

Precision in Practice

Real-World Data as the Catalyst for Transforming





A Turning Point for Diabetes Care

Just over 100 years ago, researchers made a groundbreaking discovery: insulin.

This single breakthrough didn't just change diabetes care – it reshaped the entire landscape of modern medicine. <u>Insulin</u> proved that understanding the biology of a disease can lead to targeted treatments that address root causes. Life expectancy leapt from months to decades, transforming diabetes from a fatal illness to a manageable condition.

Fast forward to today, approximately <u>591 million</u> people worldwide live with diabetes, and more than 250 million of them aren't even aware they have the condition. That means each of these individuals are unknowingly at risk for cardiovascular disease, kidney disease, nerve damage, and vision loss.

Despite advances in medical care, diabetes continues to take a heavy toll:

- More than <u>3.4 million</u> people lost their lives from diabetes in 2024
- More than \$1 trillion USD spent on diabetes in 2024

Now, a new frontier is emerging – one powered not by molecules, but by data. By harnessing real-world data (RWD), we can begin to better understand who develops diabetes and tailor management and treatment more precisely than ever before.

This whitepaper explores how RWD can be used to detect risk earlier, stratify patient populations for more targeted interventions, and evaluate the performance of treatments in everyday settings.

Real-World Data & Diabetes

Real-world data offers a glimpse into patients lived experiences.

The U.S. <u>Food & Drug Administration</u> defines RWD as "data relating to patient health status and/ or the delivery of health care routinely collected from a variety of sources." Common sources of RWD include:

- Electronic health records (EHRs)
- Claims data
- Product and disease registries
- Wearable devices
- Mobile health apps

Unlike clinical trial data, which is collected under carefully controlled conditions, RWD provides researchers and clinicians with insights into treatment adherence and blood glucose levels among diverse populations managing diabetes. It can reveal patterns that show how different approaches succeed — or fail — across everyday settings, as well as patterns that may precede a diabetes diagnosis.

Each data point represents one small facet of a person's life. Alone, it doesn't convey much. But when blood glucose readings, A1C levels, medication use, and lifestyle factors are gathered together, a clearer picture emerges. With enough data, those individual experiences illuminate broader trends, showing where patients struggle, where treatments succeed, and where opportunities exist to improve outcomes across entire populations.

PATIENT STORY

A Diabetes Diagnosis Changes Lives

At first, Amanda Cohen, MPH, Marketing Director at Veradigm, thought her 10-year-old son might've had a bladder infection.

He was making multiple runs to the bathroom during baseball games, which was very unusual. He was constantly drinking and refilling his water bottle too, a fact she chalked up to his desire to stay hydrated on long, hot game days. He seemed to be a bit slimmer than usual, but that was probably just him growing taller. Sometimes he seemed a bit out of it, but she figured that it was due to heat and exertion from a summer filled with lots of baseball.

When a friend suggested it could be Type 1 diabetes, Amanda dismissed the idea. Her son was active, slim, and there was no family history of Type 1 diabetes. Still, to be safe, she scheduled a doctor's appointment.

Amanda anticipated a quick visit and a prescription for antibiotics. Instead, they got a life-changing diagnosis: Type 1 diabetes.

"He immediately started crying when they told us he probably had Type 1 diabetes," Amanda says. "He didn't even really know what it meant, but he knew it wasn't good."

"When you look at data, it's easy to forget that this is the other side. There are very real people receiving a diabetes diagnosis every day, whose lives are about to be changed forever."



Detecting Risk Earlier: From Silent Signals to Action

Integrated data is transforming diabetes from a disease we react to into one we can anticipate and manage proactively.

RWD supports early detection and treatment of both Type 1 and Type 2 diabetes:

• For Type 1: Only about 15% of children who develop Type 1 diabetes (T1D) have a first-degree family member with the condition. Most people who develop the disease don't have a family history or any obvious risk factors. Screening for diabetes-related autoantibodies can detect T1D before it becomes symptomatic, giving clinicians an opportunity to intervene and slow disease progression.

Screening Recommendations for Type 1 Diabetes

- The Standards of Care in Diabetes 2025 recommends offering autoantibody-based screening to those with a family history of type 1 diabetes or otherwise known elevated genetic risk. Testing for dysglycemia may be used to further forecast near-term risk.
- In September 2025, a <u>European</u>
 Association for the Study of Diabetes (<u>EASD</u>) panel recommended general population screening beginning at age 2-4 years.
- Population T1D screening programs are already in place in <u>Germany</u>, <u>Italy</u>, <u>Israel</u>, <u>the UK</u>, and <u>elsewhere</u>.

 For Type 2: Monitoring blood glucose patterns, body mass index (BMI) trajectories, and healthcare encounter frequencies can help detect and predict the development of T2D.
 Real-world data can also flag the earliest signs of complications, such as kidney damage or cardiovascular disease, creating opportunities for early intervention.

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Early detection can improve patients' lives."

