

## Summary of Research and Writing Activities by Therapeutic Area

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**ONCOLOGY****Manuscripts, Posters, Slide Sets, and Abstracts in Oncology**

- 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*
- Patient characteristics affecting treatment choices in elderly patients with chronic lymphocytic leukemia for *Leukemia and Lymphoma*

- The impact of comorbidities on treatment patterns and outcomes in older patients with chronic lymphocytic leukemia for *American Journal of Hematology*
- 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 presentations on the safety and efficacy of pharmacologic interventions for Philadelphia chromosome positive chronic myeloid leukemia and myelodysplastic/myeloproliferative overlap disorders

- Slide presentation on the pathophysiology, epidemiology, diagnosis, and management of chemotherapy-induced anemia
- 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 in Oncology**

- Briefing document on FLT3 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 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 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 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 in Oncology**

- 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
- 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
- Evaluation of global health status and quality of life in patients randomized to chemotherapy or EGFR-directed therapy for *EGFR* mutation-positive lung cancer
- 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 in Oncology**

- 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 on metastatic melanoma for medical science representatives providing an in-depth review of epidemiology, diagnosis, biology, treatment algorithm, surgical interventions, systemic therapies, and patient case studies
- 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 in Oncology**

- 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
- 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 in Oncology**

- Educational brochure on cancer-associated deep vein thrombosis
- Blogs on the symptoms, risk factors, diagnosis, consequences, treatment, and prognosis of mesothelioma
- Reference guide for patients and caregivers on metastatic melanoma
- 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

## **CARDIOVASCULAR DISEASE**

### **Manuscripts and Other Publications in Cardiovascular Disease**

- Treatment patterns and survival outcomes in pulmonary arterial hypertension by functional class: a meta-analysis of randomized controlled trials and observational disease registries for *Journal of Heart and Lung Transplantation*
- Proprotein convertase subtilisin/kexin type 9 inhibition as a new therapeutic intervention for hyperlipidemia for *Pharmacotherapy*

- Application of machine learning methods to identify predictors of all-cause total healthcare costs and utilization in severe peripheral artery disease for *Value in Health*
- Application of machine learning methods to identify predictors of a cardiovascular composite endpoint in severe peripheral artery disease for *Health Services Research*
- Treatment patterns and direct medical costs of hospitalizations and readmissions associated with phosphodiesterase type 5 inhibitor monotherapy for pulmonary arterial hypertension for *Chest*
- Neurological events 2 years following transcatheter aortic valve implantation in real-world patients for *Stroke*
- A retrospective analysis of disparities in the initiation and maintenance of lipid-lowering therapies between men and women at high risk for developing coronary heart disease for *Journal of Women's Health*
- Comparative analysis of the efficacy and safety of antiplatelet medications for the management of acute coronary syndrome for *Pharmacy & Therapeutics*
- Assessment of patterns and predictors of clinical outcomes following implementation of a performance improvement intervention for heart failure in outpatient cardiology practices for *Circulation*
- Utilization of implantable cardioverter-defibrillator therapy for heart failure following participation in a practice-based performance improvement intervention for *American Heart Journal*
- Adherence to optimal medication dosing for treatment of heart failure following clinician participation in a practice-based performance intervention for *Journal of the American College of Cardiology*
- Interventions to improve the clinical management of critically ill patients receiving vasopressors for blood pressure support for *Journal of Cardiovascular Nursing*
- Variations in treatment of heart failure with guideline-recommended doses of medical therapies following participation in a practice-based performance intervention for *Circulation, Heart Failure*
- Evaluation of the effectiveness of interventions to improve evidence-based care for heart failure in outpatient cardiology practices for *Circulation*

- Predictors of variations associated with patient race/ethnicity in the effectiveness of a performance improvement intervention on clinician adherence to guideline-recommended treatment for heart failure for *American Journal of Cardiology*
- Predictors of variations associated with patient gender in the effectiveness of a performance improvement intervention on clinicians' adherence to guideline-recommended treatment for heart failure for *Journal of the American College of Cardiology*
- Practice and patient characteristics as predictors of variations in the effectiveness of a performance improvement intervention on adherence to guideline-recommended ambulatory management of heart failure for *American Heart Journal*
- Patient and physician barriers to therapy with implantable cardioverter defibrillators for treatment of ventricular fibrillation or sustained ventricular tachycardia for *Critical Pathways in Cardiology*
- Recovery of vascular homeostasis following implantation of different types of stents in porcine coronary arteries for *Circulation: Interventions*
- Gaps in adherence to guideline-recommended adjunctive therapies for heart failure for *American Journal of Cardiology*
- Review of the efficacy and safety of drug-eluting stents for *American Heart Journal*
- The influence of advanced practice nurses and dedicated heart failure clinics on delivery of recommended therapies to outpatients with heart failure for *American Journal of Cardiology*
- Comparison of medical treatment of outpatients with heart failure receiving device therapy for *Circulation: Heart Failure*
- Evaluation of the relationship between electronic medical records and quality of care for heart failure for *American Heart Journal*
- Relationship between renal function and adherence to guideline-recommended care for outpatients with heart failure for *American Journal of Cardiology*
- Predictors of cardiac resynchronization therapy utilization for heart failure for *American Heart Journal*
- Predictors of implantable cardioverter defibrillator therapy for heart failure for *Heart Rhythm*

- Assessment of long-term safety results from a randomized controlled trial of drug-eluting stents for treatment of *de novo* native coronary artery lesions for *Journal of the American Medical Association*
- Assessment of patient age and gender differences in treatment for heart failure for *American Heart Journal*
- Implications of HDL-C for cardiovascular health and lifestyle and pharmacologic interventions to increase HDL-C levels for *Critical Pathways in Cardiology*
- Therapeutic interventions for diabetic dyslipidemia and their relationship to cardiovascular disease for *International Journal of Clinical Practice*
- The efficacy and safety of pharmacologic interventions for management of dyslipidemia for *American Journal of Medicine*
- Accuracy of cardiovascular disease risk estimation models for patients with psoriatic arthritis for MedPage Today
- The association of gout with increased risk of atrial fibrillation for Medpage Today
- The role of left atrial appendage occlusion devices in the management of patients with atrial fibrillation for Medpage Today
- Nonpharmacologic interventions for the prevention of stroke in patients with atrial fibrillation for MedPage Today
- Invasive versus initial conservative management of unstable angina/non-ST-elevation myocardial infarction in octogenarians for MedPage Today
- Noninvasive imaging tests to evaluate acute chest pain syndromes to improve diagnoses, rule out noncoronary causes of pain, and facilitate risk stratification for MedPage Today
- Diagnosis and management of cardiovascular comorbidities in patients with psoriatic arthritis for MedPage Today
- The effect of off-hour presentation on in-hospital and 30-day mortality rates and door-to-balloon time for patients with ST elevation myocardial infarction for MedPage Today
- Risk stratification and a comparison of the short- and long-term outcomes of inpatient versus outpatient therapy for pulmonary embolism for MedPage Today
- Role of robotic-assisted therapy in the rehabilitation of patients following ischemic stroke for Medpage Today



- Review of the role of blood biomarkers with implications for the etiology, diagnosis, and prognosis in patients following ischemic stroke for MedPage Today
- The impact of NSAIDs and COX 2 inhibitors on risk of atrial fibrillation for MedPage Today
- The relationship between atrial fibrillation, menopausal status, and hormone therapy for MedPage Today

### **Epidemiology and Biostatistics in Cardiovascular Disease**

- Literature review to characterize global prevalence and incidence rates for chronic thromboembolic pulmonary hypertension
- Evaluation of the safety profile of selective factor Xa inhibitors for a risk management plan for venous thromboembolism and stroke
- 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
- 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 the management of mild pain attributed to arthritis and musculoskeletal conditions
- Comprehensive review of current practices regarding the evaluation, diagnosis, risk stratification, treatment, and prognosis mitral valve regurgitation for the American College of Cardiology
- Research proposal and statistical analysis plan for an evidence-based intervention to assess current practices regarding the management of patients with aortic stenosis
- Evaluation of dyslipidemia interventions including product and publication reviews, research design, statistical analysis, and interpretation of post-marketing surveillance data
- Evaluation of cardiovascular devices for heart failure including product and publication reviews, research design, statistical analysis, and interpretation

