

Real world evidence solutions to help orchestrate effectively from concept to market

Use real world evidence to build a better clinical trial and stronger market access for medical devices and in vitro diagnostics

The MedTech industry is growing and expanding, increasing the opportunities for companies working in this space. As the regulatory authorities keep up with the changes, they are asking for more real-world evidence (RWE). RWE supports the route through trials and onto the market, and adds value to products.

In the MedTech industry, RWE has traditionally been generated post-approval and post-market to support market access and provide information for stakeholders. This is changing as the MedTech market grows and the value of RWE increases.

Regulatory bodies are increasingly interested in the value added by RWE; for example, the incoming EU regulations on medical devices (MDR) and the FDA's 21st Century Cure Act ask for RWE throughout the lifecycle.

Shrinking healthcare budgets need smarter ways to meet stakeholder needs

Many MedTech companies don't have the experience or resources to keep up with the rapidly changing RWE space.

Your full-service solution partner needs to have in-depth experience in the following areas, all underpinned by an extensive and robust technology solution:

- Real-world data and RWE collection, analysis and application, both pre-approval and post-approval
- Clinical trial design strategy across the entire spectrum of medical devices, diagnostics and combination products, focused on safety, effectiveness and value generation
- Current U.S., EU and Asia-Pacific regulatory framework processes and emerging requirements around the world



Pre-approval

Support regulatory decision with the use of RWE e.g.

- Improving trial design
- Characterizing unmet needs
- Refining end points
- Conducting medical device registries

Designed to reduce costs and improve speed to market



Post-approval

Improve commercial performance and meet regulatory requirements through optimum RWE generation

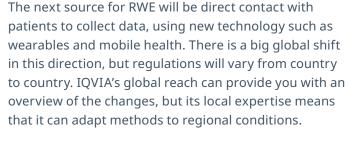
- Post-approval commitments/ active surveillance
- Medical device registries

Designed to differentiate your product, demonstrate real-world safety and effectiveness and improve product value

Finding the solution with IQVIA MedTech

IQVIA™ MedTech is a leader in the medical device and in vitro diagnostics industry with solutions, services, and a team of industry experts who can provide highly integrated and robust MedTech-focused offerings that can help you orchestrate your business from concept to market.

At IQVIA MedTech our wealth of experience and our in-house expertise means that we understand the challenges and can build solutions designed specifically with MedTech at the heart. Disease registries provide a useful resource for RWE, to help you to understand patient pathways and improve trial design, provide information for market landscaping, and data for historical control arms. Registries can also be used as sources of potential patients, physicians and sites for clinical trials. IQVIA has access to existing disease registries and can provide support in designing and populating new data sets.



IQVIA MEDTECH'S CONCEPT-TO-MARKET SOLUTIONS CAN PROVIDE YOU WITH:

- Highly integrated MedTech solutions that link functions and create a truly connected offering
- People on the ground, with both local and global experience, who can understand both national challenges and global solutions
- Teams with domain expertise that understand MedTech technologies and markets
- A breadth of offerings using innovative technology that gets the right decision-making information into your hands when and how you need it



Real-World Evidence

OUTCOMES RESEARCH

- Observational Studies
- Registries
- Expanded Access Programs
- Pragmatic Studies
- Clinical Outcome Assessments, Including PROs
- Quality Measurement, OOL
- Retrospective Database 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

MARKET ACCESS

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

EPI & SAFETY

- RWE Generation
- RM/Risk MAPS
- Health Interventions
- Prevalence and Incidence Studies
- · Safety, Surveillance
- Instrument Validation Studies
- Performance-linked Access Systems
- Natural History & Burden of Illness



IQVIA™ MedTech, part of IQVIA (NYSE:IQV), is dedicated to supporting the needs of the medical device and in vitro diagnostics industry, focusing on the orchestration of "concept to market" business processes to improve patient care. IQVIA MedTech Solutions are powered by the IQVIA CORE™, delivering unique and actionable insights and execution capabilities at the intersection extensive domain expertise, transformative technology, and large-scale analytics. IQVIA is a leading global provider of information, innovative technology solutions, and contract research services.



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