

Development of a United States Pollen Sampling Network

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Rationale

Measurements of airborne pollen concentrations are essential data inputs for the evaluation of efficacy in phase III pollen allergy studies. They are used to define the pollen season(s) during which the primary endpoint data is collected and evaluated. The Burkard Spore Trap (BST) is considered the gold standard in the European Union. In the United States (US), the greater majority of pollen traps used are Rotorods. The goals of this project are to:

- Establish a network of BSTs across the US to support clinical studies
- Establish a system to install BSTs, train users to operate and maintain the BST, and to prepare BST samples
- Establish a centralized BST sample processing and shipping facility
- Establish a centralized BST sample analysis facility



Burkard Spore Trap (Photo courtesy of Burkard Manufacturing Co, Ltd)

Methods

In the context of a clinical trial, clinical site feasibility questionnaires and pre-study interviews/visits were conducted across the northern half of the US, in which information about local pollen traps, pollination patterns, and/or external pollen data providers was collected. Additionally, a set of host site acceptability criteria was developed to facilitate selection of BST host sites for the Pollen Sampling Network. Acceptability criteria included:

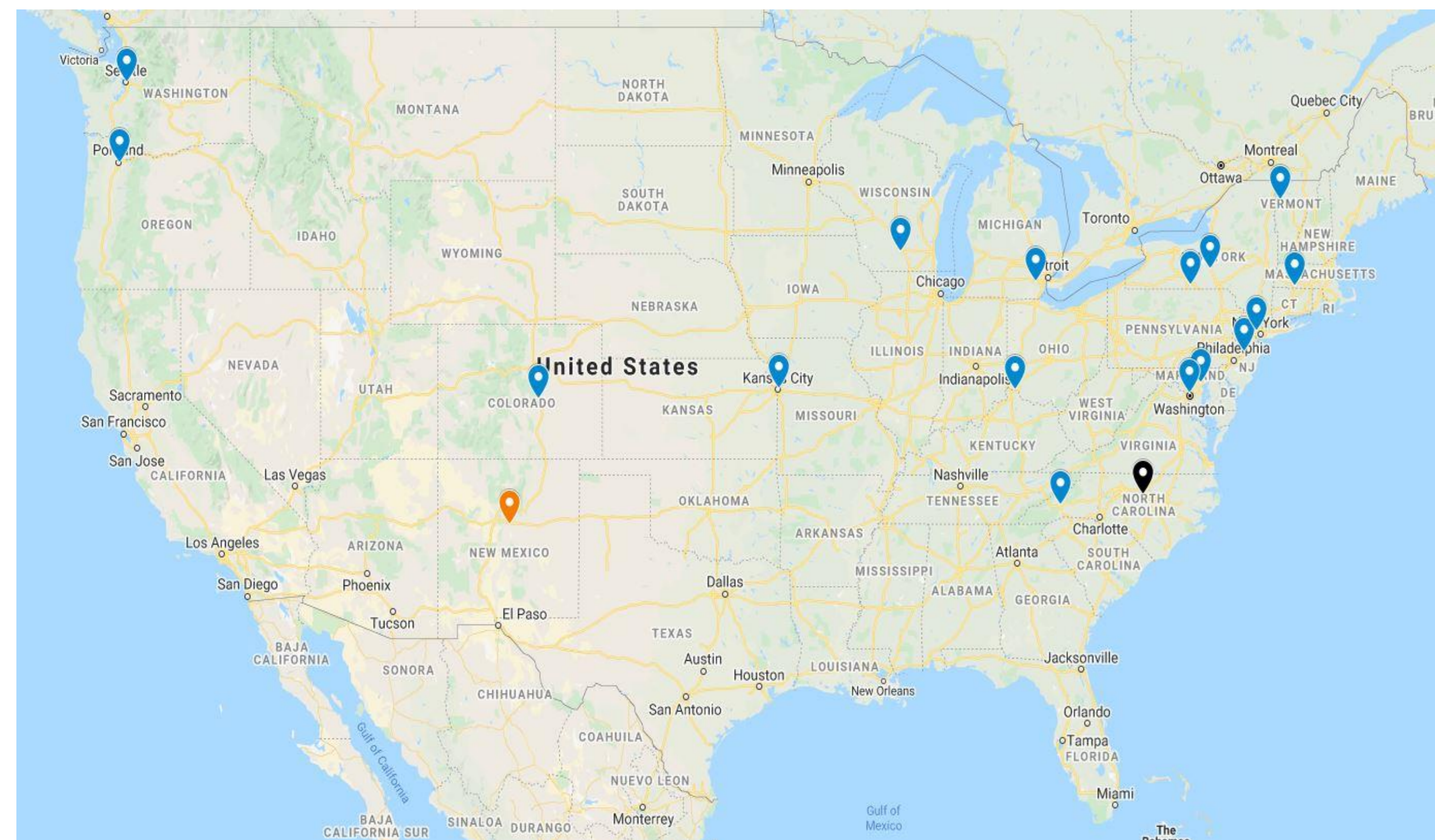
- The host site should be located at or within 100 km of the participating Clinical Investigator facility selected for a grass allergy study
- The BST should be located on a flat, horizontal surface 9 m to 18 m above ground level
- There should not be any overhanging vegetation near the BST
- Direct air flow to the BST should not be obstructed by nearby buildings or other structures

