2025 Area of Interest for Atherosclerosis

Atherosclerosis Areas of Interest

Effective January 2025, the Merck Investigator Studies Program Review Committee (MISP-RC) for Atherosclerosis will accept PRECLINICAL and CLINICAL (NON-INTERVENTIONAL) submissions within our current areas of interest (AOI). This is a competitive review process that will be conducted by the MISP Review Committee. Studies involving the use of Enlicitide (MK-0616) will not be reviewed at this time.

<u>The following areas are of interest to the Investigator Studies Program</u> <u>Committee:</u>

Implementation Studies (focus on implementation with use of validated tools):

- Studies evaluating approaches to improve use of Guideline Directed Medical Therapy by HCPs (specialty or primary care) or coordinated care models to improve adoption, adherence and persistence to lipid-lowering therapies, including approved PCSK9 inhibitors
- Including interventional studies, educational approaches and, quality improvement programs
- Implementation approaches and proven strategies to inform clinical decision making, LDL-C monitoring, and guideline concordance (including HeFH patients (both adult and pediatric))

Epidemiology and Patient Characterization:

- Studies that advance the understanding of unmet needs in patients with:
 - · Coronary atherosclerosis, including CAD, PCI, CABG, ACS/post-MI
 - Cerebrovascular atherosclerosis such as stroke or TIA, cerebrovascular revascularization

- Other comorbid conditions (including diabetes, obesity, heart failure, CKM)
- Heterozygous Familial Hypercholesterolemia (HeFH)
- Peripheral arterial disease, lower extremity arterial revascularization, endovascular stenting, etc.
- High risk for ASCVD/subclinical atherosclerosis such as high CAC
- Modeling for cumulative LDL-C risk
- Disparities in LDL-C management and/or CVOs, disposition:
 - Across specific patient populations
 - · In typically under-diagnosed/treated populations, including women

Evaluation of the PCSK9 enzyme in non-cholesterol biological pathways (not including oncology studies)