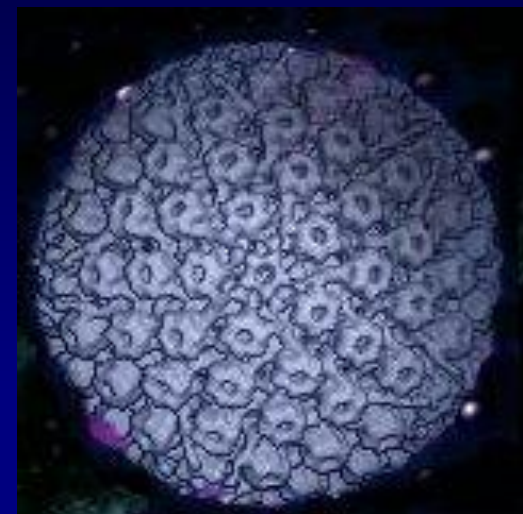
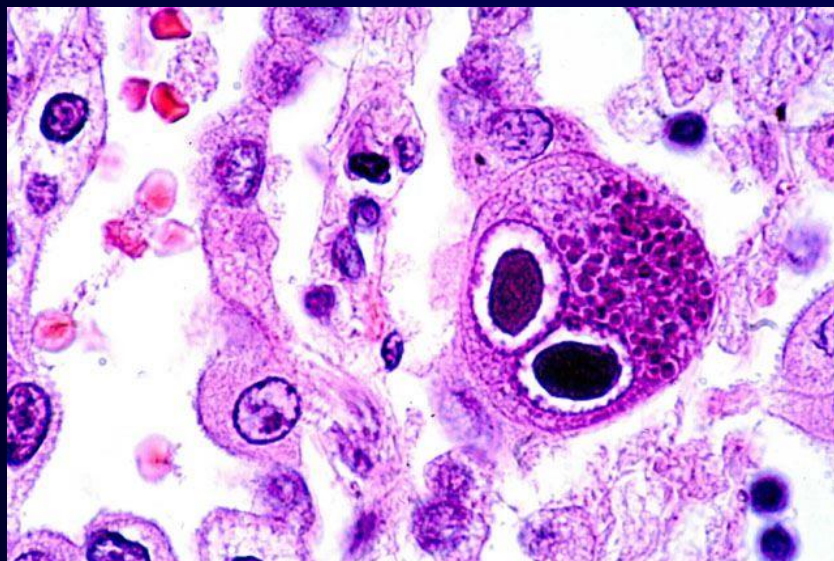


CMV definitions for clinical trials

Do we need to update the current document?



Professor (em) Per Ljungman

Dept. of Cellular Therapy and Allogeneic Stem Cell Transplantation
Karolinska Comprehensive Cancer Center
Karolinska University Hospital and Karolinska Institutet
Stockholm, Sweden

Disclosures

- Advisory boards: AiCuris; MSD, Takeda,
- Adjudication committee: MSD
- Endpoint committee: Takeda, MSD
- Speaker: MSD, Takeda, Biotest

What's in the current documents?

Two separate papers:

Clinical Infectious Diseases

INVITED ARTICLE



IMMUNOCOMPROMISED HOSTS: David R. Snyderman, Section Editor

Definitions of Cytomegalovirus Infection and Disease in Transplant Patients for Use in Clinical Trials

Per Ljungman,^{1,2} Michael Boeckh,^{4,5} Hans H. Hirsch,⁶ Filip Josephson,³ Jens Lundgren,⁷ Garrett Nichols,⁸ Andreas Pikiš,⁹ Raymund R. Razonable,¹⁰ Veronica Miller,¹¹ and Paul D. Griffiths¹²; for the Disease Definitions Working Group of the Cytomegalovirus Drug Development Forum^a

Clinical Infectious Diseases

SPECIAL SECTION/INVITED ARTICLE



Definitions of Resistant and Refractory Cytomegalovirus Infection and Disease in Transplant Recipients for Use in Clinical Trials

Roy F. Chemaly,¹ Sunwen Chou,² Hermann Einsele,³ Paul Griffiths,⁴ Robin Avery,⁵ Raymund R. Razonable,⁶ Kathleen M. Mullane,⁷ Camille Kotton,⁸ Jens Lundgren,⁹ Takashi E. Komatsu,¹⁰ Peter Lischka,¹¹ Filip Josephson,¹² Cameron M. Douglas,¹³ Obi Umeh,¹⁴ Veronica Miller,¹⁵ and Per Ljungman^{16,17}; for the Resistant Definitions Working Group of the Cytomegalovirus Drug Development Forum

- Documents for use when designing and carrying out clinical trials. Can also be used for registries when designing variables to be included in report forms.
- Not to be used as "management guidelines"
- There are other documents to be used for that purpose (ECIL, AST)

What's not in the documents/developments?

- Clinical significant CMV infection – to be included?
- Limited information about NAT based diagnosis of CMV disease in the previous document
- New data on PCR from GI tissue exists. To be included?
- Update on CMV pneumonia definitions?
- Requirement for CMV DNA from the eye to call it CMV retinitis?
- Update the CMV syndrome definition? Very difficult to use in practice.



What's not in the documents/developments?

- Resistant – refractory document.
 - Any developments?
 - Should we combine the documents?

- Is it helpful to discuss "blips" on letermovir?

- We have discussed CMV CMI in the Forum. Should it be included to help formal studies to be performed? Anything specific needed for T cell transfer studies?

What's not in the documents/developments?

- Any other items missing?
- Can we address indirect effects in any way?

- Start work November 2022 – March 2023.
- Discussion at the next TAVI meeting (April 2023?)

- Smaller writing group
- Larger reference group.