COVID-19 Compliance in Clinical Trials

The Verisense platform checks a number of key boxes to ensure the integrity and compliance of your trial is maintained while employing wearable sensors to garner crucial data endpoints. With Verisense, staff and trial participants are safeguarded in line with the challenges that COVID-19 presents.

No Physical Contact

The unique design of Verisense removes the need for any physical contact between participants and trial managers. The Verisense sensors can be sent directly to participants from our ISO 13485:2016 approved production facility, where strict hygiene procedures apply. There is no requirement for any other parties to physically handle the devices thus maintaining FDA/EMA guidance on safety.

Automated Data Collection

Verisense is designed to automatically upload data via cellular or WIFI on a daily basis, meeting leading standards on data privacy. This means that CRAs or any other personnel is not required to visit the participant, and vice-versa the participant never needs to leave their community to visit a clinic. Potential protocol deviations are avoided.

Long Lasting Battery

The Verisense battery can last for up to 6 months without charging. Replacement batteries if needed for longer trials can be supplied and fitted easily. Not needing to regularly recharge the devices removes the potential for data loss and increases compliance.

Remote Monitoring Platform

All Verisense data is collected and stored in a secure cloud based server. The trial manager has visibility on all sites and participants, and from the comfort of their own lab can access all data. Even in these times of social distancing, data can still be gathered and analyzed to address the main questions of interest.

Ease of Use

A core component of Verisense is the simplicity of its use, reducing the burden on the participant to a minimum. Setup is a simple straightforward process for the participant and will take no more than 5 minutes to complete. From there, users simply need to wear the device and nothing more.

Alert System

Should any unexpected events occur, such as the participant forgetting to wear the sensor, a sophisticated alert system will notify the trial manager who can quickly advise the participant, rectifying any compliance issues.

X

In contrast to Verisense most wearable platforms that offer clinical grade raw data, require that participants visit a clinic on a bi-weekly or monthly basis to enable the data to be collected from their device, the device memory reset and the battery recharged.

bsi. ISO 13485:2016 Medical Device Quality Management
MD 682933

CE FC