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Bringing complex, concurrent trials to a successful completion requires tremendous balance

Choosing the correct partner with strategic site support, tight long-term project management skills, a committed call center, and top quality FDA submission capabilities should be your first step.

In a recent Phase III multi-trial project, a large pharmaceutical company approached Medpace to manage four large type 2 diabetes trials concurrently. The trials were pivotal studies that needed to run aggressively so the pharmaceutical company could file their New Drug Application (NDA) by the targeted submission date. Medpace's therapeutically focused, specialized diabetes project teams were quickly mobilized to start the trials simultaneously. The Medpace teams initiated, coordinated, and oversaw all trial activities from project start-up to project completion, tracking metrics and providing a full range of services to the Sponsor.

Concurrent Trial Design and Complex Protocols can present Challenges to Successful Clinical Trial Completion

The four diabetes trials had narrow inclusion criteria that included HbA1c between 7.5 and 9.5, and a goal of randomizing over 1,400 patients worldwide. The Medpace diabetes project team determined it would be more effective to target strategic locations and researchers in order to maximize the per-patient volume at each research site, rather than saturate the site list with a numerically larger number of locations, as many other Clinical Research Organizations (CROs) would have done. In order to funnel the narrow patient population to those targeted site locations, the project team supported the key Investigators with every resource available.

Medpace engaged their best project teams to swiftly and effectively create a set of best practices that allowed the sites, Sponsor, and Medpace to deliver a completed set of trials with over 1,400 patients in record time and successfully meet aggressive US Food and Drug Administration (FDA) timelines for NDA submissions.

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Challenge:

How to efficiently manage three concurrent Phase III diabetic trials and an extension trial within an extremely demanding protocol design and rigid NDA submission dates

A very narrow First Patient First Visit (FPFV) time period was called for in the protocol, along with very aggressive submission timelines, so that the Sponsor could prove efficacy and the statistical power of the drug in a tight timeframe. This was coupled with other challenges found in concurrently run trials, such as starting the trials quickly in order to meet enrollment timelines; recruiting specific patient populations and retaining patients throughout the trial; anticipating potential FDA site audits; offering guidance throughout the entire drug approval process; facilitating the planning, executing, and tracking of pertinent clinical trial activities; and coordinating timely submissions with inflexible NDA submission dates.

Solution:

Select a clinical trial partner capable of providing careful, smart planning at every stage of the complex testing process

Medpace strategically determined that the resolution of these trial challenges was through the following:

Utilization of the Call Center:
With eligibility criteria for patients critical at a 60% screen failure rate, the Medpace Clinical Trial Manager (CTM) approached the Sponsor to use the Medpace Call Center for patient recruitment. This was met favorably by the Sponsor. A large, focused mailing was then distributed, which prompted potential patients to participate in a preliminary phone screening conducted by staff trained specifically on the trial protocols. The Call Center then sent the patients directly to the appropriate research site. The Medpace Call Center phoned over 5,000 contacts for the three concurrent trials and recruited almost 1,000 patients. In addition, 50% of the patients participating in the three trials continued their participation into the optional extension trial. This was attributed to the implementation of attractive recruitment methods such as offering the use of a glucose monitor and glucose strips / lancets during the duration of the extension trial and thereafter.

Proper Site Selection:
Medpace has built enduring and sustainable relationships with a global network of research sites. These relationships serve Medpace well when the need for special patient populations arises. Medpace was able to seamlessly expand recruitment to non-US sites in order to meet difficult protocol specifications calling for a unique diabetes patient population currently using only one diabetes drug. In addition to expanding to non-US sites, Medpace reassessed site metrics and reallocated resources to better patient recruiting sites where necessary.

Good Site Relations:
Medpace kept close communications with the sites and discovered that even though patient recruitment was tedious at times, the sites did not want to relinquish their recruitment commitments. Their incentive to perform well was attributed to their established, long-term working relationships with Medpace.

Effective Communications:
An ongoing dialogue between Medpace Clinical Operations and their regulatory, writing, data, and statistical teams was maintained throughout the trials. Medpace also communicated consistently with the Sponsor through weekly calls and updates. Sites were engaged and motivated through quarterly teleconference meetings with the site Clinical Research Coordinators (CRCs). These sessions provided a vehicle to address and share concerns, to present unique recruitment ideas, and to keep the trial fresh in the minds of the site CRCs.

Medpace Regulatory Writing, Data, and Statistical Teams:
Intense involvement of the Medpace regulatory, writing, data, and statistical teams was utilized in order to meet aggressive back-end timelines. The Medpace regulatory teams conducted in-depth, productive face-to-face meetings and efficient round-table review sessions with the Sponsor where
the intensity of the collaboration produced thoughtful feedback and a positive, constructive rapport between all team members. Because of the Medpace clinical, medical, and regulatory expertise, a well constructed first submission draft was written and approved by the Sponsor with minor changes and in record turn-around time.

Active Trial Management:
The Medpace Clinical Research Associate (CRA) supported a successful, routine, industry- standard FDA site audit by verifying the purpose and scope of the visit, working with the site to prepare for the audit, examining key trial data, and reviewing Medpace site instructions for a regulatory authority inspection.

Result:

Successful completion of three diabetes trials and one extension trial with over 1,400 patients and superior quality NDA submissions

The successful enrollment of these trials with their complex protocols and unique patient populations, the comprehensive management support Medpace provided throughout the entire duration of the trials, and the timely submission of NDA regulatory approvals, is a tribute to the successful Medpace / Sponsor and Medpace / site strategic partnerships sustained during these Phase III diabetes trials. And, the successful conclusion for the Sponsor was that the necessary data was gathered to support its product.

Furthermore, Medpace met aggressive submission timelines with success, producing well written submission documents which yielded limited questions and no issue discussions during the NDA submission and review process. Back-end timelines were met on schedule.

Additionally, these concurrent trials represented the first large composite trial Medpace managed with this particular Sponsor. The Sponsor was impressed with the range of services provided by Medpace, from the Medpace Call Center to the timely submission and superior quality of NDA documents. This relationship led to further partnerships between Medpace and this particular Sponsor.

About Medpace
Medpace is a leading global full-service Clinical Research Organization providing Phase I–IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties, Medpace has assembled the industry's most experienced and therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug development services. In June 2009, Medpace was rated as the best CRO by US Investigative Sites in the 2009 CenterWatch Site Survey. Medpace creates strategic partnerships with pharmaceutical and biotechnology companies to provide the most efficient and cost-effective path to drug development, from program planning and execution to product approval.With more than 1,000 employees and clinical trial experience in over 40 countries, Medpace has the global reach and capability to conduct studies and navigate regulatory requirements worldwide.

In addition to Phase II–IV development services, Medpace provides Phase I / IIA clinical services from Medpace Clinical Pharmacology; central laboratory and therapeutically specialized testing from Medpace Reference Laboratories; complete bioanalytical services in all stages of drug development from Medpace Bioanalytical Laboratories; and central image management and reading from Imagepace.

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