



Global Leader in Tablet ePROs

Case Study

USING TOUCHPRO IN A COMPLEX INTERNATIONAL STUDY ENVIRONMENT TO MAXIMIZE ePRO DATA OBJECTIVES

“assisTek has been a pleasure to work with from the onset and in all aspects of the association. I always feel I know exactly where we are at with assisTek and that all actions will be followed up on.”

– Clinical Research Manager, European Headquarters, Major Bio-tech Company

Contact:

assisTek

2501 N. Hayden Road Suite 102

Scottsdale, Arizona 85251

Telephone: (480) 874-9400

www.assisTek.com

THE SETTING

A leading biotechnology company was about to launch a series of domestic and international Phase II and III studies for a strategically important drug. The trials would involve over 350 sites and 1,100 patients with end stage colorectal cancer. The sponsor needed Quality of Life health questionnaire data quickly for interim analysis and they wanted 90% useable data to achieve the study objectives. Neither of these objectives could be attained with traditional paper and pencil.

THE CHALLENGE

Compliance to the protocol requirements for PRO was extremely important to the study. Among the many challenges facing the project team:

350 sites

1,100 subjects

17 Countries

18 Languages

Split CRA staff – both internal and outsourced

26 questionnaires with 20 questions per = 143,000 pages of questionnaires!

Given the prospect of 143,000 pages of questionnaires, the team faced a monumental task to coordinate and train nearly one thousand study staff individuals across many countries, languages and cultures, as well as collect this amount of data via paper and pencil and hope to get consistently high quality outcomes data in house in a reasonable time-frame to support interim analysis. The team believed that electronic data capture would be optimal if a vendor had the following characteristics:

- + Adequate global experience to deploy and support a multi national study;
- + Proven ability to deliver 90% usable data;
- + Ability to rapidly provide data for interim analysis as requested;
- + Technology solution suitable for study subject profile;
- + Leadership to help ensure a successful implementation in less developed countries.

And, at a cost that would not exceed paper and pencil.

THE SOLUTION

Given the complexity of the study demographics and due to favorable past experience collecting electronic outcomes questionnaire data, the team again chose to implement assisTek's TouchPRO solution.

assisTek's proven success in deploying global scale solutions provided the Sponsor with confidence that the issues surrounding language translation and cultural differences introduced by internationalization would be successfully addressed. In addition, assisTek's ability to support a global study 24x7 and have localized European support numbers was critical to the Sponsor. assisTek's own staff represents many different nationalities and languages; and therefore, is capable of providing a service level to international sites that is unsurpassed.

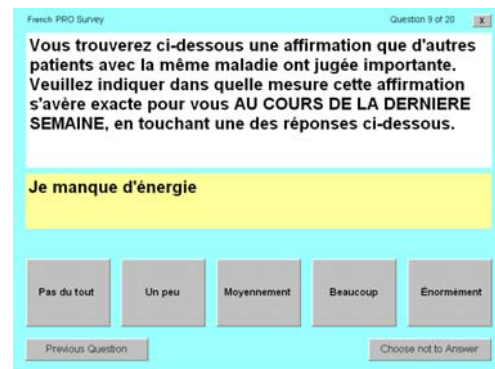
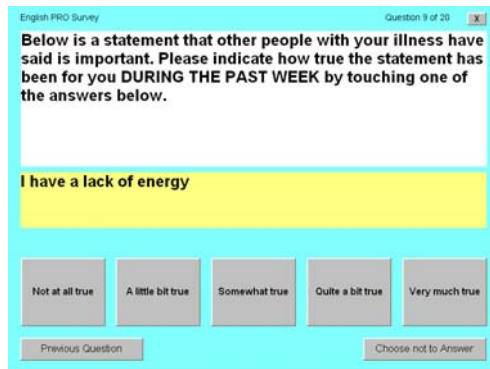
assisTek's proven data transmission process allows for near real time submission and monitoring of outcomes questionnaire data. Interim data sets can be delivered as often as needed throughout the study using assisTek's Sponsor Data Release System software. assisTek has a successful track record of delivering over 95% complete outcomes data and their data quality and compliance reporting product allows the study team to know exactly what is happening at their sites throughout the entire study. In the past, with traditional

paper and pencil questionnaires, there were often many unpleasant surprises and queries at the end of the study, and many times it was too late for any corrective action.

assisTek' unique touch screen technology with its large screen and lightweight construction makes the product highly suitable for elderly and very ill cancer patients to easily complete the health questionnaires.

RESULTS

assisTek customized the TouchPRO solution for each of the 17 countries to deliver the NCCN/FACT, EORTC-QLC and EQ5D health questionnaires in each country's local language(s). Shipment of devices was carefully managed to ensure that Customs issues were minimal and that equipment and training were delivered with optimal timing related to first patient enrollment dates on a site by site basis.



assisTek's leadership and experience resulted in a smoother implementation than the Sponsor could have imagined. As quoted by the Clinical Research Manager: "assisTek has been a pleasure to work with from the onset and in all aspects of the association. I always feel I know exactly where we are at with assisTek and that all actions will be followed up on."

To ensure commitment from the study team and instill confidence in the site staff that the technology is easy to use for coordinators and subjects, assisTek customized monitor update meetings and site training sessions that were delivered in France, Italy, Austria, UK, Hungary, and Czech Republic. The training sessions proved that data transmission from their location is simple, and helped to create direct relationships with the sites so they would feel comfortable contacting assisTek if they were to have any user questions or were to experience any problems.

The study is currently experiencing greater than 95% complete outcomes questionnaire data from the sites, exceeding their goal and expectations. Sites are utilizing the assisTek solution and are seeing a significant burden removed from their workload. The reduction in paper and ease of use is greatly appreciated. Many never want to go back to paper! And, as independent research studies have proven in the past, subjects prefer the TouchPRO to paper and pencil. As published in the Jan 2000 DIA Journal, research studies show that subjects >65 years of age with no prior computer experience prefer touch screen to paper and pencil, and from the Journal of Asthma Vol. 40, 73% of elderly subjects and 83% of all adult subjects prefer touch screens to paper and pencil.

The sponsor has realized tangible benefits from the increase in outcomes compliance, real time access to study data, reduction in the incidence of error and omissions, and subsequently reduced time and expense associated with queries and corrections. Cost model factors including sites, subjects, questionnaire types, number of questionnaire pages and cost per page indicate more than a half million dollar savings over the cost of traditional paper and pencil for this study.

CONCLUSION

This study is on-going. assisTek has shipped and trained study monitors and site staff at more than 125 sites in 16 countries, including Czech Republic, Hungary and Lithuania. eQuestionnaire data has been transmitted to the assisTek data repository from sites all around the world and the study is currently seeing more than 95% complete patient reported data.

assisTek's ability to offer a solution that could be deployed and supported internationally was a key differentiator. The study has benefited from the TouchPRO's ease of use and near real time data compliance monitoring. Overall, the TouchPRO has offered an efficient, time reducing, compliance increasing solution that helped increase savings in time and cost for the Sponsor.

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 outcomes. 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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assisTek

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Fax: (480) 874-9414

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