

2025 Area of Interest for Immunology

Immunology Areas of Interest

Effective January 2025, the Investigator Studies Program Review Committee (MISP-RC) will accept protocols within our current Areas of Interest (AOIs). There will be 4 competitive reviews in 2025 by the MISP Review Committee to determine approvals. Submissions will be evaluated, and decisions made based on the scientific merit of the protocols and their strategic alignment with AOIs. We will only be considering translational studies that are non-interventional and there is no use of study product or drug supply. We are requesting full protocols for the 4 review cycles unless discussed beforehand with the MISP chair if acceptable to provide an abbreviated protocol.

We kindly request that you carefully review the critical activities outlined and adhere to the specified submission noted 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 Investigator Studies Program Committee:

Immunology AOIs

1. Further characterization of the role of TL1a, CD30L pathways, role of T and/or B cells in rheumatologic, dermatologic, and GI immune mediated diseases, including but not limited to Crohn's disease, ulcerative colitis, systemic lupus erythematosus, vitiligo, atopic dermatitis, and systemic sclerosis.
 - a. The role of the TL1A pathway in diseases of interest, including but not limited to Crohn's disease (CD), ulcerative colitis (UC), or systemic sclerosis (SSc), using ex vivo methods or suitable animal models.
 - b. Characterization of the role of TL1A and the DR3 receptor in inflammation and fibrosis.
 - c. Plausibility of TL1A and other non-redundant pathways to consider for combination therapy for UC and/or CD using ex vivo methods or suitable animal models.
 - d. Role of CD30L in immune mediated diseases using in vitro, ex vivo, and/or in animal models.

- e. Phenotypic and/or functional characterization of Tregs, memory T cells and/or B cells from patient tissue (advanced therapy naïve or advanced therapy-experienced patient samples) with accompanying clinical data (e.g., disease history, disease activity scores, clinical biomarkers, current treatment) is recommended.
- 2. Use of novel techniques or technologies (including imaging, machine learning (ML) and artificial intelligence (AI) based methods) to inform endpoints in clinical trials and characterize disease progression in immune mediated diseases of interest, including but not limited to UC, CD, atopic dermatitis, hidradenitis suppurativa, systemic sclerosis and/or systemic lupus erythematosus.
 - a. Use of AI/ML based methods to incorporate assessments that could be novel to or routine in clinical practice (e.g., histopathologic assessments or biomarkers of clinical relevance).
 - b. Novel molecular and biochemical approaches and analytical methods for identifying predictive biomarkers in autoimmune and inflammatory diseases.
- 3. Characterization of social determinants of health, (e.g., income, job status, residential crowding) on the prevalence and outcomes of hidradenitis suppurativa and/or vitiligo.