

PHASE 4 STUDY ACHIEVES GREATER PATIENT ENGAGEMENT & IMPROVED DATA QUALITY USING ELECTRONIC DATA CAPTURE

Post-approval hemophilia study obtains high-quality data with a wearable device integrated app

SITUATION

Hemophilia is an inherited genetic disorder that impairs an individual's ability to form blood clots, increasing the risk of bleeding inside joints or the brain. The most common treatment for hemophilia is factor replacement therapy, involving the infusion of clotting factors into the bloodstream. However, complications such as antibody formation can reduce its effectiveness.

To develop better therapies, high-quality patient data is required to achieve greater understanding of the relationship between physical activity levels, infusion and the occurrence of bleeding episodes. However, the paper-based activity diaries traditionally used in clinical studies often do not integrate easily into patients' lives and are vulnerable to missing or inaccurate data entries. A digital system would reduce the burden of participation on patients, simplify the data capture process and provide more consistent data.

"Access to accurate and reliable data on patients' physical activity and bleeding is key to developing better hemophilia therapies," says Matt McCarty, VP Digital Patient, ERT. "We sought to develop a patient-oriented solution that would fit into daily life."

SUMMARY

- > Electronic data capture supported a post-approval study of 50 hemophilia patients
- > App-based solution offered simple platform to engage patients and record daily data
- > Wearable device integration enhanced the real-world data captured

IMPACT

- > Improved the consistency of collected data
- > Offered patients flexibility to use their own devices
- > Reduced burden on study participants
- > Offered an engaging experience for patients enrolled in the study

SOLUTION

The electronic data capture solution enabled study participants to log daily activities and collect bleed and infusion data using an app-based electronic diary (eDiary). This allowed entries to be made using individuals' own smartphones, or a provisioned device if required. Furthermore, a Fitbit® wearable activity tracker was integrated into the app, allowing data to be easily logged in real-time. The patient experience was further enhanced by allowing individuals to view the past two weeks of data, including bleeds, infusions and daily activities.

IMPACT

By enabling electronic data capture using patients' own smartphones, ERT's eDiary solution reduced the burden on study participants, while facilitating real-time data access for investigators. Fitbit integration permitted the capture of activity data and offered a more convenient, user-friendly experience for participants. This enhanced ease-of-use helped to minimize missing and erroneous entries, improving the quality of collected data.

The ability to view their own activity data offered real value for participants, providing positive indicators of health and well-being. Combined with motivational messages and reminders, these engagement features supported patient retention for the duration of the study.

"Sustaining patient engagement is key to generating meaningful insights from post-approval studies," says Matt. "Using wearable technology that tracked activity, we were able to add value for patients, retain participants and, ultimately, collect more robust data."

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