BACKGROUND: As age increases, prevalence of type 2 diabetes in the U.S. rises dramatically as the population approaches and enters Medicare eligibility (CDC). Although ensuring category access, CMS formulary guidelines for Medicare Part D (MVP) coverage do not take into account the effects of cost-sharing burden on patient outcomes. Our study demonstrated that higher copayment costs and consequently, the beneficial clinical impacts may likely be unrealized for many patients. OBJECTIVES: To investigate access to diabetic medications for MVP patients compared to commercially covered lives. Exploring this dichotomy, we collected data from three scenarios of drug development: (1) where biomarker development into their processes when a drug response is not optimal following the results of phase 3 studies. Usually this is when higher than expected efficacy is demonstrated. In this scenario, biomarker development enables targeting of a niche population that is representative of the responders, thus effectively increasing the efficacy making the product more attractive to payers and healthcare professionals. This late stage approach to drug development also fits with the commonly held belief that BMs are linked to reduced market access (MA), lower market shares and decreased product revenues. In such a situation BMs are only often developed retrospectively to overcome access issues. Our objective is to demonstrate that investment into BMs in the early phase of drug development (PPACA 2009) is more common than previously reported. METHODS: Case studies are built out of examining prices for the indicated to derive clinical outcomes across diverse patient populations and a variety of disparate data sources that collectively define a clinical profile at particular point in time. An outcome at time T1 is driven not only by static factors such as race, ethnicity and occupation, that are generally time-invariant but also by the condition profile and resultant outcome of the patient’s condition at T0. Our solution is an ensemble analytical framework that leverages a temporal rule induction algorithm to create derived outcomes profiles across the time continuum. It performs analysis on structured and unstructured data from a broad range of sources, including, biomarker, behavioral and demographic data sources that are integrated into a composite data warehouse via our proprietary semantic resolution and natural language processing algorithms. The outcomes profiles reflect an index or aggregate score for the amalgamation of all available data for a particular patient at a particular time. Outcomes profiles from thousands of samples are catalogued and normalized in a registry and are used to establish a baseline matrix for application in higher level statistical and predictive analyses for comparative effectiveness studies in pharmacology. Using this approach, it is possible to determine based on available data both the appropriate treatment to affect a desired outcome and the predicted outcome based on a given treatment at a given time.

PHIP107
BIOMARKERS: A CHANGING PARADIGM FOR DEVELOPMENT
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The general perception is that pharmacy companies generally incorporate biomarker (BM) development into their processes when a drug response is not optimal following the results of phase 3 studies. Usually this is when higher than expected efficacy is demonstrated. In this scenario, biomarker development enables targeting of a niche population that is representative of the responders, thus effectively increasing the efficacy making the product more attractive to payers and healthcare professionals. This late stage approach to drug development also fits with the commonly held belief that BMs are linked to reduced market access (MA), lower market shares and decreased product revenues. In such a situation BMs are only often developed retrospectively to overcome access issues. Our objective is to demonstrate that investment into BMs in the early phase of drug development (PPACA 2009) is more common than previously reported. METHODS: Case studies are built out of examining prices for the

PHIP108
THE CASE OF RARE DISEASE DRUGS BEFORE AND AFTER THE INTRODUCTION OF PRICING BODIES: LESSONS LEARNED FROM BRAZIL AND CANADA,
IMPLICATIONS FOR THE UNITED STATES
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HEROES, Independent LLC, Somerville, NJ, USA
OBJECTIVES: This poster examines the pharmaceutical price implication for rare disease products in two countries which recently developed technology assessment and pricing processes with a look toward the potential implications for the United States. METHODS: Case studies are built out of examining prices for the indicated to derive clinical outcomes across diverse patient populations and a variety of disparate data sources that collectively define a clinical profile at particular point in time. An outcome at time T1 is driven not only by static factors such as race, ethnicity and occupation, that are generally time-invariant but also by the condition profile and resultant outcome of the patient’s condition at T0. Our solution is an ensemble analytical framework that leverages a temporal rule induction algorithm to create derived outcomes profiles across the time continuum. It performs analysis on structured and unstructured data from a broad range of sources, including, biomarker, behavioral and demographic data sources that are integrated into a composite data warehouse via our proprietary semantic resolution and natural language processing algorithms. The outcomes profiles reflect an index or aggregate score for the amalgamation of all available data for a particular patient at a particular time. Outcomes profiles from thousands of samples are catalogued and normalized in a registry and are used to establish a baseline matrix for application in higher level statistical and predictive analyses for comparative effectiveness studies in pharmacology. Using this approach, it is possible to determine based on available data both the appropriate treatment to affect a desired outcome and the predicted outcome based on a given treatment at a given time.

