At PRI, we're all about **focus.**

Our niche is **medical writing**, including quality control and document preparation.

We're focused on presenting clinical data clearly and accurately.

We also concentrate on the smallest details that can derail a document.

We are passionate about your documents, and it shows.

The end result: a clear and accurate document to meet or beat your timeline.

Precision Research, Inc.
A Contract Research Organization
Specializing in Medical Writing

Precision Research, Inc.

At PRI, we focus exclusively on medical writing including quality control and submission-ready document preparation.

That's why you can turn to us when you want quality and efficiency while meeting tight timelines.

For over a decade, our mission has never changed: to create the highest quality documents. Our goal: get it right the first time.

To achieve this, we'll work closely with you to ensure that documents communicate exactly what you want to say.

We perform quality control on documents written by our clients or our writers. Together we can avoid mistakes that lead to revisions and delays, and then minimize questions from the agencies.

We prepare regulatory documents for submission using industry-approved software, including Adobe Acrobat® and ISI ToolBox®.

And we offer you a menu approach—as little or as much as you need.

Consider using us for all three deliverables—medical writing, quality control, and submission-ready document preparation. You will benefit from:

- Fixed responsibility within one company
- Fluid communication internally and externally
- Efficiency—we work together to accelerate the process
- Consistency and accuracy—we make internal and external checks—within and across documents
- High quality content—with emphasis on clarity and conciseness

The bottom line: you get better documents—faster—ready for submission.

MEDICAL WRITING

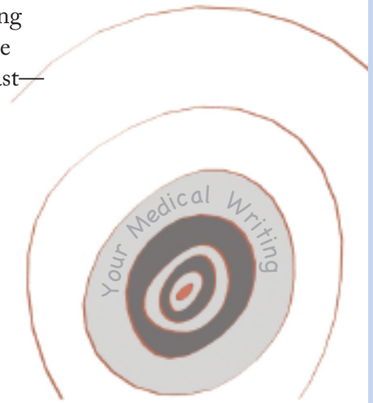
Precision Research, Inc.

You get the depth of expertise and experience you need.

Our knowledgeable and skilled writers share a commitment to serving your best interests. They:

- Create working writing templates for clinical documents in accordance with ICH guidelines
- Are well versed in regulatory requirements: ICH Guidelines and Code of Federal Regulations (CFR)
- Write clinical documents across a wide range of therapeutic indications, for all phases of development, including summary documents for submission
- Interpret statistical data accurately
- Provide clinical input based on interpretation of the data
- Write clearly, concisely, and consistently within—and across—clinical documentation
- Communicate effectively and clearly with physicians, statisticians, data managers, regulatory representatives, and all clinical team members involved in the writing process
- Have command of all aspects of WORD and electronic documentation capabilities
- **We even write the documents no one else wants to write**

Our writers are highly collaborative and skilled in managing the writing process. We work closely with you to create the best documents. We partner with clients from coast to coast—together ensuring document security.



Precision Research, Inc.

Get the medical writers who deliver peace of mind.

Few, if any, CROs have a medical writing department that can match the **PRI team**. We bring you unparalleled breadth and scope of writing experience, including these indications/therapeutic areas:

- Antibiotics
- AIDS
- Antifungals
- Asthma/Allergy
- Immunology
- Internal Medicine
- Gastrointestinal
- Osteoarthritis
- Rheumatoid Arthritis
- Oncology
- Diagnostic Imaging Agents
- Drug Delivery Systems (including liposomes, implantation devices, and transdermal patches)
- Endocrinology
- Parkinson's Disease
- Pain Medications
- Sleep Disorders
- Attention Deficit Hyperactivity Disorder
- Blood Products

You can entrust your study report, New Drug Application (NDA), or Biological Licensing Agreement (BLA) to PRI. Our writers need minimal instruction and supervision, saving you valuable time. Yet we're here when you need us—in person and via e-mail, phone, or fax.

Precision Research, Inc.

Has an agency ever posed questions arising from avoidable errors?

Document quality control is often neglected or overlooked.

As lengthy, complex, and multiple documents are developed, mistakes are often made because of:

- Inadequate or lack of knowledgeable staff on the project
- Inaccurate or incomplete information
- Inconsistent or conflicting data within or between documents
- High-pressure timelines
- Misinterpretation of data

At PRI, we view quality control as essential and complementary to medical writing. Document quality control is necessary to avoid problems that may cause delays in submission or agency review. PRI:

- Works on **all clinical documents** relevant to NDAs and BLAs
- Engenders the same kind of **collaborative approach** as with medical writing
- Partners with clients and adds value by becoming part of the **review process**
- **Detects errors** in the database that can be corrected prior to regulatory submission
- Provides **clinical input** that enhances document development
- Ensures **consistency** where needed—within and between documents

PRI routinely provides quality control for:

- Clinical Investigator Brochures and their annual updates
- Protocol and Protocol Amendments
- Clinical data (including summary tables and listings)
- Patient narratives
- Interim and Final Clinical Study Reports
- All NDA/BLA submission documents
- Periodic and Post Approval Safety Updates
- Responses to agency inquiries

Our document Quality Control is distinct from your Quality Assurance (QA) review. We focus on the document and its data.

