

The Ora Allergy System Model

Proven Site Network and Subject Database

- Exclusive investigator-network
- Large patient database of patients qualified specifically with allergic conjunctivitis to the right allergen
- Training and re-training of investigators on clinical scales

Experience

- Validation through 19 approved ocular allergy drugs that have used the Ora-CAC System
- 30 years of study experience with over 500,000 CACs conducted
- Dedicated full-time allergy team repeatedly conducting CAC studies throughout the year
- Prior conduct of Ora-CAC with Japanese Mountain Cedar pollen in the US in Japanese-Americans to support registration package for olopatadine in Japan

Operations

- Block enrollment of subjects, which is necessary to ensure both the precision of the model and efficient timelines
- Site management support by Ora's expert CAC Team on the ground at every study visit for all sites and subjects
- Developed and implemented SOPs

Proper Study Design

- Novel proprietary variations of CAC model within the Ora family of Allergy Models to match MOA of new drugs and the next generation of ocular allergy treatments
- Selection of proper model and study design to match the drug

Proper Scales and Endpoints

- Use of proper clinical scales and selection of the right timepoints
- Internal validation of CAC model within every study prior to subject enrollment

Precision of the Model

- Very high reproducibility
- Demonstration of repeated correlation between efficacy in CAC and environmental studies with efficacious studies
- Ability to demonstrate efficacy versus placebo, and sensitive enough for dose ranging and showing potential differentiation from existing marketed products

Allergen Standardization

- Procurement of proper allergen, proper grade and standardized, accepted formulations
- Standardized solubilization and formulation procedures
- Proper titration to sufficient levels to drive drug effect, but to avoid respiratory problems
- Standardized SOPs and regular training on safety procedures
- Allergen formulations made fresh daily by trained Ora staff for every study visit and site

Regulatory

- Ora-driven regulatory support and acceptance
- Full integration of clinical-regulatory strategy