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A Technical Bulletin Published by EDC Management Issue No. 25

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In the next issue of ***EDC Today:***

Computer Security: Database, Network, and Internet

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3-23-04-5219

Mobile Computing – the Basics

EDC Today *is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.*

Recently, a number of readers have requested we write about how ECS might benefit from new technology focused on those of you that are mobile (i.e., those of you that do not do all of your work while sitting at a desk!) In this issue, we discuss the basics of mobile computing, some of the new technology, new standards, and even some of the buzz words flying around, and try to provide a clinical research context (with examples!) of just how mobile computing might be relevant to someone working on clinical trials.

Introduction

With the advent of mass acceptance and extensive availability of digital networking, computing has started the move from being limited to an immobile desktop environment, available only while one was in their office at work, to one of computing anywhere and anytime. Early efforts to provide connectivity to those "on the go" were pager "alerts" limited to "call the office" types of messages. Subsequent early efforts were alphanumeric text pagers and cell phones that provided an improved level of connectivity. When digital networking went beyond the early cellular networks, the mobile computing environment truly came into being, and with it came a plethora of acronyms, cryptic buzzwords and references to wireless standards that even a professional in the field might find bewildering.

Who might be a candidate for mobile computing? Anyone whose productivity diminishes while they are not at their desk or work center is the potential beneficiary of a mobile computing solution. Sponsor personnel that are not always at a desk, for instance, CRAs, Study Monitors, people working on the shipping floor, packaging study materials such as CRFs and study agents (drugs) are other possible mobile computer users. At the investigator site, personnel that visit patients, and staff at operating and procedure rooms and even supply closets might be potential users of mobile computing solutions.

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Why Go Mobile?

At first 'why go mobile?' seems to be a very difficult question. Looking at what sort of mobile computing is pervasive today, one might use a "what is here today? – what could be here tomorrow?" approach to answering it. Currently, for many people, the primary hope for mobile computing technology is to always be connected in today's digital world. This connectivity usually consists of paging, voice (i.e., telephony), e-mail and/or text messaging. Applications that support these "connections" include personal organizers (e.g., address books containing addresses, phone numbers and email addresses) and calendars.

Mobile computing applications created for a specific vertical market or industry are emerging today. Blackberry lists a number of possible applications for Biopharma on their web site:

- Monitor a clinical trial while at an industry conference.
- Review the latest pharmaceutical research, on the Internet or on your corporate intranet, while meeting with a colleague.
- Access your Customer Relationship Management (CRM) system to view a physician's ordering history while in their clinic waiting room.
- Look up the numbers for local physicians in your contacts list, and call for an appointment while you're in their area.
- Order drug samples while with a physician on a detailing call.[1]

Another emerging application is electronic hospital charts, which replace paper notes and forms with "smart" versions (e.g., data validation done on the fly) that can do far more than just record information. With a Tablet PC, and even to some extent with "lesser" hardware, one could perform "real-time" Electronic Data Entry (EDE) into a sponsor's clinical database; perform entry into the hospital's billing system; record patient history; order procedures, medications, other supplies; or query inventory or stockroom systems.

One of the biggest process improvements that can be realized in the clinical trial arena is effective EDE. In order to be effective, EDE needs to be performed in (or near) real-time, capturing data at the source – and not on scraps of paper. By virtue of direct data entry into a record in electronic form, the age-old bane of transcription errors is eliminated at the source. The power of real-time data problem resolution, regardless of the data's end use, would finally be completely realized.

Ideally, a clinical mobile computing application could even use the mobile worker's schedule and link into the clinical and other databases to prompt them to perform a variety of things that they need to do, as well as display "reminders" and "alerts" that help streamline their work. In addition to the benefit of "smart" e-forms, mobile workers could enjoy the benefits of persistent information that could be distributed and made shareable amongst colleagues.

Quick Definition:

Persistent information is information (e.g., patient data) that is permanent, backed-up, and archived.

