



**Integrated Platforms Give
Clinical Research a New Lease
of Life**

EHR-EDC integration can whittle down costs and deliver high quality, standardized data that not only helps future research but also speeds up the process of getting a drug to market

A pharma major, that was funding a big-ticket clinical trial in the US, was struggling with data availability from sites to EDC and, ultimately, delays in clinical trials. The hiccups were way too many: fierce delays in data availability due to discrepancies, escalating trial costs, not to mention the sluggish pace of source data verification.

These challenges made it necessary to create novel approaches to the way clinical data is collected today. In June 2015, the CDER published a Federal Register (FR) Notification for "Source Data Capture from EHRs: Using Standardized Clinical Research Data." The intention of the notice was "to test and evaluate performance of end-to-end Electronic Health Record (EHR)-to-Electronic Data Capture (EDC) single-point data acquisition

approaches in a standards-based, regulated clinical research environment."

This would not only accelerate the drug trial and time-to-market for this pharma major and many others in the industry, but would also help automate data extraction without interrupting the EHR user.

There was, however, no single benchmark technology available to support the EHR-EDC integration. In response to the CDER notice, a transitory data interface, standards-based technology platform (Digital Integrated Clinical Enterprise or DICE) was built to connect EHR and EDC systems. This was done in collaboration with EHR and EDC owners and a pharma giant.

Slice & Dice

Integrating EHR with EDC systems heralds a paradigm shift in the conduct of clinical research. The cloud-based platform integrates patient and clinical research data in real time, and this integration results in quick availability of data, ready for use in analysis and reporting. What we get as

a result is: Being Clinical Data Interchange Standards Consortium (CDISC) compliant. Similar platforms can be built in collaboration with hospitals that own EHRs, technology providers, pharma sponsors and clinical research laboratories.

Transcribing and re-populating the data is an expensive process. However, when EHR data is directly sourced, it can eliminate this cost and deliver high quality/standardized (HL7, 21 CFR Part 11, CDISC) data along with built-in edit checks in the EDC systems (see Figure 1).

With the adoption of the cloud-based platform, the pharma giant could whittle down its trial cost by about \$30 million to \$40 million per drug, and automate almost 80% of its source data verification. While it took them close to 12 years to take a drug to market earlier, the platform helped bring down time-to-market by about a year.

The platform allows researchers to directly enter data into case report forms (CRF) via EHR and has the capability to pick out errors in data entry, omissions, and out of range/unexpected values as per trial protocol. The fields required for analysis are flagged in the EHR and sent downstream to the sponsor's EDC.

Encouraging data capture at the point of care and using analytics to eliminate duplication of data, reduces errors and the need for Source Data Verification (SDV). The next step is to anonymize and auto-populate data from the EHR into the study forms for research conducted by the sponsor.