You can also turn to PRI for medical writing and quality control for documents that are not part of a submission package.

Submission-Ready Document Preparation

Precision Research, Inc.

Just as document quality control is essential to high quality medical writing, so is the final preparation of documents for submission to regulatory agencies. That's why PRI:

- Prepares regulatory documents for submission using industry-approved software, including Adobe Acrobat® and ISI ToolBox®
- Inserts PDF bookmarks and hyperlinks in accordance with FDA Guidance for Industry and provides quality compliance to ensure completeness and accuracy
- Provides submission-ready output of regulatory documents in accordance with ICH and CFR guidelines

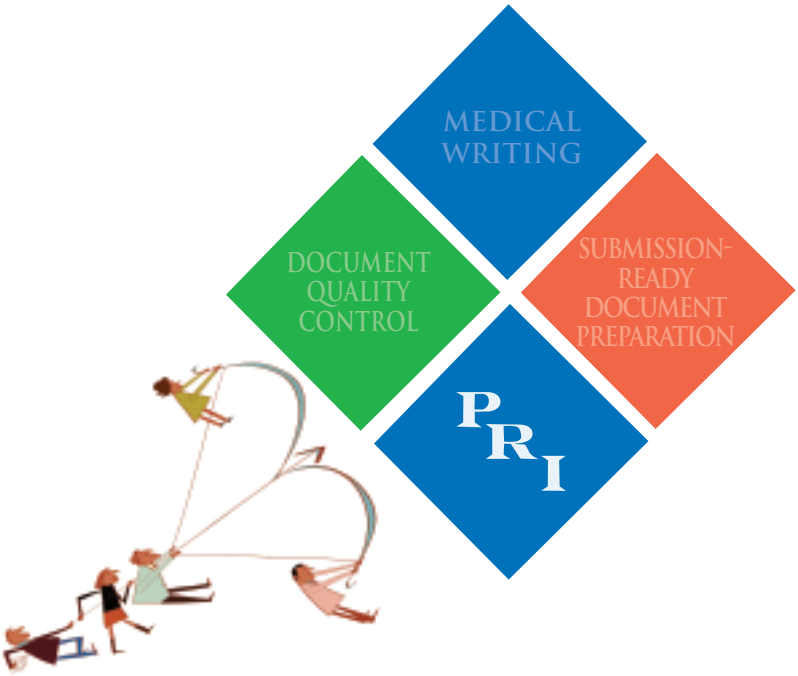
If you want agencies to receive documents in a reviewer-friendly format, PRI can help.

PRI Focuses on These Clinical Documents

Precision Research, Inc.

		Common Technical Document (CTD) Submission Format
		Clinical Overview Documents (Section 2.5)
		Overview of Efficacy (2.5.4)
		Overview of Safety (2.5.5)
		Benefit/Risk Conclusions (2.5.6)
		Nonclinical Written and Tabulated Summaries (Section 2.6)
		Clinical Summary Documents (Section 2.7)
		Summary of Clinical Pharmacology (2.7.2)
Investigator Brochure		Summary of Clinical Efficacy (2.7.3)
Protocol and Amendments	Data	Summary of Clinical Safety (2.7.4)
CRF	Phase I-IV CSRs	Integrated Summary of Efficacy
CSR Template	Patient Narratives	Integrated Summary of Safety

Blue = PRI can provide both medical writing and quality control
Red = PRI provides medical writing only
Green = PRI provides quality control only



Why PRI is the Perfect Partner

When it comes to medical writing and/or quality control of your documents, PRI can **save you time and money**. We work with you to solve problems and avoid expensive mistakes, headaches, and delays—always impacting the bottom line.

We're all about **focus**—on **medical writing, document quality control, and submission-ready document preparation.**

We deliver **peace of mind.**

For more information or to arrange a meeting:

Contacts:
Senior Director of Medical Writing:
Ms. Nancy Sobieck (email: nsobieck@precise.net)
Manager of Document Quality Control:
Mr. Chris Cusumano (email: ccusumano@precise.net)

Precision Research, Inc.
5 Great Valley Parkway, Suite 283
Malvern, PA 19355 USA
610-296-1744 • Fax 610-296-1745
Visit us online at **www.precise.net**

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