

First to File Study

“Quality Results”
in a record
period of 12 days



Situational Analysis

A U.S. based pharmaceutical company that specializes in development, manufacturing, and distribution of niche generic products was planning ANDA submission of a drug having a close by patent expiry. The sponsor approached Veeda for the execution of entire clinical trial process.

The study is one of its kind “First to file “, as it gives 180 days exclusivity to the first applicant on successful submission of ANDA. As a CRO, Veeda had the responsibility to deliver quality outputs within stipulated time period, under challenging circumstances imposed by COVID-19 globally.

Highlights of Results Delivered

Analyzed
**3700
samples**
per study within
15 hours

Submission of
the CSR to QA
was done within
38 hours

Delivered
Quality Results
within a short span
of only
12 days

Challenges

There were major challenges faced by the Project management, Clinical & Bio analytical teams at every stage starting from shipment of RLD to dispatching of final report:



Project Management Challenges

In first to file studies the timelines are always very tight. The very first challenge was to closely keep an update on the launch of RLD date. Getting approval from local authorities to conduct the study with a large sample size. Ensuring functioning of logistics amidst challenging cross border movement situation



Clinical Challenges

Training of staff under COVID-19 situation, housing large number of volunteers & intense monitoring of the dosing process



Bio analytical Challenges

Successfully completing the sample analysis without affecting the other ongoing studies. Optimising the utilization of LC-MS machines, in accordance with various changes in process planning due to delayed arrival of Plasma Samples

Action Plan

- 1.** Entire team of Doctors, PMs & Project Coordinators were tirelessly working on emergency response strategies to ensure the timeliness delivery of results
- 2.** We conducted this study at our Mehsana facility to ensure safety of our volunteers and employees, as Ahmedabad was going through a tough COVID situation. We were granted study conduction permission after a thorough inspection of the entire facility
- 3.** Staff to volunteer ratio was kept 1:1 in order to avoid any delays/error in dosings. Clinical team made sure they had a backup of volunteers in case of any adversities. All the volunteers were screened before time, the team also ensured the screening and readiness of back-up volunteers in order to have a smooth clinical and dosing process

4. A new SOP (Standard Operating Procedure) was designed to keep all COVID-19 safety measures in place, online staff training was done before hand to ease the strict timelines pressure
5. Veeda provided additional housing of one day to all its volunteers. As the RLD shipment got delayed by a day, the team had to go extra miles in order to avoid any volunteer drop out at the last moment
6. The Bio analytical planning also had to be changed and improvised thrice in terms of sample transfer to other facility, sample receipt, usage of Watson LIMS software, sample retrieval, and sample processing, equipment utilization and man power planning due to delayed arrival of plasma samples. The Bio analytical team was extremely prompt in terms of coming up with quick solutions for maximum utilization of LC-MS machines, without affecting the other ongoing studies
7. Bio analytical Method was redeveloped in advance to test two different analytes at the same time. 25 machines at two different facilities were used to complete sample analysis within stipulated timeline. Analysis was performed with maximum accuracy which is evident with ISR results of more than 98% and repeat of around 2% for both analytes
8. Bio analytical study report was prepared within 12 hours after completion of study analysis with immense coordination among Project manager-Bio analyst-Custodian-Bio analytical quality monitor-Watson LIMS team-Report writing team and quality assurance team

Results

- Completed the sample analyses of around 3700 samples per study within 15 hours of the receipt of the samples at the laboratory
- The compilation of the clinical data, review and submission of the CSR to QA was done within 38 hours of the completion of the last sample collection
- We were able to complete the statistical analysis and prepare the draft report within 24 hours .Even the CDISC report was compiled in 36 hours
- Veeda was ahead of timeline in terms of meeting sponsor's expectations. Sponsor expected the report dispatch within 14 days from the dosing (Quoted by one of our PMs), against which we were able to deliver quality results within a short span of only 12 days. We believe in going extra miles to exceed our customer expectations & deliver quality results on time