

## Summary of Research and Writing Activities in Oncology

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**Manuscripts, Posters, Slide Sets, and Abstracts**

- A retrospective analysis of registry data to evaluate the demographic and clinical characteristics; efficacy and safety outcomes; healthcare resource utilization; and patient-reported outcomes in patients with advanced non-small cell lung cancer treated with oral tyrosine kinase inhibitors for *Annals of Oncology*
- Phase 1 study of the safety and efficacy of nivolumab in combination with ipilimumab in metastatic renal cell carcinoma for *Journal of Clinical Oncology*
- Implications of luteinizing-hormone-releasing hormone (LHRH) and its analogs for the inhibition of LHRH-receptor-positive solid tumors for *Oncotarget*
- Review of new and emerging therapies for advanced, recurrent, or metastatic endometrial cancer for *Gynecologic Oncology*
- Comparative review of the mechanism of action of emerging targeted therapies for advanced, recurrent, or metastatic endometrial cancer for *Clinical Cancer Research*
- Comparison of treatment strategies for older patients with chronic lymphocytic leukemia for *American Journal of Hematology*
- Comparative effectiveness of chemotherapy for treatment of elderly patients with metastatic colorectal cancer for *Clinical Colorectal Cancer*
- Review article on recent changes in therapeutic options for prostate cancer for *Pharmacy & Therapeutics*
- Review manuscript on current and emerging treatment options for locally advanced or metastatic medullary thyroid cancer for *Pharmacy and Therapeutics Journal*
- Case series analysis of patients with metastatic breast cancer treated with albumin-bound paclitaxel for *Current Oncology*
- Clinical management of patients with colorectal cancer treated with anti-EGFR agents for *European Journal of Oncology Nursing*
- Toxicity, and solubility of novel taxanes for treatment of breast cancer for *European Journal of Cancer*
- The impact of comorbidities on treatment patterns and outcomes in older patients with chronic lymphocytic leukemia for *American Journal of Hematology*

- Patient characteristics affecting treatment choices in elderly patients with chronic lymphocytic leukemia for *Leukemia and Lymphoma*
- Prognostic factors in older patients with acute myelogenous leukemia for *Journal of Clinical Oncology*
- Appropriate clinical utilization of novel taxane formulations for *European Journal of Cancer*
- Efficacy, toxicity, and solubility of novel taxanes for the treatment of breast cancer for *European Journal of Cancer*
- Role of aromatase inhibitors in the treatment of breast cancer for *British Journal of Cancer*
- Phase II study of the efficacy and safety of a novel agent for older adults with acute myelogenous leukemia for *Clinical Journal of Oncology Nursing*
- Risk estimation, risk reduction, chemoprevention of breast cancer, and chemoprevention of breast cancer recurrence for *Menopause*
- Outcomes associated with histologic transformation in patients with follicular lymphoma who initially responded to immunotherapy for MedPage Today
- Sex differences in the diagnosis, management, and outcomes of follicular lymphoma for MedPage Today
- The ongoing debate about watchful waiting for clinically nonaggressive follicular lymphoma for MedPage Today
- Biologic and genetic factors associated with aggressive transformation in the natural history of follicular lymphoma for MedPage Today
- Excess risk of stroke following a new diagnosis of cancer for MedPage Today
- Increased risk of fractures and strategies for screening and management of bone health following breast cancer treatment for MedPage Today
- Risk, diagnosis, and management of osteoporosis following androgen deprivation therapy for prostate cancer for MedPage Today
- Clinical implications of the updated disease definition to include biomarkers, laboratory findings, and radiographic variables for the diagnosis of multiple myeloma and smoldering multiple myeloma for MedPage Today
- The effectiveness and adverse effects of risk-reducing interventions for carriers of *BRCA1* and *BRCA2* mutations for MedPage Today
- Poster on the safety and efficacy of nivolumab in combination with ipilimumab for metastatic renal cell carcinoma for the annual meeting of the European Society for Medical Oncology, 2016