PHIP109
AN OUTCOMES PROFILE REGISTRY FOR ESTABLISHING A BASELINE MATRIX IN COMPARATIVE EFFECTIVENESS STUDIES IN PREDICTIVE PHARMACOLOGY
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We propose a novel applied decision analytics solution in clinical outcomes analysis for deriving outcomes to be used as benchmarks in designing appropriate therapies in personalized medicine and predictive pharmacology. The efficacy of comparative effectiveness research in clinical medicine and pharmacology is limited by a lack of a definitive demonstration of clinical benefit. Our solution to derive clinical outcomes across diverse patient populations and a variety of disparate data sources that collectively define a clinical profile at particular point in time. An outcome at time T1 is driven not only by static factors such as race, ethnicity and occupation, that are generally time-invariant but also by the condition profile and resultant outcome of the patient’s condition at T0. Our solution is an ensemble analytical framework that leverages a temporal rule induction algorithm to create derived outcomes profiles across the time continuum. It performs analysis on structured and unstructured data from a broad range of sources, including, biomarker, behavioral and demographic data sources that are integrated into a composite data warehouse via our proprietary semantic resolution and natural language processing algorithms. The outcomes profiles reflect an index or aggregate score for the amalgamation of all available data for a particular patient at a particular time. Outcomes profiles from thousands of samples are catalogued and normalized in a registry and are used to establish a baseline matrix for application in higher level statistical and predictive analyses for comparative effectiveness studies in pharmacology. Using this approach, it is possible to determine based on available data both the appropriate treatment to affect a desired outcome and the predicted outcome based on a given treatment at a given time.

PHIP110
BIOSIMILARS LITERATURE REVIEW: THE CURRENT LANDSCAPE AND IMPLICATIONS OF RECENT HEALTH CARE LEGISLATION FOR THE UNITED STATES MARKET
Maizie JA, Lee EN, Toscani MT
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Biosimilars represent an emerging area of interest for the pharmaceutical industry. Biosimilars are defined as similarly “generic” versions of “branded” biologics, but are not considered identical to the innovator biologic. In 2009, half of the top ten selling drugs were biologics; this proportion is expected to reach 80% by 2015. Biosimilars are seen as a cost-saving alternative to payers, and as generic drugs take over the market, manufacturers are depending on biologics to drive growth. However, they will need to consider the inherent challenges in this market. This literature review was undertaken to provide a summary of the current state of affairs with biosimilars, including a review of the recent healthcare legislation and policies in countries that already have formal guidance regarding biosimilars approval. Significant resources are required to participate in the biosimilars market, including regulatory expertise, manufacturing capabilities, and global market reach. One concern to potential market players is the uncertainty regarding the approval process for biosimilars in the United States (U.S.). The Patient Protection and Affordable Care Act (PPACA 2009) authorized the FDA to develop an abbreviated regulatory pathway for biosimilar approval but guidance has not yet been issued. It is important for the U.S. to learn from other countries. This review includes a summary of other countries’ approaches to biosimilars approval. For example, since 2006, the European Medicines Agency has had extensive requirements for pre-clinical and clinical data to demonstrate quality, safety, and efficacy of the product seeking approval. Questions remain including: How will the competitive landscape look as biosimilars enter the market? What will be the comfort level with substitutability of biosimilars? Will there be patient protection for the manufacturing process? And, what will the FDA require in terms of clinical trials and other supportive data to recognize biosimilars? The literature review will address these questions and more.