- Evaluation of percutaneous coronary interventions with drug-eluting stents for coronary artery disease including reviews of published literature and conference proceedings on basic pharmacology, randomized controlled trials, patient registries, and observational studies
- Comprehensive review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions to manage hypertension and development of various materials for a comprehensive publication plan
- Global statistical analysis plan for evaluation of device interventions for cardiovascular disease
- Epidemiologic analysis of *de novo* coronary lesion length, stent length, and evaluation of efficacy and safety of drug-eluting and bare metal stents

### **Abstracts, Posters, and Presentations in Cardiovascular Disease**

- Abstract on a meta-analysis of randomized controlled trials and observational disease registries to characterize treatment patterns and survival outcomes in pulmonary arterial hypertension by functional class for the 2019 annual meeting of the International Society for Heart and Lung Transplantation
- Abstract on the cardiometabolic effects of a first-in-class fatty acid bile acid conjugate for nonalcoholic fatty liver disease or nonalcoholic steatohepatitis for the 2015 European Fatty Liver Disease Conference
- Abstract on patterns and predictors of change in the treatment of heart failure with implantable cardioverter defibrillators following participation in a practice-based clinical performance intervention for the 2010 Scientific Sessions of the American Heart Association
- Abstract on patient and practice characteristics associated with improved ejection fraction in patients with heart failure and reduced LVEF following implementation of a clinical performance intervention for the 2010 Scientific Sessions of the American Heart Association
- Abstract on the effect of a performance improvement initiative on quality of care for outpatients with heart failure for the Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke 2010 Scientific Session

- Two abstracts on changes in documentation of heart failure therapy and improvement in ejection fraction for heart failure following implementation of a clinical performance improvement initiative for the 14<sup>th</sup> Annual Scientific Meeting of the Heart Failure Society of America
- Abstract on variations attributable to medical staffing patterns in the effect of a performance improvement intervention on adherence to guideline-recommended ambulatory treatment of heart failure for the 2009 annual conference of the Heart Rhythm Society
- Abstract on the influence of patient race on the effect of a performance improvement intervention on adherence to guideline-recommended ambulatory management of heart failure for the 2009 annual conference of the Heart Rhythm Society
- Two abstracts on variations in use of appropriate dosages of medical therapy for heart failure and evaluation of a practice-based intervention to increase the proportion of outpatients receiving guideline-recommended care for heart failure for the 59<sup>th</sup> Annual Scientific Session of the American College of Cardiology
- Two abstracts on gender variations in treatment with drug-eluting stents and two-year safety results in patients with STEMI for the American College of Cardiology's Innovation in Intervention: IV Summit 2009
- Two abstracts on outpatient management of prolonged QRS duration and atrial fibrillation in heart failure for the Heart Rhythm 2009 30<sup>th</sup> Annual Scientific Session
- One abstract on outpatient management of heart failure with anticoagulants for the Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference 2009
- Two abstracts on predictors of patterns of care for heart failure for the 2008 annual meeting of the American Heart Association
- Two abstracts on the relationship of BNP and GFR to symptoms, functioning, and clinical outcomes in patients with heart failure for the 2008 annual scientific meeting of the American College of Cardiology
- Three abstracts on patterns of care for heart failure for the 2008 annual meeting of the Heart Failure Society of American
  - Poster on the influence of renal function on the treatment of heart failure for the 2009 meeting of the American College of Cardiology

- Poster on clinician adherence to optimal medication dosing for heart failure following implementation of a performance improvement intervention for the 59<sup>th</sup> Annual Scientific Session of the American College of Cardiology
- Poster on a retrospective analysis of disparities in the initiation and maintenance of lipid-lowering therapies between men and women at high risk for coronary heart disease for the 63<sup>rd</sup> Annual Scientific Session of the American College of Cardiology
- Poster on clinician adherence to optimal treatment of heart failure for patients of diverse race/ethnic affiliation following implementation of a performance improvement intervention for the 14<sup>th</sup> Annual Scientific Meeting of the Heart Failure Society of America
- Poster on adherence to guideline-recommended care for women with heart failure following implementation of a performance improvement intervention for the 59<sup>th</sup> Annual Scientific Session of the American College of Cardiology
- Poster on patient and practice characteristics associated with adherence to evidence-based guidelines for treatment of heart failure for the Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke Conference 2009
- Slide presentation on variations in the effect of a practice-based performance intervention on outpatient cardiology practices with and without an academic affiliation for the 59<sup>th</sup> Annual Scientific Session of the American College of Cardiology
- Slide presentation on cardiometabolic complications of obesity and related risk factors

### **CME Programs, Training Programs, and Related Materials in Cardiovascular Disease**

- Disease backgrounder on the epidemiology, pathogenesis, risk factors, treatment and prognosis of ischemic stroke in acutely ill, hospitalized patients
- Continuing education on optimal strategies for the management of atrial fibrillation with a focus on stroke prevention
- Nurse practitioner education and performance improvement intervention to improve the quality of care for atrial fibrillation
- Continuing medical education on the epidemiology, pathophysiology, diagnosis, prevention, and treatment of pulmonary arterial hypertension

- Training module on the current antihypertensives pharmaceutical market and the role of monotherapy and combination therapy for the management of hypertension
- Continuing medical education on the association between nonalcoholic steatohepatitis and risk factors for cardiovascular disease, including obesity, dyslipidemia, hypertension, and insulin resistance
- Continuing medical education on different options for statins in the management of cardiovascular disease
- Continuing medical education on the role of  $\beta$ -blockers for the management of hypertension
- Continuing medical education on the direct medical costs associated with acute and long-term management of stroke
- Two-day training workshop for clinical sales representatives on the role of a novel dual-inhibitor of angiotensin II receptor and neprilysin for heart failure with reduced ejection fraction
- Sales training program on tissue plasminogen activators for myocardial infarction, pulmonary embolism, and stroke
- Case-based training workshop and pre-read materials for clinical sales specialists on the diagnosis, risk stratification, electrocardiography and other imaging tests, coronary anatomy, angiographic evaluation, and pharmacologic therapies for acute coronary syndrome
- Training program for clinical sales specialists on the effect of cholesteryl ester transfer protein inhibitors on vascular function, progression of atherosclerosis, and future cardiovascular events
- White paper on implementation of continuous ST-segment monitoring for acute coronary syndromes, including an assessment of clinician attitudes and the impact of monitoring on clinical outcomes
- White paper on the impact of continuous QT interval monitoring on the clinical outcomes of patients at increased risk of sudden cardiac death due to torsades de points
- White paper on management of risk factors for cardiovascular disease in metabolic syndrome
- White paper on the criteria and methods for defining metabolic syndrome
- White paper on the role of primary care in the prevention, diagnosis, treatment, and management of metabolic syndrome

- Two scripts for video discussions on the current epidemiology, health implications, and management of elevated triglycerides
- Newsletters for physicians on evidence-based therapies for management of atrial fibrillation
- Conference summary on the proceedings of the 2006 annual conference of the International Society on Hypertension in Blacks

### **CME Proposals in Cardiovascular Disease**

- Current and emerging pharmacologic treatments for heart failure
- Current and emerging pharmacologic treatments for acute coronary syndrome
- Prevention, diagnosis, treatment, and long-term management of diverse cardiovascular conditions
- Management of risk factors for cardiovascular disease in metabolic syndrome
- Role of primary care physicians in screening, diagnosis, prevention, and treatment of metabolic syndrome
- Peripheral imaging, angioplasty, and stenting for peripheral vascular disease
- Pharmacologic and lifestyle interventions to manage cardiometabolic syndrome
- Current management strategies for the prevention of venous thrombosis
- Strategies for management of risk factors for cardiovascular disease
- Current and emerging strategies for the management of cardiovascular disease

### **EPIDEMIOLOGY AND BIOSTATISTICS**

- Systematic literature review on the efficacy and safety of immunotherapy in the treatment of cancer
- Literature review to characterize global prevalence and incidence rates for chronic thromboembolic pulmonary hypertension
- Development of a statistical data plan and interpretation of results to evaluate the impact of an online continuing medical education and quality improvement intervention to improve remission rates in patients with major depressive disorder

