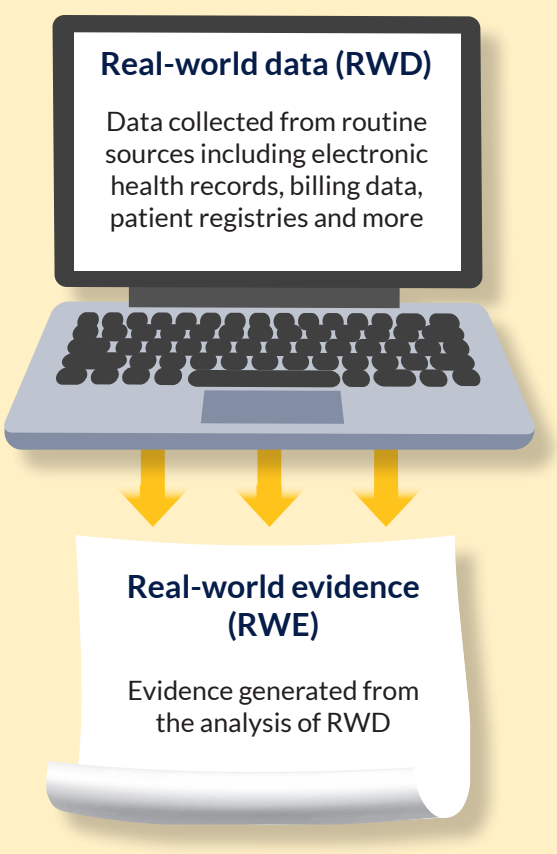
The Evidence Base®
Evidence Insights

Real-World Evidence for Medical Devices: Regulatory-Grade Data in Practice

PREMIER®



Innovative medical devices can transform patient care

However, the path from concept to commercialization is complex. Robust RWE is essential to demonstrate the safety, effectiveness and real-world impact of medical devices.

As medical device companies strive to bridge the gap between product development and real-world application, leveraging RWD for RWE generation has emerged as a gamechanger to inform product development, streamline approvals and more.

Why RWD and RWE Matter for Medical Devices

01

Saves time and resources by supporting proof of performance and reducing the burden of traditional evidence generation.

Strengthens commercialization strategy, improving trial design, feasibility and execution while streamlining post-market surveillance and ongoing monitoring.

RWD/RWE can fuel savings

02

Accelerates time to market by enabling faster evidence generation than traditional randomized clinical trials alone.

Supports pipeline growth by allowing companies to expand indications and invest in innovation more efficiently.

RWD/RWE can help reduce time to market

03

Supports approval and regulatory decisions by demonstrating a device's intended clinical value, complementing trial evidence and, in some contexts, substituting for selected trial elements to strengthen submissions and support faster review.

Enables key regulatory filings by using RWD to demonstrate performance and comparability (for example, supporting substantial equivalence arguments), potentially reducing the need for additional randomized trials.

Drives multiple high-value use cases, from assessing off-label utilization for HCPs to informing label expansion opportunities and generating deeper safety insights.

RWD/RWE can help support approval and regulatory decisions

Foundations of Regulatory-Grade RWE

Regulatory expectations for RWD and RWE in medical device evaluation continue to advance. The US FDA has finalized updated guidance on "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," providing expanded recommendations on how RWD is assessed for regulatory use.

To generate fit-for-purpose, credible, regulatory-grade RWE, sponsors need to demonstrate:

- Data provenance and governance
- Relevance and reliability
- Transparency on strengths and limitations
- Data quality
- Longitudinality

As regulators look to more flexible, data-driven approaches, longitudinal, fit-for-purpose RWD is essential for generating credible, regulatory-grade RWE that both complements traditional clinical trials and enables evidence generation when trials are not feasible.

The Premier Healthcare Database At a Glance

The Premier Healthcare Database (PHD) delivers broad, longitudinal and highly trusted RWD, enabling scalable, decision-grade evidence for medical device innovation and regulatory submissions.

Scale and Coverage

170 million+ inpatient visits

1.5 billion+ outpatient visits

Data from **1,400+** sites

Coverage across all US Census regions

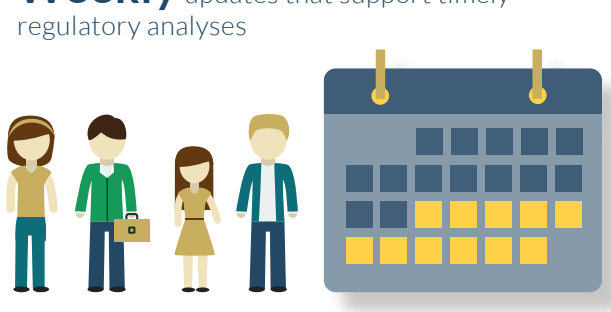
Represents **~25%** of all US inpatient admissions annually

Depth and Continuity

352 million+ unique patients

Longitudinal data since **January 2000**

Weekly updates that support timely regulatory analyses



Data Quality

< 1% missing data for most elements

< 0.01% missing for key demographics and diagnoses

Scientific and Regulatory Acceptance

> 1,200+ peer-reviewed publications

Across **~400** journals

> 200+ Premier-authored studies

Data Attributes

- Electronic health records data
- Purchasing data
- Administrative billing records
- Chargemaster data

Case Study

The Challenge

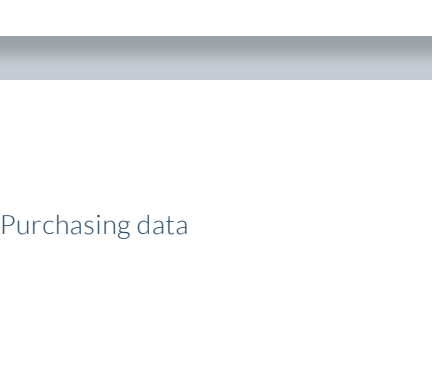
High-risk implantable device with limited visibility and long-term traceability in real-world settings

The RWE Approach

PHD-based analyses to generate regulatory-grade evidence on real-world safety and performance over time

The Impact

Improved confidence in traceability and long-term outcomes to support regulatory review

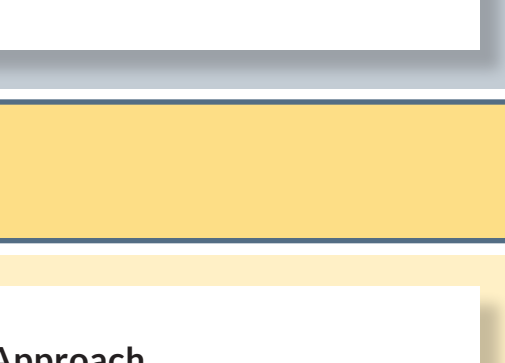


The Outcome

A real-world evidence package that is precise, clinically meaningful and fit for real-world use

Partnerships Enabling Regulatory Impact

Premier's healthcare data assets, combined with strategic partnerships including the National Evaluation System for Health Technology (NEST), an initiative within the Medical Device Innovation Consortium (MDIC), support validated and scalable, regulatory-grade evidence generation for medical device innovation and regulatory submissions.



Fit-for-purpose RWD, combined with strong public–private collaboration, is helping shape the future of regulatory decision-making for medical devices.

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Disclosure: This infographic has been created as part of the Evidence Insights feature "Real-world evidence in medical device regulation: From data to decision-ready evidence" in association with Premier.