Category: *Clinical Trials Operations - Work in Progress*

EHR-to-EDC Integration: Connecting the Clinical Research Supply Chain – Part Two

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1. Background

There is considerable redundant work and data entry being performed today in cancer clinical trials data capture due to a lack of integration between hospital and clinic Electronic Medical Record systems and sponsor Electronic Data Capture Systems. In a 2019 AACI-CRI Poster Session, KUCC described a project in which we were able to reduce the time required for trial data collection on several studies by pulling data directly from the source medical record system into the sponsor electronic data capture (EDC) system. In this follow-up poster session, we quantify the time and costs savings by visit and visit type, as well as by data source type, as compared to manual data entry. In addition, we seek to identify and quantify other notable advantages or disadvantages of automated EHR-to-EDC data collection, if any.

2. Goals

The key metrics we will focus on are a) time and cost savings by visit type, b) differences across study types (e.g. Phase I, II, and III), and c) other benefits in such areas as reduced queries.

3. Solutions and Methods

KUCC implemented a clinical trial fulfillment solution that integrates EHR data, its local clinical trial management system and related operations, and a sponsor's EDC system. The solution automates multiple aspects of clinical trial operations for study teams at the site; then leverages EMR data to populate case report forms directly into our local clinical research management system; then in turn electronically push the case report form data directly into the sponsor's EDC system. This results in zero manual data entry for some data elements and reduces the time required to complete study requirements for other data elements. KUCC employed the nCartes platform from nCoup, Inc. to perform the EHR-to-EDC automation. KUCC's in-house CTMS is WCG Velos eResearch. The sponsor EDC system used was Medidata Rave.

To quantify the difference between manual data entry and automated EHR-to-EDC data entry, we used the following protocol complexity scoring system:

Protocol Specific Scoring	
1	Any non-treatment trial (i.e. observation/registry trial) requiring no more than one clinical contact and/or specimen collection. Data forms require basic information easily captured from medical record and average no more than 15 minutes to complete. No long term follow up or survival follow up required.
2	Any non-treatment trial (i.e. observation/registry trial) requiring mulitple clinical contacts and/or specimen collection. Data forms require basic information easily captured from medical record and average no more than 15 minutes to complete. No long term follow up or survival follow up required.
3	Phase II-IV, non-drug; imaging, pallative care, etc study. Requires coordination with no more than one discipline/anciliary service. Data forms require basic information and average no more than 30 minutes to complete
4	Phase II-IV, treatment, no randomization, requiring no more than one clinical contact and collaboration with ≤ 2 discipline/ancillary services. Data forms require basic information and average no more than 30 minutes to complete
5	Phase II-IV, treatment, simple randomization, requiring multiple clinical contacts and collaboration with ≤ 2 discipline/ancillary services. Data forms more complex and average between 30-60 minutes to complete
6	Phase II-IV, treatment, complex, randomization or steps, multiple drugs requiring multiple clinical contacts and collaboration with ≥ 2 discipline/ancillary services. Data forms more complex and average between 30-60 minutes to complete
7	Phase II-IV, treatment, highly complex, randomization or steps, multiple drugs, high toxicity risks, requiring multiple clinical contacts and collaboration with ≥ 2 discipline/ancillary services. Data forms more complex, with daily to weekly completion needs and average en ≥ 60 minutes to complete
8	Any Phase I or Cell Therapy Trial

Add On Scoring:	
0.5	Patient visits occur weekly
1	Patient visits occur multiple times per week
1	Protocol requires mandatory inpatient stay
1	Mulitple Questionnaires/Surveys Captured via Paper Source
0.5	Mulitple Questionnaires/Surveys Captured Electronically
0.5	Industry/CRO Sponsored Trial
0.5	Monitor Visits (< 2 month duration or 100% SDV)
0.5	Data entry required < 10 days
0.5	Portal Requirements ≤ 2 Portals per study
1	Portal Requirements ≥ 3 Portals per study
1	Study Requires Uploading of Scans and/or De-identified Documents for Central Review

