Case Study

Worldwide's Strategies for Rapidly Meeting NDA Timelines Despite Last-Minute Supplemental Study Requests

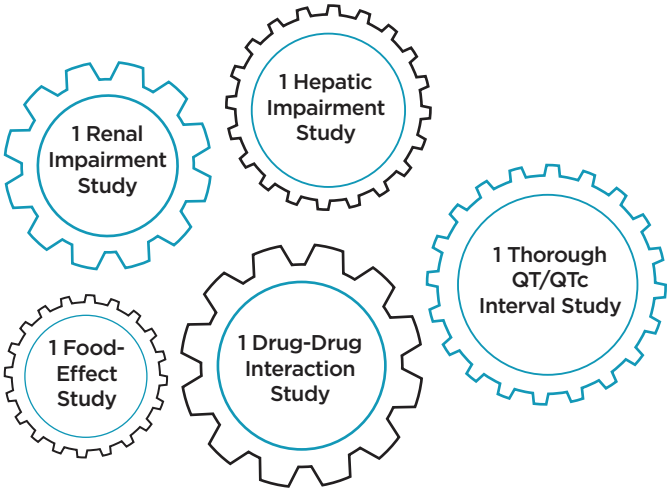
With just months left until planned submission of a new drug application (NDA), the Food and Drug Administration (FDA) mandated a series of unexpected supplemental studies for a new oncology drug.

Study Facts

Sponsor: Midsize pharmaceutical company

Study Location: Worldwide's Clinical Pharmacology Unit (CPU) in San Antonio, Texas, and partner sites in the United States.

5 Last-Minute Studies Requested



Document the effect of a high-fat diet on the study drugs pharmacokinetics, drug-drug interactions, impact on QT interval, and impact on subjects with liver and kidney disease.

These last-minute studies were completed on an expedited timeline to achieve the required NDA filing date.

The Timeline

Worldwide engaged sites to dramatically boost recruitment and improve data entry, allowing the sponsor to hit recruitment targets and database lock on schedule.

The sponsor's challenges

Timeline

The last-minute FDA requirements had the potential to significantly delay NDA submission for a program that was already near completion.

Logistics

With five unexpected studies to execute, operations had to align seamlessly to enable time-saving multitasking on clinical logistics and reporting requirements.

Without a comprehensive, organized plan and a flexible research partner, execution of five supplemental studies could have derailed the sponsor's chances of submitting its NDA on schedule.

- The sponsor selected Worldwide to manage all five studies.

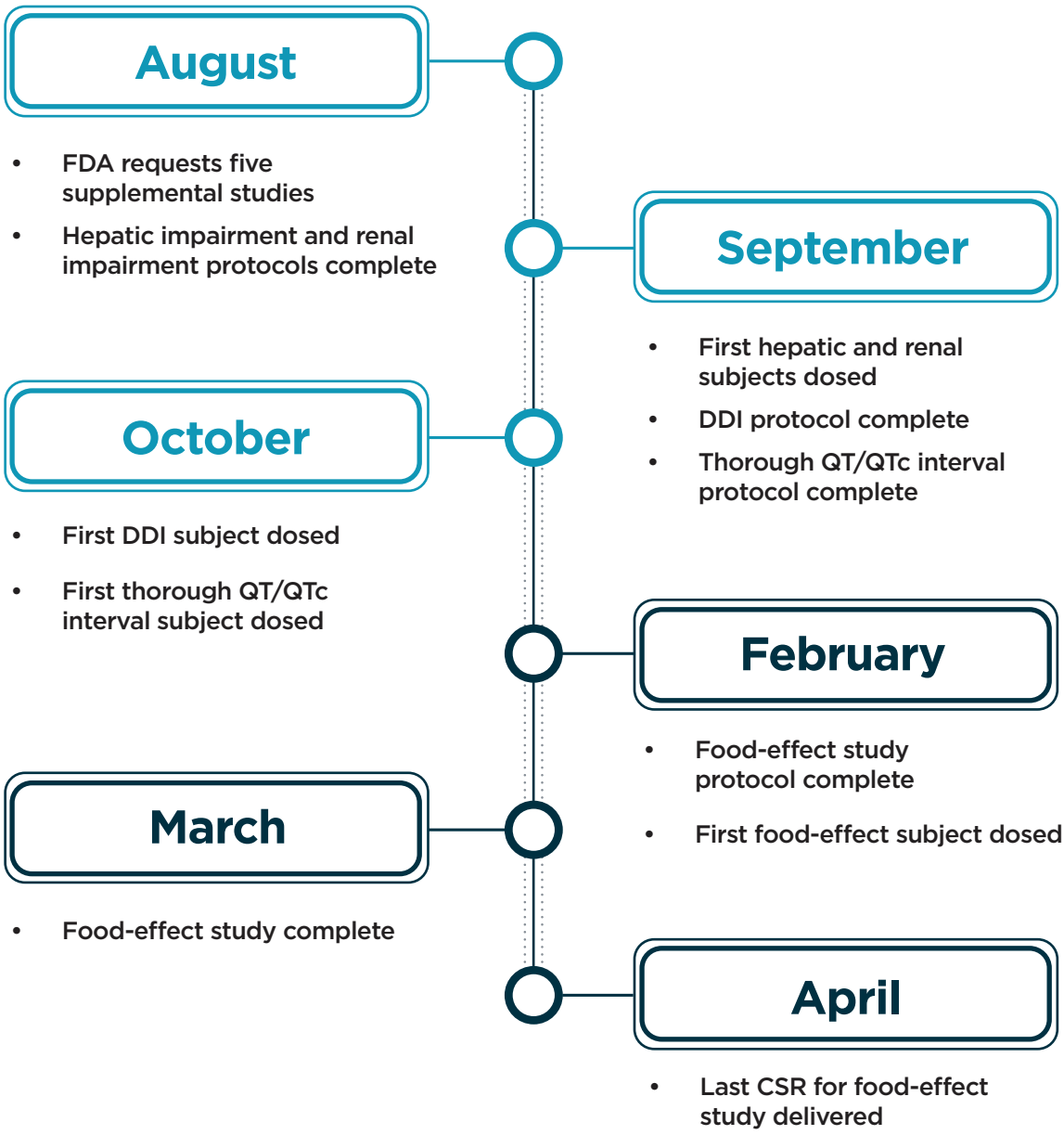
Early and continuous regulatory engagement

