

# The Next Generation of Mobile Environmental Exposure Chamber™ Systems for Allergy & Asthma Trials

"Inflamax Research's EECs are extraordinary clinical research tools that allow an unprecedented level of control in allergen exposure which leads to definitive clinical outcomes that are difficult to achieve utilizing the traditional field-based approach."

Dr. Piyush Patel, Founder & CEO, Inflamax Research



Figure 2.0. Inflamax Research's electronic Patient Data Acquisition Tablet (ePDAT) allows instantaneous symptom score collection in the Mobile EEC and real-time data capture.

## Inflamax's Mobile Environmental Exposure Chamber™ Technologies

The team at Inflamax Research has years of expertise studying allergic rhinoconjunctivitis and asthma using both traditional field and EEC models. We have developed and validated the Mobile EEC technology and have lead the development of perennial allergy models such as aerosolized cat and dust mite allergens. The airflow within the Mobile EEC is engineered to suspend and thoroughly mix airborne allergens. Our fixed EECs are state-of-the-art clinical facilities that tightly regulate temperature and humidity while simulating the level of allergen exposure patients would encounter in their everyday lives. By monitoring patients throughout the exposure, nasal, bronchial and ocular symptoms and signs, such as those consistent with allergic rhinoconjunctivitis may be evoked consistently and safely.

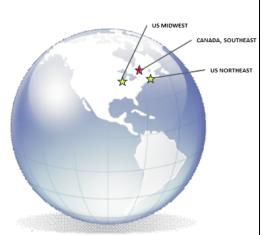


Figure 1.0. Inflamax Research Next Generation fixed EECs are validated for both perennial and seasonal allergens and can accommodate cohorts of up to 50 patients.

Important advantages include: 1) Controlled, consistent allergen exposure such that study failure due to low seasonal pollen release is prevented; 2) Inclusion of <u>only</u> those patients that demonstrate adequate allergy symptoms. This is important since traditional criteria such as skin prick and RAST do not accurately predict clinical symptomology; 3) Allows the study of seasonal allergies year round during the winter when interfering allergies can be minimized as is critical for allergen-specific Immunotherapies; and 4) Facilitates virtually 100% patient compliance since patients are prompted to complete their questionnaires or to have objective measures taken at regular intervals which provides an instantaneous read of patient allergic response status. Inflamax has developed a customizable electronic Patient Data Acquisition Tablet (ePDAT) for use in allergy trials (shown in Fig. 2.0, left).



Figure 3.0. Inflamax Research's Mobile EEC System



A sample of allergen 'hot spot' mapping for identification of Mobile EEC locations and Inflamax Investigator Network Planning. Population and allergen phenology are considered to plan ideal Mobile EEC locations.

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#### The Mobile EEC System

Inflamax's **Mobile EEC System** is a proprietary system (*patent pending*) built on the same principles and validated to the same exacting standards as our fixed EECs (see Figure 3.0, left). Our innovative technology allows for EEC mobility such that EECs can be strategically positioned anywhere in the world to facilitate costeffective and timely recruitment of key investigator sites and target patient populations. They allow us to conduct the same Allergic Rhinoconjunctivitis EEC studies in a multicenter approach. Our Mobile EECs can combine the best of single center EEC trials and the traditional multi-center field trial to control environmental provocateurs whilst allowing the recruitment advantage of gaining access to more patients, respectively.

#### Some Advantages of the Multi-center Mobile EEC System Approach:

- Identically validated and standardized EECs which operated to the same GCP operating procedures.
- Ability to take the Mobile EEC System where the patients are located reduces the risk of recruitment failures
- Controlled allergen exposure allows for:
  - Well-screened and randomized patients who are truly allergic and symptomatic
  - o The ability to conduct the trial year round.
- Access to experienced and proven Investigators in Inflamax's Allergy Network of Investigators.
- Centralized call-in center which will allow for patients to call in and be directed to their nearest Investigator and Mobile EEC System location.
- Ability to perform a hybrid study in which patients are studied both in the EEC as well as at-home. Inflamax's ePDAT system is used seamlessly across the EEC and in the field.

### **Customized EEC Study Designs**

Our experts will work with you to develop a study design to ensure that product development objectives are met and that inclusion and exclusion criteria assess the target allergy population required. Inflamax has conducted in depth research into the factors which influence the timing and extent of environmental seasonal pollen release as well as the known prevalence of allergy subtypes in North America and Europe. Perennial allergies to house dust mite, and pet dander such as cat and dog are also influenced by climatological factors. Recent climate change factors and historical allergen release data are combined in Inflamax's Allergen Phenology Database which allows us to provide informed recommendations on the placement of Mobile EEC Clinical Nodes and satellite investigator sites. A customized mobile EEC map can be developed to meet the specific recruitment needs of your study (*at left*). A recruitment plan is developed to enable successful recruitment and timely study completions.

Contact Inflamax Research today to discuss your drug development program and how our Next Generation of Mobile EECs can help improve your study efficiencies.