Regulatory Considerations for CMV in Transplantation

Project Meeting #2
May 6, 2015
Philadelphia, PA
Welcome & Introductions

Per Ljungman
Karolinska Institutet

Veronica Miller
Forum for Collaborative HIV Research
CMV Financial Sponsors

facilitating collaborative research, drug development & health policy

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Additional Thanks

- 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

- **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

- Transatlantic collaborative approach to inform drug development and regulatory guidance
Since September 2014

• 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

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

Jeff Murray
FDA
Session 1: CMV Diagnostics

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
DISCUSSION
Session 2: CMV Clinical Definitions

Moderators:
Paul Griffiths, University College London Medical
Per Ljungman, Karolinska Institutet

Updated CMV Definitions
Per Ljungman, Karolinska Institutet
DISCUSSION
BREAK
DISCUSSION
Session 4: Moving Forward

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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