Fact Sheet

Generating Real World Evidence Across the Total Product Lifecycle

Delivering strategic value and confidence with the right real world evidence

With complex market forces at play, the pressures on medical device companies to substantiate product capabilities have reached new heights. These challenges include the evolving regulatory landscape, pricing and profitability pressures, maintaining patient safety, and keeping pace with technological changes. Enhanced global requirements stress the need for innovative scientific methodologies that connect the right approach to the right question. As a proven MedTech partner with trusted expertise, we help our customers generate the right real world evidence (RWE) to meet the needs of multiple stakeholders with confidence.

Value across the product lifecycle

We provide service continuity from clinical development through post-market, by leveraging innovative approaches to study design for smarter evidence generation.

PRE-APPROVAL

Support regulatory decision with the use of RWE

- Improving trial design
- Characterizing unmet needs
- Refining endpoints
- PMA clinical performance study – non interventional
- Indication expansion
- Supplementary data / historical controls / concurrent controls

Designed to **increase efficiency**, **reduce costs** and improve medical device **speed to market**

Real World Evidence

POST-APPROVAL

Improve commercial performance & meet regulatory requirements through optimum real-world evidence generation

- Post-market clinical follow-up
- Post-market performance follow-up
- Post-approval commitments/active safety surveillance
- Post-market effectiveness evaluation
- Longitudinal follow-ups
- Device registries
- Market value messaging

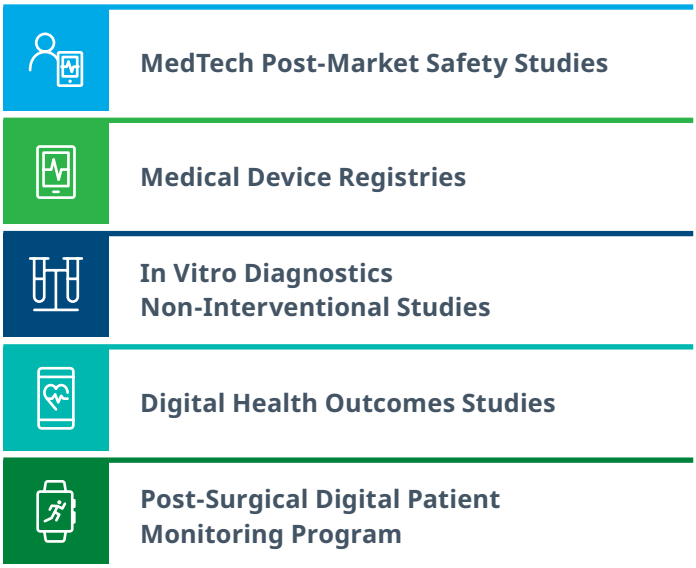
Designed to demonstrate **real-world safety**, **performance & effectiveness** and improve medical device **value**

Novel real world evidence application

Our innovative RWE solutions are underpinned by our unmatched domain knowledge across therapeutic areas, scientific rigor and operational excellence, and global and local regulatory and payer expertise. We leverage our unparalleled data assets and industry-leading technology enabled analytics, combined with flexibility and infrastructure to meet customer needs across the total product lifecycle.

Our end-to-end services are rooted in deep understanding of clinical operations and regulatory requirements. Our pre-approval solutions are designed to increase efficiency, reduce costs and improve medical device speed to market, while for post-approval our solutions are designed to demonstrate real world safety, performance and effectiveness, and improve medical device value.

With IQVIA's unparalleled real world data sources, our customers are able to create scalable and customized solutions. Our team is poised to support:



OUTCOMES RESEARCH

- Observational Studies
- Patient Registries
- Device Registries
- Pragmatic Studies
- Natural History & Burden of Illness
- Clinical Performance Studies
- Clinical Outcome Assessments, including PROs
- Quality Measurement, QOL
- Retrospective Database Studies
- Digital Biomarkers & mHealth Studies
- Instrument Validation Studies

HEALTH ECONOMICS

- Health Economic Evaluations
- Global Models and Local Adaptions
- Stakeholder-friendly Presentations of Models
- Budget Impact Models
- Meta-Analyses
- Indirect Comparisons
- Piggyback Studies
- Time & Motion Studies

MARKET ACCESS

- Market Access Strategy
- HTA Readiness
- Value Development Planning
- Global Value Dossiers and Local Adaptations
- Value Communication
- Reimbursement Submissions
- Patient Preference

SAFETY SURVEILLANCE

- Post-market Studies
- Post-market Clinical Follow-Up
- Post-market Surveillance
- RM/Risk MAPS
- Prevalence and Incidence Studies
- Safety, Surveillance
- Performance-linked Access Systems
- Natural History & Burden of Illness

IQVIA MEDTECH

CONTACT US

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