

# Let us help you meet your NDA timelines.

With 60 years of combined experience in the pharmaceutical industry, our writers take a project and run with it.

*Whether your need is URGENT or about-to-become URGENT, turn to medical writers with the experience and skill to come through every time.*

When you have to get an NDA done quickly and you don't have the time to hold someone's hand until it's done right, you need a professional medical writer who not only knows how to do the job, but will help provide the leadership to make the process as efficient as possible.

When the study reports you need get neglected—suddenly moving from the back burner to the front burner—you need writers with expertise in the subject matter, familiarity with regulatory guidelines, and the ability to complete each report with minimal supervision and revision.

That's where PRI comes in.

When you turn to us, you get the peace of mind only experienced, highly capable medical writers can deliver. On the one hand, our writers need minimal instruction and supervision, saving you valuable time. On the other hand, we're there when you need us—in person, via e-mail, phone or fax.

We approach writing for clinical documentation as a highly interactive process. Strong communication links are established between the writer and the physician, statistician, and regulatory representative. The writer becomes part of the project team and attends all meetings, whether writing for an NDA submission, protocol, or clinical study report. This close interaction with the team produces the highest quality documentation.

And that, of course, is our common goal.

## GET THE MEDICAL WRITERS YOU'VE ALWAYS WANTED.

Few, if any, pharmaceutical companies have on staff 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:

- Cardiovascular (antihypertensives, antidepressants, antiepileptics, selective serotonin reuptake inhibitors for obsessive compulsive disorder)
- Anti-infectives (antibiotics, antifungals, non-nucleoside reverse transcriptase inhibitors)
- Asthma/allergy (antihistamines, bronchodilators)
- Immune system modulators (Non-hodgkin's lymphoma)
- Internal medicine (osteoporosis, bisphosphonates)
- NSAIDs
- Gastrointestinal (proton pump inhibitors)
- Osteoarthritis
- Rheumatoid arthritis
- Oncology
- Diagnostic imaging agents
- Drug delivery systems, including liposomes and implantation devices
- Endocrinology (Type II diabetes mellitus)

At PRI, we can also provide drug development and physician support. And we maintain rigorous Quality Control of all medical writing documents.

Our medical writers possess advanced word processing skills, including mastery of complex data displays and Microsoft Word based templates. And they have experience in creating virtually any document, including:

- Phase I-IV Clinical Study Reports
- Clinical/Statistical Sections for NDAs including:
  - Application summaries
  - Risk/benefit assessments
  - Background/overview
  - Scientific rationale
  - History of FDA communications
  - Integrated summary of safety
  - Integrated summary of efficacy
  - Clinical data summary
  - Clinical pharmacology
- European submissions
  - Written summaries
  - Expert reports
- Safety Updates
- Post Marketing Clinical Reports
- Clinical protocols
- Manuscripts
- Abstracts
- Investigator brochures
- Posters

## THE PROOF IS IN THE PRODUCT.

At the end of the day, what matters is that your Clinical documents are clear, concise, and accurate. When we meet with you, we'll give you a sample of our work. You can judge its quality for yourself.

*PRI is the next best thing to having extra top notch writers on staff.*

*We'll provide you a sample of our work so you can see the PRI difference for yourself.*

