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The Challenges and Benefits of Integrating Electronic Medical Record Data into Observational Studies

The integration of solutions for querying patient electronic health records with electronic data capture (EDC) technologies generates more comprehensive data for real-world evidence, creating new efficiencies and improving data quality.

1. The Challenges of Real-world Data

Real-world data are any data collected outside the realm of a clinical trial¹. They can be collected in a more naturalistic environment such as general practitioner visits or from a hospital's medical records. The requirement to collect real-world data and draw insight from them has partly been driven by payers, which are becoming more eager to pay for health outcomes rather than volume of treatment. Randomised clinical trials will continue to have a place in proving efficacy, but are inadequate for demonstrating an intervention's long-term safety and effectiveness or its generalisability. The core reasons for this are the fundamental differences between a controlled trial environment and the real-life clinical application of a drug. A treatment in the real world, following standards of care, often has a different impact from what happens during clinical trials. In real life, patients represent a much wider sample than in clinical trials: they may come in with co-morbidities, they might not adhere to treatment, they might be taking a treatment during pregnancy, and they may suffer from drug interactions. All these scenarios are generally not tested during randomised clinical trials.

Payers are increasingly demanding real-world data to better manage uncertainty around the safety of interventions and their effectiveness for decision-making for approvals and reimbursement. More recently, the FDA has been supporting the use of real-world evidence as complementary to regulatory filings².

Real-world data, whilst promising to unlock value and reimbursement for pharmaceutical companies, are difficult to obtain; indeed, challenges and limitations exist that complicate the generation, collection and use of these data.

First, real-world data come from many, diverse sources, including primary and secondary care systems. Real-world data

also include secondary source data such as databases (cross-sectional or longitudinal), patient and population surveys, patient chart reviews, observational cohort studies, pragmatic clinical trials, registries, etc.

When it comes to primary data, which comes from electronic medical records and electronic health records (EHRs), much of the patient's medical information also resides in various, disparate clinical systems: PACS, laboratories, LIMS, pathology, imaging, anaesthesia (AIMS), ICU, pharma, operating room booking systems, etc. These multiple systems are not always integrated, even on an individual clinic level, as issues of intra- and inter-operability arise, and the costs of integration often outweigh the benefits. In addition, there is no standard definition of an electronic health record, with different doctors using the same system in different ways. All these challenges, combined, mean that trying to collect standardised data across multiple healthcare institutions in many countries is very costly – especially if trying to avoid sending someone to each site to manually find the data.

Adding to this challenge is the challenge of data privacy: data must be extracted anonymised, but for the data to be searchable and traceable, they also need to be linked to a unique ID prior to extraction.

Furthermore, there is a growing appetite for data generated directly from patients (as opposed to a treating physician), including solicited patient data (e-PRO, diary data, wearables and data coming from market-approved medical devices) and unsolicited patient data (surveys, passive data from wearables and social media analysis).

With these data sources, the challenges include not only how to get a patient's consent to release their personal data for medical research, but also how to link the data to other data sources in a way that it can be traced back to a specific treatment. For example, obtaining an idea of a patient's general health, via the proxy of the number of steps they take per day and their heart rate, would be valuable if it can be mapped against the longitudinal data of a treatment. Otherwise, we simply have aggregated data.



While the last few years have generated a great hype for real-world data³ and the promise they have for unlocking value for the pharmaceutical industry, a great number of challenges remain:

1. Anonymised data are easier to source but cannot be connected to other data sources.
2. Shallow data are broadly available but do not answer detailed research questions.
3. As you move closer to deeper data, the cost of accessing the data increases.
4. There is much data available but without the connection to clinical data, its usefulness is limited.
5. Data can easily be exported aggregated, which is useful for feasibility and site selection, but does not provide the data structure required for deep study or patient selection.

2. The Benefit of an Embedded System

Lately, a number of companies have emerged that can connect and interface with hospital information systems data on a continuous basis. These data are used for the search and identification of eligible patients for clinical trials. These companies help bridge the gap between the difficulties of re-use of big-data for research by the healthcare industry and the needs of the pharmaceutical industry. Due to the fractured nature of the global healthcare industry, patient data are contained in various silos, either at provider or country level. These solutions, therefore, offer to make the access to and analysis/query of hospital patient databases much more effective and efficient. One of the core advantages of this approach is scalability, as these systems may be linked to multiple hospital sites and clusters and therefore provide a wide overview of patient health information. The major challenge to the scalability of this approach is the fact there are varying standards, both in the architecture of EHR systems, but, more importantly, in the coding systems and conventions. Complex platforms incorporating sophisticated mapping tools and the flexibility to use unmapped coding systems are needed.

While originally created for interventional clinical trials, such systems find increasing use in real-world data generation. As these systems need to function on supranational level, many of the problems described above have been at least partially solved.

3. Pragmatic Integration Approach to Observational Studies

The solution is, therefore, firstly, an electronic data capture (EDC) solution which accesses real-world data efficiently and cost-effectively, and which is fit-for-purpose for both retrospective and prospective real-world data collection. Such a solution lightens the data capture burden on sites, and provides a cost-effective method for obtaining high-quality data, while still making it easy to use by patients.

Secondly, integration with a platform which can provide data based on EHRs from connected hospitals. With this, longitudinal data collection is further simplified as data may be automatically imported from sites where those systems are established. As only authorised research personnel will access the individual patient information, patient privacy is maintained.

Where sites do not need to enter data, imported data may be used to support edit check ranges, and eliminate the need for on-site data verification. A data integration platform can provide the backbone to the data collection and will collect into one longitudinal database all information available from the providers of continuous, longitudinal data manually entered into e-CRFs, as well as any

patient-reported data, either as e-PROs or diaries. This would enable researchers to link patient-reported data to the study data, while keeping it anonymous.

4. The Benefits of a New Combined Approach

While real-world data and evidence are increasingly being utilised by the pharmaceutical industry to demonstrate treatment value and cost-efficiency, and obtain reimbursement, the cost and ability of obtaining real-world data remain a challenge. The technology to access this data is increasing in sophistication but is still fragmented.

Through the combination of the solutions mentioned, we believe that creating an ecosystem of “best-in-class” approaches and technologies can bring great benefits to the industry. This combined approach can facilitate a faster identification of sites suitable for real-world data. Furthermore, the combined approach enables researchers to use EHR data which is imported directly into the study portal. This not only increases data quality, but also reduces the inefficiency of having to copy data from an EHR to an EDC.

This approach is still in its infancy but we anticipate that it will have a large impact on real-world research.

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