



Workshop on Validating and Using Cardiac NAMs for Toxicity Screening and Drug Development

May 7, 2024
FDA White Oak, Silver Spring, MD, USA

Free Registration Required: <https://hesiglobal.org/validating-and-using-cardiac-nams-for-toxicity-screening-and-drug-development/>

8:30 a.m. Welcome and Introduction		
	About HESI & NAMs Survey Results	Jennifer Pierson, HESI
8:45 a.m. – 12:00 p.m. Emerging Cardiac NAMs		
8:45 a.m.	Introduction to Failure Modes	Brian Berridge, B2 Pathology Solutions
9:15 a.m.	HESI U01 Validation Study Recipients: Report on assays in development	Chengyi Tu, Stanford Alex Savtchenko, Nanotools Daniel Bramham, LabCorp
11:15 a.m.	<i>Break</i>	
11:30 a.m.	Preliminary Results from Inflammatory Response Model	Li Pang, FDA NCTR
12:00 p.m. Lunch Break		
1:00 – 3:30 p.m. Current State – Cardiac NAMs in Practice		
1:00 p.m.	Cardiac NAMs Mock Study: Improving its acceptance in regulatory applications	Xi Yang , RTI
1:30 p.m.	Cardiac NAMs use in regulatory applications	Natalie Simpson, FDA
1:50 p.m.	Perspectives from Japan	Yasu Kanda, NIHS Japan
2:10 p.m.	Industry perspective – internal use of cardiac NAMs	Khuram Chaudhary, BMS
2:30 p.m.	<i>Break</i>	
2:45 p.m.	Panel Discussion	Tony Bahinski, Vivodyne Todd Bourcier, FDA Khuram Chaudhary, BMS Yasu Kanda, NIHS Japan Li Pang, FDA Natalie Simpson, FDA Xi Yang, RTI
3:30 – 4:30 p.m. Regulatory Perspectives		
3:30 p.m.	FDA iSTAND program and other paths to acceptance	Jeff Siegal, FDA
4:00 p.m.	FDA Modernization Act 2.0	Ron Wange, FDA
4:30 p.m.	Synthesis and next steps discussion	Jennifer Pierson, HESI
5:00 p.m.	Adjourn	