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

Draft AGENDA

	Title	Speakers
8:00-8:30	Registration	
8:30-8:40	Welcome and Introduction	Laleh Amiri-Kordestani, MD
8:40-9:00	Keynote Remarks	Robert Califf, MD FDA commissioner
Session 1: LV Dysfunction-Related to Cancer Therapies (Moderator: Ana Barac, MD, PhD)		
9:00-9:10	Overview- Current landscape of LV dysfunction monitoring: What are the challenges and opportunities?	Ana Barac, MD, PhD
9:10-9:25	Role of echocardiography core laboratories in detection and monitoring of oncology drug toxicity: LVEF and beyond	Neil Weissman, MD
9:25-9:40	Cardiac MR as a tool to assess cardiac structure and function in oncology clinical trials	Greg Hundley, MD
9:40-10:10	Challenges in monitoring of LV function in clinical practice today: Oncologist and cardiologist's perspectives	Chau Dang, MD and Juan Carlos Plana, MD
10:10-10:40	Panel Discussion	Panelists: Session 1 speakers, patient representative, Edith Perez, MD, Sandra Swain, MD
10:40-10:55	Break	
Session 2: Beyond LVEF: Vascular Toxicity of Novel Agents (Moderators: R. Angelo De Claro, MD, Javid Moslehi, MD)		
10:55-11:10	Vascular events with targeted agents: Who, what and why to monitor in clinical trials?	Michael Mauro, MD
11:10-11:25	Hypertension- how to monitor and what is the optimal therapy?	Benjamin D. Humphreys, MD
11:25-11:40	Can novel biomarkers be used to assess risk of vascular cardiotoxicity?	Kevin Croce, MD
11:40-12:10	Panel Discussion	Panelists: Session 2 speakers, patient representative , Michael Ewer, MD

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12:10-1:10	Lunch	
Session 3: Nonclinical (Moderator: Todd Palmby, PhD)		
1:10-1:20	Regulatory requirements for nonclinical studies of anticancer pharmaceuticals	Todd Palmby, PhD
1:20-1:35	Overview: What nonclinical studies are available to interrogate potential cardiovascular risk of a product	Hugo Vargas, PhD
1:35-1:50	Pros and Cons of hIPSC-CMs to investigate the potential effects of cardiomyocytes	Gary Gintant, PhD
1:50-2:05	Clinical perspective: How and when additional nonclinical data is needed?	Javid Moslehi, MD
2:05-2:35	Panel Discussion	Panelists: Session 3 speakers, Tom Papoian, PhD, Myrtle Davis, PhD, Paul Burridge, MD, Darrell Abernethy , MD, PhD
2:35-2:50	Break	
Session 4: Monitoring and Prevention (Moderator: Lori Minasian, MD)		
2:50-3:05	Strategies to improve monitoring of CV toxicity related to cancer treatment in vulnerable populations	Lori Minasian, MD
3:05-3:20	Pediatric survivors: Monitoring and prevention strategies of cardiovascular toxicities	Steven Lipshultz, MD
3:20-3:35	Cardiovascular phenotypes in cooperative group clinical trials: what and how to measure	Bonnie Ky, MD
3:35-3:50	Designing and Implementing CV safety registries: Call for partnership	Dan Lenihan, MD
3:50-4:00	Regulatory path to registry	Suparna Wedam, MD
4:00-4:30	Panel Discussion	Panelists: Session 4 speakers, patient representative, Shari Targun, MD
4:30	Adjournment	