

OCTOBER 21–25, 2019 PHILADELPHIA, PENNSYLVANIA, USA

CELL THERAPY TRAINING COURSE

a partnership between **ASTCT** & **ISCT**

Monday, October 21, 2019

08:00 - 08:15	Introduction by Course Co-Chairs
08:15 - 10:00	Scholar Presentations
10:00 - 10:15	Coffee Break
10:15 - 12:00	Scholar Presentations
12:00 – 13:00	Lunch
13:00 – 14:00	Scholar Presentations
14:00-15:00	Study Design, Conduct and Analysis of Clinical Trials Speakers: 1) Noelle Frey, MD, MSCE, University of Pennsylvania 2) Shannon Maude, MD, PhD, The Children’s Hospital of Philadelphia
15:00 – 16:00	Statistics Speaker: 1) Wei-Ting Hwang, PhD, University of Pennsylvania
16:00 – 17:00	Ethics Roundtable Panelists: 1) Megan Kasimatis Singleton, JD, MBE, CIP, Johns Hopkins University 2) John Barrett, MD, George Washington University

Tuesday, October 22, 2019

08:00 - 10:00	Quality Assurance Development Lectures Speakers: 1) Philip J. Cross, Philip J. Cross & Associates, Inc. 2) Anna Gilbert, BDO Life Science Services
10:00 - 10:15	Coffee Break

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10:15 - 12:00	IND Development Lectures Speakers: <ol style="list-style-type: none">1) Elizabeth Hexner, MD, MSTR, University of Pennsylvania2) Whitney Gladney, PhD, University of Pennsylvania3) Elizabeth J. Shpall, MD, MD Anderson Cancer Center
12:00 - 13:00	Lunch
13:00 - 14:00	Regulatory Affairs Case Studies Speaker: <ol style="list-style-type: none">1) Peter Marks, MD, PhD, U.S. Food & Drug Administration
14:00 – 15:00	Breakout Session: Career Development Speakers: <ol style="list-style-type: none">1) Peter Marks, MD, PhD, U.S. Food & Drug Administration2) Krishna Komanduri, MD, University of Miami3) Colleen Delaney, MD, MSc, Nohla Therapeutics4) Catherine Bollard, MBChB, MD, Children’s National Health System
16:00 – 17:00	Tour of U Penn Cell Processing Facility
17:00 – 18:00	Networking Reception Sponsored by Semma Therapeutics

Wednesday, October 23, 2019

08:00 – 09:45	Manufacturing and Release Testing Cells Part I: Non-gene Modified Speakers: <ol style="list-style-type: none">1) Catherine Bollard, MBChB, MD, Children’s National Health System2) John Barrett, MD, George Washington University3) David DiGiusto, PhD, Semma Therapeutics
09:45 - 10:00	Coffee Break
10:00 - 11:00	Manufacturing and Release Testing Cells Part II: Genetically Modified Speakers: <ol style="list-style-type: none">1) Bruce Levine, PhD, University of Pennsylvania2) David DiGiusto, PhD, Semma Therapeutics

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11:00 - 12:00	Manufacturing and Analytics of Viral Vectors Speakers: <ol style="list-style-type: none">1) Johannes (Han) van Der Loo, PhD, University of Pennsylvania
12:00 - 13:00	Lunch
13:00 - 14:00	Routes to Commercialization Speakers: <ol style="list-style-type: none">1) Colleen Delaney, MD, MSc, Nohla Therapeutics2) Usman Azam, MD, Tmunity Therapeutics Inc.
14:00 - 16:00	Pre-Clinical Development Speakers: <ol style="list-style-type: none">1) Veronika Bachanova, MD, PhD, University of Minnesota2) David DiGiusto, PhD, Semma Therapeutics3) John Barrett, MD, George Washington University
16:00 - 17:00	Clinical Trial Case Studies: Delivery of Cell Therapy Products (Infusion) Speakers: <ol style="list-style-type: none">1) Lester Lledo, MSN, CRNP, University of Pennsylvania2) Donald O'Rourke, MD, University of Pennsylvania
17:30-20:30	Scholar + Faculty Dinner

Thursday, October 24, 2019

08:00 – 09:45	Correlative Studies Lectures Speakers: <ol style="list-style-type: none">1) Jos Melenhorst, PhD, University of Pennsylvania2) Krishna Komanduri, MD, University of Miami3) Joseph Fraietta, PhD, University of Pennsylvania
9:45 – 10:00	Coffee Break

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10:00 – 11:00	Evolving Financial Models for CAR-T and Gene Therapies Speakers: 1) Krishna Komanduri, MD, University of Miami
11:00 – 12:00	Team Science Speakers: 1) Catherine Bollard, MBChB, MD, Children’s National Health System 2) John Barrett, MD, George Washington University
12:00 - 13:00	Lunch
13:00 - 14:00	Funding Sources Speakers: 1) Catherine Bollard, MBChB, MD, Children’s National Health System
14:00 - 15:30	Challenges for Gene Modified Cells and Regenerative Medicine Products Speakers: 1) David DiGiusto, PhD, Semma Therapeutics 2) Bruce Levine, PhD, University of Pennsylvania 3) Colleen Delaney, MD, MSc, Nohla Therapeutics
15:30 – 16:00	Travel to Wuxi Apptec cGMP Facility
16:00 - 18:00	Tour of Wuxi Apptec cGMP Facility

Friday, October 25, 2019

08:00 – 09:45	Scholar Presentations
09:45 - 10:00	Coffee Break
10:00 – 11:30	Scholar Presentations
11:30 – 12:30	Lunch (Grab-and-Go)