPEN
SEATS LIMITED

ABOUT THE COURSE

ASENT is pleased to offer a 2-day course March 10-11, 2025 at the Hyatt Regency Bethesda, in Bethesda, MD to introduce clinicians interested in clinical research to the principles of neurotherapeutic clinical trial development and implementation. The course will be especially relevant if you are a neurologist with clinical experience interested in conducting neurotherapeutic clinical trials.

The course covers the principles of clinical trials from pre-clinical programs to Phase III design and implementation, including necessary regulatory conversations and IND enabling studies, IRB oversight and adverse event tracking and reporting. The course considers clinical trials in the neurotherapeutic space for both drugs and devices. The faculty will also address the unique challenges inherent in developing treatments for nervous system disorders.

This year, we have expanded on those features of the course that participants the most immediate value.

Key FAQ's

DEADLINE TO APPLY: October 28, 2024

- Format: In Person
- Application: Free
- Tuition: \$450 for Accepted Applicants
- Requirements: Completed Application
- Credentials Provided: Certificate of Completion
- **Included:** Course materials, Discounted Registration for ASENT Annual Meeting, Discounted fee to Submit Abstract to ASENT.
- **Not Included:** Travel and Hotel is not included for all participants

ABOUT ASENT

The American Society for Experimental Neurotherapeutics (ASENT) is an independent non-profit organization established in 1997 by leaders in academia, government, advocacy and industry to facilitate the process by which new therapies are made available to patients with neurological disorders.

The clinical trials course is held in advance of the ASENT Annual Meeting. The ASENT Annual Meeting is the premier neurotherapeutics conference where senior leaders from payers, providers, employers, investors, fast-growing startups, pharma, policymakers, funders and innovation centers in the neurology and neuroscience space gather to ask one question: how can we improve the process of bringing neurotherapeutics to market?

The conference content focuses on the latest science in neurotherapeutics including innovations across disease states, novel delivery systems, gene therapy and biomarkers, and of course the latest drug therapies and devices. The event features plenary sessions, panel discussions, satellite luncheons, networking meetings, pipeline presentations and poster sessions.

Accepted applicants to the Clinical Trials Course receive a discounted rate to attend the annual meeting and to submit an abstract for presentation at the ASENT Annual Meeting.

To learn more about ASENT visit: [ASENT.org](https://www.asent.org)

GENERAL INFORMATION

Who Attends

- Clinician-Investigators
- Neuroscience Trainees
- Clinical Neurologists
- Industry Clinicians
- Academic Clinicians
- MDs
- MD, PhDs
- PhDs
- Early Career
- Mid Career

Testimonials

“Please offer it again next year, as this is such a unique course with top-notch experts.”

“Kudos to everyone involved all the organizers and speakers did a terrific job. They were all dedicated and very professional.”

“Panel of successful trialists was a great idea.”

“LOVED the Adverse Events breakout session! So practical!”

CURRICULUM

This 2-day course will introduce researchers and clinicians to the principles of neurotherapeutic clinical trial development and implementation and will provide participants with knowledge elements required to successfully conduct a neurotherapeutic clinical trial as a site lead or team member.

The training, which is designed to be applicable to diverse diseases of the nervous system, will equip students with a broad understanding of the various component steps in the clinical trial process.

Students will learn:

The genesis of clinical trials

- Present structure of clinical trials
- About preclinical and IND Enabling Studies
- The process complexity of selecting sites and investigators
- Steps required to ensure safety and efficacy within Phase I and II
- About the design and implementation of multicenter trials in Phase III
- How to address issues in drafting protocols and assessing adverse events
- The practical aspects of Phase III data
- In sum, students will be equipped with the skills to conduct a neurotherapeutic clinical trial as a site lead or team member, and work collaboratively with subject experts in each of the component areas.

The course combines didactic lectures with active engagement activities in which the students will be challenged to utilize the lecture material during group workshops on protocol design and adverse events.

This course is designed to provide clinicians with the practical skills necessary to successfully lead neurotherapeutic clinical trial sites. ASENT has created this new mechanism to support the education and development of clinicians to become high quality trialists.

CURRICULUM

Day 1

Time	Session	Faculty
7:00 - 8:00	Registration	
8:00 - 8:15	Welcome Remarks	Debra Ehrlich, MD, MS, NINDS Intramural Research Course Committee Chair
8:15 - 8:45	Section 1: Introduction	Kenneth Sommerville, MD Consultant Previously with Greenwich Bioscience
8:45 - 9:00	Q&A	
9:00 - 10:00	Section 2: Present Structure	Lauren Reoma, MD, NINDS Intramural Research
10:00 - 10:15	Q&A	
10:15 - 10:45	Section 3: Preclinical / IND Enabling	Michael Rogawski, MD, PhD, UC Davis
10:45 - 11:15	Q&A	
11:15 - 12:15	Section 4: IND/IDE	W. Andrew Mould, MPH, Johns Hopkins School of Medicine Nichol McBee, MPH, Johns Hopkins School of Medicine

Time	Session	Faculty
12:15 - 12:30	Q&A	
12:30 - 1:30	Lunch	
1:30 - 3:00	Workshop: Industry vs Investigator Initiated Trial	W. Andrew Mould, MPH, Johns Hopkins School of Medicine Nichol McBee, MPH, Johns Hopkins School of Medicine
3:00 - 3:15	Break	
3:15 - 4:00	Section 5: Phase I/Clinical Pharmacology and Pharmacogenetics	W. Douglas Figg, Sr. Senior Investigator, NIH
4:00 - 4:15	Q&A	
4:15 - 5:30	PANEL DISCUSSION CROs or Study Groups (TBD)	TBD
5:30 - 7:00	Cocktail Reception with Faculty	

