Fact Sheet

# How the Rapidly Evolving Regulatory Landscape Will Drive the Increasing Need for Post-market Safety Studies

The progression of medical devices regulations across the globe have reinforced the necessity to monitor devices across the the total product life cycle, with an increased focus on safety in the post-market setting.

Post-market surveillance is a crucial process to ensure that medical devices continue to be safe and effective. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the medical device, and report as early as possible potential issues in its usage.

Post-Market Safety Studies allow assessment of medical devices in a real-world setting, to ensure the security of the patient.

## IQVIA MEDTECH CAN SUPPORT YOU WITH YOUR POST-MARKET-SAFETY STUDIES THROUGH :

- Real World Evidence Generation
- Post Market Continuous Evaluation
- Post Market Clinical Follow-Up
- Post Market Surveillance
- Proactive Surveillance
- Physicians Experience Studies
- Device Utilization Surveys

**Designed to demonstrate real-world safety, performance & effectiveness to meet post-market regulatory reporting requirements**

## Why IQVIA?

### High quality delivery excellence

Design & delivery excellence across the spectrum of post market safety study types

- Prospective designs
- Retrospective designs
- Traditional & innovative methods
- Primary data collection
- Secondary data collection
- Enriched studies

### Innovative approaches

- Leverage NextGen capabilities & technologies, enabling faster recruitment and overall delivery excellence
- Integrated systems / Digital platform
- Direct to patient
- Innovative study design / Better traditional studies / Smarter evidence generation
- Unparalleled access to unique data insights

### Reliable regulatory expertise

- Global outreach
- Local expertise
- FDA CDRH (Center for Devices and Radiological Health)
- EU MDR / IVDR (Medical Device Regulation/ In Vitro Diagnostic Regulation)
- ISO 14155:200 compliant
- AHRQ (Agency for Healthcare Research and Quality) observational comparative effectiveness research guide

**CONTACT US**

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