- Systematic literature review on the incidence, risk factors, and burden of chronic opioid use following surgery
- Development of clinical study protocol, statistical analysis plan, data management, analysis, and interpretation, and research monitoring for a prospective, randomized, controlled trial comparing a wearable insulin delivery device to standard insulin optimization for type 2 diabetes mellitus
- Research, data analysis, and writing for a risk management plan submission to the Food and Drug Administration and the European Medicines Agency for authorization of a novel antibacterial agent for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections
- Systematic and structured literature reviews of the prevalence of dyslipidemia, lipids and cardiovascular events, lipid monitoring, effects of anti-retroviral regimens on lipid profiles, and management of dyslipidemia in patients with HIV-1
- Systematic literature review on the neuropsychiatric safety, tolerability, toxicity, and discontinuation of integrase strand transfer inhibitors for the treatment of HIV-1
- Literature review, summary, and interpretation of findings regarding current and emerging therapies for renal cell carcinoma
- 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
- Global value dossier on first- and second-line therapies for metastatic renal cell carcinoma
- Research proposal to evaluate interventions for the prevention of renal failure in hemodynamically unstable patients in the critical care setting
- Clinical study protocol, statistical analysis plan, data collection, and analysis for a prospective case-control study to assess the impact of arteriovenous fistula or graft dysfunctions on health-related quality of life in patients undergoing hemodialysis

- Benefit-risk analysis to support a feasibility analysis for FDA submission to approve over-the-counter access for an emergency contraceptive
- 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
- Development of a research protocol for a longitudinal observational registry study to assess the clinical outcomes of patients with advanced solid and hematologic malignancies tested by standardized next-generation genomic sequencing and treated with provider-determined standard of care
- 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 for women of childbearing potential
- Evaluation of global health status and quality of life in patients randomized to chemotherapy or EGFR-directed therapy for *EGFR* mutation-positive lung cancer
- Review of health conditions characterized by vasomotor symptoms and a feasibility analysis for FDA submission to approve over-the-counter status of a prescription medication for moderate-to-severe vasomotor symptoms
- Review of patient and disease profiles associated with increased risk of cardiovascular event 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 currently prescribed for mild pain attributed to arthritis and musculoskeletal pain
- Analysis of an administrative research database to describe the baseline characteristics of 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
- Interactive training module on research design, statistical principles, statistical analysis and interpretation, data presentation, and health economics and patient-reported outcomes for healthcare professionals
- Literature review and summary on the prevalence, incidence, and risk factors for injuries associated with high-risk movements in healthcare workers



- Development and validation of a risk prediction model for recurrent *Clostridium difficile*
- 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
- Research consultant and biostatistician on a grant submitted to the Agency for Healthcare Research and Quality for a prospective study to evaluate safety, efficiency, accuracy, and user satisfaction associated with 4 types of intravenous smart pump devices
- 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 an historical overview of current and emerging treatments
- 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
- Analysis of the association between nonalcoholic steatohepatitis and risk factors for cardiovascular disease, including obesity, dyslipidemia, hypertension, and insulin resistance
- Statistical analysis plan and randomization strategy to compare the impact of a community-based diabetes self-management intervention with and without ongoing structured support
- Analysis of differences in risk factors for hospital-acquired versus community-acquired *Clostridium difficile*
- Analysis of results from surveys, interviews, and focus groups conducted with primary care physicians, interventional cardiologists, imaging cardiologists, and cardiothoracic surgeons to assess current knowledge, skills, and practices regarding the evaluation and management of mitral valve regurgitation
- Research proposal and statistical analysis plan for an evidence-based intervention to assess current practices regarding the management of mitral valve disease

- Analysis of trends in healthcare resource utilization and costs among hospitalized patients with *Clostridium difficile*
- Systematic literature review of the impact of diabetes self-management education on clinical outcomes, quality of life, healthcare resource utilization, and indirect costs
- Analysis and interpretation of findings from the international Diabetes Attitudes, Wishes, and Needs (DAWN2) study and development of recommendations to support patient-centered care for people with diabetes, with a focus on policies, interventions, follow-up, and evaluation to improve healthcare, clinical outcomes, and quality of life
- Evaluation of the incidence, risk factors, current treatment strategies, clinical outcomes, and healthcare utilization for *Clostridium difficile* in residents of long-term care facilities
- Analysis of risk factors for hospital readmission for recurrent *Clostridium difficile*
- Analysis of the clinical and economic burden of *Clostridium difficile*-associated diarrhea among high-risk populations during hospitalization
- Analysis of the healthcare resource utilization and economic burden of *Clostridium difficile*-associated diarrhea among populations at high risk of recurrence following hospital discharge
- Data collection and analysis to support a medication use evaluation tool to improve clinical outcomes in *Clostridium difficile*
- Evaluation of the epidemiology, pharmacologic interventions, healthcare utilization, and costs associated with the treatment of *Clostridium difficile* in hospital and outpatient settings
- Evaluation of hospital readmission rates and predictors associated with *Clostridium difficile*
- Substantive writing and edits for a research proposal to evaluate an intervention to reduce the risk of prediabetes and diabetes among airforce personnel for submission to the National Institutes of Health by the Diabetes Center of Excellence, United States Air Force
- Analysis of the epidemiologic burden, risk factors, diagnosis, treatment patterns, and health consequences of endometriosis in adolescents
- Evaluation of US and international databases to characterize trends in the staging of newly-diagnosed breast cancer in western European countries

- 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
- Analysis of the worldwide epidemiologic burden of non-small cell lung cancer, associated risk factors, and emerging treatments through 2020
- Projection of the worldwide epidemiologic burden of hepatocellular cancer and associated risk factors through 2015 and 2020
- Analysis of the epidemiologic burden, risk factors, treatment implications, and prognosis for chemotherapy-induced peripheral neuropathy in response to treatment for non-small cell lung cancer
- Evaluation of US and international databases and research on non-Hodgkin lymphoma to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international databases and research on chronic lymphocytic leukemia to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international databases and research on multiple myeloma to characterize the epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international databases and research on central nervous system metastases including epidemiologic burden, risk factors, prognostic indicators, and the safety and efficacy of current and emerging therapies
- Evaluation of US and international data and research on hepatocellular cancer to characterize the epidemiologic burden, risk factors, prognostic indicators, and the efficacy and safety of current and emerging therapies
- Summary report on current classification systems, diagnosis, induction therapy regimens by patient age, consolidation therapy, relapse interventions, and salvage regimens for acute myeloid leukemia
- Retrospective analysis of the indications, prevalence, and outcomes associated with liver transplantation for hepatocellular cancer
- Review of the epidemiologic burden, trends, efficacy and safety of current and emerging therapies, 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
- Evaluation of the strengths and limitations of methods to identify, recruit, and maintain a cohort of patients with metastatic melanoma
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of pediatric solid tumors to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for approval of orphan drug designation
- Comparative analysis of epidemiologic trends among adult and pediatric populations worldwide for acute myeloid leukemia and myelodysplastic syndromes
- Comparative review of the efficacy and safety of therapeutic interventions for breakthrough cancer pain
- Analysis 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 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 approval of orphan drug designation
- Comparative review of the efficacy and safety of pharmacologic interventions for acute exacerbations of hereditary angioedema
- Analysis of the strengths and limitations of biomarkers for new drug development in oncology
- Research proposal for the development and implementation of a tracking and follow-up surveillance system for patients with hereditary angioedema and individuals at risk of hereditary angioedema
- Substantive writing and edits to the General Research and Clinical Center competitive renewal application submitted by the University of North Carolina, Chapel Hill to the National Institutes of Health (funded)
- Development of case report forms and data collection procedures for multiple myeloma treated with pegylated liposomal doxorubicin
- Systematic analysis of hyperuricemia as a biomarker for rheumatologic, metabolic, and hemodynamic abnormalities

- Preparation of a global statistical analysis plan for evaluation of device interventions for cardiovascular disease
- Epidemiologic analysis of *de novo* coronary lesion length, stent length, and evaluation of the efficacy and safety of drug-eluting and bare metal stents
- Epidemiologic analysis reviewing the safety profile of selective factor Xa inhibitors for a risk management plan for venous thromboembolism and stroke
- Epidemiologic analysis on treatments for platinum-sensitive, taxane-sensitive ovarian cancer
- Consultant on percutaneous coronary interventions with drug-eluting stents for coronary artery disease including reviews of published literature and conference proceedings on basic pharmacology, randomized controlled trials, patient registries, and observational studies
- Analysis of the epidemiologic burden, risk factors, treatment patterns, and prognosis of acute myeloid leukemia to support applications for submission to the European Medicines Agency and the US Food and Drug Administration for orphan drug designation
- Literature review, data analysis, and summary of sources of epidemiologic bias interpretation of results from population-based registries to determine the efficacy of pharmacologic interventions
- Comprehensive literature review on the efficacy, safety, and tolerability of progestins
- Assisted with the research and development of the cancer prevention and control plan for the state of North Carolina
- Comprehensive literature review on strategies for primary care providers to provide patient education and counseling about low-dose oral contraceptives
- Substantive writing and edits for a proposal on telehealth for submission by the Federation of State Medical Boards to the Health Services Resource Administration (funded)
- Substantive writing and edits for a proposal on pediatric epilepsy for submission by the University of California, San Francisco to the National Institutes of Health
- Review of published and fugitive literature for the development of a research proposal on pharmacologic interventions for schizophrenia

