Leveraging the EHR to revolutionize research

Ann Marie Navar MD, PhD
Associate Professor of Medicine
UT Southwestern Medical School
Strategic Advisor, Cerner

Eric Peterson MD, MPH
Distinguished Professor of Medicine
Duke Clinical Research Institute
Strategic Advisor, Cerner

Sandra Blumenrath, PhD
Science Writer
Scientific Communications
Drug Information Association (DIA)

Table of contents

Executive summary

The current clinical research enterprise is slow, siloed, inefficient and costly. Translating research into practice is similarly slow and inefficient. Efforts are underway to provide needed resources aimed at reducing the time, complexity and cost of traditional clinical research, and moving those insights into adoption.

Aggregated, standardized, person-centric electronic health record (EHR) data is now available to help provide the needed research-ready data to help power clinical research. A novel, nationwide *Cerner Learning Health Network*℠ (LHN) has launched that leverages the EHR and a cloud-based data platform to power clinical research across a collaboration of heterogenous health systems.

The LHN has the potential to transform observational research, clinical trials and implementation research, as well as drive improvements in quality of care. Ultimately, the LHN aims to help speed the nation's ability to discover what works, and take that knowledge to facilitate adoption into practice.

Clinical research challenges and real-world data issues

On average, it takes 17 years[1] and an estimated $2.6 billion[2] to take a promising drug target from the research bench to routine clinical practice. Despite regulatory reform, the delay associated with this process has been static over the last 10 years, yet the costs associated with the clinical research phases of this process have continued to rise.

Analyzing existing data available in EHRs could help reduce the high costs associated with conducting clinical trials. However, the aggregation of large amounts of real-world data faces issues of quality, provider-level data elements, standardization and completeness. Further, disparate data sources and multiple EHRs within health systems pose challenges to researchers due to lack of data normalization.

While the number of large data sets of real-world data is increasing, these often represent select samples of patients (like those like with particular insurance coverages), leading to potential selection biases that may confound analyses and prevent a full understanding of patterns of care in routine practice. Finally, concerns regarding data integrity and the need for replication have led to calls for more open access to data, including for external validation.

Moving forward, life sciences researchers need larger, higher quality, more accessible and representative data sources. Beyond facilitating retrospective analyses, such resources could also be used to facilitate prospective randomized clinical trial planning and operations.

Standardized EHR data from across multiple health systems provides an enormous potential for clinical research. Today, Cerner is working with more than 90 U.S. health systems to standardize and make use of EHR and other real-world data via *Cerner Real-World Data*™ and the LHN.

These data are standardized using *HealtheIntent*® — a data and insights platform that ingests, normalizes and standardizes data from different EHRs, as well as other sources, including laboratory data systems, claims data and even publicly available data sets such as air quality data. *HealtheIntent* is the data backbone of both the LHN and *Cerner Real-World Data* in that it aggregates various data, including EHR data, from across health systems

into compatible analytic data sets in near real-time. For example, with a single query, users and researchers looking to recruit clinical trial participants can identify potentially eligible patients from across multiple health systems.

