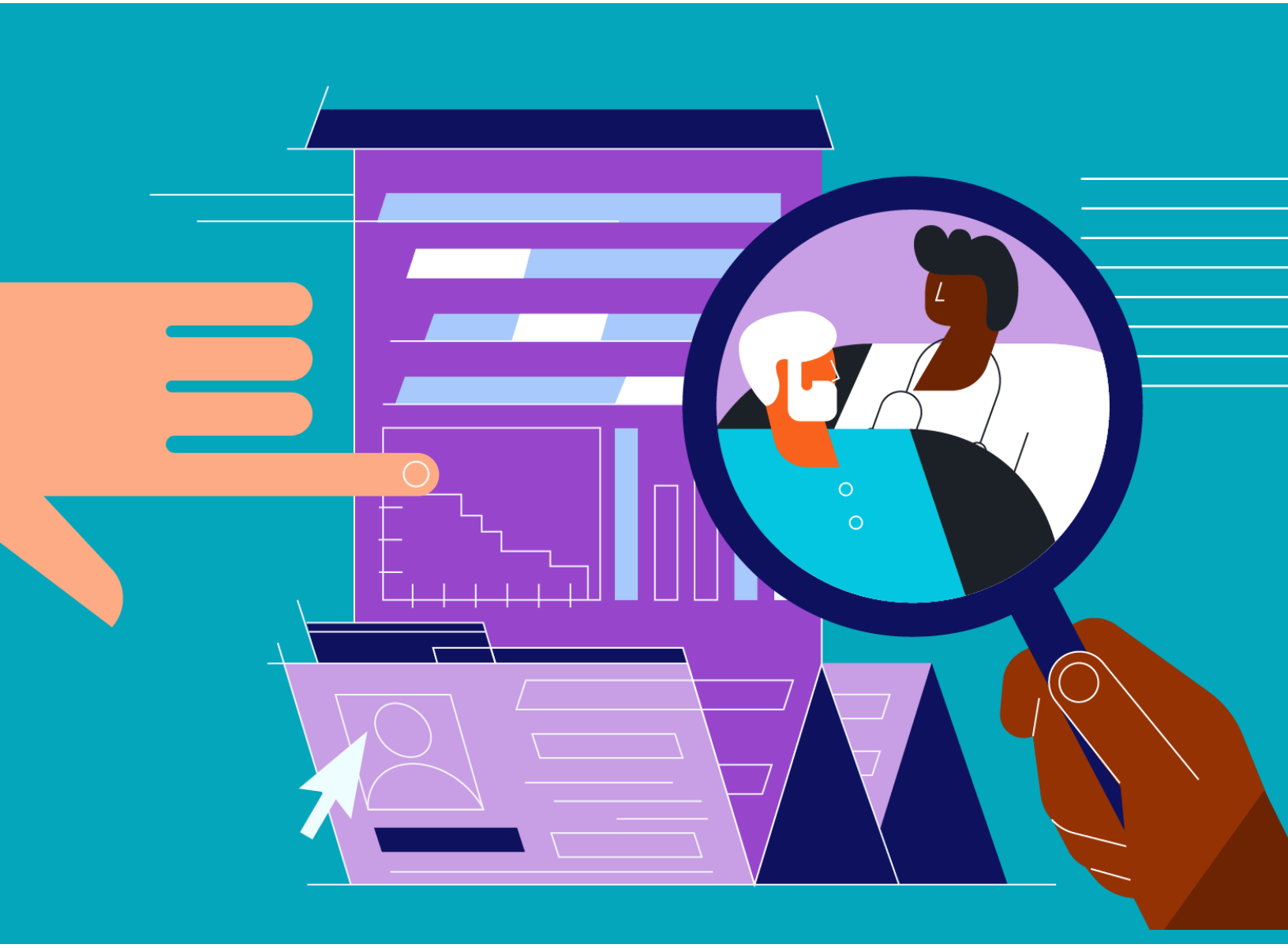
WHITEPAPER

Bringing Research to the Point of Care:
How EHR Integration Can Benefit Patients, Sites, and Sponsors



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Contents:

Introduction

Take a moment to imagine you are observing a clinical trial: Nurses manually sift through patient information to identify eligible candidates for the study. Participants travel far distances to research centers. Physicians document information in unstructured notes, which are subsequently re-entered into trial data systems by research staff; structured information such as laboratory tests are manually transcribed for study purposes. What is wrong with this present-day depiction? It emphasizes how little has changed over the past 30 years within the clinical research space. The result of lagging updates? Modern day study accrual is slow and inconvenient for patients and data collection is costly, duplicative, and error-prone. Overall, the development process is inefficient for all stakeholders involved.

