e-Tracking: An Approach to Comprehensive Patient Tracking

e-Tracking makes use of data in the contracts and grants database, the Clinical Data Management System and the Clinical Trials Management System to provide timely and accurate data for managing trials, supplies and contractual payments with greater efficiency.

***Joel Hoffman** presents a detailed insight into patient tracking during the management of clinical trials*

Investment in Clinical Data Management and Clinical Trials Management Systems can be leveraged to provide timely and accurate data for managing trials, supplies and contractual payments with greater efficiency. The administrative systems that track patient status and pay investigators do not, on the surface, seem likely to have a major impact on a pharmaceutical company's bottom line. Yet rapid completion of each clinical trial is critical to minimizing time to market, and timely payment to investigators is key to how quickly trials are completed. When investigators do not receive timely payments under their research contracts, they may be less motivated to recruit appropriate patients for a trial, slowing the research process significantly. They may also be reluctant to conduct further trials for the company.

Most pharmaceutical company systems that can be used to collect and hold data relevant to investigator contractual payments were designed for other purposes. They do not provide the timely, accurate, and consistent information required for real-time patient tracking:

- The tele-randomization system is limited to initial randomization and does not provide on-going data. It is also unlikely to cover all trials.
- CRF imaging and workflow systems are often up to six months behind in entering data-hardly conducive to timely payment to investigators.
- Central clinical laboratory data, while near real-time for most of the studies in which it is used, does not include all the data required to make payments and does not cover all studies.
- Electronic data capture systems, while they have the potential to solve this problem, are currently used in only a limited number of studies. In addition, with EDC, as with other data collection systems, data may not be timely or may be inconsistent in the degree to which it is timely.

Because there is no single, timely, and authoritative source for this information, additional systems and processes have been developed to get the required data into systems for trial management, clinical supply, grants and contracts management and investigator payment.

Manual Workarounds and Their Limits

These workaround systems typically take the form of blank weekly activity reports for each patient that are faxed to the investigator's office, to be completed and faxed back by the investigator's staff. Each report faxed back must be copied and stored in the department. Figure 1 indicates the workload and error potential for the pharmaceutical company of such an approach

These systems consume hundreds of hours of staff time that add little value to the data and introduce multiple inconsistencies with data in other systems. Both keystroke errors and other inconsistent data require additional staff time to resolve. The ultimate output of this system is a series of spreadsheets. These are not uniform but rather take a range of formats as preferred by each of the clinical research associates (CRAs). Data from these varied spreadsheets must then be entered into the trial management system and grants and contracts database.

e-Tracking

Workload model, patient activity fax system	
Typical number of simultaneous trials, large pharmaceutical company:	**70**
Investigators per trial:	**20**
Faxes sent out and returned, per week:	**1400**
Probable keystroke errors per fax for which data entered: (Based on average keystroke error rate of 3 per100).	**3**
Estimated staff hours per week required for data reconciliation (all trials):	**over 3000**

In addition to being inefficient, these workarounds may not be effective in monitoring the status of a trial. A company may be uncertain whether a trial is running on schedule and on budget, and whether each site has sufficient supplies. Because there is no unified tracking system, there is no easy way of knowing whether a lack of data means there is no new cost data to report or that data is not being properly captured. Where there is a high degree of budgetary uncertainty about a significant number of trials, the financial implications for the company can be problematic.

The E-Tracking Solution:
Efficiency, Focus, and Clean Data

Despite significant investment in clinical data management and in clinical trial management systems, timely patient tracking and study progress requires CRAs to work with investigators on a weekly basis. This is not likely to change until EDC becomes an integrated part of investigator medical practice. However, significant efficiencies can be achieved by leveraging information available in existing systems to create a single tracking system rather than having many people tracking the same data in multiple and independent systems.

We term this alternate approach "e-tracking." It makes use of data in the contracts and grants database, the Clinical Data Management System (CDMS) and the Clinical Trials Management System (CTMS) to provide timely and accurate data for managing trials, and trial supplies, as well as contractual payments, with significantly less effort. Figure 2 illustrates the data flow in e-tracking.

E-tracking is based on a consistent, centralized system that requires only exception reporting. It integrates data from the source systems to provide CRAs and sites with expected enrollment and procedure information:

- Investigator payment schedules, often stored in clinical grants databases, define in detail how investigators are to be paid for procedures.
- Study set-up data in the CDMS and CTMS provides information about subject status and the order and frequency of procedures.

