

# CMV in Transplantation: Endpoints and Clinical Trial Designs

Friday, September 05, 2014

University of California Washington Center  
1608 Rhode Island Ave NW, Washington DC 20036  
2:30 PM - 8:30 PM

## AGENDA

<b>2:30 PM</b>	<b>Welcome Reception and Check-In</b>	
<b>3:00 PM</b>	Welcome & Introductions Brief Overview of Project Goals	Per Ljungman, <i>Karolinska Institutet</i> Veronica Miller, <i>HIV Forum</i>
<b>3:30 PM</b>	<b>Session 1: Project Overview and Setting the Stage</b>	<b>Moderators</b> Per Ljungman, <i>Karolinska Institutet</i> Veronica Miller, <i>HIV Forum</i>
<b>3:30 PM</b>	Brief Overview: Advances in Clinical Management and Endpoints	<b>Presenter</b> Per Ljungman, <i>Karolinska Institutet</i>
<b>3:50 PM</b>	Key Questions for Drugs	<b>Discussants</b> Barbara Alexander, <i>Duke University</i> Jennifer Brooks, <i>Microbiotix</i> Filip Josephson, <i>EMA</i> Herve Mommeja-Marin, <i>Chimerix</i> Mark Prichard, <i>University of Alabama, Birmingham</i> Mary Singer, <i>FDA/CDER</i> Shelley Trucksis, <i>Merck Research Labs</i>
<b>4:10 PM</b>	Key Questions for Vaccines	<b>Discussants</b> Susan Barnett, <i>Novartis Vaccines</i> Lesia Dropulic, <i>NIH/NIAID</i> Jeff Roberts, <i>FDA/CBER</i> Bernie Zeiher, <i>Astellas</i>
<b>4:30 PM</b>	Key Questions for T cell Mediated Strategies and Diagnostics	<b>Discussants</b> Kurt Gunter, <i>Cell Medica</i> Louise O'Dea, <i>Oxford Immunotec</i> Karl Peggs, <i>University College London</i>
<b>4:50 PM</b>	Process -- Meeting Timelines, Working Groups, Public Meeting in 2015?	All
<b>5:05 PM</b>	<b>Break</b>	
<b>5:25 PM</b>	<b>Session 2: Viral Load Measurements and Standardization</b>	<b>Moderator</b> Hans Hirsch, <i>Universität Basel</i>
<b>5:25 PM</b>	Endpoints for Pivotal Trials: Viral Load Measurements & Thresholds: Key Questions Measurement Standardization	<b>Discussants</b> Paul Baum, <i>Roche Molecular</i> David Boutolleau, <i>Université Pierre et Marie Curie</i> Takashi Komatsu, <i>FDA/CDER</i> Tadd Lazarus, <i>Qiagen</i> Francisco Martinez-Murillo, <i>FDA/CDRH</i>
<b>5:55 PM</b>	<b>Session 3: Surrogacy and Validation</b>	<b>Moderator</b> Roy Chemaly, <i>University of Texas MD Anderson Cancer Center</i>
<b>5:55 PM</b>	CMV Viral Load and CMV Disease and Non-relapse Mortality -- New Analysis (Preview of ICAAC Latebreaker Presentation)	<b>Presenter</b> Michael Boeckh, <i>University of Washington</i>

<b>6:10 PM</b>	Discussion	<b><u>Discussants</u></b> Emily Blumberg, <i>Hospital of the University of Pennsylvania</i> Gavin Cloherty, <i>Abbott Molecular</i> Scott Hammer, <i>Columbia University</i> Li Li, <i>FDA/CDRH</i> Jeff Murray, <i>FDA/CDER</i>
<b>6:30 PM</b>	<b>Session 4: Moving Forward</b>	<b><u>Moderators</u></b> Per Ljungman, <i>Karolinska Institutet</i> Veronica Miller, <i>HIV Forum</i>
<b>6:30 PM</b>	Opportunities for Collaboration: Who has data? What is needed to move forward on validating surrogacy?	All
<b>7:00 PM</b>	Next Steps Revisit Working Groups, Next Meeting, etc	All
<b>7:15 PM</b>	<b>Round Table Adjourns</b> <b>Networking Reception</b>	
<b>8:45 PM</b>	<b>Final Adjourn</b>	

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