



CREATING A TECHNOLOGY SOLUTION TO SUPPORT PATIENT-FACING REGISTRIES

A reusable cloud platform designed to support large-scale and long-term observational studies was deployed to more than 15,000 patients in 32 countries over four years.

BACKGROUND

Patient registries are databases designed to provide a real-world view of clinical practice, patient outcomes, safety and comparative effectiveness following regulatory approval of a drug or device. Because patient registry studies are often large and may go on for several years, they need to be flexible, cost-efficient and relatively easy to use and maintain. eClinicalHealth was approached to design a solution using the Clinpal platform for two such studies related to venous thromboembolic events, stroke and systemic embolization, involving more

than 15,000 patients speaking 35 different languages.

The platform used for the studies was Clinpal™, a cloud-based 21 CFR Part 11 compliant platform configured for the enrollment and engagement of patients and sites in clinical trials. The implementations relied on the following standard Clinpal modules:

- **Presence**—a website for patients and investigative sites
- **Capture**—electronic patient reported outcome data capture (enabling patients to use their own devices) and advanced electronic site data capture

- **Educate**—integrated eLearning
- **Engage**—patient dashboard and reminders

OBJECTIVES

In contrast to traditional approaches to patient registries, eClinicalHealth sought to design a single, multipurpose solution that could be used for a variety of post-approval registries. Additionally, this single solution needed to capture data from both patients and sites while enabling both groups to use their own internet-connected devices.

CHALLENGES

- Two large-scale, global registry studies, conducted simultaneously
- Four-year recruitment period related to venous thromboembolic events, stroke and systemic embolization
- More than 15,000 patients
- 32 countries on six continents
- 35 languages / dialects
- Limited budget and resources

Other Factors Requiring Consideration

- Electronic case report forms (eCRF): An effective mechanism to capture complex data from sites was required.
- Electronic patient reported outcomes (ePRO): It was essential to determine the best way to incorporate efficient eSource data capture.
- Bring your own device (BYOD): Once it was determined that BYOD capabilities were necessary, the validity of the data entered by patients on their own devices needed to be confirmed.

instructions as they completed data entry. This greatly reduced site burden, training requirements and the number of steps completed by site personnel.

To further reduce the management and monitoring needed to resolve out-of-range data, eClinicalHealth devised a system of comprehensive edit checks that generated an automatic follow-up to a non-critical, out-of-range discrepancy. The site user confirmed the value with a single button to close the query, reducing review costs for non-critical data point errors.

Site-level management was also eased with the implementation of a personalized portal and dashboard specifically for patients. The dashboard conveniently presented each patient with tasks to be performed as part of the protocol throughout the study. Patient reminders were automatically generated by Clinpal to reduce site burden and improve patient compliance.

Fully integrated eLearning solutions were included to improve consistency among site staff and ease any retraining necessary due to site turnover in these long-term studies. To ensure training was completed in a timely manner, access to portions of the program was blocked until learning had been completed and certified within the system. The system also electronically generated training certificates with each team member's status and progress visible to study personnel. Training certifications were easily visible and auditable by the study management team.

To minimize the administrative burden of managing a large study with hundreds of sites and more than 15,000 patients, eClinicalHealth deployed an automatic system of site payments based on patient progress. Furthermore, bring-your-own-device capabilities made it possible for patients and sites to conveniently use their own devices to enter data, which also reduced administrative burden for the sites and dramatically reduced costs compared to traditional ePRO approaches. To ensure scientific validity of the patient-entered data using different devices, a BYOD validation project was conducted. This process optimized usability of the multiple ePRO

AN INNOVATIVE APPROACH

eClinicalHealth created a comprehensive clinical trial platform that includes remote data capture directly from patients. The platform's intelligent electronic case report form (eCRF) reduced data entry errors, which minimized monitoring and data management requirements, reducing the need to manually resolve data queries. The eCRF was configured with extensive dynamic constraints that ensured only the forms and fields that were required were presented to and completed by sites. Additionally, integrated instructions enabled users to see relevant eCRF

instruments in the BYOD setting and provided further evidence of the equivalence of the data entered with smartphones, tablets and laptop computers.

RESULTS

eClinicalHealth significantly reduced the costs and time associated with query management compared to industry benchmarks. To minimize the entry of erroneous data, the 48 eCRF pages in the study included 159 dynamic constraints and 145 edit checks. Edit checks were automatically made upon leaving a data field; no batch edit checks were used. On average, each patient had 4.2 queries (automatic queries created by edit checks plus manual queries), compared with the norm of 14.5 queries per patient. In the end, 98.5 percent of queries required no further review and were closed within 10 minutes, with a median of 6 seconds.

In the BYOD validation project, an instrument migration guideline was developed that incorporates the user feedback from patients and optimizes usability of the patient questionnaires used with different devices. This was pioneering scientific methodology development that has been well received by other experts in the industry.

CONCLUSION

Successful large observational studies, often undertaken over several years, need to be conducted with minimal manual processes to keep costs and administration in check. When sponsors have access to an integrated clinical research platform, they not only receive a more thorough understanding of the patient journey through a trial but also can better manage how sites support it.

Through its cloud-based Clinpal platform, eClinicalHealth eases the administration of large patient registry studies, successfully completing complex patient enrollment and engagement tasks. The platform can also be evolved over time to gain

value from new questionnaires at a lower cost. Clinpal is proven to allow researchers to conduct long-term and large-scale — even ones involving dozens of countries, dozens of languages and thousands of patients — efficiently, flexibly and cost-effectively.

Visit **Clinpal.com** for a demo.

ABOUT ECLINICALHEALTH

Headquartered in Scotland, eClinicalHealth, developers of the revolutionary Clinpal patient engagement platform, was founded in early 2012 to provide innovative clinical study solutions. The company is committed to leading open and collaborative innovation discussions about patient-centric clinical study processes and technology with pharmaceutical companies, CROs and other service and technology providers.



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