



Model-based Meta-analysis: Leveraging External Data for Strategic Decision-making

MBMA uses highly curated clinical trial data and pharmacology models to increase drug development productivity, quantitatively inform portfolio management and improve clinical trial success

Model-based meta-analysis (MBMA) is a method that integrates clinical trial efficacy, tolerability, and safety information to enable strategic drug development decisions. The strategy involves a systematic search and tabulation of summary results from public sources combined with in-house clinical trial data. These data are then analyzed to characterize the impacts of drug class, drug, dose, and time on the response(s) of interest, plus potential influence of study population characteristics or the trial conduct. Most important, MBMA provides a quantitative understanding of how a new compound will perform relative to existing standard of care and other developmental compounds.

The advantages of MBMA

Certara Strategic Consulting's MBMA approach offers two key advantages. First, it supports bridging across studies, thereby enabling comparison of treatments and patient populations that may never have been tested together in the same clinical trial. Second, MBMA models are based on pharmacologic principles which facilitate incorporating wider spectrum data with regard to dose, observation time, and clinical trial design.

Gaining insight into the comparative safety and efficacy profile of your drug

There are very few active comparator trials in drug development. However, it is often important to assess a compound's safety and efficacy profile in comparison to the standard of care and/or competitor drugs in development. MBMA enables indirect comparison, taking into account the impact of treatment, patient population, and trial characteristics on responses to medications. This type of analysis, also called 'competitive landscaping', can help us to understand potential differentiators in the drug profile and determine whether a drug is superior to its competitors in the same drug class or across drug classes.

Elucidating endpoint-to-endpoint relationships

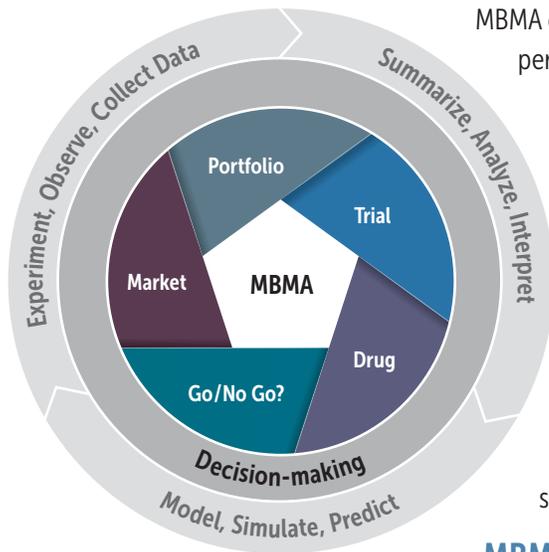
Anchoring our MBMA services are a set of 20+ clinical outcomes databases that contain large amounts of data that we have curated from published sources. This enables the application of MBMA to make biomarker-to-clinical and short-term-to-long-term endpoint predictions.

Highlights

- Compare the effectiveness of investigational drugs to other treatment options
- Scale from biomarker to clinical endpoints
- Scale to other indications

Advantages

- **Inform decision-making:** MBMA helps drug developers make decisions that will maximize their probability of success. It can help them to position a drug between existing and developing competitors.
- **Optimize trial design:** This approach aids with predicting trial results to inform go/no go decisions. It also can help optimize dosing to maximize safety and efficacy.
- **Expand indications:** Use MBMA to project efficacy/safety for a compound from one indication to another.



MBMA can also be applied to scale across indications. These analyses help predict drug performance in later stage development or in a different indication.

MBMA supports strategic decision-making

Drug development decisions are usually made with in-depth quantitative analysis of internal data from the drug candidate and a comprehensive but less quantitative review of public data or data from other candidates. Most decisions cannot be made with internal data alone. MBMA provides a quantitative framework to integrate internal and external data during drug development to inform proprietary commercial and R&D decisions. The insights gained via MBMA begin in early drug development to guide the design of less costly and more precise trials with an eye toward achieving commercial success for both the drug and portfolio.

MBMA can help answer a number of important questions including:

- **Compare your drug vs the competition:** What are the characteristics of the dose-response curves for existing drugs that are in the same class as a new compound? What are typical ranges? How does onset of effect differ between drug classes? How do baseline characteristics or background treatments impact drug response?
- **Optimize trial design:** What is the impact of trial design features (eg, time, endpoints) on treatment effects? How are specific subsets of the population represented? What is the impact of region? How do biomarker and clinical endpoint results compare? Can we predict trial results? How can we optimize dosing to maximize safety and efficacy?
- **Inform go/no go, portfolio, marketing decisions:** What are the safety and efficacy profiles for competitor drugs for a given therapeutic indication? Can we differentiate the drug as best-in-class? Where is the therapeutic window of the new drug in comparison to competitor/standard of care benchmarks? How can we best position a drug between existing and developing competitors?

What is the probability that my treatment meets the product profile?

How does my drug stack up against the standard of care?

What is the probability to have a better treatment effect vs other treatments?

Which trial design aspects cause meaningful differences in response?

What patient or trial characteristics contribute to between trial variability in treatment effect?

Can we leverage data from competitor drugs to better understand dose-response?

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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