



# JUBILANT CLINSYS

JubilantClinsys.com

## CASE STUDY OVERVIEW

- Customer Focus
- Data Management
- Global Processes
- Rapid Turnaround Time
- Team Approach

## ■ CASE STUDY: DATA MANAGEMENT

### "Global Data Consistency"

### NEED

- Dermatology trial conducted in US, Belize and India with over 25 sites and 800 subjects.
- Jubilant Clinsys was contracted to perform database design and validation, full data management, eCTD compliant CSR submission, US and Belize clinical and medical monitoring activities for the client.
- Clinical and medical monitoring activities for India were conducted by a different CRO.
- Extremely aggressive timelines were implemented since the client wanted to submit the FDA application before end of the year.
- Subject completion windows were spread out widely as site activation occurred at different time points in the study across the three participating countries.

### APPROACH



- Jubilant Clinsys operational teams worked closely with their counterparts at the other CRO ensuring smooth progress at all stages of the study.
- Wide array of real time study reports within TrialStat were identified.
- Projection of study completion dates enabled the Jubilant Clinsys teams to model a staggered database lock scenario across the three countries.
- Protocol deviations and granting of protocol deviations needed to be standardized across the three countries.
- Coding of Medical Histories, Adverse Events and Concomitant Medications had to be consistent globally.

### BENEFITS

- Real time study reports were paramount in keeping the global teams and the US-based sponsor informed of the dynamic study status.
- The final deliverable (eCTD complaint CSR) was delivered to the sponsor as per the study timeline.
- Sponsor submitted the FDA application as identified in their timelines.

### 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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