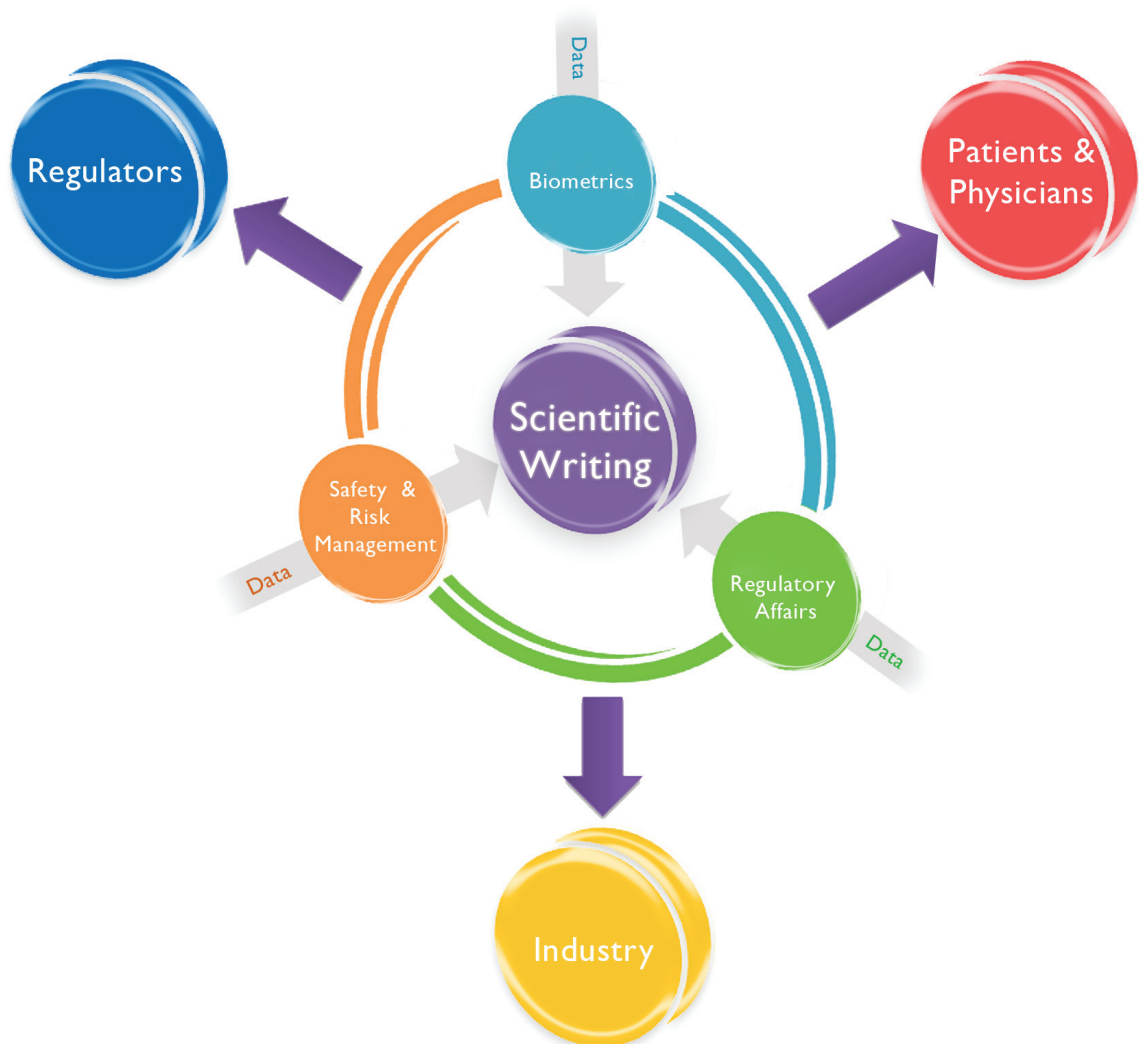


Scientific Writing

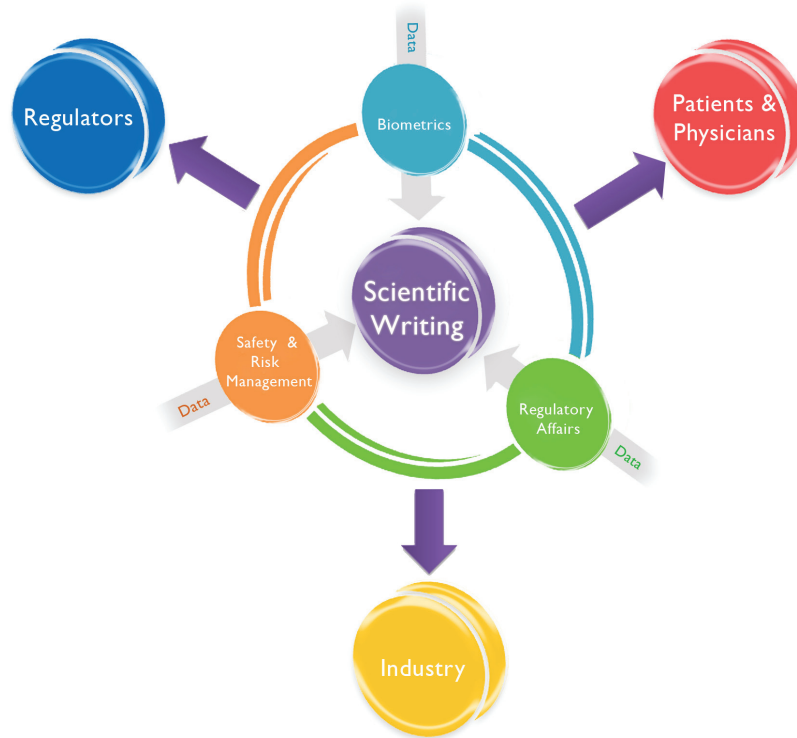
Custom Summary, Custom Communication



Our Scientific Writing Services span across all phases of the product lifecycle – from preclinical development to post-marketing surveillance. The scientific writing team actively collaborates with our biometrics, safety and regulatory teams to deliver high quality reports in the required timelines.

We succinctly summarize and communicate results, from the information we process, for dissemination to a wide range of audience including patients, physicians, regulators and the industry.

Our team of highly qualified and experienced writers includes doctorates, physicians and pharmaceutical graduates, with expertise in a wide range of therapeutic areas.



Our writers interpret and summarize data analyzed from clinical studies or from spontaneous or literature adverse event reports and present the clinical and medical relevance of the data in the reports we author. Our team has significant experience and skill in synthesizing and translating complex data analysis into cogent documents.

We have in-depth understanding of product development, safety requirements, drug approval process and US and European regulations. Our analytical skills coupled with sound medical, clinical and pharmacological understanding, help us produce a wide variety of high quality reports.

Safety Writing

The scientific writing team works closely with our pharmacovigilance team to support safety reporting for all stages of the product life cycle. Aggregate reporting is closely aligned to our pharmacovigilance service of individual case processing and we often provide both these services in tandem to our clients.

We provide complete support on aggregate reports, from maintaining the schedule and sending out calls for contributions all the way to submission of finalized document to the regulator.

Regulatory Writing

Documents that summarize safety, efficacy and manufacturing information for a product require specific understanding of the regulations for reporting & submission, especially of the CTD/eCTD format. At Sciformix, our scientific writers collaborate actively with our regulatory experts to author these regulatory documents.

