White Paper

QCentrix®

Observational studies:

Benefits and challenges in using real world data to advance research

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Introduction

Observational studies offer a unique opportunity for hospitals to leverage de-identified clinical data in medical research. Defined as studies in which investigators assess health outcomes in groups of participants without assigning participants any interventions, observational studies rely on existing patient data.[1] As a result, observational studies tend to be faster and more cost-effective than clinical trials, which involve selecting participants according to specific criteria and assigning them interventions.

While clinical trials are irreplaceable in healthcare research, the growing availability of large datasets suggests that there is great potential for hospitals to use their real world data (data captured outside of clinical trials, such as data from electronic health records, claims and billing activities, and other sources) in observational studies.[2]

The pharmaceutical industry in particular has a strong interest in real world data: in 2020, 90 percent of new drug approvals in the U.S. included real world evidence.[3] With the wealth of real world data hospitals and health systems possess, hospitals and health systems are well positioned to partner with organizations in the life sciences and pharmaceutical industries to share de-identified patient data for observational studies and advance medical research.

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This white paper explores the role of real world data in observational studies and discusses the benefits of these studies as well as the barriers to conducting them. It includes insights from both pharmaceutical and health system research directors to provide multiple experiences and perspectives on using clinical data in observational studies. Lastly, this paper offers opportunities for how hospitals and health systems can support observational studies most effectively.

Benefits of observational studies

Clinical trials have long been considered the gold standard in medical research, and for good reason.[4] These trials are a reliable and effective way to understand the impacts of medical treatments and interventions.

Observational studies are well suited to supplement clinical trial research. Providing an efficient, cost-effective way to gather findings using existing data, observational studies offer several advantages that can fill gaps in the research landscape.

- **Data are readily available.** Unlike clinical trials, observational studies can be conducted solely using clinical data that hospitals already have.
- **More diversity.** The FDA notes that people from racial and ethnic minority groups are underrepresented in clinical research.[5] Further, clinical trials tend to exclude those who may be considered high-risk, such as participants who are older or have multiple morbidities.[6] By including patients from a variety of risk levels and racial and ethnic backgrounds, observational studies can be more representative of the general population.
- **Valuable during uncertain times.** Observational studies are critical in situations when clinical trials cannot ethically or feasibly be conducted. During the COVID-19 pandemic, for instance, scholars observed an "explosion of publications" related to COVID-19, the bulk of which were observational studies.[7]

The use of real world evidence could reduce trial costs by anywhere from 5% to

- **Lower costs.** The average research and development cost for a new drug ranges from less than $1 billion to $2 billion or more.[8] As observational studies are relatively inexpensive compared to clinical trials, including them in the research process could result in lower research costs for pharmaceutical organizations and thus lower prescription drug costs for patients.[9] By some estimates, the use of real world evidence could reduce trial costs by anywhere from five percent to 50 percent.[10]
- **Greater efficiency.** Observational studies can be conducted more quickly and have potential for larger sample sizes than clinical trials, enabling researchers to gather findings more efficiently and get life-saving treatments to patients sooner.[11, 12] In conversation with a research director at a pharmaceutical organization, Q-Centrix found that the typical observational study takes approximately a year to a year and a half to conduct—and, as much of this time is spent on data cleaning, more efficient data curation processes could shorten this time frame considerably. Given that the full drug discovery and development process with multiple phases of clinical trials can take up to 10 to 15 years, observational studies can offer additional insights on a much quicker timeline, allowing researchers to efficiently gather supplemental findings as they move through the clinical trial process.[13]

Challenges

Unstructured data.
As much as 80 percent of real world data is unstructured, meaning they require interpretation and processing before they can be used in observational studies.[14] Considering the vast scope of data hospitals possess, curating these data would be a burdensome and time-consuming task for hospital staff.

Administrative burden.
Hospitals interested in supporting observational studies may find that their participation goes beyond simply providing patient data. Staff must field and review research requests from life sciences and pharmaceutical organizations, find cases that meet the desired criteria, and de-identify the relevant patient data—all on top of their regular duties. Staff may not have the time to devote to the additional work observational studies require.

Providing a sufficient number of cases.
Some observational studies may require patient data that meet such specific criteria that one hospital alone might not be able to provide enough cases. This may limit a hospital's ability to participate in these studies.

Inconsistencies in data preparation.
When hospitals undertake the responsibility of preparing data for sharing with research organizations, the lack of an industrywide standardized process means that formats and approaches can vary widely from one hospital to the next. For research organizations working with multiple hospitals to obtain the data they need, making sense of how different hospitals prepare and format their data can be an additional challenge.

Sponsor and health system perspectives on observational studies

To learn more about conducting observational studies, Q-Centrix spoke with a research director at a pharmaceutical organization that sponsors observational studies and a research director at a health system (that is also a Q-Centrix partner) that conducts these studies. Together, these insights provide a comprehensive view of considerations hospital leaders should keep in mind as they explore using their facility's data in these studies.

