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# Research Coordinator Support:

A Solution to Prevent Costly Data Delays – Remote EMR Access & Clinical Research Data Entry

## Introduction

One issue that is well known in clinical research is the extreme workload of research coordinators who are often tasked with both clinical care and many administrative duties of running clinical trials at their sites like budget negotiation and data entry into electronic databases.[6] Studies and surveys have examined the workload of research coordinators with limited proposed solutions.[2, 8] Electronic medical records (EMR) and remote monitoring have also become commonly examined topics for clinical research administrators, evaluating potential cost savings of using remote access to electronic medical records to accomplish the monitoring activities required by federal regulations for clinical studies.[1] Of interest is to what extent would remote access to electronic health records by support staff influence the timeliness of, and number of corrections needed for, data reporting in clinical research? This support will potentially improve the timeliness of data and safety reporting, reduce the workload of research coordinators, and reduce the associated costs.

*Remote clinical research coordinator (CRC) support for data entry in clinical research is a proposed solution to decrease costly delays in data submission, increase compliance, and increase safety vigilance, ultimately helping to bring innovative products to market sooner.*

# The Duties of Research Coordinators

A primary goal of a clinical study is to collect data that will support marketing approval of a new product and make it available to individuals who could benefit from its use.[6] Having valid and well-organized data collection is therefore essential, and this responsibility typically falls to the clinical research coordinator: *"The case report form is the domain of the clinical research nurse; it is crucial documentation of all subject-specific, relevant, protocol-required data."* Further, the authors note that it is generally the responsibility of the CRC to resolve queries (discrepancies noted between source data and data reported on the case report forms, or CRFs). These can take a significant amount of time and attention from the research nurse, particularly if the protocol has assessments outside of standard-of-care or if case report forms are not straightforward. Often, data must be complete and query-free before a monitor can fully verify the data and provide assurance to the sponsor that the reported data are 'clean' and ready for analysis. Several surveys of CRCs have been conducted in the previous decade to assess the roles and perceptions of research coordinators.

***Results related to data entry are reviewed here.***

*In 2004, a survey of CRCs indicated that 89.2% reported CRF completion was a primary task in all or near all trials.[7] Data entry was reported as a primary task by only 19.4% of respondents, however, the age of the article indicates that the use of electronic data capture systems was not widespread at the time.*

This article also indicated that CRCs were conducting traditional "monitoring activities" in higher than expected rates, including CRF completion and serious adverse events reporting. Further, the study identified the variety of tasks completed by coordinators, indicating the key role they play in implementation of clinical trials. Table 1 lists some of the duties that may be conducted by CRCs if and when these are delegated by the Principal Investigator (PI). A similar survey conducted by Smith in 2010 found that 33% of CRCs reported that queries and case report forms/data entry were two of their most challenging duties, exceeded only by paperwork (45%).[8] Jones and Wilson conducted additional surveys of reported CRC tasks.[4] Of 61 surveys completed, 90.2% reported that they record research data in approved source documents as part of their duties, while only 77% felt that was a task they should be performing. There were 59 tasks identified for the survey, and for 41 of those tasks, CRCs reported a significantly higher rate of 'are performed' than 'should be performed' responses. Each study acknowledged limitations of small sample sizes and suggested additional, broader surveys to verify these trends.

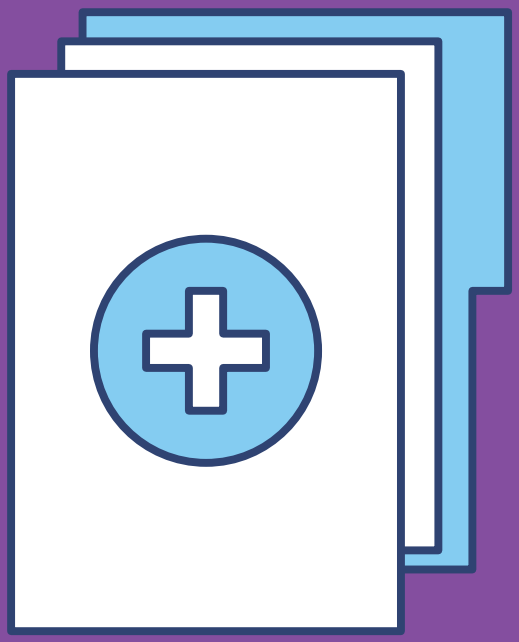
Figure 1.

