

NITs for a Reasonably Likely Surrogate Endpoint Check-In Meeting

Friday, January 17, 2025
Sheraton Reston Hotel
1810 Sunrise Valley Drive
Reston, VA 20191

AGENDA

7:30 AM	Registration and Breakfast	
8:00 AM	Session I: Introductory Remarks and Review of Goals	
8:00 AM	Introductory Remarks & Goals for the Check-In Meeting	<i>Michelle Long, Novo Nordisk; Veronica Miller, Forum; Arun Sanyal, VCU</i>
8:15 AM	Session II: Division of Hepatology and Nutrition & Biomarker Qualification Program Perspective on NITs for a RLSE	
8:15 AM	Moderators: Veronica Miller, Forum	
8:15 AM		<i>Frank Anania, Jeff Siegel, Vanitha Sekar, Tram Tran, U.S. Food and Drug Administration</i>
9:00 AM	Session III: Forum Proposal for NITs as a RLSE	
9:00 AM	Moderators: Michelle Long, Novo Nordisk & Arun Sanyal, VCU	
9:00 AM	Review of Histology as a RLSE	<i>Michelle Long & Sune Boris Nygård, Novo Nordisk</i>
9:20 AM	Overview of Forum Proposal	<i>Quentin Anstee, Newcastle University</i>
9:40 AM	Overview of Data Sources	<i>Richard Haubrich, Forum</i>
9:45 AM	Break	
10:15 AM	Session IVa: Baseline and Change from Baseline Correlation: ELF and VCTE	
10:15 AM	Moderators: Quentin Anstee, Newcastle University	
10:15 AM	Overview of Studies	<i>Richard Haubrich, Forum</i>
10:25 AM	ELF	<i>Matthew Gee, Siemens Healthineers*</i>
10:45 AM	VCTE	<i>Céline Fournier, Echosens</i>
11:05 AM	Discussion: Summary of Strengths, Weaknesses, & Gaps in Data	<i>All Participants</i>
11:35 AM	Working Lunch	
12:05 PM	Session IVb: Baseline and Change from Baseline Correlation: MRE and MRI-PDFF	
12:05 PM	Moderators: Arun Sanyal, VCU	
12:05 PM	MRI-PDFF & MRE	<i>Richard Haubrich, Forum</i>
12:20 PM	Comments	<i>Mustafa Bashir, Duke University*; Kay Pepin, Resoundant; Claude Sirlin, UCSD*</i>
12:40 PM	Discussion: Summary of Strengths, Weaknesses, & Gaps in Data	<i>All Participants</i>
1:10 PM	Session V: Progress and Challenges in Determining Thresholds & Cut-Offs: ELF, VCTE, MRE & MRI-PDFF	
1:10 PM	Moderators: Richard Haubrich, Forum	
1:10 PM	Open Discussion	<i>All Participants</i>
2:40 PM	Break	
3:10 PM	Session VI: Opportunities and Challenges in Non-Invasive Definition of Progression to Cirrhosis as a Clinical Endpoint	
3:10 PM	Moderators: Michelle Long, Novo Nordisk	
3:10 PM	Progression to Cirrhosis – Considerations in Operationalizing the Endpoint	<i>Arun Sanyal, VCU</i>
3:30 PM	Distinguishing F3 from F4 MASH	<i>Becky Taub, Madrigal Pharmaceuticals</i>

3:45 PM	NIT Diagnosis of Cirrhosis- Can we come to a consensus?	<i>All Participants</i>
4:30 PM	Session VII: Addressing the Identified Gaps	
4:30 PM	Moderators: Michelle Long, Novo Nordisk; Veronica Miller, Forum; Arun Sanyal, VCU	
4:30 PM	Open Discussion	<i>All Participants</i>
5:00 PM	Adjourn & Networking Reception	
	*indicates remote participation	