Insight Brief

Global Market Entry: How to set up medical device clinical trials to meet global regulatory requirements

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Regulatory authorities worldwide have raised the bar on medical device clinical data requirements. Compared to a decade ago, agencies such as the U.S. FDA, the European Commission, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) all demand more robust data on long-term safety and effectiveness, among other areas.

Data used to secure regulatory clearance in the U.S. may also support market authorization in other regions. Because regulatory requirements vary by country, a proactive approach to data collection helps bridge gaps across multiple markets, including the EU and Japan.

In this white paper, IQVIA MedTech and MCRA experts share their expertise on how to design clinical studies to support a global regulatory strategy. Topics discussed include:

- How to meet global regulatory requirements with one study design
- The role of real-world evidence across pre- and post-market activities
- Key statistical considerations when evaluating regulatory data
- How to build a clear regulatory pathway across your product's lifecycle

Develop regulatory and clinical strategies in parallel

For efficiency and to ease the submission process, we recommend medical device manufacturers integrate regulatory strategy into clinical development as early as possible. These two teams must continue to work in parallel throughout the product lifecycle.

Manufacturers must determine the product's intended use, indications for use, regulatory pathway, and regulatory requirements before running a clinical study. Clinical information impacts regulatory strategy, while the regulatory pathway dictates requirements around study design, data collection methods, and patient population, among others. Waiting to factor in regulatory considerations later often leads to costly rework to resolve data discrepancies, to collect additional data, or to amend study protocols mid-execution.

Many regulatory agencies offer formal programs that allow manufacturers to engage in early discussions which helps clarify the regulatory path and expectations. The FDA's Q-Submission program enables manufacturers to receive specific feedback on regulatory pathways and regulatory requirements, including study design and submission preparation.[1] The European Commission (EC) offers scientific advice in advance of clinical investigations for Class III and Class IIb active medical devices intended to administer or remove medicines.[2] In Japan, the PMDA's Pre-Submission Consultation Program includes general and preliminary meetings, several types of pre-submission consultations for new and/or high-risk devices, and an RS General Consultation for procedural questions and development planning.[3]

These programs are particularly valuable for complex or novel devices without a clear predicate or established regulatory precedent. Early engagement helps align data requirements across multiple agencies, increasing the likelihood that a single well-designed study can support submissions in more than one market.

Before requesting a meeting, have at least the following in place:

- Intended use and indications for use
- Device descriptions and workflow
- Proposed regulatory pathway
- A study design synopsis, including primary objective, endpoints, and intended patient population

The U.S., EU, Japan, and regulatory bodies in other regions, including the UK and Canada, all have mechanisms to provide regulatory and scientific advice. Engage with these officials as early as feasible to get a solid understanding of their respective requirements for bringing a device to market.

A three-step framework for a global regulatory strategy

Clinical data collection for multiple regulatory bodies requires a prospective approach with ongoing collaboration between regulatory and clinical teams.

1. **Define intended use and map your markets early.** Know where you're going — and in what sequence — before designing your study. A precise intended use statement dictates device classification, regulatory pathway, and evidence requirements in every target market. A clear picture of the clinical claim and device workflow helps ensure compliance and supports reimbursement.
2. **Identify where requirements overlap and where they diverge.** Most major market requirements share common ground; the gaps are manageable with the right upfront analysis. A harmonized evidence generation plan that addresses the overlaps efficiently and fills the gaps deliberately reduces the risk of repeat studies.
3. **Treat your regulatory strategy as a living document.** Requirements evolve. Build in a process for monitoring regulatory changes in target markets across the full product lifecycle, not just at the point of submission.

Essential data considerations by region

Major global markets share many common data requirements, principles, and standards, but they also diverge in several areas. Understanding both the overlap and the gaps is essential to designing a study that works across markets.

FDA: The FDA requires that clinical data represent the intended U.S. patient population. That benchmark applies to studies conducted both inside and outside the U.S. As a practical rule of thumb, we often recommend manufacturers conduct the study such that at least 50% of the study data are collected from representative U.S. populations.

The agency expects a breakdown of device performance by cohort (subgroup analysis) to demonstrate consistent performance and support generalizability across patient populations. If the manufacturer decides to exclude a cohort, it must justify why that cohort will not affect overall device performance.

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EU MDR: We typically recommend manufacturers follow MDR — and more specifically, ISO 14155:2020 — as a best practice when conducting clinical studies inside and outside Europe. Designing to this standard from the outset eases the CE Marking process and demonstrates that data gathered outside Europe applies to the EU population and clinical practice. It also facilitates entry into markets that accept CE Mark documentation, including Switzerland, Turkey, the United Kingdom, and members of the European Economic Area (EEA). Countries including Australia, Canada, Israel, and Japan have mutual recognition or reliance agreements with the EU that may further accelerate the submission process.