Having a CRO that is experienced in the common FDA-required studies for NDA submission can make or break the submission timeline. Nimble responses and expert logistics setups can make all the difference.

1. **Regular communication with the FDA** revealed the request early enough in the timeline to accommodate the requirements without sacrificing the targeted NDA submission date.
2. **Rapid start-up processes** and utilization of our own experienced CPU and multi-site network allowed the design and launch of the first of the five required studies in less than one month.
3. **Parallel clinical, project management, and regulatory work** processes on the studies resulted in fast protocols, rapid recruitment, prompt test results, and the successful execution of multiple studies simultaneously.

The Outcome: Keeping NDA on schedule after unexpected FDA feedback

Five last-minute studies were accommodated, executed, analyzed, and properly documented for the FDA and EMA in just eigth months. The sponsor submitted the NDA as planned - on schedule, and the FDA approved the drug, putting it on the market for cancer patients.



4 Strategies to Avoid NDA Submission Hiccups

Below are four takeaways for CROs and sponsors to adapt in order to successfully accommodate last-minute requests for supplemental studies from the FDA or other regulatory bodies.

1

Talk with the regulatory bodies early and often.

Communicate on a regular basis a year or two leading up to submission about current clinical trial findings and drug metabolism data. This proactive communication helps avoid last-minute surprises in the weeks leading up to a scheduled NDA submission date.

2

Try to anticipate likely requests for supplemental studies.

Leave room for extra studies to examine the effects of the drug on special populations, metabolic concerns, or DDI issues discovered during the planned course of clinical research. This leeway gives your program wiggle room to accommodate supplemental studies or unexpected timeline shifts (from any cause).

3

Build in time to investigate issues discovered during standard trials.

Many studies struggle with compliance either among patients or study staff. In this case, patients were not sufficiently reporting symptoms – required as part of the primary endpoint – in the electronic diary, which disrupted the timeline and jeopardized data integrity. Make sure to incorporate early checkpoints in your study to monitor where issues can arise.

4

Optimize processes to expedite timelines.

Adapt to last-minute requests by optimizing processes and timelines, allowing operations to run as efficiently as possible. It's also beneficial to coordinate with all relevant key parties to guarantee rapid turnaround times and to leverage network-wide resources to cut time from sample processing, recruitment, data analysis, and regulatory processes.documentation.

Meet Your Partners

Our industry thought leaders and seasoned professionals are ready to consult and advise your next project to optimize data and give you the competitive advantage you deserve. Meet a few of our team members:

Sherilyn Adcock, PhD, RPh

Chief Scientific Officer, Early Phase Development

With a background in pharmacy and clinical operations, Dr. Adcock has dedicated her career to early phase development. She has been an integral part of Worldwide's Early Phase business transformation from a small clinical site operation focused on generic compounds to the highly innovative business it is today. Dr. Adcock has been instrumental in expanding the Early Phase business to an integrated 200 bed, highly flexible, fit for service, clinical pharmacology unit, pharmacy compounding services, specialty pharmacy services, and full bioanalysis laboratory renowned for its medical and scientific foundation and its services, staff, and accessibility.

Before joining Worldwide, Dr. Adcock served in executive clinical research roles for SCIREX Corporation and Biomedical Research Group (now Premier Research), Phoenix International Life Sciences (now Celerion), HealthQuest Therapy and Research Institute, and Pharmaco International (now PPD). Prior to entering clinical research, she spent several years working in hospital and clinical settings as a pharmacist and development and oversight of specialty pharmacy services.

Dr. Adcock earned her BS in pharmacy, an MS in health science, and a PhD specializing in community health and biostats, all from the University of Texas. She is licensed by the Texas State Board of Pharmacy and holds certifications in sterile product preparation, immunization, and pharmacogenomics.

Lona Sheeran

Senior Vice President, Clinical Operations Early Phase

Lona serves as the Senior Vice President of Early Phase Clinical Operations at Worldwide Clinical Trials. With over 20 years operating in early phase environment, Lona has a track record of driving organizational and financial excellence through risk and benefit oversight and Lean Six Sigma techniques. She holds a BS degree from Concordia University in Wisconsin.

Worldwide
Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.

Anchored in our company's scientific heritage, we are therapeutically focused on cardiovascular, metabolic, neuroscience, oncology, and rare diseases. Our deep therapeutic knowledge enables us to develop flexible plans and quickly solve problems for our customers.

For more information on Worldwide, visit www.worldwide.com or connect with us on LinkedIn.

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