Our writing team employs a clearly defined and time-bound process for preparation, assembly, and review of documentation that includes adequate scientific and regulatory inputs from our experts. We employ our proprietary style guide, based on defined standards. We also use client templates and formats, when necessary.

Safety Writing

Specifications & Standards

- Post-marketing periodic safety reports - PSURs, NDA PRs/PADERS, Summary Bridging Reports, Ad-hoc Reports
- Pre-marketing safety reports - IND ARs, EU ASRs
- Safety case narratives
- Patient Medication Guides
- Risk Management Plans

Regulatory Writing

Study Design

- Company Core Data Sheets (CCDS)
- Summary of Product Characteristics (SmPC)
- Patient Information Leaflets
- Nonclinical & Clinical Overviews (Modules 2.4 & 2.5 of CTD)
- Nonclinical & Clinical Summaries (Modules 2.6 & 2.7 of CTD)
- Application for Bio-waivers

Clinical Writing

Our scientific writing team works extensively with our Biometrics team, therapy area experts and the client's clinical operations team to deliver a variety of documents to support clinical development. Most of our writers have several years of experience in authoring clinical documents for global clinical trials.

Our scientific writing services leverage our medical and writing expertise to create the messaging that will help you in the launch and brand positioning of your product. Our writers develop medico marketing literature that will help you reach the target audience, be it consumers, prescribers, health care providers or key opinion leaders.

Clinical Writing

- Clinical trial protocols
- Investigator's Brochure (IB)
- Clinical Study Reports (CSR) & web synopses
- Informed Consent Documents
- Abstracts & Manuscripts
- Product Monographs
- CME Content and Training Modules
- Patient Education Material
- Standard responses to medical queries
- Product-specific Web content

Talk to us to identify how we can help you deliver the right message.

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