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Scaling EHR-To-EDC Across the Clinical Research Portfolio: Lessons from MSK

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1. Background

Electronic health record (EHR)-To-Electronic data capture (EDC) technologies enable sites to run clinical trials more efficiently by reducing manual data entry tasks, saving time and improving data quality. Enabling use of EHR-To-EDC on a study requires upfront time and resources to accommodate unique database structures and study requirements. Although this effort declines with subsequent studies it can still pose a barrier to scalability.

2. Goals

Memorial Sloan Kettering Cancer Center (MSK) began piloting EHR-To-EDC technology in November 2023, to address operational challenges associated with running a large-volume clinical research program, and to help improve the productivity of its workforce. Initial pilots proved using EHR-To-EDC to electronically populate EDC systems saved time, reduced errors and was preferred by data managers (DMs) over manual data entry. As a result of these positive findings, MSK enabled the technology on additional investigator-initiated trials (IITs) in Q4 2024, increasing its EHR-To-EDC portfolio by 600 percent (pre-Q4 2024: 2 studies, end of Q4 2024: 14 studies). Herein we share efficiency savings metrics and highlight MSK's approach to scaling.

3. Solutions and Methods

MSK utilizes Archer EHR-To-EDC technology developed by IgniteData. Archer is EHR and EDC agnostic and leverages HL7-FHIR standards for optimal data exchange. After an initial pilot stage with Archer, we performed improvements in three key areas to facilitate the expansion of EHR-To-EDC across the enterprise's research portfolio:

<u>Technical</u>

DMs launch Archer from CTDataHub, a homegrown application that combines subject data (e.g. labs, adverse events), with study management data (e.g. protocol status, visit dates). By integrating CTDataHub and Archer, DMs can perform all their data entry tasks through a single unified experience. Improvements were also applied to eCRFs to optimize EHR-To-EDC compatibility.

<u>Legal</u>

Use of EHR-To-EDC on an externally funded study requires an addendum to the Clinical Trial Agreement. In collaboration with MSK's legal team, we developed a set of bullet points to guide sponsors drafting amendments.

<u>Operational</u>

To best prepare DMs for the workflow change from manual to EHR-To-EDC we worked closely with leadership and study teams garnering feedback from stakeholders throughout the implementation process. We developed a self-paced training package containing a User Guide and 13-question multiple-choice/select assessment. DMs much achieve a score of 100 percent prior to gaining Archer access. To measure workflow impact, a 15-question survey was sent to all DMs after three weeks of use. The survey assessed ease of use and learning, trust, perceived time and efficiency savings, and workflow preference using the 5-point Likert scale (i.e. 1=strongly disagree to 5=strongly agree).

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4. Outcomes

MSK enabled EHR-To-EDC on 15 trials within its research portfolio. As a result of the technical, legal and operational improvements, EHR-To-EDC setup time decreased by 71 percent (pilot stage: 17 weeks, post-pilot: 5 weeks). To date, over 17k data points have been transferred electronically and DMs report the workflow is easy to learn (5.0/5.0), easy to use (4.6/5.0) and more efficient than manual data entry (4.2/5.0).

5. Learned and Future Directions

Building eCRFs with EHR-To-EDC in mind and enabling newer studies poses less risk than retrofitting older studies. Further product and process improvements are needed to sustainably support wide-scale and long-term adoption of EHR-To-EDC.