EXECUTIVE BRIEF

Acquiring, curating, and reusing data to deliver lifesaving therapies

Healthcare

Pharmaceutical and biotechnology companies focus on producing drugs and other products that help people live healthier lives, recover from injuries, and fight illnesses. These critical, life-enhancing advances are achieved through a combination of practical evidence, engaged patients and physicians, and standardized reusable data.

Bringing therapies to market relies heavily on clinical trials. But challenges with sharing data from electronic health records (EHRs), specialty pharmaceutical companies, and clinical research organizations can create longer timelines for drug delivery. In an ideal setting, clinical trials should combine material evidence and EHR data, as well as information from patient wearables to gain analytics that ensure strong drug performance in therapeutic areas and vaccines.

Improving medical treatments requires advanced research that relies on studies that are reliable, easily accessible to participants, and open to wide range of people. It would seem that the public agrees with this sentiment—at least in the US—where "roughly 4 in 5 adults said it's important that clinical trials are easy for participants to get to and that they're diverse," according to a poll by **Morning Consult**.[1] In addition, more than half the participants in the poll stated they "would consider joining a virtual trial."

The status quo is not the answer

Many clinical trial approaches today are manual, slow, and costly. Pharmaceutical and biotechnology companies design their own forms-based tools for data gathering. The individuals responsible for developing the tools need to recruit clinicians to help them identify patients, while pharmaceutical and biotechnology companies attempt to stem attrition rates for both patients and clinicians. Unfortunately, for many of these tools, developers wind up dealing with a lack of interoperability, an inefficient forms processing system, and mountains of data on paper. Trials need data that's formatted and computable so that clinicians can quickly extract meaning from it.

The pharmaceutical industry relies heavily on spreadsheets and manual transcription of data to manage all the information from clinical trials. Complex storage of paperwork, difficulties in searching data, and inefficiencies with moving through all the various steps toward therapy approval, hamper overall effectiveness and efficiency. And the more companies rely on manual processes, the higher the probability of error.

Greater accuracy and efficiency would be achieved if pharmaceutical and biotechnology companies could acquire, curate, and reuse virtually any type of healthcare data at scale. To accomplish this, companies should work with a technology partner that has market-leading expertise in Fast Healthcare Interoperability Resources® (FHIR®) API management—since the FHIR standard can be used to tap into and use legacy data and convert it to a usable format. The guidance from such a partnership could help shift organizations to the cloud and help them move fast, preserve capital, and offload management of information technology (IT) systems that are readily available and secure.

A pharmaceutical or biotechnology company's expertise grows from clinical trials and medication development and distribution, not via data acquisition, curation, and interoperability standards. This makes it all the more critical for companies to seek external support to ensure they can quickly deliver therapies and vaccines that save and enhance lives.

How Infor can help

Infor Cloverleaf® streamlines the exchange of clinical and RWE data for pharmaceutical and biotechnology companies to help improve health outcomes and business operations. Combined with the offerings outlined here, healthcare organizations can achieve a higher level of interoperability with the ability to acquire, curate, and reuse virtually any type of healthcare data at scale.

Infor Cloverleaf Secure Courier helps facilitate the flow of data between healthcare entities, send and receive data in any format, and expand connections between care partners to securely exchange patient information over the Internet, without requiring the recipient to have technical expertise or connection to a virtual private network (VPN).

Infor FHIR Bridge offers a single point of integration that connects traditional clinical systems with the emerging FHIR-based application ecosystem. This helps streamline care coordination by providing the right amount of needed information to providers and patients.

Infor FHIR Server sits at the core of this FHIR-based application ecosystem. Not only is data stored as FHIR resources that are ready to be accessed by modern applications, but FHIR Bridge can feed legacy data to FHIR Server, exposing otherwise siloed data that can be accessed and worked with via new, innovative applications and services.

Infor Cloverleaf API Gateway allows healthcare organizations to keep pace with the rapid evolution of healthcare. Today's medical research and technological innovations require higher levels of patient engagement that can be achieved and enhanced via advanced interoperability capabilities.

How RWE benefits patients

With few patients even aware that clinical trials exist, using RWE can be an essential component to bringing critically needed products to patients more quickly. Tapping into data, not just for randomized clinical trials, but for an analytical view of what's really happening within patient populations, will help pinpoint which drugs are more urgently needed by various population segments. Gathering information from EHRs helps determine who would be eligible for clinical trials and target patients who may be interested in participating. Also, clinical trials often involve complex case report forms or questionnaires that need to be completed for each participant. If pharmaceutical and biotechnology companies could pre-populate the forms with information from EHRs, vast amounts of time could be saved.

Being able to harness RWE and use data from sources such as direct-to-patient engagement channels will help gain rapid insights to deliver critical products to patients faster and help meet patient expectations in a more timely and personalized manner.

Maintaining regulatory compliance and data governance speeds therapy delivery

Delivering safe, efficacious, quality therapies to market requires data governance. Many organizations would benefit greatly from enhanced regulatory compliance, data governance, and analytics capabilities to ensure effective use of RWE. In addition, to fully leverage the ever-increasing volume of data for responsive process control, quality assurance, and quality auditing, it's crucial for companies to set up robust and secure networks.

Accessing valid sources of secure, material data means partnerships are needed with a broader ecosystem of players, including nontraditional direct-to-patient channels and technology start-ups.

What the future could look like

Embracing a data-driven approach can help pharmaceutical and biotechnology companies to better engage and retain patients and gather data for clinical trials. Working with an experienced technology partner can help organizations leverage the very latest data integration and interoperability to aggregate computable and interoperable data sets. The right partner can also help organizations identify candidates for trials; recruit and engage participants directly; and gather RWE automatically via remote monitoring, devices, and patient apps. This not only lessens the manual burden of gathering information, but it speeds up the delivery of vitally needed therapies and treatments to patients.

[1] Gaby Galvin, "Clinical Trials Are Slow and Expensive. Industry Leaders Want That to Change in 2022," Morning Consult, December 21, 2021.

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