#### Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials December 1, 2017

Organized by FDA with support from: AACR, ACC, AHA & ASCO Co-Chairs: Dr. Laleh Amiri-Kordestani and Dr. Javid Moslehi

AGENDA			
	Topics	Speakers	
8:30-9:00	Registration		
9:00-9:10	Welcome and Introduction	Laleh Amiri-Kordestani, MD FDA/CDER Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program	
	uno-Oncology and Combination Immunothera		
9:10-9:25	Immunology Overview	Andrew Lichtman, MD, PhD Harvard Medical School Pathology	
9:25-9:40	Introduction to Cancer Immunotherapies	James Gulley, MD, PhD National Cancer Institute Center for Cancer Research Immunotherapy	
9:40-9:50	Combination Cancer Immunotherapies	Jeffrey Sosman, MD Northwestern University Robert H. Lurie Comprehensive Cancer Center; Immuno-Oncology	
9:50-10:10	Summary and Panel Discussion Question and Answer	Douglas Johnson, MD, MSCI with Panel Vanderbilt-Ingram Cancer Center Hematology/Oncology	
Moderators: Ap	eral Toxicities of Cancer Immunotherapies postolia (Lia) Tsimberidou, MD, PhD; MD Ander ehi, MD; Vanderbilt School of Medicine Cardio-0	rson Cancer Center	
10:10-10:25	Clinical Toxicities with Immunotherapies	Michael Atkins, MD Georgetown-Lombardi Cancer Center Medical Oncology; Immunotherapy	
10:25-10:35	Eligibility Criteria for Immune-oncology Trials	<b>Douglas Johnson, MD, MSCI</b> Vanderbilt-Ingram Cancer Center Hematology/Oncology	
10:35-10:50	Autoimmunity Associated with Checkpoint Inhibitors: Rheumatologist's perspective	Paul "PJ" Utz, MD Stanford School of Medicine Rheumatology	
10:50-11:10	Panel Discussion Question and Answer	Nicole Gormley, MD and Panel FDA/CDER	
11:10-11:25	Break		

## Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials

December 1, 2017

Organized by FDA with support from: AACR, ACC, AHA & ASCO Co-Chairs: Dr. Laleh Amiri-Kordestani and Dr. Javid Moslehi

