

PHARMACEUTICAL GOMMERCE

Business Strategies for
Pharma/Bio Success

The Patient-Level Approach to Studying Healthcare

Longitudinal patient-level data answer pressing questions about patient safety, outcomes and medication acceptance

By Jody Fisher, SDI

The country's dialogue about the healthcare system mostly centers on the patient. Questions about the usefulness of electronic medical records, the need for transparency of information, and the ability to link information across healthcare entities have, in many ways, already been solved by the biopharma industry. Technology and capabilities in these areas have been growing exponentially for over a decade in the form of longitudinal patient-level data studies.

The biopharma industry itself is one of the main beneficiaries of (and supporters of) longitudinal studies. These studies can reveal vital information on how well a drug has been accepted in the healthcare community and by patients, the interplay between drug choices and diagnostic testing, or the patterns of first-line or second-line therapies (prescribing preferences) by providers. But increasingly, longitudinal studies are benefiting the community of healthcare providers, the insurers, and healthcare policy analysts.

Prior to the availability of longitudinal patient-level data, manufacturers and other healthcare concerns were effectively tied to two tools to help assess the needs of, and utilization by, patients:

- Non-patient-centered, aggregated prescription data from pharmacies
- Small-sample primary market research

The first tool had the benefit of a large sample but lacked transparency to patient behavior since the information com-

monly captured details about the prescriber, payer, pharmacy, and product, but sliced off any patient-identifiable information, making it impossible to infer any behaviors about the individual filling the prescription.

The second tool had the benefit of being highly customized to the business need and problem, but was limited in terms of available sample, time to conduct the study, and, of course, cost to produce the results.

Patient-level data studies have progressed rapidly since their emergence in the late 1990s, having been driven mainly by three factors:

- The accepted standardization of electronic data interchange for use across the payment system
- The increased capacity to store complex records by the billions, as well as the speed to transfer the information quickly across distance
- The influence of HIPAA and patient key methods that ensure patient anonymity while still tracking the patient consistently over time

While the first two factors were necessary and foundational, the creation of patient key systems was the most significant in terms of the measurement improvement that it afforded. The patient key is a unique code assigned to each patient based on information commonly found on healthcare claims. The same key is created every time a patient's information is entered.

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The patient key protects privacy while also allowing de-identified patient activity to be tracked over time and between different healthcare settings. The ability to track patients over time and across dimensions was the genesis of patient-level data studies, creating a powerful way for pharmaceutical companies to understand the behaviors of the true end-users of their products without having to rely on small-sample primary research methods.

Availability of patient-level data has grown across dimensions (data sources) over the past decade. The first phase, the single-dimension view, was based on prescription claims data. The second phase, the multi-dimensional view, includes data from a variety of healthcare provider settings. We'll look at the capabilities of each phase in turn.

PHASE I: THE SINGLE-DIMENSION VIEW

Initially, patient-level data were limited to activity in retail pharmacies, or, more specifically, the information provided on prescription claims. De-identified patients could be tracked across time and across pharmacies, but the data were limited to this single channel of their activity. Healthcare organizations started to develop "best-practice" approaches in deploying patient-level data studies. Several study types became the norm, increasing in complexity as study design methods became well known and accepted.

Source of business

Source-of-business studies classify prescriptions as distinctly new, continuing, or switch/add-on, providing more specific and truer measures of each patient's prescription activity. Source-of-business studies are used to more accurately monitor prescription sales growth.

An increasing volume of prescriptions filled by patients new to therapy, which can only be determined by using patient-level data, is a much better indicator of growth than new prescription (NRx) gains. The traditional NRx metric measures only the number of new prescriptions, which are often for continuation of therapy rather than for patients who are truly new to a drug.

Persistence/compliance/adherence

Adherence studies track patients over time to determine how long they remain on a therapy and if they follow their physician's prescribing instructions correctly. In addition to identifying whether or not patient adherence needs to be addressed, these studies are often used by manufacturers to determine whether their existing programs, kits, and physician support materials have been successful at improving patient persistency and compliance.

