PART OF REAL CHEMISTRY

Momenta Pharmaceuticals

INTRODUCTION

Specialty and rare diseases have undefined patient populations who are undiagnosed or misdiagnosed, healthcare providers who are unaware of disease states and their manifestations, as well as treatment journeys that are not well-understood. IPM.ai transforms real world data into real world insights that uncover the ideal patient, their treatment journey and their healthcare ecosystem so that life sciences companies can accelerate the successful development and commercialization of life-savings therapies for specialty and rare diseases that lead to optimal patient outcomes quicker, with less risk.

THE CONDITION

Warm autoimmune hemolytic anemia (wAIHA) is an autoimmune disorder characterized by the premature destruction of healthy red blood cells (hemolysis). Autoimmune diseases occur when one's own immune system attacks healthy tissue. In the case of wAIHA, red blood cells are "tagged" by antibodies and are then destroyed by other types of immune cells. WAIHA is the most common type of autoimmune hemolytic anemia; it affects approximately 1 to 3 per 100,000 people every year and can occur at any age. The disease is termed "warm" because the antibodies are active and cause hemolysis at body temperature, which is not necessarily the case in other types of autoimmune hemolytic anemia.

THE CHALLENGE

Using proprietary antibody engineering technology, Momenta Pharmaceuticals developed nipocalimab (M281), a monoclonal antibody for the treatment of wAIHA. However, with no specific ICD 10 diagnosis code, identifying wAIHA patients and assessing the clinical course of the disease was challenging. To remedy this, Momenta sought to: 1) identify a wAIHA cohort using a collection of specific diagnostic codes; 2) evaluate whether a collection of diagnostic codes could bisect severe versus non-severe wAIHA patients; 3) observe the frequency of comorbidities and anemia symptoms in severe and non-severe wAIHA groups; and; 4) use a predictive model to validate clinical variables and prevalence estimates.

THE SOLUTION

IPM.ai built an ideal patient profile based on a diagnosis code of "autoimmune hemolytic anemia" (AIHA) with multiple distinct events within 36 months. Patients were required to have at least 30 days of steroid use over 36 months, and utilization of a known drug regimen for treatment of an autoimmune disorder. Patients were classified as severe if claims related to transfusion or blood composition testing, or if high frequency interactions with a hematologist,were observed in the 36-month period. In addition, codes for comorbidities, treatments and procedures were grouped and analyzed within the most recent 12 months for each patient. Disease prevalence was then estimated via machine learning and artificial intelligence look-alike modeling in conjunction with a real world data universe of over 300 million de-identified patients.

THE OUTCOME

Using claims variables for hemolytic anemia, other blood count abnormalities, and medical procedure claims commonly used for the diagnosis and management of wAIHA patients (such as Coombs and haptoglobin testing), IPM.ai identified a cohort of 1,548 wAIHA patients evenly distributed by gender with ae median age of over 65. The cohort showed evidence of anemia, anemia symptomatology (such as shortness of breath, cough, and fatigue), and wAIHA-specific testing and treatments. The rate of disease-relevant claims was disproportionately higher in the severe cohort versus the non-severe cohort; over the 12 month study period, variances ranged from 61% higher (for anemia-based comorbidity codes) to as high as 570% higher (for anemia-based procedural codes). Primary hypertension, hyperlipidemia, gastroesophageal reflux, and evidence of chemotherapy use were also present in wAIHA patients; all of these conditions were observed more frequently for severe patients. Of interest, lupus was observed more frequently in the non-severe wAIHA cohort. Almost 44% of wAIHA claims for the full cohort were associated with Hospital/Emergency care, or 48% for the severe group. In the end, IPM.ai's predicted population supported prevalence estimates of 30,000-49,000 patients in the United States.

About IPM.ai

IPM.ai, part of Real Chemistry, is an Insights as a Service (IaaS) provider that empowers the world's leading life sciences companies to better understand and improve the lives of patients through the development and commercialization of precision medicine for specialty and rare diseases. IPM's system of insight optimizes drug development, clinical study, product launch and commercial operations through granular-level longitudinal analytics, artificial intelligence and machine learning in conjunction with a real world data universe of over 300 million de-identified patients and 65 billion anonymized social determinants of health signals.