



Capturx Helps Streamline Data Collection and Processing for Patient-Reported Outcomes

United BioSource Corporation (UBC) is a leader in scientific and innovative approaches to technology solutions for collecting Patient-Reported Outcomes (PRO) data as part of the medical product development life cycle for life science companies. Pharmaceutical and medical device and diagnostic companies work with UBC to identify, analyze, and present real-world evidence, including the design of clinical trials for evaluating the safety, efficacy, and effectiveness of new products. These trials are fundamental to the development of innovative medicines and vaccines that treat and prevent illness.

Situation:

United BioSource Corporation collaborates with pharmaceutical and biotech companies to develop Patient-Reported Outcome (PRO) measures for use in upcoming clinical trials. The development of these PRO measures requires qualitative and quantitative information provided by patients in focus groups and one-on-one interviews. Patients involved in these studies take part in either group or one-on-one discussions to help researchers understand their experience with a specific disease or to help test the content validity of newly developed PROs. In addition to qualitative data, patients also respond to questionnaires containing sociodemographic and clinical questions which are generally recorded on paper.

When the study is complete, the data needs to be processed and summarized to provide reliable evidence to characterize the study sample and to support the primarily qualitative interview study results. During many such studies, research staff manually process the collected questionnaire data. The data must be entered twice into two separate databases and then compared for accuracy before being passed to other teams for further analysis. Manually processing the data typically requires additional staff resources and time.

Challenge:

Collecting qualitative data about patients in focus groups and interviews creates large volumes of information that is, in practice, collected on paper. Teams can spend a considerable percentage of the total project time processing paperwork, this impacts the amount of time and resources spent on the primary purpose of the studies, qualitative results. Taking longer to complete studies and provide analysis can result in slower dissemination of the data and access to critical information.

Although every effort is made to improve the efficiency and quality of studies, like cutting focus group data process time, this can be hampered by a necessary but time-consuming policy, where two research assistants enter patient data followed by a comparison of the data between databases to ensure accuracy.

Summary

Customer: United BioSource Corporation leader in technology solutions for design of clinical trials.

Challenge: Large amounts of paper-based data to be manually entered and then disseminated to complete research.

Solution: Capturx Forms for Excel to eliminate data entry, and improve processing times.

Results: Research staff increase productivity by getting more immediate and accurate data without manual data entry.

Solution: Capturx Forms for Excel

To help with streamlining focus group studies and decreasing the amount of time it takes to process data, UBC has decided to evaluate Capturx Forms for Excel – a digital forms data collection solution using ordinary paper with digital pens.

With Capturx, research teams can print forms on normal paper using office printers, and then fill out the forms or give them to patients to complete. The forms are printed from Excel using the Capturx add-in, which creates a unique digital watermark enabling the form to be read by the digital pen. As patients or research staff write on the form with the digital pen, a normal ink record of the data collected is created on paper while a digital copy is also created and stored in the pen's memory. Each stroke of the pen on the paper form creates new digitized data. When the pen is docked into its USB port on a PC or laptop, the field data is automatically integrated into Excel and reviewed for accuracy using Capturx's integrated data review feature. There is no new technology to learn or data to re-enter.

Significant time and consequently cost savings of as much as 50% have been achieved by eliminating the step of manually entering data twice into two separate databases by research assistants.

Digital pens enable the use of paper forms that can be custom made for specific populations or clinical trials without large investments in more complex devices that are not always appropriate in clinical trial settings.

Results

Increases Productivity – More Immediate and Accurate Data Without Manual Rekeying

With Capturx, clinical staff no longer need to transcribe patient responses from paper. Capturx not only reduces paperwork processing, but it also enables teams to stay focused on the patients and study outcomes.

Studies are Now Stored as Electronic Data With Paper Backup

Although the data backlog was not an issue, the build-up of paper records was. With Capturx, that data is stored in electronic format within Excel, and can be easily exported into other systems or used in Microsoft Office – the paper version becomes a physical back up.

Works the Way Focus Groups Are Conducted

Capturx automates the process without changing their simple and reliable paper-based data collection. The pen is durable, easy to carry, and the data upload can be performed by nearly anyone.

When the pen is docked to a PC, the data is instantly available for editing or upload into IT systems. Unlike mobile computers, Capturx does not require complex training, support or management of hardware or software.