PHIP111
OVER INFILTRATION OF THE GENETIC CONTRIBUTION TO SCHIZOPHRENIA: IMPLICATIONS FOR NOVEL THERAPEUTICS
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Schizophrenia is a complex disease with diverse etiological mechanisms and current therapeutic options remain suboptimal. Although the genetic contribution to schizophrenia is suggested, a clear genetic pathway to schizophrenia has not yet been established. Novel therapeutic approaches aimed at understanding the genetic contribution to schizophrenia and moreover may also invalidate many of the reported study findings. This literature review uncovers serious flaws in the methodologies and statistical analyses used in studies. These flaws tend to artificially inflate the perceived genetic contribution to schizophrenia and moreover may also invalidate many of the reported study findings. There exists an absence of a replicable and consistent finding indicating a clear genetic pathway to schizophrenia. Novel therapeutic approaches aimed at neurotransmitter receptor site abnormalities should not therefore be discouraged but rather marked by the fundamental refusal on gene therapy approaches.

PHIP112
DEFINITIONAL CRITERIA FOR CHRONIC FATIGUE SYNDROME: A CRITICAL REVIEW
Christley Y, Duffy T, Martin CR
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Chronic Fatigue Syndrome (CFS) is an enigmatic and misunderstood clinical entity. A broad range of etiological mechanisms have been suggested including endocrine, immune, infectious, muscular and neurological abnormalities. However, the cause remains elusive thus impacting on developing models of evidenced based therapy approaches.

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pestic intervention and trial monitoring and outcome evaluation. Complicating this situation is inconsistencies in CFS case definition. The main objective is to provide a critical review of the similarities and differences between the varying approaches to CFS case definition. The conflicts and controversies that have emerged as a result of the different conceptual criteria for CFS are highlighted and the potential impact on future research is identified. A critical review of the most frequently used case definitions in CFS was conducted. There are currently five case definitions of CFS, however, the most prominent is the 1994 Centre for Disease Control and Prevention Case Definition. However, prima facie comparative advantages of this definition are elusive and indeed, it has been widely criticized for its lack of specificity. Counterintuitively, there is little compelling evidence to support the efficacy of any of the case definitions have produced evidence to demonstrate their accuracy or precision at defining cases of CFS. A summary description of the symptom profile for each of the case definitions is provided. The inconsistencies that have emerged in CFS research as a consequence of differing approaches to case definition are contrasted and discussed. Clinical and research implications are highlighted.

PP113
IQWIG AND HIQA, WHAT ARE THEY GOOD FOR? THE EVOLUTION OF THE HTA AGENCY: TIME FROM CREATION TO FIRST ASSESSMENT AND IMPACTFUL APPRAISAL
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OBJECTIVES: To evaluate the time spent from the creation or charter of an HTA agency to endpoints indicating their effectiveness, such as publication of assessment reports. This study is the first to incorporate assessment into meaningful measures influencing patient access to health technologies. METHODS: This study looks at the creation of HTA agencies (e.g. AHRQ, HIQA, IQWIG, PBAC, CADTH and NICE) and their evolution in terms of roles in assessment (advocacy, coordinating, decision-making), and the time they have with appraisal. RESULTS: It has been demonstrated that the time it takes for an agency to generate assessments impacting patient access varies widely. For example, in Ireland, HIQA was chartered in May 2007, and entrusted with performing HTA assessments. In 2008 and 2009, HIQA has published one health technology assessment per year, both of which were received and in turn implemented by the Minister for Health and Children. In comparison, NICE in the UK was founded in 1999, but its appraisals were not supported by mandate until 2005. Meanwhile, HTAs driven by DAHTA/SDMII in Germany are known to rarely play a role in pricing and reimbursement. CONCLUSIONS: The evolution of HTA bodies has varied from country to country. However, evolution in scope and impact may provide useful lessons for countries where HTA is receiving renewed emphasis or where appraisal is under consideration for implementation, especially as new agencies are created and existing agencies evolve.

