

Course Directors: Rema Raman, PhD and Joshua Grill, PhD

VIRTUAL COURSE AGENDA

All times are Pacific times

DAY 1	September 14, 2020
08:45-9:00	Course Start Time: Audio/Video Testing & Logistical Questions
09:00-09:30	Welcome: Rema Raman, PhD and Joshua Grill, PhD
09:30-11:30	<i>SESSION 1: AD Trial Designs</i> Chair: Paul Aisen, MD
09:30-10:00	Live lecture: <i>ADRD Trials and Objectives</i> Paul Aisen, MD
10:00-10:30	<i>10 Minute lightning presentations</i> <ul style="list-style-type: none"> • Nomenclature: Ronald Petersen, MD, PhD • Nonpharmacological trials: Jeffrey Burns, MD • Behavioral trials: David Sultzer, MD
10:30-11:30	<i>Panel discussion</i>
11:30-12:00	Break
12:00-14:00	<i>SESSION 2: Participant-Related Issues</i> Chair: Joshua Grill, PhD
12:00-12:30	Live lecture: <i>Trial Design, Recruitment & Retention</i> Joshua Grill, PhD
12:30-13:00	<i>Conversation Café Lecture</i> Neelum T. Aggarwal, MD, Carl V. Hill, PhD
13:00-14:00	Community Conversation Cafe Neelum T. Aggarwal, MD, Carl V. Hill, PhD
14:00-14:30	Day 1 Closing Remarks Rema Raman, PhD and Joshua Grill, PhD

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DAY 2	September 15, 2020
08:45-09:00	Opening remarks Rema Raman, PhD and Joshua Grill, PhD
09:00-10:30	WORKSHOP 1: Critical evaluation of Literature Moderator: David Knopman, MD
10:30-10:45	Break
10:45-12:15	SESSION 3: ADRD Trial Ethics Chair: Joshua Grill, PhD
10:45-11:15	Live Lecture: Research Decisions, Capacity and Other Ethical Issues Jason Karlawish, MD, Holly Fernandez Lynch, JD, and Joshua Grill, PhD
11:15-12:15	Panel discussion Jason Karlawish, MD, Holly Fernandez Lynch, JD, and Joshua Grill, PhD
12:15-12:30	Break
12:30-14:00	SESSION 4: Design and Analysis: Nuts and Bolts Chair: Michael Donohue, PhD
12:30-13:00	Live Lecture: Design features in ADRD trials Michael Donohue, PhD
13:00-13:30	<i>10 Minute lightning presentations</i> <ul style="list-style-type: none"> • Randomization and Blinding: Mark Espeland, PhD • Missing data in Analysis: Daniel Gillen, PhD • Data and Study Integrity: Rema Raman, PhD
13:30-14:00	<i>Panel discussion</i>
14:00-14:30	Day 2 Closing remarks Rema Raman, PhD and Joshua Grill, PhD ADJOURN PROFESSIONALS TRACK

Small group activities separately scheduled for all trainees	WORKSHOP 2: Presentation and Communication Skills Bri McWhorter, Activate to Captivate
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DAY 3	September 16, 2020
08:45-9:00	Course Start Time: Audio/Video Testing & Logistical Questions
09:00-09:15	RESET/INTRO to Fellowship Track specific portion Rema Raman, PhD and Joshua Grill, PhD
09:15-10:15	SESSION 5: Design choices
09:15-09:45	<i>Scientific Point Counterpoint: Traditional vs. Adaptive designs:</i> Paul Aisen, MD and Reisa Sperling, MD
09:45-10:15	<i>Discussion</i>
10:15-10:30	Break
10:30-14:00	SESSION 6: Populations, Indications, and Outcomes Chair: Mary Sano, PhD
10:30-10:50	Live Lecture: Populations, Indications & Outcomes Overview Mary Sano, PhD
10:50-11:10	Dementia Trials Stephen Salloway, MD
11:10-11:30	MCI/Prodromal Trials Ronald Petersen, MD
11:30-11:50	Preclinical Trials Reisa Sperling, MD
11:50-12:10	Non-pharmacological Trials Laura Baker, PhD
12:10-12:40	<i>Panel discussion</i>
12:40-13:00	Break
13:00-13:10	Next Gen Cognitive Outcomes: Dorene Rentz, PhD
13:10-13:20	Next Gen Fluid Biomarker Outcomes: Robert Rissman, PhD
13:20-13:30	Next Gen Imaging Outcomes: Christopher Van Dyck, MD
13:30-14:00	<i>Panel discussion</i>
14:00-14:30	Day 3 Closing remarks Rema Raman, PhD and Joshua Grill, PhD

Small group activities separately scheduled for all fellowship trainees	Protocol Development Work Groups – Design Choices 1. Introductions and discussion of trial designs 2. Choosing a sample [developing inclusion criteria] 3. Selecting a primary (and other) outcome measures 4. Statistical analysis plans 5. Safety monitoring and other conduct considerations
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DAY 4	September 17, 2020
08:45-09:00	Course Start Time: Audio/Video Testing & Logistical Questions
09:00	Opening remarks Rema Raman, PhD and Joshua Grill, PhD
09:00-09:45	SESSION 7: Statistical Considerations Chair: Mark Espeland, PhD Panel: Daniel Gillen, PhD, Gopalan Sethuraman, PhD, Michael Donohue, PhD, Hiroko Dodge, PhD, Rema Raman PhD
09:45-10:00	Break
10:00-12:00	SESSION 8: Study Management: Serving as Principal Investigator Chair: Michael Rafii, MD
10:00-10:30	Study Leadership: Michael Rafii, MD
10:30-11:30	<i>10 Minute lightning presentations</i> <ul style="list-style-type: none"> • Clinical Informatics: Gustavo Jimenez-Maggiore, MBA • Safety & Clinical Monitoring: Gregory Jicha, MD, PhD • Institutional Review Boards: Karen Bell, MD • Data Safety and Monitoring Boards: Rema Raman, PhD • Budget Planning and Execution: Jeremy Pizzola
11:30-12:00	<i>Panel discussion</i>
12:00-12:15	Break
12:15-13:45	WORKSHOP 3: Securing trial funding
12:15-13:00	I: Funding agency presentations: <ul style="list-style-type: none"> • Kristina McLinden, PhD/Laurie Ryan, PhD, NIA • Maria Carrillo, PhD/Heather Snyder, PhD, Alzheimer's Association • Howard Fillit, MD, ADDF
13:00-13:45	II. Reflections from study section panel <ul style="list-style-type: none"> • Mary Sano, PhD • Robert Rissman, PhD • Michael Donohue, PhD • Rema Raman, PhD
13:45-14:30	Overall Closing remarks Rema Raman, PhD and Joshua Grill, PhD ADJOURN FELLOWSHIP TRACK