

eSource: The Future is Here

By Norman M. Goldfarb

There are five primary sources of data in a clinical research study:

- Existing medical records
- Text data collected during a study visit
- Lab data
- EKG, image and other data generated by equipment
- Subject diaries

This article reviews three products that streamline the process of collecting text data collected during study visits.

Paper Process

The traditional process is very paper intensive. For example:

1. Study coordinator elicits data from subject.
2. Study coordinator enters data into source documents.
3. Study coordinator copies data from source documents to paper case report forms (CRFs).
4. Site monitor collects CRFs and carries or sends them to sponsor.
5. Sponsor personnel enter CRF data into study database, perhaps with a manual "double key" data entry process to ensure accuracy.

In this process, each piece of data is manually entered onto a piece of paper or into a computer up to four times. (In addition, to ensure that the source document is neat and legible, the study coordinator may first write data on an unofficial piece of paper that no-one else sees.)

eCRF Process

Electronic CRFs (eCRFs) streamline the process substantially:

1. Study coordinator elicits data from subject.
2. Study coordinator enters data into source documents.
3. Study coordinator copies data from source documents into computerized case report forms (eCRFs).
4. Data is automatically uploaded to study database.

In this process, each piece of data is manually entered onto a piece of paper or into a computer twice.

Several problems remain with eCRF-based processes:

- Each study typically requires study coordinators to learn a different eCRF system.
- Study coordinators generally believe that eCRFs take perhaps 25% longer to complete than paper CRFs. (This estimate may not consider benefits such as reduced data queries.)

- Manual transcription of data from source documents to eCRFs has an error rate greater than zero.
- Study coordinators do not see edit checks and subsequent data queries until long after the subject visit. As a result, it is difficult and time-consuming for study coordinators to find missing data and correct errors. The nature of eCRF data entry encourages batching of the work, increasing the time delay.

eCRFs are a partial solution. Sponsors clearly benefit from the use of eCRFs because sites do their data entry work for them. Study coordinators, however, do not share in those benefits. Quite the opposite; as mentioned above, eCRFs probably increase their workload. Any new process or technology that benefits one party to the disadvantage of another will generate heel-dragging and ill-will.

eSource Process

The complete solution is eSource: Enter the data into the computer once during the study visit. The cost, timeliness and quality advantages are clear for both sponsors and sites:

- No time-consuming and error-prone manual transcription
- No delays in transmitting the data to the sponsor (especially important with the advent of adaptive trial designs)
- Fewer, shorter monitoring visits
- No (or many fewer) after-the-fact edit checks and data queries

Depending on the implementation, eSource offers many additional benefits:

- Step-by-step scripting of study coordinator through subject visits so all data is collected at the right time and in the right order
- Alerts when computer detects an issue such as a conflicting concomitant medication
- Handwriting and voice capture for progress notes with automated or near-real-time transcription in a low-wage country
- Real-time searchable access to the informed consent form, protocol, investigator's brochure, site SOPs, etc.
- Real-time chat with a medical monitor
- Real-time integration with sponsor's database for sophisticated multifactorial edit checks
- Automatic biometric authentication throughout the process through voice or handwriting recognition
- Automatic time reporting (how long do study activities really take?)
- Immediate backup of data to secure location

This article reviews three very different eSource solutions:

- **LifeTree eClinical's ICTM** is a comprehensive EDC system for Phase I-IV trials, registries and surveillance projects. LifeTree Hub is a customizable portal and secure repository for accessing study-related data and documents.
- **Data Capture International (DCI) SureLynx** uses barcode-enabled hand-held devices (PDAs) to automate electronic data capture in inpatient studies.
- **IVRAS IVAtrial** enables study personnel dictate data in a structured format through any telephone.

The five tables below describe these products based on information provided by the companies. To learn more about these products, contact the companies.

Table 1. General Information

Parameter	LifeTree	DCI	IVRAS
Contact name	Kit-Bacon Gressitt	Troy McCall, Ph.D.	James Chu
Title	Vice President, Marketing	President	Vice President, Business Development
Telephone number	1.800.211.2799	404-384-0145	1.415.307.6730
Email address	kbgressitt@lifetree-tech.com	tmccall@datacaptureintl.com	jchu@ivras.com
Website address	www.lifetreeclinical.com	www.datacaptureintl.com	www.ivras.com
Product name	LifeTree ICTM 4.4 and LifeTree Hub 1.0	SureLynx v2.0	IVAtrial v1.2
Demonstration available	www.lifetreeclinical.com/web_pages/demo/lifetree.html	Contact company for local demo.	Contact company for local or remote demo.
Number of wireless studies to date	None, but 19 standard EDC studies completed or in progress.	Over 200	2 pilot projects currently in progress
Set-up price in typical configuration	Midrange pricing with superior functionality makes pricing very competitive. User hardware extra.	Typically 15-20% more than paper	See below
Unit price in typical configuration	Midrange pricing with superior functionality makes pricing very competitive.	Not available	Function of trial size and system usage