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One form of mobility, often used in the past, has been of the "pack and go" type, where one downloads information to a portable computing device, performs ones work "unconnected" to any network, and when done, dials-up or connects at the office to get synchronized (i.e., upload and re-download "fresh" information.) This approach has been used in a somewhat limited fashion for many years, and its shortcomings — such as synchronization problems and lost, broken or stolen devices (resulting in lost information) — have limited the appeal of this approach. The newer form of mobile computing is the wireless "connected" to a secure server. This approach greatly enhances the utility of the information available to the mobile worker, as well as alleviates concerns about lost information due to the device being lost, broken, or stolen (particularly if those electronic records exist only on the device!)

Mobile Computing Form Factors

There are a number of form factors (i.e., size, shape, and configuration) available today for mobile computer users.

Listed roughly by size, these form factors include:

- Tablet PCs (Personal Computers),
- Pocket PCs,
- Personal Digital Assistants (PDAs),
- Digital Cell Phones,
- Blackberry Wireless Handhelds, and
- Alphanumeric Text Pagers.[2]

Tablet PCs resemble slim notebooks and run Microsoft Windows XP/Tablet Edition Operating System (OS.) This OS allows the user to run any current Windows application like Microsoft Office suite members such as Word, Excel, PowerPoint, and Outlook, as well as Internet Explorer and other commonly used applications. The Tablet Edition of Windows XP supports the input information via a stylus (or pen). With a wireless network connection, these devices permit users to do anything they can do with a desktop computer, with the added ability to move about while working and to work at places that are a long way from the office.

Pocket PCs, or Windows CE (Compact Edition)-based handhelds, look like very small notebooks, some of which can be slipped into a large pocket. These devices can run a number of windows-based applications, including slimmed-down versions of Microsoft Office suite members and a slimmed-down version of Internet Explorer.

PDAs, known widely as "palm pilots" after the company Palm Computer that invented them, are thin, calculator-sized devices meant to fit comfortably in an open hand and store easily in a coat pocket. They run the Palm OS and versions of word processors, database viewers (e.g., a program that displays restaurant listings by city or distance from a hotel), address books, and with a modem or other network connection device, e-mail access and Internet browsers (with some display limitations due to size.)

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Blackberry wireless handhelds look a lot like small cell phones with a PDA display showing application icons. Some Blackberry devices have small "two-thumbs typing" keyboards and some of them function as cell phones and/or Long-Range Digital Walkie-Talkies and have the usual PDA applications such as personal organizers, calendar/scheduler, e-mail, and Internet browsers.

What is "Wireless" Networking?

An early form of wireless communications used by computing devices (i.e., computers and peripherals such as printers) involved very short range, direct line of sight infrared signals. This means of wireless communications is usually limited to connecting desktop PCs and notebooks to nearby peripherals such as keyboards, mice, printers, and in some instances, PDAs. In order for it to work, the connection distance is limited to about six (6) feet and there can be nothing in between the devices being connected. Obviously the limitations of infrared have prevented its widespread use in the mobile computing world.

Radio-based signals on the other hand do not suffer the same limitation as infrared, and have become the medium of choice for wireless networking. Some forms of radio-based "wireless" networking are far reaching, including some of the more esoteric networks used by expensive satellite fax/phones. We will discuss only a couple forms of "wireless" networking, those commonly used by mobile computing — Wireless Ethernet and Digital Cellular.

Wireless Ethernet is also known as Wireless Local Area Network (LAN). The most common forms of wireless Ethernet are Bluetooth and WECA (or Wi-Fi.) Bluetooth is often referred to as Personal Area Networking (PAN.) According to Curt Franklin, in his article titled "How Bluetooth Works":

> Bluetooth is a standard developed by a group of electronics manufacturers that allows any sort of electronic equipment — from computers and cell phones to keyboards and headphones — to make its own connections, without wires, cables or any direct action from a user. Bluetooth is intended to be a standard that works at two levels: It provides agreement at the physical level — Bluetooth is a radio frequency standard. It also provides agreement at the next level up, where products have to agree on when bits are sent, how many will be sent at a time and how the parties in a conversation can be sure that the message received is the same as the message sent.[3]

