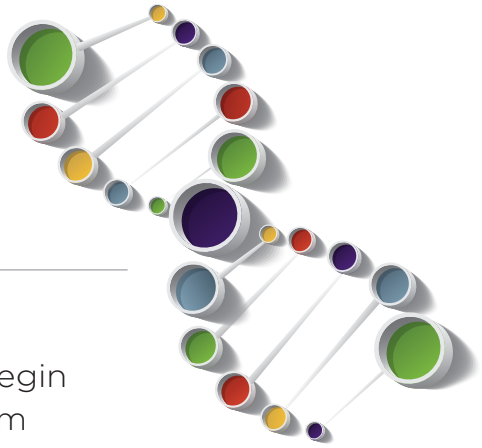
CASE STUDY

# Successful Transfer of Multiple Studies

## Enabled by Close Executive Engagement and Resource Planning



## BACKGROUND

PPD Biotech partnered with a mid-sized biotech company to begin transitioning 14 studies as a part of a multiple asset transfer from a large pharmaceutical company. Our approach resulted in successful transfer, significant improvement in data quality and a recent successful audit.

## OBJECTIVE

While working with the biotech client, as well as the company from which the assets were being transferred, we were tasked with planning and executing an efficient transition, while ensuring quality and completeness of data transferred.

## CHALLENGES

Transition of projects from one company to another can be challenging for many reasons—working effectively across multiple companies, issues with proprietary information and data, and ensuring the outgoing company remains engaged. This was, at points, a contentious situation. The outgoing company had to relinquish trials and data they had been working on for years. Many on the team were disappointed by the transition and thus were not always forthcoming with information. Further complicating this particular process, together with the client, we found out there were multiple problems with the studies, most significantly with data collection processes, which required addressing.

## STRATEGY

PPD Biotech was able overcome these challenges by leveraging our considerable program experience, relationship management expertise—with both sites and client—and our professional teams.

### Resource Mobilization and Empowerment

PPD Biotech, the client and the outgoing company assembled oversight teams to review projects and anticipate, identify and/or resolve issues. This allowed us to rapidly mobilize resources where needed as new studies were transitioned and problems were identified.

**14**
**STUDIES**
successfully transitioned, including

**250**
**SITES**
in all key regions

**1,000**
**PATIENTS**

**CONSISTENT, CAREFUL COMMUNICATION & EXPERT OVERSIGHT**

PPD® Biotech Partnering to Drive Innovation

www.ppdbiotech.com

## Successful Transfer of Multiple Studies

These oversight teams included:

- The portfolio transition team, which met weekly and included 50 members of the core team across the three companies
- A joint operating committee, which met monthly
- An executive operating committee, meeting quarterly to ensure progress

In addition, we appointed knowledgeable and experienced functional leads who had both empowerment and accountability for making timely decisions and escalating issues as needed. These teams maintained consistent and around-the-clock operational support.

### Data Tracking and Transfer

There was a considerable amount of sensitivity about proprietary information on a broad range of documentation, including EC submissions, TMFs, regulatory submissions and monitoring reports. Although the client went through a long negotiation process with the outgoing company to allow for access to certain documents, the transition required PPD Biotech and our client to be flexible with data formats received. Persistent and well-considered communication from PPD Biotech was critical.

> Constant contact with the outgoing company ensured all study data was managed appropriately, allowing us to work with this information immediately as databases were migrated.

A comprehensive portfolio transition plan, project-level transition plans, vendor and site transition plans, and database migration plans were also put in place at the start of the transition, enabling successful flow of data.

## THE RESULTS

Through our experience, executive committee structure and resource planning, as well as our team's professionalism, persistence and endurance, we were able to successfully transition these studies on time and significantly improve quality.

We recently completed an NDA submission audit with no findings. Upcoming audits expect to have the same result.