Cross-Border Alignment Checklist for Global Regulatory Submissions

Use this practical checklist to help your team stay aligned, reduce duplication, and streamline submissions across the US, EU, UK, Asian and other markets.

1. Create a Unified Global Evidence Strategy

- Build a high-level global evidence matrix that maps your clinical endpoints, study populations, and comparators across each target region ☐
- Align early with both regulatory and clinical teams to integrate this strategy into study protocols and literature review plans ☐
- Flag any divergences in regulatory expectations that could lead to future gaps ☐

2. Know the Non-Negotiables

- Identify region-specific regulatory "must-haves," e.g., local trial requirements, language localization, or specific safety outcomes ☐
- Build a living tracker or internal dashboard to keep the team aligned on these region-by-region priorities ☐

3. Align Clinical and Regulatory Timelines

- Work backwards from market launch goals to map your submission timelines ☐
- Build a collaborative schedule that accounts for both clinical milestones (e.g., LPLV, data lock) and regulatory deliverables (e.g., CERs, PMCF plans) ☐

4. Standardize Study Documentation and Reporting

- Design data collection tools, such as CRFs and study reports, to serve multiple regions from the outset ☐
- Use harmonized language, outcome measures, and statistical analysis plans to simplify downstream reporting ☐

- Check that your documentation aligns with all global requirements (e.g., GCP, GDPR) ☐

5. Plan Early for Post-Market Surveillance

- Don’t wait until the device is on the market to plan for PMCF or literature surveillance ☐
- Integrate post-market strategies into your roadmap early to avoid reactive planning or missed deadlines ☐
- Consider tools like automated literature monitoring to reduce long-term compliance burden ☐