While many other industries have recently embraced technological advancements, the clinical research industry (particularly clinical data and operations methods) continues to fall behind. In fact, according to *Principles of Health Interoperability,* "Healthcare remains the largest remaining market for pens, paper, and fax machines."[1] Yet, technology is available to improve and enhance clinical trials for those willing to embrace new and evolved ways of working. In particular, given the role that electronic health records (EHRs) already play in documenting clinical care, leveraging this point-of-care tool for clinical research can streamline clinical research operations, benefiting patients, sites, and sponsors.

Current Challenges with the EHR for Research

In discussing the current state of the EHR for research, Neal J. Meropol, MD, a medical oncologist and clinical investigator who serves as Vice President of Research Oncology and the Scientific and Clinical Lead for Clinical Research for Flatiron Health, said, "EHRs are a tremendous repository of clinical information, but they weren't designed primarily for research purposes."

While there has been considerable momentum in processing EHR data for retrospective research, in prospective clinical research the EHR has largely been used as a source of select data elements, which then require manual transcription into other data collection tools. This manual process is not only operationally burdensome and error-prone for sites, but also inefficient as it means sponsors receive trial data more slowly due to poorly linked systems of data collection and analysis. This delays database closure, analyses, and ultimately the evidence generation necessary to bring new therapies to patients.

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UNDERSTANDING VARIED DATA TYPES

Unlocking the potential of EHR data for use in clinical research through new technologies and point-of-care workflows requires an understanding of the data types available in the EHR. Here are some frequently used terms relevant to research applications of the EHR:

- Structured data: Refers to data "organized into specific fields as part of a schema, with each field having a defined purpose"[2]; i.e., laboratory results, vital signs, demographics
- Unstructured data: Refers to text and images which may lack the structural organization required by machines for analysis[3]; i.e., free text clinical notes, including physician narratives, pathology, and radiology reports.
- Routinely collected data: Also known as secondary data; "data that are generated during a physician's encounter with a patient and are commonly documented within the patient's electronic health record (EHR) during routine clinical care"[4]
- Intentionally collected data: Also known as primary data for clinical research; "data whose collection is above and beyond what would otherwise be collected as a part of routine practice. These parameters that are required by the clinical study protocol may include data elements that are not part of routine care at all, or might be routinely collected but the protocol specifies some aspect of their collection (e.g., specific interval for certain clinical assessments such as radiographic imaging or diagnostic blood tests)"[4]

Using the EHR for clinical research

There is growing recognition of the potential for the EHR and EHR-integrated technologies to address these challenges. Utilizing the EHR for clinical research can make participation in trials and trial operations more seamless. Dr. Meropol noted that, "Since most data required for clinical trials is, in fact, part of routine care, we have found that technology can reduce several burdens for study sites related to patient identification, data collection, and data entry." He explained five unique ways that using the EHR can optimize today's clinical research operational models:

1. **Increased patient diversity:** EHR data from many different sites can be aggregated and analyzed to allow clinical trial sponsors to optimize the design of their trial protocol, enabling enrollment of more diverse and representative patient populations. For example, the data can be analyzed to assess the impact of certain inclusion and exclusion criteria on the proportion of patients with low socio-economic status who are eligible, and the inclusion criteria could be adjusted accordingly to optimize representation.
2. **Improved patient identification and screening:** Automated tools that pull data from the EHR and match eligibility criteria may be used to help sites identify appropriate studies for their population and surface patients for specific studies at the point-of-care—overall, assisting in matching and enrolling patients to trials faster.

3. **Fewer Protocol Deviations:** Clinical teams and study teams can be prompted automatically to perform certain tests at specific visits by digitizing a protocol's schedule of assessments and pushing this information to the EHR. These automated reminders can help avoid potential protocol deviations.

