Worldwide Clinical Trials | Oncology

Case Study

Scaling a Global Phase III Pancreatic Cancer Trial in a Competitive Development Landscape

An oncology biotech company was advancing its lead asset into a pivotal Phase III study for first-line metastatic pancreatic ductal adenocarcinoma (PDAC), one of the most competitive areas in oncology drug development. The sponsor was transitioning from early-phase development into a large-scale global pivotal program and needed a CRO capable of supporting significantly greater operational complexity and geographic reach. With limited global infrastructure outside the United States, the sponsor required strong regulatory, startup, and operational support across multiple regions.

At a Glance

Study Design Global Phase III Pancreatic Cancer

Scope ~150 sites across 15 countries in NA, EU, and APAC

Planned Enrollment ~600 patients

Benefits

- 60+ sites activated within 4 months of first activation
- Regulatory approvals up to 1 month ahead of schedule
- First patient enrolled 4 weeks ahead of plan
- Enrollment more than 2x expected at reported milestone

The study called for approximately 150 sites across 15 countries, with a planned enrollment of approximately 600 patients and a geographic footprint spanning North America, Europe, and Asia-Pacific. Knowing they needed to balance speed, quality, and global execution in a crowded first-line PDAC landscape, the sponsor reached out to Worldwide Clinical Trials.

Study Challenges

Crowded Development Landscape

Multiple sponsors were actively starting studies for previously untreated metastatic pancreatic cancer patients, creating intense competition for the same investigators, sites, and eligible patients. Larger competitors often entered discussions with established site relationships, greater name recognition, and broader development infrastructure. Sites were evaluating multiple first-line pancreatic cancer protocols simultaneously, making study differentiation critical.

Global Startup & Regulatory Complexity

Large-scale startup activities were required across 15 countries and ~150 sites. The sponsor needed support navigating regulatory requirements and startup processes across multiple regions, and study timelines depended on activating sites quickly while maintaining momentum across global operations.

Scaling Beyond Early Development

The sponsor was moving from a smaller development model into global pivotal execution, a transition that demanded operational maturity, coordinated global oversight, and the ability to compete effectively for patients in a crowded trial environment.

Solutions

Worldwide implemented a coordinated strategy designed to generate early momentum, establish strong investigator engagement, and position the study for successful enrollment.

Strategic Global Site Selection

Worldwide conducted extensive feasibility assessments to identify sites with access to the target first-line PDAC population, prioritizing site quality, enrollment potential, and operational readiness rather than simply maximizing site count. The team evaluated competitive study activity when selecting sites and countries and leveraged Worldwide's oncology expertise and site relationships to identify a network capable of supporting rapid activation and enrollment. Worldwide established a strong global footprint across North America, Europe, and Asia-Pacific.

Site Engagement & Study Differentiation

Recognizing that the study was competing directly with multiple first-line pancreatic cancer programs for investigator attention and patient enrollment, Worldwide worked closely with the sponsor to communicate the study's scientific rationale, clinical significance, and the drug's mechanism of action and differentiation from competing options. This messaging was delivered during feasibility discussions, pre-study visits, investigator meetings, and ongoing site communications. The team focused on building investigator enthusiasm and commitment before enrollment began, creating momentum that extended from startup and activation into enrollment.

High-Touch Partnership Model

Frequent governance, direct communication, rapid escalation and decision-making and functioning as an extension of the sponsor team were essential for the study.

Startup & Regulatory Execution

Worldwide coordinated startup activities across participating countries to enable efficient study activation. The team delivered high-quality regulatory submission packages and proactively addressed authority and ethics committee questions, helping maintain momentum across the global footprint.

Outcomes

Working with the sponsor, Worldwide achieved rapid startup and sustained enrollment performance.

Rapid Startup & Activation

More than 60 sites were activated within 4 months of the first site activation. Several regulatory approvals were obtained on schedule, while others were achieved as much as 1 month ahead of planned timelines.

Enrollment Success

A site in Worldwide's global site alliance enrolled the first patient approximately 4 weeks ahead of the originally planned first-patient milestone. Multiple patients had already enrolled by the originally planned FPI date, and enrollment performance exceeded projections during early study conduct. Enrollment momentum was achieved one month ahead of plans, and enrolled twice as many participants than expected, before the full global footprint was active.

Helping Sponsors Successfully Scale into Global Pivotal Oncology Development

This study is one example of Worldwide's ability to help sponsors successfully transition from earlier-stage development into global pivotal oncology execution. By combining strategic site selection, startup excellence, global operational expertise, and a collaborative partnership model, Worldwide helped a sponsor establish momentum in a highly competitive first-line pancreatic cancer landscape while positioning the study for enrollment success and long-term execution.

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About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global contract research organization (CRO) serving development-stage biopharmaceutical companies. In 2026, Worldwide acquired Catalyst Clinical Research, a strategic combination that added functional service provider capabilities, delivered immediate uplift in oncology experience, and improved technology platforms—enhancing speed, transparency, and value for customers.

With operations spanning more than 70 countries and a workforce of over 4,000 professionals, Worldwide's therapeutically dedicated teams bring direct expertise in neuroscience, oncology, rare disease, and internal medicine – delivering flexible service models and global capability through a high-touch, relationship-led approach.

From first-in-human clinical pharmacology through large-scale Phase III registration trials, Worldwide delivers comprehensive support across every development phase. The company's flexible service model—spanning full-service trial management to functional service partnerships through Worldwide Flex—enables sponsors to tailor engagement based on program complexity, timelines, and strategic goals.

Worldwide's teams are enabled by intuitive technology platforms designed to improve data transparency, provide real-time visibility into study performance, and support proactive communication and informed decision-making with customers.

For more information, visit www.worldwide.com.

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