Mobile Natural Exposure Chamber™ Technology Standardizes Controlled Environmental Exposure Chamber Challenges Across Multi-Center National and International Allergy Trials

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Abstract

Rationale: Traditional static allergen challenge chambers provide controlled allergen exposures which improve patient selection and reduce symptom variability; however, they cannot be utilized in multi-center trials due to limited/exclusive availability, fixed locations and fundamental operational differences. To meet this need, we designed a mobile Natural Exposure Chamber (NEC).

Methods: Novel mobile NEC technology utilizes advanced anti-static surfaces and engineering to provide a transportable NEC that is deployed within hours in any suitable location proximal to investigator sites, and seating up to 50 patients. The pollen of interest is aerosolized to mimic natural patient exposures whilst providing a controlled and consistent allergen exposure which is validated spatially and temporally, accomplished by the integrated mobile Environmental Control Unit (ECU).

Results: After manufacture, NEC installation, operation and performance qualifications are performed at the central site. The NEC is transported to the clinical site and set-up and configuration occurs within hours. Minimal on-site validations are required prior to utilization in study setting. Deployed mobile NECs are operated to centralized, standardized operational procedures and personnel. 21CFR11 compliant computer control systems integral to the ECU allow for centralized operation and archiving of environmental conditions across all NECs within the NEC network.

Conclusions: The mobile NEC provides the technology necessary to enable the clinical advantages of controlled allergen exposure to be realized across multiple national and international sites in multi-center allergy trials. This will improve the sensitivity and specificity of allergy drug testing and constitutes a considerable advancement in access and conduct of controlled clinical trials.

Introduction

Traditional fixed allergen challenge chambers provide controlled allergen exposures which improve patient selection and reduce symptom variability[1]; however, they cannot be utilized in multi-center trials due to limited/exclusive availability, fixed locations. Fundamental operational differences like chamber specifications and tolerances, SOP's make utilization of different locales too variable. FDA has stated it requires EEC standardization, geographic diversity and avoidance of single site bias. To meet this need, we designed a mobile Natural Exposure Chamber (NEC).[1,2]

A mobile NEC enables easier recruitment of specific populations, reduction of timelines and costs as well as a effectual capacity to run allergen environmental exposure visits with as little variance as possible while incorporating all of FDA requirements. Studies can be performed throughout the year regardless of locale nor season.

Methods

Novel mobile NEC technology utilizes advanced anti-static surfaces and engineering to provide a transportable NEC that is deployed within hours in any suitable location proximal to investigator sites, and seating up to 50 patients. The pollen of interest is aerosolized to mimic natural patient exposures whilst providing a controlled and consistent allergen exposure which is validated spatially and temporally, accomplished by the integrated mobile Environmental Control Unit (ECU).

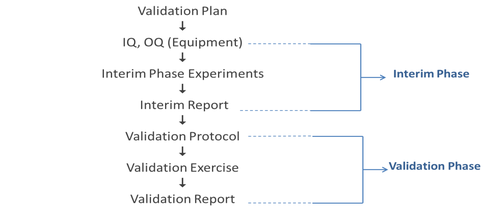
Figure 1. Inflamax's patented Mobile Environmental Exposure Unit (MEU)™ with environmental controls of temp, Rh and allergen

The Mobile EEC Advantages

Regulatory	• Multi-center studies eliminate potential single center bias • Diverse populations in different geographic locations/jurisdictions • Allows specific KOL's to be part of EEC studies
Operational	• Easier to recruit and reduced cost/stipends • Controlled allergen exposure regardless of season • Allows expansion of EEC locations if recruitment proves difficult mid-study • Capacity increased, not limited to fixed seating capacity
Patient populations	• Access to treatment naive populations • Access to pre-determined databases
Client needs	• Study timelines & costs predictable • Allows studies in geographic areas preferred by client: eg Europe consortium, Japan consortium

Results

After manufacture, NEC installation, operation and performance qualifications are performed at the central site. The NEC is transported to the clinical site and set-up and configuration occurs within hours. Minimal on-site validations are required prior to utilization in study setting. Deployed mobile NECs are operated to centralized, standardized operational procedures and personnel. 21CFR part 11 compliant computer control systems integral to the ECU allow for centralized operation and archiving of environmental conditions across all NECs within the NEC network. The mobile EEC is validated to the same exacting standards as fixed EECs utilizing the process outlined in Figure 2.0 below.



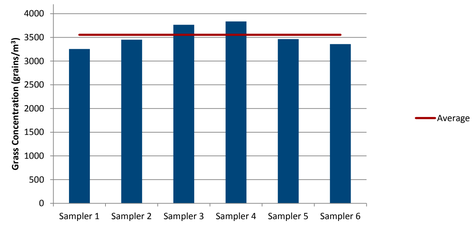


Figure 3. Spatial Uniformity of Allergen Aerosolization. Validation of the MEU parallels effective aerosolization of allergen in the fixed chamber spatially across the room over 3 hours.

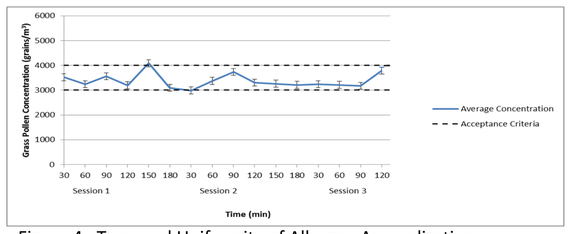


Figure 4. Temporal Uniformity of Allergen Aerosolization. Validation of the MEU parallels effective aerosolization of allergen as seen in the static chamber temporally across 9 hours.

Results

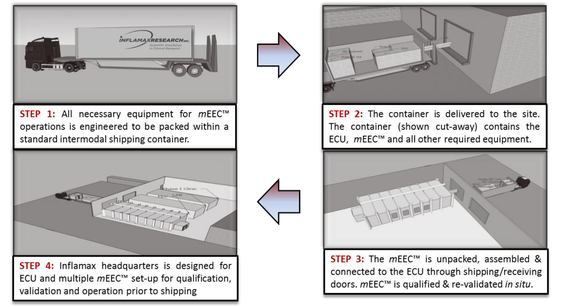


Figure 5. Top: Steps to mobile NEC transport and assembly. Bottom: Geo-positioning of mobile NEC.

Conclusion

The mobile NEC provides the technology necessary to enable the clinical advantages of controlled allergen exposure to be realized across multiple national and international sites in multi-center allergy trials. This will improve the sensitivity and specificity of allergy drug testing and constitutes a considerable advancement in access and conduct of controlled clinical trials.

References

1. Salapatek A. Benefits of EEC Model to Clinical Research. FDA Advisory Panel, Allergenic Products, May 2011.

2. Rabin R. Environmental Exposure Units for Phase III Studies. FDA Advisory Panel Allergenic Products, May 2011.

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