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A New Generation of Remote Data Entry: Using WAP-Phones in Clinical Trials

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Abstract

This paper presents an introduction to a new approach in the field of clinical trial information technology. During the last years, more and more modern tools have found their ways to the different tasks during the design, the realization and data processing in the clinical trial. Choosing tools depends on a variety of conditions and aspects that have to be considered. Besides issues in the field of trial software, the focus of research also turns over to special hardware used in the trial.

The Wireless Markup Language (WML) offers the possibility of using handheld devices like mobile phones (handy) or Personal Digital Assistants (PDA) for remote data entry. These widespread, easy to use hardware devices could use wireless access to the standard internet for use in their applications. This combination seems to become a success because of the existing infrastructure, the ongoing efforts in improving and enlarging the internet platform and not at last because the approach is so similar to the well accepted World Wide Web (WWW). As today this technology has not yet matured, different criteria have to be mentioned when choosing hard- and software for this application. We will show some aspects related especially to modern handheld devices and the belonging software.

1. Introduction

Today, one of the most challenging tasks during the design of a clinical trial is the decision of the optimal information technology (IT) infrastructure. This means that choosing the right hard- and software gets more and more important. Different approaches on the field of clinical trials (e.g. [1], [2], [3]) generally focus on the change from paper-based to an online solution. In this case online is either used as directly inserting data into the trial database or as inserting the data into a database that is physically located at the clinical centre and update the trial database with the new data once a day or once a week. All these approaches use the commonly accessible PCs as hardware platform. There are a few approaches that also incorporate other systems like clinical information systems (UNIX workstations, Mac-cluster, etc.) or laboratory information systems (special hard- and software). Some new approaches use handheld computers for data input. These Personal Digital Assistants (PDA) seemed to be just the "managers toys" but advanced and have become more common. Consequently, this hardware could be used for special tasks in medicine (diabetes diary [W1]) and in clinical trials (e.g. pain diary [4]). Even if market penetration with PDAs increases, the diversity of devices doesn't show common use of one special PDA. So there will be a limited general use of this type of device. One of the last "hypes" of information technology are advanced cellular phones. These are multipurpose devices and there is a

tendency to transform all kinds of applications to be used in combination with them. This special kind of hardware will be explained in depth in the next chapter.

Looking at the trial software system there are two main issues: the trial software is completely written from scratch or a standard software system (database, statistical software, workflow management software) is modified according to the needs of the trial. Approaches vary from an easy data input module to the professional statistics software up to a trial design software for commonly used database systems. Most approaches based on the database systems use a special purpose communication channel for exchange of data. Other solutions that are not based on existing software could use or incorporate other features, e.g. different hardware as data source. These "hand-made" trial systems were the first which used the internet service WWW as a base for data exchange. Even if there has been a fast success of these systems, there are still some mayor drawbacks that prevent them from being generally accepted. Besides the question of data security there are some aspects of data quality (accepted ranges, data typing, etc.) because of the limited potential of the HyperText Markup Language (HTML), the language of the WWW. At this moment there is a change from this first generation language towards a second generation. These eXtensible Markup Languages (XML) possibly prevent from getting into problems that sometimes arise with HTML. Besides common advances, they better fit to special purpose devices like PDAs or cellular phones. The third chapter of the paper will stress on a new special purpose language for mobile phones with enhanced features (e.g. graphical display). The last chapter deals with embedding this technology as part of a clinical trial. The conclusion and future expectations will end the paper.

2. Hardware

When switching to remote data entry in clincal trials the common approach seems to use one or more personal computers (PC) with clinical trial software. There are different software products that could be used. A discussion of these applications is beyond the scope of this paper.

Since some time another family of devices is emerging: Mobile User Agents (MUA) like cellular phones ("handy"), pager and similar devices. Beginning with the Apple Newton, one of the first "handheld" (but not handy) computers, first examples of using this kind of mobile devices in the field of medicine were presented (see images in [W1]). Even if the experiments seemed to be promising, there was no wide acceptance of this technology. Reasons came from a variety of facts like the weight of the portable computer, the completely unknown way of using a "pen" for work, the pricing and other aspects. The end to this approach came when production of the Newton was stopped. Later similar new devices "shrunk" to an acceptable size and so the generation of PDAs (also called palm computer) emerged. Also with these devices experiments were led but still until today there was no real break-through.

Since 1997 cellular phones with alpha-numeric keyboard and a pixel display are available on the market. The first generation phones only presented system information like the dialled phone number, status of power supply, volume etc. on the display. Advanced devices offered the possibility to store dialing shortcuts that were typed with the multi purpose keys. The next advance was Short Message Sending (SMS). Cellular phones were able to present short text messages to the user. These were received from special service units. As the cellular devices matures, more and more features are added: voice dialing, address book, calendar, games (with images, [W2]) and so on.

The last advances came from the synthesis of the internet with those possibilities of adding features to the cellular phones: a browser to work with the Wireless Markup Protocol (WAP) was added to the built-in applications ([5], [W3]). Extensive use of presenting simple text and images in a WWW-like manner was made possible. On the side of hardware, special keys (e.g. scroll keys) were designed into these models to support easy use of the browser software.