On the other hand, WECA, which stands for Wireless Ethernet Compatibility Alliance, is targeting the enterprise or office use. They support the use of Wi-Fi, which stands for "wireless fidelity", much like Hi-Fi for "high fidelity" in audio equipment.[4] The primary advantage to Wi-Fi (as opposed to the proprietary Bluetooth) is that it operates using the original Institute of Electrical and Electronics Engineers wireless-Ethernet specification, known as IEEE 802.11. Why is this an advantage? First, its not a proprietary standard like Bluetooth, but rather is available to any company that wants to develop wireless networking products that can (fairly) easily connect to products manufactured by others. The second advantage is that Wi-Fi is basically an extension of same networking standard that operates over a wire – so the networking IT staff doesn't need to learn a completely new set of information in order to make wireless networking available to mobile workers, they need only set up some devices that 'bridge' the computers on the wireless LAN to those on the wired LAN.

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Like most standards, IEEE 802.11 is an evolving one, trying to keep up with the changes in computer technology. The first revision of the standard, 802.11b, sets the network communication speed to 11 Mbps (Megabits per second) whenever possible. If signal strength or interference is disrupting data, the devices will drop back to a slower speed. A later, backwards compatible, revision of the standard, 802.11g, sets the speed that devices communicate at up to 54 Mbps, conditions permitting.[5]

The devices that 'bridge' the wireless LAN to the wired LAN are called "Access Points" and basically consist of a wired connector, some computer circuitry and a radio transmitter/receiver. The physical area covered by the Access Point (WI-FI operates to about 300 feet) is known as a 'hotspot'. With older wireless devices, a Service Set Identifier (SSID) and (radio) channel are established and manually entered into both the access point and mobile computer's wireless device. This sets up communications between the two. In newer wireless devices, the access point 'broadcasts' the SSID (and channel) information as the hotspot's name – so connecting to the hotspot (with Windows XP) is a matter of selecting it from a list presented from an icon found in the computer's system tray.

The IEEE 802.11 standard also covers means to keep communications between the computer and the access point secure. The Wired Equivalent Privacy (WEP) algorithm is used to protect wireless communication from eavesdropping. A secondary function of WEP is to prevent unauthorized access to a wireless network; although this function is not an explicit goal in the 802.11 standard, it is frequently considered to be a feature of WEP. WEP is considered weak (i.e., not very secure) and there are a number of replacements being developed as this is being written.

Cellular Networking

Ordinary cell phones offer a means of sending and receiving text messages. There are currently three systems for transmitting information over cellular wireless networks: Short Message Service (SMS) is a text-only service that works with many Instant Messaging programs (e.g., ICQ); Enhanced Messaging Service (EMS) adds simple image and sound capabilities; and Multimedia Messaging Service (MMS) adds sophisticated voice and video functionality.[7] Advances in this area are quite rapid, and its very likely that soon there will be other additions to this acronym jungle.

In addition to ordinary cell phones, "Blackberry" is a company that is pushing its own brand of mobile computing, one that uses the cellular phone network. It uses one or more of a specific type of cellular networking (most of which are fairly new in the United States) – These networking standards are CDMA, PCS, GSM/GPRS, or iDEN.[6] Please see table titled "Cellular Networking Standards" for more details on these and other standards.

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Table: Cellular Networking Standards[8]

Analog		
AMPS	Advanced Mobile Phone Service	AMPS was the industry standard starting in 1978.
Digital		
TDMA	Time Division Multiple Access	This is also called Digital AMPS.
CDMA	Code Division Multiple Access	This is based on a form of spread spectrum technology that separates voice signals by assigning them digital codes within the same broad spectrum.
PCS	Personal Communication Services	Used to describe a newer class of wireless communications services recently authorized by the FCC. PCS systems use a different radio frequency, the 1.9 GHz band, than cellular phones and generally use all-digital technology for transmission and reception.
GSM	Global System for Mobile Communications	This is based on an improved version of TDMA technology. GSM is currently the only one of the three technologies that provide data services such as email, fax, internet browsing, and intranet/LAN wireless access, and it's also the only service that permits users to place a call from either North America or Europe.
GPRS	General Packet Radio Service	A packet switching technology for GSM networks. It's an advanced data transmission mode that does not require a continuous connection to the Internet, as with a standard home modem. Instead, GPRS uses the network only when there is data to be sent, which is more efficient.
iDEN	Integrated Digital Enhanced Network	This provides Digital Cellular Phone, Digital Two-way Radio and Pager all in one unit (i.e., handheld-cell phone.)

