**The 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, \([\text{CO}_2], \text{allergen type/concentration}\)
- all subjects exposed to the same predetermined concentration of allergen for the duration of the study period

highly reproducible results

**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

**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)**

- Kingston General Hospital, Kingston, ON CANADA

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

**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."

CDER April 2000