- Poster on the efficacy and safety of carfilzomib, lenalidomide, and low-dose dexamethasone for relapsed or progressive multiple myeloma for the annual meeting of the American Society of Clinical Oncology, 2013
- Poster on the efficacy and safety of single-agent lenalidomide for relapsed/refractory mantle cell lymphoma following bortezomib therapy for the annual meeting of the American Society of Clinical Oncology, 2013
- Poster on the efficacy and safety of single-agent lenalidomide for mantle cell lymphoma for the annual meeting of the American Society of Clinical Oncology, 2013
- Poster on treatment-related risk of second primary malignancies in multiple myeloma for the annual meeting of the American Society of Clinical Oncology, 2013
- Poster on the pharmacokinetics and tolerability of a new agent for relapsed/refractory multiple myeloma for the annual meeting of the American Society of Clinical Oncology, 2013
- Poster on an enhanced viewing device to improve adenoma detection rate during colonoscopy for Digestive Disease Week 2012
- Two posters on the treatment of myelodysplastic syndromes for the 51<sup>st</sup> American Society of Hematology Annual Meeting and Exposition
- Poster on the renal safety of bisphosphonates for the 2006 Congress on Cancer-Induced Bone Disease
- Slide set summaries on hematologic malignancies presented at the 57<sup>th</sup> American Society of Hematology Annual Meeting
- Slide presentation on the efficacy and safety of lenvatinib for hepatocellular carcinoma and potential biomarkers for clinical outcomes for the annual meeting of the International Liver Cancer Association, 2013
- Slide presentation summarizing state of the science treatment options for gastric adenocarcinoma
- Slide presentation on the pathophysiology, epidemiology, diagnosis, and management of chemotherapy-induced anemia
- Slide presentations on the safety and efficacy of pharmacologic interventions for Philadelphia chromosome positive chronic myeloid leukemia and myelodysplastic/myeloproliferative overlap disorders

- Abstract on the implications of natural luteinizing-hormone-releasing hormone (LHRH) and its analogs for the inhibition of LHRH-receptor-positive prostate cancer for the 2017 American Society of Clinical Oncology Genitourinary Cancers Symposium

### **Competitive Strategic Analysis and Publication Planning**

- Briefing document on targeted antibody treatment for newly-diagnosed multiple myeloma
- Briefing document on FLT-3 inhibitor treatment for 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
- Scientific platform and publication plan for a targeted cytotoxic peptide conjugate for ovarian and endometrial cancer
- Analysis of key messages, audiences, authors, and journals to characterize the publication history for a second-generation ALK inhibitor
- Comparative review of emerging treatments for relapsed/refractory multiple myeloma
- Competitive analysis of targeted therapies for BRAFV600-mutation positive metastatic melanoma
- Analysis of the role of an investigational, orally active 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
- Preparation of a payer value proposition communication plan for the role of bevacizumab in the treatment of colorectal cancer, glioblastoma multiforme, non-small cell lung cancer, and renal cell carcinoma
- Analysis of preclinical and clinical research on a novel androgen receptor antagonist for castrate-resistant prostate cancer to support new product launch
- Comparative review of the efficacy and safety of therapeutic interventions for breakthrough pain among cancer patients to support development of a publication plan

- Analysis of preclinical and clinical research on monoclonal antibodies for treatment of breast cancer including identification of strengths and limitations of current publications and presentations and development of strategies to support future publication efforts
- Analysis of preclinical and clinical research on the efficacy and safety of inhibitors of apoptosis for treatment of diverse solid tumors including identification of strengths and limitations of current publications and presentations and development of strategies to support publication planning for new product launch
- Analysis of preclinical and clinical research on antiangiogenic therapies for treatment of diverse solid tumors to identify strengths and limitations of current publications and presentations and identify strategies to support publication planning for new product launch
- Review of published and fugitive literature, interviews with subject matter experts, and preparation of gap analysis on pharmacologic interventions for angiogenesis inhibition and development of various materials for a comprehensive company publication plan
- Comprehensive literature review on disparities in cervical cancer morbidity and mortality for a competitive marketing analysis
- Literature review on disparities in cervical cancer morbidity and mortality for a competitive marketing analysis
- Literature review on barriers and motivators to compliance with an HPV vaccine program for a competitive market analysis
- Review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions to manage hormone-refractory prostate cancer and associated pain for a publication plan
- Review article on the strengths and limitations of biomarkers for new drug development in oncology

### **Epidemiology and Biostatistics**

- Systematic literature review on the efficacy and safety of immunotherapy in the treatment of cancer
- 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
- Evaluation of global health status and quality of life in patients randomized to chemotherapy or EGFR-directed therapy for *EGFR* mutation-positive lung cancer
- Development of a longitudinal, observational, registry study protocol to assess clinical outcomes of patients with advanced solid and hematologic malignancies tested by standardized next-generation genomic sequencing and treated with provider-determined care plans
- Analysis of an administrative research database to describe the baseline characteristics for patients with ALK-positive non-small cell lung cancer, identify anti-cancer therapy prior to initiation of ALK+ therapy, and analyze treatment patterns including discontinuations and dose modifications associated with ALK+ therapy
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of glioma to support an application for submission to the European Medicines Agency for approval of orphan drug designation
- Evaluation of US and international databases to characterize trends in the staging of newly diagnosed breast cancer in the US and Europe
- Review of the epidemiologic burden, risk factors, therapeutic options, and prognosis for breast, non-small cell lung cancer, gastric cancer, and brain metastases to support phase 2/3 clinical research on new therapeutic regimens
- Review of the epidemiologic burden, risk factors, therapeutic options, and prognosis of ovarian cancer to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for approval of orphan drug designation
- Analysis of the worldwide epidemiologic burden of non-small cell lung cancer, risk factors, and emerging treatments through 2020
- Projection of the worldwide epidemiologic burden of hepatocellular carcinoma and associated risk factors through 2015
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of glioblastoma multiforme to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for orphan drug designation

