

STRATEGIC MEDICAL WRITING

MEDRIKA

CONSULTING S.L.



WHO WE ARE

MEDICAL WRITERS WITH A
STRATEGIC VISION TO
SUPPORT YOU BEYOND
JUST WRITING

MEDRIKA
CONSULTING S.L.



- ★ Focus on your audience
- ★ Strategic thinking
- ★ Optimization of document development
- ★ Creative problem-solving
- ★ Project Management - to shepherd your team toward a timely high-quality delivery
- ★ Seniority - experienced Medical Writers
- ★ Writing in **ENG-GER-SPA-FRA**

1A REGULATORY WRITING

STUDY CONDUCT OPTIMIZATION

- Protocol & Synopsis
- Informed Consents
- Investigator's Brochures
- Consistency checks of trial docs (CRF, SAP)

STUDY MATERIALS

- SIV's slide decks
- Site newsletters
- instructions for patients/sites

STUDY OUTPUTS

- Clinical Study Reports
- Patient narratives
- Biomarker Reports

1B REGULATORY WRITING

CLINICAL DEVELOPMENT

Pediatric Plans (EMA, FDA)
Clinical Modules 2.5, 2.7
Briefing Documents (EMA, FDA, CDE, PMDA)
Answers to Objections
FDA Diversity Plan

SAFETY OVERVIEWS

Investigator's Brochure
Benefit-Risk Strategy
Documents
SmPC

MEDICAL DEVICES

Clinical Evaluation Reports
Clinical Investigational Plans
Clinical Investigational Reports
Instructions for Use
Technical Dossiers

2 MEDCOMMS - PEER-REVIEW

ARTICLES

Reviews

Study results (e.g., clinical trials, NIS)

Case reports

Editorials

White papers

PRE-SUBMISSION CHECKS

Publication guidelines checks

Quality control article

SUBMISSION

Cover letters

Responses to peer reviewers

Publication plan management

Re-formatting to new journal

Creation of reference libraries

3 MEDCOMMS - CONGRESSES

PRE-CONGRESS

Abstracts

Posters

Scripts for video posters

Slide decks for oral presentation

Congress planner

Pre-congress eBook decks

POST-CONGRESS

Congress highlights

Congress reports

Congress poster book decks

Congress newsletters

4

MEDICAL AFFAIRS

SLIDE DECKS

- Global core content decks
- Pipeline overview decks
- Key clinical questions decks
- Key study results decks
- Competitive clinical landscape decks

LEAVE-BEHIND LEAFLETS

- Products
- Clinical summaries

REFERENCES

- Citation style checks
- Creation of reference libraries
- Sanity check of reference

- Proactive & reactive marketing materials
- Advisory Board coverage
- Product monograph
- White papers
- Value stories
- Literature searches

5 PROCESS DEVELOPMENT & OTHERS

REGULATORY DOCUMENTS

Standard Operating Procedures

Working Instructions

Medical Writing process set-up

Style guides

Regulatory document templates

6 WORKSHOPS

REGULATORY WORKSHOPS

Briefing Documents: for Medical Writers
Clinical Study Protocols
Clinical Study Reports

MEDCOMMS WORKSHOPS

EndNote training
Lean & deductive writing

7 QUALITY CONTROL

REGULATORY DOCUMENTS

Protocols

Clinical Study Reports

Investigator's Brochures

eCTD modules

Any other regulatory deliverable

MEDICAL COMMUNICATION

Articles

Literature

Any other MedComms deliverable