

**Q3 develops a Mobile Application to facilitate clinical trials, allowing patients and doctors to record and transmit data to centralized Web servers.**

Q3's global sourcing model gives the maximum benefit to customers in terms of cost savings, improved quality, access to highly talented professionals, flexibility of operations and reduced time to market.

# Case Study - Mobile Application to facilitate clinical trials

## Company Profile

The Client is a global healthcare provider and specializes in creating patient-oriented, reliable clinical data collection solutions for CROs, pharmaceutical, biotech, medical device companies and academic institutions conducting Phase I to IV clinical studies or post-marketing surveys. The Client is the first provider to offer tools allowing customers to build and deploy electronic patient reported outcome ePRO solutions on their own.

The Client has a need to develop a customized PDA- based application to allow the Client's personnel or Administrators and Investigators to design studies/applications on desktop, send/install them on PDAs, collect data recorded by the patient, and transmit data through GPRS/Wi-Fi/Acoustic transmission. The data collected is securely sent to the Acoustic server using proprietary APIs. Thereafter the Server Agent on the Acoustic server sends the answers to the Client's server, where the answers are mapped with corresponding questions and merged files produced and sent to the Administrators and Investigators. The client has a proprietary hardware that supports PALM OS. The device supports extensive assessments, visual scales, and pictures, and manages data transmission using acoustic technology (voice based transmission).

### The specific requirements of the requisite application are as follows:

- » The data is first encrypted and then sent to the acoustic server and decrypted there. The application receives the decrypted data and prepares a readable file containing actual questions and answers given by patient.
- » Designing studies/applications includes customizing the administration and application screens, creating/editing questionnaires, questions, messages, and alarms for the studies/applications, and applying edit checks on questions/messages. This application is designed for three types of users: the Administrator, the Investigator and patients.
- » The Administrator is intended to work on the Standalone application on Desktop. Using this application, the Administrator is able to design studies, build the studies, deploy the studies on the SD cards for PDAs, and synchronize the studies. Each screen while designing on desktop can be accompanied by an edit check in order to control patient data entries by forcing the patient to answer a question within certain authorized limits.
- » The Investigator and patients are intended to work on the PDA. The application allows the Investigator to create login IDs for patients, assign a study to patients, and set alarms for PDA using the screens defined by the Administrator. The patients use the PDA to answer questions presented by the application.
- » The application provides two sections for patients: Training and Questionnaires. The Training section allows patients to answer questions in Training mode in which the answers are not saved. The Questionnaires section allows the patient to answer the questionnaires under the study.

## Business Situation

- » The answers are securely sent to acoustic server using proprietary APIs. Thereafter the Agent on acoustic server sends the answers to the Client's Server, where the answers are mapped with corresponding questions and merged files are produced.

## Application Features

- » Powerful data entry system that allows investigators and administrators to make immediate decisions based on having cleaner data.
- » Dynamic creation of questions and messages on the desktop which are rendered on the PDA.
- » Designing of each question constituting the questionnaires using a computer Assisted Personal Interview (CAPI) system.
- » Edit checks & branching logic are designed on the desktop and implemented on the PDA.
- » Secure, permanent memory: data cannot be lost
- » Can be used/reprogrammed for use in subsequent studies
- » Easily carried by patients to collect data at anytime throughout the trial
- » Complete stand-alone unit: no additional cables, wires, chargers, or modems are needed
- » Date- and time-stamped data collected by patients
- » Multiple language platform - diaries available in any language
- » Integrated review and update process by investigators
- » VAS scale capability
- » Programmable alarms for improve patient compliance
- » Acoustic or GPRS/Wi-Fi data transmission
- » Flexible generation of reminders and alerts for patients.

Q3 realized that it was important to build the requisite application in a technology through which clients could maintain and enhance the application in-house as per changing requirements in the health services sector.

The mobile-technology experts at Q3 thoroughly studied the client requirements and unearthed the hidden complications by using the existing third party application and investigating the various features provided by the application. For example, Q3 discovered that the application is supposed to be used by multiple patients.

Furthermore, Q3 suggested improvements and alternative ways to build the application. For example, Q3 proposed to integrate the requisite application with an emulator so that the design of studies can be viewed on Desktop itself.

Besides the actual application development, an important client requirement was that there should be complete documentation of the entire product cycle and the document should meet the GAMP4 standards. This meant a lot of additional efforts; still, Q3 went out of its way to explore the GAMP4 standards and delivered appropriate documentation using industry standard version control system, VSS.

## Technical Solution

## Technologies

- » Desktop application Visual Studio 2005, C#/.Net, Windows XP/Windows Server 2003/ Windows Vista, .NET Framework version 2.0 & 3.5, SQL Server 2005 & SQL Server 2008, Microsoft Excel, XML Support
- » Mobile Application Visual Studio 2005, C#/.Net, Windows mobile for pocket PC 5.0 or above with Service Pack 2.0, Compact framework 2.0, Acoustic technology, GPRS or Wi-Fi connectivity, Memory card

### Why the customer chose Q3 Technologies?

- » Q3 has been chosen based on three values that it commits to:
  1. Customer Success
  2. Integrity and Transparency
  3. Excellence in what we do
- » Q3 is a pioneer in Product engineering services and offers offshore software development.
- » Q3 has a dedicated team of professionals in mobile technology.
- » Q3 is committed to help you to achieve your goals and maximize your long term systems potential.
- » Q3 treats each project as a unique one.
- » Q3 works closely with clients to ensure that all needs and objectives are understood for Custom software development.
- » Q3 continually reviews its working methods to provide improved standards and innovative solutions.
- » Q3 acts with integrity and honesty to develop trusting working relationships with clients.
- » Q3 is capable of meeting the criteria requested by the clients in order to make the project a success within the stipulated time frame.