Study Specific Procedures were developed, in accordance with Levietin¹, to be used by BST host sites.

- J151-001 Setting Up A Burkard Spore Trap
- J151-002 Preparation, Mounting, and Unmounting of the BST 7-Day Sampling Drum
- J151-003 Creating Microscopy Slides From Burkard Spore Trap Samples

Two corporate entities were engaged for discussions concerning the development of a centralized BST sample handling and shipping facility. Three organizations were engaged for discussions concerning the development of a centralized BST sample analysis facility and methods to improve the reliability and reproducibility of pollen identification and counting.

Results



- Asheville, NC
- Baltimore, MD
- Bethesda, MD
- Cincinnati, OH
- Colorado Springs, CO
- Corning, NY
- Cortland, NY
- Kansas City, MO
- Madison, WI
- Portland, OR
- Seattle, WA
- South Burlington, VT
- Springfield, MA
- Trenton, NJ
- Verona, NJ
- Ypsilanti, MI
- Chapel Hill, NC
- Moriarty, NM

City	State	Latitude	Longitude
Asheville	NC	35.53913	-84.8069687
Baltimore	MD	39.2848182	-76.6907084
Bethesda	MD	38.9816741	-77.1536821
Cincinnati	OH	39.1364521	-84.6106131
Colorado Springs	CO	38.8258676	-104.8987871
Corning	NY	42.1480121	-77.0703751
Cortland	NY	42.6000583	-76.1950921
Hillsborough	NC	36.0786078	-79.168642
Kansas City	MO	39.0921167	-94.8559131
Madison	WI	43.0851588	-89.5465061
Portland	OR	45.5428679	-122.7944124
Raleigh	NC	35.946965	-78.644257
Seattle	WA	47.6131746	-122.4821495
South Burlington	VT	44.4677575	-73.7883682
Springfield	MA	42.1129465	-72.6163818
Trenton	NJ	40.2161138	-74.8092251
Verona	NJ	40.8836305	-74.206157
Ypsilanti	MI	42.2425949	-83.6417771
Chapel Hill	NC	35.9210777	-79.1093315
Moriarty	NM	35.0088512	-106.1015046

- 17 sites were identified that met the acceptance criteria to host a BST
- All sites signed a CDA and negotiations to place a BST are ongoing (blue map marker)
- A centralized sample handling and shipping facility was identified. A CDA was signed and contract negotiations are ongoing (yellow marker)
- A centralized BST sample analysis facility was identified. A CDA was signed and contract negotiations are ongoing (black marker)

Conclusions

This program has identified a standardized methodology to generate reliable and reproducible pollen data in the US.

The data will provide valuable insights and provide pollen season dates to support the evaluation of qualitative and quantitative clinical endpoints in exploratory phase III field clinical trials.