NITAL PATEL, MS, MBA, VICE PRESIDENT, REAL WORLD DATA AT VERADIGM



PATIENT STORY

Why Early Detection Matters

Despite having her Master's in Public Health, working in healthcare, and having a high level of health literacy, Amanda wasn't aware of the symptoms of T1D before her son's diagnosis. She didn't know that it's possible to detect the disease before symptoms develop, or that early intervention can slow the immune system's attack on the insulin-producing cells of the pancreas.

"Awareness and education around the symptoms for Type 1 diabetes is so far behind what it should be," she says. "My mission now is to raise awareness of Type 1 diabetes. I'm advocating for routine screening for diabetes autoimmune antibodies and routine blood glucose testing in children. If you delay the onset of insulin dependence; that's a huge lifestyle improvement for patients and families."

Stratifying Populations for Personalized, Precision Care

Diabetes doesn't follow a single script, and neither should its care.

Every person's experience with the disease is shaped by their age, lifestyle, environment, and access to resources. A teenager who develops Type 2 diabetes (T2D) needs a different management plan than a 70-year-old who's had T2D for years. A young adult with T1D who attends college near a tertiary care center will face very different challenges than someone the same age who's working a minimumwage job in a rural community. Their needs, challenges, and opportunities for support are entirely different – and our approach to care must reflect that.

RWD enables segmentation based on clinical, behavioral, and social characteristics. Segmentation helps researchers and clinicians identify subpopulations and more accurately assess:

- Treatment adherence. The best drugs and devices in the world can't meaningfully improve patient lives or lessen the global burden of diabetes if people aren't using them. RWD gives stakeholders insights into patient behavior across settings.
- Clinical outcomes. RWD makes it possible to see how drugs, devices, and treatment strategies perform across different populations — by age, sex, genetics, comorbidities, or social context — revealing where certain therapies are most effective, and where adjustments may be needed.
- Opportunities for intervention. Spotting gaps in care, as well as underserved patient groups and intriguing clinical signals, is easier when you have access to RWD that enables flexible, multi-dimensional analysis.

Today's vast data sets can also super-charge the creation of personalized diabetes management plans. "We've moved away from the standard data sets that were used traditionally and incorporated additional sources of data, including custom registries that allow us to gain deeper insights," Patel said. "Providers can now tailor personalized therapies, rather than applying a standard approach to all patients."

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By leveraging real-world data, researchers can evaluate treatment pathway, identify comorbidity clusters, and monitor longitudinal outcomes."

NITAL PATEL



PATIENT STORY

Data in Action: Personalizing Care

Before Amanda's son got an insulin pump, his blood sugar levels frequently plummeted during the night.

Thankfully, his continuous glucose monitor (CGM) detected his lows and sounded an alarm. "I'd have to wake up and give him some juice or candy in the middle of the night to boost his glucose level," Amanda explained. "He'd be half asleep and wouldn't even remember the next day that he had candy in the middle of the night."

Now that he has an insulin pump, his CGM and pump work together to maintain his blood sugar. The CGM tracks his glucose levels and sends that info to his insulin pump, which can increase or decrease insulin accordingly. Before he heads to baseball practice, he can set his pump to Exercise Mode, which reduces insulin delivery, so his glucose levels don't drop too much during physical activity. His levels have been more stable – and his parents are more at ease.

"Since he's had the pump, he hasn't had a single overnight low," Amanda says.



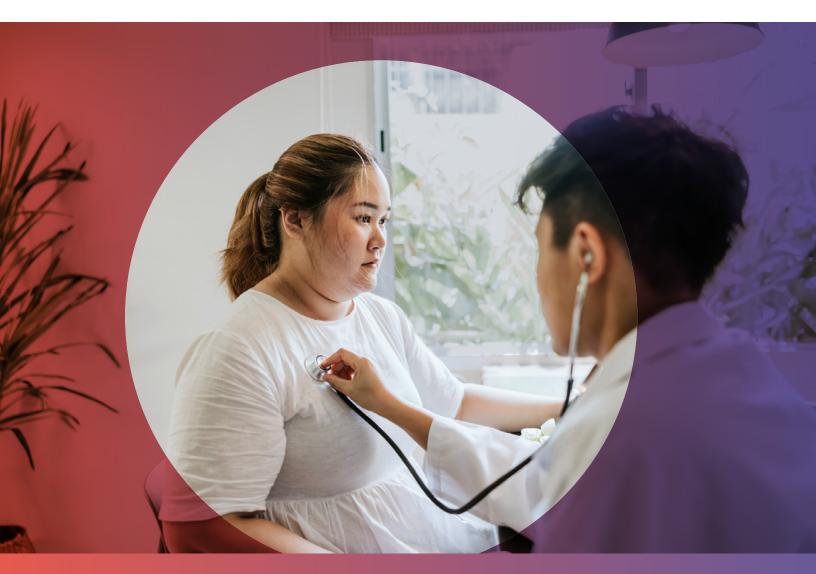
Evaluating Devices &Therapies in the Real World

People living with diabetes navigate dynamic, ever-changing environments.

