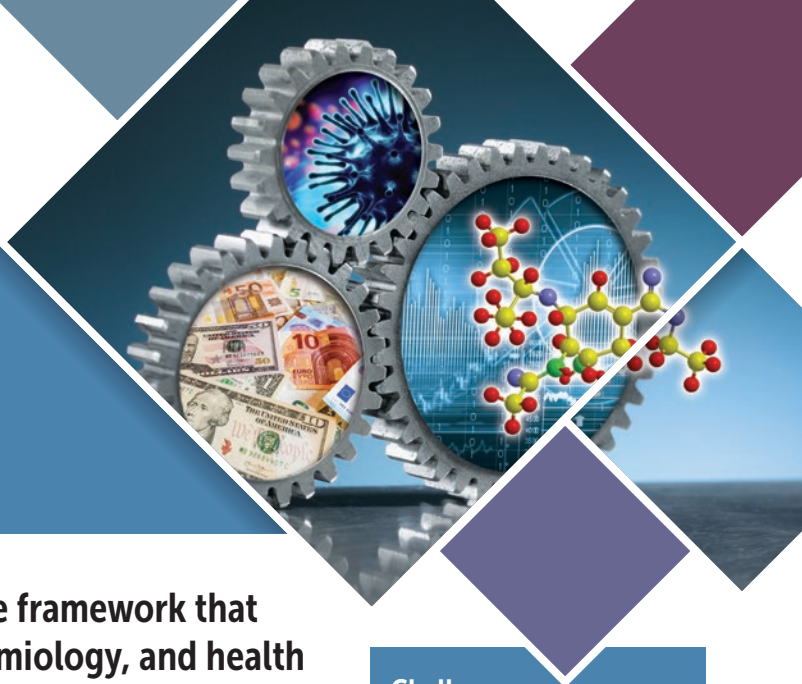
CERTARA

Establishing Novel Quantitative Approaches to Connect Pharmacology to the Payer



The Certara team helped develop a quantitative framework that bridges the disciplines of pharmacology, epidemiology, and health economics to support meaningful dialogue between industry, regulators, and payers

Background

Historically, modeling of infectious diseases has been conducted in discrete silos wherein the pharmacology of treatments, epidemiology of outbreaks, and health economic impacts were not linked. Consequently, inappropriate assumptions have been made about adjacent disciplines. In addition, for today's drug developer, regulatory success alone is not enough. Increasingly, pharmaceutical companies must justify the pricing of medicines to society and payer.

Challenge

The traditional drug development paradigm draws the "finish line" before the payer. Regulatory approval leads directly to reimbursement by payers and patient access. Historically, payers had reluctantly accepted this paradigm and provided reimbursement with little influence on what they were receiving or whether they chose to accept it.

Today, the finishing line for novel drugs is different; navigating the payer landscape in Europe can take up to two years after attaining regulatory approval. This results in many patients experiencing unacceptable delays in accessing lifesaving medicines.

A pharma client wanted to know if it was possible to quantify the societal impact of a new dose regimen or novel candidate against an emerging pandemic influenza strain. They sought to help optimize decision-making under multiple scenarios based on infectivity, virulence, and drug resistance.

As a test case, they used oseltamivir, the cornerstone of national stockpiles in the case of pandemic influenza. An added advantage of picking oseltamivir was the relatively rich evidence base from pre-clinical pharmacology, epidemiology, and clinical evidence from which to draw on. Oseltamivir was the first oral neuramindase inhibitor to be commercially developed. It is used to treat and prevent infection with both influenza A and B. Oseltamivir is a prodrug that is extensively metabolized to its active carboxylate metabolite (OC) by the liver. Elimination is primarily in the urine as the OC metabolite.

Challenge

A pharma client wanted to know if it was possible to quantify the societal impact of a new dose regimen or novel candidate against an emerging pandemic influenza strain.

Solution

Certara led and managed execution of developing a "pharmacology to payer" framework that linked pharmacology of treatments, epidemiology of outbreaks, and health economic impacts.

Benefit

Our work enables early and quantitative exploration of the health economic impact of a new dose regimen or novel candidate against an emerging pandemic influenza strain, under various scenarios.

Solution

Certara provided thought leaders in influenza, clinical pharmacology, PK/PD modeling, epidemiological modeling and health economics to tackle the ambitious goal. They facilitated the construction of an integrated road-map.[1,2]

Briefly, it included how to cater to the key inputs of an emerging virus through the framework.

- How disease impacted on individual patient disease
- Propagation of influenza through a community
- Where drug directly impacted an individual or indirectly a population via shedding
- How disease from a population level and health care utilization influenced health economics

The team also led and managed execution of the overarching project as well as its technical components, including PK/PD analyses and epidemiological and health economic modeling. The PK/PD module showed the relationship between oseltamivir exposure and time to cessation of viral symptoms and resolution of symptoms. The epidemiology module used a SEIR (susceptible, exposed, infected, recovered) influenza epidemiology model that was adapted to incorporate oseltamivir PK/PD. The SEIR model then was used to simulate the number of patients infected under different pandemic and treatment intervention scenarios. The number of infected patients for each scenario was entered into the health economics module to determine the change in quality-adjusted life-years relative to base case.

Benefit

An integrated modeling approach that linked pharmacology to the payer was established, along with a practical decision framework.[1,2] This enables early and quantitative exploration of the health economic impact of a new dose regimen or novel candidate against an emerging pandemic influenza strain under various scenarios. The framework also facilitates predicting the number of patients who become infected in an epidemic based on viral transmissibility, antiviral dosing, and the percentage of patients treated. Under most pandemic scenarios, oseltamivir reduced the number of infected patients, increased quality-adjusted life years by averting deaths, and was cost-saving. Such insights provide opportunity for earlier meaningful discussions between developers, regulators, and payers.

Impact

The P2P framework has been applied to other global health indications. P2P method innovations have made it realistic to "capture and determine the health economic impact of individual and community patient journeys." Such application was considered the missing link to bring P2P methodologies beyond medical countermeasures and infectious diseases into all other disease areas, including oncology and chronic inflammatory and neurodegenerative diseases, including Alzheimers and multiple sclerosis. The approach may inform early target product profile (TPP) requirements for investigational drugs, procurement strategies, and strategic pricing and deployment decisions, including combination with adjacent non-therapeutic interventions.

References

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2. Wu DBC, Chaiyakunapruk N, Pratoomsoot C, Lee KKC, Chong HY, Nelson RE, Smith PF, Kirkpatrick C, Kamal MA, Nieforth K, Dall G, Toovey S, Kong DCM, Kamauu A, & Rayner CR. Oseltamivir use in an Influenza Outbreak: Linking Pharmacology to Pharmacoeconomics. Presented at IDWeek: A joint meeting of IDSA, SHEA, HIVMA, PIDS. October 8-12, 2014, Philadelphia, PA. Accessed from https://www.certara.com/wp-content/uploads/Resources/Posters/IDSAposter-Rayner-FINAL.pdf

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

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