Agenda

- **An overview of EHR-to-EDC connectors**
  10 minutes
- Sanofi's implementation experience
  5 Minutes
- Implementation considerations at the site level
  10 minutes
- Q&A
  15 minutes

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Overcoming EHR-to-EDC Implementation Challenges in Oncology Trials

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Data entry problems impede clinical trial efficiency and cost effectiveness for sites and sponsors

TODAY'S CHALLENGES	FACTS AND FIGURES
Burden & complexity of **data capture** is increasing	Late stage trials typically use **3X more** data vs. 10 yrs ago[1]
Data **quality assurance** is costly & time consuming	Data management represents **25-40% of overall trial costs**[2]
Staffing shortages & turnover impede research	**63% of sites** list staff retention as a top concern[3]
Manual data entry is prevalent & resource intensive	**74% of sites** still use paper for source data collection

EHR-to-EDC technology **automates data transfer between systems**, leading to **faster data entry, improved data accuracy**, and **reduced site burden**.

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[1]Tufts Center for the Study of Drug Development. "Rising Protocol Design Complexity Is Driving Rapid Growth in Clinical Trial Data Volume, According to Tufts Center for the Study of Drug Development." GlobeNewswire NewsRoom, Jan 2021
[2]Key Cost Drivers of US Trials. 2016
[3]2023 Clinical Research Site Challenges Survey Report. WCG, June 13, 2023
[4]Streamlining Clinical Trials with eSource: Insights from MSK. Applied Clinical Trials, August 19, 2024

Recent research shows a substantial portion of oncology trial data is eligible for EHR-to-EDC transfer

BACKGROUND:
This study describes the availability of data eligible for EHR-to-EDC transfer across a portfolio of oncology trials.

METHODS:
Five oncology studies were selected to represent diverse phases and disease types; data volume by element/field was ascertained for each, and data elements were reviewed for EHR-to-EDC transfer eligibility.

RESULTS:
Across 5 diverse oncology trials, **86% (n = 15799) of collected data points were eligible for EHR-to-EDC transfer**.

Volume of Patient Data Elements and Proportion Eligible for EHR-to-EDC Transfer

Study Phase	Disease	No.	%
		Total collected	Eligible for transfer
I	Acute myeloid leukemia	2813	87
III	Breast cancer	3175	85
II	Gastric cancer	2063	81
III	Lung cancer	7180	87
I/II	Multiple myeloma	3207	86
Total		**18438**	**86**

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Salcuni, et. al.; AMIA 2025; Optimizing Data Collection: Assessing EHR-to-EDC Data Transfer Potential Across Structured and Unstructured Data.

Flatiron Clinical Pipe™ captures more data than other tools, including trial-specific and unstructured data

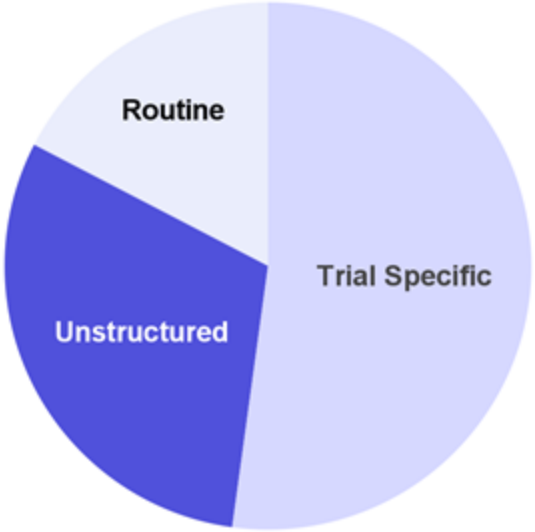
42,132

Data points collected across 82 patients for 12 month active enrollment period[1]

92%

Clinical Pipe eligible data[1]

Example Trial Data Source Breakdown



1 Routinely Captured **Structured** Data

Routinely captured data with high completeness & quality via EHR integration

2 Trial-Specific **Structured** Data

Industry-first, EHR-embedded trial-specific capture

3 **Unstructured** Data

Proprietary unstructured data capabilities to supplement structured data

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[1]Internal analysis of Clinical Pipe usage across 12 months in Multiple Myeloma clinical trial at 4 sites with Top 5 pharma company

Clinical Pipe™ supports 90+ research sites across academic and community healthcare settings

Sites using Clinical Pipe™ complete fewer time-intensive, duplicative data entry tasks

- Enables sites to spend **more time on protocol adherence** and **taking care of patients**
- **Reduces** the number of **queries** and **onsite monitoring visits**
- **Free for sites** to use and **does not commercialize data**
- Only requires a **one-time set-up and contracting**, after which sites may use on any future Flatiron Clinical Pipe-enabled protocol
- Onboarding and ongoing usage supported via **1:1 trainings, group trainings, onsite and virtual support, and dedicated email support**

[This study] is the easiest study for me to do data entry for... Clinical Pipe™ helps reduce transcription errors. It's been great… I would like it for all of my studies…"

- Data Manager, large academic medical center

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Poll #1

Are you interested in learning more about Flatiron Clinical Pipe?

