

# Summary of Strategic Competitive Analysis and Publication Planning

Carole Alison Chrvala, PhD

919.545.2149 (Work) 919.951.5230 (Mobile)

[cchrvala@centurylink.net](mailto:cchrvala@centurylink.net)

[www.healthmattersmedwriting.com](http://www.healthmattersmedwriting.com)

- Publication plan and scientific platform for a novel inhaled prostacyclin for pulmonary arterial hypertension, New York Heart Association Class II-IV
- Systematic review of published and fugitive literature on current and anticipated challenges in the management of pulmonary arterial hypertension to support the development of a publication plan
- Briefing document on targeted antibody treatment for newly-diagnosed multiple myeloma
- Briefing document on FLT-3 inhibitor treatment of relapsed and refractory acute myeloid leukemia for submission to the Oncologic Drugs Advisory Committee, US Food and Drug Administration
- Strategic analysis to identify, assess, and prioritize engagement with key opinion leaders and international congresses with a focus on pipeline therapies for 11 tumor types
- Preparation of slide presentations and supporting materials for submission to a Food and Drug Administration Advisory Committee to review the efficacy and safety of a humanized, anti-eosinophil monoclonal antibody for the treatment of severe uncontrolled asthma with eosinophilic phenotype
- Disease area review to identify unmet needs and develop a value proposition to support a selective monoclonal antibody for moderate-to-severe hidradenitis suppurativa
- Pragmatic landscape review, evidence mapping, and development of a payer value story to support a selective beta<sub>3</sub>-agonist for overactive bladder
- Literature review, summary, and interpretation of findings regarding current and emerging therapies for renal cell carcinoma
- Global value dossier on first- and second-line therapies for metastatic renal cell carcinoma
- Data collection, analysis, and strategic direction on the economic burden and patient-reported outcomes associated with primary and secondary patency loss of arteriovenous fistula access in patients with chronic kidney disease and peripheral artery disease
- Preparation of an investigational new drug briefing package for submission to the Food and Drug Administration to change the marketing status of an emergency contraceptive product from prescription to over-the-counter status

- Benefit-risk analysis to support a feasibility analysis for FDA submission to approve over-the-counter access for an emergency contraceptive
- Scientific platform and publication plan for a targeted cytotoxic peptide conjugate for ovarian and endometrial cancer
- Comparative review of emerging treatments for relapsed/refractory multiple myeloma
- Review of patient and disease profiles associated with increased risk of cardiovascular events to support a feasibility analysis for FDA submission to approve over-the-counter status for short-term use of nonsteroidal anti-inflammatory drugs and cyclooxygenase-2 selective inhibitors for mild pain associated with arthritis and musculoskeletal pain
- Review of health conditions characterized by vasomotor symptoms and a feasibility analysis for FDA submission to approve over-the-counter status for an agent prescribed for moderate-to-severe vasomotor symptoms
- Research consultant and biostatistician for a quasi-experimental study to evaluate the impact of a patient safe-handling intervention on rates of healthcare worker injuries and identify barriers and incentives to worker adherence to the intervention
- Comprehensive analysis of overactive bladder syndrome including incidence, prevalence, symptoms, risk factors, diagnosis, disease progression, comorbid conditions, physical and psycho-emotional consequences, direct and indirect economic costs, and a temporal overview of current and emerging treatments
- Competitive analysis of targeted therapies for BRAFV600-mutation positive metastatic melanoma
- Analysis of the role of an investigational, oral tyrosine kinase inhibitor for advanced malignancies, including ALK-positive non-small cell lung cancer with and without brain metastases, compared with crizotinib, ceritinib, and alectinib
- Evaluation of the costs and benefits of early intervention for nonalcoholic steatohepatitis to reduce the risk of cardiovascular disease
- Publication plan for a new product launch based on analysis of preclinical and clinical research on the epidemiology, pathophysiology, and treatment of lysosomal acid lipase deficiency