PP114
OPTIMIZING THE ORGANIZATION; MIGRATING HEALTH SCIENCES RESEARCH OPERATIONS INTO THE COLLABORATIVE SCIENCE CENTER OF EXCELLENCE
Benson J, Enterline L

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The execution and management of Health Sciences Research projects can be an onerous task. Often there is no centralized body of knowledge within an organization around process and requirements. This leads to long execution timelines, difficulties with vendors and ultimately reduced productivity. The Collaborative Science Center of Excellence (CSCoE) was established in 2008 at Bristol-Myers Squibb (BMS). This group manages the global operations of a wide variety of programs, a portion of which includes worldwide investigator sponsored research, non-clinical research, expanded access, and risk evaluation and mitigation programs. Beginning June 1, 2010, the operations management of the entire US Health Economics and Outcomes Research (HEOR) book of work was moved from the OR Scientists into the CSCoE. This included administration, contract execution, master service agreement negotiation, financial management, protocol writing, AMCP dossier updates, and invoice tracking and payment. Within the first year over 90 service agreement negotiation, financial management, protocol writing, AMCP dossier updates, and invoice tracking and payment. Within the first year over 90

POSTER SESSION I:
DISEASE-SPECIFIC STUDIES

Cardiovascular Disorders – Clinical Outcome Studies

PCV1
DOES ROUTE OF ADMINISTRATION FOR ESTROGEN THERAPY IMPACT RISK OF VENOUS THROMBOEMBOLISM? ESTRADIOL TRANSDERMAL SYSTEM VERSUS ORAL ESTROGEN-ONLY HORMONE THERAPY
Laliberté E1, Dea K1, DuS M2, Kahler KH1, Rolli M1, LeFebvre P1
1Groupe d’Analyse, L’île, Montreal, QC, Canada, 2Analysis Group, Inc., Boston, MA, USA

OBJECTIVES: To evaluate the risk of developing venous thromboembolism (VTE) events associated with the use of estradiol transdermal system (ETS; Vivelle-Dot®) relative to oral estrogen-only hormone therapy (HT) agents. METHODS: A health insurance claims analysis was conducted using the Thomson Reuters MarketScan database from January 2002 through October 2009. Patients ≥35 years old newly initiated on an ETS or oral estrogen-only HT with ≥2 dispensions were analyzed. VTE was defined as ≥1 diagnosis code for deep vein thrombosis or pulmonary embolism. As a secondary outcome, incident VTE resulting in hospitalization. Cohorts of ETS and oral estrogen-only HT were matched 1:1 based on both exact factor and propensity score matching. Incidence rate (IRR) was used to compare the rates of VTE between the matched cohorts. Remaining base-case assumptions from matched cohort were included in an sensitivity analysis. RESULTS: Among the matched ETS and oral estrogen-only HT users (27,018 subjects in each group), the mean (SD) ages of the cohorts were 48.9 (7.1) years; in each cohort 6,044 (22.4%) and 1,786 (6.6%) patients had a hysterecromy and an oophorectomy at baseline, respectively. The mean (median) drug exposure for the ETS and oral estrogen-only HT cohorts was 391 (264) and 401 (272) days, respectively. A total of 115 ETS users developed VTE compared to 164 subjects in the estrogen-only HT cohort (unadjusted IRR: 0.72; 95% CI: 0.57-0.91, P=0.006). After adjustments, ETS remained statistically significantly associated with a lower incidence (55% reduction; 95% CI: 0.03-0.13) of VTE. The incidence reduction for hospitalization-related VTE events among the ETS users was even more pronounced with the adjusted incidence being 62% lower for ETS users relative to oral estrogen-only HT users. CONCLUSIONS: Results of this large population-based study showed that patients receiving ETS had a significantly lower incidence of VTE compared to patients receiving oral estrogen-only HT.

