

SESSION 3: CMV CLINICAL TRIALS

facilitating collaborative research
drug development & health policy

Moderators:

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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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	Number of Studies	RCT	n
HSCT	16	9	6450
SOT	13	7	2052
Both	3	1	407

SUMMARY OF PUBLISHED STUDIES

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- 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

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

SUPPORT FOR SURROGACY?

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- 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?

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