An inside look from an observational study sponsor

Direct access to clinical data is especially valuable. Pharmaceutical organizations can do more with a partner organization's data if they can access the data directly. The transparency of specifying the patient cohort, detailing the data elements needed, and then receiving the data for the sponsor to use directly yields the fastest results.

Clean, ready-to-use data are ideal. Finding high-quality, fit-for-purpose data can be a major challenge. The data a sponsor receives may require a great deal of cleaning and quality checks before they can be used.

Healthcare organizations are eager to do more with their data. "We've done a lot of work, especially over the course of this year, to partner with academic medical centers because we've noticed that a lot of them are really eager to become leaders in this space," said the research director of the pharmaceutical organization Q-Centrix spoke with. "I do think more and more are now looking for ways to creatively and in a compliant manner share their data—because at the end of the day, if we have data and they're just sitting on it, no one's benefiting."

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Conducting observational studies within a health system

Care must be taken to ensure high-integrity data. The data required for observational studies tend to be very disparate. Because of this, the health system Q-Centrix spoke with follows several steps to clean and review the data. The health system's research team abstracts the data, notes the troublesome data elements, creates guidance to help abstractors avoid those pitfalls, and regularly checks the work of the abstractors.

Preparing the data requires a nuanced understanding of how EHRs differ. With the average hospital using upwards of 16 different electronic health records (EHRs), abstractors must understand the nuances of every EHR they work with.[15] To pull data from EHRs most effectively, it is important to understand the construction of the EHR and know where to find the data. Healthcare facilities should document in advance how data may differ across providers or across EHRs and develop a plan for dealing with those discrepancies.

Finding the right staff can be challenging. Due to turnover and the nature of abstraction work, experienced abstractors can be difficult to find and retain. To retain staff in these roles, the health system research director recommends finding ways to show appreciation for the work abstractors do. This may include ensuring abstractors understand the value of their work, setting achievable goals, and celebrating their accomplishments.

According to Victor Wang, senior vice president of data and research at Q-Centrix, these challenges are fairly common among hospitals and health systems. "There is a big bottleneck in hospitals around producing data for research," he explained. "People know they have valuable data and want to do more research, but it is hard to produce consistent datasets with the current staff. Q-Centrix works with these teams to help build the right datasets and bring in sponsors for funding and partnership where appropriate."

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›› Opportunities

Work with clinical data management experts.

Many hospitals lack the resources and staff to review and process large amounts of unstructured data, but third-party organizations are uniquely qualified in clinical data management, employing a team of clinical data experts who can process and clean unstructured data. “I know it’s a big ask, having clean data,” said the research director at the pharmaceutical organization Q-Centrix spoke with. “Hospitals and healthcare centers were not made for this. Having the right partner that can help them with it, in the end, really does save them the trouble…. You’re talking about something taking months if not years versus going through a company that can get it to you within weeks.”

Develop standardized procedures for preparing data.

For hospitals planning to tackle data processing without the aid of a third party, consistency is crucial. Hospitals should develop established processes for how the data will be structured and reviewed. At the health system Q-Centrix spoke with, the research team develops guidance for abstractors and conducts regular quality assurance of abstractors’ work to reduce errors and ensure consistency.

Join a research network.

In a research network, a third-party organization works with hospitals and health systems to handle research requests and manage clinical data needs for all participating facilities. Instead of requiring hospital staff to comb through patient data to find cases that suit the needed criteria, the research network’s clinical data manager can review the pool of data for all hospitals in the network to identify cases and manage end-to-end data delivery and de-identification. This approach broadens the scope of projects a hospital may participate in, as a research network can provide more cases than a single hospital may be able to.

This also helps hospitals ensure their data are processed in a standardized way. “When you have a company that has a footprint across multiple institutions, it really does make life a bit easier, because you know it’s all consistent across the board,” said the pharmaceutical organization’s research director.

Make decisions about data-sharing logistics ahead of time.

The early stages of partnering with a research organization can be slow-moving. The pharmaceutical organization Q-Centrix spoke with shared that the process from having an initial conversation with an academic medical center through to signing the contract can take about six months or longer. Hospital leaders can help move this process along by working with their legal and clinical departments ahead of time to decide on the parameters of data-sharing partnerships.

Conclusion

The vast amount of patient data hospitals possess holds enormous potential for clinical research. Whether hospitals choose to conduct the research in-house or partner with researchers in the life sciences or pharmaceutical industries, hospitals have the ability to leverage their clinical data for use in observational studies and help make clinical research more efficient, less costly, and more inclusive.

About Q-Centrix

Q-Centrix believes there is nothing more valuable than clinical data—it is critical in delivering safer, consistent, quality healthcare for all. Providing the industry's first Enterprise Clinical Data Management (eCDM™) approach, Q-Centrix utilizes its market-leading software, the largest and broadest team of clinical data experts, analytics and reporting data structure, and the best practices from more than its 1,200 hospital partners to curate meaningful, high-fidelity, complete, and secure clinical data. Its solutions address a variety of clinical data needs, including regulatory, cardiology, oncology, trauma, research and more. For more information about Q-Centrix, visit www.q-centrix.com.

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