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# Solving the EHR-to-EDC Challenge: A Scalable- First Approach

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## Table of Contents

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Introduction	3
Why Solve the EHR-to-EDC Challenge?	4
Industry Changes Have Finally Enabled the Development of a Scalable Solution	7
Medidata's Multi-Disciplinary Approach to Overcome the EHR-to-EDC Challenge	10
Summary	14
References	15

## Introduction

As most readers are likely aware, **Electronic Data Capture (EDC) systems have been used in clinical trials for many years to collect, clean, transfer, and process data, primarily through the use of electronic case report forms (eCRFs).** However, despite the significant progress and widespread adoption of Electronic Health Records (EHRs) following the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, their integration into clinical research has been comparatively slow. EHRs are real-time, patient-focused records that incorporate information from various healthcare providers involved in a patient’s care. The widespread adoption of EHR systems, with over 95% of U.S. hospitals implementing them, has resulted in improved efficiencies, increased reimbursements, and enhanced patient care (ONC, 2019).

**EHRs contain a rich collection of information that can provide several benefits when leveraged for clinical research purposes, including (McCord, 2019; Nordo, 2019):**



Reduced trial costs



Faster trial completion



Increased generalizability of results



Enhanced recruitment



Feasibility assessment of research protocols



Improved outcome analysis



Expanded scope of research



Earlier identification of safety events

EHRs also facilitate the connectivity and interoperability required for the exchange of electronic health information with other systems, such as in the case of increasing engagement between regional- and national-level Health Information Exchanges (HIEs). HIEs are secure electronic central repositories of patient data that allow relevant stakeholders to safely access and seamlessly transfer a patient’s medical information, with some even allowing users to tap into EHRs without point-to-point integrations (ONC, 2023).

## Why Solve the EHR-to-EDC Challenge?

**While clinical researchers have long sought to repurpose EHR data at scale for conducting clinical studies, several hurdles have hindered this progress, including poor interoperability between EHRs and other systems, poor data quality, and the intensive effort required by sites to manually transcribe electronic data from EHRs (and other systems) to EDC systems (Collen, 1990; Garza, 2020).** These challenges are exacerbated by the fact that the sheer volume of data being collected is constantly increasing, with Phase III trials collecting 3.6 million data points on average—a sevenfold increase in volume from 20 years ago (Tufts CSDD, 2021). Additionally, healthcare systems often store data in systems outside EHRs, with Johnson et al. (2018) reporting that more than half of the hospitals in their sample used four or more electronic methods to transfer summaries of their care records to organizations outside their hospital system.

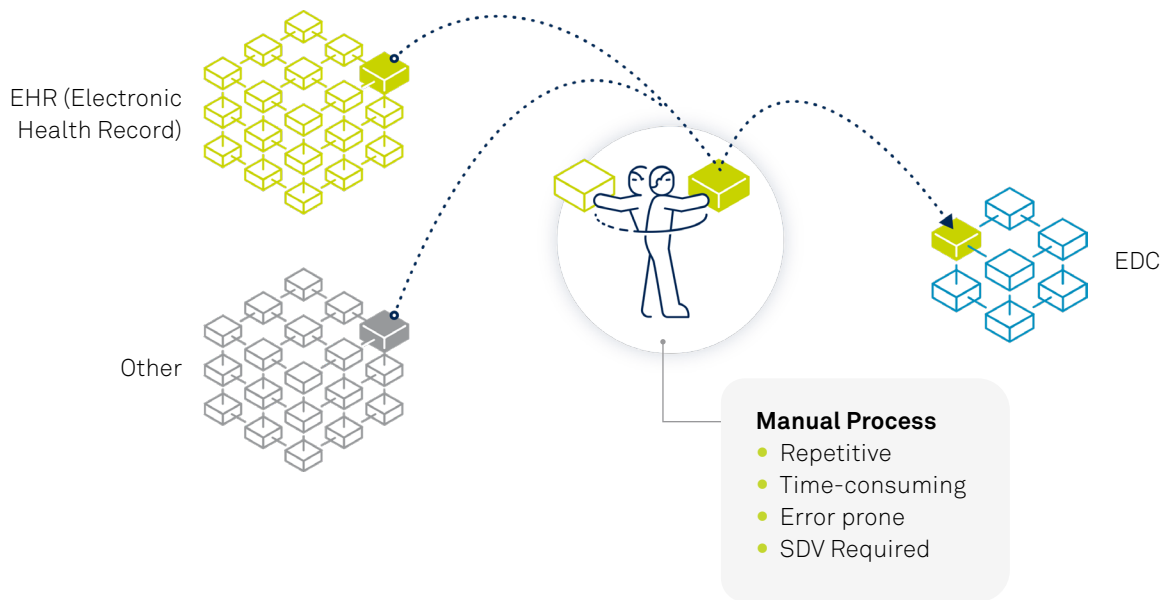
Overall, a pain point that is commonly highlighted by site research coordinators is:



