



eQuestionnaires Global Leader

Formerly Assist Technologies

Case Study

The TouchPRO Advantage: One company's success story selecting the eQuestionnaire global leader to reduce the cost and burden of collecting Visual Analog Scale data.

"We have continued to be astounded by the exceptional service provided by assisTek. We are recommending assisTek to everyone we know!"

– **Clinical Research Manager, leading European Pharmaceutical Company**

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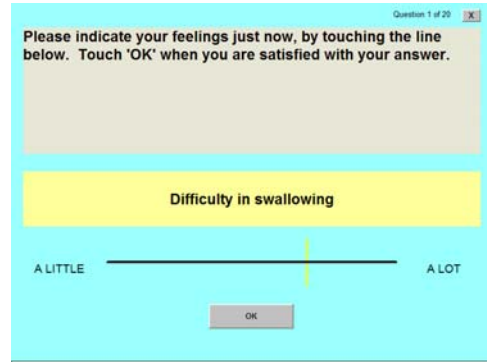
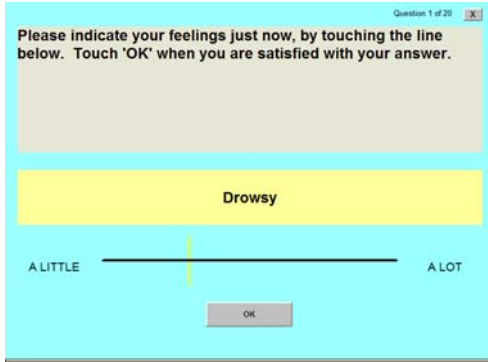
THE SETTING

A major European pharmaceutical company designed a study specifically for insomnia patients to provide them with a new product focusing on sleep maintenance. The study design required more than 148,000 visual analog scales be completed and scored as important secondary endpoint data in this study.

THE CHALLENGE

The VAS questionnaires, with 51 visual analog scales per questionnaire, would be administered once before dosing, and hourly thereafter for a total of 12 questionnaires each visit. This would result in approximately 148,000 visual analog scales to score for analysis. A conservative labor investment of 3 minutes per VAS scale to measure, score, and data enter each VAS data point equates to over 7,500 man hours, or 3.5 person years to produce a final data set. This investment and timeline was unacceptable.

With an aggressive study timeline, the Sponsor needed an electronic solution for the VAS measurements. Because the protocol required the VAS questionnaires to be administered hourly, the solution had to be reliable so there would be little to no risk of missing data due to technical issues. The system must also be easy to use due to the sedative and mood effects the subject could be experiencing. The Sponsor needed a vendor with experience and a proven track record of success.



Sample Screens

With Visual Analog Scales from the Study

THE SOLUTION

Given the need for a reliable and proven electronic solution, the study team selected assisTek to implement the VAS health questionnaires for their trial.

assisTek's depth of experience supporting more than 70 clinical trials and implementing more than 50 different health questionnaires, including VAS questionnaires, with their TouchPRO solution provided the level of trust and confidence that the team required in an electronic vendor. In addition, data from independent research studies proved that the use of the touch screens was a validated method of collecting VAS data from patients.

assisTek's rapid data delivery track record was also a key decision factor in selecting the TouchPRO solution. Because assisTek could deliver a dataset within 1 to 2 business days after patient visits, the assisTek TouchPRO was just the solution the study team was looking for to meet their aggressive timelines.

assisTek's unique, large touch-screen design accommodated the sedated state the subjects may be experiencing in while completing the questionnaires, and also accommodated precise, real time scoring of the patient's responses.

RESULTS

assisTek customized their TouchPRO software and configured devices for the study site. The site staff was trained in a one hour teleconference with an assisTek training coordinator the day before the first subject visit. Due to the overnight stay requirement of the study, most visit dates were on Saturdays. After the 12 hour observation period was concluded and all health questionnaires were complete, the site staff transmitted the data from the device to the assisTek data warehouse.

Enrollment went very quickly and the final subject visit was completed just 63 days from study start. The final visit occurred on Saturday March 13th, and a complete study dataset was delivered to the sponsor on Monday, March 15th. This data set contained all data from the 81 unique subjects. With less than 5% missing response data, this resulted in more than 138,000 visual analog scales scored, which would have taken an estimated 3.5 person years to compute manually. assisTek delivered a complete data set one business day after the last patient visit. Only one query resulted from the complete data set delivery and data lock of the VAS data was achieved within less than one week. The reaction from the Clinical Research Manager was amazement: “We have continued to be astounded by the exceptional service provided by assisTek. We are recommending assisTek to everyone we know!”

Additionally, the computed savings of implementing assisTek’s TouchPRO eQuestionnaire solution is a staggering \$350,000 over paper and pencil.

CONCLUSION

Without the use of the assisTek eQuestionnaire solution, VAS data for this study would have taken multiple resources many weeks or months to manually score, data enter and validate. Instead, the Sponsor received data files mid study and was able to begin a more thorough analysis of the data without the burden of data entering and reconciling the VAS data. The TouchPRO proved an invaluable tool in obtaining the highest quality outcomes data possible to support their study submission with increased compliance and the elimination of an enormous effort to measure the visual analog scales manually.

ABOUT ASSISTEK

assisTek is the eQuestionnaires global leader, delivering a unique turn key solution for implementing scientific health questionnaires developed by respected experts in the field of Health Economics. The TouchPRO system greatly increases the quality of outcomes data collected in clinical trials which results in more useable data to support FDA claims. Interim and final data sets can be delivered within one business day of the last patient visit, providing more analysis time. The TouchPRO is a lightweight, touch screen notebook used for collecting patient reported eQuestionnaire data. assisTek's large tablet screen and unique interface makes the system very easy to use and the preferred choice by patients from all demographic backgrounds. The TouchPRO system reduces the workload for the study team, data management team and the site personnel. All at a cost that is less than paper and pencil. assisTek's customers include top 12 pharmaceutical companies around the world. assisTek is headquartered in Scottsdale, Arizona, USA.

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