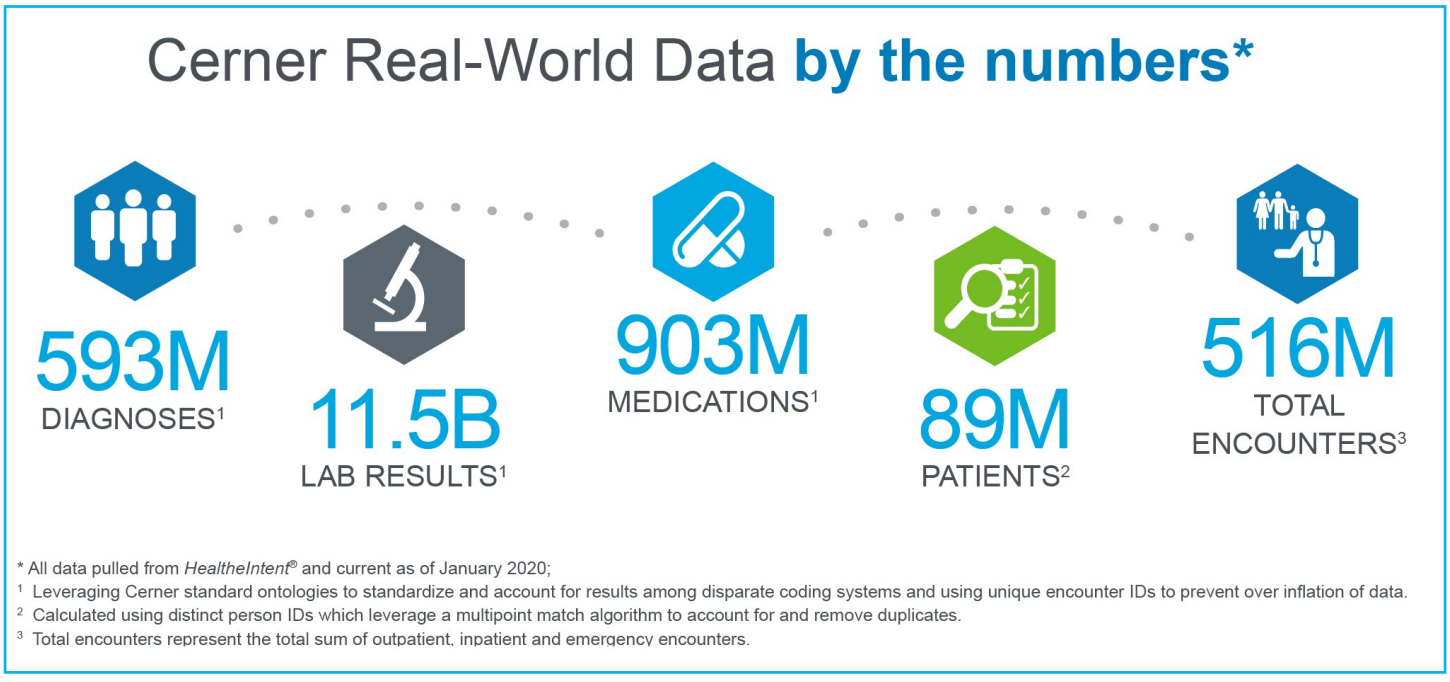
Cerner Real-World Data

Designed to facilitate meaningful insights and advance research discovery for retrospective studies, *Cerner Real-World Data* offers life sciences access to national, aggregated, de-identified, encrypted and secured clinical data sets that are updated quarterly.

As of 2020, more than 90 health systems across the U.S. have agreed to contribute their fully de-identified data for clinical research purposes. *Cerner Real-World Data* includes a variety of elements from the EHR including demographics, inpatient and outpatient medications, vital signs, labs, procedures and clinical diagnoses from inpatient, outpatient and emergency room settings.

Use of Cerner Real-World Data in research studies

To date, the reliability of EHR data has been limited by concerns regarding EHR data quality. As part of an initial pilot project, researchers at the Duke Clinical Research Institute, in collaboration with the University of Missouri and The University of Texas Dell Seton Medical School, evaluated the reliability of diagnoses and events captured via EHR data with nearly 2,000 manual chart reviews. Information from these chart reviews is being used to refine the case definitions for key events in cardiovascular clinical trials and important comorbidities in epidemiologic research, like heart attacks, stroke, bleeding events and death. Ultimately, the case definitions developed as part of this effort will be shared across all users of the data to help clinicians improve delivery of care.



Launching the Cerner Learning Health Network

In 2019, Cerner announced the launch of the LHN to help facilitate the use of EHR data for clinical research studies. The LHN is a growing collaboration of 47+* U.S. health systems that have agreed to share their EHR data and conduct multicenter clinical research. While *Cerner Real-World Data* is designed for *retrospective* epidemiology studies, the LHN is designed to facilitate the efficient conduct of *prospective*, multi-institution research studies. Research projects range from epidemiological studies and clinical registries, to clinical trials and implementation or quality improvement initiatives.

