

Experience – Making a Difference in Your Success: Medical Consulting and Writing Services

Providing you with years of experience for your medical product development strategies and writing needs

Strategic. Accurate. Compliant.

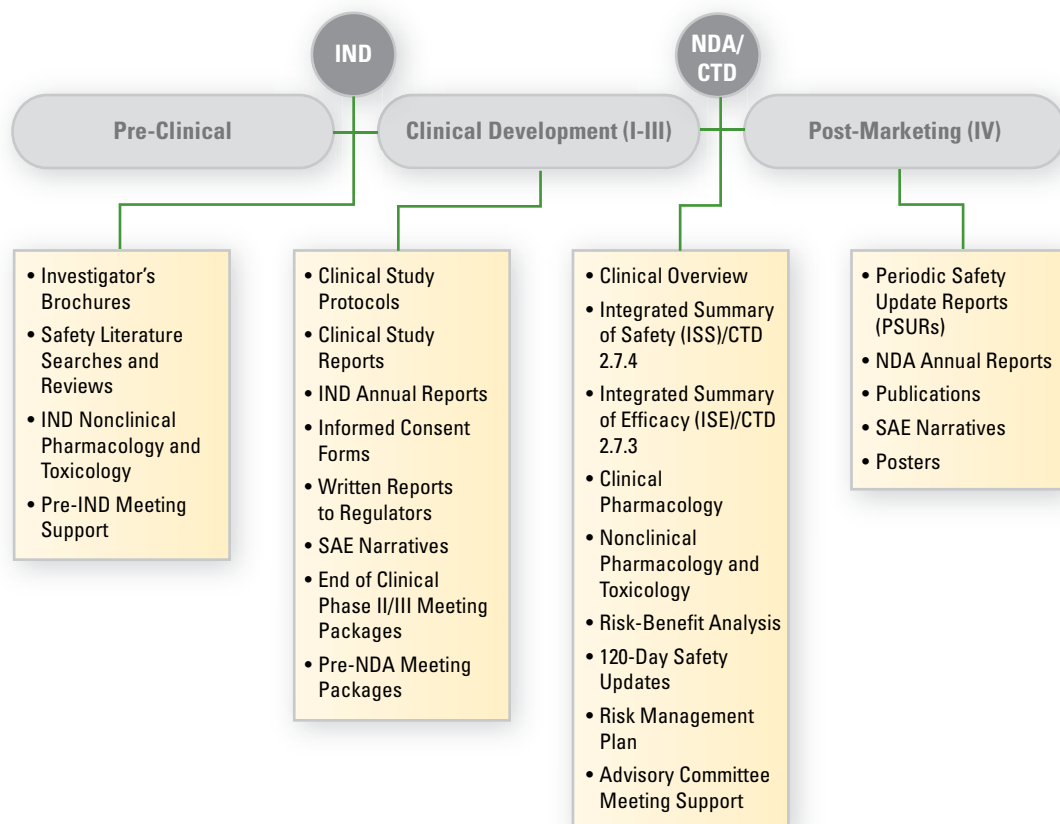
Strict regulatory guidelines and increased drug safety vigilance call for careful consideration in all of your clinical development and post-marketing activities. From developing effective strategies to making accurate safety assessments to ensuring regulatory compliance in your clinical trial reports, we can help you achieve your clinical development and post-approval goals.

Broad Capabilities Focused on Quality

Our medical consulting and writing capabilities run deep. We have extensive experience in most therapeutic areas, knowledge of US and European regulations, and an intimate knowledge of product development and approval processes and safety requirements. Coupled with our broad operational know-how and our commitment to effective medical communications, we will provide you with thoughtful, cohesive deliverables that will stand up to regulatory and industry scrutiny.

Document Preparation: Planning, Writing, and Review

Our medical writing consultants help you develop submission-quality clinical and regulatory reports—from planning, to writing, to review—during each phase of product development.



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Medical Consulting Services

Providing Solid Insight and Deliverables Throughout Product Development

Regardless of the development stage of your new product, our experts can provide trusted strategic consulting and document preparation. Our services include:

- Strategic clinical program development plans
- Pre-IND meetings
- End of clinical phase II/III meetings
- Pre-NDA meetings
- Signal detection
- Risk-benefit analyses
- Risk management plans
- Advisory committee meetings
- Safety literature searches and reviews
- Medical monitoring for clinical trials
- Adverse event and concomitant medication coding review
- Regulatory meeting support

Experience You Can Trust

The experience of your experts and writers can play a critical role in the success or failure of your new products. Our medical professionals have years of experience, so you can count on them to provide objective guidance and deliver comprehensive, high-quality written reports that conform to regulatory requirements, which in turn improves your probability for success.

Expect Excellence

We are dedicated to providing personalized services, customized to meet each client's needs. You'll benefit from our collegial work environment and straightforward, efficient processes. Here, you can expect to work with professionals who are focused on meeting your objectives and a team that remains intact from the initial kick off to completion of your project. We've set the bar high for ourselves and are committed to your satisfaction every step of the way.

Benefit from Our Medical Consulting and Writing Experience

We have experience helping multinational biopharmaceutical companies evaluate and report safety data to regulatory authorities. Our services can be tailored to meet the needs of:

- Small to large pharmaceutical and biotech companies
- Generic drug manufacturers
- Contract research organizations

To learn more about our capabilities, please visit us online at www.rtihs.org, email us at rtihealthsolutions@rti.org, or call one of our offices listed on the front.