# AGENDA

Moderator:     Jeffrey Sosman, MD; Northwestern Univ. Robert H. Lurie Comprehensive Cancer Center       11:25-11:35     Immunotherapy-associated Myocarditis: Dilemmas for the Practicing Clinician     JoAnn Lindenfeld, MD, PHSA Vanderbilt Heart and Vascular Institute Heart Failure/Cardia Transplant       11:35-11:45     Cardiovascular Toxicities Associated with Checkpoint-Inhibitors     Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program       11:45-11:55     Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective     Kevan Herold, MD Yale School of Medicine Perspective       11:55-12:05     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Andrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       12:05-12:15     Cardiovascular Complications-associated with Other Cancer Immunotherapies     Chaohong Fan, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:25-1:40     General Pathophysiology of Myocarditis     Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City: Cardiovascular Research Management       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Andrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD       1:40- 1:55					
Immunotherapy-associated Myocarditis:       JoAnn Lindenfeld, MD, FHSA         11:25-11:35       Dilemmas for the Practicing Clinician       Vanderbilt Heart and Vascular Institute Heart Failure/Cardiac Transplant         11:35-11:45       Cardiovascular Toxicities Associated with Checkpoint-Inhibitors       Javid Moslehi, MD         11:35-11:45       Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective       Kevan Heroid, MD         11:45-11:55       Cancer Immunotherapy-associated Myositis and Myasthenia Gravis       Andrew Mammen, MD, PhD         11:55-12:05       Cancer Immunotherapy-associated Myositis and Myasthenia Gravis       Andrew Mammen, MD, PhD         11:55-12:05       Cardiovascular Complications associated with Other Cancer Institute Center for Cancer Research Cellular Therapy       Christian Hinrichs, MD         12:05-12:35       Panel Discussion Question and Answer       Chaohong Fan, MD, PhD         12:35-12:40       General Pathophysiology of Myocarditis       Kirk Knowiton, MD         12:25-12:40       General Pathophysiology of Myocarditis       Kirk Knowiton, MD         11:40- 1:55       Clinical Myocarditis: Diagnosis and Management       Kareword Medicine Cardiovascular Disease         11:40- 1:55       Panel Discussion Question and Answer       Shari Targum, MD         12:35-2:30       Panel Discussion Question and Answer       Shara	Session 3: Cardiometabolic Toxicities in Immuno-Oncology Trials				
11:25-11:35     Immunotherapy-associated Myocarditis: Dilemmas for the Practicing Clinician     Vanderbilt Heart and Vascular Institute Heart Failure/Cardia Transplant       11:35-11:45     Cardiovascular Toxicities Associated with Checkpoint-Inhibitors     Javid Moslehi, MD       11:45-11:55     Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective     Vanderbilt School of Medicine Cardio-Oncolegy Program       11:45-11:55     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       12:05-12:35     Cardiovascular-Complications-associated with Other Cancer Immunotherapies     Christian Hinrichs, MD National Cancer Institute Center for Cancer Research Cellular Therapy       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:25-1:26     Lunch     Kirk Knowton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research Maraell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease       1:40- 1:55     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
11:25-11:35   Dilemmas for the Practicing Clinician   Vanderolit Heart Failurg/Cardiac Transplant     11:35-11:45   Cardiovascular Toxicities Associated with Checkpoint-Inhibitors   Javid Moslehi, MD     11:45-11:55   Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective   Kevan Herold, MD     11:45-11:55   Cancer Immunotherapy-associated Myositis and Myasthenia Gravis   Andrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation     12:05-12:15   Cardiovascular Complications associated with Other Cancer Immunotherapies   Christian Hiaricks, MD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation     12:05-12:35   Panel Discussion Question and Answer   Chaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbit School of Medicine Cardio-Oncology Program     12:25-1:40   General Pathophysiology of Myocarditis   Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research Leducq Foundation Cardiovascular Research     1:40 - 1:55   Clinical Myocarditis: Diagnosis and Management   Mariel Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease     1:40 - 1:55   Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology   Shari Targum, MD FDA/CDER     1:40 - 1:55   Panel Discussion Question and Answer   Shari Targum, MD FDA/CDER	11:25-11:35	Immunotherapy-associated Myocarditis:			
Heart Failure/Cardia (Transplant         11:35-11:45       Cardiovascular Toxicities Associated with Checkpoint-Inhibitors       Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program         11:45-11:55       Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective       Kevan Herold, MD Yale School of Medicine Immunobiology         11:55-12:05       Cancer Immunotherapy-associated Myositis and Myasthenia Gravis       National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation         12:05-12:15       Cardiovascular Complications associated with Other Cancer Immunotherapies       Christian Hinrichs, MD National Cancer Institute Center for Cancer Research Callular Therapy         12:05-12:35       Panel Discussion Question and Answer       Chaohong Fan, MD, PhD FDA/CBER         12:35-1:25       Lunch       Kirk Knowlton, MD         11:25-1:40       General Pathophysiology of Myocarditis       Intermountain Medical Center; Salt Lake City; Cardiovascular Disease         1:25-2:05       Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       Mariel Jesup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease         1:35-2:05       Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