Adherence has garnered a lot of media attention due to its ripple effect across the healthcare continuum. For example, a patient's failure to take a heart medication may lead to the patient requiring a significant intervention, which in turn raises costs across the system. Smartly designed adherence programs create a win-win-win for the patient, manufacturer, and healthcare system as the patient's health is stabilized, the manufacturer secures a higher patient lifetime value, and potentially negative costs do not ripple into the healthcare system.

Concomitancy/drug-burden studies

Concomitancy or drug-burden studies identify the number of treatments and which specific treatments are being used together within the same, or across multiple, therapeutic classes. By tracking every patient prescription, analysis can be done to determine the most common drug regimens and patient pill burdens.

Complex conditions such as HIV, diabetes, or asthma often require that many drugs be taken as part of a regimen. Manufacturers commonly study the regimens to assess the protocols and combinations of medications that are most frequently used to treat these conditions. Another area where this type of study has become important is in tracking Medicare Part D drug burden, as the key behavioral measure requires an assessment of the total expenditure across a calendar year.

Path of therapy

Path-of-therapy studies monitor a patient's prescription activity over time to see changes in treatment patterns. These studies help identify common drug and regimen pathways that patients take as their disease progresses and are especially

Before Longitudinal Studies

useful for manufacturers whose drugs are used as second-line or adjunct therapy. They are also commonly done for more complex diseases such as HIV, diabetes, asthma or hypertension. Pharmaceutical manufacturers often conduct these analyses by using tree diagrams to help visualize the specific therapeutic path of patients who flow through the therapies of interest.

What these studies all have in common are that they focus more on the behavior of the patient than on the behavior of the prescriber. The studies describe the end-user experience in a more detailed way. These types of measures alleviate the pain caused by measuring end-use behavior in a system that does not permit end users to make choices the way they do when selecting and purchasing a non-regulated consumer packaged good.

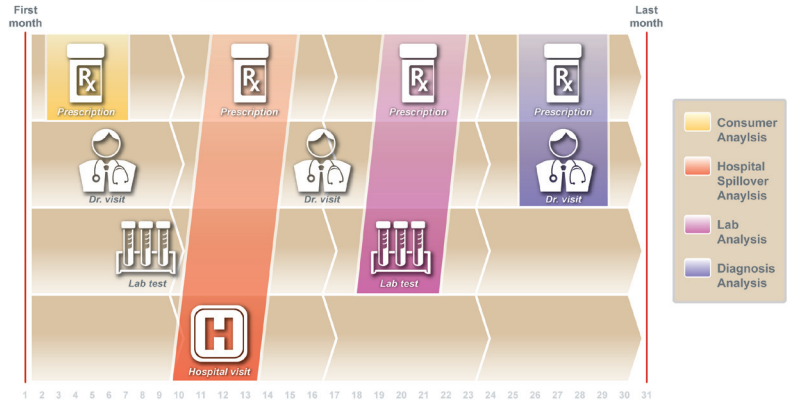
No patient information



Single Dimension View



Multi Dimension View



PHASE II: A MULTIDIMENSIONAL VIEW

However useful prescription-only patient-level data studies are, they don't offer information about many facets of patient behavior, characteristics, or healthcare treatment. For instance, a pharmacy visit provides information about the prescribed medication and dosage, but doesn't capture information about the specific diagnosis that prompted the prescription. Some medications are taken for multiple conditions, and some are given based on condition severity or laboratory values. A prescription-only view provides just part of the story.

As analysis methods became more sophisticated and the need for more complete information became more apparent, data providers invested in acquiring data from other healthcare entities, such as hospitals, labs, physician offices, and long-term care facilities, all of which could be connected with the use of the patient key. With the patient key unifying these touch points, patients could be tracked across a continuum of multiple healthcare events, and a longer and more complete healthcare record could be studied.

