

Data Is the Difference

Unlock the Power of RWD and RWE to Maximize Value

Leverage the power of one of the world's largest, most inclusive healthcare databases to transform your decision-making, streamline operations, reduce costs and improve patient outcomes.





Bridging the Gap: RWD for Meaningful RWE

Named as the [number one trend](#) for three consecutive years by ISPOR – The Professional Society for Health Economics and Outcomes Research, real-world evidence (RWE) is a driving force in healthcare and a [critical factor](#) in assessing the safety and effectiveness of medical devices and drugs.

But meaningful RWE is impossible without real-world data (RWD). RWD, or data about patient health and/or care delivery, constructs a rich framework for what's happening in clinical environments and why. The better the data, the higher the ceiling for actionable information that translates to real-time, measurable impact on patient outcomes and your business.

Together, [RWD and RWE](#) play a vital role in helping life sciences companies understand the value of healthcare interventions in everyday practice.

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As life sciences companies continue to bridge the gap between medical solutions development and real-world application, leveraging real-world data for real-world evidence generation has emerged as a game changer.

Myla Maloney

Chief Growth Officer, Premier Applied Sciences

Premier data and solutions drive innovation and differentiation in the pursuit of better, smarter, faster care. And at Premier Applied Sciences – the data and research division within Premier – our sharp focus on differentiated data, groundbreaking research and clinical trials innovation helps drive speed to value – delivering efficiencies, lowering costs, reducing health disparities and improving patient outcomes. With the industry's largest outpatient chargemaster database and deep expertise drawing actionable conclusions from the data, we help organizations solve tough challenges and open new doors for meaningful improvements in healthcare.

This resource covers the characteristics of strong healthcare data, which types of data are most significant for life sciences companies, specific use cases and far-reaching benefits.



Strength in Numbers: Data Is the Difference

In Premier's experience, organizations across the healthcare industry are facing increased data demands to demonstrate efficacy, safety and quality outcomes. To succeed in the race to value, life sciences companies, providers and payers must strategically utilize actionable data and advanced technology. Best-in-class data – and the insights gleaned – help differentiate medical device and drug products and ward off commoditization while enabling personalized patient care.

RWD usage is also on the rise, with [90 percent](#) of global life sciences executives indicating plans for leveraging this data in decision-making across a product's life cycle. Furthermore, [one study found](#) that 116 out of 378 FDA-approved New Drug Applications (NDA) or Biologics License Applications (BLA) incorporated RWD/RWE in the submission, with the share of approvals incorporating RWD/RWE increasing each year between 2019 and 2021. And, in 2023, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health put RWD/RWE into action when it approved the [first label expansion](#) granted to a medical device based entirely on RWE derived from device electronic health records.



116/378

inclusion of
FDA-approved
NDAs and BLAs
between January
2019 and June
2021.

Percentage of RWE Used to Provide Therapeutic Context



2019



2020



2021

(through June 30)

Robust, Standardized RWD Fuels AI Algorithms

ML processes large datasets and recognizes patterns.

NLP reads and interprets more than two million records per hour.

Together, RWD and the insights it delivers have the potential to improve healthcare delivery and quality while ensuring medical innovations reach the right patients at the right time. RWD/RWE can potentially help:

- Address the growing demand for data to demonstrate efficacy and safety.
- Analyze market dynamics and inform strategies to maximize future sales.
- Inform device development with critical data on drug and device performance and safety, ensuring high standards in diverse settings.
- Differentiate products in a “sea of sameness” competitive landscape.
- Assess therapeutic interventions not studied in randomized clinical trials (RCTs).
- Complete Total Cost of Care (TCOC) assessments.
- Support and streamline regulatory submissions and approvals.
- Shorten the runway to commercialization in the continued race to value.

In a landscape where speed is the name of the game, data is the fuel that wins the race.

How AI-Enabled Data Delivers Speed to Value

Forward-thinking life sciences companies are combining robust, de-identified patient datasets with artificial intelligence (AI)-powered machine learning (ML) that processes the data and recognizes patterns. Natural language processing (NLP) can [read and interpret](#) more than two million records per hour, placing even the most needle-in-a-haystack insights at organizations’ fingertips.

