

Virological and immune assays. How do combine?



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Are there situations in study design
where we would like to combine
virological and immune assays?



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Possible scenarios



Define the patient population

Part(s) of a study endpoint.

Starting/stopping rules



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Define the population



- Inclusion and exclusion criteria
- Determine risk status/stratification



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Define the population



- Depending on type of intervention
 - Antiviral studies
 - Vaccine studies
 - T-cell therapy studies



Define the population - example

- Should a patient receive preemptive antiviral therapy?
- Start 3 months after allogeneic HSCT
- Patients included if virological assay positive and immune assay negative – study of therapy effect
- Patients included if virological assay positive and immune assay negative – study of deferred therapy



Define the study endpoint - success



- No CMV replicating and a positive immune assay response
- Vaccine studies
- T-cell studies
- Antiviral studies



Define the study endpoint - failure



- CMV replicating and no immune response
- Vaccine studies
- T-cell studies