



Accelerating patient recruitment demands advance strategic planning – seamless integration of trial start-up and patient recruitment functions – which contributes to early patient recruitment

Medpace was able to complete patient recruitment five weeks ahead of schedule. The secret? Employ a “best process” attitude with existing IRB and site relationships, integrating trial start-up with early site and patient enrollment for a record breaking finish to patient recruitment

Patient enrollment completed five weeks ahead of schedule? Not an unusual occurrence for a Medpace project team when the trial start-up and patient enrollment teams work together to initiate a “best process” view of the total project. When Medpace was awarded a Phase II obesity and type 2 diabetes trial with a new Sponsor, Medpace committed to an aggressive trial timeline that depended upon achieving swift patient enrollment. The Sponsor was impressed with the proposed timeline, having received longer proposed enrollment periods from competitors. For the Medpace team, delivering those results represented business as usual.

The Medpace trial start-up and project team were determined and confident that they could make the time requirement based upon their best practice operating procedures, designed to keep studies on track. The key to this process is to integrate parts of trial start-up with early patient identification to gain time advantages and avoid situations that traditionally slow down the patient enrollment process.

CHALLENGE:

Keep the trial start-up process on track managing 58 US sites and 25 global sites in terms of essential document preparation, site contracts, informed consent forms, and IRB approvals, while simultaneously initiating early patient identification

In order to reap the benefits of trial cost containment, reducing time while maintaining quality is the number one factor to be considered. Identifying which best processes in trial start-up and early patient identification can be streamlined to conduct activities simultaneously rather than sequentially, is a clear advantage.

SOLUTION:

Choose a clinical trial partner with strong trial start-up methodologies, innovative recruitment strategies, and experienced project management teams

Trial Start-up

Medpace existing relationships with the central IRB and CEC speeds protocol and document approval:

A proven, strong relationship with local regulatory officials, central IRBs, and global country ethics committees (CECs) contributes to the likelihood of success in the IRB approval process. Because of past experience, the IRB could expect appropriate documentation from Medpace and the sites, and

Medpace could expect fast turnaround on reviews and approvals from the designated IRB. For example, due to strategic protocol document preparation meetings between the Sponsor and Medpace, and the understanding Medpace has of the selected central IRB review requirements, the Sponsor received quick protocol review and approval.

The Medpace Regulatory Submissions team's prior working knowledge of central IRB document preferences reduced document approval time. The team communicated that information to the sites, and distributed forms and documents to the sites so they could complete and submit them directly to the IRB. This process significantly contributed to a faster IRB review and approval period.

Medpace existing relationships with sites limited time consuming site negotiations: Because the Medpace Regulatory Submissions team had previous working experience with a majority of the sites, Medpace was able to prepare site contracts customized to each site's conditions and requirements. The team was familiar with previously negotiated terms, contract language, payment preferences, site organization, and contract requirements. The Medpace legal team used language acceptable and appropriate to each particular site. This familiarity shortened the negotiation time considerably.

Early Patient Identification Processes

Medpace designed a "Selected Site Program": Medpace selected 5 sites for this program based on their strong previous performance.

The "selected sites" were chosen from the 58 US sites. These sites were eligible to take part in an early site initiation visit. The visit took the form of a pre-investigator meeting, a one-on-one session with the Clinical Research Associate (CRA), preparing each of the 5 sites to start recruitment early. This early start opportunity brought confidence to the site team, motivating and hastening patient recruitment.

Medpace designed a "Milestone Program": To keep patient recruitment moving swiftly, reward superior performance, and recognize accomplishments of outstanding sites, Medpace established a "Milestone Program" whereby sites received compensation upon achievement of designated milestones such as IRB approval, site contract approval, and third patient screened. The pro-active "Milestone Program" was a valuable incentive that motivated the sites to maintain or surpass patient recruitment timelines and other key milestones.

Medpace reallocated additional CRA resources to the program: To maintain a smoothly run trial and to accommodate the rapid patient recruitment, which occurred as a result of the innovative recruitment strategies employed, Medpace reallocated additional CRAs to the trial in order to keep site visits and data monitoring on schedule and to continue to exceed trial timelines. In addition, prior to the trial actually starting, Medpace called many of the sites to discuss performance expectations and establish an informed working relationship.

RESULT:

The Medpace team improved patient recruitment time 25% over the original time frame, completing enrollment five weeks ahead of schedule

Considering 75% of patient studies do not make their timelines, the benefit of completing patient enrollment ahead of schedule is one of the best practices in providing Sponsors with competitive advantages from both a cost containment and time-advantage-to-market standpoint. The added benefits of accelerating this particular trial included: avoiding patient recruiting over holiday periods, identifying future high-performing sites, lowering patient recruitment advertising costs for sites, and saving costly additional IRB renewal expenses by keeping the trial under 12 months. In addition, the Sponsor awarded Medpace with a second type 2 diabetes trial.

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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