- Review of published and fugitive literature and interviews with subject matter experts regarding the epidemiologic burden, risk factors, treatment, and prognosis for various respiratory conditions
- Development of the Annual Cancer Review for the state of North Carolina
- Assisted with the development and conduct of a survey of health insurers regarding benefits for the primary and secondary prevention of cancer

### STRATEGIC COMPETITIVE ANALYSIS AND PUBLICATION PLANNING

- Briefing document on targeted antibody treatment for newly-diagnosed multiple myeloma
- Briefing document on FLT3 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
- 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
- Literature review, summary, and interpretation of findings regarding current and emerging therapies for renal cell carcinoma
- Pragmatic landscape review, evidence mapping, and development of a payer value story to support a selective beta<sub>3</sub>-agonist for overactive bladder
- Global value dossier on first- and second-line therapies for metastatic renal cell carcinoma
- Benefit-risk analysis to support a feasibility analysis for FDA submission to approve over-the-counter access for an emergency contraceptive
- 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

- Scientific platform and publication plan for a targeted cytotoxic peptide conjugate for ovarian and endometrial cancer
- 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
- Comparative review of emerging treatments for relapsed/refractory multiple myeloma
- 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
- 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
- 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 based on an analysis of preclinical and clinical research on the effect of SGLT2 inhibitors for type 2 diabetes mellitus

- Publication plan for preclinical and clinical research on a combination of long-acting insulin and a GLP-1 inhibitor for type 2 diabetes mellitus
- 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
- 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
- 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
- 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
- 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
- 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 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 therapies, and the role of angiogenesis inhibitors
- Analysis of emerging therapies 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 preclinical and clinical research published in 2010 addressing the management of breast cancer
- Comparative evaluation of therapies and toxicities for hematologic cancers, with an emphasis on allogeneic and autologous bone marrow transplantation and graft-versus-host disease
- 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 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
- Comparative analysis of new therapeutic interventions for pulmonary arterial hypertension
- 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 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 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
- Review of 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
- 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 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

## DIABETES

### Manuscripts and Other Publications in Diabetes

- Impact of critical limb ischemia and diabetes on healthcare resource utilization, costs, and clinical outcomes for *Diabetic Medicine*
- Application of machine learning methods to identify predictors of a cardiovascular composite endpoint in diabetic patients with severe peripheral artery disease for *European Journal of Vascular and Endovascular Surgery*
- Therapeutic interventions for diabetic dyslipidemia and their relationship to cardiovascular disease for *International Journal of Clinical Practice*
- Systematic review of differences in glycemic control associated with diabetes self-management education delivered by trained or credentialed educators compared with educators without diabetes-specific training for *Patient Education and Counseling*
- Evaluation of a diabetes education intervention for endocrinologists, primary care physicians, and nurse practitioners to improve patient medication persistence with pharmacologic treatment of type 2 diabetes mellitus for *Current Medical Research and Opinion*
- The role of gastric bypass surgery in the management of obese patients with type 2 diabetes mellitus for *MedPage Today*
- The risks and benefits of intensive insulin therapy for critically ill patients requiring medical or surgical intensive care for *MedPage Today*
- White paper on results of a clinician survey on insulin initiation, insulin titration, and optimization of insulin therapy for diabetes

- White paper on a first-in-human surgical intervention for type 2 diabetes mellitus
- White paper summarizing presentations at the 49<sup>th</sup> annual meeting of the European Association for the Study of Diabetes on the safety and efficacy of a novel endoscopic intervention for type 2 diabetes
- White paper on continuous blood glucose monitoring in type 1 and type 2 diabetes mellitus
- White paper on patterns and predictors of nonadherence to continuous blood glucose monitoring in type 1 and type 2 diabetes mellitus
- White paper on technologic advances in continuous blood glucose monitoring in type 1 and type 2 diabetes mellitus
- White paper summarizing clinical recommendations for diabetes management by family caregivers and caregivers of patients residing in assisted living settings

#### **CME Programs, Presentations, and Epidemiologic Consulting in Diabetes**

- Development of clinical study protocol, statistical analysis plan, data management, analysis, and interpretation, and research monitoring for a prospective, randomized, controlled trial comparing a wearable insulin delivery device to standard insulin optimization for type 2 diabetes mellitus
- Continuing education program on the role of new and emerging injectable therapies for type 2 diabetes mellitus
- Nurse practitioner education and performance intervention to improve the care and clinical outcomes for type 2 diabetes mellitus
- Educational program on global results from the second Diabetes Attitudes, Wishes and Needs (DAWN2) study for the 2013 annual meeting of the European Association for the Study of Diabetes
- Educational symposium on individualized treatment strategies, insulin initiation and up-titration, and complementary agents to achieve optimal clinical outcomes for type 1 and type 2 diabetes mellitus
- Development and evaluation of a comprehensive diabetes management curriculum for physicians, nurses, and diabetes educators
- Case study pre- and post-test evaluation of presentations at the European Congress on Endocrinology

- Summary of the proceedings of an advisory board on emerging pharmacologic agents to treat diabetes in Hispanic/Latino populations
- Summary of the proceedings of an advisory board on emerging pharmacologic agents to treat diabetes in African American populations
- Meeting attendance and preparation of a newsletter on key presentations at the 69<sup>th</sup> Scientific Sessions of the American Diabetes Association
- Summary of the proceedings of an advisory board on emerging pharmacologic agents for diabetes
- Analysis of preclinical and clinical research on long-acting insulin and a GLP-1 inhibitor for type 2 diabetes mellitus to support a publication plan
- Analysis of preclinical and clinical research on the effect of sodium-glucose co-transporter (SGLT2) inhibitors for type 2 diabetes mellitus to support a publication plan
- Comparative review of the efficacy and safety of pharmacologic interventions for type 2 diabetes mellitus
- Analysis and interpretation of findings from the international Diabetes Attitudes, Wishes, and Needs (DAWN2) study and development of recommendations to support patient-centered care for people with diabetes with a focus on policies, interventions, follow-up, and evaluation to improve healthcare, clinical outcomes, and quality of life
- Newsletter supplement based on interviews with 6 subject matter experts on a pharmacologic intervention for diabetic retinopathy
- Literature review on the efficacy and safety of GLP-1 analogues and DPP-4 inhibitors for type 2 diabetes mellitus
- Substantive research, writing, and edits for a research proposal to evaluate an intervention to reduce the risk of prediabetes and diabetes among airforce personnel for submission to the National Institutes of Health by the Diabetes Center of Excellence, United States Air Force
- Review of epidemiology, risk factors, and treatment of diabetes for a consumer health information website

### **CME Proposals in Diabetes**

- Management of diabetes for critically ill, hospitalized patients
- New technologies for insulin delivery
- Emerging options for the diagnosis and management of diabetes

## MUSCULOSKELETAL AND RHEUMATOLOGIC DISORDERS

### Manuscripts, Posters, and Other Publications in Musculoskeletal and Rheumatologic Disorders

- Pooled analysis and evaluation of the safety of topical diclofenac for osteoarthritis for *Drugs and Aging*
- Review manuscript on current and emerging issues in the diagnosis and management of osteoarthritis for *ADVANCE for Physician Assistants*
- Supplement on current and emerging issues in the diagnosis and management of osteoarthritis for *Current Clinical Practice*
- Monograph on patient-centered chronic pain management strategies for *Practical Pain Management Journal*
- Six posters for the 2007 symposium of the American Society of Regional Anesthesia and Pain Medicine
- The epidemiology and pathogenesis of secondary osteoporosis in patients with gastrointestinal disorders for MedPage Today
- Identification and management of pediatric populations at risk for osteoporosis and fragility fractures for MedPage Today
- An overview of the burden of illness and unmet needs in patients with rheumatoid arthritis for MedPage Today
- Reproductive health issues in women with rheumatoid arthritis for MedPage Today
- Progression of joint damage and disability associated with disease flares in rheumatoid arthritis for MedPage Today
- Comparing the effects of weight-bearing exercise and resistance training to resistance training alone on postmenopausal bone loss for MedPage Today
- Physical activity and balance training to prevent falls in persons at risk for osteoporosis for MedPage Today
- The association of periodontitis with chronic inflammatory conditions including rheumatoid arthritis and osteoarthritis for MedPage Today
- Risk factors for bone loss and prevention of osteoporosis-related fractures in HIV-infected populations for MedPage Today
- Optimal foot healthcare and outcomes in rheumatoid arthritis for MedPage Today

