

- ✔ Better Data
- ✔ Better Decisions
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Equivital™ drives efficiency in pharmaceutical clinical trial

Hidalgo

Hidalgo is a Cambridge based company that develops mobile human monitoring solutions commercialised under the “Equivital™” brand. Equivital™ products enable simplified ‘round the clock’, high quality human health and performance monitoring.

The Pharmaceutical clinical trial landscape

Pharmaceutical clinical trials are an essential but time consuming and expensive component of the drug development process.

Although there are increasing organisational and regulatory challenges in running clinical trials, overall the drug development process is delivering lower rates of success than were previously achieved. There are continuing difficulties with subject compliance and the collection and subsequent handling of trial data.

It is the combination of the environmental and operational challenges that are driving the need for increasing efficiency in the management of clinical trials.



Challenge

- Multi centre European trial
- Continuous, non-invasive, ambulatory monitoring of trial subjects (including during sleep) is required
- Secure, simple data collection
- Formatted data export compatible with clinical trials database

Solution

- Logistics service provided
- EQ02 LifeMonitor for continuous unobtrusive subject monitoring of thermoregulatory, cardiovascular and activity data.
- Secure, reliable subject data collection and storage using customised software for data export and formatting (plug and play)

Challenge

Hidalgo was approached by a major pharmaceutical manufacturer (Pharmaceutical Company X) with the intention of conducting a Phase Three, European Multi-Centre clinical trial. The trial included over 200 participants and was to be conducted over a one year period, across three countries with 20 clinical trial centres and 60 healthcare practitioners involved.

The trial protocol included the continuous monitoring of participants, day and night for extended periods of time. During this period the trial protocol critically required the collection of core temperature and heart rate data from subjects.

Due to the number of patients, sites and healthcare practitioners involved in the trial execution, the risk of data corruption and other data management issues was highlighted early. Pharmaceutical company X wanted to ensure that the data would be collected and handled in such a way so as to mitigate the risk of data loss and to reduce the time required to do this to a minimum.

To achieve this, a system needed to be identified and introduced that could both continuously and noninvasively monitor subjects while at home (with minimal set up) as well as securely handle data at multiple sites.

Solution

Hidalgo created a configuration which comprised current Equivital™ products and a newly customized, regulatory compliant software tool.

The Equivital™ EQ02 LifeMonitor was used because it provides high quality, continuous, non invasive monitoring whilst being simple to wear and operate. The system can monitor cardiorespiratory and thermoregulatory data as well as activity and movement. This functionality is all incorporated into one, non-invasive sensor product that can unobtrusively be worn by a subject whilst going about their normal day to day routine. The system can be used day or night.

A service was provided by Hidalgo that ensured a configured pack was created for each subject and each health care practitioner. This included a preconfigured EQ02 LifeMonitor, correctly sized belts and clear instructions for use.

In addition to the physiological monitoring requirements of the clinical trial, Hidalgo developed a customised data export software tool which removed any element of manual data handling from the data management process and protected against the corruption of data that had already been collected. It enabled the collected data to be exported automatically and directly into the clinical trial database without the need for manual extraction, conversion or formatting.

This foresight was crucial to the trial success.

Building on success

The flexibility of Equivital™ sensor products and software platforms allows for increased adoption by E- Clinical Trials customers. These are studies in which primary digital processes are used to collect and handle the data required for the conduct and management of a clinical trial.

The 3 key areas of benefit which could be delivered by an Equivital™ Pharmaceutical Clinical trial solution are:

Clinical monitoring: Equivital™ systems provide the ability to continuously and unobtrusively measure multiple types of physiological data from subjects in remote locations. They can also give real-time access to data from individual subjects and feedback from trial sites, increasing the efficiency of clinical monitoring. This enables the data and the activities of the sites to drive the trial schedule.

Patient recruitment: By providing continuous, real-time access to recruiting information from study sites Equivital™ systems can increase the efficiency of patient recruitment.

Pharmacovigilance: By providing real-time access to data, Equivital™ systems can improve the pharmacovigilance process. The ability to customise elements of the system to match the criteria of the stakeholders and the trial protocol ensures that the vigilance process can be more easily adhered to.

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Equivital™ by Hidalgo, part of the Jaltek group of companies

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Equivital™ EQ02 Sensor Electronics Module

Part of the Equivital™ Platform, the EQ02 senses, monitors, records and intelligently processes data captured from the human body. The EQ02 is able to then transmit this data over a wireless or wired interface. The EQ02 is a FDA & CE Cleared medical device.



Simultaneous data outputs:

- ECG
- Heart rate
- R-R interval
- Respiratory rate
- Skin & Core temperature
- Tri-axis accelerometer
- Body position
- Motion status and fall alert
- Device alarms and subject alert
- Oxygen Saturation (including Photoplethysmograph at 16 bit resolution)
- GPS
- GSR
- Dermal Temperature Patches