

## 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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### 1. 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 to sponsor EDC via HL7-FHIR.

### 2. Goals

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 three weeks with approximately one data transfer per week during the 11/14/23-1/09/24 timeframe. Impact on DM TE was calculated by comparing self-reported manual vs. electronic data entry time per case report form page.

### 3. Solutions and Methods

A total of six patients with 28 unique visits and 1,614 data points were transferred (Table I) as of 2/9/2024. Surveys had a 100 percent 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.

**Table I. App Use Versus Manual**

Study	Subjects	Unique Visits	#Labs Sent	#Vitals Sent	Manual Time (h)	App Time (h)	TE Reduction (%)
Sponsor	5	19	702	421	2.12	1.09	49
Site	1	9	491	NA	7.80	2.50	68

### 4. Outcomes

*Category: Training, Career Development, and Staff Retention – Work in progress*

Archer decreased data abstraction times for labs and vitals up to 68 percent for DMs versus manual workflows. In addition to DM satisfaction, the app was preferred and easy to use versus manual methods for the data being abstracted.

#### **5. Lessons Learned and Future Directions**

In 2024 we plan to expand data types to include medications, response, and adverse events.