Creating vision beyond what we see

Ora Mobile Allergen BioCube®

The Ora Mobile Allergen BioCube® (mABC) is a state-of-the-art allergen exposure chamber for the controlled, safe, and uniform release of allergens, providing increased precision and higher quality data-sets.

Why the Ora mABC® is the best exposure chamber in clinical research:

1. It provides the advantages of an environmental clinical trial while conducted in a controlled setting.
2. The uniform pollen delivery system and precise individual allergy sign and symptom severity scales reduce data variability, resulting in lower required sample size, fewer sites, and a more robust dataset.
3. The mABC® platform leverages Ora's large investigator site network and study subject databases.
4. Small size (5 subjects/time) allows for rapid, precise, and comprehensive (both subjective and objective) assessment of of subjects exposed to different types of allergens at different sessions.
5. Accepted FDA environmental model to evaluate the efficacy of novel therapeutics for allergic conjunctivitis (AC), allergic rhinitis (AR), and asthma. Study specific endpoints are highly adaptable based on the disease indication.

Above: *The Ora Mobile Allergen BioCube Fleet.*

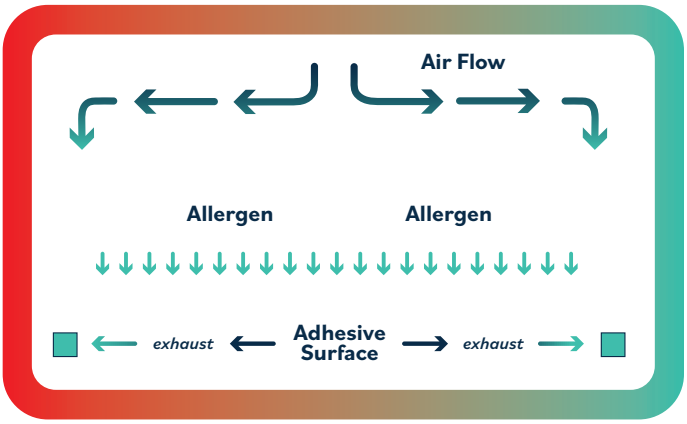
Above: *Subject set up in the Ora mABC® versus large "stadium seating" competitors.*

Traditionally, clinical studies of AC, AR and asthma have been conducted during the pollen season under natural environmental conditions, often using field studies in which patients are exposed to allergens in an outdoor setting or in a large stadium style setting with up to 100 subjects at a time. These studies have undeniable limitations, including variability in allergy concentration and types between sites and single locations, and are weather and season dependent.

In order to evolve beyond the limitations of classic allergy studies, Ora transformed a clean room into a controlled allergy environment, the Ora mABC®. The validated mABC® utilizes a real-time laser detection system and Rotorod particle collection to deliver a pre-determined aeroallergen concentration to patients, resulting in consistent clinical results[1-3].

The small size of the mABC ® provides clear advantages in allergy clinical trials over larger traditional “stadium seating” models.

- Mobile model can travel to any clinical trial site in the country - ensuring geographic distribution of patient population.
- Investigator to collect objective data on each subject, not just composite symptoms as is done in large classic chambers.
- Nasal objective measures: nasal mucosa swelling, nasal discharge, Peak Nasal Inspiratory Flow (PNIF), and sneeze counts.
- Lung function objective measure: Forced Expiratory Volume (FEV1).
- Ocular objective measures: eye redness and swelling.
- Prompted time stamped e-diary (Ora EyeCup™ powered by SDC Capture) allows real-time collection of individual symptoms.



Above: *The mABC® can accommodate up to 5 subjects and qualified clinical staff. The distribution system transports the allergen in a pre-determined rate and volume and mixes it with HEPA-filtered air. The allergen/air mixture is radially distributed into the top of the room using laminar flow. Air is recaptured by return ducts that are flush with the floor along the perimeter of the room, HEPA-filtered, and returned for recirculation.*

Ora’s Allergic Expertise Profile

Proven track record of supporting partners in the approval of 23 anti-allergic therapeutic products from FDA, EMA, and PMDA over the past 45+ years. [4-10]

Extensive and experienced allergy trial site network with large detailed patient databases. We are able to refine searches by disease and allergen sensitivity.

The intimate small design and uniform pollen delivery system of the mABC® coupled with the precise standardized individual sign and symptom severity scales will continue to mold the future and efficiency of allergy clinical trials. Additionally, the mABC® endpoints are highly adaptable to sponsor specific studies based on the disease indication (AR, AC, or asthma). Partners who use the mABC® for their clinical trials will experience reduced data variability leading to a lower required sample size, fewer sites, and a more robust data set.

References

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Ora

Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora’s 45+ years of experience, the company has assisted in bringing more than 85+ products to market. Ora’s team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.