CASE STUDY PRESENTED BY PREMIER RESEARCH

When Other CROs Said No, We Said Yes — to the Nearly Impossible

The client asked the nearly impossible — a task so daunting that two other CROs had simply said "no, thanks." Completing a new drug application typically takes a year to a year and a half, but the time available here was six months. And the short timeline was only the half of it.

So we got busy. Really busy.

A dozen years of data

The sponsor was finishing its Phase III study for an antimicrobial, anti-infective drug and needed to complete its NDA submission by June 30, 2015. So little time meant no room for hiccups, but there was a lot of history to overcome. The development effort went back more than a dozen years, and having performed none of the clinical studies on the drug, Premier Research was quickly immersed in more than 12 years of unfamiliar data. The client had not even asked the FDA for a pre-NDA meeting, a milestone that typically precedes the application by up to a year.

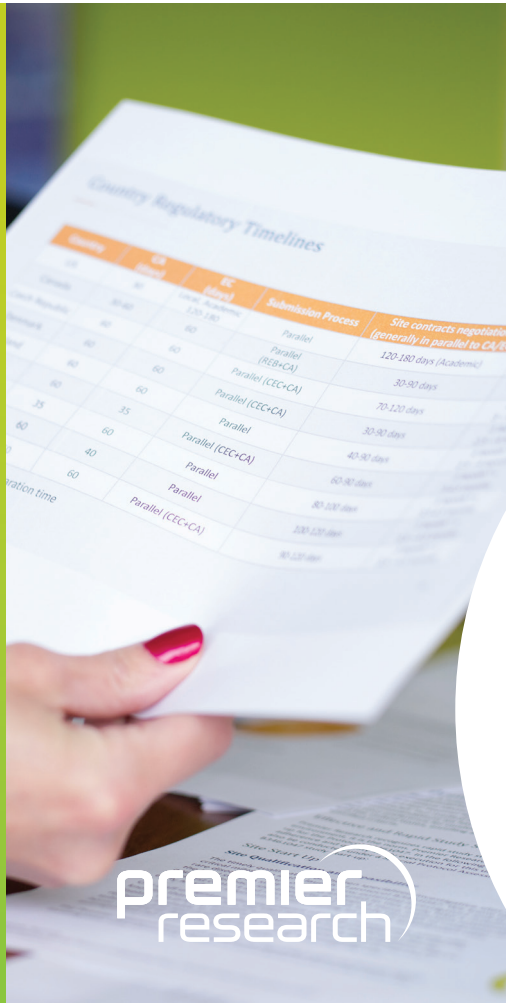
Parlaying our deep regulatory experience, we scheduled the FDA meeting months earlier than the sponsor could arrange on its own. Despite hopes that older data would be less relevant to the review, the agency was specific in requiring that all legacy data be updated and presented — and that's where things really got interesting. Information retrieved from old systems was incomplete and existed in disparate formats. It was a statistician's worst nightmare, and we worked day and night, tracking down people who no longer worked for the client to fill in gaps, reconstructing data, and performing analysis.

When heroics just aren't enough

Heroics aside, we still could not meet all of the FDA's requirements by the end of June. So we took the unusual step of negotiating a rolling submission, providing by the due date enough information for the agency to begin its review, and filling in the rest over the following weeks.

Accepting a challenge other CROs declined, committing specialized talent wherever and whenever it was needed, and using our regulatory know-how, Premier Research turned mission impossible to mission accomplished

REGULATORY AFFAIRS



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The Difference Between Impossible and Nearly Impossible? We Do Whatever It Takes

Study Description:
Phase III study for an antimicrobial, anti-infective drug.

Services Provided:
Scheduled FDA meetings on short order, analyzed information compiled over 12 years from disparate sources, filled in significant data gaps, and negotiated a rolling submission to meet an otherwise impossible filing deadline.

Outcome:
The FDA confirmed successful submission of the application, which Premier Research prepared and delivered in record-breaking time.

premier research
IT'S WHAT WE DO. BEST.™

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