ABSTRACT

Last year during the opening session of SUGI 25, Dr. Goodnight introduced the SAS user community to the potential for using SAS programs to deliver information to handheld devices over a wireless network. Several papers and presentations in SUGI’s demo area that same year elaborated on what Dr. Goodnight introduced by going into the details of Palm computing and WAP protocol specifications and requirements.

Since that time, wireless devices have proliferated in the U.S., increasing the value of a SAS IntrNet server as a wireless information delivery mechanism. In addition to the Palm VII, there are also WAP telephones and Pocket PC’s. The Bluetooth protocol will make these and other new devices more valuable and more ubiquitous.

Each of these platforms has its strengths and weaknesses. SAS programs can be written to run on the server and then deliver output to some or all of these platforms so that your users can choose whichever device fits their needs. Developing SAS programs with multiple outputs helps prevent your program library from becoming obsolete, even as output devices change.

After SUGI 25, Synteract immediately began developing wireless SAS applications. In this paper, we discuss the infrastructure required for wireless delivery, and presents several in-use wireless SAS applications that show how Synteract modified its existing library of SAS programs to function in the context of wireless information delivery, using only base SAS and SAS/IntrNet.

INTRODUCTION

We are already able to have near-universal access to stock quotes, e-mail and traffic and airline information. We are not far from the day when I can pre-order my grande non-fat latte using my telephone on the way to Starbucks. This kind of universal access to information, goods and services is generating changes in many aspects of our lives, and SAS programming for clinical trials is no exception.

One of the obvious difficulties of developing for wireless handheld devices is the pace of change. Most of Synteract’s wireless development in 2000 has been done for Palm devices with wireless capability (Palm VII, Vx, and Ile). We chose Palm as our initial development platform because of the popularity of Palm devices in the U.S. But our conversations with SAS at SUGI 25 made us realize that the continuation of this popularity could not be taken for granted, and that we needed to be prepared to support other devices, in particular the WAP telephones that were already widely used in Europe. In addition to Palm and WAP devices, shortly after SUGI 25, several vendors introduced the Pocket PC, which uses a modified version of the Window operating system and can be accessorized for wireless internet access.

This rapid pace of change is particularly disconcerting to those of us who work in the biotechnology and pharmaceutical industries, where it is expected that applications are stable, validated, and maintained in a controlled environment.

When SAS rewrote its software for the Nashville release and separated the data processing tasks from the data output tasks (via the ODS), it provided a good model for SAS programmers to follow if they are seeking to participate in the wireless revolution without subjecting themselves to endless rounds of redevelopment and revalidation.

The examples we present today are meant to show:

- How wireless applications can benefit patients in a clinical trial
- How they can benefit sponsors of a clinical trial
- How SAS programs can be written as flexibly as possible to produce multiple output destinations while minimizing the work involved in revalidating programs as a result of technological changes.
- How a single wireless SAS application can be written to send output to any or all of the different wireless platforms.
- How a simplified Palm Query Application can serve up applications with virtually no need for repetitive downloading of files to the handheld device when applications change or new ones are developed.

In each case the Palm query application sends
parameters to a SAS/IntrNet session, runs a SAS program against a live database, and returns the results to the device.

For technical reasons we will demonstrate these applications with screen shots, but we will have Palm devices available for anyone who wishes to see a live demonstration of any of the applications presented.

**A SAMPLE SAS PROGRAM: RANDOMIZATION IN A CLINICAL TRIAL**

One of our clients presented us with a requirement to make the process of randomization available to them on the internet while keeping the SAS processing and programming under our control. We were in the process of implementing this last year around the time of SUGI.

We already had the randomization algorithm written and validated for standard web output. So to meet our client's requirement, we decided to add to the functionality of this program. We left the randomization code alone, but developed the output portion of the program to retain the ability to output standard HTML for a traditional web browser and then to add to its output capability by writing a new section of code that outputs the randomization results following the protocol for Palm devices. Since we had just learned about the WAP protocol, we also created WML output at the same time.

The modified program produced:

- Randomization assignments based on user parameters.
- Standard HTML output for web browsers.
- Web-clipped output for queries from Palm devices.
- WML output for queries from WAP devices.

We found it useful to think of the three different outputs as an output delivery system like SAS's ODS, where different (or even multiple) outputs can be produced for the same information.

Although we felt we were being far-sighted in laying the groundwork for future WAP delivery, we figured that we probably didn’t know the full extent of the future. So we wrote the code so that future validation would only be required for new outputs, leaving the core randomization code untouched. In this way, we had created a flexible program that we felt would serve us well and the technical world continued to change around us.

Since this program randomizes patients with advanced liver disease waiting for liver transplants, the speed with which they can be given cohort assignments and begin treatment is extremely important. The program is short and its output is limited, and so the code was an excellent candidate for wireless delivery.

**SAMPLE PROGRAM: DISTRIBUTION OF ADVERSE EVENT INFORMATION**

Wireless delivery of clinical information can also benefit medical reviewers who must review and respond to serious adverse events as they occur. Our second sample wireless SAS application provides such reviewers with the ability to view summary tabulations of adverse events, drill down into detail records, view full-text descriptions of adverse events, and even e-mail that text along with comments to another person.

Since the e-mail is generated in the context of the SAS application, the text can be captured and stored in a data set as a record of pharmacovigilance activities.

**SAMPLE SAS PROGRAM: OPERATIONAL REPORTS FOR ROAD WARRIORS**

For clinical monitors who spend a lot of time traveling from one investigational site to another, accessing timely information about a clinical trial can reduce the inconvenience of travel. In addition to the more traditional uses of handheld devices to check flight departure gates or make reservations, Synteract's monitors also use their Palms to get up-to-the-minute information on CRF's that have been collected and queries that have been generated.

Using wireless access ensures that this information is as current as it can be.

**THE PALM QUERY APPLICATION ON THE DEVICE: INSTALLATION AND SECURITY**

Because we constantly develop new wireless applications as our clients need them, it was important to develop a methodology for distributing them that did not require that users to re-download PQA's. Instead, we install only an extremely simple log-in application, which verifies the device id and
then returns a list of available applications.

This list is maintained as a data table, which can be updated with new applications without user intervention. In addition, access to specific applications can be controlled at our server, so that the list of available applications is tailored to the identity of the user. This greatly simplifies the requirements for the wireless client. If a new application becomes available, then the user sees it on the list when he or she next logs in.

The Palm device id and the passwords go over a public wireless network. Palm encrypts these items between the device and their server. From there, we use the HTTPS protocol to protect the data between the Palm server and our corporate server. Synteract’s server verifies that each request originates with the web-clipping proxy at Palm.net and authenticates the username and password information entered by the user. Additionally, a record of each request is maintained in a log.

AVAILABILITY OF PRESENTATION

Following SUGI 26, a copy of the slides used during this presentation, including screen shots using the Palm emulator for demonstrating specific SAS applications, will be available at www.synteract.com.

REFERENCES

For SAS developers wanting to write programs to display output on handheld wireless devices may want to consult:

- Web Clipping Developers Guide at www.Palm.net

For more information about implementing WAP solutions, see:

- WAP-Enabled SAS Applications, SUGI 26 Proceedings, S. David Riba

For anyone wishing to develop applications for handheld devices that do not need real-time wireless access to a server, consult:

- Getting Data From SAS to Your Palm, SUGI 26 Proceedings, Jack Hamilton.

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