MEDPACE

CASE STUDY

STRATEGIES TO ACCELERATE ENROLLMENT TIMELINES FOR TRIALS IN COMMONLY SPREAD DISEASES

A CASE STUDY: PHASE II, TYPE 2 DIABETES TRIAL

The enrollment and retention of study participants is critical in ensuring a trial runs smoothly and without delay. But for many studies, especially those for common or widely spread diseases with many competing trials, recruitment and retention can present a significant challenge and pose a risk to delaying timelines, adding cost, and impacting probability of success.

The following case study outlines strategies that Medpace has taken to accelerate the enrollment timeline, contributing to the successful execution of a recent Phase II, Type 2 Diabetes study.

The Medpace team implemented strategies to overcome recruitment challenges and achieve the enrollment timeline despite a two month delay. Our relationship with the sponsor was always transparent and collaborative which ultimately supported study success.

STUDY CHALLENGES

The study team faced numerous challenges, starting with an unexpected two-month delay in study start-up due to sponsor funding. The study protocol required a Metformin washout period which impacted enrollment and presented challenges for the clinical sites to identify eligible subjects. Retention was also challenging. Due to adverse events of the study medication, the study dropout rate was higher than expected. The increased dropout rate presented a significant challenge to overcome in order to meet enrollment timelines, especially given the two-month delay.

RESULT

Achieved Enrollment Timelines (33 weeks)

1623
PATIENTS SCREENED

46.37%
SCREENING RATE

571
PATIENTS RANDOMIZED

61.31%
RANDOMIZATION RATE

LOCKED THE DATABASE
1 DAY EARLY

135 SITES (96%)
SCREENED AT LEAST 1 PATIENT

118 SITES (84%)
RANDOMIZED AT LEAST 1 PATIENT

SOLUTIONS

Site selection during two-month delay

The Medpace team used the unexpected two month delay to complete the site selection process – once the study was ready to move forward, the sites had been identified and could be quickly activated.

- Utilized majority of central IRB sites
- Continued to keep sites engaged with routine communications regarding study status
- Continued sponsor discussions to support study progression with system builds and go-live efforts
- Continued meetings with sponsor to ensure updates were provided transparently to support site engagement efforts

Prescreening

To support identification of quality subjects and decrease the screen failure rate, Medpace study team implemented supplemental site budgets for quality prescreening efforts. Sites were given ability to prescreen subjects for the study utilizing a study specific Informed Consent Forms (ICF) and enable patients to begin their study required wash-out period prior to formally screening. This decreased study screen failure rates and also supported sites in expedited the screening window enabling the study to pull in enrollment timelines.

Study promotions

Medpace implemented a central ad campaign for sites and reviewed site prescreening measures to avoid unnecessary screen failures. Advertisement funds were also initially included in study budgets and revisited with collaboration from the sponsor to quickly expedite review and finalization to support site recruitment efforts. This promoted site motivation to support study recruitment timelines.

Primary lab sample collection

Medpace took all efforts to ensure sites were avoiding sample collection errors, missing collections that could yield un-analyzable blood sample collections for HbA1c and FPG and protocol deviations.

- Ensured sites were trained properly on collecting and processing samples
- Ensured sites were trained on fasting and dosing requirements to effectively train their subjects on expectations to support study endpoints

Leveraged ClinTrak® proprietary Clinical Trial Management System

Via ClinTrak®, labs were available for the Clinical Trial Managers to review following lab sample analysis. With those lab results in hand, our team had immediate visibility into whether a site missed a visit, didn't ship samples, or if samples were confounded in any way. This enabled the team to quickly mitigate risks and retrain personnel – or schedule retests if we did see issues with labs. To avoid delays in sample analysis, the team preformed a weekly review of the expected sample listing received by Medpace Reference Laboratories to proactively remind sites to ship collected samples.

Continued site education

The study team initiated site education efforts to address challenges in retention and drop rate. Medpace study team implemented routine teleconferences with sites to share site success stories regarding recruitment and retention. During these routine reviews, Medpace and sponsor also discussed the mechanism of action of the study drug that supported proactively addressing potential adverse effects. This open discussion engaged the Investigators to foster subject relationships and ultimately support study retention efforts.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective. If you have an upcoming trial that needs seamless execution, contact Medpace to learn more.

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