Worldwide Clinical Trials

Case Study

Tailored Solutions for Successfully Managing Hybrid Clinical Trials

A sponsor approached Worldwide Clinical Trials (Worldwide) for help in conducting a clinical trial in patients with phenylketonuria (PKU). To support an inclusive patient participation strategy, the study required traditional sites in combination with a virtual solution.

Study Facts

Condition:
Phenylketonuria

Endpoints:
Efficacy and safety of the investigational treatment

Study Design:
Hybrid – 1 virtual (decentralized) U.S. site and 24 brick-and-mortar sites across Canada and Georgia

Enrolled Patients:
150

Study Challenges

In this study, Worldwide utilized a virtual site approach in conjunction with brick-and-mortar sites to manage a wider geographical enrollment of the target population and reduce the burden of participation. The virtual site enrolled 65% of the patient participants, and the traditional sites utilized various decentralized clinical trial (DCT) elements to ease participation for the rest of the patients.

While DCTs offer numerous benefits for drug development programs, DCTs are not a one-size-fits-all solution. Many investigational products, patient populations, and protocols will not be conducive to DCT elements, such as at-home visits by nurses or direct-to-patient shipping, and should only be implemented after a careful evaluation of benefits and risks from an experienced DCT implementation team. Additionally, there may be country-specific requirements or limitations for different DCT elements.

Worldwide was presented with the following challenges in implementing this study:

Site Management

The traditional sites had the option to use many of the decentralized services. However, because of the rarity of DCT studies, the traditional sites were unfamiliar with the various DCT elements implemented in the study and required additional support and training during site setup.

01

Vendor Management

The study utilized several DCT vendors, which provided the platform and resources for the virtual site and hybrid elements used for the brick-and-mortar sites. Setting up the vendors and coordinating with the traditional sites required thorough advance planning, strong communication with sites, and close operational support.

02

eSource Implementation

While most of the applied decentralized elements increased study efficiencies, the use of eSource encountered challenges such as duplicate data collection and integration issues with the electronic data capture (EDC) system. These issues highlighted the need for careful consideration with respect to DCT tools employed for trial-specific requirements.

03

Worldwide's Solutions

Worldwide implemented a number of decentralized elements into this study, including:

1. **eConsent and Telemedicine**
   Both eConsent and telemedicine services were incorporated into the study and were highly successful. These tools facilitated patient participation and streamlined data collection, contributing to the trial's overall efficiency.

2. **Home Health Nursing**
   Home health nursing was instrumental in collecting samples, verifying the completion of ediaries, obtaining signatures for record release permissions, and data management. While this solution was not available in Georgia, the home health nursing service in the U.S. and Canada considerably reduced patient burden and enhanced data quality.

3. **Direct Shipping of IP and Supplies**
   Directly shipping the investigational product and medical supplies to the patients' homes minimized disruptions and allowed timely access to the necessary materials.

Additional Solutions

Along with DCT solutions, Worldwide provided other solutions to support this study:

- **Optimized Patient Recruitment Strategy**
  Worldwide collaborated with patient advocacy groups to further bolster recruitment efforts, ensuring an inclusive approach to enrollment to allow a representative patient population access to the treatment option. As a result, enrollment timelines were on target.

- **Site Training**
  The strategic deployment of DCT elements required a cohesive organizational approach to ensure all stakeholders were aligned and informed. Worldwide provided training and educational materials to the sponsors, sites, and vendors to familiarize them with DCT operations. This proactive approach allowed CRAs to be well-equipped to support site initiation visits (SIVs) and other study needs.

Study Outcome

During the study, Worldwide conducted the assessments with high data integrity and found that the treatment was ineffective. Fortunately, our commitment to maintaining deadlines and high-quality data collection allowed the trial to be terminated before any unnecessary costs were incurred.

Worldwide
Clinical Trials

Partner with Worldwide for Your Next Decentralized or Hybrid Study

It's important to recognize that DCTs and hybrid studies are not a one-size-fits-all approach. Rather, each study requires a personalized approach, and upon our evaluation of the study and potential patient and site burden, Worldwide can determine if DCT solutions will allow us to address a trial's needs. Working with an experienced CRO partner like Worldwide that understands the possible pitfalls of DCTs and hybrid models guarantees these trials are managed with the expertise required to navigate their complexities.

Last Update: 10252024