Session 3: CMV Clinical Trials

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Updates from Clinical Trials Working Group
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A. Literature review/ table of studies
B. What are the strengths and limitations of existing data?
C. What is needed to move forward on validating surrogacy?
D. Opportunities for collaboration
## Summary of Published Studies

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<th>Number of Studies</th>
<th>RCT</th>
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<td>SOT</td>
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<td>7</td>
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<tr>
<td>Both</td>
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Summary of Published Studies

• HSCT
  – 5 prophylaxis only
  – 8 pre-emptive only
  – 1 pro+pre
  – 2 reviews

• SOT
  – 7 prophylaxis only
  – 1 pre-emptive only
  – 1 treatment
  – 2 observational
Primary Endpoints

- CMV disease
- Mortality/survival
- CMV viremia
- CMV infection
- Initiation of therapy
- Kinetics of viral decline
- Acute graft rejection
Support for Surrogacy?

- CMV viremia → emergence of disease
  - 12 “yes” (some disagreement)
- ↑ DNA → ↑ disease
  - 10 “yes”
- ↓ DNA → ↓ disease
  - 8 “yes” (some disagreement)
- ↔ DNA → ↔ disease
  - 3 “yes” (some disagreement)
Support for Surrogacy?

- Strong
  - 4
- Moderate
  - 10
- Weak
  - 13