

Medical Writing

Medical Writing and Document Management – Bringing our experience to enhance your business

Medical writing
and document
management
expertise you
can *depend* on

- ✓ Well-integrated, efficient group with many years of working together
- ✓ Adequate size to ensure smooth workflow during peak and trough times
- ✓ Complementary skills and knowledge to provide the full range of writing and consultant services
- ✓ Broad experience of different pharmaceutical products and therapeutic areas
- ✓ Broad experience of working in international and cross-functional teams
- ✓ Existing international contacts and reputation

As members of various international expert working groups since 1992, we have actively contributed over the past decade to the development of the following crucial guidance documents:

- ✓ ICH E3 “Structure and Content of Clinical Study reports”, issued in 1995
- ✓ ICH M4 “Common Technical Document”, issued in 2000
- ✓ “Good Publication Practice for Pharmaceutical Companies”, issued in 2003

With our insight into these guidelines, we can support your template development and onsite training, and help you interpret and apply key ICH and other principles most effectively to the design of your regulatory documentation and to your strategic publication planning. The bottom line of any clinical study program will always be the risk-benefit ratio, and you can be sure that by using the **ACCOVION approach**, this will be presented in the most timely and convincing way to your key audiences.

✓ Service Summary

Medical Writing Services

- ✓ Investigator brochures
- ✓ Investigational medicinal product dossiers (IMPDs) for clinical trial applications
- ✓ Investigational new drug (IND) applications
- ✓ Preclinical reports and summaries
- ✓ Clinical study protocols for all development and postmarketing study phases
- ✓ Clinical study reports for all development and postmarketing study phases, including population pharmacokinetics, health outcomes research and pharmacogenomics
- ✓ Patient safety narratives
- ✓ Clinical summaries and overviews (expert reports) for worldwide regulatory submissions
- ✓ Responses to questions from regulatory authorities
- ✓ Clinical publication manuscripts and conference posters
- ✓ Standard operating procedures
- ✓ Manuals and templates for document standards

for more information visit us at

www.accovion.com

Medical Writing

Document Management Services

- ✓ Production of published and fully cross-referenced preclinical and clinical reports and registration dossiers.
- ✓ Expertise with the latest high-speed scanning and image enhancement technology (Ascent Capture®, Imaging for Windows®, ISIFile™) and document management and publishing software applications (Documentum® and CoreDossier™)
- ✓ Streamlined business process: Full integration of the publishing specialists and document managers into the project team - seamless cooperation with the medical writers, biostatisticians, IT specialists and regulatory affairs specialists.
- ✓ Entirely electronic compilation of documentation: Documents made available both electronically and as paper, with GCP-compliant physical archiving.

Management, Consultancy, Standardization and Training

- ✓ Management and development of the medical writing business, contacts with freelancers, CROs and agencies
- ✓ Input into clinical development and project plans on medical writing issues
- ✓ Resource management of medical writers
- ✓ Co-ordination and management of medical writing activities on international project teams
- ✓ Interpretation of regulatory guidance and structuring of clinical submissions
- ✓ Development and maintenance of internal standards and templates for:
 - *Clinical development plans*
 - *Clinical study protocols*
 - *Clinical study reports*
 - *Investigators brochures*
 - *Tables for clinical data*
 - *Clinical summary documentation*

—✓ Document Power:

Powerful documents add power
to your results, power to your message
and power to your business.

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