



Analytics Platform Makes Offline Direct Data Entry Possible

Avania helped overcome the challenge of direct data collection in ORs and ICUs with unstable internet connections



Product Type: Medical Device
(class IIb, CE-marked)

Therapeutic Area: Respiratory
(COVID-19)

Situation

One of Avania's clients was looking to utilize an electronic data capture (EDC) system that served their need for direct, real-time reporting in the operating room (OR) and intensive care unit (ICU) during surgical procedures. To accomplish this, an EDC usually requires a stable internet connection, as well as software access from a computer or laptop.

Challenge

The quality and availability of internet access in the clinical setting can differ depending on the site location but is very often substandard in the OR and ICU. Consequently, sites frequently suffer from inconsistent and unreliable connections to their EDC systems, complicating and slowing down the process. On top of that, it can be a struggle to even find the space for an extra computer or laptop in the OR during surgery.

Solution

Avania proposed the design of an EDC solution that would not only allow for offline data entry but would also provide more flexibility in the moment using repeat time points for recording results. Using hand-held devices for convenience and portability, Avania and the client opened clear lines of communication to every investigational site, resulting in seamless online/offline data collection in both the OR and ICU.

The key benefits of this approach were:

- Reliable data reporting that is mindful of site needs
- Flexible data solutions for areas with unreliable internet
- Trusted offline data entry, uploaded as soon as the device comes online
- Data entry via tablet/smartphone, meaning more consistent and timely entries
- Data that are available much quicker than traditional EDC
- No transcriptions needed, meaning reduced data entry and SDV time
- Dependable, fast, and satisfactory user experience
- Quick delivery and easy integration, saving time and money
- Fully customizable design to suit any size or project demand

Results

Avania's comprehensive overview of the client's data collection and the resulting user experience uncovered a fitting and compliant solution for the online/offline data collection demands of the OR and ICU. This flexible and innovative data collection method also granted the client easier access to their data, which collectively secured and maintained a long-term business relationship.

Avania worked with the end users of the eCRF to design the study database to be an intuitive and comprehensive data entry experience. The eCRF was developed within 6 weeks, and it was delivered on time with no updates required once it was live. Additionally, the eCRF was successfully integrated into OR and ICU environments by more than 15 different users at over 10 investigational sites. The eCRF provided a rapid, reliable, and gratifying user experience in each situation.

The intuitive design of the eCRF allowed sites to directly enter data via tablets and smartphones, eliminating paper-based manual entry and the time-consuming transcription of this data to the EDC. As a result, time was saved across the board with a reduction in overall monitoring and the omission of secondary verification, as there was no duplication of the source data from the beginning. Each of these efficiencies produced a significant reduction in trial expense and increased the chances the product would make it to market.

The implementation of an online/offline data entry solution can be made at any site in any location, even in remote countries or areas with unreliable internet. At the same time, these solutions do not require your entire database to operate in an online/offline mode, and they can often serve as an extra functionality alongside a more traditional approach to EDC.

**When you need innovative EDC solutions
powered by insight and informed by experience,**

IT TAKES AVANIA

Avania is an integrated global, full-service CRO with specialized expertise in medical device, novel technology, and combination products. They advance products from feasibility all the way through post-approval in analytics, clinical trials, consulting, regulatory, reimbursement, and more.