| TYPICAL DUTIES OF CRCS (IF/WHEN DELEGATED BY PRINCIPAL INVESTIGATOR) | | |
|---|---|---|
| *Screen patients and conduct assessments* | *Maintain site investigator/ regulatory files* | *Supervise other CRCs and/or ancillary personnel* |
| *Consent subjects* | *Order labs and assessments from other care units* | *Attend site initiation visits (SIVs) or study meetings at startup* |
| *Assist with enrolling subjects* | *Schedule subject procedures and appointments* | *Attend calls or meetings during the study* |
| *Collect data at procedures and follow-up visits* | *Conduct product accountability activities* | *Interface with recruitment support vendors* |
| *Enter data in EDC systems* | *Treat subjects during follow-up* | *Serve as point of contact between sponsor and investigator for study updates* |
| *Resolve data discrepancies and queries* | *Send de-identified consent forms and medical records to sponsor if requested* | *Manage submissions and reports to IRB* |
| *Host monitor visits and complete requested tasks* | *Send records from investigator files to sponsor for trial master file (TMF)* | *Communicate with sponsor/CRO on investigator's/ investigators' behalf* |

An additional survey of 80 critical care research coordinators from North America, Europe and Latin America was conducted about role perceptions of CRCs, including workloads and best and worst aspects of their jobs.[2] For the previous 12 months, 78 coordinators described their workload: 78% (61/78) of the respondents reported being involved in 1–10 clinical studies (clinical trials, studies, surveys and audits), while another 21% (16/78) reported participation in 11–25 clinical studies. Respondents were also asked about their most commonly performed tasks from a list of 29 predefined items. Over 90% reported data collection, and over 80% reported data entry, as regular activities, among many other critical areas including obtaining consent, patient screening and assessment, and regulatory submissions. Further, 73% of respondents reported both designing data collection tools and data transcription as regular activities. When asked to describe the worst aspects of their jobs, respondents provided statements related to themes of workload and work hours, lack of support, feelings of isolation, as well as data entry.[2] In discussion of the results, the authors noted that CRCs felt inadequately remunerated for their efforts and were dissatisfied with the "excessive time required to maintain the high standards of their role and with the lack of peer support and recognition."

*For coordinators, the strain of a large workload and tedious data entry responsibilities which detract from providing care point to a need for improvements in how research is conducted. The unreasonable workloads and time spent on data entry can lead to delayed data entry in clinical studies. Delayed data entry can lead to consequences for both sites and study sponsors, including delayed awareness of serious safety concerns and adverse events, and delayed statistical analysis to support reports or marketing applications.*

# Electronic Medical Records and Electronic Data Capture Systems in Clinical Research



Today nearly half of all new clinical trials are initiated using electronic data capture systems (EDC), and investments in EDC systems will rise at a nearly 15% compound annual growth rate to over $3 billion.[9] The competitive global market for drug and device development has emphasized the need for collecting quality data more quickly and accelerating data processing.

The usability of EDC systems can be a barrier; investigators and sponsors have noted that use of an EDC can be too burdensome for a busy clinic environment.[9] Training CRCs on the use of EDC systems is challenging, particularly for CRCs that often carry multiple studies from multiple sponsors using multiple EDC platforms. Retaining system-specific passwords can be challenging enough, let alone the subtle differences in entering data or resolving queries. The authors focus on the challenges associated with implementing EDC systems to improve efficiencies in developing countries, an important topic in the global clinical research landscape. “With EDC, technology is not the solution, but the enabler. In order for any technology to be effective, it cannot be implemented without consideration of the context in which it will be used, the processes it will be used alongside, and the results required.”[9]

