

DERMATOLOGY ISS Areas of Interest

Atopic dermatitis

- **Dupilumab in Atopic Dermatitis**
 - Evaluate the [optimal] utilization of dupilumab for the treatment of AD within the evolving therapeutic landscape
 - Real world AD patient / disease characteristics, burden of AD and comorbid conditions
 - Dupilumab use patterns, effectiveness, and other attributes in real-world setting
 - Special populations (e.g., skin of color)
 - Studies to measure the effect of dupilumab on AD symptoms and other important disease domains that are insufficiently characterized (sleep, pain, mental health, sensory processing, executive function, etc.)
 - New mechanistic insights into dupilumab MOA, including effect on important inflammation markers in lesional and non-lesional skin not studied previously
 - Effect of dupilumab in AD patients with comorbid type 2 inflammatory diseases (e.g. AD with comorbid asthma ± allergic rhinitis ± food allergy, etc.)
 - Effect of early AD treatment with dupilumab on the development of type 2 comorbidities, atopic march and disease modifying aspects in general
 - Dupilumab in the context of COVID-19 pandemic
 - Effectiveness of dupilumab across different phenotypes and endotypes.
- **AD Disease State**
 - AD time course (natural history)
 - New mechanistic insights into AD pathophysiology, including the identification of distinct phenotypes and endotypes
- **AD Epidemiology**
 - Prevalence of AD by gender, age group, age of onset, associated comorbidities, special populations
 - Treatment patterns throughout the course of AD
- **Mechanistic**
 - Further understand the AD mechanism of disease, or dupilumab mechanism of action in relevant pathobiological contexts
 - Pathobiology of IL4Ralpha in chronic itch
 - IL4/13 signaling in fibrosis and skin remodeling

Other Dermatological Diseases – prurigo nodularis, chronic spontaneous urticaria, chronic cold-induced urticaria, chronic pruritus of unknown origin, bullous pemphigoid.

- Patient population
 - Epidemiology
 - Natural history including disease progression
 - Burden and unmet needs including limitations of current therapies
- Pathogenesis
 - Pathogenesis including the role of IL-4 and/or IL-13 and mechanisms of itch
 - Barrier disruption and tissue remodeling
 - Characteristics of lesional and non-lesional skin
- Clinical practice
 - Diagnosis and assessment including biomarkers and imaging
 - Disease endotypes
 - Comorbidities including Type 2
 - Special populations including skin of color

Other dermatologic diseases beyond the diseases listed above, where existing data suggest that IL-4 and/or IL-13 may play a central role.

- Effect of dupilumab

NOTE: Prior to submission via the ISS portal, proposals must undergo preliminary review to evaluate regulatory/patent risk and ensure there is no overlap with ongoing initiatives.