In the EU, notified bodies assess conformity to MDR before a device enters the market. Currently EU member states have designated 52 notified bodies.[4] Each organization has its own procedure and there is no formal pathway for preliminary advice or feedback. Manufacturers may be able to initiate a dialogue with their notified body to gauge alignment on clinical or regulatory strategy.

Under MDR, manufacturers demonstrate safety and performance through clearly defined endpoints showing superiority or non-inferiority relative to existing devices or the state of the art. Studies with significant data from populations outside the EU will likely require a post-market clinical follow-up (PMCF) study to confirm that the device is safe and performs as intended in the EU population.

Regardless of market, all studies need sufficient participants in each patient subgroup to produce meaningful performance data. A multinational study may not need to reach statistical significance in each country individually, but manufacturers will be expected to present a credible argument for performance in each market.

PMDA: While Japan's core data requirements share common ground with the FDA's, the PMDA has distinct expectations around patient population and standard of care. When conducting global studies, a Japanese or Asian patient population of about 10% of the total study population is generally considered acceptable, provided it supports meaningful subgroup analysis. The PMDA will want to review that analysis.

The agency has become more flexible in recent years in its acceptance of foreign clinical data, provided the data is high quality and the manufacturer can demonstrate it is applicable to the Japanese population and standard of care. For novel devices, the PMDA will typically require a post-market surveillance (PMS) study to confirm that real-world outcomes in Japan align with global study results.

Real-World Evidence: pre-and post-market requirements

Medical device manufacturers may use real-world evidence (RWE) for both pre- and post-market activities. It can support premarket submissions as well as post-market approval studies and labeling changes.

The FDA's final guidance on RWE, published in December 2025, outlines which real-world data (RWD) sources are relevant and reliable for regulatory decision making.[5] Provided the RWE is created on Good Clinical Practices principles, the agency, under certain circumstances, will accept RWE to "inform or augment" its understanding of the benefit-risk profile of the device at various points in its life cycle. RWD can be used to test a hypothesis, serve as a comparator arm in a randomized-controlled trial, or to map out patient pathways across cohorts.

When planning for RWD collection, consider the following:

- What do you intend to prove: safety, effectiveness, performance, generalizability, or long-term outcomes?
- Are the endpoints measurable with routine data?
- Have you planned adequate patient follow-up?
- How will you mitigate potential data bias?

Under EU MDR, RWD collected in other markets can contribute to the clinical evidence package required for CE marking, provided it is presented within a rigorous methodological framework and demonstrates applicability to the European population and clinical practice. MDR also permits manufacturers to use clinical data from equivalent devices — including RWE on state-of-the-art comparators — to contextualize their own device's performance, which can be useful where head-to-head trial data is not available.

Japan's RWE framework is less formalized than policies in the U.S. and EU, but it is expanding as part of broader regulatory modernization. Its most useful and relevant during post-market surveillance studies required for novel devices and to support reimbursement decisions.

Conclusion

Designing clinical studies to meet evolving regulatory requirements is challenging enough. Mapping data requirements to multiple regulations requires deliberate planning, collaboration across teams, and an understanding of regulatory similarities and differences across markets.

Fortunately, the EU, the U.S., and Japan share common principles that align with ISO standards. A well-designed study can serve as the evidentiary backbone for multiple submissions. Manufacturers that succeed in this endeavor engage with regulatory authorities in advance of committing to a protocol and consider regulatory implications throughout the product lifecycle.

References

1. U.S. Food and Drug Administration. “Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.” May 29, 2025. https://www.fda.gov/media/114034/download

2. 2. European Medicines Agency. “Guide to manufacturers on the procedure for requesting advice from Expert Panels on clinical investigations and/or clinical development strategies for high-risk medical devices. Advice to manufacturers for high-risk medical devices.” January 17, 2025. https://www.ema.europa.eu/en/documents/other/guide-manufacturers-procedure-requesting-advice-expert-panels-clinical-investigations-or-clinical-development-strategies-high-risk-medical-devices_en.pdf

3. Pharmaceuticals and Medical Devices Agency. Consultations. https://www.pmda.go.jp/english/review-services/consultations/0002.html

4. European Commission. Notified Bodies. https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/free-search?filter=notificationStatus:1,legislation:34,choice:3

5. U.S. Food and Drug Administration. “Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.” December 18, 2025. https://www.fda.gov/media/190201/download

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Chava brings biostatistical expertise to MCRA where she is responsible for clinical trial design, data analysis, and regulatory strategy as regards to the use of statistical methods in the evaluation of diagnostic devices. Chava brings over a decade's experience, including time at the FDA, in the design and analysis of clinical trials of diagnostic devices in the regulatory setting.

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