



REGULATORY CONSIDERATIONS FOR CMV IN TRANSPLANTATION

PROJECT MEETING #2

MAY 6, 2015

PHILADELPHIA, PA

WELCOME & INTRODUCTIONS

facilitating collaborative research
drug development & health policy

Per Ljungman
Karolinska Institutet

Veronica Miller
Forum for Collaborative HIV Research

CMV FINANCIAL SPONSORS

facilitating collaborative research
drug development & health policy



ADDITIONAL THANKS

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drug development & health policy*

- Forum Staff
 - Erik Lontok*
 - Nivedha Panneer
 - Natalie Chan
 - ◉ UC Santa Barbara
- Informed Horizon LLC
 - Margie Poole
 - David Poole
 - Summer Fosdick
 - Suzan Tugman

*now at FasterCures

PROJECT GOALS & OBJECTIVES

*facilitating collaborative research
drug development & health policy*

- Overarching goal
 - Safe/effective drugs (therapeutic strategies) and vaccines for this unmet medical need
- Objectives
 - Review & discuss specific key questions to inform regulatory guidance
 - Identify gaps in knowledge
 - Discover/implement opportunities for collaboration to fill the gaps

IDENTIFIED NEED

*facilitating collaborative research
drug development & health policy*

- Transatlantic collaborative approach to inform drug development and regulatory guidance

SINCE SEPTEMBER 2014

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- First steps to address goals & objectives
 - Review/standardize disease definitions
 - Review/discuss standardization of diagnostics
 - Review/discuss clinical trial designs
 - ◉ Review state-of-the-evidence informing relationship between CMV DNAemia and disease

OBJECTIVES FOR TODAY

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- Discuss updates on regulatory perspectives
- Report/discuss working group progress
- Discuss path forward
 - Realign as needed

UPDATE ON FDA PERSPECTIVE

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Jeff Murray
FDA

SESSION 1: CMV DIAGNOSTICS

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Moderators:

Hans Hirsch, University of Basel

Lesia Dropulic, National Institute of Allergy and Infectious Disease

Updates from Diagnostics Working Group

Hans Hirsch, University of Basel

Lesia Dropulic, National Institute of Allergy and Infectious Disease

Veronica Miller, Forum for Collaborative HIV Research



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DISCUSSION

SESSION 2: CMV CLINICAL DEFINITIONS

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Moderators:

*Paul Griffiths, University College London Medical
Per Ljungman, Karolinksa Institutet*

Updated CMV Definitions

Per Ljungman, Karolinksa Institutet



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DISCUSSION



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BREAK



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DISCUSSION

SESSION 4: MOVING FORWARD

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Moderators:

Per Ljungman, Karolinska Institutet

Veronica Miller, Forum for Collaborative HIV Research

- A. Publication plans
- B. Big picture: How far did we come; how far still to go, are we following the right path?
- C. Action items and Next Steps



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