11:35-11:45     Cardiovascular Toxicities Associated with Checkpoint-Inhibitors     Vanderbilt School of Medicine Cardio-Oncology Program       11:45-11:55     Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective     Kevan Herold, MD       11:45-11:55     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Andrew Mammen, MD, PhD       11:55-12:05     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Andrew Mammen, MD, PhD       12:05-12:15     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinrichs, MD       12:05-12:35     Cardiovascular Complications associated with Other Cancer Immunotherapies     Chaohong Fan, MD, PhD       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD       12:35-1:25     Lunch     Stora Barac, MD, PhD; MedStar Health Research Institute       12:35-1:40     General Pathophysiology of Myocarditis     Kirk Knowlton, MD       11:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, PhA, FESC, FACC       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Andrew Utherm, MD, PhD       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Pathology       1:55-2:30     Panel Discussion Question and Answer     Shari Targum, MD					
11:35-11:45     Checkpoint-Inhibitors     Vanderbilt School of Medicine Cardio-Oncology Program       11:45-11:55     Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective     Yale School of Medicine Immunobiology       11:45-11:55     Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's Perspective     Xandrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       11:55-12:05     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinrichs, MD National Cancer Institute Center for Cancer Research Cellular Therapy       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER       12:35-1:25     Lunch     Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:35-1:26     General Pathophysiology of Myocarditis     Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research       1:40-1:55     Clinical Myocarditis: Diagnosis and Management     Mariel Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Pathology Javid Moslehi, MD       2:05-2:30     Panel Discussion Question and Answer     Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Product;		Cardiovascular Toxicities Associated with	-		
Diabetes associated with Immune Checkpoint Inhibitors-Endocrinologist's PerspectiveKevan Herold, MD Yale School of Medicine Immunobiology11:45-11:55Cancer Immunotherapy-associated Myositis and Myasthenia GravisAndrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesChristian Hinrichs, MD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:35Cardiovascular Complications associated with Other Cancer ImmunotherapiesChristian Hinrichs, MD National Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research Leducq Foundation Cardiovascular Disease1:40-1:55Clinical Myocarditis: Diagnosis and ManagementKirk Knowlton, MD Intermountain Medical School Patholpy Javid Moslehi, MD Vanderbilt School of Medicine Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Question and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	11:35-11:45		Vanderbilt School of Medicine		
11:45-11:55     Checkpoint Inhibitors-Endocrinologist's Perspective     Yale School of Medicine Immunobiology       11:55-12:05     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Andrew Mammen, MD, PhD       11:55-12:05     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Andrew Mammen, MD, PhD       12:05-12:15     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinricks, MD       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD       12:05-12:35     Lunch     Chaotong Fan, MD, PhD       12:35-1:25     Lunch     Chaotong Fan, MD, PhD       12:35-1:26     General Pathophysiology of Myocarditis     Kirk Knowlton, MD       11:25-1:40     General Pathophysiology of Myocarditis     Mariell Jessup, MD, FAHA, FESC, FACC       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, FAHA, FESC, FACC       1:40- 1:55     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Mariell Jessup, MD, FAHA, FESC, FACC       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Pathology       2:05-2:30     Panel Discussion Ouestion and Answer     Shari Targum, MD       2:05-2:30     Panel Discussion Ouestion and Answer     Shari Targum, MD <td>Cardio-Oncology Program</td>			Cardio-Oncology Program		
PerspectiveImmunobiology11:55-12:05Cancer Immunotherapy-associated Myositis and Myasthenia GravisAndrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesChristian Hinrichs, MD National Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25Lunch12:35-1:26General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40-1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardio-Oncology Program1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	11:45-11:55	Checkpoint Inhibitors-Endocrinologist's	Kevan Herold, MD		
11:55-12:05Cancer Immunotherapy-associated Myositis and Myasthenia GravisAndrew Mammen, MD, PhD National Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesChristian Hinrichs, MD National Cancer Institute Center for Cancer Institute Center for Cancer Institute Center for Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research Mariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;			Yale School of Medicine		
11:55-12:05Cancer Immunotherapy-associated Myositis and Myasthenia GravisNational Cancer Institute Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesNational Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerCharlong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchSession 4: Myocarditis Overview Moderator: And Barac, MD, PhD; MedStar Health Research InstituteKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research Catdiovascular Disease1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementAndrew Lichtman, MD, PhD Harvard Medical School Pathology1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Question and AnswerAndrew Lichtman, MD, PhD Harvard Medical School Pathology			Immunobiology		
