

PDAS AND CLINICAL DATA MANAGEMENT

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Abstract: *Monitors, study coordinators, and investigators are using personal digital assistants (PDAs) more often and interest in using mobile information technology to manage clinical trials data is growing. This article provides an overview of PDAs, including the positive reaction of patients and clinical research staff to these devices. Influences on the use of PDAs in clinical trials—the Clinical Data Interchange Standards Consortium, the Society of Clinical Research Associates, and U.S. Food and Drug Administration (FDA) 21 CFR Part 11—are described. The benefits of using PDAs in clinical trials—enhanced efficiency, increased compliance, decreased cost, and faster time to market—are outlined.*

PDAs are personal digital assistants and are sometimes referred to as Palm Pilots or handheld computers. There are two primary operating systems for PDAs: Palm OS and Pocket PC. Linux OS handhelds are also available. Some of the more familiar Palm OS devices are Handspring, Palm, IBM Workpad (a palm clone), Sony, HandEra, Kyocera (phone), and Samsung (phone). Common Pocket PCs are Toshiba, HP/Compaq, Cassio, PC e-Phone (phone), and Trium (phone).

PDAs are primarily used in research for data collection. Electronic data capture can be divided into two categories: electronic data capture and remote data entry. Electronic data capture is what you do at the bedside; it consists of making a single entry using a handheld device. Remote data entry is another way of

collecting information electronically. Generally, you collect information on a piece of paper and then transfer it to a laptop or PC and send it via the Internet.

Researchers, study coordinators, and monitors can store many references on a handheld device, such as drug databases, the Merck manual, or Harrison's. Some protocols are being ported over to the handheld format, so you can carry the protocol with you. The handheld device is then used at the bedside to collect the data that are required by the protocol. So the research team is using handhelds to store references and to store data collected at the point of care.

Subjects are using PDAs for electronic patient diaries. They enter the data into the handheld device and transmit the data via modem, generally over a toll-free line, to the

data entry people. This results in less paperwork and can improve response rates by researchers to problems that patients are having because the researchers receive the data daily.

The *British Medical Journal* published an article in May 2002 (www.bmj.com) that examined data collected using paper diaries and electronic patient diaries. The authors found that only 11% of the entries made in the paper diaries could have been made at the time the subjects said they had made them. When the patients used electronic patient diaries, 94% of the entries were made on time. That is a significant difference in the credibility and accuracy of the data being collected in patient diaries.

Patients have also demonstrated a high level of acceptance of electronic patient diaries. It is easier for them

to remember to enter and send data, since the device chirps to remind them to perform both of these tasks. It seems to work really well for both the data collection aspect and patient or study subject participation.

When entering data onto a PDA, generally there is a pick list. It is a pull down menu. You select the screen you want, tick the boxes, and move on to the next page. The device can be configured so the person entering the data cannot move to another page until all of the required information is entered. This can prevent some of the gaps in data that can occur with paper documents.

Handhelds have been used in a few studies at our facility. In several pain studies, the study coordinator used a handheld device to collect data. Most of the responses from study staff were positive. They were enthused about using the PDAs and thought that sending information via modem was really cool. The number of studies at our site that include handhelds for data collection and transmission is increasing.

There are several cool devices that use handhelds. Two that I find fascinating are ActiveECG and VivoMetrics. ActiveECG (www.Activecenter.com) is a three-lead ECG device that connects to a handheld device. This device was approved by FDA in June 2002. It connects to a Palm OS handheld device; the company is working on a Pocket PC version. ActiveECG displays the waveform in real time and can even display paced heart beats. Data can be sent via modem to the cardiologist and/or the patient chart. It is quite compact and is a little bigger and deeper than a handheld device. The handheld device stores the information so when you use the cradle and put it onto the PC, you can view the

waveform on graph paper and measure the intervals. Some visiting nurses in California have been using this device for their post-operative coronary artery bypass patients.