The result is a greater pool of information from which to choose when designing a patient-level data study. Often, a singular view of patient activity is still useful, though now the

view doesn't need to be limited to the pharmacy. Some studies take many of the single-dimensional prescription studies and enhance their utility by adding information that makes the measurement much more targeted. For example, differences in patient adherence or drug burden in the cardiovascular market, examined by condition, can add exponential information to marketing and targeting plans. In some markets, failure to add an indication dimension to drug analysis will bias results, measurements, and the business actions that the studies can otherwise drive.

Although the possibilities are almost endless, several patient-level data studies have emerged as the most common. They include:

Diagnosis analysis

Diagnosis analyses identify specific treatments for specific conditions and what diagnoses are being treated most often by a drug of interest. Drugs often are used to treat more than one condition. For some drugs, the conditions they treat differ dramatically between acute and chronic or severe and mild, and, logically, physician and patient action will vary greatly depending on the patient's condition.

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Through medical claims originating during patient visits to physicians, diagnoses are captured. By linking that information to the prescriptions being filled, these analyses identify the most popular treatments for specific conditions. More in-depth analyses study how the suffered-from condition affects the average length of time a patient remains on treatment, the volume of hospital or lab visits, and paths of therapy.

Hospital Spillover Analysis

Hospital spillover analyses center on what percentage of hospital-initiated therapy continues once patients leave the hospital and must fill their prescriptions at a retail pharmacy. These studies also identify which diagnoses, tests, and/or procedures preceded the initiation of therapy, and how each affects the likelihood of continuation.

Emergency and non-emergency visits to a hospital can have a major impact on how a patient is being treated for existing or newly diagnosed conditions. Often, patients undergo tests, procedures, and receive new medications during their time in the hospital. For manufacturers whose drug is initiated in a hospital setting, looking at patients' activity longitudinally, after they leave the hospital, is crucial.

Lab result studies

Lab result studies focus on understanding how lab results affect physician and patient behavior. Laboratory tests are an important tool providers use to help diagnose or monitor the severity of different conditions. Based upon the results of these tests, providers may choose to begin therapy, change therapy, or continue the current treatment plan.

Not only can the occurrence of tests be monitored, so can the test results. Analyses are done to understand physician behavior, specifically which treatments, as well as dosage and frequency, they prescribe based on test results. Studies also identify how patient behavior differs based on the severity of their condition.

Consumer attribute studies

Consumer attribute studies provide a better understanding of how personal patient characteristics affect patient health-

care behavior. Consumer psychographics and demographics, beyond age and gender, are collected by agencies outside of the healthcare industry. By linking these outside data through use of the de-identified patient key, patients can be grouped according to attributes and then studied in large groups.

Studies are now done that include attributes such as patient ethnicity, wealth, education, and media preferences. The most popular types of studies include statistical modeling such as clustering and decision trees that help identify the patient groups that exhibit wanted or unwanted behavior. Based upon the results, patient profiles can be created for targeting and marketing purposes.

Ultimately, healthcare is driven by the patient. Since patient-level data studies were created over 10 years ago, measurements of the healthcare marketplace have evolved from a single-dimension longitudinal patient approach to a connected view that tracks the patient across the entire healthcare spectrum. An increase in healthcare measurement sophistication is perfectly timed because healthcare issues have grown increasingly complex. Many of the thorniest problems relate to healthcare "cause and effect" and higher costs, and can now be diagnosed and studied in a way that makes decision-making more objective and responsive. With the current national healthcare discourse focused on requiring more evidence, reduced costs, and improved outcomes, the ability to measure patient activity and behavior is a powerful tool to achieve those goals. [PC](#)

About the Author



Jody Fisher is SDI's Vice President of Marketing. He maintains expertise in best-practice use of pharmaceutical market research including de-identified patient data. Jody has consulted with virtually every major pharmaceutical company regarding secondary marketing research strategy and data interpretation. He has over 13 years of industry experience designing and implementing marketing and data solutions for the biopharmaceutical industry.