BLA REGULATORY

✅ Sponsor Readiness Checklist

Task	Status
Trial registered on ClinicalTrials.gov or CTIS	☐
Form 3674 completed and signed	☐
Results reporting planned within required timeline	☐
Trial metadata (e.g., PI, dates, phase) consistent across systems	☐
Internal SOPs for ongoing registry updates	☐
Global registry harmonization across study teams	☐
Lay summary prepared (EU only)	☐
Audit trail of changes and version control in place	☐