Cardiovascular Toxicity Assessment In Oncology Trials Workshop
September 22, 2016
Organized by FDA
with support from: AACR, ACC, AHA & ASCO
Co-Chairs: Dr. Laleh Amiri-Kordestani and Dr. Ana Barac

AGENDA

8:00-8:30	Registration	
8:30-8:40	Welcome and Introduction	Laleh Amiri-Kordestani, MD
Session 1: LV Dysfunction-Related to Cancer Therapies (Moderator: Ana Barac, MD, PhD, FACC)		
8:40-8:50	Current Landscape of LV Dysfunction Monitoring: What are the Challenges and Opportunities?	Ana Barac, MD, PhD, FACC
8:50-9:05	Role of Echo Core Labs in Detection & Monitoring of Oncology Drug Toxicity	Neil J. Weissman, MD, FACC, FASE
9:05-9:20	CMR Techniques to Detect Cardiac and Vascular Injury after Treatment for Cancer	W. Gregory Hundley, MD, FACC, FAHA
9:20-9:40	Cardiotoxicity – Monitoring for Left Ventricular Dysfunction: From Oncologist Perspective Challenges in Monitoring of LV Function: The Cardiologist Perspective	Chau T. Dang, MD and Juan Carlos Plana, MD, FACC, FASE
9:40-10:10	Panel Discussion	Panelists: Session 1 speakers, Debra Madden, Sandra M. Swain, MD, Michael S. Ewer, MD Laleh Amiri-Kordestani, MD
10:10-10:30	Break	
Session 2: Beyond LVEF: Vascular Toxicity of Novel Agents (Moderators: R. Angelo de Claro, MD and Javid J. Moslehi, MD)		
10:30-10:45	Vascular Events with Targeted Agents: Who, What and Why to Monitor in Clinical Trials?	Michael J. Mauro, MD
10:45-11:00	Hypertension- how to monitor and what is the optimal therapy	Benjamin D. Humphreys, MD, PhD
11:00-11:15	Can Biomarkers be Used to Assess Risk of Vascular Cardiotoxicity?	Kevin J. Croce, MD, PhD
11:15-11:45	Panel Discussion	Panelists: Session 2 speakers, Debra Madden, Michael S. Ewer, MD, PhD, JD, Babak Navi, MD, MS
11:45-12:45	Lunch	

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Session 3: Nonclinical Cardiovascular Risk Assessment in Oncology (Moderator: Todd Palmby, PhD)		
12:45-12:55	Regulatory Recommendations for Nonclinical Studies of Anticancer Pharmaceuticals	Todd Palmby, PhD
12:55-1:10	Perspectives: Cardio-Oncology	Javid J. Moslehi, MD
1:10-1:25	Overview: What Nonclinical Studies are Available to Interrogate Potential Cardiovascular Risk of an Oncology Product?	Hugo M. Vargas, PhD, DSP
1:25-1:40	Human Induced Pluripotent Stem Cell Derived Cardiomyocytes: Evolving Roles in Cardio-Oncology	Gary Gintant, PhD
1:40-2:10	Panel Discussion	Panelists: Session 3 speakers, Thomas Papoian, PhD, Myrtle D. Millin, DVM, PhD, Paul W. Burridge, PhD, Darrell Abernethy, MD, PhD, Nicole Gormley, MD
2:10-2:20	Break	
2:30-2:50	Keynote Remarks: The Imperative of Complete Assessment of Therapeutics	Robert Califf, MD, MACC FDA commissioner
Session 4: Monitoring and Prevention (Moderator: Lori Minasian, MD, FACP)		
2:50-3:05	Strategies to Improve Cardiovascular Phenotyping in Cancer Clinical Trials	Lori Minasian, MD, FACP
3:05-3:20	Pediatric Survivors: Monitoring and Prevention of Cardiovascular Toxicities	Steven E. Lipshultz, MD
3:20-3:35	Cardiovascular Phenotyping in Cooperative Clinical Trials – What and How to Measure?	Bonnie Ky, MD, MSCE
3:35-3:50	Designing and Implementing Cardio-oncology Safety Registries	Daniel J. Lenihan, MD
3:50-4:00	Regulatory Perspective: Opportunities for Postmarketing CV Safety Outcomes Collection	Suparna B. Wedam, MD
4:00-4:30	Panel Discussion	Panelists: Session 4 speakers, Debra Madden, Shari Targum, MD
4:30	Adjournment	