UNIVERSITY OF MIAMI

Clinical Trials Symposium

"Improving Clinical Research in the Age of Precision Medicine"

University of Miami Office of Research Compliance in Collaboration with FDA

Wednesday, September 14,2016

7:00 AM - 8:00 AM		**Registration & Breakfast**	
8:00 AM - 8:30 AM		Welcome	**Johanna Stamates, RN, MA** Executive Director, Research Compliance and Quality Assurance University of Miami
		Welcoming Remarks	**Julio Frenk, MD, MPH, PhD** President University of Miami
		Opening Remarks	**Thomas LeBlanc, PhD** Executive Vice President and Provost University of Miami
			John L. Bixby, PhD Vice Provost for Research University of Miami
			Jonca Bull, MD Assistant Commissioner for Minority Health Office of Minority Health U.S. Food and Drug Administration
8:30 AM - 9:15 AM		Keynote Speaker	**Robert M. Califf, MD, MACC** Commissioner of Food and Drugs U.S. Food and Drug Administration
9:15 AM - 10:15 AM	**D1S1**	Compliance in Clinical Research: "Doing it Right the First Time"	**Cynthia Kleppinger, MD** Senior Medical Officer, Office of Scientific Investigations Division of Clinical Compliance Evaluation Good Clinical Practice, Assessment Branch Center for Drug Evaluation and Research U.S. Food and Drug Administration
10:15 AM - 10:30 AM		**BREAK**	
10:30 AM - 11:30 AM	**D1S2**	Regulatory Perspective: Recruitment Challenges - Precision, Personalized and Diverse: New Tools and Strategies	**Jonca Bull, MD** Assistant Commissioner for Minority Health Office of Minority Health U.S. Food and Drug Administration
11:30 AM - 1:00 PM		**LUNCH**	
1:00 PM - 2:00 PM	**D1S3**	Developing UM Central IRB for Multi-site studies: Challenges and Potential Solutions for Efficient Reliant Review Process	**Khemraj Hirani, PhD** Associate Vice Provost for Human Subject Research University of Miami
2:00 PM - 3:00 PM	**D1S4**	FDA's Clinical Research Inspectional Process	**Ethan Stegman, BS** Investigator / Bioresearch Monitoring Florida District U.S. Food and Drug Administration
3:00 PM - 3:15 PM		**BREAK**	
3:15 PM - 4:15 PM	**D1S5**	FDA Perspective on Investigator-Sponsored Clinical Trials	**Bhanu Kannan, MS** Consumer Safety Officer, Office of Compliance and Biologics Quality Division of Inspections and Surveillance Bioresearch Monitoring Branch, Center for Biologics Evaluation and Research U.S. Food and Drug Administration
4:15 PM - 5:00 PM	**D1QandA**	Panel Discussion	U.S. Food and Drug Administration and University of Miami Representatives

UNIVERSITY OF MIAMI

Clinical Trials Symposium

"Improving Clinical Research in the Age of Precision Medicine"

University of Miami Office of Research Compliance in Collaboration with FDA

DAY 2

Thursday, September 15,2016

7:00 AM - 8:00 AM		Registration & Breakfast	
8:00 AM - 8:15 AM		Welcome Day 2	**Johanna Stamates, RN, MA** Executive Director, Research Compliance and Quality Assurance University of Miami **Dushyantha T. Jayaweera , MD** Executive Dean for Research and Research Education University of Miami **Susan Turcovski, BS** Director Florida District Southeast Region Office of Regulatory Affairs U.S. Food and Drug Administration
8:15 AM - 9:15 AM	D2S1	Research Compliance Structures and Quality Systems	**Johanna Stamates, RN, MA** Executive Director, Research Compliance and Quality Assurance University of Miami **Ann Glasse, RN, MBA** Director, Regulatory Support University of Miami
9:15 AM - 10:15 AM	D2S2	Understanding Medical Devices in Clinical Research	**CAPT James Saviola, OD** Director, Division of Bioresearch Monitoring Center for Devices and Radiological Health U.S. Food and Drug Administration
10:15 AM - 10:30 AM		BREAK	
10:30 AM - 11:30 AM	D2S3	Emerging Issues and Trends in FDA Regulated Clinical Research	**Craig A. Garmendia, MS** Consumer Safety Officer, Florida District Southeast Region Office of Regulatory Affairs U.S. Food and Drug Administration
11:30 AM - 1:00 PM		LUNCH	
1:00 PM - 1:30 PM	D2S4	CDER Small Business & Industry Assistance (SBIA)	**Renu Lal, Pharm D** Pharmacist, Small Business & Industry Assistance Program Center for Drug Evaluation and Research U.S. Food and Drug Administration
1:30 PM - 2:30 PM	D2S5	Investigator Responsibilities in Clinical Trials	**Cynthia Kleppinger, MD** Senior Medical Officer, Office of Scientific Investigations Division of Clinical Compliance Evaluation Good Clinical Practice, Assessment Branch Center for Drug Evaluation and Research U.S. Food and Drug Administration
2:30 PM - 3:00 PM	D2QandA	Panel Discussion	U.S. Food and Drug Administration and University of Miami Representatives
3:00 PM - 5:00 PM		NETWORKING SESSION	
NETWORK			