

**NEWSMAKERS**

**CLINIC**

Record breaking Period 1 subject dosing across all India locations – 350

**LATE PHASE**

In 2019, Cliantha faced 13 USFDA inspections, out of which 5 were for Neuropsychiatry and 4 were for 4 Dermatology for late phase trials.

**LAB**

**New methods**

- Paclitaxel (Protein-Bound Particles for Injectable Suspension – albumin bound)
- Doxorubicin (Liposomal formulations)

**New Initiatives**

- 10 successful methods developed and validated on 96 well platforms (Micro elution)
- Set up of in vitro analytical lab for service offerings next year

**PKBS**

- New services: Statistical analysis of Carcinogenicity studies, In-vitro dissolution, Population BE and assay stability

**Early Phase FIRSTs**



**Ahmedabad**

- First TQT study for an anti-diabetic molecule (Saroglitazar)
- First Biosimilar (Trastuzumab) infusion study with 60 subjects
- First DPI (Dry Power Inhalation) study

**Vadodara**

- Long Housing study of Octreotide injection in >200 subjects

**Software Launches**

**CodeLisa**

CodeLisa is new software which increases process efficiencies at various stages of bioequivalence studies. Currently, modules related to screening and pathology lab are in development phase.



- Web based software (access inside / outside Cliantha premises).
- Electronic IT admin system (system generated Email notification for user management, master management, role management, password policy and authentication process).
- Centralized database for Volunteers Registration through biometric (IRIS), Unique ID generation facility.
- Volunteer access across the location by shifting process.
- Maintain Volunteer track history, volunteer blocking to avoid cross participation.
- Dynamic facility to search volunteer by using different criteria.
- Multiple document upload facility.
- Dynamic report generation facility.
- View and export each and every activities audit trails.

**Colmtrack**

- Colmtrack helps in extending column life cycle.
- Helps in accurate column selection and speeds up method development
- Compliance with all major guidelines (CFR part 11)



**Cliantha Canada**

Currently 8 studies are going on.

- BA/BE: 4 in total - 1 pivotal and 3 pilots
- EEC: 2 Phase III EEC studies for ragweed allergy. One of them is for an ocular IP and the second one is for a nasal spray.
- Phase I: 1 SAD & MAD study, route of administration is first in human.
- Patch: 1 non-latex gloves allergy study.

**Consumer Research Milestones**

- 4 month HRIPT study completed with 240 enrolled subjects
- 3 baby studies have been conducted on [0 to 36 months] babies for Baby products
- Safety Evaluation of Synthetic Detergent using Hand Immersion Test
- Inter-Scorer Variability across the Cliantha Locations established across all Consumer research sites in India and North America with a 3 day Live Irritation Training Study by Qualified and experienced scorer, Ms. Maheshvari Patel
- 'Fibra.One' Instrument from DiaStron for evaluation of claims support for greater than 15 claims
- Dental study for Sugar free Chocolate to substantiate claim of "No Tooth Decay"

**First Phase III trial in EEC**

We have commenced the first Phase III trial to be conducted in Cliantha's Environmental Exposure Chamber (EEC) for the study of a novel drug, Reproxalap, for the treatment of allergic conjunctivitis. This is the first FDA approved EEC trial for Phase III.

For more information [click here](#)

**Conferences and Events**

**6th Annual Food Quality & Safety Congress**

Cliantha participation in 6th Annual Food Quality & Safety Congress on 28 November 2019 by Ms. Maheshvari Patel (Consumer Research) and Mr. Kandarp Thakkar (Business Development).



**WAC 2019**

Dr. Anne Marie Salapatek (Executive VP & Chief Science Officer) and Cynthia Day O'Brien (Sr. Director, Business Development) attended the World Allergy Conference (WAC) in Lyon, France on 12-14 December, 2019.