- Analysis of the epidemiologic burden, risk factors, treatment implications, and prognosis for patients who develop chemotherapy-induced peripheral neuropathy in response to treatment for non-small cell lung cancer
- Analysis of preclinical and clinical research on hedgehog pathway inhibitors for basal cell carcinoma to support a new product launch
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of pediatric solid tumors to support applications for orphan drug designation for submission to the European Medicines Agency and the US Food and Drug Administration
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of acute myeloid leukemia to support applications for orphan drug designation for submission to the European Medicines Agency and the US Food and Drug Administration
- Projection of the epidemiologic burden of hepatocellular carcinoma and associated risk factors in the United States through 2020
- Evaluation of US and international research on non-Hodgkin lymphoma including, epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging treatment options
- Evaluation of US and international research on chronic lymphocytic leukemia to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging treatment options
- Comprehensive report on current classification systems, diagnosis, and induction therapy regimens for acute myeloid leukemia by patient age, consolidation therapy, relapse interventions, and salvage regimens
- Evaluation of US and international research on multiple myeloma to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging treatment options
- Evaluation of US and international research on central nervous system metastases, including epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging treatment options
- Evaluation of US and international research on hepatocellular cancer to characterize the epidemiologic burden, risk factors, prognostic indicators, and the efficacy and safety of current and emerging treatment options



- Retrospective analysis of the indications, prevalence, and outcomes associated with liver transplantation for hepatocellular carcinoma
- Review of the epidemiologic burden, trends, efficacy and safety of current and emerging treatment options, and prognosis for acute myeloid leukemia
- Evaluation of the strengths and limitations of methods to identify, recruit, and maintain a cohort of patients with relapsed diffuse large B cell lymphoma
- Review of merging treatment options and patient forecasting for triple negative breast cancer
- Evaluation of the strengths and limitations of methods to identify, recruit, and maintain a cohort of patients with metastatic melanoma
- 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
- Comparative analysis of worldwide epidemiologic trends for acute myeloid leukemia and myelodysplastic syndromes in adult and pediatric populations
- Epidemiologic analysis on the treatment of platinum-sensitive, taxane-sensitive ovarian cancer
- Case report form and data collection process for multiple myeloma treated with pegylated liposomal doxorubicin
- Case report form and data collection process for a case series study of erlotinib for non-small cell lung cancer
- Cancer prevention and control plan for the state of North Carolina
- Assisted with the development of the Annual Cancer Review for the state of North Carolina

### **CME Programs, Training Programs, and Related Materials**

- Support for a consensus meeting on the pathophysiology, risk factors, clinical presentation, diagnosis, and treatment of hepatic veno-occlusive disease following myeloablative hematopoietic stem cell transplantation
- Infographic on 3-year survival outcomes for nivolumab with ipilimumab versus nivolumab monotherapy or ipilimumab monotherapy in advanced melanoma
- Subject matter expert and consultant for the development and review of content for eight training workshops on the role of lenalidomide, dexamethasone, and pomalidomide for multiple myeloma

- Literature review on the evolving role of immunotherapy in squamous cell carcinoma of the head and neck
- Educational content and instructional design for a case-based workshop on enasidenib for relapsed or refractory acute myeloid leukemia
- Detailed review of clinical trials and results on current and emerging therapies for non-Hodgkin lymphoma
- Educational program on best practices for metastatic melanoma and metastatic renal cell carcinoma with high-dose interleukin-2
- Slide content development and review for 20 comprehensive oncology training slide presentations addressing breast, colorectal, head/neck, and hematologic cancers for presentation at regional CME symposia
- Online case studies and expert commentary characterizing the challenges and solutions in the treatment of progressive multiple myeloma
- Online case studies and expert commentary characterizing the challenges and solutions in the second-line treatment of metastatic colorectal cancer
- Content development and review for educational program on neoadjuvant therapy for breast cancer
- Content development and review for live, comprehensive oncology training programs addressing breast, colorectal, head/neck, and hematologic malignancies for regional continuing medical education symposia
- Reference guides for physicians and nurses on metastatic melanoma and metastatic renal cell carcinoma including disease state overview, current treatments, best practices, and guidelines for optimal care
- Educational program for physicians on the epidemiology, clinical presentation, diagnosis, and therapeutic options for chemotherapy-induced anemia
- Educational program addressing physician-patient communication about risk/benefits of therapeutic interventions for diverse health conditions
- Educational program on strategies to improve physician communication skills for patients with cancer about end of life care and treatment decisions
- Educational program on the efficacy and safety of therapeutic interventions for breakthrough pain among cancer patients
- Multiple print, DVD, and web education materials for clinicians about a novel immunomodulatory treatment for advanced, hormone-refractory prostate cancer

