ERT
Confidence at every turn™

CASE STUDY

OBSERVATIONAL STUDY MAXIMIZED ENROLLMENT THROUGH ELECTRONIC DATA CAPTURE

Global pharma company ramped up enrollment by integrating participation into everyday life

SITUATION

Observational studies are a vital tool for gathering data regarding the effectiveness of treatments in the real world. They can be highly informative but should be "low touch", meaning researchers have limited interactions with patients and must rely on information captured through the normal course of treatment and everyday life.

In this observational study, a global pharma company required a robust data capture solution to support a three-year, multi-faceted study of approximately 1000 respiratory (COPD and asthma) patients to track the effectiveness of a marketed product. This needed to provide both remote patient data capture and site-based data capture, including validated instruments, in Europe and North America.

SOLUTION

ERT's Post-Approval platform enabled site assessments to be delivered via provisioned tablets and remote assessments to take a bring-your-own-device approach. This meant patients could choose to use their own computer, smartphone or tablet to complete assessments. Importantly the remote data capture solution was able to provide the widest choice possible for patient participation by delivering simultaneously as an iOS app, Android app and web interface. By offering a multi-modal BYOD solution, with the added option of provisioning devices if necessary, potential technological exclusion criteria were removed to facilitate optimum patient enrollment.

"Our client wanted to ensure that technology was not a barrier to patient participation. So when they saw we could deploy this system simultaneously across all platforms they were very impressed."

—Matt McCarty, VP Digital Patient, ERT

SUMMARY

- Electronic data capture for a long-term observational study
- Native app plus web interface provided flexible device options for patients
- Incorporated Visual Analogue Scale, locked to a minimum size across all devices

IMPACT

- Multi-modal data collection maximized enrollment
- Platform solution simplified delivery to meet first-patient-in deadline
- Easy-to-use interface reduced the number of help desk calls
- Study provided a cohort of patients for future study recruitment

The solution included multiple validated instruments, including a Visual Analogue Scale (VAS). To manage this, a minimum size requirement to access the VAS was incorporated to prevent access via unsuitable devices and ensure measurement validity.

Finally, each assessment (quarterly or annual) was only available for patients to complete during the designated time window. A message schedule was constructed which provided notifications to patients when assessment windows were open for completion.

MAXIMIZE ENROLLMENT THROUGH PATIENT CHOICE

IMPACT

By allowing patients to decide which device they'd like to use during the study and bringing the data collection process directly to them via the devices they use every day, participation was seamless and the patient burden reduced.

These choices helped to optimize enrollment rates and reduce patient drop out, while, at the same time increasing the quality and quantity of data collected.

To date, the study has achieved a steady rate of enrollment, and a high rate of on-time and in-full survey completion across all device platforms. The support team has experienced a very low rate of help desk calls and log-in queries, even in the early days of the study, suggesting the interface is intuitive and user-friendly. This is an important benefit, as early drop-out rates could be linked to frustration with cumbersome or confusing technology.

The study will also provide the sponsor with a cohort of patients for potential participation in future studies.

Facilitate enrollment and reduce patient burden with electronic data capture. To learn more, go to ert.com or email info@ert.com.