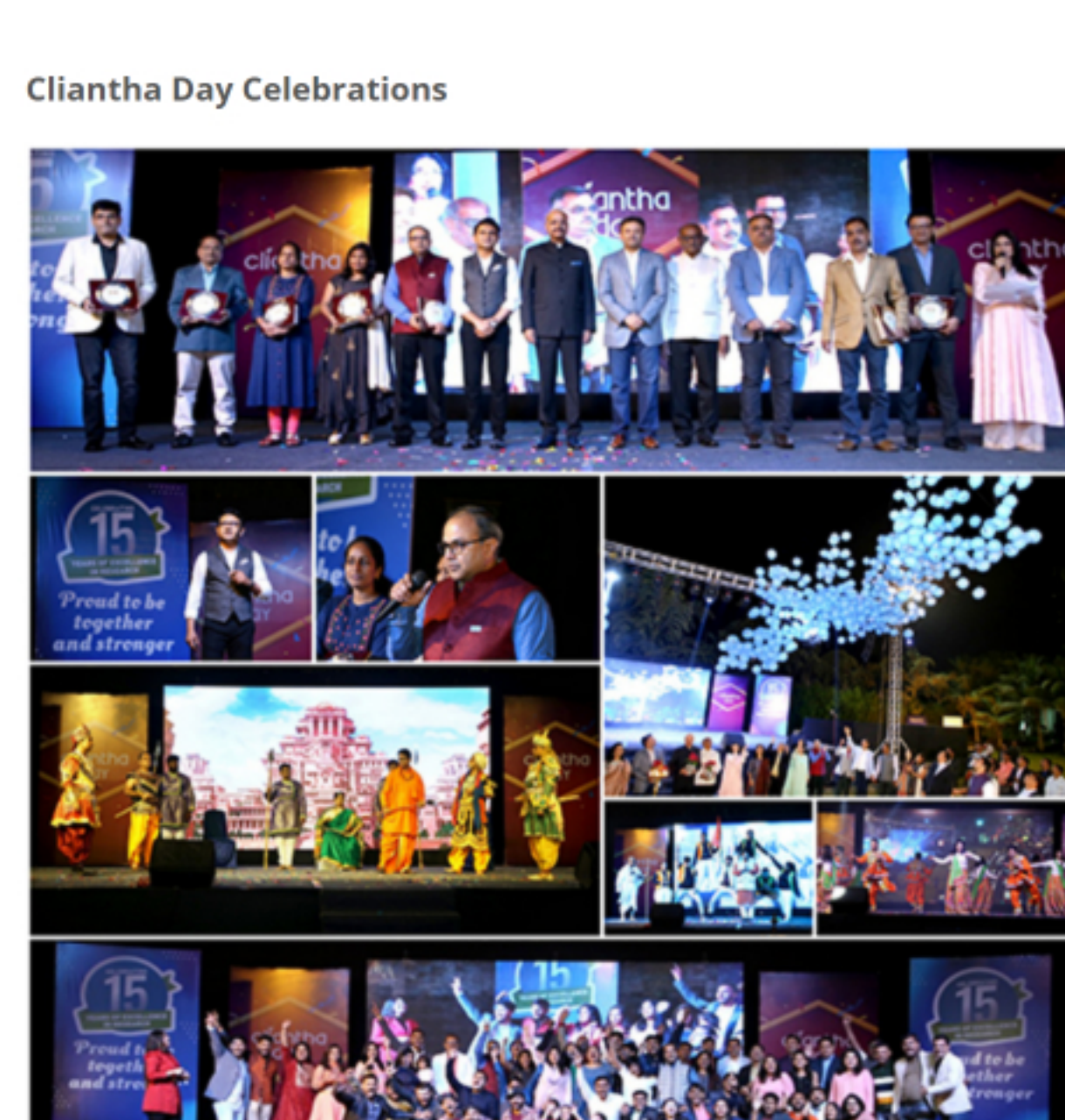


**Poster Presentation**

Dr. Anne Marie Salapatek resented the poster on "Characterization of self-reported pollen food syndrome (PFS) in birch and oak allergic subjects exposed to oak pollen in an Environmental Exposure Chamber (EEC) in Canada" at World Allergy Conference (WAC 2019) in Lyon, France on 12-14 December, 2019.



**Cliantha Day Celebrations**



**Christmas Celebration**



**Holiday party at Cliantha Mississauga!**

