VERISTAT

Expert Regulatory Filings to See Your Regulatory Strategy Through

Format, compile, publish and submit clinical trial and regulatory documents with confidence

Supported Marketing Applications for **12%** of all FDA Novel Drug Approvals in 2021

Submitting Through the Electronic Submissions Gateway (ESG)

An important aspect of any registration plan is a regulatory publishing workflow designed to support a high-quality submission, using a proven process guided by a team of publishing experts.

Veristat's regulatory publishing team offers extensive expertise across the full scope of regulatory requirements, including your applications, amendments, supplements and reports to the United States Food and Drug Administration (FDA) through the Electronic Submissions Gateway (ESG).

Types of Filings Published

- Pre-IND, IND, NDA, ANDA and BLA – inclusive of all supporting submissions (i.e., protocol amendments, investigator documents, expedited pathway submissions, annual reports, etc.)
- Drug Master File (eDMF)
- Commercial Investigational New Drug Application (IND)[1]
- 505 (b)(2), ANDA
- Orphan drug designation
- Fast track designations

A Growing Record of Success Over the Past Two Years

>50 sponsors supported with publishing of INDs, clinical trial documents and marketing applications

29 INDs published

4 Marketing Applications published

>1,750 submissions across the FDA Gateway

[1] Noncommercial INDs and certain medical device INDs reviewed by CBER are exempt from electronic submission. Noncommercial INDs will be accepted electronically, but it is not a requirement.

Providing Oversight, Expertise and Ability to Successfully Publish eSubmissions to the FDA

Backed by the strength of a world-class CRO with 27 years' experience in clinical trial planning and execution for novel therapies, Veristat's regulatory publishing support is part of our regulatory submission solution. Our clients benefit from having end-to-end services – the same team works on your program from a regulatory, CMC and clinical perspective, writes your regulatory documents, and then submits them through the ESG to the FDA.

Our project managers average 10-14 years of publishing experience across a number of therapeutic categories and are ready to put their deep knowledge to work for your submission, providing:

- A collaborative, team-based approach to advise and strategize on your submission
- Overflow publishing expertise available as needed
- Project and timeline management for the publishing process
- Conversion from paper submissions to eCTD format
- Use of standardized templates
- Simplified TS.xpt creation
- Document level publishing
  - Word formatting: styles, captions, cross-references, tables, etc.
  - Report level publishing of E3 and legacy CSRs
  - Validated and QC'd hyperlinks, bookmarks and technical specifications with the support of TRS Toolbox
- Submission level publishing: eCTD placement, cross-document links, study tagging files (STF), submission metadata
- Submission quality control (QC) and validation
- Transmission of submissions to FDA via Electronic Submissions Gateway
- Archive and document transfer: archival of final Word docs and submission sequence

The Publishing Technology: EXTEDO eCTDmanager

Veristat publishing experts manage electronic submissions to the regulatory agencies using EXTEDO eCTDmanager – an eCTD management software solution designed to ensure compliance with ICH and regional regulatory requirements. The technology solution allows us to build, view, validate and publish eSubmissions that are compliant with all global regulatory agencies.

Consult Our Regulatory Publishing Experts

Learn how our regulatory publishing experts will establish realistic timelines and best practices for publishing single documents or full marketing applications.

vwww.veristat.com/services/regulatory-affairs/regulatory-publishing