4. **Reduced staff burden:** Automating the transfer of routinely collected EHR data into study databases can reduce the burden of transcription of trial information. In addition, forms embedded directly into the EHR – termed "research tabs" by the FDA[5] – can be used to intentionally collect data needed for a clinical study in a structured format. Once structured, these data can then be automatically transferred in a matter of clicks to the study EDC. This process alleviates the time traditionally required from site staff for duplicate data transcription between systems, ultimately allowing site staff to focus on other important tasks.

5. **Enhanced data quality:** Automation of data transfer can also help improve data quality by reducing the risk of data errors and discrepancies that arise from manual transcription between systems. This can lead to more accurate, cleaner data.

Emily Akin, MBA, Research Network Lead for Flatiron Health, underscored the challenges sites face in adopting new technologies for research. While efficiencies brought about by technology can help sites regain time to focus on patients, it remains imperative to minimize the impact on site personnel and workflows given the high stakes involved in therapeutic development and the effort required to learn new tools. "At this point," Akin said, "we have proven there is a way to safely, respectfully, and compliantly use these technologies." Companies that provide high-touch support to sites implementing such technologies will make utilization far more feasible and enduring.

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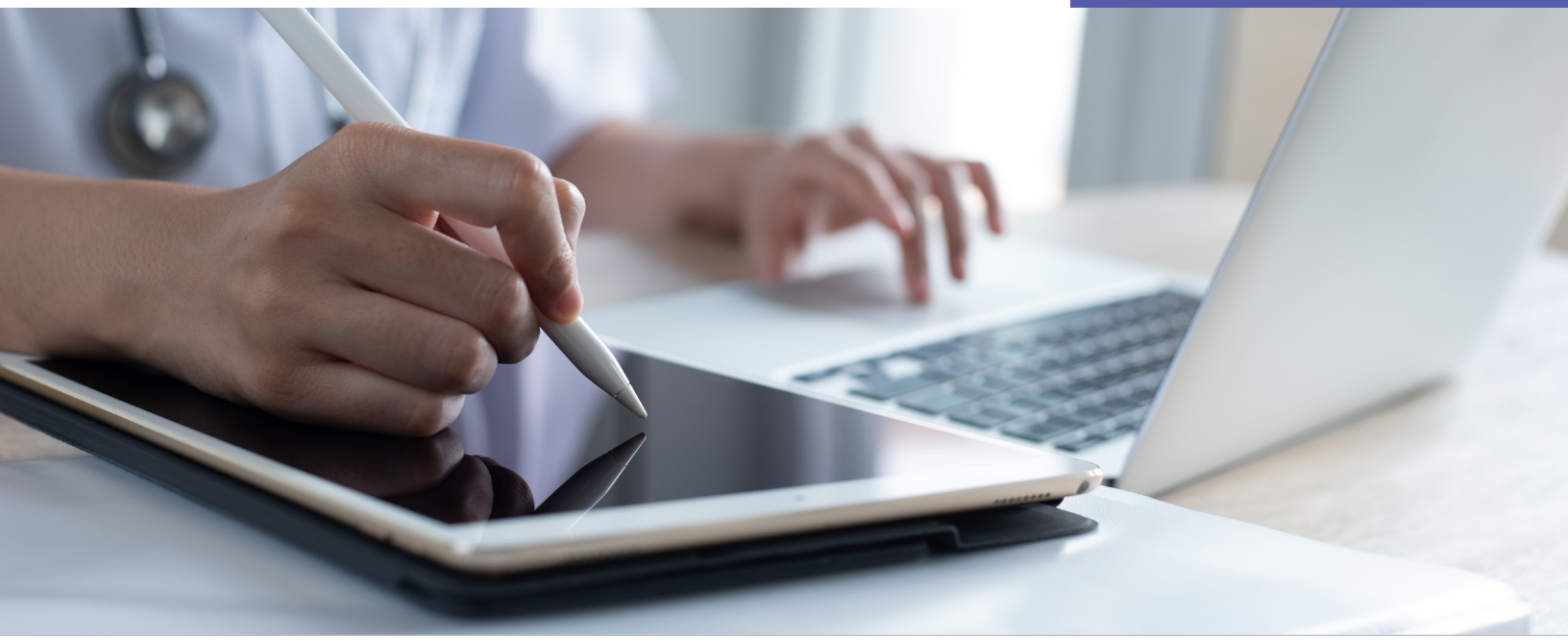
>
> EMILY AKIN, MBA
> Research Network Lead
> Flatiron Health



