SUMMARY OF MEDICAL WRITING EXPERIENCE

OVERVIEW

- Extensive training and experience in medical writing and management; average of 8 years regulatory and post marketing experience
- Ten years of experience working with members of the biostatistics department on multiple projects and writing assignments
- Experience with several successful NDA submissions

DOCUMENT PORTFOLIO SYNOPSIS

Individual Clinical Study Reports

- Three bioavailability studies for an oral asthma medication
- A dose escalation study for an injectable asthma medication
- Seven Phase 1 and Phase 2 studies for a long-acting anticholinergic agent for COPD under development in both MDI and nebulized formulations
- A Phase 1 and four Phase 2 studies of a topical medication for atopic dermatitis
- A Phase 1 bioequivalence study, an open label study, and a Phase 3b study of a medication for psoriasis
- Six studies (Phase 1 through Phase 3) for a soft steroid administered intranasally for allergic rhinitis
- A Phase 1 study in patients with relapsed multiple myeloma
- Two Phase 2 studies in patients with metastatic colorectal or ovarian cancer
- A Phase 1 study in patients with solid tumors
- A Phase 2 study of a topical medication for wound healing
- Two Phase 1 studies for an injectable medication for multiple sclerosis

SUMMARY OF MEDICAL WRITING EXPERIENCE (p. 2)

New Drug Applications

- Preparation of a full NDA, including ISS, ISE, Summary of Risk Benefit and other summary sections for an oral asthma medication
- Preparation of a full NDA for a long-acting beta agonist for COPD, including Clinical Study Reports for Phase 1 – Phase 3 studies, ISS, ISE, and other summary sections
- Preparation of a full NDA for a nasal steroid for allergic rhinitis, including Clinical Study Reports for 13 studies, ISS, ISE, and other summary sections
- Preparation of a full NDA for an ocular antihistamine for allergic conjunctivitis, including ISS, ISE, Application Summary, preclinical sections, and individual study reports of 19 studies
- Preparation of a full ISS for a rare disease drug submitted to EMEA

Investigator Brochures

- Three Investigator Brochures for a nebulized COPD medication
- Investigator Brochure for an asthma medication
- Investigator Brochure for a medication for Idiopathic Pulmonary Fibrosis
- Investigator Brochure for a cardiovascular medication
- Investigator Brochure for an autoimmune disease medication

Commercialization Support

- Commercialization support of a marketed oral asthma medication, including a Phase 4 trial and several articles published in peer-reviewed journals with PROMETRIKA staff as co-authors
- Phase 4 support of an oral antibiotic indicated for AECB, including pharmacoeconomic analyses for formulary submission and a Phase 4 trial

Other Documents

- Several pre-NDA packages for medications for allergic rhinitis, asthma, allergic conjunctivitis, and COPD
- Numerous protocols for Phase 1 to Phase 4 studies in a variety of indications