PRA Health Sciences

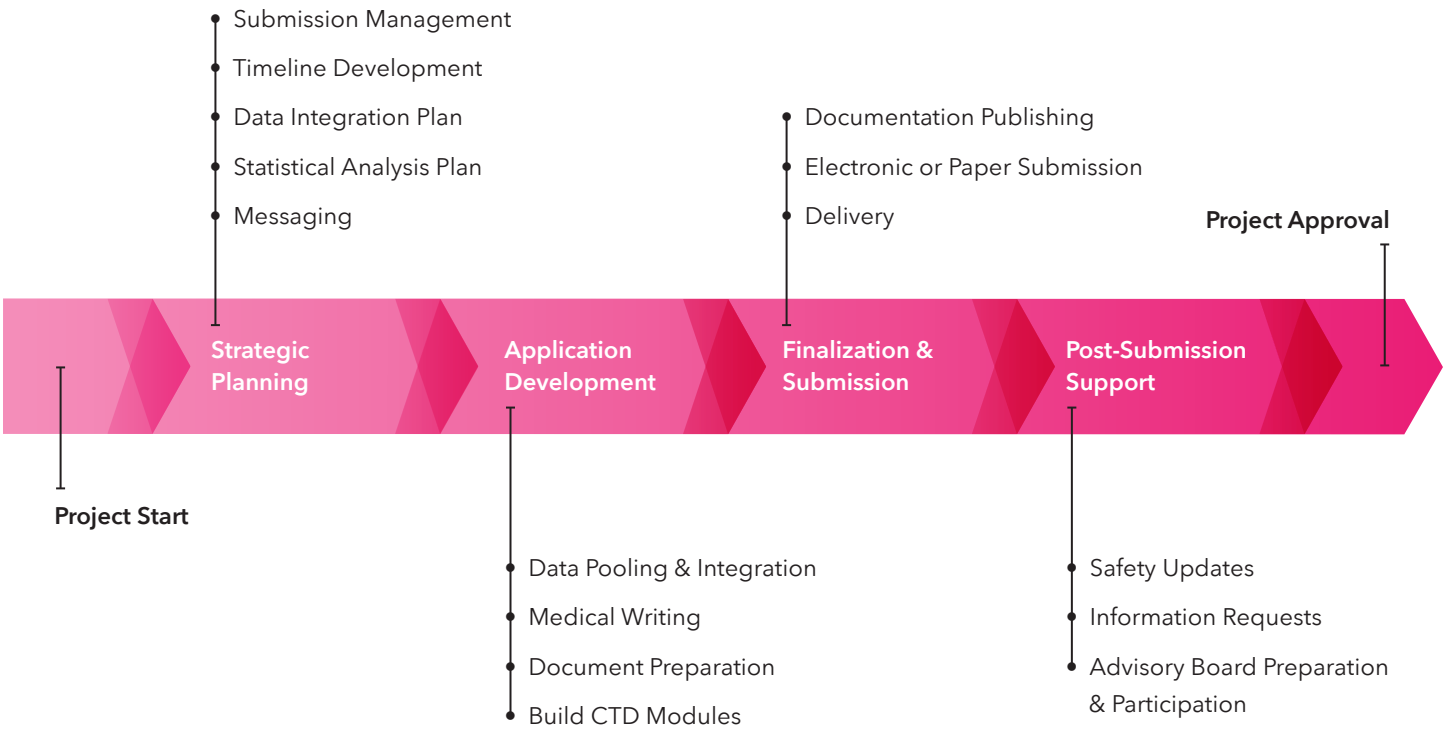
SLIP SHEET

Marketing Application Submission Services

Biopharmaceutical companies' marketing applications must present the history of their unique development programs and provide renewed hope for patients seeking safe and effective therapies. PRA Health Sciences has the necessary experience to deliver comprehensive marketing applications (NDA, BLA, MAA, etc) across all therapeutic areas and in all regions.

Our expert team of biostatisticians, medical writers, project managers, and regulatory professionals apply best practices from decades of submissions experience to collaborate with our sponsors in the development of a customized application strategy.

PRA's Submission Process



Your Partner for Strategic Planning & Execution

During the planning stages, we develop innovative approaches to reduce project costs and application timelines. Once the strategy is adopted, our primary goal is to produce a high- quality, fully compliant application structured to expedite reviews by the regulatory agency. All of our submissions have been accepted for filing.

State-of-the-Art Delivery & Tools

- **EXACT™ –** A comprehensive and flexible metadata management and conversion tool used to create CDISC-compliant deliverables including SDTM, ADaM, and define.xml.
- **MedDRA, WHO Drug –** Access to the latest versions of these and other top dictionaries ensures our sponsors receive thorough, accurate coding services.
- **LORENZ authorBridge™ –** Standardized CTD submission templates ensure consistency across documents.
- **TRS Toolbox Pharma Edition (formerly ISI Toolbox) –** Specialized plug-ins for Adobe Acrobat that aid in bookmarking, inter- and intra-document hyperlinking, page scaling, etc.
- **LIQUENT InSight for Publishing™ –** Powerful software publishes fully compliant eCTD submissions and CSRs.
- **FDA Electronic Submission Gateway (ESG) Account –** Enables direct electronic submissions to the FDA, reducing delivery and review times.
- **PRA Portal –** Secure Web application that facilitates information sharing with sponsors, allowing real-time access to PRA's information systems.

Case Study:

NDA Swiftly Approved – PRA's Submission Services Lead to Success

PRA was instrumental in helping a sponsor achieve FDA approval of its women's health product. The diverse team included representatives from the sponsor, multiple vendors, and multiple disciplines within PRA.

FDA approval came 10 months after the submission, following a single FDA review cycle. PRA assisted the sponsor with responding to the FDA's questions and provided evidence of the drug's safety and efficacy. In addition, a PRA PK expert prepared responses that satisfied the agency's PK questions. Our knowledge and teamwork brought the consistency and perseverance needed to complete the project.

Experienced Teams Delivering a Full Spectrum of Services

Submission Management
Overall project coordination
Team communication
Timeline development and maintenance
Financial management
Risk mitigation
Biostatistics
Recode data to current library specifications for consistent presentation
Pooling of data in CDISC format including documentation (eg, define files)
Summary tables, listings, and figures (TLFs) from integrated data
Medical Writing
Authoring eCTD documents (ie, ISS/SCS, ISE/SCE, and other summaries)
CSR development
Literature searches
Publishing
Document tracking
Document e-submission preparation (bookmarks, hyperlinks, headers, footers, TOCs, eCTD metadata, eCTD XML backbone)
Application preparation and submission
Scientific Consultation
PK/PD
Toxicology
Non-clinical
Regulatory Affairs
Development of documents for CTD Module 1
Consultancy on all CTD modules

Next Steps

Contact Melanie Hasek, Manager, Regulatory Publishing (HasekMelanie @prahs.com) to learn more about our services.