- Educational program based on key opinion leader interviews and expert perspective articles addressing emerging issues in oncology
- Online training curriculum for pharmaceutical commercial team on the epidemiology, biology, diagnosis, treatment, and prognosis of malignant melanoma
- Training program for clinical sales specialists on an oral multi-kinase inhibitor for treatment of metastatic colorectal cancer and gastrointestinal tumor
- Online training program for pharmaceutical commercial team including anatomy and physiology, pathophysiology, epidemiologic burden, risk factors, symptoms, diagnosis, and current and emerging treatments on gastrointestinal stromal tumors
- Training program for clinical sales specialists on ovarian cancer including epidemiologic burden, risk factors, diagnosis, current and emerging treatment options, and the specific role of antiangiogenesis inhibitors
- Comprehensive training program for medical science liaisons on genetic biomarkers associated with increased risk of breast cancer
- Online, interactive learning center for medical science representatives providing an in-depth review of epidemiology, diagnosis, biology, treatment algorithm, surgical interventions, systemic therapies, and patient case studies on metastatic melanoma
- Review of a monograph on non-small cell lung cancer for medical accuracy and coordination of final revisions
- E-newsletter mini-review of recent clinical trials evaluating efficacy and safety of new treatment for advanced non-small cell lung cancer
- Electronic newsletters on strategies for the diagnosis and clinical management of lung cancer
- Design and evaluation of a case study library reviewing new treatment options for non-small cell lung cancer
- Slide program summarizing the findings on emerging therapies for colorectal and non-small cell lung cancer for an advisory board with pharmacy and medical directors of leading private care payers
- Advisory Board on a strategic platform to review pre-launch and launch materials and publication plan for a targeted cytotoxic peptide conjugate for ovarian and endometrial cancer

- Summary of advisory board proceedings on treatment options for recurrent ovarian cancer
- Summaries of monthly advisory board meetings on pharmacologic interventions for colorectal cancer
- Summary of advisory board proceedings on pharmacologic options for non-small cell lung cancer
- Conference summary on current treatment options for renal cell carcinoma presented at the American Urologic Association
- Conference summary on pancreatic cancer for the 2006 Lustgarten Foundation Annual Pancreatic Cancer Conference
- Conference summary on multiple myeloma for the 2006 Multiple Myeloma Research Foundation Advisory Panel
- Moderator's guide for a workshop on gastrointestinal stromal tumors

### **CME Proposals**

- Current and emerging immunotherapies, targeted therapies, and chemotherapy for metastatic melanoma
- Current and emerging therapies and optimal patient management for locally advanced and metastatic pancreatic cancer
- Comparative analysis of current and emerging interventions for glioblastoma multiforme
- Comparison of the safety and efficacy of current and emerging therapies for platinum-sensitive ovarian cancer
- Comparative review of the efficacy and safety of new therapies for metastatic castrate-resistant prostate cancer
- Histologic and genetic markers to optimize therapy for non-small-cell lung cancer
- Treatment challenges and solutions in non-Hodgkin lymphoma and chronic lymphocytic leukemia
- Emerging treatment options for chronic myelogenous leukemia
- Impact of genetics in the treatment of colorectal cancer
- Novel therapeutic agents for advanced gastric cancer
- Optimizing outcomes in metastatic breast cancer
- Hormonal therapy for hormone-positive, early stage breast cancer in postmenopausal women

- Aromatase inhibitors for hormone-positive, early stage breast cancer in postmenopausal women
- Advances in adjuvant therapy for breast cancer
- Management of side-effects associated with chemotherapy
- Impact of genetics on the treatment of colorectal cancer
- Taxanes for metastatic breast cancer
- Hormone therapy for postmenopausal, metastatic breast cancer
- Immunomodulatory therapies for metastatic melanoma
- Emerging treatment options for hematologic malignancies
- Nanotechnology to facilitate efficacy of treatment regimens for multiple tumor types
- Epidemiology and clinical management of HER-2 positive breast cancer
- New treatment options for recurrent ovarian cancer

### **Consumer Medical Education**

- Educational brochure on cancer-associated deep vein thrombosis
- Reference guide for patients and caregivers on metastatic melanoma
- Blogs on the symptoms, risk factors, diagnosis, consequences, treatment, and prognosis of mesothelioma
- Reference guide for patients and caregivers on metastatic renal cell carcinoma
- Multiple print, DVD, and web materials on a novel immunomodulatory treatment for advanced, castrate-resistant prostate cancer
- Summary of current research findings for the Multiple Myeloma Research Foundation consumer newsletter
- Chronic disease, sexuality, and the impact of cancer on psycho-emotional well-being