Once aggregated and de-identified, life sciences, academics and LHN members can leverage the LHN to conduct retrospective analyses. Once patient consent is received, LHN sites can also opt to participate in studies that require individual patient data to leave the Cerner environment. The LHN can facilitate registry and clinical trial operations by providing sites with centralized research tools created by Cerner, like enrollment dashboards, to identify and track potentially eligible patients, centralized data harvests and EHR-augmented case abstraction forms.

The Learning Health Network: facilitating clinical research

Studies facilitated by the LHN range from observational studies to randomized trials to implementation science studies.

Observational studies and registries

cvMOBIUS is a five-year prospective cardiovascular registry conducted by the Duke Clinical Research Institute in partnership with Amgen, Inc. It includes patient data collected from consented patients at 200+ health systems. In addition, a subset of health systems is also contributing EHR data as part of an ancillary study to evaluate broader patterns of care. The research questions being asked include:

- Are data from the EHR comparable to data manually abstracted in a clinical research study?
- How can we use the EHR to facilitate enrollment in a research study?

COLLABORATIVE DATA SHARING

COVID-19

The COVID-19 pandemic highlighted the need for real-world data to understand trends in conditions, risk factors, complications rates and potential therapies. Recognizing this need, Cerner and Amazon Web Services (AWS) collaborated to create a data set of patients with possible COVID-19 infection from over 50 health systems.

Academic researchers from 30+ institutions across the U.S. are now actively leveraging the data set in a variety of COVID-19 studies. Cerner and AWS are providing access to the data and computing environment free of charge and updating the data set regularly throughout the pandemic.

*Current as of October 12, 2020

- What can we learn about broader patterns of care in the participating health systems?

Sites in the registry that have opted to use the EHR arm through Cerner are able to participate with little additional effort. In return, Cerner is still in process of building tools to facilitate patient identification to help identify eligible patients for the consented arm.

Randomized trials and pragmatic trials

The LHN will be leveraged for clinical research beyond observational studies, with an early focus on using it for randomized trials. EHR-based tools are being developed* to facilitate several aspects of trial conduct. To help improve enrollment, EHR data can be used to identify potentially eligible patients, including the location and dates of future follow-up appointments where they may be approached. Cerner is creating dashboards that sites can leverage to pre-screen and identify patients for clinical trials. In addition, for studies requiring manual data extraction, an EHR-augmented case report tool can be used that's auto-populated with data from the EHR or that can guide abstractors to the area of the medical record where relevant information is used. Finally, site monitoring may be augmented using data from the EHR, for example, comparing the accuracy of manually extracted data to data in the EHR or evaluating the proportion and characteristics of eligible patients enrolled in any given study.

As randomized trials become more and more pragmatic, opportunities to use the EHR and the *HealtheIntent* platform for research will grow. For example, the patient portal can be used for patient outreach and collection of patient-reported outcomes. Studies seeking to augment endpoint collection using claims data can also leverage the platform to link claims data to data from the EHR.

Improving patient care through implementation science

The research journey does not end with a successful clinical trial. Decades of research and experience have shown utilization of guideline-recommended, often life-saving therapies remain inadequate, and the uptake of new therapies is slow and heterogeneous. Gaps in care still exist in many areas, often widening racial and economic disparities.

