

**Pharmaceutical Sciences Seminar Series**

Wednesday, April 27, 2022

4:00pm

NCRC Building10 Research Auditorium

Hybrid option

[Link](https://umich.zoom.us/j/97466817829?pwd=Y2xmZ2J3OW15UXRvOVhncy9yL0lOUT09)

**“Integrated Exposure-Response of Dupilumab in Pediatric and Adult Patients with Atopic Dermatitis using Categorical and Continuous Endpoints: A Population Analysis”**

Presented by:



**Emily Briggs**

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(Mentor: David E. Smith)

**Abstract:** Atopic dermatitis is a chronic, relapsing skin disease characterized by inflammation and pruritis of the skin that affects 10 – 20 percent of children and 5 – 10 percent of adults in the United States. Atopic dermatitis is developed by a combination of epithelial-barrier defects, increased type 2 immune responses (Th2), and environmental factors. For clinical research studies, atopic dermatitis severity is measured using multiple subjective scales. The most prominent assessments are the Eczema Area and Severity Index (EASI) and the Investigator Global Assessment (IGA), a continuous bounded outcome score assessment and a five-point ordered categorical assessment, respectively.

Dupilumab, trade name Dupixent, is a fully human monoclonal antibody that is administered via subcutaneous injection for patients with moderate-to-severe atopic dermatitis. Dupilumab is an interleukin (IL)-4 receptor alpha antagonist that blocks interleukin-4 and interleukin-13 signaling. In the United States, dupilumab is approved for moderate-to-severe atopic dermatitis (6+ years), asthma (12+ years), and chronic rhinosinusitis with nasal polyposis (18+ years). For clinical trials, moderate-to-severe baseline disease severity is defined as an IGA score ≥ 3 and an EASI score ≥ 16, and body surface area (BSA) involvement of ≥ 10%.

The goal of this project was to fit semi-mechanistic structural models to the dupilumab concentration and clinical endpoint data, thus predicting specific response outcomes across age groups from children to adult. Key parameters in this analysis were the maximum inhibitory drug effect (Imax) and the steady-state concentration that achieves 50% of the maximum effect (IC50) for dupilumab in patients with AD.

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