

Introduction

The CDL is a new role that will become a standard in the industry for companies that want to make more efficient use of limited resources: time and money. A CDL is key in that he or she conducts real-time data review and facilitates centralized control of data management.

The CDL role within a CRO is the link to a successful clinical trial. This individual has the ability to influence the three Cs of site management: connect, communicate, and control.

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The Role of the CDL in the Clinical Trial Process

A CDL, as the name implies, must have extensive clinical-trial experience, a working knowledge of data management and GCP and ICH guidelines, as well as the ability to act as a liaison between other in-house staff members, coordinators, physicians, and sponsors. The CDL position combines the clinical research training skills of the clinical monitor with the data expertise and discipline of a clinical data manager. As such, CDLs are the first to review CRFs to make sure that the protocol is being followed. They are responsible for timely review of data safety values, such as SAEs, AEs, lab values, and ECGs that are critical to the safety of the patients; they do this in the context of the overall database. This is especially important, as the field monitor's perspective is based on the review of individual site visits. The CDL is attuned to the overall monitoring and data management process from real-time data receipt to data lock, because he or she designed the database with the protocol in mind.

Thus, the CDL is an integral part of the clinical team. This individual typically reports to the project manager, works with in-house statisticians to ensure tables and listings are in sync with the database, and provides real-time and weekly or bi-weekly reports to the sponsor. In addition, and most importantly, the CDL connects with the monitor before and after each site visit.

Reducing Monitoring Costs

The CDL is the focal point for the continuous process of CRF receipt and review and works closely with the sites to obtain clean data before the field monitor reviews the CRFs. This real-time CRF data workflow improves the efficiency of the clinical monitoring/data management process, which results in better service to sponsors, investigators, and staff. This is done through the collection of real-time data and analysis of real-time information and is absolutely necessary to efficiently manage trials.

In essence, the CDL flattens and improves the workflow process in three ways. First, there is no hierarchy or barrier to the flow of the data. Data are reviewed and queried in a continuous process, which spreads the burden more evenly among the team members, i.e., coordinators, field monitors, and clinical data management staff. Second, because the workflow is continuous, at no time does the job become overwhelming. The “clean as you go” philosophy forces timely review and reinforcement of the protocol and CRF thereby allowing all of the team members to do their jobs better. Third, the data become timely and useful information, which are available to all stakeholders for decision-making that can effect the outcome of a study.

One of the CDL’s main functions is to alleviate the burden of the monitors in the field, allowing them to concentrate on their main job, which is source document review, when visiting a site. Too often, monitors are overwhelmed with outstanding queries that they must address and respond to before the review process can even begin. Within the parameters of an improved workflow process — the daily analysis of real-time data — CDLs address queries, prepare query packages, and in many cases, answer the queries by the time the monitor arrives at the site.

Because CDLs review the CRF data in real time, editing can take place within days of a patient visit so that the correction process is more efficient. Using Web-based tools, the CDL can also manage the field monitors’ visit schedules by profiling the quality of each site and determining the sites that require more or fewer visits. Correcting data errors directly with those sites reduces the field monitors’ work at the site during each visit, and allows them to concentrate on source document

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review. This reduces the number and duration of field monitoring visits, a major cost in managing clinical studies.

Therefore, a solid workflow process should include: an in-house trained CDL for each field monitor to reduce the amount of clerical work and corrections the field monitor must make at site visits so that he or she can concentrate on source document verification, protocol compliance, and patient recruitment. The teaming of the CDL and CRA is essential to an efficient field monitoring process. Monitors are a precious resource and, after patient acquisition costs, represent one of the most expensive components of a trial.

Sponsor Benefits

Site selection is a key to executing a successful study, but timely patient enrollment and valid clinical data are critical to the results of each study. Through the use of technology it is possible to receive real-time data from the sites, which are analyzed by the CRO's CDLs.

This new workflow paradigm allows the CDL to integrate the data into the database as information is received. Updated information about the study can be incorporated into daily reports provided to the field staff, the sites, and the sponsor .

One of the key benefits for the sponsor is that the CDL team can profile those screened patients who become screen failures and those who are randomized successfully. These profiles can be provided directly to the sites and in some studies, allow a sponsor to reduce the number of screen failures, resulting in a major cost savings.

Because the CDL has access to real-time data from the IVR or other technology platforms, he or she can make mid-study corrections to project patient recruitment with the use of patient recruitment tools or increase the numbers of sites, which can shorten the enrollment period. This can be a cost savings for the sponsor, but more importantly, the study can be completed as originally planned.

Real-time data analysis can also point to a number of factors that might impact patient recruitment, such as the physician's database, the protocol itself, or the availability of patients — in terms of geography — for the disease factor being studied. Decisions can be made earlier to drop certain sites, amend the protocol, or add sites in different countries. In essence, the appropriate workflow that incorporates CDLs into the process provides timely information for sponsor decisions. The sponsor has real numbers and doesn't have to work from screening logs and CRF data that are weeks old to try to project patient enrollment.