**Why am I manually entering data that is already available somewhere else?"**

Given that approximately 70% of the data entered into EDC systems are duplicated from EHRs and other source systems, this reaction is not surprising (Sundgren, 2021). Today's industry standards require research coordinators to manually transcribe large volumes of data already existing in EHRs for the purpose of entering them into EDC systems. This process involves identifying and reviewing specific patient and visit records in the EHR (as well as in systems outside the EHR) and then determining the data that need to be transferred to the EDC from specific reports. This is carried out by toggling between the EHR (or another system outside the EHR) and EDC systems to identify and capture accurate information, which often involves copying EHR data onto a sheet of paper before manually entering them into an EDC system (Figure 1). Unsurprisingly, this manual re-entry of EHR data into EDC systems is an enormous challenge for sites. According to the results of a survey conducted by the Society of Clinical Research Sites, 98% of sites indicated that they manually re-enter data into EDC systems, while nearly 70% of them stated that more than 50% of their EDC data is re-entered using existing EHR data (Society for Clinical Research Sites, 2022). In addition to the huge amount of time that this process consumes, it also introduces transcription errors, resulting in additional time and effort spent on raising and resolving queries—a laborious undertaking, given that the average number of queries per Phase III study ( $n = 20$ ) has been found to be 96,980 (Stokman, 2021).

**Figure 1. Today's industry standard involves manual data (re)entry.**



The EHR-to-EDC challenge, and indeed the overall data entry challenge, continues to plague almost all personnel involved in the clinical trial ecosystem. According to Medidata’s research, solving this challenge at scale can address specific concerns raised by sites, sponsors, and partners, including the following:




**SITE CONCERNS:** Data already existing in the EHR, requirement for excessive data entry, high frequency of toggling.

**SPONSOR CONCERNS:** High monitoring costs, too many data entry errors, and desire to keep sites satisfied.

**PARTNER CONCERNS:** Industry demand for better technologies to improve processes, desire to keep sites satisfied.

While several one-off solutions have been developed in an attempt to allow for data extraction from EHR to EDC, they are unfortunately not scalable for a variety of reasons (Table 1). One such reason is the requirement for a significant level of effort at the site since the solutions have been limited to single-EHR and single-institution implementations. Furthermore, these limited solutions require an IT infrastructure to be developed, systems to be installed, data to be mapped, and many data agreements to be negotiated between the site, the vendor, and the sponsor for each specific trial. After completing all these initial steps, the system can finally be connected to the EDC system.

