JUBILANT CLINSYS

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CASE STUDY OVERVIEW

Customer Focus
Data Management
External Collaborations
Rapid Turnaround Time
Team Approach

CASE STUDY: DATA MANAGEMENT

"*Meeting Customer Needs and Timelines*"

NEED

- Dermatology trial conducted in India with over 50 sites and 1200 subjects.
- Jubilant Clinsys was contracted to perform database design and validation, full data management, biostatistics and eCTD compliant CSR submission activities for the client.
- Clinical and safety monitoring activities were conducted by a different CRO.
- Extremely aggressive timelines since the client wanted to submit the FDA application before end of the year.
- Several of the sites did not have wired internet connectivity and had to access TrialStat via wireless networks

APPROACH

- Jubilant Clinsys functional teams collaborated very closely with the other CRO at the study startup phase.
- Robust IT support ensured that any site issues related to connectivity were resolved promptly.
- Critical study reports were identified and made available to the study team via TrialStat.
- Rapid setup times with the TrialStat database enabled Jubilant Clinsys to present a working prototype of the study database at the Investigators Meeting.
- Database changes necessitated as a result of protocol amendment were implemented swiftly with negligible down time to the sites.
- Bookmarking and hyperlinking capabilities had to be developed in-house by the Jubilant Clinsys data management team.

BENEFITS

- Critical study reports were instrumental in keeping the internal teams, other CRO and the US based sponsor well informed with all processes being transparent.
- Data tracking, cleaning and database lock occurred as stated in the timelines.
- All corresponding activities following database lock proceeded smoothly and with requisite quality
- Sponsor submitted the FDA application as stated in their timelines
- FDA audited five of the study sites in India with no findings or citations

ABOUT JUBILANT CLINSYS

Jubilant Clinsys Inc. is a global, scientifically focused contract research organization that provides pharmaceutical, biotechnology and medical device companies with a full range of services in support of Phase I – Late Phase drug and device development. Founded in 1992, the company is a subsidiary of Jubilant Life Sciences and a fully integrated partner with Jubilant Biosys and Jubilant Chemsys. Jubilant Clinsys has regional offices in Bedminster, New Jersey, USA; Raleigh, North Carolina, USA; Ottawa, Ontario; Canada; Noida and Bangalore, India; and Düsseldorf, Germany.

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