That's why it's crucial to assess the use and impact of medical devices and therapies in real-world settings. As Sara Brenner, MD, MPH, Principal Deputy Commissioner of the US FDA, <u>stated</u> in September 2025, "RWE allows us to study large, diverse datasets from real-world settings, revealing treatment patterns, safety signals, and gaps in care that clinical trials alone may not capture."

Recent research underscores the point: A <u>2025</u> analysis of 19 million U.S. patients illustrates prescribing trends and real-world effectiveness of GLP-1 therapies, revealing that approximately 1 in 5 patients with T2D had an active GLP-1 prescription in 2022-2024.

RWD also plays a critical role in after-market monitoring. While clinical trials offer valuable insights into how interventions work in controlled environments, RWD helps us understand surface outcomes and adverse effects in diverse populations and settings.



Building the Infrastructure for Responsible, Scalable RWD Use

Big breakthroughs require more than big data.

To truly unlock its potential, we need a strong, responsible infrastructure – one that responsibly gathers, de-identifies, collates, and maintains vast amounts of data. Just as important are interoperable systems that allow seamless sharing and integration across platforms, providers, and populations.

Two common challenges include:

- Incomplete data capture. If a patient has blood work done at a private lab rather than their regular clinic, those results may not appear in the EHR. That means providers may not see the full picture, and those results won't be included in datasets built from EHRs alone. Integrating multiple sources, such as claims data and EHRs, helps close these gaps.
- Biased representation. For data to be meaningful, it must accurately reflect the patient population of interest. A dataset drawn mainly from urban populations, for example, may offer limited insight into the experiences of people with diabetes in rural areas.

Specialized health data platforms, like those offered by Veradigm, are building the infrastructure needed to make real-world data usable at scale: aggregating millions of patient records, enriching unstructured notes with natural language processing, linking EHR and claims sources, and maintaining strict privacy and governance standards. By combining scale, quality, and interoperability, these platforms turn raw data into actionable insights that support research, regulatory submissions, and patient care.

Privacy Matters

Patients and families understand that data can help researchers discover breakthroughs that will make their lives easier. They want to advance the science of diabetes care and are eager to experience the benefits of safer, more effective treatments.

But alongside that hope, there's concern. People want to know if their data is being used responsibly. They worry about privacy, transparency, and whether their information might be misused.



What to Look for in a Responsible RWD Partner

- Privacy first: Robust deidentification, HIPAA/GDPR compliance, and clear patient consent practices.
- 2. Interoperability: Ability to link EHR, claims, lab, and device data using standardized models (e.g., OMOP, Sentinel).
- **3. Transparency:** Clear documentation of data provenance, methods, and limitations.
- **4. Representativeness:** Commitment to reducing bias and including diverse, underrepresented populations.
- **5. Regulatory alignment:** Adherence to FDA, EMA, and other global guidance on RWD/RWE use.
- 6. Scalability & security:
 Infrastructure built to securely
 handle large, complex datasets
 across settings.



The Future of Precision Diabetes Care

Here's the reality of diabetes: "Diabetes is a life-threatening disease if not managed properly – and the medication you need to manage Type 1 diabetes, insulin, can also kill you if taken improperly," Amanda said.

Everyone living with diabetes understands that tension. A century after the discovery of insulin and numerous other breakthroughs, families continue to grapple with access to treatment, cost, and adverse effects.

Data can help shape the future of precision diabetes care through:

- Predictive modeling. A 2022 study published in Diabetes & Metabolism Journal demonstrated that predictive models can predict diabetes development within 1-2 years, highlighting the potential of modeling to support early intervention strategies
- Virtual clinical trials. A 2025 PLOS Digital
 Health demonstrated how RWD, combined
 with generative AI and causal learning, can
 emulate randomized controlled trials and
 extend findings to broader populations. The
 model accurately reproduced the impact
 of GLP-1 agonists on A1c levels, validating
 this approach
- Al-assisted decision tools. Integration of Alassisted decision tools into the EHR can bring the power of predictive modeling to the point of care. These tools can analyze a patient's clinical history in real time to flag risks, suggest tailored interventions, and support more precise treatment decisions.



Real-world data and AI, if used correctly, can save patient lives."

NITAL PATEL

The next great shift in diabetes care will come from the insights currently hidden in the data. Unlocking those insights will require responsibility, collaboration, and vision.



5 Key Takeaways

1. Early detection saves lives.

Real-world data can reveal risk signals for type 1 and type 2 diabetes years before symptoms appear, enabling earlier intervention and slowing disease progression.

2. One size doesn't fit all.

Stratifying patients by age, comorbidities, genetics, and social context allows for truly personalized, precision care.

3. Evidence must extend beyond the clinic.

RWD validates how drugs, devices, and therapies perform in everyday life, capturing outcomes and safety signals clinical trials may miss.

4. Infrastructure is the foundation.

Scalable, interoperable, privacy-first data systems are essential for responsible use and trustworthy insights.

5. The future is predictive and proactive.

Predictive modeling, virtual trials, and Al-assisted decision tools are poised to transform diabetes care from reactive management to proactive precision.

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