CFR
labeling
data evaluation
IB
regulatory
CSR
approval
multidisciplinary
clinical trials
simultaneous submission
investigators
placebo-controlled
double-blind
DSUR
adverse events
risk/benefit ratio
IRB
mg/dL
pharmacokinetic
peer-review
mmHg
protocol
FDA
statistical analysis
ICH

Augment your regulatory writing process

MedVal
Scientific Information Services, LLC

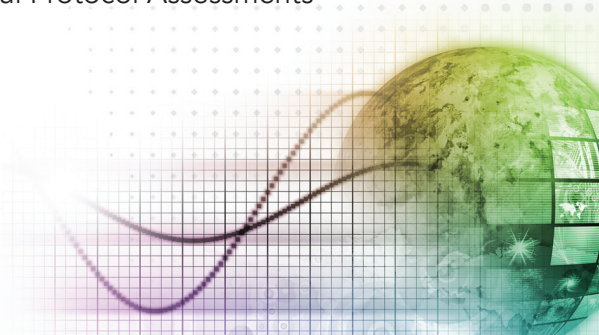
Concise • Strategic • Experienced

MedVal
Scientific Information Services, LLC

Stay ahead of an ever-changing regulatory environment by augmenting your team with our team.

We are your end-to-end regulatory writing solution, with the expertise and resources to provide writing services from preclinical through all phases of clinical research and registration, as well as post-approval.

- Experienced, professional scientific writers who can effectively summarize and integrate data and statistical analyses, presenting information accurately and clearly
- Key documentation in all lifecycle phases of drug/device development
- Flexibility to provide "a la carte" or full-service partnership to enhance your team organizational experience, expertise, and resources
- Devices, pharmaceuticals, *in vitro* diagnostics, vaccines, orphan drug designation, literature-based applications, Special Protocol Assessments



Preclinical Development

At the discovery phase we help you develop an effective regulatory documentation strategy.

Working in partnership with your staff experts, we prepare preclinical reports and summaries. Our experts analyze and interpret data and, with our medical writers, help you pave the way through the regulatory approval process.

- Preclinical reports and summaries
- Pharmacokinetic, pharmacodynamic, and toxicology analyses
- ADME, including drug interactions and toxicokinetics
- Literature searches and reviews

Meetings with Regulatory Authorities

At critical points in the product development and registration lifecycle, it is important to consult with regulatory authorities and present proposals for the next stage in the process. Preparation for these meetings requires the distillation of key issues and questions into a concise "Briefing Package" that will be used to guide discussion and solicit feedback from regulators. It also serves to focus you on the most effective pathway to market approval, identifying opportunities, barriers to success, and enhanced benefit-risk perspectives.

MedVal can help prepare these critical documents, and with our experience in conducting regulatory meetings we can also provide meeting preparation and logistical support.

Our writers will collaborate with your team or manage the document development process to ensure compliance with regulatory guidance and industry best practices.

We understand the importance of a well-written clinical study report (CSR) as a core document in any regulatory submission. We will work closely with your in-house experts to ensure accurate data presentation and interpretation, as well as strict adherence to regulations, guidelines, current industry standards, and your company-specific preferences. Our team of experienced medical writers can quickly analyze data and present these clearly and accurately. In addition, we involve an independent quality assurance team to ensure that the highest standards are met in producing all of your documents.

Research results are positive. Your product is fast-tracked for clinical trials. You need to submit your INDs and IDEs... yesterday.

- We recommend a plan based on your clinical trial development needs, worldwide protocols, product type and class, and innovation level
- Team expertise, coordination, literature search, review process, and submission protocols and scheduling are determined and documents initiated
- Data and documents reviewed and completed, with formal submission to regulatory authorities

Clinical Development

To initiate clinical trials, regulatory authorities in most countries require evidence that investigational products demonstrate potential therapeutic value and an acceptable safety profile, based on preclinical studies and literature references. This evidence must be provided in formal submissions to the authorities for approval prior to initiating the clinical studies.

At MedVal we can provide these specific formal submission documents to initiate clinical trials. We help map out your regulatory needs and provide accurate documentation compliant with applicable regulations and guidelines. Our team of knowledgeable scientific and medical writers produces fit-for-purpose documents consistent with your specifications through all phases of the clinical development process. Our expertise in data interpretation, organization, and presentation enable us to provide high-quality:

- INDs, IDEs (FDA)
- ITAs (Devices for Health Canada)
- CTAs (EU and Health Canada)
- Investigator brochures (including preclinical and CMC sections)
- Protocols
- Literature reviews
- Posting to clinical trials registry
- Informed consent documents
- Investigational product labels
- Clinical safety and efficacy study reports (all phases)
- Patient narratives

Marketing Application and Post-Application

Once the clinical program has been completed, documents prepared are assembled into complex and multi-layered dossiers with integration of data across studies to represent aggregate results. MedVal can construct and submit:

- Module 2 and 5 Common Technical Document (CTD) overviews and summaries
- Integrated Summaries of Safety (ISS) and Integrated Summaries of Efficacy (ISE)

With our experience in preparing submissions, we can guide you in crafting the registration documents in a way that most supports approvability. Types of dossiers include:

- NDAs, MAAs, BLAs, NDSs
- Orphan drug applications
- 505(b)(2) applications

Post-Application

The lifecycle of regulatory documentation doesn't end with a marketing application. With product enhancement and continuing clinical studies and research, new and novel approaches require specialized documents:

- Regulatory response documents
- FDA Advisory Committee briefing documents and presentation slides
- RMPs, RiskMAPs, and REMS
- Clinical trial disclosure
- Postmarketing documents

MedVal's team can complement your existing team by providing "a la carte" services or full-service offerings within the dynamic discipline of regulatory writing.