**Table 1: Challenges associated with scaling traditional EHR-to-EDC solutions.**

 <b>POINT TO POINT SITE CONNECTIONS</b>	 <b>DATA MAPPING</b>	 <b>SLOW ADOPTION</b>
<p>Need dedicated IT resources from sites</p> <hr/> <p>Individual data sharing agreements</p> <hr/> <p>Time spent on configuration, testing, reconfiguration</p> <hr/> <p>Often involves EHR vendor resources and additional costs to sites</p>	<p>Healthcare data is inherently complex</p> <hr/> <p>Not effective at scale given time and effort required</p> <hr/> <p>Inability to control for all variables in data, human verification still needed</p>	<p>Still no universal and widely adopted standard</p> <hr/> <p>Ambiguity in current standards</p> <hr/> <p>EHR to EHR configuration variations</p>

While many of these solutions are EDC-agnostic, they still require significant amounts of time and effort for installation and configuration, before even beginning a study. This typically takes multiple months to accomplish, and implementing these solutions is generally a heavy burden on sites.

Furthermore, IT resources, data sharing agreements, and the time spent testing and configuring the solution often involve an EHR vendor. While the industry is dominated by major enterprise vendors, such as Epic, Cerner, Centricity, and Allscripts, there are many small and specialty vendors as well, with one estimate suggesting that there are more than 1,000 EHR systems available on the market (Fouque, 2022).

In addition, since many enterprise EHRs are site-hosted and site-configured, variability among even single implementations of the same EHR is often observed. Overall, a primary challenge in the sharing of EHR data for clinical research is the different and inconsistent data standards followed by organizations using different EHRs and EHR vendors, and between clinical care and research sites. With such enormous variability between, and within, healthcare and clinical research systems, a major challenge has been to identify a suitable method to handle this variability in the context of standards that lack flexibility and are not readily adaptable to the diverse needs of different stakeholders across its many potential use cases.

## Industry Changes Have Finally Enabled the Development of a Scalable Solution



**Fundamental regulatory and data standard changes have provided significant opportunities for organizations to integrate EHRs and EDCs and finally develop scalable solutions to solve the EHR-to-EDC challenge.**

The 21st Century Cures Act (the “Cures Act”), passed in 2016, sought to reduce the regulatory burden associated with the use of EHR systems through provisions focused on advancing interoperability and requiring developers to not engage in information blocking or preventing the access, exchange, or use of electronic health information. This legislation also includes the provision that every healthcare organization within the country must share data with entities that have rightful access to it, and this sharing must be digitally conducted in a format that adheres to specific structures and standards.

The Office of the National Coordinator for Health Information Technology (ONC) was tasked with implementing the key provisions of the

Cures Act designed to advance interoperability, including supporting the access, exchange, and use of electronic health information and addressing occurrences of information blocking (Federal Register, 2020). Furthermore, the ONC has adopted API-enabled “read” services and recommended using the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard, which lays down the established technical requirements for software developers while also offering a set of accepted implementation specifications (ONC, 2020). The HL7 FHIR standard, often referred to as the “next generation” standards framework (Garza, 2020), is a simple yet highly versatile benchmark that allows for the accommodation of diverse healthcare processes, be it as a stand-alone standard or in tandem with other widely used standards. HL7 FHIR is increasingly being used to support healthcare data exchange using a variety of applications, with all U.S. healthcare organizations supporting some level of exchange utilizing HL7 FHIR.

Overall, HL7 FHIR has enabled the health applications market to leverage data from any EHR in a standard format, while also allowing for a standardized interface that functions seamlessly with EHR operating systems by feeding information directly into the provider workflow to facilitate document-based exchange.

While the industry has been trying for many years to find the best methodology, practice, workflow, and approach for extracting data from EHRs and feeding them into EDC systems, addressing this complex industry-wide challenge requires a novel and multi-pronged approach because mapping existing EHR data to the information required by EDC systems is an extremely difficult task, with even the most advanced solutions not able to map anywhere close to 100% of the necessary data.