At the moment there is a change in the WAP movement from an enthusiastic attitude "down" to the realistic view of the possibilities of today's technology. Especially the limited bandwidth of the GSM channel system (9.6 kBit/s) shows the limits of this technology. When upcoming systems like GPRS (General Packet Radio Service) or UMTS (Universal Mobile Telecommunications System) will offer sufficient bandwidth (> 50 kBit/s resp. >384 kBit/s) for more complex applications, user acceptance will increase substantially with the invention of much more useful applications. This evolution will carry on in parallel with the maturing of the mobile devices (larger and coloured displays, intelligent user interfaces, etc.). These expectations lead to the conclusion, that there will be broad acceptance of mobile devices in daily live. This increased penetration offers a platform for applications like clinical trial data capture tools, too.

3. Software

As mentioned earlier, the World Wide Web Consortium (W3C) defined a meta language for the definition of other languages: the eXtensible Markup Language ([6], [W4]). XML offers a set of rules for defining other computer languages that are similar to the well-known HTML. These rules are necessary for the use of common software (e.g. general message parser), in order to get a cut between the content information and the formatting information, for human readability and automated processing in computers.

One of the possible languages that could be defined by the use of XML is specially designed for the needs of the cellular phones or pager systems. These have some characteristics in common:

- Small, low resolution display screens (only 8 – 12 characters per line, up to 100 x 100 pixels)
- Special input devices like numeric keypad and few other special function keys
- Limited computational power (small memory, slow processor)
- Low bandwidth (down to 300 bit/s) and hence slow response rates

There are some consequences that arise of these characteristics. They include the physical organisation of the data presentation in the files, special adaptation for reduced input devices and so on. All XML-based languages are tag-oriented (message is compressed when submitted). The tags should be self explaining. For coding purposes Unicode or ASCII is used since the languages should be human readable.

Each WML-application consists of different units, called decks. A deck is a content transmission unit and has an unique identifier (like the concept of URLs for the WWW). The deck is devided into one or more cards. One card at a time is presented in the display of the device. Many features like automatic line breaking, scrollbars when necessary etc. are implemented in the same way as todays HTML.

As mentioned in the hardware section user input is somehow limited because of the characteristics of the mobile user agent (small display, few keys, etc.). So the concept of

timer controlled card exchange gets more importance. For the same reason attributes have been newly created, e.g., an attribute to the input field: appending formatting information can switch the multi-purpose keys to numeric keys and hence offer a flexible but also easy to use device to the user (this feature is a real advantage compared to standard HTML).

Developing applications for the new generation of Mobile User Agents seems to be easy since all major MUA-producer (e.g. Nokia, Ericsson, Siemens, etc.) offer integrated development environments for their agents ([W5],[W6]). Editing, compiling the application and even simulating the input on the different devices is supported in an acceptable way. More intelligent applications that need some kind of programming will use WML Script ([7]). This script language was derived from ECMAScript / JavaScript ([W7]) and was modified to the special needs of the WAP Protocol.

Switching the application to real world, nevertheless, needs some more efforts: an interface between the "normal" internet and the wireless network has to be established. This WAP-gateway (also called WAP proxy) will offer WML pages from internet servers to the wireless "world" and will manage conversion of simple HTML-pages to WML. Many providers of cellular phone services will offer this interface from wireless to the wired internet.

4. Conclusion: Integrating the new devices into the clinical trial

Today Wireless User Agents (WUA) are in the focus of development in IT-industry. There is much potential for switching paper based trial questionnaire like a drug diary or a pain protocol to devices like cellular phones or pagers. If the possibilities of the programming language WML (in combination with WMLScript) are used in a reasonable manner, compliance by the trial patients are expected to be higher than those to other devices like Personal Digital Assistants (PDA) since general use of cellular phone is widely accepted. One drawback that has to be dealt with relates to the limited possibilities of the input (e.g. keys) and output (e.g. screen) section of the WUA. Here the need for "intelligent" applications is obvious. Since the market for cellular phones is rapidly growing and since right from the beginning developers could use professional tools for the design of applications, there is potential for this technology to grow similarly to the WWW. On the other hand, WML version 1.0 has been designed by a small group of manufacturers of cellular phones who have an enormous interest in the use of their products. Will this group stay together with the WAP or do we have to expect different "slangs" of such a language? Or will all cellular phones be able to present ordinary HTML-pages some day? Nevertheless, we think that use in clinical trials already today seems to be reasonable in those cases where a simple, direct, "just in time" user input is necessary. This could be a pain diary in a dose finding trial or just a remind functionality in a trial for hay fever drugs. Other scenarios could be added to the list.

As a conclusion, it can be stated that the wireless access protocol in combination with the new generation of wireless user agents offers potential for being used in clinical trials. This is true not in general, but this kind of alternative input could be used especially when direct input by the patient is required or when patient data have to be monitored continuously during some time (e.g. ecg). At this moment it seems to be unrealistic to use this technology in long term trials (app. 3-5 years) since the future of this technology can not be predicted in any way, it may rise or it may disappear. But for short time trials (some weeks of duration), WUAs offer a innovative way to connect

patient data directly to the trial system and hence open the opportunity to receive better data quality at an earlier date.

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