11:55-12:05     Cancer Immunotherapy-associated Myositis and Myasthenia Gravis     Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       12:05-12:15     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinrichs, MD       12:05-12:35     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinrichs, MD       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER       12:35-1:25     Lunch     Session 4: Myocarditis Overview       Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute     Kirk Knowlton, MD       1:25-1:40     General Pathophysiology of Myocarditis     Intermountain Medical Center; Salt Lake City; Cardiovascular Research       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, FHD, FHD, Harvard Medical School       1:40- 1:55     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Andrew Lichtman, MD, PhD       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Pathology       2:05-2:30     Panel Discussion Question and Answer     Shari Targum, MD			Andrew Mammen, MD, PhD		
11:55-12:05     and Myasthenia Gravis     Center for Cancer Research Laboratory of Muscle Stem Cells & Gene Regulation       12:05-12:15     Cardiovascular Complications associated with Other Cancer Immunotherapies     Christian Hinrichs, MD National Cancer Institute Center for Cancer Research Cellular Therapy       12:05-12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:35-1:25     Lunch       Session 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute     Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Disease       1:40- 1:55     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Andrew Litchman, MD, PhD Harvard Medical School       1:40- 1:55     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Andrew Litchman, MD, PhD Harvard Medical School       2:05-2:30     Panel Discussion Ouestion and Answer     Panel Discussion Ouestion and Answer     Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;			National Cancer Institute		
Laboratory of Muscle Stem Cells & Gene Regulation12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesNational Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25Lunch12:35-1:26General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementKark Knowltom, MD, PhD Harvard Medical School Pathology1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyMariel Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	11:55-12:05		Center for Cancer Research		
12:05 12:15     Cardiovascular Complications associated with Other Cancer Immunotherapies     National Cancer Institute Center for Cancer Research Cellular Therapy       12:05 12:35     Panel Discussion Question and Answer     Chaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:35 1:25     Lunch     Session 4: Myocarditis Overview       Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute     Kirk Knowlton, MD       1:25 1:40     General Pathophysiology of Myocarditis     Intermountain Medical Center; Salt Lake City; Cardiovascular Research Mariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease       1:40 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Cardiovascular Cardiovascular Cardiovascular Disease       1:55 -2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Panel Discussion Ouestion and Answer       2:05 -2:30     Panel Discussion Ouestion and Answer     Shari Targum, MD		and Myasthenia Gravis	Laboratory of Muscle Stem Cells & Gene		
12:05-12:15Cardiovascular Complications associated with Other Cancer ImmunotherapiesNational Cancer Institute Center for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25Lunch12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute1:25-1:40General Pathophysiology of Myocarditis1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementKirk Knowlton, MD Intermountain Medical Center; Salt Lake City: Cardiovascular Research1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;			Regulation		
12:05-12:15with Other Cancer ImmunotherapiesCenter for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CDER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute1:25-1:40General Pathophysiology of Myocarditis1:40-1:55Clinical Myocarditis: Diagnosis and ManagementKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;			Christian Hinrichs, MD		
12:05-12:15with Other Cancer ImmunotherapiesCenter for Cancer Research Cellular Therapy12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute1:25-1:40General Pathophysiology of Myocarditis1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;		Cardiovascular Complications associated	National Cancer Institute		
12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:25-1:40General Pathophysiology of Myocarditis1:40-1:55Clinical Myocarditis: Diagnosis and ManagementKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	<del>12:05-12:15</del>		Center for Cancer Research		
12:05-12:35Panel Discussion Question and AnswerChaohong Fan, MD, PhD FDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute1:25-1:40General Pathophysiology of Myocarditis1:25-1:40General Pathophysiology of Myocarditis1:40- 1:55Clinical Myocarditis: Diagnosis and Management1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology2:05-2:30Panel Discussion Ouestion and Answer			Cellular Therapy		
12:05-12:35Panel Discussion Question and AnswerFDA/CBER Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute11:25-1:40General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
12:05-12:35     Panel Discussion Question and Answer     Javid Moslehi, MD and Panel Vanderbilt School of Medicine Cardio-Oncology Program       12:35-1:25     Lunch       Session 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute       1:25-1:40     General Pathophysiology of Myocarditis       1:25-1:40     General Pathophysiology of Myocarditis       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       2:05-2:30     Panel Discussion Ouestion and Answer					