For instance, Ganza et al. (2020) mapped clinical study data elements from three therapeutically diverse studies (labeled “A,” “B,” and “C”) to HL7 FHIR resources. All exchangeable contents were defined as “resource,” representing a small collection of clinical and administrative information that could be captured or shared, such as “Observation,” “Patient,” and “Specimen.” With regard to FHIR coverage, this investigation revealed considerable variability in the percentage of data that was mappable across the three studies, which was 45%, 55%, and 79% for studies “B,” “A,” and “C.” The results of this study offer valuable insights into the coverage and utility of the FHIR standard, further underscoring the need for multi-pronged approaches that do not rely solely on FHIR-based mapping (but rather, leverage FHIR as one of many integration standards).





The enactment of the Cures Act paved the way for an efficient EHR-to-EDC integration solution by codifying data exchange standards, which can be used by industry, providers, payers, and technology vendors to guide the design of their health IT systems for seamless information flow. This important regulatory tailwind has been the fundamental driver of organizations becoming more standards-compliant and achieving ubiquitous interoperability. The fact that the use of HL7 FHIR and other standards-based interoperability mechanisms is now federally mandated for all healthcare organizations across the U.S. has been a game-changer for retrieving data from a diverse set of clinical sources.

Additionally, over the past decade, there has been an increasing number of healthcare providers participating in HIEs, as they offer a variety of benefits, such as helping facilitate coordinated patient care, reducing duplicative treatments and testing, and increasing efficiency by eliminating unnecessary paperwork and handling.

Lastly, regulatory agencies have long recognized the benefits of EHR data in clinical research and have encouraged the development of solutions that advance their use in such research. While the FDA has published guidance on the use of EHR data in FDA-regulated clinical studies (FDA, 2018), the European Commission has adopted a recommendation on a European electronic health record exchange format to facilitate the cross-border interoperability of EHRs in the European Union (European Commission, 2022). Furthermore, multiple large-scale efforts have been underway for several years, to specify patient clinical information standards in a manner that enables computable interoperability among diverse systems across the world (Nordo, 2019).

These changes in the industry landscape have enabled the development of a scalable multi-disciplinary approach to solving the EHR-to-EDC challenge that is less focused on mapping data and more focused on presenting data to users. This solution is further described in the following section.

## Medidata’s Multi-Disciplinary Approach to Overcome the EHR-to-EDC Challenge

**Although previous attempts at EHR-to-EDC integration were too complex to solve the problem practically, it is still vital to enhance data quality and release some of the burden on sites by making data entry simpler and faster, while also reaping the previously discussed benefits of using EHR data in clinical research.**

Medidata’s priority, in this context, is “scalability first.” Consistent with this priority, it adopted a

multi-pronged approach when building its EHR-to-EDC solution—[Rave Companion](#). This solution consists of two complementary capabilities: “Click” and “Connect.” Essentially, Rave Companion brings the EDC experience directly into any EHR, thus enabling users to make the most of any occasion that requires them to find information in an EHR. Table 2 outlines some of the primary benefits of the two functionalities in Rave Companion that work together effortlessly.

**Table 2: Rave Companion provides two solutions that work together seamlessly.**

RAVE COMPANION	
Eliminates bouncing between apps	
Easier, faster, more accurate data entry. Fewer queries.	
CLICK	CONNECT
Takes the Rave EDC experience with you into your EHR	Brings your EHR experience into Rave EDC
Instant Scalability	Reduces monitoring burdens
Works with any EHR	Standards-based connectivity to any site



## RAVE COMPANION - CLICK

**Rave Companion's Click capability is an out-of-the-box solution that brings the EDC experience into an EHR.** Considering that not all data elements need to be mapped between the EHR and EDC systems, Click enables users to identify and click on the required data in the EHR system, which is then automatically captured into Rave EDC.