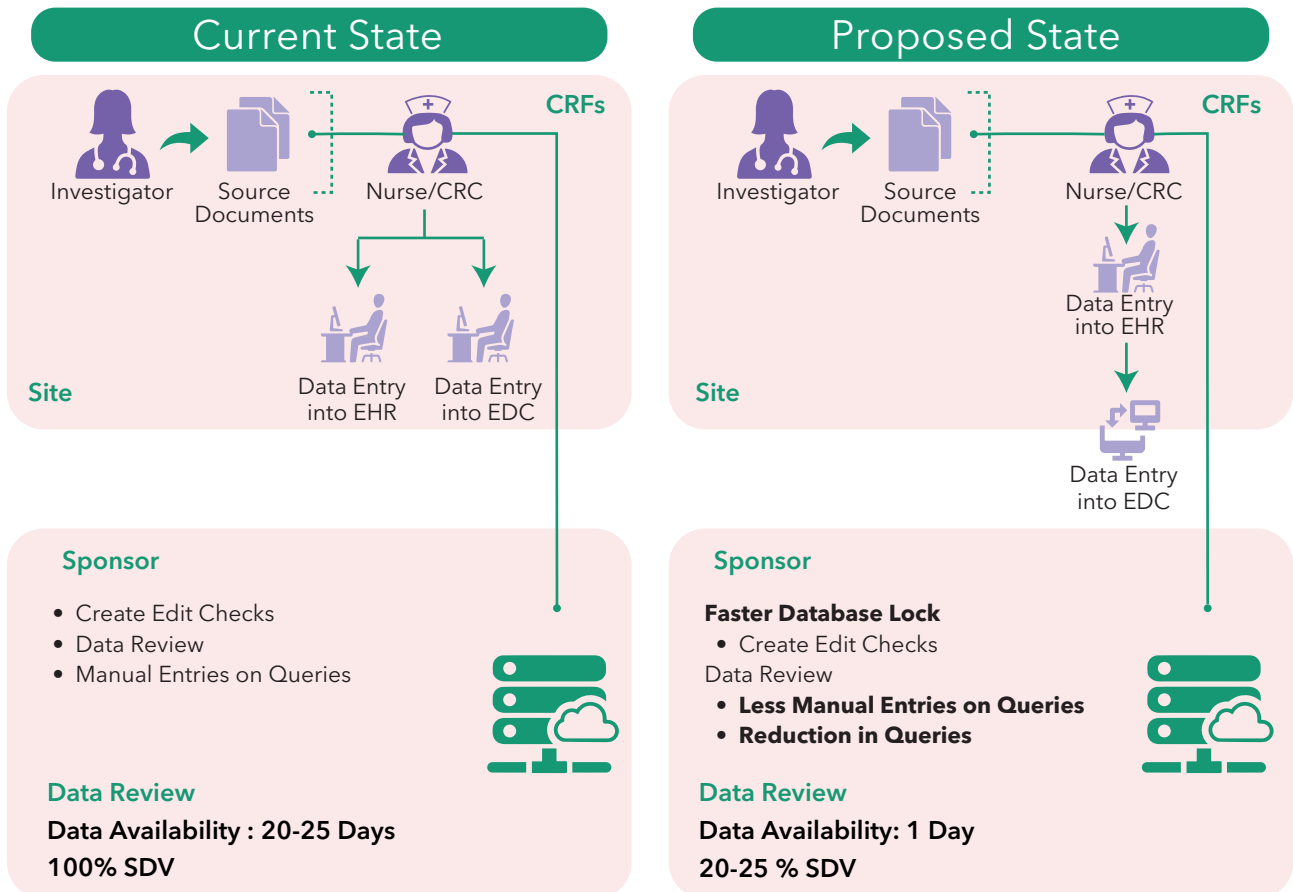


Figure 1: EHR-EDC integration: Current to Proposed State



Digital transformation and technology disruption are the next steps in improving operational excellence and speeding up clinical research in Life Sciences. EHR-EDC integration holds great promise in reducing the burden on trial investigators, improving trial recruitment, accelerating trial execution, and increasing patient safety.

Alan S. Louie, Research Director at IDC Health Insights



There are four major advantages in doing this:

- The digital records facilitate the remote monitoring of data, reducing the number of onsite visits by Clinical Research Associates (CRA) required to monitor research-related activity
- Data is populated in the EDC in real time

- Data from multiple sources is integrated, making close to 80% of clean CDISC formatted data available
- By preventing tampering or editing of data we maintain data integrity

Path To Integration

For the integration platform to be effective, users need to design a new data model with the following steps:

- **Evaluate and understand source data** of each of the applications along with strategy for populating and storing de-identified transactional data at the point of data exit from sites
- **Validate the Operational Data Store (ODS) layer** for missing and duplicate data records populated from source applications
- **Map and transform data** from source to target
- **Validate the data model** with respect to the target data model

- **Establish standard EDC functionality** for review and query of data points; map common data points from EHR to CRF Demographics page

Underlying this is the need to follow key data standards such as HIPAA for patient privacy and data de-identification, CDISC Operational Data Model (ODM) for common data transport and HL7 for data exchange between EHR and EDC.

The technology framework developed by us (see Figure 2), within which the above steps must be executed, uses middleware for data transformation. Only cleaned, anonymized, standardized, analyzed and filtered data is pushed to clinical researchers.