Question and Answer   Vanderbilt School of Medicine Cardio-Oncology Program     12:35-1:25   Lunch     Session 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute     1:25-1:40   General Pathophysiology of Myocarditis     1:25-1:40   General Pathophysiology of Myocarditis     1:40- 1:55   Clinical Myocarditis: Diagnosis and Management     1:40- 1:55   Clinical Myocarditis: Diagnosis and Management     1:55-2:05   Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     1:55-2:05   Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     2:05-2:30   Panel Discussion Ouestion and Answer	12:05-12:35		-		
12:35-1:25LunchSession 4: Myocarditis Overview Moderator: Ana Barac, MD, PhD; MedStar Health Research InstituteKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:25-1:40General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
12:35-1:25     Lunch       Session 4: Myocarditis Overview       Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute       1:25-1:40     General Pathophysiology of Myocarditis       1:25-1:40     General Pathophysiology of Myocarditis       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Kirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management     Mariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Andrew Lichtman, MD, PhD Harvard Medical School Pathology       2:05-2:30     Panel Discussion Ouestion and Answer     Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
Session 4: Myocarditis Overview       Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute       1:25-1:40     General Pathophysiology of Myocarditis       1:25-1:40     General Pathophysiology of Myocarditis       1:40- 1:55     Clinical Myocarditis: Diagnosis and Management       1:55-2:05     Clinical Myocarditis: Diagnosis and Management       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology       2:05-2:30     Panel Discussion Ouestion and Answer	12.35-1.52	Lunch			
Moderator: Ana Barac, MD, PhD; MedStar Health Research Institute1:25-1:40General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40-1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
1:25-1:40General Pathophysiology of MyocarditisKirk Knowlton, MD Intermountain Medical Center; Salt Lake City; Cardiovascular Research1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	•				
1:25-1:40General Pathophysiology of MyocarditisIntermountain Medical Center; Salt Lake City; Cardiovascular Research1:40-1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	Moderator: An	<b>a Barac, IVID, PhD;</b> Meastar Health Research ins			
City; Cardiovascular Research1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	1.25 1.40	General Pathophysiology of Myocarditis	-		
1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementMariell Jessup, MD, FAHA, FESC, FACC Leducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	1:25-1:40				
1:40- 1:55Clinical Myocarditis: Diagnosis and ManagementLeducq Foundation Cardiovascular Disease1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyAndrew Lichtman, MD, PhD Harvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
1:40-1:55     Management     Leducq Foundation Cardiovascular Disease       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Andrew Lichtman, MD, PhD Harvard Medical School       1:55-2:05     Immune-Checkpoint Inhibitor Related Myocarditis: Pathophysiology     Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program       2:05-2:30     Panel Discussion Ouestion and Answer     Shari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;	4.40.4.55		••••••		
1:55-2:05     Immune-Checkpoint Inhibitor Related     Andrew Lichtman, MD, PhD       1:55-2:05     Immune-Checkpoint Inhibitor Related     Pathology       Javid Moslehi, MD     Vanderbilt School of Medicine       CardioVascular Disease     CardioVascular Disease       1:55-2:05     Immune-Checkpoint Inhibitor Related     Pathology       Javid Moslehi, MD     Vanderbilt School of Medicine       Cardio-Oncology Program     Shari Targum, MD       FDA/CDER/Division of Cardiovascular and Renal Products;     and Renal Products;	1:40- 1:55				
1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyHarvard Medical School Pathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerShari Targum, MD FDA/CDER/Division of Cardiovascular and Renal Products;					
1:55-2:05Immune-Checkpoint Inhibitor Related Myocarditis: PathophysiologyPathology Javid Moslehi, MD Vanderbilt School of Medicine Cardio-Oncology Program2:05-2:30Panel Discussion Ouestion and AnswerFDA/CDER/Division of Cardiovascular and Renal Products;					
1:55-2:05     Myocarditis: Pathophysiology     Javid Moslehi, MD       Vanderbilt School of Medicine     Cardio-Oncology Program       Cardio-Oncology Program     Shari Targum, MD       Panel Discussion     FDA/CDER/Division of Cardiovascular and Renal Products;					
Myocarditis: Pathophysiology     Javid Moslehi, MD       Vanderbilt School of Medicine     Cardio-Oncology Program       Cardio-Oncology Program     Shari Targum, MD       Panel Discussion     FDA/CDER/Division of Cardiovascular       Ouestion and Answer     and Renal Products;	1:55-2:05				
Cardio-Oncology Program     Cardio-Oncology Program     Shari Targum, MD     Panel Discussion   FDA/CDER/Division of Cardiovascular and Renal Products;					
Panel Discussion     Shari Targum, MD       Point Discussion     FDA/CDER/Division of Cardiovascular       and Renal Products;     and Renal Products;					
<b>2:05-2:30</b> Panel DiscussionFDA/CDER/Division of Cardiovascular and Renal Products;					
2:05-2:30 Panel Discussion and Renal Products;	2:05-2:30				
2:05-2:30 and Renal Products;			FDA/CDER/Division of Cardiovascular		
			and Renal Products;		
Wir. John Dewolf and Panel			Mr. John DeWolf and Panel		
Patient Perspective			Patient Perspective		

### Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials

December 1, 2017

Organized by FDA with support from: AACR, ACC, AHA & ASCO Co-Chairs: Dr. Laleh Amiri-Kordestani and Dr. Javid Moslehi

### AGENDA

Session 5: Screening/Monitoring for Cardiovascular Toxicities associated with Cancer Immunotherapies Moderator: Daniel Lenihan, MD; Washington University			
2:30-2:40	How to Screen for Cardiotoxicity	Susan Gilchrist, MD MD Anderson Cancer Center Cardiology	
2:40-2:50	Imaging Modalities to Diagnose Cardiovascular Toxicities	Bonnie Ky, MD, MSCE University of Pennsylvania, Perelman School of Medicine Translational Cardiovascular Epidemiology	
2:50-3:00	Adjudicating Cardiovascular Events in Immuno-Oncology Trials	Marc Bonaca, MD, MPH Brigham and Women's Hospital, Harvard Medical School Heart & Vascular Medicine	
3:00 to 3:25	Panel Discussion Question and Answer	Alexander Lyon, MA, BM, BCh, PhD, FRCP, FHFA and Panel Royal Brompton Hospital, London Cardiology	
3:25 to 3:35	Break		
3:35 to 3:50	Modernizing Eligibility Criteria for Oncology Clinical Trials	Julia Beaver, MD FDA/CDER	
	Big data to Smart Data for Identification of Ca		
Moderators: S	ean Khozin, MD; FDA/OCE and Elad Sharon, M		
3:50-4:00	Leveraging Big Data in Drug Development: Toxicity Assessment & Signal Detection	Sean Khozin, MD, MPH FDA/OCE	
4:00-4:10	ASCO's CancerLinQ: Using real-world evidence for discovery	Robert Miller, MD, FACP, FASCO CancerLinQ American Society of Clinical Oncology	
4:10-4:20	Patient-Generated Data	Sally Okun, RN, MMHS Patients Like Me	
4:20-4:40	Post-Marketing Drug Safety Surveillance: Cardiovascular Toxicities	Connie Cheng, PharmD, BCOP FDA/CDER/Office of Surveillance and Epidemiology (OSE) Pritpal Singh, PharmD, BCOP FDA/CDER/OSE	
4:40-5:00	Panel Discussion Question and Answer	FDA/CDER/OSE: Daniel Woronow, MD; Afrouz Nayernama, PharmD; Peter Waldron, MD; and Panel	
5:00	Adjournment		