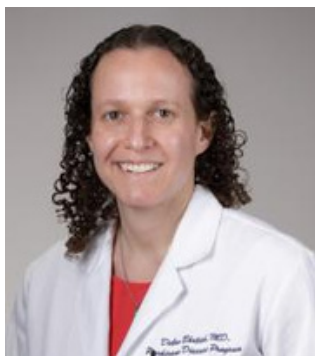
CURRICULUM

Day 2

Time	Session	Faculty
7:30 - 8:00	Registration	
8:00 - 8:15	Welcome Remarks - Day Two	Debra Ehrlich, M.D. NINDS Intramural Research Course Committee Chair
8:15 - 9:15	Section 6: Phase II/Phase III	Gail Farfel, Ph.D. Consultant
9:15 - 9:30	Q&A	
9:30 - 10:30	Section 7: Phase III/Design and Implementation of Clinical Trials	Robert Wechsler, MD, PHD, FAES, FAAN Consultants in Epilepsy and Neurology, PLLC
10:30 - 10:45	Q&A	
10:45 - 12:30	Workshop: Work out a Phase 3 Draft Protocol Design - Breakout Groups Participants will work in small teams to design protocols according to provided scenarios	Gail Farfel, Ph.D., Consultant O'Neil D'Cruz, MD, Consultant

Time	Session	Faculty
12:30 - 1:30	Lunch	
1:30 - 2:30	Operationalizing a Phase II/III Trial	Svetlana Shore, Ph.D., Neurocrine
2:30 - 2:45	Q&A	
2:45 - 4:00	Workshop: What do you do with an Adverse Event Breakout Groups	Svetlana Shore, Ph.D., Neurocrine Gail Farfel, Ph.D., Consultant
4:00 - 4:15	BREAK	
4:15 - 5:20	PANEL DISCUSSION CROs or Study Groups	TBD
5:20 - 5:30	Closing Remarks - Adjourn	Debra Ehrlich, M.D. NINDS Intramural Research Course Committee Chair
5:30 - 8	Cocktail Reception	

FACULTY



Committee Chair

DEBRA J. EHRLICH, M.D., M.S.

Director of the Parkinson's Disease Clinic,
Staff Clinician
National Institute of Neurological Disorders and Stroke
(NINDS), National Institutes of Health (NIH)

Course Faculty



GAIL FARFEL, PH.D.

Biotech Executive
Consultant



W DOUGLAS FIGG, SR

Senior Investigator
Associate Director, Center for Cancer Research, National Cancer
Institute, National Institutes of Health
Acting Chief, Genitourinary Malignancies Branch, CCR, NCI, NIH
Chief, Clinical Pharmacology Program, Office of the Clinical Director,
CCR, NCI, NIH

FACULTY



NICHOL MCBEE, MPH, ACRP-CP

Research Associate (faculty), Department of Neurology
Executive Director, BIOS Clinical Trials Coordinating Center
Faculty Director, JHU ICTR Trial Advisor Program (TAP)
Executive Director, Johns Hopkins Trial Innovation Center
Johns Hopkins University School of Medicine



W. ANDREW MOULD, MPH

Research Associate, Department of Neurology
Associate Director, BIOS Clinical Trials Coordinating Center
HEAL Director, JHU SSRC HEAL Pain ERN
Project Lead, JHU Trial Innovation Center (TIC)
Johns Hopkins School of Medicine



LAUREN BOWEN REOMA, M.D.

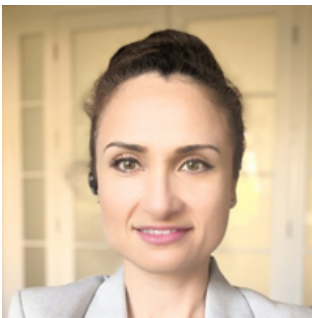
Staff Clinician and Director of the NINDS Clinical Trials Unit in
the Office of the Clinical Director
Lead, Clinical Trials Compliance and Safety Oversight Office

FACULTY



MICHAEL A. ROGAWSKI, M.D., PH.D.

Professor, Department of Neurology and Pharmacology, School of Medicine, University of California, Davis,
Director of the Institute for Neurotherapeutics,
Associate Director, UC Davis CounterACT Center of Excellence,
Principal Investigator, University of California Drug Discovery Consortium



SVETLANA SHORE, PH.D.

Director, Clinical Development,
Neurocrine Biosciences



KENNETH W. SOMMERVILLE, M.D., FAES, FAAN

Pharmaceutical Industry Consultant



ROBERT T. WECHSLER, M.D., PH.D., FAES, FAAN

Owner, Consultants in Epilepsy & Neurology, PLLC
Owner, Idaho Comprehensive Epilepsy, PLLC

APPLICATION PROCESS

Step 1:

Submit your application using the link below.

You will be asked to upload the following items:

- your CV
- a 1 page personal statement

There is **no fee** to submit an application

APPLY

Step 2:

Your application will be reviewed by our faculty.

Please note there are limited seats. In order to secure your seat for the 2025 course please submit your application early.

Step 3:

Those applicants that are accepted will receive notification with a link to register and pay the \$450 registration fee.

This will be provided via email upon acceptance.

Please note: There are limited seats. If an accepted applicant does not register within the deadline noted we will need to proceed to another applicant on the waitlist.

Important: The registration fee includes teaching fees and onsite materials. It **does not** include accommodations for networking event, travel and hotel expenses, and other expenses not specifically mentioned in the fees.



ASENT 2025 Neurotherapeutics Clinical Trials Course

March 10-11, 2025

HYATT REGENCY BETHESDA, MD

For more info contact jessica@asent.org

APPLY TODAY