Best-in-class databases fueled by AI can potentially enable suppliers to:

- Analyze extensive datasets for ***earlier patient identification and previously unidentified risk factors.***
- ***Accurately and more efficiently identify clinical trial participants*** from diverse populations who are likely to benefit or may be at higher risk.
- Forecast the pharmacokinetic profiles of drugs and predict device performance in various patient populations to ***determine appropriate dosing regimens and care.***
- ***Optimize clinical trial site selection,*** “flipping the funnel” to recruit based on where patients are versus where relationships exist – and based on predictive analytics of sites’ historical performance.
- ***Realize the efficacy of post-market therapeutics and devices*** across diverse populations, helping to ensure they meet safety and performance standards in varied real-world conditions.

A Cut Above: All Healthcare Data Is Not Equal

Despite the rapid increase in RWD/RWE usage, questions remain about what type of data is most meaningful – and when and how RWD/RWE can inform the medical solution decision-making process or regulatory submissions. The answers are imperative for achieving business goals and the betterment of patients worldwide.

Let's start here: RWE is only as good as the data from which it's sourced. Life sciences companies need different sources of data that, when united, can deliver accurate, actionable information. And the **right** RWD is key – robust, high-quality data that fuels evidence-based and population-based analyses of drugs, devices, other treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.

The [**Premier Healthcare Database \(PHD\)**](#) is one of the most comprehensive electronic healthcare data repositories and the **largest outpatient chargemaster database**, driving measurable impact for life sciences organizations conducting research across the product lifecycle. More than 1,400 Premier member sites contribute data to the PHD. For nearly 25 years, it has served as a valuable resource for the pharmaceutical and device industries, academia, federal and national healthcare agencies, as well as for Premier's member hospitals and health systems.

A HIPAA-compliant, retrospective database, the PHD comprises U.S. service-level, all-payer information on 1.5 billion outpatient visits* and about 25 percent of annual U.S. inpatient admissions. And, for most data elements, less than 1 percent of patient records are missing information. For key elements such as demographics and diagnostic information, less than 0.01 percent are missing data.

Additionally, while data sources often specialize in a field of medicine such as cardiology or oncology, the PHD spans multiple disease types. This information supports improved clinical decision making and patient care, especially in [**multimorbidity cases**](#) where two or more chronic diseases are present.

Unlike most healthcare databases, the PHD also includes chargemaster data.

Alongside claims data, this data set – the largest of its kind in the country – is valuable for analyses of medical devices or drugs because it identifies every device and drug used, delivering essential context to inform the decision-making process.

Breadth and Depth

The PHD includes de-identified data* from:

More Than 1,400 Sites

1.5B Outpatient Visits

**About 25% of Annual U.S.
Inpatient Admissions**

**More Than 353M
Unique Patients**

Chargemaster Data

Included in the PHD



Cost of Care

Physicians

Drugs

Diagnoses

Department Detail

Demographics

**Acute Inpatient and
Outpatient Encounters**

*As of December 2024. Information in the PHD, a retrospective database, is de-identified and HIPAA-compliant in accordance with the HIPAA Privacy Rule.



The PHD's comprehensive data set includes:

- **Chargemaster data:** Provides information on a significant number of interventions used as well as cost of care, physicians, drugs, diagnoses, department detail and demographics.
- **Electronic health record (EHR) data:** Includes access to structured clinical data, such as vitals and lab results, as well as unstructured abstract data types.
- **Closed claims data:** Encompasses those covered by Medicaid and Medicare Advantage as well as the commercially insured, illuminating enrollment history, healthcare claims and both medical and pharmacy claims from all care settings. Compared to open claims, closed claims deliver a more longitudinal view outside of the inpatient healthcare system.
- **Purchasing data:** Shows SKU-level direct and distributor orders from provider enterprise reporting (ERP) systems, which returns near real-time market share insights.
- **Administrative billing records:** Offers a wealth of data to round out the PHD.

From admittance to discharge, the PHD constructs a rich story of the complete patient journey, and not just day-to-day but hour-to-hour.

Worried about connecting the dots between disparate datasets? Thanks to tokenization, we can easily link them. The PHD is tokenized in every major tokenization engine. This expedites data pulls and analyses – and helps supply solutions for even the steepest challenges.

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Premier consistently exceeds expectations by ensuring each study is meticulously designed and executed efficiently. Working with them truly delivers outstanding value, going above and beyond what is expected. I highly recommend partnering with them if you seek a collaborative, enjoyable and impressive thought partner.

