The IQ Consortium is a not-for-profit organization of pharmaceutical and biotechnology companies with the mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators and the broader R&D community.

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Model Informed Drug Development Working Group

The mission of the MIDD WG is to to promote the use of MIDD applications. One of the WG objectives was to publish a paper discussing the benefits and value of the FDA MIDD paired meeting pilot program based on IQ member company experience with the program.

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IQ shows FDA's MIDD Paired-Meeting Pilot Program has Demonstrable Benefits

THE CHALLENGE

Discussions of Model Informed Drug Development (MIDD) at 2019 a scientific exchange meeting between the US FDA's Office of Clinical Pharmacology and the IQ Clinical Pharmacology and Translational and ADME leadership groups resulted in an IQ commitment to assess the potential impact and benefits of FDA's MIDD Paired Meeting Pilot Program from an industry perspective. If the assessment were positive, sharing of this information may facilitate the program's continuation as part of PDUFA VII.

OBJECTIVES & APPROACH

To quantitate any benefits of participation in the pilot program, a survey of member companies who had participated in the program was conducted. The focus of the survey was to assess potential benefits of the program as an aid in the consideration of the program's continuation.

Development Cost Savings

Million (USD)	N
0 - 1	1
1 - 10	2
10 - 30	2
30 - 70	3

11 responses of not applicable

Development Time Savings

Months	N
0-3	2
9-12	2
12-15	1
15-18	1
18-24	3
>24	3

See paper for the other 7 responses

Survey results: Benefits from participation in the MIDD Paired-Meeting Pilot

RESULTS

The survey results revealed considerable benefit and impact and results were published.[1] IQ representatives also shared the results at a PMDA Workshop: Role of Model Informed Drug Development, March 23rd 2021. The PMDA workshop was well attended with over 400 participants in attendance. Per program savings are noted in the following tables.

IMPACT

- Companies have recognized savings in resources, achieved alignment with the FDA on developmental strategies, and gained clarity on important aspects of programs and product characteristics.
- The estimated savings also provide significant value to patients and the medical community as successful medications will reach the market faster. Additionally, the savings on resources and cost of development can be applied to the advancement of other promising candidates. Further, MIDD principles can be used to identify compounds that do not have acceptable safety and efficacy more efficiently resulting in the termination of development with fewer patients or volunteers exposed.
- Further, these meetings helped champion the application of MIDD strategies within pharmaceutical companies and have facilitated adoption of MIDD strategies across programs within a company.

The totality of evidence of the value of this program demonstrates a definite benefit to patients, the medical community, and pharmaceutical companies. Hence, the permanent adoption and expansion of these meetings and their principles is strongly encouraged.

[1] Galluppi, G.R., Brar, S., Caro, L., Chen, Y., Frey, N., Grimm, H.P., Rudd, D.J., Li, C.-C., Magee, M., Mukherjee, A., Nagao, L., Purohit, V.S., Roy, A., Salem, A.H., Sinha, V., Suleiman, A.A., Taskar, K.S., Upreti, V.V., Weber, B. and Cook, J. (2021), Industrial Perspective on the Benefits Realized From the FDA's Model-Informed Drug Development Paired Meeting Pilot Program. Clin Pharmacol Ther, 110: 1172-1175. https://doi.org/10.1002/cpt.2265