- The increased risk of melanoma, nonmelanoma skin cancer, and other cancers in patients with psoriasis and psoriatic arthritis for MedPage Today
- Are individuals with psoriasis and psoriatic arthritis at increased risk for suicide and suicidal ideation for MedPage Today
- Rising rates of falls and fractures among community-dwelling older adults for MedPage Today
- Assessing the value of routine laboratory testing to identify secondary causes of osteoporosis in older men for MedPage Today
- The incidence, prevalence, risk factors and treatment options for hearing loss in rheumatoid arthritis for MedPage Today
- Treatment patterns and biomarkers associated with changes in the long-term progression of structural joint damage in rheumatoid arthritis for MedPage Today
- Incidence and risk factors for sexual dysfunction in individuals with psoriasis and psoriatic arthritis for MedPage Today
- The potential for personalized medicine in rheumatoid arthritis: genetic loci, gene-gene interactions, gene-environment interactions associated with risk for and response to therapy for MedPage Today
- Biological and structural changes associated with an increased risk of osteoporosis and fractures among individuals with spinal cord injuries for MedPage Today
- The primary care clinician's guide to the management of acute gout for MedPage Today
- The relationship between ulcerative colitis, bone mineral density, and the incidence of fractures for MedPage Today
- Bone mineral density testing in men following a distal radial fracture for MedPage Today
- Major depressive disorder as an unrecognized risk factor for osteoporosis for MedPage Today
- Patterns and predictors of medication discontinuation and switching in patients with osteoporosis for MedPage Today
- Multidisciplinary, multifaceted interventions to improve patient management following a fragility fracture for MedPage Today
- The efficacy and safety of vitamin D and calcium for osteoporosis for MedPage Today

- Diagnosis and management of cardiovascular comorbidities in psoriatic arthritis for MedPage Today
- Evaluation of therapeutic exercise on symptoms and quality of life in ankylosing spondylitis for MedPage Today
- The indirect costs associated with rheumatoid arthritis, including absenteeism, presenteeism, disability, and quality of life for MedPage Today

### **CME Programs and Related Materials in Musculoskeletal and Rheumatologic Disorders**

- Review, updates, and edits to an eLearning program on rheumatoid arthritis
- Case-based interactive program on optimal treatment strategies for rheumatoid arthritis
- Educational program on the direct and indirect economic implications of rheumatoid arthritis
- Educational program on the burden and treatment of musculoskeletal disorders in menopausal women
- Educational program on emerging issues in rheumatoid arthritis for primary care providers
- Educational program on current and emerging issues in the diagnosis and management of osteoarthritis for family practice physicians and physician assistants for the 2008 Spring CME Conference of the Association of Family Practice Physician Assistants
- Educational program on the epidemiology, pathophysiology, and current treatment options for rheumatologic disorders
- Moderator's guide for a continuing medical education workshop on osteoarthritis
- E-newsletter on the relationship between depression, pharmacotherapy for depression, and bone health
- Literature review and summary on the prevalence, incidence, and risk factors for musculoskeletal injuries associated with high-risk movements in healthcare workers
- Newsletter on current concepts in pain management
- Current and emerging pharmacologic treatments for rheumatoid arthritis
- Comprehensive literature review on the epidemiology and new therapeutic options for the prevention and management of fractures



- Comprehensive literature review and a training monograph on primary and secondary osteoporosis
- Review of the epidemiology, risk factors, and treatment of osteoarthritis for a consumer health information website
- Review of the epidemiology, risk factors, and treatment of rheumatoid arthritis for a consumer health information website
- Review of the epidemiology, risk factors, and treatment of osteoporosis for a consumer health information website

## NEUROLOGY AND PSYCHIATRY

### Manuscripts, Other Publications, and Posters in Neurology and Psychiatry

- Evaluation of an performance improvement initiative to promote measurement-based approaches for achieving and maintaining remission in adults with major depressive disorder for *Journal of Continuing Education in the Health Professions*
- Considerations regarding nonoral therapies for moderate-to-severe acute migraine for *Clinician Reviews*
- Comparative analysis of global migraine prophylaxis treatment patterns based on clinical practice data from the US, France, Germany, and Japan for *Headache, The Journal of Head and Face Pain*
- Impact of disease severity on clinical burden and healthcare resource utilization in Alzheimer's disease for *BMC Neurology*
- Pharmacologic treatments for generalized anxiety disorder for *Expert Review Drug Profiles*
- Epidemiology, diagnosis, treatment and management of Parkinson's disease as a supplement for *European Journal of Neurology*
- Comprehensive review of schizophrenia characterizing the epidemiologic, social, and societal burden; patterns, predictors, and implications of relapse and progression; direct and indirect costs; new diagnostic criteria; advocacy and policy implications of healthcare reforms; patterns, predictors, and implications of treatment adherence; and past, current, and emerging classes of therapeutic interventions for *P&T Digest*
- Childhood epilepsy, febrile seizures, and risk of attention deficit hyperactivity disorder for *MedPage Today*

- Traumatic brain injury increases the risk of childhood attention deficit hyperactivity disorder for MedPage Today
- The role of the circadian clock in exacerbation and control of the symptoms of attention deficit hyperactivity disorder for MedPage Today
- Healthcare utilization, comorbid health conditions, and quality of life in binge eating disorder for MedPage Today
- Challenges associated with the diagnosis and management of binge eating disorder in primary care settings for MedPage Today
- Clinical implications of the underrepresentation of men in research on binge eating disorder for MedPage Today
- The neurobiological basis of binge eating disorder for MedPage Today
- Charting brain connectivity networks to facilitate the diagnosis of attention deficit disorder in youth for MedPage Today
- Online cognitive behavioral therapy and psychoeducation for bipolar disorder for MedPage Today
- The role of magnetic resonance imaging in diagnosing and monitoring disease progression and treatment response in multiple sclerosis for MedPage Today
- Genetic factors associated with the development and progression of Parkinson's disease for MedPage Today
- The psychological impact of chronic pain for MedPage Today
- The role of neuroimaging in the diagnosis and monitoring of Parkinson's disease for MedPage Today
- Central nervous system reorganization and imaging in diverse chronic pain conditions for MedPage Today
- The role of multidisciplinary care in the management of chronic pain for MedPage Today
- Management of noncancer-related chronic pain in the elderly for MedPage Today
- Interventions to relieve the burden of chronic pain for MedPage Today
- Progression from acute to chronic pain following surgery for MedPage Today
- White paper on the challenges associated with the development of new pharmacologic treatments for central nervous system disorders
- Poster on the impact of tardive dyskinesia on health-related quality of life for 2018 meeting of the American Psychiatric Association

- Abstract on the impact of a continuing education and performance improvement initiative to promote measurement-based approaches for achieving and maintaining remission in adults with major depressive disorder for the 2019 meeting of the American Psychiatric Association

### **CME Programs, Training Programs, and Related Materials in Neurology and Psychiatry**

- Educational program on new and emerging treatment modalities and strategies to manage the complications of multiple sclerosis
- Case-based virtual training, digital materials, and interactive training workshop for clinical sales specialists on the epidemiology, symptoms, consequences, non-pharmacological interventions, and pharmacotherapy for agitation in Alzheimer's disease
- Nurse practitioner education and performance intervention to improve the care and clinical outcomes in attention deficit hyperactivity disorder
- Educational program on the optimal treatment of multiple sclerosis in women, with a focus on contraception, reproductive care, and sexual health
- Six educational programs on the challenges of treating schizophrenia in diverse clinical and social settings
- Interactive program on attention deficit hyperactivity disorder
- Monograph with case studies on the clinical evaluation and treatment of sleep-wake disorders, including obstructive sleep apnea, shift work sleep disorder, and delayed sleep phase syndrome
- Summary of the proceedings of an advisory board on pharmacologic interventions for epilepsy
- Comprehensive literature review on the epidemiology of psychiatric disorders for an abnormal psychology textbook
- Review of published and fugitive literature on pharmacologic interventions for schizophrenia