PCV2
THE RISK OF CARDIOVASCULAR EVENTS ASSOCIATED WITH DIETARY CALCIUM AND VITAMIN D SUPPLEMENTS IN PATIENTS WITH OSTEOPOROSIS
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OBJECTIVES: Calcium and vitamin D supplements have been widely recommended and recommended for women to prevent or delay the onset of osteoporosis and the risk of future fractures. Other benefits include the improvement of bone mass and lipid levels and a lowering of body weight. In theory, the beneficial effects of calcium and vitamin D suggest improvements in cardiovascular health. Recent publications suggest the contrary and allow to increase serum calcium as a risk factor for adverse cardiovascular events. This study examines whether the exposure to these supplements are associated with cardiovascular events. METHODS: This study was based on California Medicaid (Medi-Cal) fee-for-service administrative claims data from January 1995 to December 2002. The study population consists of patients >50 years with recorded diagnoses of osteoporosis followed from diagnoses date to the end of eligibility. Patients were excluded for prior use of the supplement or diagnosis of cardiovascular events or drug induced osteoporosis. Propensity score matching based on age, gender, elixhauser comorbidities and eligibility data created case (n=1594) and control groups (n=4782). Chi-square analysis was conducted for comparison of the cardiovascular events defined as ICD-9 codes for myocardial infarction and searchable terms of “cerebral hemorrhage, ischemia” for stroke. RESULTS: No statistically significant relationship was found between the study groups for stroke (p=0.56) and myocardial infarction (p=0.54). Components of stroke included cerebral artery occlusion (p=0.94), precruceral artery (p=0.27), intracranial hemorrhage (p=0.05), and subarachnoid hemorrhage (p=0.05). The clinical benefits of the supplements were evident with subarachnoid hemorrhage with 0 recorded diagnoses in the case group compared to 12 recorded diagnoses in the control group; however statistical significance was not established. CONCLUSIONS: The use of calcium and vitamin D supplementation is not associated with adverse cardiovascular events. Moreover, no broad cardio-protective effects can be concluded from the study.

PCV3
RISK OF HOSPITALIZATIONS FOR VENOUS THROMBOEMBOLISM IN ATYPICAL VERSUS TYPICAL ANTIPSYCHOTIC USERS IN A NATIONAL SAMPLE OF MEDICARE BENEFICIARIES: A CLAIMS DATA ANALYSIS
Dharmarajan SH, Yang Y, Athavale AS, Bentley JP, Null KD, Banahan BF
University of Mississippi, University, MS, USA

OBJECTIVES: To examine the difference between typical and atypical antipsychotic drug use in the risk of hospitalization for venous thromboembolism (VTE) in an elderly Medicare patient population. METHODS: This is a retrospective cohort using 5% national sample of 2006-2007 Medicare claims data. Medicare beneficiaries with continuous Part A, B, and D enrollment in 2006-2007 and who initiated atypical or typical antipsychotic drug therapy in July 2006-June 2007 were included. All study subjects were followed for a period of 180 days from the date of index prescription. Atypical and typical users were matched on propensity score, calculated using pre-index demographics, clinical comorbidities, and medication use. A conditional logistic regression model stratified on the propensity score-matched pair using the Green matching algorithm was used to compare the risk of hospitalization for VTE in new users of atypical and typical antipsychotic drugs. Sensitivity analysis in the unmatched cohort was performed using propensity score as a continuous, linear term in logistic regression. RESULTS: A total of 15,637 new users of atypical and 2,337 new users of typical antipsychotic drugs were identified. There were 472 (2.6%) hospitalizations with a diagnosis code for VTE during follow-up among atypical and 55 were typical antipsychotic users. A 1.1 propensity score match yielded 2,333 matched pairs (4,666 individuals). In the matched cohort, 55 typical and 64 atypical drug users were hospitalized for VTE in the follow-up period. Compared to typical antipsychotic users, users of atypical antipsychotics were less likely to have