In 2015, EMRs (electronic medical records) are now mandated for healthcare facilities to meet the American Recovery and Reinvestment Act requirements. Data reported for clinical trials still requires that information is reviewed in the EMR and manually entered into the eCRFs. One of the greatest challenges for clinical research data quality is redundant data entry between medical records and case report forms, but lack of standardization in EMRs makes integration with EDC systems difficult.[3] Other significant challenges to integration of EMR and EDC systems are regulatory requirements for protecting personal health information, including HIPAA and HITECH, and for the integrity of electronic files and signatures, including 21 CFR Part 21. Further, not all data for all studies will be available in all EMRs, because there is still great variability in the way these systems are used and in the way individual research sites collect data. Often, data that is only collected for the study, or for non-standard of care assessments, are recorded on paper-based source worksheets and entered into EDC systems. Still rare are the cases where the approved protocol specifically allows for direct entry into the EDC at the time of data collection.

The hope for integration of EMR and EDC systems is not new; Bleicher discussed this goal and identified challenges nearly a decade ago. The author discussed many of the challenges facing the desire to integrate EDC and EMR systems to avoid duplicating data entry efforts and reduce costs associated with source data verification by monitors.[1] One main challenge is that EMR systems are designed to collect a variety of data sources, including dictated notes, scanned handwritten notes, lab results, and directly-entered information, while EDC systems are designed with more specific data fields. Populating eCRFs with EMR information would require significant effort to enable data migration in a secured, validated manner. Potential solutions were assessed including direct entry into EDC systems and exporting data to populate EMR systems, collecting data in a local system that would integrate with both EDC and EMR systems, or incorporating eCRFs in an EMR system. In each case, significant challenges were identified that would indicate limited support from sponsors or success. The authors indicate the value of integrating EMR and EDC systems but acknowledged the significant challenges, effort, and potentially limited immediate benefits. Since this earlier discussion, some solutions have begun to take shape. However, no perfect solutions have become ubiquitous in the research industry, and significant challenges still exist. Until improved solutions are developed and validated, an element of human control is still required for clinical research data entry.

