



case study:

i3 CNS OVERCOMES EDIARY CHALLENGES IN ANALGESIA STUDY

Challenge: E-diary data collection in a large Phase III analgesia trial. In this study, much of the trial's primary efficacy data were collected via a handheld electronic device. Both site personnel and patients needed to learn how to use the device properly, as the quality of efficacy data depended solely on its successful application. However, even after data are successfully collected, additional inherent challenges remain in reconciling electronic data with other forms of data collected (i.e., the clinical database). For instance, in this study, the number of rescue medications taken as recorded in the e-diary do not always match that recorded by the site staff after pill counts are recorded on the case report form and entered into the clinical database.

Solution: Foresight, communication, planning. Staff members at i3 appreciate the value of choosing the data capture method matched to the type of data, the study design, and the investigative site — not just using the most high-tech means available. i3 also underscores the importance of thoughtfully and proactively discussing quality control responsibilities and processes for electronic data capture when a third party is involved.

From the beginning, i3 staff worked closely with the third-party supplier of the e-diary system in collaboration with the customer to train site personnel and patients on how to use the electronic patient diary with planned communications weekly. Issues were proactively identified and brought to the customer's attention, and clear action plans were developed. Analyses were carefully pre-planned in conjunction with review of data specifications for e-diary programming. Site coordinators were supplied with detailed, IRB-approved information packets and were trained to use the device, enabling them to pass that training onto patients. E-diary data were closely monitored by i3 in collaboration with the customer and the vendor.

Result: Timely, accurate data. Despite the data reconciliation challenges, i3 successfully delivered a locked database to the customer on time. The customer not only received primary efficacy data for their trial in a timely fashion, but they were also able to have confidence in its accuracy.