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Integrating all the pieces of a global trial is a complex puzzle.

Choosing a clinical research organization (CRO) with the expertise, global connections, and communication plan to make all the pieces fall into place is a critical choice in clinical development.

A recent, pivotal Phase III global study—randomizing 250 patients over 51 global sites to study a lipid altering therapy— was completed in record time to the Sponsor's approval. The key to the project's successful completion was deep expertise in the therapeutic area, a well-developed site relationship in emerging markets, and the implementation of a strong communication plan utilizing a best-in-class technology platform to achieve accelerated patient recruitment.

Challenge:

A global, multi-site trial demanded key global therapeutic experts in hypertriglyceridemia, as well as seasoned clinical teams with expertise in conducting multi-site global trials. Meeting an aggressive timeline, gaining access to necessary patient populations, and an integrating a global communication plan to keep all elements of the project moving forward at accelerated speed was a challenge. That challenge was best met with a CRO who understood the steps to navigate a complicated global clinical trial.

Solution:

Choose a CRO strategic partner with a proven track record of therapeutic expertise in metabolic disorders, combined with stellar clinical operations teams on a global level. Add to that mix, an organization with global investigator relationships and ready patient access to expedite site selection— and you are ahead of the game.
Once those challenges are met, the key is to keep the project on track with a communication plan using a proprietary software program that keeps everyone in the loop around the world to ensure the project delivers seamless results.

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Best Practices:

1) Medpace assigned a well-seasoned therapeutic team for strategic consultation and design of the project Assigned to the team were experts in the field of metabolic disorders from the Medical Monitor, to CTMs to CRAs with expertise in this therapeutic field and previous experience with global trials. The project was well-designed from the outset giving the project the best chance of success from both a therapeutic and operational point of view.

   The level of experience, coupled with lower that average industry turn-over rate with Medpace, kept a high level of consistency for clinical monitoring at global sites, making for efficient visits with knowledgeable CRAs.

2) Medpace leveraged global experience in emerging countries, having good familiarity with both site selections and regulatory submissions at the local level.

   The level of experience with carefully selected global investigative sites in the Medpace Investigator site database was robust. Medpace utilized regional experts familiar with local regulations and requirements capitalizing on aggressive regulatory submissions activities for speed of start-up.

   The Clinical Trial Submissions team worked aggressively with the CTM and Project Coordinator, dedicating a person per site to expedite the contracting and submissions packets, accelerating this phase of the study.

3) Investigator Site Relations contributed to global feasibility

   Expertise in the study of lipids allowed Medpace to use its long-term relationships with investigative sites and global key opinion leaders to facilitate and deliver a real feasibility plan for accelerated trial conduct. Medpace maintains a large global database and is able to quickly select and initiate sites into trials based on prior site activity. In addition, the review of feasibility by site takes into effect the prediction of potential patients available for each project.

4) The study team utilized Clintrak, Medpace's proprietary software platform for clinical trials as the communication platform. Clintrak embodies best –in-class attributes, from process to decision-support, and provides real-time access and valuable insights to all stakeholders.

   Intensive communication between all project members including the Sponsor kept the project on track and on time. Medpace provided comprehensive communication tools that were used by the Sponsor to see trial status at any moment in time on a global basis.

   Clintrak, served as the primary source of project status information and allowed all project team members to access study reports in real-time.

   Clintrak utilized a secure, single log-in, trial website for all project team members ensuring fast communication and updates for all project issues, query resolution, patient randomization status reports, project time lines, monitor visit status, newsletters, meeting agendas and minutes.

Result:

An excellent working relationship between the Sponsor and Medpace delivered an accelerated trial outcome. The successful relationship was facilitated by trusted expertise, site selection, solid feasibility, and a well-integrated global communication platform.

About Medpace

Medpace is a scientifically-driven, global full-service clinical research organization (CRO) providing Phase I-IV clinical development services for drug, biologic, and device programs. Medpace's physician-led, high-science, and disciplined operating approach leverages regulatory and therapeutic expertise to accelerate the global development of safe and effective medical therapeutics across all major areas including oncology, cardiovascular, metabolic/diabetes, infectious disease, and neuroscience. Learn more at Medpace.com.