Data from these three systems can be used together to accurately determine patient progress, clinical supply needs and investigator payment requirements and thus, the accrued costs of a study. Patient activity dates can be retrieved from tele-randomization, EDC systems, data from a central lab, or by contacting the site. Combining this with information from the clinical grants database, the CDMS or the CTMS, it is possible to generate a schedule of expected patient activity which specifies dates on which a patient is expected to have office visits, specific diagnostic work, and treatment. In particular, the date of the next trigger for an investigator payment can be predicted.

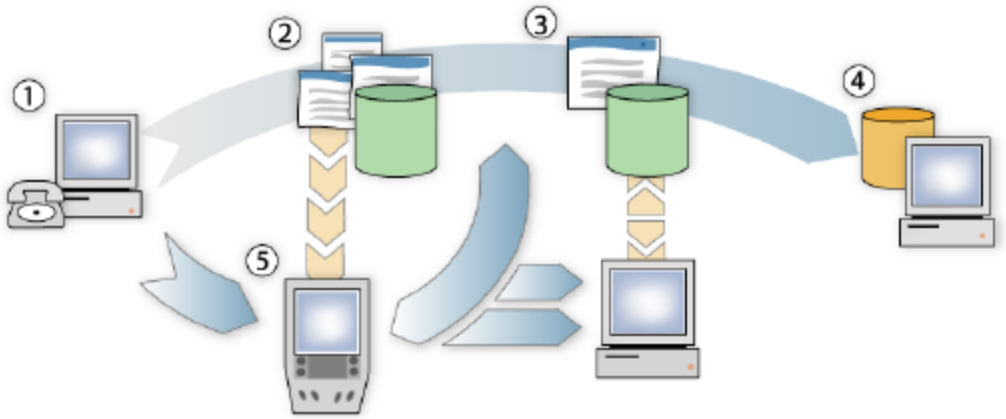
In this model, each investigator receives either a FAX or an e-mail that says, in effect,
"Here is the activity we expected to see this week for each of your patients. Is this what actually happened?" If the site verifies that the information is correct the system initiates a request for the appropriate investigator payment. If the site modifies the data, then the source database can be corrected and thus kept current.

Where investigators have access to the Internet or wireless devices, e-tracking can all but eliminate manual processing. They receive a weekly e-mail with a web link that connects them to a secure website where they can look at the projected activity report for their patients. If data is correct, they check yes to close the feedback loop in the system. If the data is not correct, it can be corrected over the web.

Investigators who do not use the web in this way receive a fax form with predicted patient activity. They mark any exceptions to the projected activity, and fax the form back. Forms with no exceptions can be processed automatically. Manual processing is therefore only required for those reports where investigators are not using the Internet and there are exceptions to the projected activity patterns.

This process cuts labor requirements at every stage, and increases the consistency with which incoming data is handled:

- The investigator's staff need only enter exceptions, rather than all activity.



1. Tele-Randomization
CRF Imaging
Central Labs
EDC

2. Clinical Database
Clinical Trial
Management System

3. Grants and
Contracts
Database

4. G/L System

5. ACTIVITY
REPORT

- Forms can be easily tailored to specific needs.
- Even with some tailoring, reports are much more standardized in format than with the current fragmented approach. This means data entry can be handled by a single group, making the process simpler to track, monitor and manage.
- With less data entry required, keystroke errors and other sources of data inconsistency are greatly reduced.
- Fewer hand-offs of the data result in faster data flow and more timely payment.
- The projected activity data, as modified by the exceptions indicated, can go directly into the CDMS or CTMS as appropriate, then to the grants and contracts database. From there it can go to the general ledger for payment or to the clinical supplies system for shipping supplies.
- Sites with large numbers of discrepancies can be targeted for additional training and/or CRA visits.

Integrating systems and processes is not trivial. Substantial investment is required to put processes in place that define studies early and to develop systems that enable the definition and collection of meta-data. But many companies have already made this investment in CDMS and other systems. What they have not done is leveraged the investment to its greatest advantage.

When electronic data capture is used for all clinical trials and the approach used eliminates delay between patient activity and central data capture, the information required to assure prompt payment of clinical investigators will be readily available. Until that point, however, e-tracking-the integration of existing systems and processes to project patient activity and confirm actual activity-offers a superior way to track clinical progress, maintain adequate clinical supplies, generate prompt payments to investigators and monitor the accrued costs of clinical trials.

About the Author

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