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Treading Lightly

As with most new technology, the promise and the excitement caused by it needs to be approached with some caution. The very "newness" of mobile computing means that there are a number of unexpected, unresolved, or yet-to-be worked out areas that could cause the unwary unnecessary expense and/or a lot of grief. It should be borne in mind that wireless technology is pretty new and standards are rapidly evolving - an evolution that might leave your solution unexpectedly obsolete overnight. Another consideration to keep in mind with new technology is that it will always have some "bugs" that have not yet been ironed out.

Currently, there are some recognized problems with digital wireless networking. Many of you are probably already aware of the fact that cellular phones that work with one technology may not work on another (or even with another service provider using the same technology!) Public annoyance with cell phone use, or fears that they may cause interference with critical electronic equipment has lead to the creation of cell phone free zones, some of which are the very areas in which the mobile clinical worker would want to use them (e.g., in hospitals, restaurants and airplanes.)

Electronic records are another area in which there remain unresolved, or yet to be worked out issues that will take some technological and procedural maturity before they can be addressed. For instance, just how e-signatures (or print out and sign) should be captured and just how they should work is still unclear. Also, if the records are stored on the mobile computing device, there will be a need to make sure that the records are not lost, meaning some form of data backup and preservation will be necessary (i.e., all data are "frequently" copied to removable media or uploaded to a server.)

Wireless LAN security is currently being scrutinized, and it appears that it isn't as secure as it should be; for instance, many public "hotspots" are secured with relatively weak Wireless Equivalent Protocol (WEP) or not at all. Browser hijacking is also a concern. When one tries to connect to a public hotspot, oftentimes, you get a list of strangely named wireless LANs within range. When one selects one by launching a web browser, a page appears asking them to "log in". This method of logging in can be easily spoofed and an unscrupulous hotspot provider could "hijack" you and steal confidential information.[9]

Other issues with wireless LAN include some of it current limitations, such as the coverage area of a hotspot being too small (or large!), external radio interference causing noise leading to slow connections, or wireless radio signals interfering with critical electronic equipment. Even with the newer Access Points and familiar LAN configuration, IT staff may have trouble setting up "Guest User" accounts; and even things like SSIDs, WEPs, and other user authentication (log in) schemas.

Lastly, expense of network access may be an unpleasant surprise. Due to fragmentation (the result of dozens of companies competing in the marketplace all with somewhat limited geographical "coverage") you may end up needing multiple accounts with a number of providers to be somewhat sure that you will be near a hotspot.[10] Or, like some other companies, you may find that even mundane things like unsolicited email (e.g., spam) being delivered over an expensive network route (especially cellular ones like Blackberry's) can quickly make the monthly cell phone bill far larger than what was budgeted.

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Conclusions

With the acceptance and availability of digital networking, computing has started the move from a desktop only environment to one of computing anywhere and anytime. When digital networking went beyond the early cellular networks, mobile computing came into being and with it came a plethora of bewildering jargon and acronyms. Certainly there is great promise in mobile computing for those whose work takes them away from their desk for any significant periods of time. Being able to get or remain "connected" can help prevent one's productivity from sagging. Furthermore, it offers a degree of comfort and security when on the road for company business.

Current wireless solutions offer voice and text messaging, e-mail, Internet access, and personal organizer functions like scheduling, personal calendars, and address books. Emerging, vertical market applications offer exciting promises for biopharmas, including those of breakthroughs in effective EDE; advances in secure, persistent, shareable electronic record keeping; and efficient electronic patient charts and even patient diaries. The long promised paperless work environment might finally come into being when electronic paper proves its ability.

Digital networking standards are rapidly being introduced and/or enhanced. The best thing about all this change is that there is hope that a secure, private, and "at your fingertips" form of communication will come about in the future. For those of you who like to live out there on the bleeding edge, tread lightly and investigate what mobile computing can do for you today. For those of you who like things that work smoothly, reliably, each and every time, we hope you will at least understand the excitement of those that forge the way and keep an informed eye on the new developments that surely will come.

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Who's behind the research?

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