



## PROVIDING MANPOWER TO SPEED UP PHASE 2 OF CLINICAL TRIAL



### THE CLIENT

The end customer is a multi-billion dollar Pharmaceutical company with 6,000+ employees.



### BUSINESS NEED

The customer wanted to speed up the analysis process during the Phase 2 of the Clinical Trial phase for a cancer medicine. With 180+ participants, the trial is expected to run across the US region. It involves collection of data from participants to assess dosing and efficacy of the new intervention. The challenges in this process include:

- To identify and engage experienced resources who can analyze and generate clinical reports for FDA submissions
- To generate reports to obtain additional safety data to obtain FDA and EMA approval



### TECHNOLOGY USED

- SAS Drug Development
- SAS/BASE, SAS/GRAPH, SAS/STAT
- FDA, CDISC, ADaM, 21 CFR Part 11



### SOLUTION DELIVERED

AL TEN Calsoft Labs with experience in identifying consultants for a specific study helped in identifying the suitable candidates. We also engaged trained and internal pool resources within few days of signing the SOW. Key highlights of this engagement includes

- Ramped up resources from 2 to 23 within 2 weeks
- Conducted 125+ interviews within 2 weeks and on boarded 9 candidates in a short time
- Trained consultants on CDISC standards to become aware and follow the trial process



### BUSINESS BENEFITS

- Deliver better services by providing consultants on time
- Lower cost yet skilled resources helped saving project cost
- Improved joining rate and stable resources in the engagement

### ABOUT AL TEN CALSOFT LABS

AL TEN Calsoft Labs is a next gen digital transformation, enterprise IT and product engineering services provider. The company enables clients innovate, integrate, and transform their business by leveraging disruptive technologies like mobility, big data, analytics, cloud, IoT and software-defined networking (SDN/NFV). AL TEN Calsoft Labs provides concept to market offerings for industry verticals like education, healthcare, networking & telecom, hi-tech, ISV and retail. Headquartered in Bangalore, India, the company has offices in US, Europe and Singapore. AL TEN Calsoft Labs is a part of AL TEN group, a leader in technology consulting and engineering services.

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