SMS Reportable Event Management Systems (SREMS)

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Agenda

- Background
- Program Objectives & Requirements
- Development Tools
- Concept & Methodology
- Program Features
- Application
Background

**Regulatory**
- Clinical trial sponsors are required under regulatory and ethical guidelines to disseminate clinical trial adverse event reports to investigators and institutional review boards (IRBs) involved in the clinical trials.

**Research**
- The current system for protecting individuals participating in clinical drug trials is outdated and needs to be overhauled. (Overhaul of Clinical Trials to Improve Patient Safety: *JAMA*, Mar., 2001)
- Serious concerns have been raised regarding the process by which the safety of participants in clinical trials is currently monitored. (Overhaul of Clinical Trials to Improve Patient Safety: *JAMA*, Mar., 2001)
- Each year 2.2 million Americans suffer serious adverse reactions to drugs, which is referred to as Adverse Drug Reactions (ADR) or Adverse Events (AE). Of these 2.2 million Americans, more than 100,000 will die. Annually, the costs of treating adverse reactions in the U.S. are almost $4 billion. (*Pharmaceutical Drug Discovery and Development: Serious Adverse Events; Tim Furey, Mar., 2005*)

**Technology**
- E-mail and mobile phones are communication tools prevalent in modern society
- Mobile technology has made a recent and rapid appearance into low and middle-income nations. *The Economist* “The power of mobile money.” *The Economist* 14 Sept, 2009

Study Background

- 10 Visits / Volunteer; 24 month study period
- 19 Clinical Case Record Forms / Volunteer
- 162 enrolled volunteers
- Estimated 15% of serious adverse events/reportable events will occur
- Involved persons who are both local and abroad enter data in eCRF via iDataFax 4.1.1
### Objective & Requirement

- To detect the AE/SAE that has been entered in iDataFax eCRF by clinical site staff
- All notifications can be sent to sponsors, investigators and related persons who are in various locations at any time
- AE/SAE are required to be initially reported to designated parties involved and to the EC/IRB as soon as possible
- To implement strategies that help safety monitoring requirements
- The SMS/email transmission status can be tracked

### Program Requirement

- To export data from DataFax database to SQL every hour
- Check condition of AE/SAE from clinical database
- The SMS/Email will automatically alert persons involved
- Do not allow all persons to edit data after report submission to EC/IRB
- Any updated data - program will be repeated as follow up report
Developing Tools

- DFsqlload command
- MS-SQL Server 2008 R2
- MS-Exchange 2007 server
- SMS Gateway provider
- PHP programming tools
Concept & Methodology

DataFax Server

Database Server of SREMS

Web Server of REMS

SMS Gateway

Web Server

Manual Send SMS

Auto Send SMS

Send E-Mail

Send SMS to person as follow CRC, SI, VSI, PI, AI, SPONSOR, COO, SMM, LMM, COG and PVC

Auto export SAS data to Database server (MS-SQL) of SREM System

Example of SMS/Email Alerts

Transmission Summary Report
### Tracking Email Alerts

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<tr>
<th>Project</th>
<th>Sending Reference</th>
<th>To</th>
<th>Message</th>
<th>Return</th>
<th>Status</th>
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Total 6 Record : 1 Page : 1

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Thank you