MODERN TECHNOLOGY EXAMPLES

The following technologies are all integrated with leading EHRs, providing useful ways to begin closing the gap between care and research*:

- OncoTrials®: an application that helps to identify and match patients for clinical trials, while also managing trial-enrolled patients at a practice.
- Intentional Data Collection: a feature aiding in capturing unstructured clinical research data, such as adverse events, into structured data fields. This is currently available in OncoEMR®, with implementation into Flatiron Clinical Pipe™ planned for 2023.
- Flatiron Clinical Pipe™: an application allowing for the transfer of relevant study data from the EHR to the EDC quickly and with accuracy.

**Non-exhaustive list of example EHR-integrated technologies to improve trial operational efficiencies*

Patient benefits

In the FDA's 2020 Drug Trials Snapshots Summary Report, which assessed 53 novel drug approvals, only 8% of participating patients were Black or African American, 6% Asian, and 11% Hispanic, compared to 75% White[6]. Additionally, among patients who participated in trials, another study found they traveled an average of 67 miles one way, translating to countless hours spent journeying to research sites[7].

Reducing the burden of clinical trials by leveraging the EHR and embedded technology makes research opportunities more feasible for a wider variety of sites, particularly community sites where over 80% of patients receive care, positively impacting the number and types of patients who can participate in studies and the burden of participating overall[8]. By enabling more community sites to conduct research, patients can participate in trials much closer to their home, alleviating some of the time and cost burdens associated with traveling to traditional research sites. Easing these burdens also means that underserved patient populations that have lacked adequate access to clinical research settings can now participate in trials locally, improving representation in trials and creating more generalizable results that can guide both regulatory and routine treatment decisions.

Site benefits

In addition to using the EHR to expand the ability of community sites to conduct clinical research operations, this technology can also address critical staffing challenges. According to the Clinical Trials Trends & Reports by the WIRB-Copernicus Group® (WCG), nearly 52% of sites indicated challenges in maintaining adequate staffing in 2022[9]. Dr. Meropol acknowledged the site burnout and staffing crisis:
"This very real challenge is greasing the skids for the adoption of new tools to make clinical trials less burdensome for sites."

While sites may initially view the adoption of new applications as causing friction (due to the installation and onboarding time), patient identification, screening, and EHR-to-EDC tools ultimately save time by making it easier to leverage existing EHR data and reducing the burden of duplicate data entry between different systems, giving time back to site staff to focus on other, more fulfilling tasks. In fact, Akin anticipates that EHR-to-EDC technology will become a required part of many clinical trials "within the next two years."

Sponsor benefits

For sponsors, leveraging the EHR for clinical research can enable improved data cleanliness, faster decision-making, and overall more efficient clinical trials. Using EHR-to-EDC technology, inclusive of point-of-care intentional data capture workflows, enables automated data transfer between the systems, reducing the errors associated with manual data transfer and getting clinical trial data into the EDC more quickly. This automated data entry also means that source data verification is not needed (or can be significantly reduced) and overall query volume is lower, saving critical study time and money. Additionally, when data is entered more quickly into the EDC, sponsors have the ability to start analyzing data sooner, identifying trends (including safety trends), more quickly. Overall, this translates to lower costs, shorter trial timelines, and getting new treatment options to market faster, which, according to Akin, "is good ROI for sponsors and the right thing to do for patients."

Moving forward

While utilizing the EHR to advance clinical research will require agility and thoughtful change management, it stands to substantially benefit patients, sites, and sponsors alike. Closing the gap between care and research requires solutions that address the inadequacies of legacy systems. As Dr. Meropol predicts, "There's no reason why every oncologist can't also be a clinical investigator. This is the only way we'll be able to generate the evidence that cancer patients so desperately need. [...] In spite of all the ways tech has changed our lives in the past few decades, we are still executing clinical trials like the day I entered my fellowship. Today we have the tools to transform the whole evidence generation enterprise to streamline clinical trials for the benefit of patients."

Learn more about how Flatiron Health is bridging the gap between care and research.

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NEAL J. MEROPOL, MD
VP of Research Oncology
Flatiron Health

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