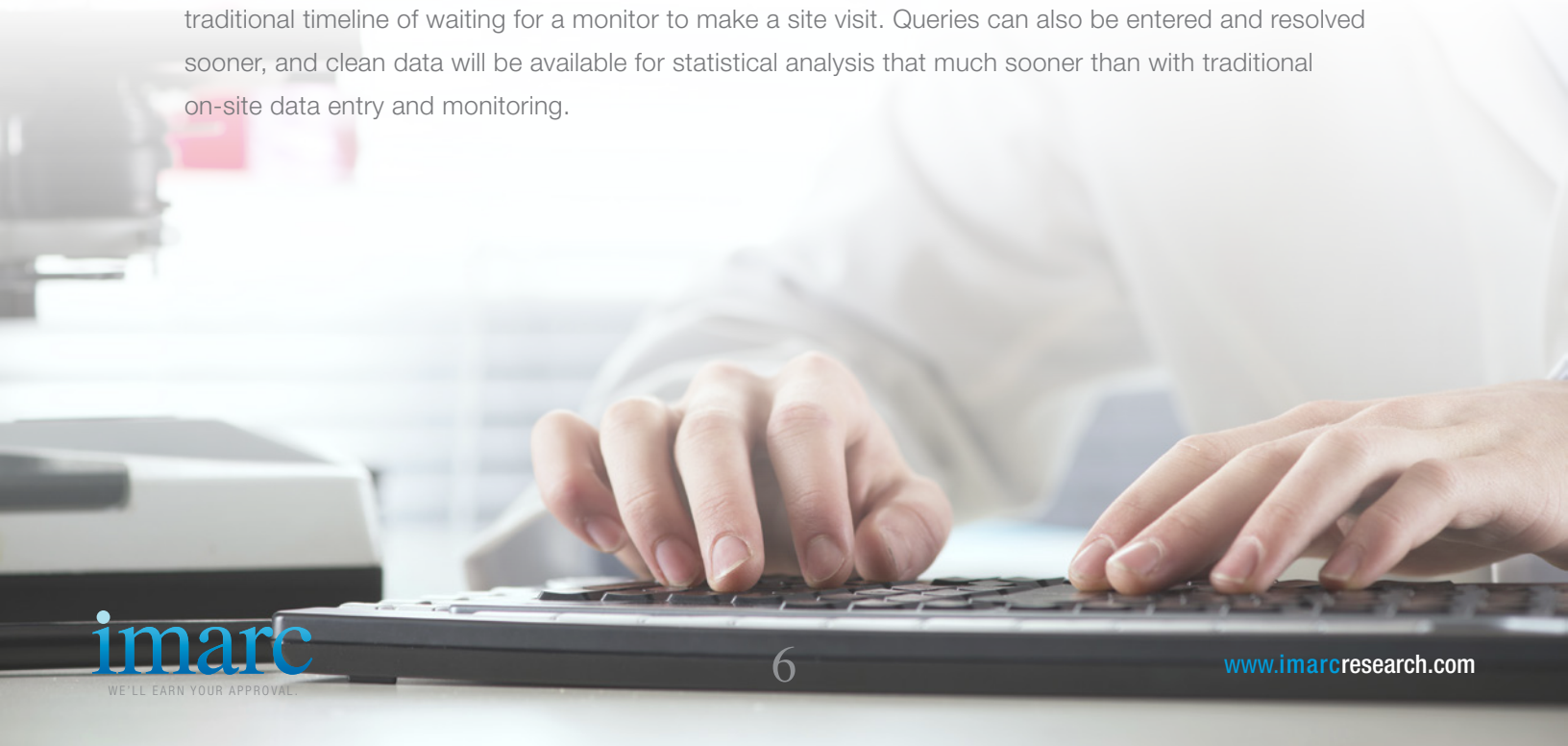
In 2011, Mitchel et al. conducted a study to assess the number of changes required in an EDC system for a multi-center trial and demonstrated that the majority of these changes (71.1%) were due to data entry error corrections.[5] However this result varied based on the type of eCRF page that required changes. For instance, changes to an adverse events page were more likely to be related to additional information than data entry errors (62.5% and 33.3%, respectively). Changes to a numerical-based eCRF for uroflowmetry were primarily related to data entry error corrections (94.5%). While this study assessed several centers submitting data into a controlled EDC system and a straightforward assessment of changes to data and the corresponding reasons, what was not explored here was the influence of the protocol and EDC system design on how data are collected and the errors that result. Protocol and eCRF design as well as proper training could have a distinct effect on the volume and types of data changes. Further, the effect of strenuous workloads on the number of data entry errors was not assessed. Potentially with well-trained, dedicated remote support staff and well-designed eCRFs, these errors could be minimized through remote data entry.

*Direct integration of EDC and EMR systems still appears a daunting challenge without an immediate solution. The current trend of intense workloads for CRCs with a significant amount of time dedicated to data entry and query resolution appears unsustainable and inefficient. However, remote access to EMR systems for data entry presents an intriguing avenue not yet explored in clinical research. Remote support staff with a focused set of responsibilities may reduce the number of corrections required in EDC systems as well as improve the timeliness of data reporting.*

# Remote EMR Access for Remote CRC Support

The advent of risk-based monitoring has spurred discussion about leveraging remote EMR access to allow monitors the ability to conduct source data verification without the traditional on-site visits. Many discussions center on how to reduce on-site visits with predictive risk assessments, while others assess the feasibility of procuring remote EMR access. One such study was conducted by Uren et al. in 2013, where the authors conducted a feasibility study to assess remote access to EMR systems for clinical monitors to conduct source data verification of eCRFs and potential cost savings.[10] One monitor conducted 6 monitoring visits, 4 of which were conducted remotely with access to the EMR, which resulted in cost savings to the study sponsor. The monitor was provided with software and controlled access to the EMR portal, was required to follow internal procedures, reviewed the subject's informed consent prior to reviewing medical records, and signed an agreement to maintain confidentiality and access the records in secured areas at designated times. Over the course of the feasibility study, travel costs were successfully reduced by approximately two-thirds.

