A System Agnostic and Secure Platform to Exchange Clinical Research Data Via HL7-FHIR from Site to Sponsor to Increase Efficiencies and Satisfaction

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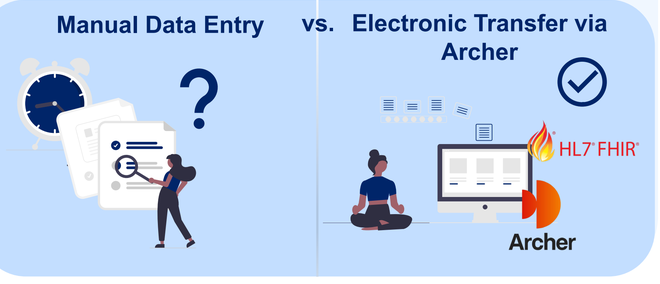
Background

Manual abstraction of data from a site's clinical systems to a biopharmaceutical firm's electronic data capture (EDC) system is inefficient and error prone. In the first partnership of its kind, sponsor, and site data managers (DMs) leveraged a scalable system-agnostic web application, Archer, to reduce the effort associated with this process. Archer is a virtual research assistant that enables DMs to easily transfer clinically validated local lab and vitals data from the site Electronic Health Record (EHR) to sponsor EDC via HL7 FHIR.



Goals

- Reduce time associated with data entry
- Increase job satisfaction
- Measure impact of EHR2EDC
- Improve data quality and accuracy

Outcomes

A total number of 6 patients with 28 unique visits and 1,614 data points were transferred (Table I) as of 2/9/2024. Surveys had a 100% response rate (n=2 for sponsor trial, n=1 for IIT). Time in the DM role varied across all three users: 0.5, 1.0, and 2.0 year, and all strongly agreed (5.0/5.0) the App was easy to use and learn, and all agreed (4.3/5.0) that the App was less time consuming, more efficient, and was preferred over manual methods.

Figure 1: Average time spent entering data manually versus electronically via Archer. When compared to manual data entry, data entered electronically took 49% less time for the Industry-sponsored trial and 68% less time for the Investigator-initiated trial.

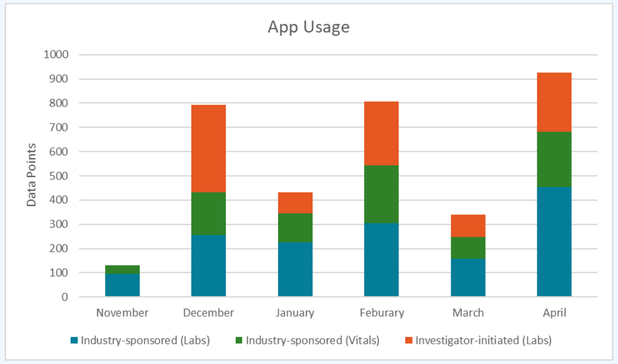


Figure 2: Total data points transferred electronically since go-live. An average of 571 data points were transferred per month. Data reported as of 4/30/2024.

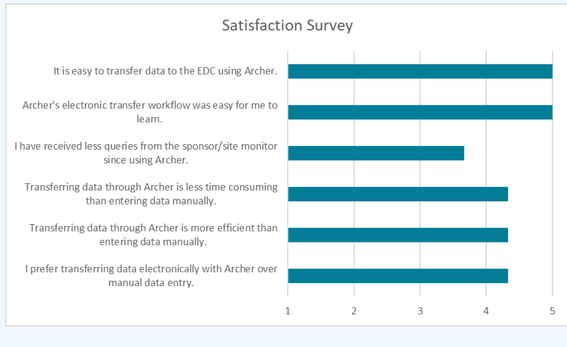


Figure 3: User satisfaction measured using 5-point Likert scale. 1=Strongly disagree, 5=Strongly agree

Solutions and Methods

Archer was released to DMs in November 2023 at a large, high-volume academic cancer center for two myeloma interventional clinical trials: 1) industry-sponsored and 2) and investigator-initiated trial sponsored by the site. To evaluate the App's impact on DMs, an 11 question 5-point Likert scale survey agreement score (1= strongly disagree, 2= disagree, 3= neutral, 4= agree, 5= strongly agree) assessed: 1) App use and learning, 2) time and effort (TE) savings, 3) efficiency, and 4) preference versus manual workflows. Surveys were sent to all DMs receiving access to Archer after using the App for 3 weeks with approximately 1 data transfer per week during the 11/14/23-1/09/24 timeframe. Impact on DM time and effort (TE) was calculated by comparing self-reported manual vs. electronic data entry time per CRF page.

Lessons Learned and Future Directions

- Electronically transferring data to an EDC using Archer is less time consuming and more efficient than manually entering data.
- DMs prefer transferring data through Archer over manual data entry.
- Coordination between site, sponsor, and data broker is essential to EHR2EDC success.
- Plans to measure impact of EHR2EDC method on data quality and accuracy.
- In the near term, expand electronic transfer capabilities to include medications, adverse events, and tumor response.
- In the long term, enable DMs to transfer 100% of clinical trial data electronically.
- Expand solution to additional commercially sponsored and investigator initiated clinical trials.

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