### **CME Proposals in Neurology and Psychiatry**

- Prevention, diagnosis, treatment, and long-term management of bipolar disorder
- Current and emerging treatments for Alzheimer's disease

- Prevention, diagnosis, treatment, and long-term management of major depressive disorder
- Comorbid conditions associated with attention deficit hyperactivity disorder

## INFECTIOUS DISEASES

### Manuscripts, Reports, Posters, and Abstracts in Infectious Diseases

- Systematic literature review on the neuropsychiatric safety, tolerability, toxicity, and discontinuation of integrase strand transfer inhibitors for the treatment of HIV-1
- Systematic and structured literature reviews of the prevalence of dyslipidemia, lipids and cardiovascular events, lipid monitoring, effects of anti-retroviral regimens on lipid profiles, and management of dyslipidemia in patients with HIV-1
- The incidence, risk factors, and economic burden of nonventilator hospital-acquired pneumonia in the United States for *JAMA Internal Medicine*
- Risk factors for exposure to *Legionella pneumophila* among dental practitioners for *Journal of the American Dental Association*
- A retrospective, observational, multicenter study to characterize the incidence and identify nursing strategies for the prevention of nonventilator, hospital-acquired pneumonia for *JAMA Internal Medicine*
- A phase 3, multinational, stratified, randomized, double-blind study of oral delafloxacin versus intravenous vancomycin plus aztreonam for acute bacterial skin and skin structure infections for *Clinical Infectious Diseases*
- A phase 3, multinational, stratified, randomized, double-blind study of intravenous plus oral delafloxacin versus intravenous vancomycin plus aztreonam for acute bacterial skin and skin structure infections for *Journal of Antimicrobial Chemotherapy*
- A multicenter, phase 2, randomized, open-label, active comparator dose-finding study of oritavancin for subjects with *S. aureus* bacteremia for *Diagnostic Microbiology and Infectious Disease*
- Oritavancin compared with vancomycin for gram-positive acute bacterial skin and skin structure infections for *Antimicrobial Agents and Chemotherapy*
- Understanding the “true” hospital burden of paediatric respiratory syncytial virus in the United Kingdom for *Acta Paediatrica*

- A randomized, single-blind, dose-range study to assess the immunogenicity and safety of a cell-culture-derived A/H1N1 influenza vaccine in a pediatric population for *Pediatrics*
- A multicenter, randomized, controlled study to evaluate carriage prevalence of *N. meningitidis* combined serogroups at 1 month following a single dose of MenACWY conjugate vaccine and carriage prevalence of virulent sequence types of *N. meningitidis* group B at 1 month following 2 doses of 4CMenB vaccine for *Lancet*
- Comparison of the viral kinetics of two agents for chronic hepatitis B for *Hepatology International*
- Evaluation of the safety of a conjugate meningococcal vaccine administered to healthy infants in conjunction with routine pediatric vaccinations for *Vaccine*
- Five-year follow-up evaluation of the efficacy, safety, and histologic changes in hepatic function associated with tenofovir versus adefovir dipivoxil for chronic hepatitis B for *New England Journal of Medicine*
- New directions in antimicrobial agents for *Journal of Antimicrobial Chemotherapy*
- Evaluation of an intervention to improve nurses' clinical decisions the management of sepsis for *Intensive Care Medicine*
- Clinical management of sepsis for *Critical Care Medicine*
- Pharmacokinetics of an anti-fungal agent for onychomycosis for *Journal of Drugs in Dermatology*
- Assessing and managing neurocognitive disturbances in patients with HIV for MedPage Today
- Clinician and patient barriers and incentives for preexposure prophylaxis in individuals at high risk for HIV for MedPage
- Poster on the integrated safety results from randomized controlled trials evaluating the safety and efficacy of a novel aminomethylcycline antibiotic for acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia for **IDWeek 2018**
- Poster on a phase 3, multinational, stratified, randomized, double-blind study of intravenous plus oral delafloxacin versus intravenous vancomycin plus aztreonam for acute bacterial skin and skin structure infections for **IDWeek 2016**

- Poster on an evaluation of digital versus manual assessment of lesion size in a phase 3 trial of delafloxacin for acute bacterial skin and skin structure infections for **IDWeek 2016**
- Poster on the *In vitro* activity of delafloxacin and microbiological response against fluoroquinolone-susceptible and non-susceptible *S. aureus* isolates from 2 phase 3 studies of acute bacterial skin and skin structure infections for **IDWeek 2016**
- Poster on the characteristics of patients hospitalized for acute bacterial skin and skin structure infections from 2009 to 2013 for **IDWeek 2016**
- Poster on the pharmacokinetics of an anti-fungal agent for onychomycosis for the 2008 annual scientific meeting of the American Podiatric Medical Association
- Abstract on the integrated safety results from randomized controlled trials evaluating the safety and efficacy of a novel aminomethylcycline antibiotic for acute bacterial skin and skin structure infections and community-acquired bacterial pneumonia for **IDWeek 2018**
- Four abstracts on a novel aminomethylcycline antibiotic as once-daily oral and intravenous treatment for acute bacterial skin and skin structure infection for **MAD-ID 2018**

### **CME Programs, Training Programs, Advisory Boards, and Epidemiologic Consulting in Infectious Diseases**

- Research, data analysis, and writing for a risk management plan submission to the Food and Drug Administration and the European Medicines Agency for authorization of a novel antibacterial agent for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections
- E-learning program for clinical sales specialists and medical science liaisons on the diagnosis of nontuberculous mycobacterial lung infection
- Disease backgrounder on the epidemiology, pathogenesis, risk factors, treatment and prognosis of pneumonia, urinary tract infections, pyogenic arthritis, osteomyelitis, endocarditis, and cellulitis in acutely ill, hospitalized patients
- Educational program on the development and validation of a risk prediction model for recurrent *Clostridium difficile*

- Evaluation of the incidence and risk factors, current treatment strategies, clinical outcomes, and healthcare utilization for *Clostridium difficile* diagnosed in residents of long-term care facilities
- Educational program on risk factors for hospital-acquired versus community-acquired *Clostridium difficile*
- Educational program on risk factors for rehospitalization among patients with recurrent *Clostridium difficile*
- Educational program on trends in healthcare resource utilization and costs among hospitalized patients with *Clostridium difficile*
- Educational program on the clinical and economic burden of *Clostridium difficile*-associated diarrhea among high-risk populations during hospitalization
- Educational program on the epidemiology of HIV/AIDS and adherence to HIV/AIDS therapeutic regimens
- Educational program on healthcare resource utilization and the economic burden of *Clostridium difficile*-associated diarrhea among patient populations at high risk of recurrence following hospital discharge
- Educational program on vancomycin resistance
- Educational program on *Staphylococcus aureus* resistance to antibiotics
- Web-based program on pharmacologic options for hepatitis B
- Summary of the proceedings of an advisory board on diagnosis, treatment, and long-term management of primary immune deficiency disorder

### **CME Proposals in Infectious Diseases**

- Changes in the epidemiologic burden, screening, and treatment for demographically diverse patient groups with HIV
- Changes in the epidemiologic burden and treatment recommendations for HIV in women, children, and traditional high-risk populations
- Current and emerging epidemiologic trends and pharmacological treatments for HIV
- Current and emerging pharmacological treatments for HIV
- Screening, diagnosis, and optimal management of hepatitis B
- Current and new treatment regimens for relapsed or refractory hepatitis C
- Treatment regimens tailored to meet the health, educational, and social needs of black, Hispanic, and female populations with HIV

- Culturally appropriate interventions to promote adherence to HIV treatment regimens, including management of comorbid health conditions
- Emerging issues for the management of fungal infections
- Pharmacologic options for hepatitis B
- Critical analysis of a continuing medical education grant proposal on hepatitis B and C

## WOMEN'S HEALTH

### Manuscripts and Other Publications in Women's Health

- Epidemiology of menopause, pathophysiology, and management of the symptoms of the menopause transition including lifestyle modifications, pharmacologic interventions, and complementary medicine interventions for *Journal of Women's Health*