Click is extremely useful in situations where users need to find data that is unstructured and buried inside a PDF or that is contained in a clinical system outside the EHR. Click can capture both numbers and text, including entire paragraphs of clinical notes, using simple click-and-drag functionalities. Furthermore, Rave Companion automatically detects the presence of Protected Health Information (PHI) and alerts the user, who can then remove the PHI before the data are saved into Rave EDC. Additionally, there is complete traceability and visibility of the method used to transfer data via Rave Companion to Rave EDC. Figure 2 presents a screenshot of Click accompanying a user while they look up data in their EHR system.

**Figure 2: With Rave Companion Click, you can simply point-and-click or drag to capture data from an EHR or any other source system into Rave EDC.**

The screenshot shows an EHR interface for a patient named Jane Medlock. A table of lab results is displayed, and a 'Click' overlay window is open, allowing the user to select data from the table to be captured into Rave EDC.

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
<b>Renal Panel (10)</b>					
Glucose	93		mg/dL	70-99	01
BUN	14		mg/dL	6-20	01
Creatinine	0.91		mg/dL	0.57-1.00	01
eGFR	84		mL/min/1.73m2	>59	01
BUN/Creatinine Ratio	15			9-23	01
Sodium	135		mmol/L	134-144	01
Potassium	4.4		mmol/L	3.5-5.2	01
Chloride	104		mmol/L	96-106	01
Carbon Dioxide, Total	28		mmol/L	20-29	01
Calcium	9.0		mg/dL	8.7-10.2	01
Phosphorus	3.2		mg/dL	3.0-4.3	01
Albumin	3.9		g/dL	3.8-4.8	01

The 'Click' overlay window shows a list of lab results with input fields for each value, such as 'Albumin' with a value of 3.9 and 'Sodium' with a value of 135. A 'Rave' button is visible at the bottom of the overlay.

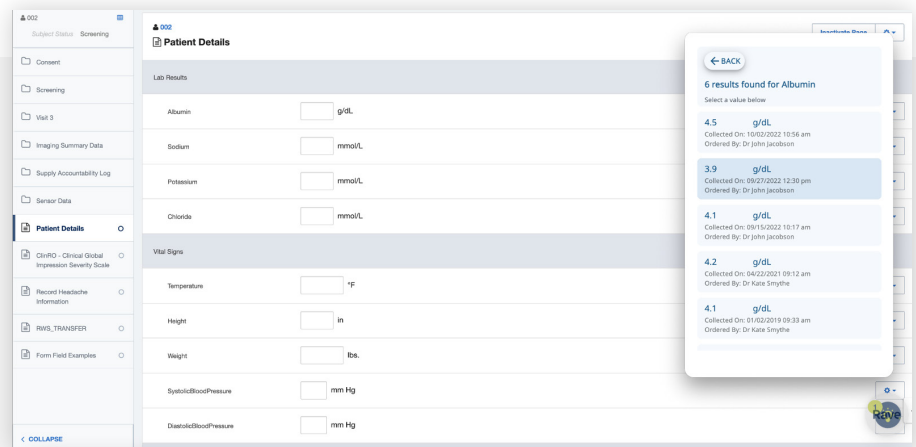


## RAVE COMPANION - CONNECT

Largely focused on structured data elements (e.g., lab results and vitals), Rave Companion's Connect identifies matching structured data in the patient's health record and presents it to the user, who can then review the suggested matches and select the correct data to populate the Rave EDC form. Figure 3 provides a screenshot of Connect.

Rave Companion has been designed with the user in mind. It is highly focused on presenting data to the user. Notably, Companion directly writes data into Rave EDC forms, but provides users with the opportunity to review and make edits to the data before saving it. This is important since our initial research found that users did not prefer a direct flow of data from the EHR into the EDC system. In this way, users can first review the data to ensure it reflects the right value, the right visit, the right date and time, etc., thus ultimately facilitating the completion of the form with no requirement for manual data entry. Furthermore, provenance is maintained in the audit trail for every field in the eCRF to easily determine whether the data were manually entered into Rave EDC or captured by Companion's Click or Connect capabilities.

