Integrating Technology to Support Data Management Abstraction of Adverse Events (AE) and Concomitant Medications (ConMed) from the Electronic Health Record (EHR) to Sponsor Electronic Data Capture (EDC) Systems Using Design Thinking Methodology To Increase Efficiency and Help Reduce Staff Turnover

Leemor Yuravlivker, Nancy Bouvier, Michael Buckley, Sundar Jeevarathnam, Steve Lazan, Mairi McKellop, Renata Panchal, Joseph Lengfellner, Stephanie Terzulli, Paul Sabbatini

Memorial Sloan Kettering Cancer Center, New York, NY

Background
Manual abstraction of data from a site's EHR to pharmaceutical sponsor's EDC system is labor intensive, error prone and frustrating which results in Clinical Research Coordinator (CRC) burnout and staff turnover. To reduce the time and effort of this process for data managers, a web-based application, Clinical Trials Data Hub (CTDatAhub), was developed using design thinking methods. It extracts and consolidates AE and ConMed data from the EHR and displays it in a user friendly, automated, and consolidated view for easy entry into EDC forms.

Understanding the CRCs and Their Painpoints
We first conducted user research to interview 12 CRCs at MSK to understand their current workflows and painpoints. We ran 12 1-hour remote sessions - 30 minutes of observation of their current workflow followed by a 30-minute interview. We used those insights to build empathy with the coordinators and understand their data management journeys.

Our research found that CRCs oversee between 4-6 protocols at one time and spend approximately 2-15 minutes finding adverse event (AE) data, such as nausea or fever, and 30-90 minutes finding medication data per patient on a protocol each week using current clinical systems. The results from this initial user research found that CRCs spend up to 50% of their week doing data entry and that a primary, time-consuming painpoint for them is the time it takes to identify which medications are given to a patient in response to an AE.

Testing our Hypothesis
We developed a working proof-of-concept application, CTDatAhub, using Splunk [2] as a pilot to test whether it could help reduce the time it takes to find the right medication and AE data. CTDatAhub enabled CRCs to look up patients on the protocols they oversee and aggregated a single view of adverse events and medication data for those patients.

To inform the desirability of features within CTDatAhub, we ran a KANO [1] survey to validate which needs must be met for our tool to be adopted. The KANO survey showed 2 use cases (use case 1: basic easy to find medication linked to the AE, and use case 2: complex, where the medication linked to the AE is found in a 23-page document) using their current workflow (A) versus CTDatAhub (B) where a 5-minute training occurred prior to testing. We hypothesized that CTDatAhub would outperform current systems across 3 primary outcomes: 1) correct data identification, 2) time to identify data, and 3) using a modified Single Ease Question (SEQ) rating scale to assess how difficult users found the task.

Results
The results of A/B testing are below in Figure 5.

Use Case 1 Use Case 2 (more complex)

<table>
<thead>
<tr>
<th>Current clinical systems</th>
<th>CTDatAhub</th>
<th>Current clinical systems</th>
<th>CTDatAhub</th>
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<tbody>
<tr>
<td>Correct data identification rate</td>
<td>83%</td>
<td>80%</td>
<td>50%</td>
</tr>
<tr>
<td>Time to identify data (in minutes)</td>
<td>10.25</td>
<td>7.25</td>
<td>8.37</td>
</tr>
<tr>
<td>SEQ (1 = difficult, 5 = easy)</td>
<td>2.9</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 3 - Jobs-To-Be-Done Outcomes

Figure 4 - Pilot of CTDatAhub Developed with Splunk

Figure 6 - Screenshot of CTDatAhub

Digital product development using design thinking methodology has the potential to improve operational efficiency and the clinical staff user experience. This is particularly important in an industry that has struggled with burnout, cost containment, and high turnover.

References
2. Splunk. [https://www.splunk.com/]
3. Design Thinking Model. Stanford University.
4. Jobs To Be Done (JTBDo) toolkit. [https://jtbdtoolkit.com/]
5. Image of stack of papers provided by Stock