These results highlight the possibilities for remote EMR access; if monitors are able to secure access with proper controls in order to verify source data, it follows that remote access could be used to review and extract data to allow remote data entry into EDC systems. This would reduce the data entry burdens on CRCs and allow them to focus on more critical research tasks including screening subjects, obtaining informed consent, and conducting assessments. Given the diversity of duties that CRCs are asked to conduct, deploying a strategy that includes both remote CRC support for data entry would free up the on-site CRC for essential duties including recruiting, screening, consenting, and treating study subjects. Further, remote CRC support could make remote monitoring even more beneficial; by promoting timely data entry, remote source data verification by monitors could be done much sooner than with the traditional timeline of waiting for a monitor to make a site visit. Queries can also be entered and resolved sooner, and clean data will be available for statistical analysis that much sooner than with traditional on-site data entry and monitoring.

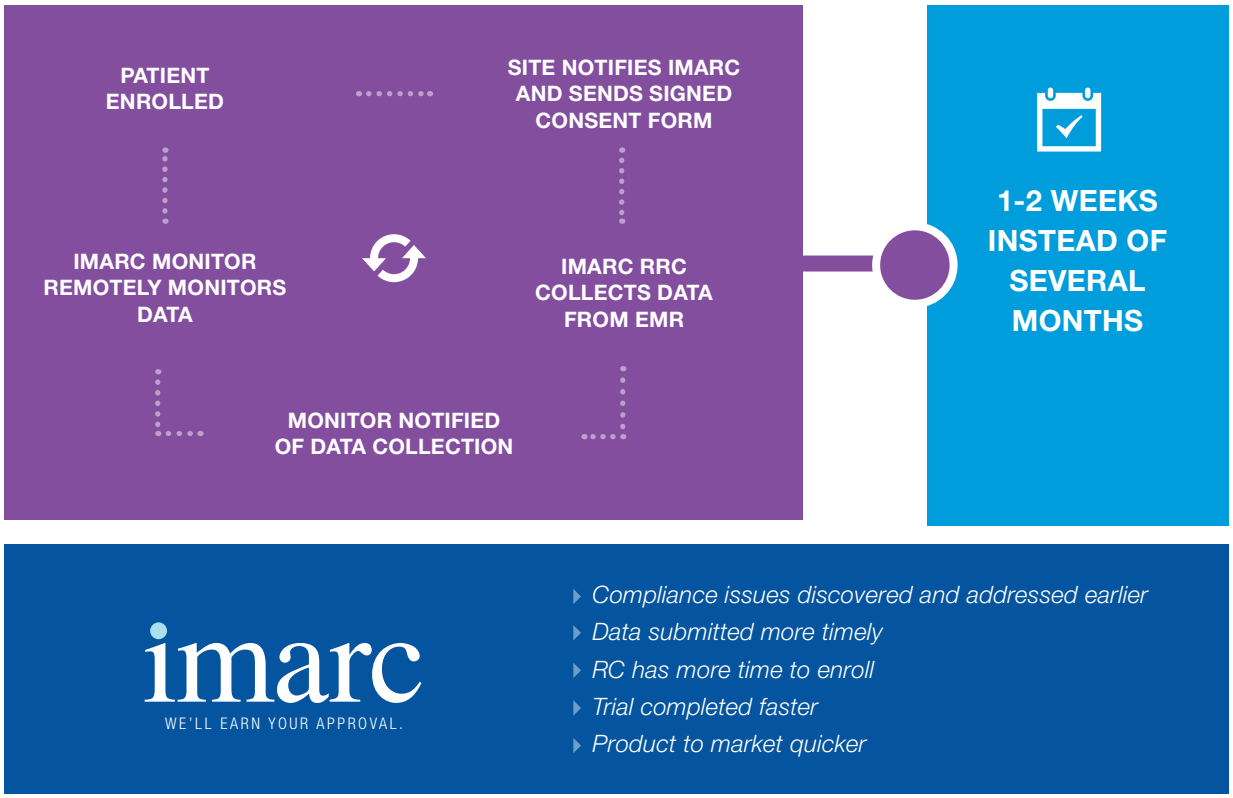


## Remote CRC Support: Potential Benefits and Challenges

Timeliness of data reporting is a well-known issue; sites that routinely fall behind in this area effectively hold data hostage from the sponsor/CRO (clinical research organization). Delayed data entry leads to a cascade of other issues, including delayed logic checks, queries and query resolution, source data verification by monitors, analysis for annual reports or regulatory submissions, and internal review of safety events through Clinical Events Committees (CECs) or Data Safety Monitoring Boards (DSMBs). Delayed safety reporting is particularly serious, as missing safety data creates an inaccurate picture of the investigational product's risks as the study progresses.

Using remote support to help offset the on-site CRC's workload can help increase compliance with the protocol, agreement, IRB, and regulations, as these can each specify timelines for reporting data and safety events. In effect, delayed data entry can be a serious noncompliance with one or more of these areas. Safety vigilance is also likely to be improved through more timely data entry, since review and adjudication as needed can be completed in nearly real-time by sponsor/CRO staff. Remote CRC support offers a solution that can decrease the cycle of gathering, cleaning and making data available for analysis from several months to approximately two weeks, particularly if remote monitoring is also employed (see Figure 2).

Figure 2.