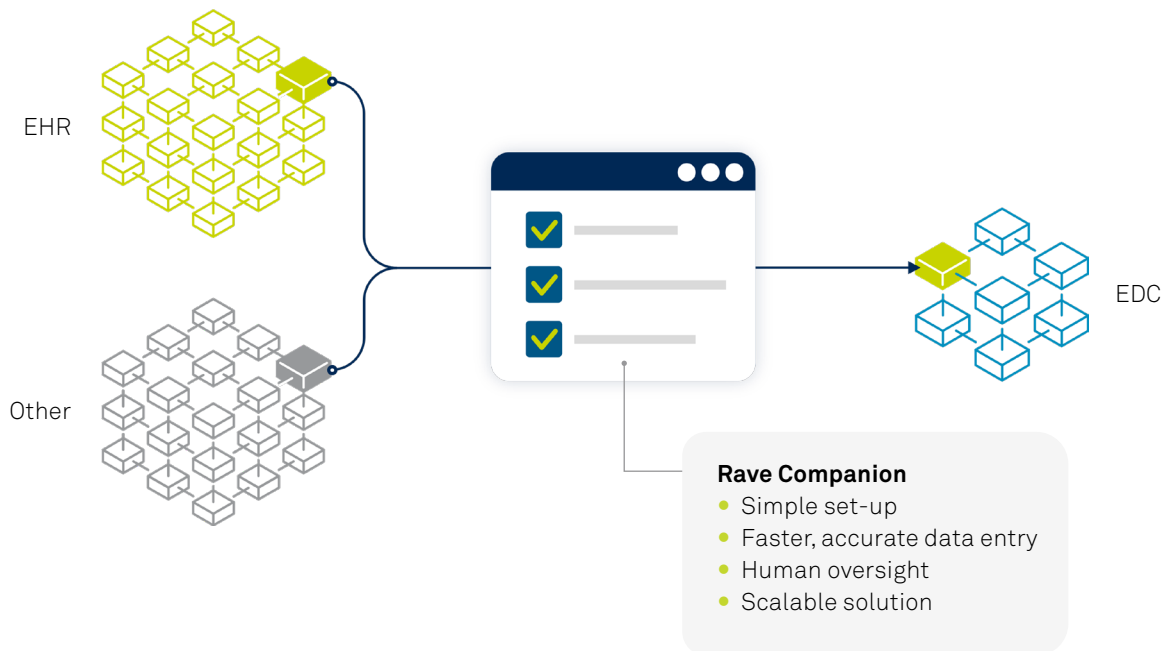
**Figure 3: With Rave Companion Connect, sites are presented with potential matches from the patient's EHR, from which the site reviews and selects the right data point for the eCRF. Once a data point is selected, all other data points within the eCRF can be auto-filled from the EHR data based on the date range selected.**



Most importantly, Companion is a completely scalable solution, as it doesn't require complex integration and mapping to be performed, and can be used by any site, with or without connection to patients' health records. Moreover, it can be used by any member of a study team at any time, provided they have access permission to enter EDC data.

While Companion can be connected to any specific site's EHR system, Medidata has designed the tool to leverage the Health Information Exchange approach as much as possible by also connecting to hubs that are already well-connected to the necessary sites.

**Figure 4: A novel user-friendly and scalable EHR-to-EDC approach.**



## Summary



**EHRs provide a comprehensive collection of information that can provide several bona fide benefits to clinical trials**, such as faster trial completion, enhanced recruitment, and earlier identification of safety events. Furthermore, they facilitate the connectivity and interoperability required for the exchange of electronic health information with other systems.

**While traditional approaches to EHR-to-EDC have existed for years, changes in the industry landscape, the adoption of new technologies, and openness to interoperability are all opportunities to create solutions that scale.**



To learn more about Rave Companion visit:

<https://www.medidata.com/en/clinical-trial-products/clinical-data-management/rave-companion/>

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