Michelle Sosa

Health Economics and Outcomes Research, Reimbursement & Market Access, Stryker

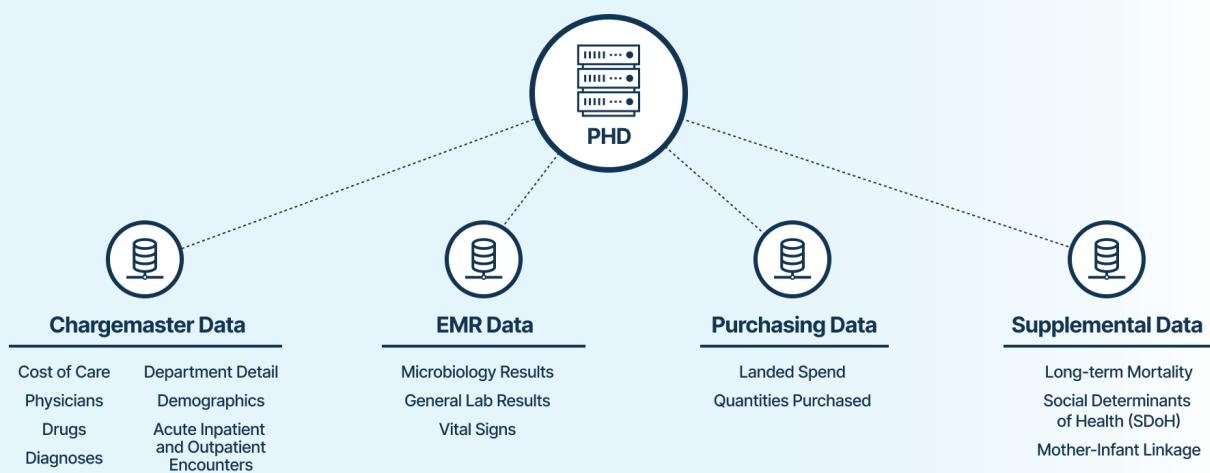
What's Inside: Unpacking the Premier Healthcare Database

The PHD contains rich outpatient and inpatient information. Data in the PHD covers patient demographics (age, gender, race, ethnicity and marital status) and disease states; admission and discharge diagnoses; information on billed services including costs at the departmental level; patient disposition and discharge health status; and International Classification of Diseases (ICD) codes:

- ICD diagnosis codes for each encounter identify disease states and comorbid conditions.
- ICD-10-CM codes, or Z codes, identify non-medical factors that may impact a patient's health status.
- ICD procedure codes as well as provider-submitted Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes identify diagnostic and therapeutic codes ordered during encounters.

Choose our standard package or add supplementary datasets such as mortality, [mother-baby](#), [social determinants of health \(SDOH\)](#), EMR purchasing, [procedural supplies](#), and microbiology, vitals and lab data (via an EHR feed).

Because patient privacy is paramount, all PHD data is tokenized.





Inciting Innovation: A Partner for the Journey

To get the most benefit out of RWD/RWE, finding the right partner is critical. This includes access to broad, standardized and clean datasets, research-ready testing networks, and AI-enabled solutions for speed to value. It also calls for scientific rigor and a spirit of collaboration.

While few question the value of RWD/RWE, life sciences companies, payers and providers have only begun to tap into its full potential. Many mix and match datasets without recognizing potential longitudinal and actionable insights. Some are unsure about which types of data are most compelling. This, in turn, yields fewer relevant, timely takeaways that support research efforts, ensure regulatory compliance and inform novel medical solutions that meet uncharted patient needs while unlocking new revenue streams.

This is where the value of an expert partner comes into play.

Premier delivers solutions to two-thirds of all healthcare providers in the U.S. Our vast network and deep relationships help connect suppliers with providers for mutually beneficial healthcare partnerships that improve the health of the communities they serve.

Our strategic alliances also give us an up-to-the-minute, ground-level understanding of what's happening across healthcare, infusing our work on behalf of life sciences companies with a unique perspective found nowhere else in the industry. This, in turn, creates a robust framework for using RWD/RWE to achieve significant advancements in research and development. Our clinicians and data scientists leverage a wealth of diversified experience to deliver novel insights that move the needle for our clients.

From optimizing clinical trials to tailoring new devices or drugs to fit the market, Premier can empower organizations to realize the full potential of RWD for transformative outcomes.



We've been able to leverage the Premier Healthcare Database, test multiple hypotheses and share outcomes without the expense and time involved in a lengthy clinical trial.

Amanda Nelson

Director of National Accounts, Solventum



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Companies are coming up with innovative products that can slow or even cure devastating diseases, but in many cases, patients are in a race against time. Data not only helps identify potential patients, but it can also help our clients find them earlier, when the therapy is more likely to succeed.