Table 2. Architecture

Parameter	LifeTree	DCI	IVRAS
Delivery format	Windows-based tablet computers	Symbol Technologies' ruggedized PDAs, server at investigative site, wireless access points	Any telephone and headset or dictation-type device. Telephones are available everywhere, including developing countries. Application Service Provider (ASP)
Connectivity	Wired or wireless with Internet connections to client or LifeTree server	Wireless connection to local server at site. Batch or real-time uploads to DCI or client server	Telephone to IVRAS servers (real-time)
Integration with other CTMS systems for sites and sponsors	Data uploads	Data uploads	Various architectures with EDC and data management systems

Table 3. Data Capture & Storage

Parameter	LifeTree	DCI	IVRAS
Data collected	Clinical data including CRFs, safety data, lab data, study events, monitor visits, and biomedical images	Study events, e.g., dispensing of study drugs; vital signs	Text data obtained during subject visits.
Data entry (e.g., stylus, voice)	Stylus, keyboard, virtual keyboard, mouse (and equivalents) and voice	Stylus or finger on virtual keypad, barcodes	Voice over telephone
Voice capture for progress notes	Yes, if supported by the Tablet PC	No	Yes, with transcription in realtime to 2 hours.
Handwriting and/or voice capture for progress notes	Yes, handwriting recognition is supported by hardware	No, progress notes can be keyed into computers.	Yes, structured voice data is recognized and translated into digital form in real time. Free speech (unstructured comments) is captured and transcribed by IVRAS in maximum of 2 hours.
Edit checks	Over 100 standard edit checks. Others can be created upon request. Edit checks can be performed either locally or on server.	Custom per protocol	Yes, client creates them using IVRAS tool
Data storage and security	Data uploads are stored on client or LifeTree server.	Data uploads are stored on client or DCI server.	Voice inputs are digitized and stored on IVRAS server in real-time so they cannot be lost or tampered with. Data is available in real-time.
Data import	Can upload or link to medical imaging data and soon any scannable document.	Barcode scanning	No
Data export	Yes, available in SAS, Excel, XML and text file formats. Data extracts can be filtered, e.g., for "accepted pages". XML output is CDISC compliant	Yes, in client-defined format.	Yes, in real-time (every 5 seconds) to any CDISC-XML compliant system. Other formats on request

Table 4. Set-up & Training

Parameter	LifeTree	DCI	IVRAS
Study set-up	CRF development wizards and other tools enable insertion of template elements (such as headings, text labels, text boxes, drop-down lists, text areas and lists) and edit checks; page and element formatting, A typical 30 page/250 edit check CRF can be created in 3-4 weeks; a typical 50 page/450 edit check CRF takes 5-6 weeks. CRF templates can be reused without charge. Customer control of many system functions and tools to create CRF pages minimize reliance on Lifetree consulting services.	2-4 weeks. 1-2 hours to setup hand-held devices.	Maximum of 2 weeks for initial version of voice scripts
User training	Web-based teleconference training takes 2-4 hours online.	1 hour for handheld device. 1-2 days for system administration	Very short learning curve: 15 minutes online and telephone

Table 5. Features

Parameter	LifeTree	DCI	IVRAS
Alerts	Automatic email, PDA and telephone alerts to study personnel, e.g., for study visits based on built-in study calendar.	No	
Reports	40 standard reports, some for sponsor, some for site, and some for both. Ad-hoc reporting as well.	10 standard reports plus 5 custom reports included.	
Scripting	Yes, context-driven presentation of next CRF page based on site, user role, and data. Instructions can be incorporated in the form or in pop-up windows; User can be directed to another form, e.g., to report an AE in more detail.	Yes, when coordinator scans barcode on subject's wristband, specimen collection tube, or medication, SureLynx verifies correctness and directs coordinator to perform next step.	Yes

Real-time user access to study documents	Yes	No	No
Real-time communications with a medical monitor	No, but alerts can ask someone to call immediately.	No	Yes, system can autodial call through telephone
Audit trail	Yes: (a) Visually scroll through the eCRF versions. (b) Create PDF of current CRF with text audit trail attached. (c) Reports.	Yes, all activities are time-stamped. Audit trail is accessed through administrator module.	Yes, all data inputs are time/date/identity-stamped
Biometric user authentication	Whatever is supported by the hardware, such as a thumbprint.	No	Yes, biometric voice recognition
Real-time visibility for sponsor	Yes, data is visible to sponsor within seconds	Sponsor can watch progress of visit in real-time.	Sponsor can watch progress of visit in real-time.
Automatic time reporting	No	Yes	Yes

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