### CME Programs, Training Programs, and Related Materials in Women's Health

- Benefit-risk analysis to support a feasibility analysis for FDA submission to approve over-the-counter access for an emergency contraceptive
- Preparation of an investigational new drug briefing package for submission to the FDA to change an emergency contraceptive product from prescription to over-the-counter status
- Educational program on the burden and treatment of musculoskeletal disorders affecting menopausal women
- Review of health conditions associated with vasomotor symptoms and a feasibility analysis for FDA submission to approve over-the-counter status of a prescription medication for the management of moderate to severe vasomotor symptoms
- Educational program for primary care and specialist clinicians on individualized treatment decisions regarding hormone therapy for the management of menopause symptoms
- Education and performance improvement intervention for nurse practitioners to improve the quality of care for patients with fibromyalgia
- Educational program on screening, counseling, and management of endometriosis by primary care providers
- Educational program on current and emerging methods of contraception



- Educational program on communication regarding the risks and benefits of contraception
- Educational program on current issues regarding the incidence, risk factors, symptoms, diagnosis, and treatment options for depression in women
- Educational program to increase physician awareness, utilization, and ability to provide patient education about a vaginal contraceptive device
- Educational program with case studies on emerging health issues and current practice gaps associated with the screening and treatment of sexually transmitted infections
- Training program for clinical sales specialists on pharmacologic treatments for overactive bladder
- Moderator's guide, slide presentations, and summaries of advisory boards with primary care physicians and gynecologists on management of menopausal symptoms and related health conditions
- Differential diagnosis and management of fibromyalgia syndrome
- The relationship between atrial fibrillation, menopausal status, and hormone therapy
- Training program for clinical sales specialists 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
- Summary report on the proceedings of a consensus meeting on emerging issues associated with the screening and treatment of sexually transmitted infections
- Diagnosis, treatment, and management of female urologic conditions
- Lifestyle and pharmacologic interventions to manage the symptoms of perimenopause, menopausal transition, and postmenopause
- Literature review on the efficacy, safety, and tolerability of progestins
- Literature review on strategies for patient education and counseling about low-dose oral contraceptives
- White paper on topical treatments for sexually transmitted diseases for the American Society of Obstetricians and Gynecologists Clinical Practice Guidelines Committee

## DERMATOLOGY

### Manuscripts in Dermatology

- Review manuscript on the pathogenesis, epidemiology, quality of life, and current management strategies for generalized pustular psoriasis
- Histopathologic response to treatment of facial skin photodamage with tretinoin emollient cream 0.02% for *Journal of Drugs in Dermatology*
- Efficacy and safety of a topical agent for pain management during dermatologic procedures for *Journal of Cosmetic Dermatology*
- Efficacy and safety of a novel combination medical therapy for moderate to severe acne vulgaris for *Journal of Drugs in Dermatology*
- Pilot evaluation of the efficacy and safety of laser therapy for moderate to severe psoriasis for *Journal of Drugs in Dermatology*
- Six manuscripts on the efficacy, safety, and tolerability of medical therapy for acne vulgaris in different patient populations for *Skin and Aging and Cutis*
- Efficacy and safety of a topical agent for acne rosacea for *Journal of Drugs in Dermatology*
- Role of laser therapy for plaque psoriasis refractory to topicals and biologics for a supplement in *Skin & Aging*
- Pharmacokinetics of an anti-fungal medication for onychomycosis for *Journal of Drugs in Dermatology*
- Randomized controlled trial of PUVA for plaque psoriasis for *Journal of Drugs in Dermatology*
- Efficacy and safety of a topical medication for hyperkeratosis for *Journal of Drugs in Dermatology*
- Improving the diagnosis and management of children and adolescents with psoriasis for MedPage Today
- Evaluation of the risk of chronic obstructive pulmonary disease and Parkinson disease in patients with psoriasis for MedPage Today
- Is there an increased risk of melanoma, nonmelanoma skin cancer, or other cancers in patients with psoriasis and psoriatic arthritis for MedPage Today
- Are individuals with psoriasis and psoriatic arthritis at increased risk for suicide and suicidal ideation for MedPage Today
- Incidence and risk factors for sexual dysfunction among individuals with psoriasis and psoriatic arthritis for MedPage Today

- Increased risk for depression, anxiety, and diminished quality of life in patients with psoriasis and their caregivers for *MedPage Today*

### **CME Proposals, Training Programs, Advisory Boards, and Focus Groups in Dermatology**

- Current and emerging pharmacologic interventions for psoriasis
- Summary of the proceedings of an advisory board on the role of biologics in psoriasis
- Summary of key findings from consumer focus groups on current and emerging therapies for rosacea

### **OTHER THERAPEUTIC AREAS**

#### **Manuscripts, Reports, Posters, Abstracts, and Other Publications in Other Therapeutic Areas**

- Evaluation of all-cause mortality and predictors associated with the progression of nonalcoholic fatty liver disease or nonalcoholic steatohepatitis for *Gastroenterology*
- Incremental increases in healthcare resource utilization and direct medical costs associated with the progression to end-stage liver disease in patients with nonalcoholic fatty liver disease or nonalcoholic steatohepatitis for *Hepatology*
- Review, edits, and revisions to an analysis of the effect of a compounded topical, transdermal analgesic for the treatment of chronic pain in opioid-experienced patients for *Postgraduate Medicine*
- Systematic literature review on the incidence, risk factors, and burden of chronic opioid use following surgery
- The imperative for increased transparency in reporting industry- and government-sponsored research for *Health Affairs*
- Randomized clinical trial comparing two surgical approaches for the repair of anal fistulas for *World Journal of Colorectal Surgery*
- Treatment patterns and symptom control among patients with mild asthma in China for *Respirology*

- Decreased pain and opioid use following administration of a compounded topical, transdermal analgesic: third interim and preliminary control group results from the Optimizing Patient Experience and Response to Topical Analgesics (OPERA) observational study for *Journal of Pain Research*
- Changes in rates of opioid overdose or poisoning in a commercially insured population following the introduction of a reformulated opioid with abuse-deterrent properties for *Journal of Pain*
- A cross-sectional real-world survey to establish patient characteristics and disease burden of mild asthmatics consulting for routine care currently receiving GINA Step 1 or 2 treatment for *Lancet Respiratory Medicine*
- Confidence in inhaler device technique and adherence to treatment for COPD for *Respiratory Medicine*
- Defining and characterizing patient-handling injuries, identifying risk factors for such injuries, and developing and sustaining interventions for healthcare workers and organizations to reduce the occurrence of patient-handling injuries for *American Nurse Today*
- Efficacy and safety of a C1 esterase inhibitor concentrate for long-term prophylaxis in hereditary angioedema: Findings from a large international registry for *Journal of Allergy and Clinical Immunology: In Practice*
- The distinction between surveillance and monitoring in patient care: Implications for clinical outcomes and safety for *BMJ Quality & Safety*
- Evaluation of nurses' knowledge about the identification and treatment of unintentional hypothermia in the perioperative setting for *Association of Perioperative Registered Nurses (AORN) Journal*
- Use of a C1 esterase inhibitor concentrate for hereditary angioedema in pediatric populations for *Journal of Allergy and Clinical Immunology: In Practice*
- Evaluating the relationship of inhaler device satisfaction, adherence, smoking history, and allergic rhinitis with patient outcomes: real world observations of US adult asthma patients for *Journal of Asthma and Allergy*
- Physician-patient concordance in the management of the symptoms of chronic obstructive pulmonary disease for *COPD: Journal of Chronic Obstructive Pulmonary Disorders*
- Current management strategies for chronic kidney disease and hypertension for *The Nurse Practitioner*

- Lab reference-based pricing benefit: an evidenced-based solution for healthcare shopping behavior towards commodity lab services for *American Journal of Managed Care*
- The impact of a clinical decision support tool on patient point of care and clinical work flow in a telemetry unit for *Journal of Clinical Outcomes Management*
- The impact of evolving developments in regulatory risk management and risk evaluation and mitigation strategies on the knowledge, attitudes, and behaviors of patients, physicians, and pharmacists for *Drug Information Journal*
- Methods and results of an accountable care demonstration project implemented at multiple healthcare settings for *Health Affairs*
- Monograph characterizing patterns and predictors of medication non-adherence and interventions to improve adherence among diverse patient populations in primary care settings for *Journal of the American Academy of Nurse Practitioners*
- Evaluation of the impact of a worksite risk prediction model and risk reduction intervention on the incidence of short- and long-term disability for *Journal of Occupational and Environmental Medicine*
- Therapeutic interventions to reduce clinical complications and the need for urgent care interventions for patients with chronic obstructive pulmonary disease for *Disease Management*
- Evaluation of the impact of comparative effectiveness research and clinical marketing on the healthcare industry for *Health Affairs*
- Comparative review of the efficacy and safety of intravenous immunoglobulin therapy for primary immunodeficiency disorders for *Pharmacy & Therapeutics*
- Review of the efficacy and safety of pharmacologic interventions for primary immune deficiency for *Pharmacy & Therapeutics*
- The challenges and benefits of remote patient monitoring in the intensive care setting for *American Journal of Critical Care*
- Integration of automated patient monitoring into hospital-based information systems for *Journal of the American Medical Informatics Association*
- The role of clinical decision support systems in the clinical management of critically ill patients for *Medicamundi*