Please contact MedVal to assist you with your next regulatory initiative.

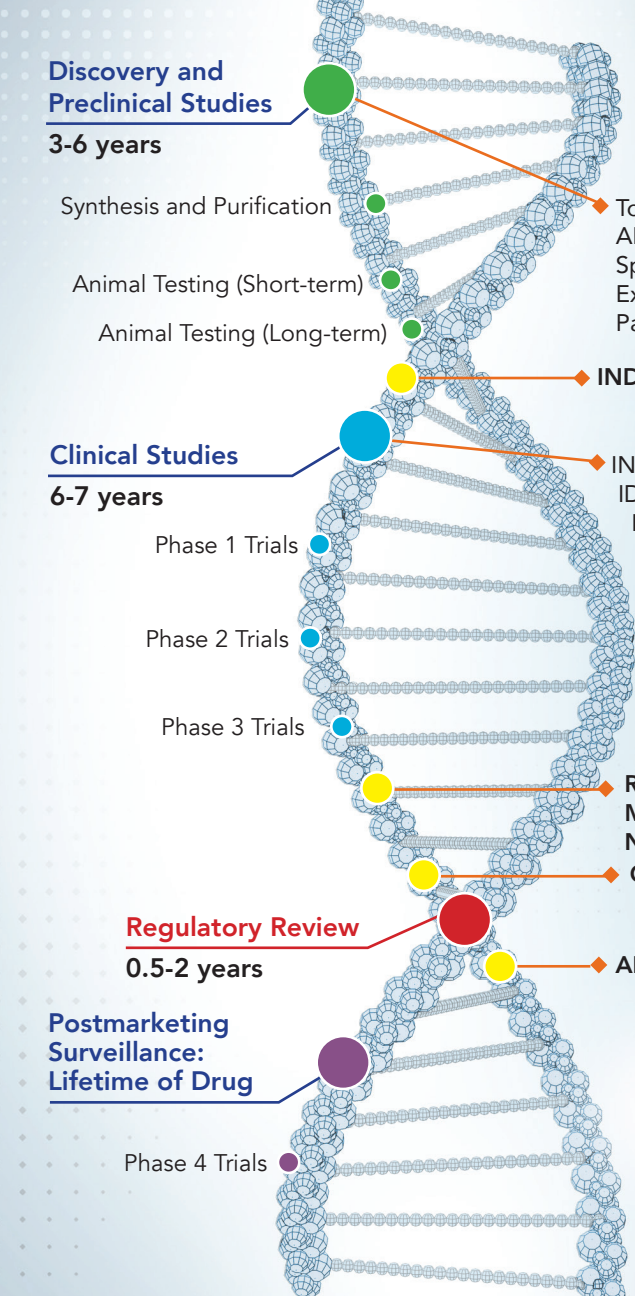
609-945-8832

MedVal

Scientific Information Services, LLC

Drug Development Process

Regulatory Writing/Consulting



Discovery and Preclinical Studies

3-6 years

Synthesis and Purification

Animal Testing (Short-term)

Animal Testing (Long-term)

Toxicology reports
ADME (drug interactions, toxicokinetics)
Specialized periodic reports
Expedited safety reports
Patient narratives

IND submission to FDA (US) or EU regulator

Clinical Studies

6-7 years

Phase 1 Trials

Phase 2 Trials

Phase 3 Trials

INDs (FDA)
IDEs (FDA)
ITAs (Devices for Health Canada)
CTAs (EU and Health Canada)
Investigator brochures (preclinical and CMC sections)
Protocols
Literature reviews
Posting to clinical trials registry
Informed consent documents
Investigational product labels

Registration: NDA/BLA submission to FDA
MAA submission to EU regulator
NDS submission to Health Canada

Generics: ANDA submission to FDA

Regulatory Review

0.5-2 years

APPROVAL granted by regulator; marketing begins

Postmarketing Surveillance: Lifetime of Drug

Phase 4 Trials

MedVal
Scientific Information Services, LLC

Augment your regulatory application team with precision, expertise, and experience

MedVal
Scientific Information Services, LLC

Contact
Rosie Lynch, RPh, CMPP
President
MedVal Scientific Information Services, LLC
175 Wall Street
Princeton, NJ 08540

Direct: 609-945-8832
rosie.lynch@medvalsci.com

www.medvalsci.com/Regulatory-Writing