SPEAKout

Provided by: Certara

Changing the Drug Development Playbook – MODEL-INFORMED DRUG DEVELOPMENT HAS ARRIVED

Imagine that you can reduce the number of patients required for a complex, hard-to-recruit clinical trial by ten-fold.

Imagine that you can use technology alone to add dosing information for special populations – such as pediatric patients, pregnant women or those with impaired organ function – to the drug label, shaving many months and significant cost off your development timeline.

Imagine that you can leverage information from your competitor's clinical trial results to differentiate your drug development program, potentially gaining millions of dollars in commercial value.

Imagine that the regulatory agency tells you to use a specific in silico *technology to understand the variability in your data, so they can move forward and approve your drug.*

Imagine no longer. Welcome to the world of model-informed drug development (MIDD).

What is MIDD and when should it be leveraged?

During the past few years, MIDD has evolved from a research nicety to a regulatory necessity. More than 90 percent of novel new drug approvals now leverage one or more MIDD technologies.

MIDD is used by sponsors at every step along the drug development pathway from discovery through pre-clinical and clinical studies to patient care. It advises new drug candidate selection, first-in-human dosing, and labeling language regarding possible drug-drug interactions and the product's use in specific populations. It also allows data to be fully leveraged from one phase to the next (both backwards and forwards), from one indication to the next, and from drug development to clinical care.

Certara's technology-based products and services are used to inform key safety and efficacy decisions, identify and validate drug targets, determine optimal drug dosing, design clinical trials, triage compounds, make comparisons with competitor compounds, and assess mechanistic drug performance.

They are used to explain and justify scientific decisions in research and development, go/no-go decisions by commercial teams, and pricing decisions to payers.

Regulators embrace MIDD

Global regulators are actively promoting MIDD. The US Food and Drug Administration (FDA) has included MIDD in its Prescription Drug User Fee Act (PDUFA) VI negotiations and it is expected to be included in the 2017 PDUFA reauthorization. Furthermore, the FDA is partnering with the European Federation of Pharmaceutical Industries and Associations to develop best practices for model-informed drug discovery and development. The Japanese Pharmaceuticals and Medical Devices Agency and China FDA are also pursuing these approaches.

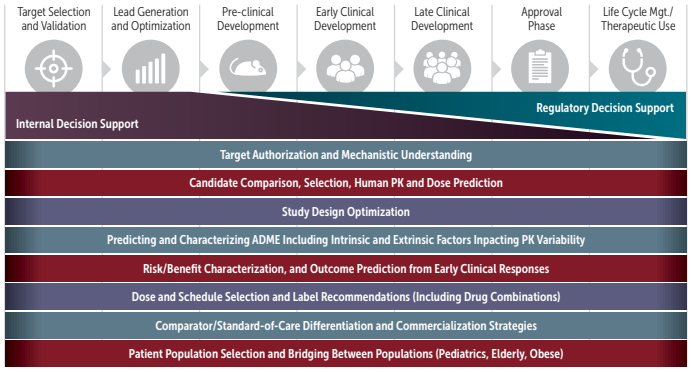
According to FDA spokesperson Kristofer Baumgartner, MIDD already has resulted in shorter trials with fewer patients, fewer postmarketing studies and tailored drug dosing. "The use of modeling and simulation has the potential to make the interpretation of data more efficient, improve the prediction of drug safety and efficacy, and explain variable patient responses."[2]

ROI from MIDD is clear and growing

MIDD has the power to reduce R&D cost and improve the return on investment (ROI). It can allow go/no-go decisions to be made earlier, obviate the need for certain clinical trials, and enable comparisons to be made between new drug candidates and potential competitors so accurate market share assessments can be produced.

Sponsors are definitely benefiting from model-informed drug discovery and development. There is evidence that these approaches enabled a $100 million reduction in Pfizer's annual clinical trial budget and increased late-stage clinical study success rates.[1] Additionally, Merck & Co/MSD has reported significant cost savings ($500 million) through model-informed drug discovery and development impact on decision-making.[1]

Range of Applications for MIDD[1]



Conclusion

Certara is committed to changing the game in drug development by fully leveraging MIDD across the development cycle. We believe that this approach will enable our clients to develop new therapies more quickly and efficiently, unlock millions of dollars in savings, expand indications to meet unmet medical needs, and differentiate products from a competitive perspective. Sponsors, regulators, payers, and most important, patients will benefit.

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Ellen Leinfuss is senior vice president at Certara, a leading decision support technology and consulting organization committed to optimizing drug development and improving health outcomes.

1. Marshall et al. Good Practices in Model-Informed Drug Discovery and Development. *CPT Pharmacometrics Syst. Pharmacol.* (2016) 5, 93–122; doi: 10.1002/psp4.12049

2. *BioCentury*, September 5, 2016, page 23.