2025 Area of Interest for CMV

CMV Areas of Interest

Effective December 2024, the CMV Investigator Studies Program (MISP) Committee will accept proposals within our current Areas of Interest (AOIs) up to July 24, 2025. This is a competitive process that will be conducted by the CMV MISP in 2025. Decisions will be made based on scientific merit and strategic fit within the AOIs. Please review the critical activities and abide by the timelines as outlined below. The program requests that investigators specify how they will support diversity in enrollment to include traditionally underrepresented minorities/ethnic groups.

The following areas are of interest to the Investigator Studies Program Committee:

- Clinical interventional/treatment or clinical non-interventional (EHR-based retrospective studies) studies that provide insights into the effectiveness of primary CMV prophylaxis with letermovir in the following adult Kidney Transplant Recipients (KTR) populations:
    - HLA/ABO mismatch,
    - highly sensitized recipients,
    - elderly (>65 (60) yrs of age),
    - those experiencing delayed graft function (DGF) for any reason,
    - and/or receiving ATG for allograft rejection prevention or treatment with endpoints that may include but are not limited to impact on graft outcomes, and impact on patient care including but not limited to MMF dose adjustments, healthcare resource utilization.

- LET vs VGCV dose adjustments Real World Evidence (RWE) showing impact on patient adherence including but not limited to patient reported events/ medication dosing changes & clinical outcomes such as but not limited to: CMV viremia, MMF dose adjustment, CMV disease, organ rejection/failure and/or all-cause mortality in adult and pediatric D+/R- KTR

- Real World Data highlighting LET vs VGCV impact on HCRU burden and costs include cost saving associated with avoiding lymphopenia & neutropenia clinical management
- Real World Observation studies that outline the clinical & economic impact of late-onset CMV, studies demonstrating prevention of poor outcomes and burdens including late CMV reactivations in the adult allogeneic HSCT populations that would benefit from 200 days of letermovir primary prophylaxis but only receive 100 days of prophylaxis
- Use of LET for primary CMV prophylaxis in pediatric allo HSCT RWE outside the United States
- Clinical intervention/treatment or clinical RWE studies describing efficacy of primary CMV prophylaxis with letermovir in patients undergoing CAR-T therapy or patients with multiple myeloma receiving bispecific antibody (BSaB) therapy