- Yes
- No

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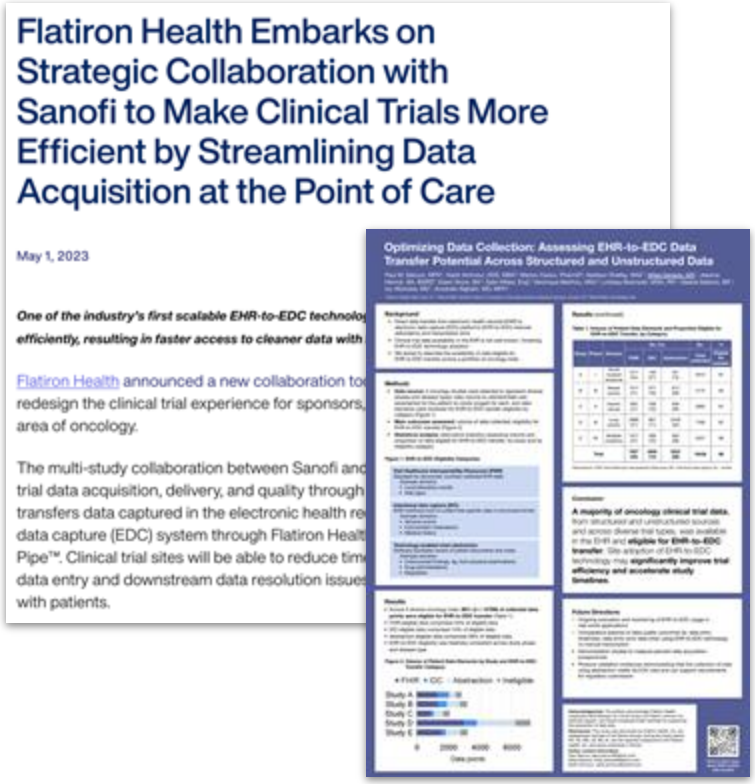
Sanofi deployed Clinical Pipe™ to transfer data for Phase I oncology studies

Existing Partnership Overview

- Sanofi began using Flatiron Clinical Pipe in 2023 for routinely-collected structured data to enable a reduction in time and costs associated with both manual, high-volume data entry and downstream data resolution issues for sites
- Clinical Pipe has supported **two oncology trials** (one ongoing, one closed), with more planned to follow
- The evidence from the closed study indicated that using Clinical Pipe even for the limited scope of structured data provided the below benefits:
  - **Over 2.2K data points transferred** during pilot
  - An average of **1 hour of time savings** per patient visit on laboratory data entry alone
  - **~90% query reduction** compared to data entered manually at other sites for these forms
  - More time back for study coordinators to **focus on entering complex data types** (AEs, SAEs, etc.)


Flatiron Health Embarks on Strategic Collaboration with Sanofi to Make Clinical Trials More Efficient by Streamlining Data Acquisition at the Point of Care

May 1, 2023

Optimizing Data Collection: Assessing EHR-to-EDC Data Transfer Potential Across Structured and Unstructured Data

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Key takeaways from Sanofi's Clinical Pipe implementation

Set-up and testing the integration of Clinical Pipe presented **minimal impact** to the Sanofi study teams

Clinical Pipe's **flexible mapping** supported Sanofi's requirement that the eCRF **not require special fields or redesign**

With **ongoing support and training**, site acceptance of Clinical Pipe was encouraging

Leveraging standard forms paired with the associated mappings **enhances reusability across studies** and **increases efficiency of use** for new study teams and trials

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Common challenges impacting site adoption

OVERLOAD OF TECH TOOLS

55% of sites[3] listed supporting various tools as a top concern when participating in tech enabled clinical trials

STAKEHOLDER MISALIGNMENT

95% of sponsors believe sites value their software, but only **62.5% of sites**[2] feel that sponsors adequately address their technology needs.

RESOURCE ALLOCATION

Sites are **juggling requests** for implementations, troubleshooting, and other tasks that **strain their internal resources**.

CONTRACTING AND BUDGETING

43% of sites[3] listed financial compensation as a significant barrier to participating in a tech-enabled trial.

WORKFLOW DISRUPTION

76% of sites[1] rank **sponsor willingness to integrate** with their systems as their top technology expectation.

PRIVACY AND LEGAL REVIEWS

For each new technology, sites must undertake privacy and legal reviews that **extend contracting and startup timelines**.

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[1]Florence Healthcare. *2025 State of Technology-Enabled Clinical Trials Report*. https://learn.florencehc.com/hubfs/1-florence/reports/RP-2025-State-of-Technology-Enabled-Clinical-Trials-Report-TOFU.pdf.
[2]Florence Healthcare. 2024 State of Tech-Enabled Clinical Trials Report. https://23578418.fs1.hubspotusercontent-na1.net/hubfs/23578418/1-florence/reports/RP-2024-State-of-Tech-Enabled-Clinical-Trials-Report-TOFU.pdf .
[3]SCRS. 2024 Site Landscape Survey. Florence Healthcare. Available at: https://myscrs.org/access-your-download/download-id/20505/

Poll #2

What additional barriers to site adoption have you encountered?

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Strategies to overcome site adoption challenges

Explore paths to **standardize budget and contracting** and **support technology reimbursement**

Partner with sites to identify areas for technological investment and to review potential vendors

Select technology **that integrates with sites' current tech and processes**

Work with vendors to support **initial training** and **ongoing support and retraining** for sites

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Poll #3

What other topics related to clinical trial innovation would you like to see discussed in a future webinar?

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Thank you