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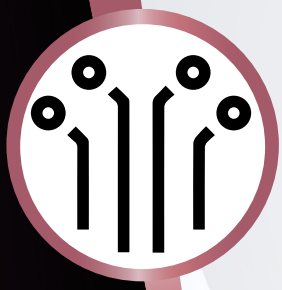

Successful Digitalisation Pathways

How EHR Interoperability Can Facilitate Successful Clinical Trials

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An overview of Electronic Health Records (EHRs) and how EHR tools could mark a new era in healthcare interoperability and be a valuable source of patient data for clinical trials.

Key Points

- Clinical data exchange is crucial for patient treatment and clinical trials.
- EHR tools that communicate without barriers could mark a new era in healthcare interoperability.
- EHRs can become a valuable source of patients' health information for clinical trials.
- However, interoperability, or sufficient access to data stand in the way of mainstream EHR use for clinical trials.

Clinical data exchange is crucial for not only patient treatment but also clinical trials. However, so far its level has proven insufficient. As a Veeva 2019 Clinical Operations Survey found out, 99% of the interviewees note the need to unify clinical applications to achieve better visibility and control (70%), swifter trials (63%), and smoother stakeholder cooperation (61%). Will EHR interoperability ever reach a sufficient level for providers to achieve all this? Let's figure it out.

EHR Interoperability: The Current State

Today, EHR is used by 86% of providers, so EHR tools that communicate without barriers could mark a new era in healthcare interoperability. But is it the case with the present-day EHR solutions? Unfortunately not. The efforts to promote EHR interoperability are ongoing, with providers following two main paths:

FHIR-driven interoperability

The lack of universal data standards in the U.S. healthcare industry had been blamed for insufficient interoperability in the field. But then, the Fast Health Interoperability Resources (FHIR) standard was adopted across the industry.

The standard provides a clear collection of data formats and application programming interfaces (APIs) that providers can employ to exchange electronic health records. On the surface, the standard seems to successfully solve the basic issues industry players deal with. However, at a closer examination, the task is not that simple.

The point is that the key FHIR elements contain 5 to 50 assets or resources. However, healthcare facilities tend to select only some of them, and this can undermine the intended interoperability because the main FHIR elements are closely connected. To establish interoperability with the FHIR standard, providers need to embrace broader sets of elements and resources.

Health information exchange

Health information exchanges (HIEs) are IT solutions that enable healthcare organisations (hospitals, providers, their patients, labs, and other medical facilities) to share patients' data safely and efficiently without the need to establish integrations with disparate healthcare systems. Besides, vital patient information transmitted in due time can enable informed decision-making at the point of care and let providers:

- Lower spontaneous readmissions rate
- Prevent errors in medications and treatment
- Scale up diagnostics
- Avoid repetitive tests and procedures

Given the promise HIEs hold, state governments have started investing in the solutions. As a result, diverse HIEs operate statewide and cross-state.

Statewide HIEs

Seeking to improve care coordination and patient experience, healthcare organisations from many states came to the decision to set up statewide HIEs. Though such HIEs serve the needs of providers, researchers, and patients from one state, their significance is hard to ignore. For example, Indiana HIE

(IHIE) scattered across 92 counties of the state propelled vaccination efforts during the pandemic. IHIE experts still maintain informative vaccination dashboards in six languages to keep their patients informed about the present-day situation. Moreover, the team strives to enable health information sharing across the state's clinics.

Regional HIEs

These programmatic solutions cast the net for secure health information sharing across several clinics in neighbouring states. One of the brightest examples of such a solution is New England HIE Consortium uniting HealthInfoNet from Maine, RIKI from Rhode Island, and VITL from Vermont. The Consortium helps build up regional interoperability, which contributes to improving population health and the overall quality of care in the region.

EHR Interoperability for Clinical Trials: Three Use Cases

EHRs can become a valuable source of patients' health information for clinical trials. Here are the three primary cases describing how EHR data can be employed for medical research:

EHR for patient recruitment

One of the biggest advantages of using EHRs for clinical trials may be their facilitation of patient recruitment and its outcome assessment. Such a method is called EHR screening for eligibility. According to a 2021 article in Trials Journal, about 50% of the study participants used EHRs to recruit patients for clinical trials (O'Brien et al. 2021). However, they pointed out that there are some difficulties in implementing this type of screening, including restricted access to EHRs across providers. Improved EHR interoperability could help improve the situation.

EHR-based RCTs

There is a separate type of clinical trial called randomised controlled trials that fully rely on the clinical data available in EHRs. Researchers carry out such trials to design new clinical guidelines or reconsider the existing ones.

In this case, EHRs are studied and conclusions are drawn based on the data stored in the EHR solutions used by participating healthcare organisations. Among other things, this data includes patient-generated health data uploaded to the EHR several times a day.

Such research can help speed up scientific discoveries and provide insights for proper treatment approaches and strategies consolidation, patient safety, and evidence-based care for patients with complex diseases, as well as patients at risk. For such studies, interoperability is very important because it helps to track a study participant's dynamics over time.

One of the biggest advantages of using EHRs for clinical trials may be their facilitation of patient recruitment and its outcome assessment

Large clinical trials

These types of trials are broader-scale (over 5K patients) and require extensive funding and a large number of participating medical facilities. Such studies greatly affect medical research and practice, but conducting them takes a lot of effort. The lack of productive communication and siloed systems are the key factors that prolong and complicate large trials. At times, those factors also threaten the credibility and quality of the results.

HIEs can have a major impact on trials of such kind by enabling access to relevant clinical information in a couple of clicks at the state, regional, and national levels.

Conclusion

Clinical trials require access to patient data to ensure the quality and accuracy of research as well as patient benefits. EHR is the tool available at the majority of healthcare organisations. It hosts a wide scope of patient data and can serve as a data source for clinical trials. So far, only interoperability, or sufficient access to data for all interested parties and the ability to use it, stand in the way of mainstream EHR use for clinical trials. However, things are changing fast.

Both clinical and healthcare IT communities have put a lot of effort into ensuring full-scale health information sharing. In this regard, cross-state data sharing efforts via HIEs look promising. With the help of those tools, providers and their IT partners can ensure interoperability via technology harmonisation and/or data standardisation. At some point, those efforts will eventually lead to ensuring health information interoperability nationwide. This in turn can allow organising large clinical trials on the national scale to improve patients' health outcomes and quality of life.

Conflict of Interest

None. ■

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