

Small-Fiber Polyneuropathy: Preparing for Multisite Clinical Trials

Agenda

Sunday May 13: Pre-program Dinner – Harvest Restaurant, Cambridge

Monday May 14 8:30 Breakfast buffet at meeting

Morning Session 1 Framing the questions and tasks

9:00 – 9:05	Welcome and Workshop Logistics	Max Klein PhD, MGH
9:05 – 9:30	Forging New England collaborations NEALS	Robert Brown MD, DPhil, UMass Medical School
9:30 – 10:00	Self-introduction of workshop participants and overview of their neuropathy research	All
10:00 – 10:30	NINDS U01 RFP and 1 st submission	AL Oaklander MD PhD, MGH
10:30 – 10:45	Coffee Break	

Morning Session 2 Clinical Trial considerations

10:45 – 11:15	Trial design – considerations for US trials	Deb Steiner MD, Biogen
11:15 – 11:45	Identifying immune mediated small fiber neuropathies	Norman Latov MD, PhD Weill-Cornell Medical Col.
11:45 – 12:05	Trials at MGH Translational Research Center	Yuan-Di Halvorsen PhD & Rajesh Ranganathan PhD, MGH

12:05 – 1:00 Lunch Break (provided)

Afternoon Session 1 – The big picture

1:00 – 1:30	IgG in neuropathy: Mechanisms of action and new advances	Mel Berger MD, PhD CSL Behring
1:30 – 2:00	Targets for immunotherapy trials	Marinos Dalakas MD Philadelphia Univ.
2:00 – 2:20	SFPN and autoimmunity: Other data	A.L. Oaklander MD, PhD, Mass. General Hospital
2:20 – 2:50	Lessons on multisource data collection from ADRC	Emily Merrill, MS, MGH
2:50 – 3:00	Questions/Discussion	
3:00 – 3:15	Coffee Break	

Afternoon Session 2 – MGH and Partners resources

3:15 – 3:30	New England Neuropathy Network central IRB	Kjersten Reich, MGH
3:30 – 3:50	The Small-fiber Symptom Survey (SSS)	Gary Zirpoli PhD, MGH
3:50 – 4:10	Standardized examinations	A.L. Oaklander MD, PhD, Mass. General Hospital
4:10 – 4:30	Questions/Discussion	

5:15 Assemble at the Harvard Faculty Club for conversation and dinner

Tuesday May 15

8:30 Breakfast Buffet available

Morning Session 1 – Outcomes and Biomarkers

9:00 – 9:30	Biomarkers and metrics for fatigue and exercise intolerance	David Systrom MD, Brigham & Women's Hosp.
9:30 – 10:00	Lessons from immunotherapy trials for Alzheimer's Disease	Steven Arnold MD, Mass. General Hospital
10:00 – 10:30	Clinical trials in pediatric patients	Chuck Berde MD, Boston Children's Hospital
10:30 – 10:45	Coffee Break	

Morning Session 2

10:45 – 11:05	Noninvasive surrogate biomarkers	Max Klein PhD, Mass. General Hospital
11:05 – 11:35	Use of skin biopsies in clinical trials	Frank Rice PhD Intidyn
11:35 – 12:05	Trial design – considerations for painful neuropathies	Roi Treister PhD University of Haifa
12:05 – 12:15	Questions/Discussion	

12:15 – 1:15 Lunch Break (provided)

Afternoon Session 1

1:15 – 1:45	Patient-centered outcomes and patient participation	Leslie Levine PhD, VMD, JD, PCORI
1:45 – 2:15	Discussion of projects to include in U01, participants, and preliminary data	All
2:15 – 2:30	Grant logistics and deadlines	Max Klein PhD, MGH
2:30 – 3:00	Forging New England Neuropathy Network collaborations – priorities and publications	A.L. Oaklander MD, PhD, Mass. General Hospital
3:00	Adjournment	

Other Participants:

Verne Caviness, MGH Pediatric Neurology
Philip Joseph MD, BWH Pulmonology
Sudeshna Das PHD, MGH Bioinformatics
Chris Gibbons MD, BIDMC Neurology
Haatem Reda MD, MGH Neurology
Reza Seyedsadjadi MD, MGH Pedi Neurology
Julie Tracy MS, BWH Pulmonology
Heather Downs BS, MGH Neurology
Kate Dawson MD, Biogen