Advances in Cardiac Safety Assessments Workshop

May 8, 2024
FDA White Oak, Silver Spring, MD, USA
8:30 a.m. – 5:00 p.m.

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

Meeting Purpose: HESI maintains a longstanding, collaborative partnership with the US FDA, exemplified by the active FDA participation in the HESI Cardiac Safety Committee. This enduring partnership is highly valued by HESI and FDA, alike. Through this meeting, our goal is to share comprehensive updates on the Committee's progress, offer those unfamiliar with HESI an opportunity to gain insights and pose questions, and engage in meaningful discussions to align our priorities and foster continued collaboration.

Meeting Goals and Objectives:

1. Establish Common Goals and Priorities:
   - Clarify and align objectives of HESI Cardiac Safety Committee and US FDA concerning cardiovascular safety testing in drug development
   - Identify common priorities to foster a more effective public-private partnership
2. Review Current Research Initiatives
   - Provide updates on ongoing research initiatives related to cardiovascular safety and drug development
   - Discuss potential synergies and opportunities for collaboration
3. Enhance Information Sharing and Communication
   - Develop additional strategies to improve communication channels between HESI And FDA for sharing scientific data, research findings and emerging trends

Advances in Cardiac Safety Assessments Workshop

9:00 a.m.	**Welcome and Introduction**	
	About HESI	Jennifer Pierson, HESI
9:15 a.m.	**Welcome Remarks**	
	Welcome Remarks from FDA's Acting Chief Scientist	Dr. David Strauss, FDA
9:30 a.m. – 12:00 p.m.	**Current Research Initiatives**	
10:00 a.m.	*Break*	
	HESI Cardiac Biomarkers Working Group	Eric Schultze, Lilly Marjory Brooks, Cornell University
	HESI Integrative Strategies Working Group	Mike Foley, AbbVie
	ABPM Studies and BP Initiatives	Tejas Patel, US FDA
	HESI ProA Working Group	Jean-Pierre Valentin, UCB Todd Wisialowski, Pfizer
	HESI & FDA Stem Cell Research	Ksenia Blinova, US FDA
	Q&A Session	All Speakers
12:00 p.m.	***Lunch Break***	
1:00 – 4:00 p.m.	**Breakout Strategy Sessions**	
1:00 p.m.	1. Novel Cardiac Biomarkers for prediction of hemostasis 2. Ion Channel Issues and ProA Risks	
2:30 p.m.	3. Preclinical Blood Pressure Studies for use in integrated risk assessment 4. Cardiac Stem Cell assays for use in CV predictive studies	
4:00 – 5:00 p.m.	**Report Back and Wrap Ups**	
4:00 p.m.	Breakout groups report back major discussion points	Assigned reporters
5:00 p.m.	**Adjourn**	