Clinical Research Coordinator User Experience Across Multiple Electronic Medical Information and Data Capture Systems

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Background and CRC Profile

Following the shift from paper source documentation to electronic records in healthcare and clinical research, clinical research coordinators (CRCs) navigate multiple electronic systems to manage clinical data. CRCs extract information from multiple databases, including electronic medical records (eMRs), then enter it into the sponsor's electronic data capture (EDC) system(s).

Recently, clinical trial sponsors have started to develop and test data abstraction technology to streamline data collection. This study explores CRC system-to-system interactions in the current manual data workflow to assess CRC end-user experiences and preferences.

The primary goal of this study was to map clinical research staff interactions between electronic data systems at a large academic cancer institution. In February 2024, we conducted five user interviews with CRCs at the UAMS Winthrop P. Rockefeller Cancer Institute. Each interview lasted approximately one hour. The CRCs ranged in experience from 6 months to 18 years (Figure 1).

Clinical Research Coordinator	Tools	
 Experience: Five Years	**UAMS Systems and Applications**	**Sponsor Systems and Applications**

Key Characteristics
• Responsible for clinical trial documentation and data entry requirements
• Responsible for eight protocols
• Liaison between PIs, CRNs, regulatory staff, study sponsor staff, protocol contacts, study monitors, other clinical staff, and patients
	• AR-CRIS
	  • AERS
	  • ET
	  • OpenClinica
	  • PSC
	  • RPRS
	  • TrialSearch
	• eMR
	• iLab
	• Microsoft Office
	• RedCap
	• Search Engines
	• Teams
		• Almac
		• Amgen
		• BioClinica
		• Castor
		• Clin'Form
		• CTSU Systems
		• Investigator Space
		• IPS
		• Marken Lab
		• MD Anderson ONE Access
		• Medidata Rave
		• MedNet
		• Neocoast
		• Q2 Lab
		• Signant Health
		• STS
		• TALMMY
		• Triad
		• Vault EDC
		• Xcellerate
		• YPrime

Figure 1. CRC Persona

CRC User Experience Interviews

The CRCs reported using an average of 14 systems and applications[1] for clinical trial data collection and entry. The CRCs reported using an average of 8 internal systems and applications and 6 external systems. The lowest number of systems and applications reported was 8 and the highest number reported was 20. The number of systems and applications is likely higher since the responses were based on immediate recall. During one user interview, the CRC navigated between 8 systems and applications and 2 paper resources to enter data for one treatment visit (Figure 2).

[1] The CRC can access internal systems and applications through institutional login access. For external systems and applications, an external party outside of the institution must provide login access.

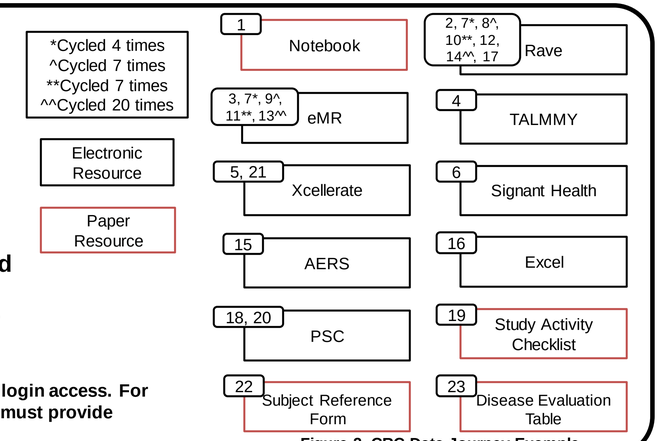

Figure 2. CRC Data Journey Example

CRC Data Journey

For some of the data entry tasks, CRCs had to take an additional step between data collection and entry to prepare the data for entry such as performing conversions, calculations, assessments, and translating findings (Figures 2, 3). Some of the data entry preparation steps could be eliminated by adding features or logic to the eMR or the sponsor's EDC systems.

Figure 3. User Interview Data Map Example

Step	Definition
Conversions	Many eMR lab units and reference ranges do not match the sponsor's case report forms (CRFs). The CRCs had to perform complex conversions prior to entering the data.
Calculations	Some CRFs required values unavailable in a subject's eMR, so the CRC calculated values like BSA themselves.
Translations	The eMR report language and the sponsor's CRF results descriptions did not always match. The CRCs reported additional training and communication with clinical staff to translate the results (i.e. pathology results).
Assessments	CRCs had to request assessments by other clinical staff according to sponsor guidelines (e.g. disease progression).
Additional Research	Some of the sponsors' required data was not immediately available in the eMR, so the CRC went to other applications or websites to collect or verify information, such as concomitant medication information.

Figure 4. Data Preparation steps

Future Recommendations

Product improvements often focus on one single system or application. This study demonstrates the importance of understanding the coordinator's experiences across systems and applications. The CRCs' recommendations to improve their user experience centered around features that offer directional guidance and collaborative tools. These recommendations could improve data quality and reduce the time spent on data collection.

For internal systems and applications, the CRCs suggested the following initiatives would improve their experience:

- **Align language across systems and from the protocol to each system,**
- **Make subject information more accessible, and,**
- **Synthesize protocol and subject information across and within systems.**

Sponsors and sites should continue to collaborate to enable local customization in the EDC system. The CRCs reported certain EDC features were helpful when available, including:

- **Auto-population for lab reference ranges, units, and cycle start dates,**
- **A multi-select option for a list of multiple ongoing items, "all the above," and "none of the above" selections,**
- **The use of icons with clearly distinguished status for action items, including conditional items, and,**
- **Auto-calculation for values not typically available in the site's medical records using values that are available.**

Conclusion

The study's findings are in alignment with industry data indicating a high burden on CRCs due to the number of systems required to navigate and highlights this as an ongoing issue.

CRCs are a focal end user group in clinical trial research as improvements to their user experience has the potential to improve the quality of experiences for all stakeholders, including site staff, sponsors, and patients.

We hope the findings will encourage collaboration among research institutions and clinical trial sponsors to limit the number of applications and systems required to manage clinical trial data. In the future, the results of the study will be used to advocate to improve the CRC's user experience.