Potential challenges to implementing remote CRC support staff include ensuring continued Principal Investigator oversight and maintaining confidentiality for protected health information (PHI). The remote CRC should be delegated to conduct data entry by the PI who is in agreement with the potential benefits and who wants to help offset their on-site CRC's workload. Oversight can be ensured by taking steps to integrate the remote CRC into the site study team when possible. For instance, the remote CRC can attend the SIV to meet the team, call in for meetings, and the PI sponsor/CRO can encourage communication between the remote and on-site CRCs and the PI. Remote CRCs will need to be trained on study, site, and IRB policies regarding use of the study EDC and the site EMR. Consideration should be given to meeting regulatory and confidentiality requirements for health records, while utilizing EMRs for the benefit of research.

The often unreasonable workload for research coordinators can compromise timely data and safety reporting of investigational products. To date, leveraging electronic health records to reduce the data entry responsibilities of clinical research coordinators has not been adequately assessed. An exploration of these issues could identify potential efficiencies for clinical research data and safety event reporting. Access could be granted for qualified remote CRC support staff to supplement the on-site CRC.

*Delayed data entry can lead to a host of issues that require extra resources to manage and increased study costs. The remote data entry support could help offset the CRC's increasingly unmanageable workload, resulting in improved timelines, increased compliance, and increased safety vigilance, which have the potential to speed an investigational product's time to market.*

## Common Acronyms

| ACRONYM | MEANING |
|---|---|
| *CEC* | *Clinical Events Committee* |
| *CRC* | *Clinical Research Coordinator* |
| *CRF/eCRF* | *Case Report Form/ Electronic Case Report Form* |
| *DSMB* | *Data Safety Monitoring Board* |
| *EDC* | *Electronic Data Capture* |
| *EMR* | *Electronic Medical Records* |
| *PI* | *Principal Investigator* |
| *PHI* | *Protected Health Information* |

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## Rachel Silver-Kessler, BS, CCRA,

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Utilizing her background as a biomedical engineer, Rachel brings a unique perspective and valuable tool set to clinical research. Her critical thinking skills allow her to apply the regulations across various protocols and have influenced her advancement to her current position as Director of Clinical Support Services at IMARC.

Rachel was part of the core leadership team that launched IMARC University, a series of affordable online training and continuing education courses designed to prepare clinical research professionals for compliance. Rachel also assisted IMARC in achieving ISO 9001 certification with the implementation of a robust quality management system in August 2014.

She has been a member of the Association of Clinical Research Professionals since 2011 and became a Certified Clinical Research Associate in 2013. She holds a Bachelor of Science degree in Biomedical Engineering from Case Western Reserve University and is a student in the Clinical Research Administration Master's program through The George Washington University.

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