An automatic weekly assumption of 5 hours per week (260 hours per year or 21.67 hours per month), should be built into workload for administrative responsibilites not directly related to patient care/study visits. Such responsibilities include attending study initiation visits, internal kick off meetings, 1:1 meetings with their managers, team meetings, staff meetings, PI meetings, departmental required trainings, etc. **Please note: Pre-screening clinics/patients hours are **not** calculated in the protocol

Visit Hours Based on Protocol Complexity and are calculated on a per visit basis (see additional sheet for justifications):

Score (Based on Protocol Complexity and any add	CRC Hrs Screen	CRC Hrs Actively On Tx	CRC Hrs F/U	CRC Hrs Survival Only		Data Hrs Screen	Data Hrs Actively On Tx	Data Hrs F/U	Data Hrs Survival Only
1	1	0.5	0	0		0.5	0.25	0	0
2	1	0.5	0	0		0.5	0.25	0	0
3	1	1	0.5	0.25		0.5	0.5	0.25	0.25
4	2.5	1	0.5	0.25		1	0.5	0.25	0.25
5	4	1.5	1	0.25		2	1	0.5	0.25
6	6	2	1	0.25		2	1	0.5	0.25
7	8	3	1.5	0.25		6	1.5	1	0.25
8	8	4	2	0.25		8	2	1	0.25
>8	10	5	3	0.25		9	3	1.5	0.25

4. Outcomes

The results showed a total time and cost savings of approximately 50%. The time and cost savings were similar across visit types. Table 1 below shows the estimated time and cost for data entry using manual data entry for one test study. Table 2 shows the results using the nCartes EHR-to-EDC platform for the same study.

Table 1

Estimated Data Hours and Costs Study 1 Manual Entry											
Patients Screened	Patients Enrolled	Total Number Tx Visits (all visits through EOT)	Total Number FU Visits	Total Number of Unscheduled Visits	Total Hrs Associated W/Screening Visit	Total Hrs Associated W/Tx Visits	Total Hrs Associated W/FU Visits	Total Hrs Associated W/Unscheduled Visits	Total Hours	Average Hourly Rate for Data Coordinator (including fringe)	Estimated Total Data Costs
XXX1	XXX2	34	1	0							
XXX2	XXX6	35	0	0							
XXX3	XXX7	34		0							
XXX5	XXX8	36		1							
XXX6											
XXX7											
XXX8											
7	4	139	1	1	56	278	1	1	336	$65	$21,840

Table 2

Estimated Data Hours and with Structured Data Entry											
Patients Screened	Patients Enrolled	Total Number Tx Visits (all visits through EOT)	Total Number FU Visits	Total Number of Unscheduled Visits	Total Hrs Associated W/Screening Visit	Total Hrs Associated W/Tx Visits	Total Hrs Associated W/FU Visits	Total Hrs Associated W/Unscheduled Visits	Total Hours	Average Hourly Rate for Data Coordinator (including fringe)	Estimated Total Data Costs
XXX1	XXX2	34	1	0							
XXX2	XXX6	35	0	0							
XXX3	XXX7	34		0							
XXX5	XXX8	36		1							
XXX6											
XXX7											
XXX8											
7	4	139	1	1	28	139	0.5	0.5	168	$65	$10,920

With respect to time and cost savings achieved through structured data sources (such as labs, demographics) versus unstructured data sources (such as progress notes and pathology reports), end users estimated that approximately 80% of the time savings was derived from structured data. The total time and costs savings, the time and cost savings by visit type, and the proportion of time savings attributable to structured versus unstructured data were similar across the three studies tested.

With respect to data quality, of the fields that were electronically sourced, no data entry errors were found. By contrast, errors rates with manual data can be extensive. One of the more detailed studies of EDC data entry errors rates is described in the July 2011 Drug Information Journal *Evaluation of Data Entry Errors and Data Changes to an Electronic Data Capture Clinical Trial Database.* In that study, Mitchel et al. found an error rate 4.42% attributable to data entry errors.

5. Lessons Learned

EHR-to-EDC integration significantly reduced the amount of time and cost required to complete study data capture on the studies we tested and can also materially increase data quality as compared to industry experience.