The EHR is the most used health technology in clinical practice. While traditionally used for documentation and billing, there is emerging interest in using the EHR to improve care across racial and economic boundaries. Decision-support systems can facilitate implementation of guideline-based care pathways, risk scores can be auto-calculated, alerts can be used to flag areas for clinical improvement or potential harms, patient information can be provided, and providers can track their performance and benchmark to their peers. Beyond the EHR as a tool to improve care, EHR-based networks can be used to track the impact of clinic or system-level quality improvement initiatives, facilitating the

Supporting scalability

To create an elastic, scalable, analytic environment with the data researchers can leverage to query and optimize analysis for big data, Cerner has collaborated with AWS to create a data science ecosystem built on AWS. All research data from the LHN and *Cerner Real-World Data* clients is hosted on an AWS-based cloud environment, secured with the same level of data security used for other EHR data at Cerner.

*All solution/services under development. Cerner makes no assurances that the capability described herein will be provided in the solution/services.

conduct of cluster-randomized studies testing out population health interventions.

LHN investigators are launching a project that will focus on using the EHR to help improve gaps in care for patients with peripheral arterial disease across 20 health systems.

Future opportunities

In the future, additional capabilities will be explored, developed and launched to further assist with research resources*:

- New mechanisms for data cleaning and research readiness
- Tailored data exploration experiences
- Linkage of EHR to new data sources
- Advancements in natural language processing and data curation
- Exploration, standardization and incorporation of genomic data types
- Development of custom, study-specific tools:
  - Interoperable frameworks
  - Shared decision-making
  - Patient-based tools

*All solution/services under development. Cerner makes no assurances that the capability described herein will be provided in the solution/services.

PROTECTING PATIENTS AND HEALTH SYSTEMS

LHN GOVERNANCE COUNCIL

Although all data in *Cerner Real-World Data* is de-identified, the founding members of the LHN and the Cerner research team sought to establish strong protections that all uses of the data reflect the fundamental goal to improve research and patient care. To that end, Cerner established a governance council comprised of members from LHN health systems, patient representatives, Cerner leadership and research stakeholders. It reviews all LHN research proposals. The review process helps safeguard the data by reviewing and approving only those research questions that:

- Are appropriate and an ethical use of the data
- Can be answered with the data requested
- Pose no privacy or confidentiality threats to the individuals or the health systems

Any research request that involves data leaving the Cerner AWS environment, requires access to patient or health system identifiers, or requires patient consent must also be approved by the governance council.

Sources and disclosures

1 *The answer is 17 years, what is the question: understanding time lags in translation research.* (2011, December). National Center of Biotechnology Information. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3241518/

2 Sullivan, T. (2019, March 21). *A tough road: Cost to develop one new drug is $2.6B; approval rate for drugs entering clinical development is less than 12%.* Policy and Medicine. https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html

3 All data pulled from *HealtheIntent* and current as of January 2020.

4 Leveraging Cerner standard ontologies to standardize and account for results among disparate coding systems and using unique encounter IDs to prevent over inflation of data.

5 Total encounters represent the total sum of outpatient, inpatient and emergency encounters.

About Cerner

Cerner health technologies connect people and information systems at thousands of contracted provider facilities worldwide. Cerner assists clinicians in making care decisions and organizations in managing the health of their populations. The company also offers an integrated clinical and financial system to help manage day-to-day revenue functions, as well as a wide range of services to support clinical, financial and operational needs focused on people.

About DIA

DIA is a global, multidisciplinary, membership association of health care professionals that works towards the advancement of lifesaving medicines, therapies and technologies around the world. As a member-driven volunteer organization, professionals from 80 countries have affected health care outcomes by engaging with DIA through its unparalleled membership network, educational offerings and professional development opportunities.

DIA is based in Washington, DC (US) with regional offices representing the Americas (Horsham, PA, US); Europe, the Middle East, and Africa (Basel, Switzerland); and Asia (Beijing and Shanghai, China; Mumbai, India; and Tokyo, Japan).

Contact us for more information

- realworlddata@cerner.com
- Cerner.com

2800 Rock Creek Pkwy.
Kansas City, MO 64117

- Publications@DIAglobal.org
- DIAglobal.org

21 Dupont Circle, NW, Suite 300
Washington, DC 20036

2364907127_Leveraging the EHR to revolutionize research_v1/October 2020