- Interpretation and use of statistics in medical research for *AACN Advanced Critical Care*
- Evaluation of family member satisfaction with remote patient monitoring in the intensive care setting for *Critical Care Nurse*
- Analysis of the concept of patient surveillance in nursing to improve safety and clinical outcomes for *Journal of Advanced Nursing*
- Use of clinical decision support systems to improve the clinical management of critically ill patients receiving medications for blood pressure support for *Computers, Informatics, Nursing*
- Efficacy and safety of ranibizumab for neovascular age-related macular degeneration for *Managed Care*
- Results of a national survey of allergists and immunologists on their knowledge and experience concerning the epidemiology, symptoms, caseload, diagnosis, and treatment of hereditary angioedema for *Annals of Allergy, Asthma, & Immunology*
- Summary of the process and results from a Delphi exercise with key opinion leaders to identify leading educational issues in the assessment/diagnosis and treatment/long-term management of obstructive sleep apnea, circadian rhythm sleep disorder, restless leg syndrome, narcolepsy, insomnia, and excessive sleepiness for *The Primary Care Companion to the Journal of Clinical Psychiatry*
- Position paper for clinicians summarizing the recommendations of a panel of subject matter experts on issues related to opioids, anti-inflammatory medications, and transdermal agents for chronic pain
- The prevalence of work-related musculoskeletal disorders, cancer, and other medical conditions in healthcare personnel who work in interventional cardiology or radiology laboratories for *MedPage Today*
- Structural brain abnormalities associated with cognitive deficits in patients with chronic obstructive pulmonary disease for *MedPage Today*
- The essential elements of pulmonary rehabilitation for patients with chronic obstructive pulmonary disease for *MedPage Today*
- Current and emerging interventions to maintain the nutritional status of patients with cystic fibrosis for *MedPage Today*
- The impact of pancreatic exocrine insufficiency on the quality of life of patients with pancreatic cancer for *MedPage Today*

- Sex differences in the prevalence, pathophysiology, symptoms, management, and comorbidities associated with chronic obstructive pulmonary disease for MedPage Today
- Diagnosis and management of fibromyalgia for MedPage Today
- Optimal dose and administration schedule for pancreatic enzyme replacement therapy in patients with pancreatic exocrine insufficiency for MedPage Today
- Position paper for primary care clinicians on opioids and alternative pain management interventions
- White paper on medication administration and management for caregivers of patients in the assisted living setting
- Presentation on the effect of an online educational and quality improvement intervention to address practice gaps in the monitoring and management of patients with new or recurrent major depressive disorder for the 2019 meeting of the American Psychiatry Association
- Poster on an evidence-based protocol for lateral patient transfer to reduce healthcare worker injuries for the 2015 Safe Patient Handling and Mobility meeting of the Tampa Research and Education Foundation, Inc.
- Abstract on changes in the use of critical care health services and costs before and after treatment with a noninvasive open ventilation system for the 2015 meeting of the American Thoracic Society
- White paper on the use of clinical decision support tools to improve clinical outcomes and cost-effectiveness of healthcare delivery in hospital settings
- Review of published and fugitive literature and interviews with subject matter experts for the development of a quarterly publication on respiratory conditions
- Abstract on healthcare utilization and costs before and after initiation of treatment for respiratory insufficiency with a non-invasive open ventilation system for the 2014 annual meeting of the American College of Chest Physicians
- Abstract on changes in COPD Assessment Test scores before and after initiation of treatment for respiratory insufficiency with a non-invasive open ventilation system for the 2014 annual meeting of the American College of Chest Physicians

- White paper on the role of clinical decision support tools, clinical outcomes associated with alarm fatigue, and emerging solutions to reduce alarm fatigue in critical care settings

### **CME Programs, Training Programs, and Related Materials in Other Therapeutic Areas**

- Educational symposium for nurse practitioners characterizing the diagnosis and long-term management of irritable bowel syndrome with diarrhea
- Four scripts characterizing the diagnosis, treatment initiation, and challenges in the long-term management of patients with hereditary angioedema
- Backgrounder on the role of long-term care, rehabilitation, and skilled nursing for patients hospitalized for acute medical illnesses
- Disease backgrounder on the epidemiology, pathogenesis, risk factors, treatment and prognosis of renal impairment in acutely ill, hospitalized patients
- Educational program on the dialogue between clinicians and patients about obesity and strategies for management
- Advances in immunopathogenesis and immunomodulatory therapies for inflammatory bowel disease
- Educational program on guidelines for adolescent vaccinations, current vaccination rates, and strategies to improve compliance with national vaccination recommendations
- Nurse practitioner education and performance intervention to promote pediatric medication safety
- Interactive monograph on the epidemiology, risk factors, pathogenesis, differential diagnosis, and current and emerging treatments for chronic constipation and irritable bowel syndrome with constipation
- Educational program on the epidemiologic burden, direct and indirect costs, risk factors, assessment methods, guidelines for management, and tailored strategies to promote and sustain weight loss
- Nurse practitioner education and performance intervention to promote health risk assessment, interventions, and adoption of preventive health behaviors in adult patients
- Nurse practitioner education and performance improvement intervention to improve the quality of care for chronic obstructive pulmonary disease



- Educational program and DVD script addressing physician-patient communication about the risks and benefits of therapeutic interventions for diverse health conditions
- Innovative nurse practitioner health education tool for youth and parents to increase awareness and compliance with preventive health behaviors
- Monograph with case studies on clinical evaluation and treatment of sleep wake disorders, including obstructive sleep apnea, shift work sleep disorder, and delayed sleep phase syndrome
- Monograph on medication management for patients residing in assisted living facilities
- Case-based module on autolysis as a novel method of debridement for wound care
- Educational program for clinical sales specialists on the implications of healthcare reform, the Affordable Care Act, and accountable care organizations on wound care
- Training module for clinical sales specialists on current approaches to optimal management of chronic wounds
- National E-learning curriculum for clinical sales specialists and medical science liaisons on the pharmaceutical and non-pharmaceutical management of the symptoms of autosomal dominant polycystic kidney disease
- Training program for clinical sales specialists on pharmacologic interventions for retreatment in smoking cessation
- Summary of an Advisory Board on emerging therapeutic options for allergic rhinitis
- Program development, presentation slides, and meeting summary for an advisory board on the educational needs of medical residents and fellows
- Application for continuing medical education accreditation to the Accreditation Council for Continuing Medical Education
- Review of published and fugitive literature and interviews with subject matter experts on pharmacologic interventions for chronic obstructive pulmonary disease and development of materials for a comprehensive publication plan
- White paper on the efficacy, safety, and cost-effectiveness of a non-surgical treatment for eustachian tube dysfunctions in adults and children

- Comprehensive literature review and summary of the epidemiology of psychiatric disorders for an abnormal psychology textbook

### **CME Proposals in Other Therapeutic Areas**

- Changes in the epidemiologic burden and treatment recommendations for chronic obstructive pulmonary disease
- Current and emerging immunosuppressive therapies for solid organ transplantation
- Optimal management of patients undergoing solid organ transplants
- Emerging medical issues in liver transplantation
- Prevention, diagnosis, and management of chronic allograft nephropathy
- Current issues in the management of anemia in chronic kidney disease

### **Consumer Education Programs and Materials in Other Therapeutic Areas**

- A position paper for consumers summarizing subject matter expert recommendations on opioids, anti-inflammatory medications, and transdermal agents for management of chronic pain
- Print and online materials about opioids and alternative pain management interventions
- Print and online materials for diabetes
- Print and online materials for attention deficit hyperactivity disorder
- Slide presentation on the impact of chronic wounds and chronic wound care, including payer issues, patient-reported outcomes, and quality of life
- Print and online materials on fibromyalgia
- Print and online materials on pediatric medication safety
- Print and online materials on atrial fibrillation
- Print and online materials for adult health promotion and risk reduction
- Print and online materials for adults with chronic obstructive pulmonary disease
- Print and online materials for teen health promotion about mental health, nutrition, physical activity, safety, sexuality, and substance use