

The Environmental Exposure Unit (EEU)

EEU The Environmental Exposure Unit
UNMATCHED EXPERTISE FROM THE LEADERS IN ENVIRONMENTAL EXPOSURE UNIT TECHNOLOGY SINCE 1988. www.eeu.on.ca

Innovators in Allergy Research
Bringing the outdoors...indoors.

Research
Interested in conducting a study at the EEU?
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Difficulties in Conducting Rhinitis Trials

Key Issues:

- ◆ subjects with multiple allergic triggers
- ◆ recruitment of asymptomatic / mild rhinitis subjects
- ◆ subjective symptom scoring
- ◆ inter- and intra-individual variability of allergen exposure
- ◆ difficulty in estimating peak of pollen season (site differences)
- ◆ wide variety of study designs (endpoints, durations, data analysis)

Environmental Exposure Unit (EEU)

- ◆ first described in the 1980s
- ◆ specially designed room to host study participants in a controlled environment

Concept:

uniform exposure to controlled levels of allergen enables an accurate analysis of treatment efficacy without the variables inherent in traditional studies

- ◆ control of air flow and quality, temperature, humidity, [CO₂], allergen type/concentration
- ◆ all subjects exposed to the same predetermined concentration of allergen for the duration of the study period

→ highly reproducible results

Day JH and Brozice MP. Ann Allergy Asthma Immunol (1999) 83:89-93.

Environmental Exposure Unit (EEU)

Kingston General Hospital, Kingston, ON CANADA



- ◆ Capacity: from 10-140 subjects (303 m²)
- ◆ Pollen: 3500 ± 500 grains/m³



Environmental Exposure Unit (EEU)

- ◆ year-round capability / weather independent
- ◆ predetermined and consistent pollen exposure individually and between cohorts
- ◆ consistent levels confirmed by documented pollen counts
- ◆ controlled environment, pollen species and antigenicity
- ◆ subjective/objective measures – reproducible results
- ◆ short term and long term studies

Draft FDA Guidance Role for EEU Studies

Draft - FDA Guidance for Industry Allergic Rhinitis: Clinical Development Programs for Drug Products

Re. Onset of Action

"An inhalation chamber study (also known as environmental exposure unit or EEU) in which previously asymptomatic patients are exposed to a relevant allergen (generally a seasonal allergen, such as ragweed) in a controlled indoor setting and, following dosing, have their nasal symptoms evaluated on an hourly basis."

Re. SAR Prophylaxis Trials

"Performance of an EEU study may address the adequate prophylaxis period for a seasonal allergen."

Guidance for Industry

Allergic Rhinitis: Clinical Development Programs for Drug Products
DRAFT GUIDANCE

The guidance document is being distributed for comment purposes only. Comments should be submitted to the Center for Drug Evaluation and Research, Division of Allergy, Immunology, and Respiratory Diseases, Office of Biologics, U.S. Food and Drug Administration, 10155 Montz Road, Rockville, MD 20850. Comments should be received by the date indicated on the cover page.

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Food and Drug Administration
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<http://www.fda.gov/cder/guidance/2718dft.pdf>