



**Clinical Trials Masterclass
March 13-14, 2024**

Location: West End Lab, 125 West End Ave.

Day 1: March 13, 2024

8:00AM-12:00PM

12:30-1:30PM Lunch and Learn

2:00PM-5:00PM

5:00-7:00PM Reception

Session:		
Time	Topic	Facilitator
8-8:30 am	Breakfast, Networking	
8:30-8:40 am	Welcome & Introductions West End Lab guest protocol	Mary Howard Peter Sheehan
8:40 am – 9:40 am Panel Q&A	Future of Clinical Trials	Jen Horonjeff, Savvy Cooperative Linda Malek, Crowell & Moring
Track 1 9:45-10:30 am 10:30-10:45 Q&A	Planning for compliance and operations a Drug, Device, Software clinical trial <i>inc coi</i> (IRB), data safety monitoring gps	Kathi Durdon, Upstate
Track 2 9:45-10:30 am 10:30-10:45 am Q&A	Best Practices in Recruiting for Health Equity: Designing a Successful Protocol for Recruitment	Deborah Viola WMC, Ryan Brown, H1 Linda Malek/Jason Johnson, Crowell & Moring

Track 1 10:50-11:25 am Recap 11:25- 11:35 am	Presentation of Attendee Clinical Trial Site Checklist: Feedback from Professionals	Sunit Jariwala, Montefiore Stefanie Juell, Montefiore Linda Malek, Crowell & Moring
Track 2 10:50-11:25 am Recap 11:25- 11:35 am	Presentation of Attendee Clinical Trials with focus on recruiting	Ryan Brown, H1 Jason Johnson, Crowell & Moring
11:35-12:00	LUNCH BREAK	
Lunch & Learn 12:00-1:00 pm	Make or Buy	
Session: Fairer, faster, measured, engaged trials		
Track 1 1:05-2:30 pm Q&A 2-2:30 pm	Study Design Considerations: outcome and study design: where submit IRB, Funding	Sunit Jariwala, Montefiore Stefanie Juell, Montefiore
Track 2 1:05-2:30pm Q&A 2-2:30 pm	Best practices for health equity -reg req't to protect most vulnerable -fighting stigma assoc with underserved -clinical research	Reginald Swift, Rubix Life
2:35 pm-3:30 pm	Topic: Building a team to deliver a successful clinical trial program	Kevin Palisi, Ancora Search Katya Sverdlov, Jelikalite
3:30-3:45 pm	Break	

Track 1 3:45-4:35 pm Recap 4:35-4:45 pm	Presentation of study design checklist to facilitators	Deborah Viola, WMC
Track 2 3:45-4:35 pm Recap 4:35-4:45 pm	Presentation of recruitment plan to address health equity issues to facilitators	Thao Doan, WMC Erida Castro, WMC
4:45-5pm	Recap of Day 1	Mary Howard

Day 2: March 14, 2024

8:00AM-12:00AM

12:30-1:30PM Lunch and Learn

2:00PM-5:00PM

Session: Overcoming Challenges to Diverse Clinical Trial Implementation		
8:30am-9am	Breakfast & Welcome	
9-10 am	New Resources Platform data & tools, patients, disease treatment, wellness, prevention New Tools and Resources for Clinical Trials	Guannan Gong, Ctrl Trial, Founder
10:05-10:35 am Q&A 10:35-10:45	Clinical Trials: Decentralized health care Legal and Budget considerations	
Track 1 10:45-12 Q&A 11:30-12 pm	<u>Compliance:</u> <u>Regulatory:</u> Conflicts of interest, <u>Clinical Trial Operations</u> Communications, Logistics	Thea Marx, Vis Pre-Surgery Adi Wallach, CalmIGO

	Starting an Int'l Clinical Trial	
Track 2 10:45-11:30 Q&A 11:30-12 pm	Health equity goals and External validation of Impact	Deborah Viola, WMC Reginald Swift, Rubix Life
12 pm – 12:15 pm	Break/Pick up Lunch	
12:15-1:15 pm Lunch and Learn	Topic: Government Policy Changes: Regulatory change	
Track 1 1:20-1:55 pm Recap 1:55-2:05	Presentation of Conflict of Interest, Communications and Logistics plans for feedback by facilitators	
Track 2 1:20-1:55 pm Recap 1:55-2:05	Presentation of health equity goals and external validation of impact plans for feedback by facilitators	Claudia Lechuga, Einstein/Montefiore Walter Lindop, Yale New Haven Health Marjorie Lazarre, PharmD, MBA, Yale New Haven Health
2:10-2:40 Q&A 2:40-3 pm	Medical Device Clinical Trials	Craig Carder, C3 Jeremy Wiygul, Pelex
Day 2 Recap	2 nd Day recap	Mary Howard