Myla Maloney

Chief Growth Officer, Premier Applied Sciences



Data in Action: 11 Ways to Use RWD/RWE

Advancements in RWD have forged an unprecedented opportunity to use RWE across nearly every segment of the healthcare ecosystem. Here are 11 applications of RWD plus insights for life sciences companies:

1. **Outcomes research** evaluates the end results of therapeutic treatments on the healthcare system and processes of care for patients and populations.
2. **Market analysis** determines the products or treatments for a given disease state highlighting patient, visit and site characteristics.
3. **Risk assessment and predictive modeling** identify the risk factors for and estimate the probability of an outcome or differences in outcomes based on historic data and characteristics of patients, visits and hospitals.
4. **Comparative effectiveness** measures the efficacy of multiple therapeutic interventions including outcomes, safety and harms.
5. **Burden of illness** reports describe the epidemiology and disease state burden of relevant diseases including current treatment.
6. **Health economics research** helps illustrate the economic impact of therapeutic treatments on the healthcare system and processes of care for patients and populations.
7. **Market trending** reviews real-world uptake of products in the market and/or compares uptake vs. competitive products.
8. **Post-market surveillance** happens after a medical product is approved and marketed. RWE can give life sciences companies critical insight into the safety and effectiveness of their product as it performs in a real-world setting. It can also expand companies' understanding of a product's value in relation to care and highlight off-label use and effectiveness.
9. **Formulation of clinical care guidelines** can derive evidence from comparing outcomes among different populations or for different treatments among a more uniform population.
10. **Clinical studies and trials** manifest multiple applications for RWE informed by RWD. RWE can complement traditional clinical trials by providing data about a broader and more diverse patient group, filling in gaps for researchers, clinicians and their partners. It can enable [decentralized clinical trials](#) and the use of synthetic control arms (SCAs) to potentially replace or supplement traditional control groups. It can also provide data that might not otherwise be available, such as patient-generated data. RWE can even serve as a useful tool in pre-trial study design, helping researchers identify potential participants.
11. **Regulatory submissions** that include RWD to demonstrate product safety and efficacy, provide therapeutic context and/or support expanding label indications and guidance for treatment are primed for success.



Case in Point

Achieving Research Savings of Up to \$3 Million

One medical device company partnered with Premier Applied Sciences to streamline their processes, save money and avoid more randomized clinical trials (RCTs). The company wanted to analyze their device and its safety, outcomes and benefits to patients from utilization. Understanding these factors would allow the company to expand indications to align with outcomes and generate RWE to enhance its device utilization.

They began with data analysis to garner evidence needed to support a regulatory filing for expanded device indications and identify potential patients. One primary goal was to identify current evidence-based indications for their device and determine options for label modification while maintaining device safety and effectiveness.

The company worked with Premier Applied Sciences, using the PHD to inform their efforts. Employing a robust and standardized PHD dataset, they confirmed that usage of their device with expanded indications could have similar safety and positive patient outcomes. PHD data supported the company's regulatory filing, ensuring that the right patients could benefit from their device.

By leveraging the PHD and working with the Premier team to draw powerful insights, the medical device company was able to avoid additional RCTs – reducing their launch research spend by up to \$3 million.

Progress in Print: Robust Data Fuels Publication

Life sciences organizations frequently leverage the rich data available from the PHD, along with support from the Premier team, to author or co-author leading-edge studies.

Analyses using the PHD have appeared in more than **1,200 peer-reviewed publications**, including nearly 220 articles authored by Premier experts in multiple therapeutic and quality improvement areas.



Unlock the Power of RWD and RWE to Maximize Value

To stay ahead of today's myriad challenges, life sciences companies must work to harness the power of comprehensive datasets and strategically apply the intelligence they deliver. Doing so will not only differentiate organizations in the market – but it will also position them for long-term growth and create optimal value for the patients and communities they serve.

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Real-world data is transforming how life sciences organizations develop, discover, commercialize and receive reimbursement for drugs and devices. But having the right data and the right partner is critical. Together, we can help shape the future of healthcare.

Denise Juliano

Group Vice President, Premier Applied Sciences



Ready to solidify your position as a leader in a more resilient and patient-focused future?

Learn more about **Premier Applied Sciences** and how you can use the gold-standard PHD to conduct evidence-based analyses of devices, drugs and disease states and accelerate medical solution development.