



AGENDA

March 23 and 24, 2023

2023 Research Roundtable for Epilepsy

Biomarkers

DAY 1 – Thursday, March 23, 2023

9:00 – 9:20am Meeting Welcome & Updates

9:00am Welcome, Meeting Goals, and Deliverables

**Drs. Jacqueline
French and Nathan
Fountain**

9:10am Updates on Previous RRE Topics

**Drs. Jacqueline
French and Nathan
Fountain**

9:20 – 9:55am 2023 Challenge and Overview

9:20 - 9:35am Biomarkers for Regulatory Use

Dr. Teresa Buracchio

9:35 – 9:55am Industry Perspective-Epilepsy

Dr. Aneeta Saxena

9:55 – 10:25am Patients & Family Partners Impact Panel

**Alison Zetterquist
Nicole Murray
JayEtta Hecker
Moderator: Caitlin
Grzeskowiak**

10:25 – 10:40am BREAK

**10:40–12:00pm Session I: General Discussion on Biomarkers/
Defining Biomarkers**

**Moderator: Dr.
Nathan Fountain**



10:40 -11 am	The Use of Neuroimaging in Multiple Sclerosis Development Programs	Dr. Paul Lee, FDA
11 – 11:15am	Industry Perspective: What have we learned from other disease areas	Dr. Lee Honigberg
11:15 - 11:30am	Biomarkers in Clinical Epilepsy	Dr. Jacqueline French
11:30 – 12:00pm	Open Discussion	
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12:00-12:45 pm	LUNCH	
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	Session II: Evidence for biomarkers in epilepsy	Moderator: Dr. Dan Friedman
12:45 –3:30 pm	<p>EEG biomarkers:</p> <p>12:45 – 1:00 Use of IIEDs</p> <p>1:00 – 1:15 Use of background EEG</p> <p>1:15 – 1:30 RNS long episodes</p> <p>1:30 – 1:45 Electrographic seizures</p> <p>1:45 – 2:15 DISCUSSION</p> <p>Systemic biomarkers:</p> <p>2:15 – 2:30 Neuroimaging: MRI</p> <p>2:30– 2:45 Genetic biomarkers</p> <p>2:45 – 3:00 Serum</p> <p>3:00 – 3:15 TMS</p> <p>3:15 – 3:30 Discussion</p>	<p>Drs. Jeff Buchhalter, Thadd Reeder, Nathan Fountain, Nick Abend</p> <p>Drs. Alon Friedman, Sanjay Sisodiya, David Henshall, Alex Rotenberg</p>
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3:30 – 3:45 pm	BREAK	
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3:45 –5:00 pm	Session III: Case Examples with Development Implications - Potential Use Cases	Moderator: Dr. Jacqueline French
3:45 – 4:30pm	<p>3:45 – 4:00PM EEG Interictal Epileptiform Discharges</p> <ul style="list-style-type: none"> o CSWS case example <p>4:00 – 4:15PM EEG novel analysis</p> <p>4:15 – 4:30PM EEG “long episodes” of suspicious EEG (RNS)</p>	Drs. Sudha Kessler, Thadd Reeder, Dan Friedman
4:30-5 PM	Open Discussion	
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DAY 2 – Friday, March 24, 2023

9:00 – 9:30 am	Session III Continued: Case Examples with Development Implications	Moderator: Dr. Nathan Fountain
	9:00 – 9:15 Biomarkers of Inflammation 9:15 – 9:30 PTE Biomarkers: quo vadis?	Drs. Manu Hegde, Pavel Klein
9:30 – 9:50 am	Machine Learning/AI to develop biomarkers	Dr. Jacob Donoghue
Session IV 9:50-10:45	Discussion and Conclusions of Main Agenda 9:50 – 10:45 Conclusions	Drs. Jacqueline French & Nathan Fountain
10:45 – 11:00am	BREAK	
11:00am– 11:55pm	Session IV: Hot Topic: Remote Outcomes Assessment	Moderator: Caitlin Grzeskowiak
11:00 – 11:05am 11:05 – 11:20am	Setting the Stage Typical assessments in epilepsy studies	Drs. Jacqueline French and Nathan Fountain
11:20 – 11:35am	Industry perspective with case example	Dr. Svetlana Shore
11:35 – 11:55am	Patient impact	Terry Jo Bishell JayEtta Hecker Anna Williams
11:55-12:25	General principals, scales and measurements, and advantages	Presenter(s): Dr. Michelle Campbell, FDA
12:25 – 1:25pm	LUNCH	
1:25 – 2:30pm	Open Discussion	
2:30pm	Adjourn	