VivoMetrics (www.vivometrics.com) is a lifeshirt. This is a non-invasive continuous ambulatory monitoring system for respiratory and cardiac vital signs. It was approved by FDA in April 2002. The patient wears the shirt, which has many sensors that monitor information. Data are collected and stored on the handheld device. Information is taken from the handheld device and transferred onto the PC. You can look at a continuous readout and identify trends in the vital signs. It is like having a mobile intensive care unit worn by the study subject.

PDAs and Clinical Trials

The Clinical Data Interchange Standards Consortium (CDISC), the Society of Clinical Research Associates (SOCRA), and FDA 21 CFR Part 11 are all influencing the use of PDAs in clinical trials. CDISC is working to develop standardized methods for data collection and form design for electronic data submission (www.cdisc.org). For example, some sponsors want the study subject's date of birth entered as the year, month, and day. Others want you to enter the day, month, and year, or the month as three letters and the day and year numerically. It would be easier for electronic data collection forms if the date of birth was entered in a consistent format. CDISC is composed of people from stakeholders such as pharmaceutical companies, data management companies, and contract research organizations who have a keen interest in developing these standardized tools for data collection and transmission. The goal is to standardize data collection in order

to reduce the number and types of forms used, the way forms look, and speed the transmission of data.

SOCRA sponsors educational programs that cover the use of PDAs (www.socra.org). FDA's 21 CFR Part 11 (www.fda.gov) deals with computerized systems used in clinical trials. Part 11 addresses electronic case report forms, electronic patient diaries, electronic health records, software validation, and source documents. PDAs are also covered in Part 11, which also covers electronic signatures, audit trails, and date and time stamps. That is important because when you collect and send data according to the protocol, there must be some evidence that the data were collected by the appropriate individual and at the appropriate time in accordance with the protocol.

Benefits of PDAs in Clinical Trials

Accuracy, faster data lock, and reduced costs are three potential benefits of using PDAs to collect and transmit data to the data entry people. Accuracy is improved through the use of lock-out windows for missed data. For example, if you need to collect data between hour two and hour four after a particular intervention, the PDA can be set up so that you cannot enter that data before or after that window; whereas with a paper form, you can enter data early or late. PDAs also foster the collection of complete information. If you do not complete all of the information, you cannot move on to the next screen on the handheld device. It also has a date stamp, so the date and time of data collection are recorded.

Faster data lock is another potential benefit of PDAs. With electronic data capture using a PDA, you have single data entry and the data can be transmitted at the point of care. Legibility is increased because there are no handwritten entries.

When you make corrections, they are legible and the date and time that the correction was made can be viewed. PDAs can also help decrease the number of queries generated. Data entry using a PDA helps identify discrepancies immediately. Either the device will not let you send the data because of the discrepancy or when it reaches the data entry people, they will recognize that there is a discrepancy and turn it around quickly so you can address the query right away. It also leads to increased accuracy, especially with electronic patient diaries.

Potential reduced costs include less use of paper and fewer courier shipments of documents. The frequency and duration of monitoring visits can be reduced if the study site has electronic health records and the monitor has access to the electronic health record and the data that you are submitting via the PDA. Storage requirements are reduced when many documents are stored electronically.

There is enhanced efficiency. The way the data are collected and submitted is more efficient and regulatory documents are managed more efficiently using PDAs. Compliance from the clinical research staff and patients is increased. Clinical research staff must enter data within the appropriate windows or they are locked out. The handheld device reminds patients to enter and send data daily. Costs are decreased. The use of PDAs can translate into faster time to market. And faster time to market is a goal of the pharmaceutical industry.

Table 1 outlines the potential benefits to the pharmaceutical industry of using PDAs to collect and send data. PDAs offer the opportunity to get accurate data that was collected at the required time intervals. Using PDAs also has the potential for prompt adverse event identification. The benefits of PDAs in research include increased accuracy, protocol compliance and patient safety plus faster data lock. The final result can be a safe drug in the hands of those who need it quickly!

TABLE 1
The Advantages of PDAs in Clinical Trials
<ul style="list-style-type: none">• Enhanced efficiency• Increased compliance• Decreased cost• Faster time to market

References

ActiveECG www.activecenter.com
PDAcortex www.PDAcortec.com
SoCRA www.socra.org
Vivometrics www.vivometrics.com