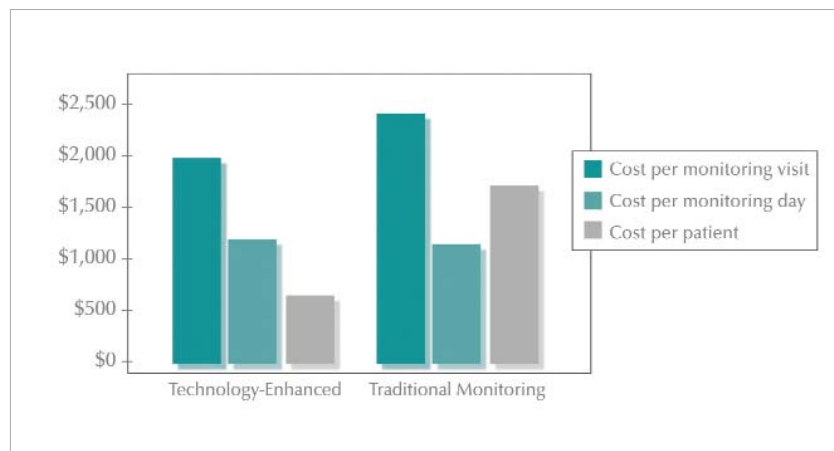
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Streamlining the Process

In-house clinical data liaisons (CDLs) clean and correct data before the field monitor makes his or her visit to the site. This process streamlines the CRA's on-site role, which is to troubleshoot patient enrollment and to check source documents. Within days of each patient visit, data from the sites are transmitted to the CRO where the data are processed and queries are generated within 48 hours of receipt. Query resolutions are completed and clean CRFs are provided back to the field monitoring staff.

Technology-enhanced monitoring from a centralized location reduces the number of days to complete on-site queries, trims the number and duration of site visits, and reduces the number of days needed in the field.

Because CDLs monitor site data daily, they are able to identify potential problems before they arise thereby reducing the cost of field monitoring per patient by as much as half when compared with traditional monitoring.



Responsibilities of a Clinical Data Liaison

Study Start-Up:

CRF and Database Development

- Assist with the development of the CRF to be used for data collection. Relate CRF design to protocol to ensure consistency.
- Assist with the development of primary database structure and tables, and coordinate the testing and validation of the database prior to release into production. Includes performing the validation of text/data fields captured in the database against the CRF, using test patient data.

Development of Logic Checks, Programmed Study Edits, and Reports

- Define and develop list of programmable study edits, based on study protocol, CRFs, and statistical analysis plan. Test and validate the edits after programming has been completed. Identify complex checks (standard and non-standard) for which manual review will be required. Define self-evident changes that can be made to the data.
- Work with programmer to design, create, and validate study-specific reports and data listings to be used for reporting data and/or for performing quality-control checks of data.

Study Conduct:

- Coordinate data review and discrepancy management activities within the data management section in order to assure the integrity of the clinical data with respect to data guidelines and sponsor specifications.
- Develop and utilize ad hoc database queries that will identify data errors and inconsistencies (duplicate records, unmatched records, inconsistent dates, etc.) using relational database tools.
- Act as liaison with statistical group, programmers, and study team members in identification and resolution of data management issues.
- Act as liaison with monitors to address queries prior to site visit.

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- Coordinate database lock preparation activities and perform QC of clinical study data listings for content, format, and output.
- Review and provide feedback on data management related documents.

Qualifications:

- BS/BA in a scientific or medical field or equivalent relevant industry experience.
- Excellent attention to detail, and strong analytical and problem solving skills.
- Proficient in medical terminology.
- Knowledge of relational databases and database design.
- Understanding of clinical research processes.
- Knowledge of CRF design and understanding of CRF relation to the protocol and clinical trial database.
- Computer literacy, including MS Windows environment and its applications, and experience with various technology platforms.
- Understanding of basic programming concepts required; experience with SAS and SQL is beneficial.
- Demonstrates good organizational and planning skills in order to meet deadlines and handle multiple projects.
- Ability to work both independently and as a team member.
- Effective interpersonal and communications skills.

Conclusion

To really improve the workflow process, the CDL is a clinical and data expert who connects team members – sites, CRAs, and data managers – through the use of data collection technologies that are used in a workflow that emphasizes real-time receipt and review. The ultimate benefit of the workflow that is managed through the CDL is to reduce the barriers between monitoring and data management.

The CDL function will continue to evolve. The ability to connect the field monitoring and in-house data management, communicate real-time information for decision-making, and thereby control the processes of patient recruitment and data acquisition improves trial efficiencies and reduces costs. Sponsors want control over their timelines and budgets. One of the ways this is possible is to have the position of a Clinical Data Liaison, who teams with the monitor in the field, resolves queries early on, and locks the database to meet the study timelines.

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About Criterium Inc.

Criterium is a full service, global and technology driven contract research organization that offers a unique mix of high-quality, innovative clinical research solutions for the biopharmaceutical, and pharmaceutical, medical device and CRO industries. From thought to finish, Criterium provides timely and accurate clinical trial data and support services at every phase of development allowing customers to make sound and cost effective decisions about their clinical trials. Drug development companies can benefit from Criterium's expertise, high-value services and products and high-end results.

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