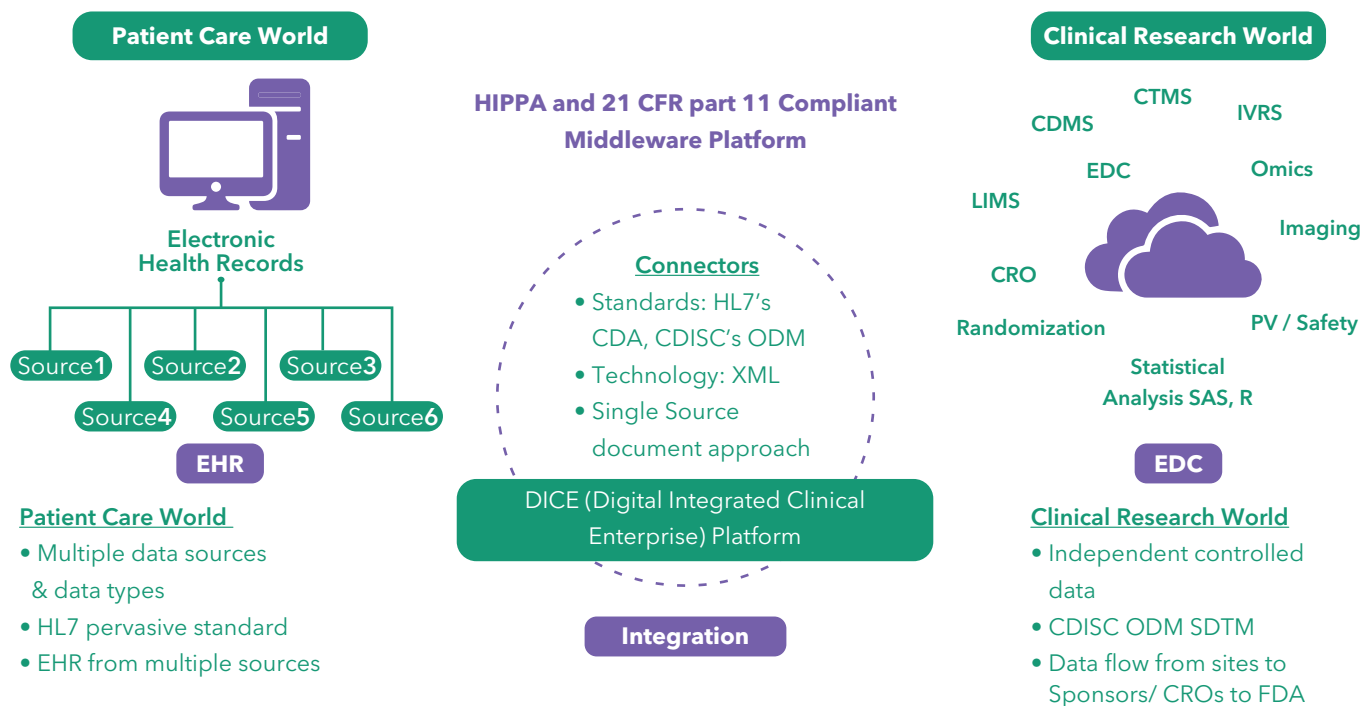


Figure 2: Proposed technology framework

The Big Impact

The impact of the framework and methodology on clinical research is significant. For companies in the industry like the pharma giant, the advantages are many.

The benefits could include:

- 60% decrease in queries and rework, enabling faster completion of trials
- Cyclic Redundancy Check (CRC) effort reduced by 50%, improving CRA time spent with study team at sponsor location. Reduced CRA site visits as well

- Data compliant with regulatory standards and easy to integrate with standard-based applications
- Faster time to market, leading to faster ROI per drug (by about 6 months)

Integration can have its share of challenges -- from privacy concerns to regulatory requirements. Therefore, proper work flow design and application of a rules-based approach is what is needed.



Empowering The Researcher

The adoption of EHR to EDC integration promises to place quality data in near real time in the hands of researchers. Live patient data combined with risk and event information will ensure that researchers can take quick and accurate decisions on clinical operations.

The new integration processes will also give rise to new forms of digital data and will eliminate the need for database build, providing flexibility and reusability of electronic data transfer from EHR to EDC with bidirectional traceability.

The biggest upshot of creating such an integration platform is the ability to put all the saved resources—CRA availability, time and cost—into new research that creates better ways to serve the future of modern medicine.

References:

Source Data Capture from Electronic Health Records (EHRs), U.S. Department of Health and Human Services,

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