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Fact sheet

The Data Already Knew. MBMA Found the Answer.

Three real-world examples of model-based meta-analysis reducing uncertainty before pivotal development decisions.

Some of the biggest calls in drug development can't wait for the next study to read out and often they don't have to. Model-based meta-analysis (MBMA) pulls together everything that's already known, including published clinical trial data, your own data, and evidence from across the therapeutic area, to clarify where your program stands and how a trial is likely to perform. Here are three examples of how it changed the outcome.

MBMA forecast called a Phase 3 before it ran

Weight loss

A small six-week study was added to a weight loss picture built from 74 published trials. From there, MBMA was used to simulate the full 48-week Phase 3 and put a number on its probability of success. **When the real trial read out, the observed weight loss matched the prediction.** That gave the team a solid, defensible read on the risk before they committed to the pivotal study.

Why it mattered:
a real probability-of-success number, months before the data existed.

MBMA strengthened a submission approval

Multiple sclerosis

There was no clean way to compare these MS treatments head-to-head, so MBMA predicted it. Using published data from 26 trials, MBMA evaluated how 17 treatments truly compared in slowing disability progression by accounting for differences in dose, treatment duration, and prior therapies, ensuring a fair comparison. The **findings supported the regulatory submission and approval**.

Why it mattered:
placebo and cross-therapy context no single trial could provide, in a form regulators accepted.

MBMA stood in for a missing control arm

Relapsed or refractory ALL

A single-arm Phase 2 study in 185 patients with relapsed or refractory ALL had no comparator. Using efficacy data from other salvage-therapy studies, an MBMA built an external control arm to benchmark the new drug directly. **Both the FDA and the EMA referenced that analysis during the accelerated approval process.**

Why it mattered:
a credible comparison where there simply wasn't one, supporting accelerated approval.

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Notice the pattern

The data was already there.

None of these examples required a new study. MBMA simply made better use of existing evidence, including published clinical trials, earlier studies, and internal data sets.

The question came first.

Predict a trial, size up the field, replace a missing control arm. The method was chosen to fit the decision, not the other way around.

Regulators actually used it.

These weren't just slides for an internal meeting. Some of the work went into submissions and agencies referenced it, which is about as high a bar as it gets.

It improved confidence in critical decisions.

From go or no-go decisions to pivotal trial design and regulatory strategy, the model reduced uncertainty at the moments that mattered most.

Where does this fit for you?

MBMA is just one tool in the toolkit. It works alongside population pharmacokinetics (PopPK), exposure-response (ER) response analysis, pediatric modeling, concentration-QTc (C-QTc) analysis, physiologically based pharmacokinetic (PBPK) modeling, and quantitative systems pharmacology (QSP). The right approach depends on the question you're trying to answer. **That's a conversation worth having.**

What are you trying to figure out? Tell us the decision on your plate, and we'll show you what the data can already say.

Learn more

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