BACKGROUND: As age increases, prevalence of type 2 diabetes in the U.S. rises dramatically as the population approaches and enters Medicare eligibility (CD). Although ensuring category access, CMS formulary guidelines for Medicare Part D (MFD) coverage do not take into account the effects of cost-sharing burden on patients. The overall burden is reduced with higher copayment costs and consequently, the beneficial clinical impacts may likely be unrealized for many patients. OBJECTIVES: To investigate access to diabetic medications for MFD patients compared to commercially covered lives. Exploring difference between those with and those without MFD coverage. METHODS: The outcomes profile registry. 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. 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 the lack of a definitive 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-independent, but also by the condition profile and resultant outcome of the patient's condition at T2. 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 clinical, biologic, 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.

PHP107
BIOMARKERS: A CHANGING PARADIGM FOR DEVELOPMENT
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The general perception is that pharma 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 poorer than expected efficacy or safety are observed. In this scenario, BM 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 BM development also fits with the currently 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 retroactively to overcome access issues. Our objective is to demonstrate that investment into BMs in the early phase of drug development (DO) is more commercially attractive. In this scenario, BMs have been developed and introduced into the market at various stages and how this affects risk-reward were assessed. RESULTS AND CONCLUSIONS: The scenario analysis demonstrates that by shifting investment to earlier in the DD process, costs associated with investment-heavy Phase III will be reduced. Early incorporation of BMs into DD will improve the commercial and healthcare benefits and the drug will have the potential to benefit from shortened approval time, early MA and higher price.

PHP108
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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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...