A Practical Guide for Managing Multiple Global Regulatory Pathways

Why Simultaneous Submissions Matter

Global regulatory agencies are becoming increasingly aligned in data expectations. This makes coordinated, near-parallel marketing application submissions possible.

Veristat has supported 190+ global marketing applications, including 90+ in the past five years, many delivered within synchronized review windows.

The 7-Step Framework for Success

01 Map the Global Path Early

- Establish global regulatory goals early in development.
- Identify target agencies and request scientific-advice (SA) meetings.
- Align dossier plans using the International Council for Harmonisation (ICH) Common Technical Document (CTD) format.

Action Tip: Build one integrated roadmap linking all regions' milestones.

02 Build a Common Dossier Core

- Develop a single master set of CTD Modules 2–5.
- Use a shared library of summaries, templates, and controlled terminology.
- Standardize all review workflows.

Action Tip: Assign document owners and enforce consistent version control.

03 Coordinate Data & Documentation

- Synchronize analytical outputs, statistical summaries, and clinical narratives.
- Prepare early table, listing, and figure (TLF) shells.
- Support both FDA's dataset-first review style and EMA's narrative-first approach.

Action Tip: Maintain regular cross-functional meetings across clinical operations, data management, statistics, programming, medical writing, safety, and regulatory.

04 Govern the Process as One Program

- Designate a global submission lead with cross-regional authority.
- Use one master timeline and risk log.
- Keep all contributors aligned on priorities.

Action Tip: Adopt a single real-time dashboard for tracking progress and dependencies.

05 Confirm Readiness Before Submission

- Validate that all CTD Modules 1–5 are complete and consistent.
- Ensure datasets meet Clinical Data Interchange Standards Consortium (CDISC) requirements.
- Confirm technical compliance with each agency's electronic submission gateway.

Action Tip: Perform a unified global "go/no-go" readiness review.

06 Account for Different Review Timelines

- Anticipate agency-specific pacing and question styles.
- Prepare potential question lists during dossier development.
- Establish a rapid-response structure for regulatory queries.

Action Tip: Use a standing cross-functional response team.

07 Capture & Respond: Learning From Regulatory Queries

- Expect early clarification requests and follow-up analyses after submission.
- Assign topic-specific owners for question handling.
- Maintain a library of supporting analyses and justification materials.

Action Tip: Debrief after each submission cycle to refine templates and response strategies.

Global Regulatory Alignment Is Accelerating

Programs such as the FDA–EMA Parallel Scientific Advice (PSA) initiative and Project Orbis demonstrate increasing convergence in scientific review expectations. Integrated planning strengthens consistency, reduces duplication, and supports timely global decisions.

Why Partner With Veristat?

- **End-to-end capabilities across regulatory strategy, biometrics, medical writing, and publishing**
- **Experience delivering simultaneous FDA and EMA submissions**
- **Proven ability to manage complex review cycles and rapid regulatory responses**

Learn More

Case Study

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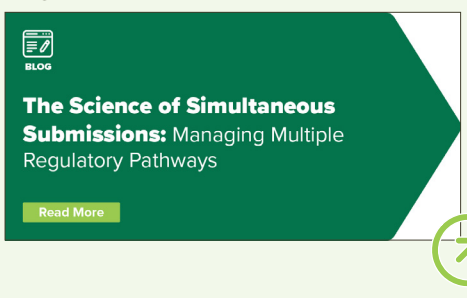

Ready to advance your therapy across multiple global agencies?

Connect with Veristat's regulatory experts to plan a coordinated submission strategy tailored to your program. Visit veristat.com to get started.

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