

Regulatory Issues in CMV Drug Development Meeting #3
Fenway Health, Ansin Building
1340 Boylston Street
Boston MA 02215
June 18, 2016

SESSION	Speaker/Panelist
10:00 AM Welcome and Introductions	<i>Michelle Berrey, MD, MPH, Chimerix, Inc.</i> <i>Per Ljungman, MD, PhD, Karolinska Institutet & Karolinska University Hospital</i> <i>Veronica Miller, PhD, Forum for Collaborative HIV Research</i>
10:15 AM Session 1 -- Updates	Moderator: <i>Veronica Miller, PhD, Forum for Collaborative HIV Research</i>
Disease Definitions Manuscript	<i>Per Ljungman, MD, PhD, Karolinska Institutet & Karolinska University Hospital</i>
Discussion	<i>All</i>
10:45 AM Session 2 -- CMV DNAemia as a Surrogate Endpoint	Moderators: <i>Roy Chemaly, MD, MPH, FACP, FIDSA, University of Texas MD Anderson Cancer Center</i> <i>Andreas Pikis, MD, U.S. Food and Drug Administration</i>
Systematic literature review for CMV viral load in transplant recipients	<i>Yoichiro Natori, MD, University of Toronto</i>
Discussion <i>Where does that leave us?</i> <i>What else is needed?</i> <i>How do we get there?</i>	<i>All</i>
11:45 AM What are collaborative opportunities to validate diagnostics based on recent trials: databases and biobanks	<i>All</i>
12:30 PM LUNCH	
1:30 PM Session 3 --Clinical Trial Design Issues	Moderator: <i>Paul Griffiths, MD, DSc, FRCPath, University College London Medical School</i>
Recent Experiences	<i>Michelle Berrey, MD, MPH, Chimerix, Inc.</i>
2:30 PM Discussion <i>What are the Lessons Learned?</i> <i>What are the implications for future research?</i> <i>What are the next steps?</i>	<i>All</i>
2:30 PM SUMMING UP	<i>Per Ljungman, MD, PhD, Karolinska Institutet & Karolinska University Hospital</i> <i>Veronica Miller, PhD, Forum for Collaborative HIV Research</i>
2:45 PM ADJOURN	