

# Harnessing the Power of Real-World Evidence Across the Diagnostic Lifecycle

*Enabling smarter diagnostic decisions through real-world evidence*

Bringing innovative screening, monitoring and diagnostic tests to market can be challenging and Real-World Evidence (RWE) is quickly becoming a key differentiator for companies generating cost-effective, high-quality evidence data that can help drive both regulatory approval and market access.

Generating robust evidence for diagnostic tests in real-world intended use populations requires careful planning and execution. Manufacturers need to find the right balance between scientific rigor and operational feasibility, ensuring studies reflect routine clinical practice while remaining scalable and cost-efficient. Success relies on strategies that integrate seamlessly into standard of care, maintain data quality, and deliver meaningful insights for regulatory approval and market adoption.



This can lead to questions about how to generate evidence to meet multi-stakeholder needs, such as:

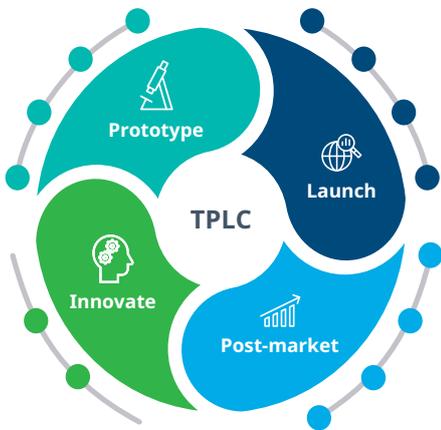
- 1 How can I conduct a study in an intended real-world setting?
- 2 What is the least burdensome approach to meet multi-stakeholder needs?
- 3 How can I validate my test with positive and negative cases in a cost-effective manner?
- 4 How can I generate relevant, reliable, and high-quality data in a real-world population?

## RWE can offer a powerful framework to overcome these challenges

Real-world studies are well-suited for diagnostic clinical investigations as they typically involve minimally invasive low-risk sample collection such as routine blood draws, conducted in intended-use settings without introducing experimental procedures or interventions. These studies align with standard of care, minimize patient burden and allow for the generation of robust RWE through observational or non-interventional study designs. By leveraging existing secondary data and prospective site-based approaches, these studies support cost-effective, small and large-scale validation of test performance in real-world conditions, while meeting regulatory and payer needs.

# Benefits of RWE for diagnostic clinical development and clinical utility in real-world populations

- Generate clinical evidence in intended use environment and populations, and **improve diagnostic test speed-to-market**
- Demonstrate real-world safety, performance & clinical utility and **improve diagnostic test value**



Regulatory RWE use cases	Payer RWE use cases
RWE as a historical control or as one source of data in a hierarchical model	RWE to demonstrate health economics and outcomes improvements
Generate hypotheses to be tested in a clinical study	RWE sources for demonstrating clinical utility of approved devices
Generate evidence for post-market surveillance	RWE to support expanded coverage
Generate evidence for expanding a label	RWE to support payment negotiations

Examples derived from (list is not exhaustive): FDA CDRH, Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices, Guidance for Industry and Food and Drug Administration Staff (December 18, 2025)

## Why IQVIA MedTech?

With our extensive industry experience, IQVIA MedTech can partner with you to design and deliver analytical validation, clinical validation, clinical performance, and clinical utility studies. We do this by leveraging these key factors that drive success:

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**Participant and site-centric study execution**  
 IQVIA MedTech can help to accelerate start-up and recruitment timelines, by selecting high-performing sites using data-driven approaches and offering flexible data collection methods that reduce burden on both participants and sites
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**Integrated, high-quality data generation**  
 We ensure high-quality, compliant data capture through unique population insights, regulatory-ready EDC systems, real-time automated data cleaning, and seamless integration across multiple data sources
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**Specialized diagnostic study expertise in real-world settings**  
 Our cross-functional diagnostics and real-world evidence teams apply regulatory-aligned processes, quality-by-design principles, and proactive risk mitigation to deliver reliable data and safe, complete specimen collection

*With IQVIA MedTech powered by Real-World Solutions, you move forward faster with confidence and help to realize the potential of preventative medicine.*



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