



DataBuddy- CRF Relay Enhancement

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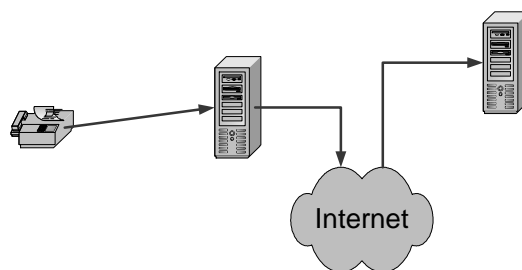
A Quick background on SCHARP

- SCHARP is the Statistical Center for HIV/AIDS Research and Prevention
- Affiliated with the HIV Prevention and HIV Vaccination Trials networks
- SCHARP has processed 3.4 Million CRF pages since it was started
- SCHARP currently processes an average around 40K pages per month

SCHARP (continued)

- SCHARP currently has studies in 18 countries at approximately 50 sites
- The majority (approximately 80%) of faxes are sent by internet ready fax machines

Start With A Little Background: Simplified Internet CRF Relay



Common CRF Relay Issues: Form Discrepancy

- Site claims they have faxed the forms, but they appear on the QC report as not sent
 - Forms may stick together in fax machine
 - Other factors
 - Forms faxed improperly
 - Computer/system issues

Common CRF Relay Issues: Infrastructure

- CRF relay failures due to limited infrastructure
 - Limited or intermittent electrical power or Internet connection
 - Fax machines in need of maintenance or replacement
 - Network changes
 - External circumstances (lightning, flood, etc)

Common CRF Relay Issues: Trucking

- Some international sites have limited infrastructure, which requires trucking CRF forms from remote clinics
- CRF delays or failures due to trucking forms from remote sites to central location
 - Any time CRFs are physically removed from the site where data is collected, it can be misplaced or lost
 - If the site is far from the central faxing location, delays may occur due to the transportation process

Common CRF Relay Issues: Data Backup and Storage

- Some sites do not currently have electronic backup and storage capacity
 - No method available to electronically store faxed CRFs
 - Without the ability to electronically backup CRFs, there is no cost effective method of sending large volumes of data in the case of a relay failure

Common CRF Relay Issues: Relay Status

- Currently there are limited methods to determine if the CRF Relay is functioning properly
 - No remote diagnostics on the relay system- small problems can become big problems
 - QC Report indicates many missing forms, several weeks later

The Solution To These Problems?



What is DataBuddy?

- A combination of hardware and software that save and send electronic copies of the CRFs
 - Small Linux PC connected to the Internet
 - Simplified web interface (does not require monitor, keyboard, or mouse)
 - Perl and CGI scripts perform certain functions (e-mail, encryption, etc)
 - CD data transfer/storage
 - USB key data transfer/storage
 - Built-in diagnostic modem
 - Compact, easy to ship

What Does DataBuddy Do?

- Sends diagnostic information to SCHARP
- Provides a method for electronic data backup
- Provides dedicated mail server to fax machine
- It can encrypt electronic data
- Allows data transfer from remote satellite clinics

DataBuddy: Remote Diagnostics

- Data Buddy can indicate if the CRF relay is functioning
 - Periodic status e-mails
 - Number of fax pages sent
 - TIFF Checksums
 - Network diagnostics
 - DataBuddy Status (drive space, etc)

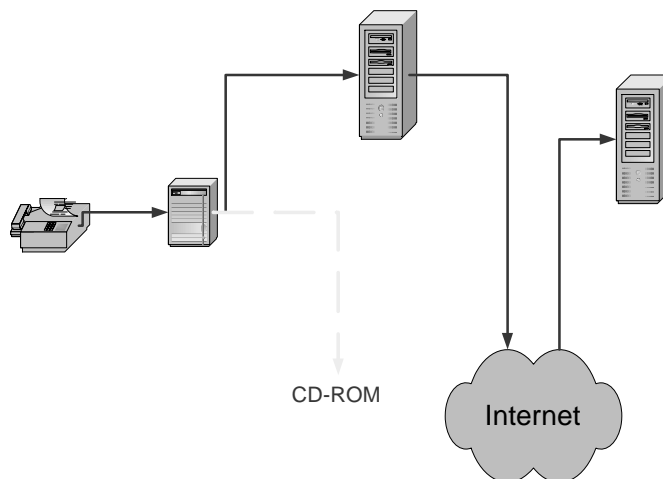
DataBuddy: Electronic Data Backup

- DataBuddy has the ability to copy electronic data to CD-R, CD-R/W or USB Memory Stick
 - Allows for data to be sent via Fed-Ex on a CD-ROM, while CRF pages stay at site
 - Allow for comparison and troubleshooting of CRF relay system

DataBuddy: Data Security

- DataBuddy provides a dedicated mail server for the internet ready fax machine
- DataBuddy can be configured to encrypt CRF e-mails and data prior to sending them
 - DataBuddy uses GnuPG (gpg) encryption

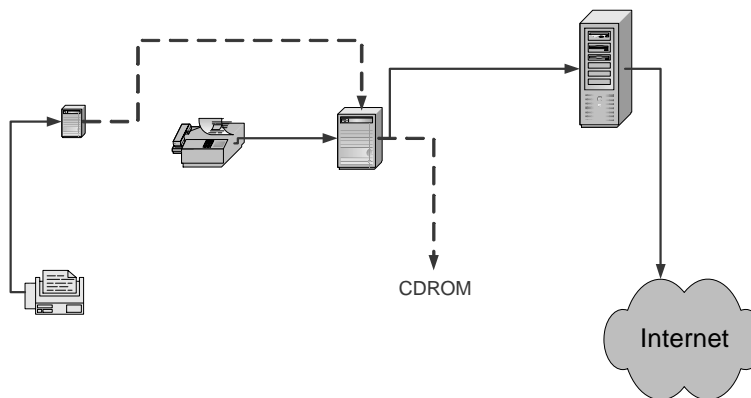
How it works



TruckBuddy

- A “lite” version of DataBuddy that provides remote sites with the ability to save electronic copies of the CRFs
 - Eliminates the need for remote sites to truck CRFs to a central location for faxing
 - Satellite sites are not required to have a phone or Internet connection

Data Buddy / Truck Buddy



DataBuddy /TruckBuddy Advantages

- Increased data security
- Allows remote sites with limited infrastructure to data relay
- Provides diagnostic data on CRF Relay
- Helps prevent small CRF relay problems from becoming large problems

DataBuddy/TruckBuddy Considerations

- Theft and security issues
- Potential for unit loss/failure
- More complex than existing CRF relay systems
- Additional cost
- Additional space



CRF Relay
Backup System

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