



STREAMLINING DIABETES RESEARCH WITH A REMOTE STUDY MODEL

A remote method of capturing self-reported blood glucose measurements enabled a clinical study to be conducted with no site visits, resulting in a 200 percent efficiency gain at the site level, an 18 percent increase in patient compliance and exceptionally high patient satisfaction ratings.

BACKGROUND

Patient recruitment and engagement using traditional methods continue to be a challenge. While remote online recruitment and engagement technologies show much promise in the realm of streamlining the clinical study process, more metrics are required.

Diabetes studies conducted remotely typically rely on two different devices to collect data from patients: a blood glucose meter and an e-diary. This combination can be a costly and cumbersome burden on study

participants and doesn't easily provide for real-time collection and review of data. The need for multiple devices also adds complexity and hinders scalability.

eClinicalHealth led a study in Finland with partners Sanofi, Langland and Mendor utilizing a single wireless blood glucose meter in a completely remote clinical setting.

OBJECTIVES

By implementing Clinpal™, a cloud-based system, eClinicalHealth aimed to reduce or eliminate

patient visits to investigative sites while simultaneously reducing site burden. The study also examined the platform's ability to improve patient recruitment by prequalifying candidates more effectively. Additionally, it looked at ways Clinpal could enhance patient engagement remotely in ways that were efficient and that had a positive effect on compliance. Finally, the study looked at remote, real-time methods to capture data from complex self-management of blood glucose (SMBG) protocols. The efficiency, scalability and overall feasibility of this process were evaluated in this study.

CHALLENGES

- Although electronic informed consent has been generally accepted, there is still reluctance to incorporate it into study protocols.
- The study required 100 percent of the candidates to be from outside the existing patient network, which required non-traditional approaches to recruitment.
- Researchers had to keep patients fully engaged without any in-person contact.
- The study required capturing valuable personal insight from the patient without compromising privacy or study blinding.
- The completely remote study with an older, diabetic population made engagement and compliance even more challenging, especially given the complexity of the glucose profiling task; the average age of the patients who completed this study was 56 years old.
- The devices and study materials needed to be distributed to participants without involvement from the site.

AN INNOVATIVE APPROACH

Patients were recruited on Facebook, prequalified online and then referred to the virtual site for enrollment. A remote electronic consent form was presented to and electronically signed by each patient. After patients were accepted, the study materials — including a single, intelligent, connected device for blood glucose measurements — were delivered directly to the patients along with instructions for registering the device with their personal online Clinpal account to capture their structured blood glucose profiling routine.

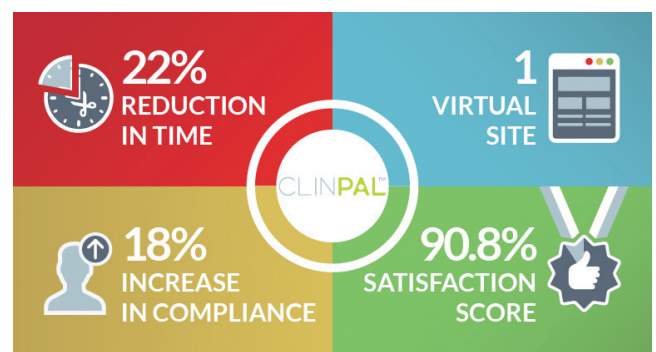
During the study, patients self-measured their blood glucose levels using the device and had access to a personal dashboard, enabling them to manage their compliance. Results were instantly and automatically transferred to the Clinpal system where a logbook view and compliance dashboards were available to study personnel for remote management.

ENROLLMENT

- 74 registered candidates recruited
- 60 of 74 registrations were enrolled in the study (81 percent conversion rate)
- 51 participants started the glucose profiling task
- 46 participants completed profiling successfully (9 percent drop-out rate)
- Average age of completers: 56 years old
- Median time spent in the study per patient as reported by participants: two hours

RESULTS

- Faster patient recruitment
- 18 percent increase in compliance (fewer readings required)
- 22 percent faster completion of the structured profiling routine
- 200 percent efficiency gain at the site level
- Patient satisfaction score assessing Clinpal's guidance to complete the necessary tasks: 4.47 out of 5
- Satisfaction score for the Smart meter: 4.6 out of 5
- Overall satisfaction with study participation: 4.52 out of 5
- Average satisfaction score across all 17 ratings: 4.38 out of 5



CONCLUSIONS

The elements of remote research used in this study were noteworthy: online recruitment via Facebook, remote prescreening, shipment of an electronic blood glucose monitor (BGM) delivered directly to qualified patients, BGM readings captured by the patient, and compliance monitoring and participant follow-up using Clinpal, eClinicalHealth's web-based patient engagement platform.

This study indicates that remote patient monitoring has application in large studies because it is scalable and can be performed with a variety of enabled devices. With data automatically collected by Clinpal in the cloud, compliance and patient participation are enhanced and sponsors and project managers have real-time access to more complete and accurate study data. Clinpal also facilitates a secure and convenient mechanism for patients to ask questions remotely and receive a timely response.

When combined with the Clinpal platform, advances in technology such as wireless blood glucose meters can be utilized via streamlined remote clinical studies with a high degree of patient compliance and satisfaction, along with impressive efficiency gains.

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.



Head Office:

Logie Court – First Floor C Wing
Stirling University Innovation Park
Stirling
FK9 4NF
United Kingdom
Tel: +44 333 012 4205

CLINPAL

Clinpal.com