# TEAMWORK AND INNOVATIVE IDEAS TRANSFORM RESULTS: CDARO CASE STUDY

A leading, global pharmaceutical company with no data management or statistics team engaged Covance to perform global data management and analysis for a Phase III study. The two-part study was to be completed over a multi-year period and included several hundred Chinese patients.

## Understanding the Challenge

- Complex study design with multiple external data sources and a third-party vendor responsible for database design
- No standard format for data management
- Multi-pronged communications loop with teams in Beijing, Shanghai, Sydney, Tokyo and the UK

## Exceeding Expectations Through Precision Delivery

To help facilitate better communication, create a forum to discuss concerns and address opportunities to improve study design, we instituted face-to-face meetings with our client and third-party vendor. We also created a better-defined project governance structure, including an issue-escalation process. Study progress was monitored through an issue-tracking log, as well as weekly project team meetings and a monthly report. This ongoing open and honest communication promoted an increased level of trust and a willingness to accept new ideas among the various stakeholders.

Creating insight from past experience, our global CDARO organization offered solutions to help ensure SOPs and global consistency. For instance, we compressed timelines and split the EDC buildup into multiple phases, including EDC submission and patient recruitment. We then advised using a CDISC data standard and implemented a modified data flow structure to fully integrate the data, including eCRF and external documents. Next, leveraging our experience in Asia Pacific and our understanding of local requirements, we recommended a data analysis structure that resulted in high-quality reports and no additional requests from the China Food and Drug Administration.

By working through the challenges together and establishing a robust communication process, our team was able to achieve database lock ahead of schedule and received NDA approval 11 months later. The decision to use a global CDISC standard was a departure for our client, who was initially reluctant to change their template. But by overcoming data integration barriers, our CDARO team was able to generate a high-quality statistical analysis. This enabled the NDA dossier to be reviewed by the China Food and Drug Administration much more efficiently and expeditiously.

Complex trials involve multiple people, places and processes that are not always easy to navigate. We can help by leveraging more than 30 years of clinical experience and data management expertise to reveal opportunities that drive results.

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