- Development and quarterly updates for a 3-year publication plan to support a novel treatment for nonalcoholic steatohepatitis and nonalcoholic fatty liver disease based on an in-depth review and analysis of clinical data, published and fugitive literature, conference proceedings, interviews with subject matter experts, CME activities, and medical press
- Case-based training workshop and pre-read materials for clinical sales specialists on the diagnosis, risk stratification, electrocardiography, other imaging tests, coronary anatomy, the role of angiographic evaluation, and pharmacologic therapies for acute coronary syndrome
- Preparation of a payer value proposition communication plan for the role of bevacizumab in colorectal cancer, glioblastoma multiforme, non-small cell lung cancer, and renal cell carcinoma
- A global analysis of current practice gaps and educational needs based on literature reviews and interviews with thought leaders in multiple sclerosis, HIV/AIDS, dementia, diabetes, psychiatry, and cardiovascular disease
- Publication plan based on an analysis of preclinical and clinical research on a combination of long-acting insulin and a GLP-1 inhibitor for type 2 diabetes mellitus
- Publication plan based on an analysis of preclinical and clinical research on the effect of SGLT2 inhibitors for type 2 diabetes mellitus
- Training program for clinical sales specialists characterizing preclinical and clinical research on endometriosis and uterine fibroids, including pathophysiology, incidence, prevalence, symptoms, risk factors, disease progression, comorbid conditions, physical and psycho-emotional impact, economic burden, and the risks and benefits of current and emerging therapeutic options
- Analysis of preclinical and clinical research on a novel androgen receptor antagonist for castrate-resistant prostate cancer to support new product launch
- Training program for clinical sales specialists on an oral multi-kinase inhibitor for metastatic colorectal cancer
- Analysis of the effect of cholesteryl ester transfer protein inhibitors on vascular function, progression of atherosclerosis, and future cardiovascular events to support a new product launch

- Sales training program on tissue plasminogen activators for myocardial infarction, pulmonary embolism, and stroke
- Comprehensive analysis of the global burden of uterine fibroids including evaluation of incidence, prevalence, symptoms, risk factors, disease progression, comorbid conditions, physical and psycho-emotional impact, and current and emerging therapeutic options
- Training program on ovarian cancer for clinical oncology specialists including epidemiologic burden, risk factors, diagnosis, current and emerging treatment options, and the role of angiogenesis inhibitors
- Comparative evaluation of treatment options and toxicities for hematologic cancers, with an emphasis on allogeneic and autologous bone marrow transplantation and graft-versus-host disease
- Analysis of emerging treatment options and patient forecasting for triple-negative breast cancer
- Comprehensive analysis of the worldwide epidemiologic burden of endometriosis among the general population and high-risk women, including evaluation of incidence, prevalence, symptoms, risk factors, disease progression, comorbid conditions, physical and psycho-emotional impact, and a temporal overview of past and current therapeutic options
- Analysis of the epidemiologic burden of obesity and comorbid health conditions and a comparative review of the efficacy and safety of pharmacologic and surgical interventions for obesity
- Analysis of preclinical and clinical research published in 2010 addressing the management of breast cancer
- Analysis of preclinical and clinical research on novel immunotherapies for hormone-refractory prostate cancer to support new product launch
- Comparative review of the efficacy and safety of pharmacologic interventions for type 2 diabetes mellitus
- Analysis of preclinical and clinical research on the efficacy and safety of inhibitors of apoptosis for diverse solid tumors, including identification of strengths and limitations of current publications and presentations and development of a publication plan for new product launch
- Comparative analysis of new therapeutic interventions for pulmonary arterial hypertension

- Comparative analysis of new therapeutic interventions for HIV-1 and chronic hepatitis B
- Analysis of preclinical and clinical research on monoclonal antibodies for breast cancer, including identification of strengths and limitations of current publications and presentations and development of strategies to support future publications
- A comprehensive, competitive market analysis on current and emerging health issues and the healthcare delivery system in China
- Comparative analysis of new therapeutic interventions for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis
- Comprehensive competitive market analysis on current and emerging health issues and the healthcare delivery system in Russia
- Analysis of preclinical and clinical research on antiangiogenic therapies for diverse solid tumors to identify strengths and limitations of current publications and presentations and identify strategies to support a publication plan for a new product launch
- Review of published literature and conference proceedings on basic pharmacology, randomized controlled trials, patient registries, and observational studies for a gap analysis on percutaneous coronary interventions with drug-eluting stents for coronary artery disease
- Review of published and fugitive literature, interviews with subject matter experts, and preparation of a gap analysis on pharmacologic interventions for angiogenesis inhibition
- Consultant to pharmaceutical company on dyslipidemia interventions, including product and publication reviews, research design, statistical analysis, and interpretation of post-marketing surveillance data
- Consultant to medical device company on the efficacy and safety of devices for heart failure, including publication reviews, research design, statistical analysis, and interpretation
- Consultant to pharmaceutical company on product and publication reviews, research design, and statistical analysis and interpretation
- Comparative review of the efficacy and safety of GLP-1 analogues and DPP-4 inhibitors for type 2 diabetes mellitus

- Competitive market analysis based on a comprehensive summary of literature on barriers and motivators to compliance with a vaccine program for HPV
- Publication plan based on a review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions for chronic obstructive pulmonary disease
- Publication plan based on a review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions for castrate-resistant prostate cancer and associated pain
- Publication plan based on a review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions for hypertension