veeda clinical research®

VEEDA UPDATES

Digitization at Veeda

- **Bureau Veritas** certifies **Veeda with ISO 27001:2013** and validates it's quality compliance of its Information Security Management System (ISMS) at par with international standards
- **E-Registration of volunteers using Cronos** - completion of clinical module is expected by March 2020

Regulatory Audit in 2018-19

- Total number of audits by **FDA** at our Clinical trial Investigators' sites: 17
- Successful in-house and site auditing by independent external auditor
- Cleared **2 patient** trial inspection with **No 483** by USFDA since Aug 2018.
- Zero FDA 483 observations by any of the 3 USFDA inspections in August 2019
- Successful Inspection by **NPRA** and **WHO** with closure letters
- **ANVISA** inspection in 2019 concluded with no observations
- Approval of a new clinical facility at Mehsana with validity until 2024 by CDSCO

Special studies conducted since Aug 2018

- 4 Inhalation studies
- Performed 2 Patch studies
- 4 BE study with Long housing of volunteers (>1 week)
- 1 Long acting injection BE study with high sample size
- 3 Geriatric studies
- 1 Post-menopausal women study

Average patient dropout ratio has been around 2%, the main reason being subjects not reporting to the facility.

Expansion of clinical infrastructure

New state-of-art clinical facility at Mehsana, Gujarat comprising of four clinics, a pharmacy and archive facilities.

Patient studies - Updates

- **Database of Investigators:** Over 1100 investigators with expertise in varied therapeutic areas
- Enrollment of more than 200 patients during Aug 2018 to Sep 2019
- Completion of two liposomal doxorubicin studies, one long-acting injection study for risperidone, and one capecitabine oral product study
- 8 ongoing studies in different trial phases in therapeutic areas such as oncology, psychiatry, cardiology, and gynecology

Development of complex assays in Veeda's bioanalytical laboratories

- Incurred Sample Reanalysis (ISR) passing ratio of 98.1% for 245 projects from September 2018 to August 2019
- Developed methods for Salmeterol, Amphotericin (Free and Liposomal), Levosalbutamol, Ipratropium, Thiamine, Doxorubicin (Free and Liposomal)

Training & Development Programs

- **Workshop on "Scientific and Medical Writing"** that includes honing of technical/scientific writing skills and basic grammar skills for all medical writers
- **Development of an in-house application called 350 interactive e-Module** using in-house standard operating procedures (SOPs) to enable online e-learning/training through LMS
- **Interactive workshop on "Root Cause Analysis"** by external industry experts to bolster qualitative research, brainstorming, and problem solving

Institutionalizing the "Quality First" mindset at Veeda

Monthly Quality Review Meetings (QRMs) that focus on:

- QA audit observations and trend analysis for compliance evaluation
- Corrective and Preventive Actions (CAPA) and assessment of effectiveness
- Identification of additional improvement areas

Open and transparent reporting of any issues, deviations, or errors from all levels of the organization is encouraged irrespective of hierarchy.

Veeda's Vision Ahead

- Augmenting our scientific skills in conducting complex studies
- Pursuing inorganic growth opportunities in core markets to expand our range of services to cover drug development programs of existing clients

Frost & Sullivan Recognized Veeda Clinical Research as "The Clinical Research Organisation of the year 2019"