Worldwide Clinical Trials FLEX

Case Study

Accelerating NDA Submission for a Novel Chronic Kidney Disease Therapeutic: A Strategic Partnership

A late-stage private biopharmaceutical company focused on advanced therapies for chronic kidney disease (CKD) partnered with Worldwide Flex to prepare a pivotal NDA submission for a novel calcimimetic. The drug, intended to treat secondary hyperparathyroidism in CKD patients on dialysis, needed comprehensive regulatory documentation after two Phase III trials.

With both studies reaching their data lock point simultaneously, the sponsor faced an aggressive 6-month timeline to prepare and submit a complete NDA package. Successfully meeting this deadline ensured uninterrupted drug development and timely regulatory review, supporting the company's strategic goal of rapidly advancing this therapy to market. The submission scope encompassed Clinical Study Reports (CSRs), clinical summaries, nonclinical summary quality control (QC), CMC documentation, regulatory document formatting, and Biometrics tables, listings, and figures (TLFs) for integrated summaries.

Challenges

Our Worldwide Flex team was tasked with several challenging asks during this study, including:

1. Compressed NDA Timeline with Simultaneous Data Lock Points

The sponsor mapped out the NDA preparation timeline. With two pivotal Phase III studies completing their double-blind phases concurrently, the company needed to prepare comprehensive CSRs and begin drafting NDA modules. The compressed schedule required initiating key document development before final TLFs were available, creating coordination challenges across workstreams. The parallel nature of both trials meant that resources had to be strategically allocated to ensure neither study's documentation suffered delays.

2. Extensive Data Integration & Version Control Requirements

As the project progressed, TLF revisions created substantial challenges for version control. Each change required precise alignment across CSRs, clinical summaries, and integrated summary documents to ensure data consistency throughout. The extensive back-and-forth demanded robust systems to track modifications and their downstream impact across all affected documents. Without systematic oversight, the risk of data inconsistencies, version-control errors, and document misalignment could threaten the submission.

3. Maintaining Quality Standards Under Time Pressure

The sponsor required rigorous QC processes that typically run sequentially after document completion, yet the compressed timeline could not accommodate traditional review workflows. The need to conduct parallel sponsor and QC reviews without slowing timelines posed a significant operational challenge, requiring innovative approaches to maintain quality standards while keeping the aggressive schedule intact.

Solutions

To combat the challenges faced in this trial, Worldwide implemented several solutions:

1. Proactive "Write-Ahead" Strategy

Recognizing the compressed timeline and the challenge of simultaneous dual CSR preparation, Worldwide began preparing comprehensive document shells, topline CSRs with key messages, and clinical summaries in advance of receiving the final TLFs. This proactive approach ensured that key structural components and narrative sections, including study design, methodology, patient disposition, and baseline characteristics, were drafted early using protocol information, interim data, and topline results. This action minimized downstream bottlenecks and enabled rapid data integration once final outputs became available.

2. Integrated Cross-Functional Services

Worldwide's Medical Writing and Biometrics teams worked seamlessly together in close internal collaboration to produce Integrated Summary of Safety (ISS) TLF outputs, facilitating faster, better-coordinated planning and reducing sponsor oversight requirements. This integrated, flexible, cross-functional service model, covering statistical programming and medical writing, ensured that author-MWQC-sponsor collaboration remained tight and efficient throughout the project lifecycle.

3. Dual-Track Quality Control Process

To maintain the highest quality standards without compromising timelines, Worldwide implemented a dual-track review process in which internal quality checks were conducted in parallel with sponsor reviews. This innovative approach allowed the team to identify and resolve technical issues, formatting inconsistencies, and data discrepancies concurrently with client feedback cycles rather than sequentially. The parallel QC model ensured continuous quality and speed, providing multiple layers of validation while maintaining the aggressive schedule intact.

4. Dedicated TLF Change-Tracking System

As TLF revisions accumulated throughout the project, Worldwide developed a customized, dedicated TLF change tracker to monitor updates in real time and ensure that all CSRs and clinical summaries accurately reflected the latest data outputs. The tracker was not a generic version-control tool but a purpose-built document linking TLF identifiers, change descriptions, impact assessments, and the corresponding CSR/clinical summary sections that required updates.

Outcomes

Overcoming all challenges and uncertainties, Worldwide Flex successfully partnered with multiple stakeholders to fully develop NDA modules that met both quality and timeline expectations. The strategic partnership delivered exceptional results across all critical success metrics.

- **Timeline Achievement**

Submission-ready CSRs and clinical summaries were delivered significantly ahead of schedule, exceeding the sponsor's aggressive 6-month target. Key sections were ready early, minimizing downstream bottlenecks and enabling rapid data integration throughout the submission process.

- **Quality & Consistency**

The team produced highly consistent, regulator-ready documentation across all modules with standardized formatting, terminology, and presentation. All documents remained aligned with the latest data outputs at each milestone through systematic change management, eliminating data-version discrepancies and reducing rework.

- **Comprehensive Deliverables**

Worldwide Flex developed and harmonized more than 300 narratives, including additional requests from the FDA, demonstrating the team's flexibility and responsiveness to evolving regulatory requirements.

- **Strengthened Partnership**

The successful submission led to scope expansion during the submission process, reflecting the sponsor's confidence in Worldwide Flex's capabilities. The sponsor's leadership continues to seek Worldwide Flex's suggestions and solutions, with the team becoming an integral part of the sponsor's extended team. Worldwide Flex continues to support post-submission deliverables, leveraging functional and operational insights gained during the NDA preparation.

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About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global CRO serving development-driven biopharmaceutical companies, with more than 4,400 professionals operating across more than 70 countries. The company delivers therapeutically dedicated expertise in neuroscience, oncology, rare disease, and internal medicine, with comprehensive support across every development phase – from early-stage and first-in-human studies through Phase III registration trials.

The company's flexible service model – spanning full-service trial management to functional service partnerships through Worldwide Flex – is powered by a people-first, partnership-driven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decision-making. This provides sponsors with tailored, adaptable solutions that keep pace with the evolving demands of clinical research.

Learn more at www.worldwide.com.

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