Connecting The Supply Chain

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INTRODUCTION

There is considerable redundant work being performed today at both cancer centers and trials sponsors as a result of a lack of systems and data integration both within cancer centers and their related hospital Electronic Medical Record systems and Clinical Trial Management Systems as well as between cancer centers and trial sponsors. This is beginning to change as cancer centers and trials sponsors alike recognize the need and opportunity for transformation or to do what we call connecting the clinical research supply chain.

Goals The goals were to test whether we could reduce the amount of time required to complete study tasks and case report form data entry and, in the process, accelerate the speed at which clinical trials can be completed. To cite one metric, according to a 2017 study completed by Tufts, it takes an average of eight days from the time a subject visit occurs for sponsors to receive visit data. The work KUCC has done, both within KUCC and between KUCC and a large clinical trial sponsor, demonstrates the material time savings that can be achieved through the integration of systems and study execution tasks both within our cancer center and between us and study sponsors

FUTURE DIRECTIONS

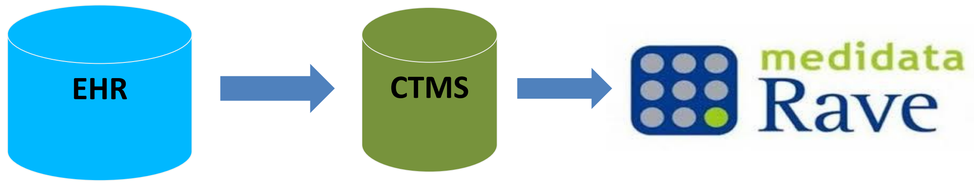
The lesson learned is that significant time savings can be achieved through integration of EMRs, local clinical trial management systems, and sponsor EDC systems. The future direction, now that the proof and concept is complete, is to scale the solution and bring in other cancer center and study sponsors collaborators to both improve and benefit from the solution.

KEY VALUE METRICS

3	Number of studies undertaken
380	Estimated data hours with manual data entry
190	Estimated data hours with structured data entry
$24,700	Estimated cost with manual data entry
$12,350	Estimated cost with structured data entry
50%	Estimated hours and cost reduction using structured data entry

METHODS

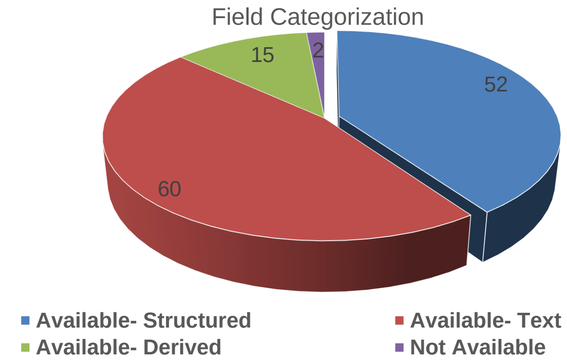
KUCC implemented a clinical trial fulfillment solution that integrates EMR data, its local clinical trial management system and related operations, and a sponsor's EDC system. The solution automates multiple aspects of clinical trial operations for study teams at the site; then leverages EMR data to 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. As a natural byproduct, study data accuracy also increased and source data became automatically available and connected to the study, both of which also save time and money for sites and sponsors alike.

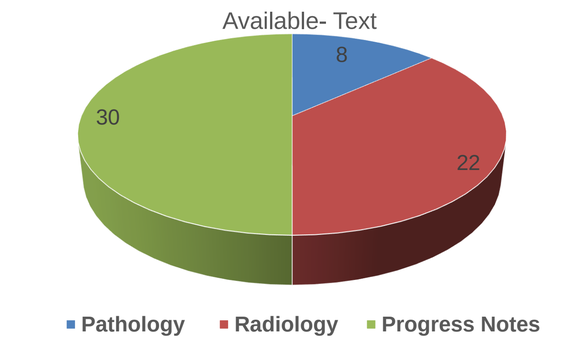


Data Flow Diagram

RESULTS

The major finding of the project is multiple hours of time savings for study coordinators to complete study data requirements on patient visits in this sponsor-funded proof of concept. For each study tested, the time savings was significant. For one study, the average time savings for one screening visit was about four hours. The time savings for other recurring visits was about two hours per visit. At scale, this translates to very substantial reductions in the amount of time and effort required to complete clinical studies and as a by-product the pace at which trials can be completed





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