CERTARA

Know how your drug compares before you run the trial

Model-based meta-analysis (MBMA) turns curated trial data into comparative evidence for dose selection, trial design, and positioning.

Active comparator trials are rare, but you still have to know how your compound performs against standard of care and assets in development. MBMA models efficacy, tolerability, and safety from published trials alongside your own data, accounting for drug, dose, time, patient population, and trial conduct. You get a quantitative read on how your compound compares before you have direct evidence.

Where MBMA changed the decision

Competitive Landcsaping

Virtual head-to-head trials

Challenge: Judge whether a compound would beat an established competitor without running an active comparator study.

Impact: MBMA simulations estimated the probability of superiority or non-inferiority against a comparator, across several endpoints modeled at once.

Case study: Using MBMA to run virtual head-to-head trials

Dose Selection I Phase III

Phase III dose selection, milvexian

Challenge: Choose a Phase III dose in atrial fibrillation where direct clinical comparisons and validated biomarkers were both limited.

Impact: A quantitative model-informed analysis supported the dose decision, published in peer-reviewed literature.

On-demand webinar: Quantitative Model-Informed Dose Selection for a Milvexian Phase III Study in Patients With Atrial Fibrillation.

Cross-Indication Scaling

Neuropathic pain comparator model

Challenge: Establish one efficacy benchmark spanning diabetic peripheral neuropathy, post-herpetic neuralgia, and fibromyalgia.

Impact: A single model fitted across all three indications let data from each inform the others, guiding eligibility criteria and dose selection for future trials.

View the science

Partner Programs

MBMA in practice with GSK

Challenge: Show where MBMA shifts decisions across therapeutic settings with very different evidence bases.

Impact: Joint case studies spanning hepatitis B, inflammatory disease, and oncology, presented with GSK.

On-demand webinar: From Data to Decisions

The decisions it informs

- **Differentiation:** Is the compound separated enough to compete, and against which benchmark?
- **Dose and duration:** What dose(s), for how long, and in whom?
- **Target product profile (TPP):** What is the probability of hitting our target before committing to Phase 3?
- **Go/no-go:** What does our readout say about where we stand against competitors?
- **Reimbursement:** What comparative evidence will payers expect, and can it be generated before Phase 3 closes?

Built on CODEX

Curated clinical outcomes data, ready for analysis

Start with evidence that is ready for analysis. Certara MBMA is powered by CODEX, our curated clinical outcomes database spanning safety and efficacy endpoints, trial design, and patient characteristics across 60+ indications and 8,000+ studies. All data are curated in house and explorable through an interactive analytics interface.

MBMA at Certara

Certara has been applying model-based meta-analysis across therapeutic areas for over two decades, backed by the largest global team of model-informed drug development (MIDD) experts and by CODEX, our curated clinical outcomes database platform.

60+	8,000+	120+	20+
indications covered in CODEX	curated clinical studies	PhD, PharmD and MD consultants	years of MIDD leadership

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Model-based meta-analysis

Why model-based, and not just meta-analysis

Few development decisions can be made from internal data alone. MBMA supplies the quantitative framework for integrating your own results with the published record — raising development productivity and informing portfolio choices.

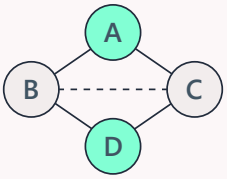
Pairwise (PMA)

Direct evidence only

One pooled effect

Network (NMA)

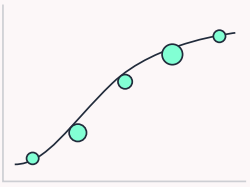
Adds indirect links



Ranks all treatments

Model-based (MBMA)

Adds dose and time



Predicts new doses

MBMA goes further than pairwise or network methods. Dose and time enter as continuous terms rather than fixed labels, enabling response to be estimated at doses and durations not directly studied. Trial-level covariates account for variability introduced by differences in patient populations and trial conduct.

What we do with it

Synthetic control arms

Build control arms that mimic a specific trial population, comparing treatment effects with less reliance on traditional observational methods.

Competitive landscaping

Position your compound against standard of care and development-stage rivals, within class and across classes, including its therapeutic window and onset of effect.

Trial optimization

Test design choices before committing: eligibility criteria, dose, endpoints, duration, and region.

Endpoint bridging

Link biomarkers to clinical outcomes and early readouts to long-term results, adjusting for baseline characteristics and background therapy.

Reimbursement strategy

Generate the comparative evidence payers ask for early enough to shape the Phase 3 design, rather than defend it afterwards.

Indication expansion

Project efficacy and safety from one indication into another to support portfolio and expansion decisions.

Talk to our MBMA team

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Start with a complimentary consultation.

Learn more

About Certara

Certara transforms drug discovery and development for good, helping scientists and clinical teams generate regulatory-grade evidence faster. Its solutions combine biosimulation, clinical intelligence, and regulatory science, and are embedded in the workflows of drug developers worldwide. Certara clients include more than 2,600 biopharmaceutical companies, academic institutions, and global regulatory agencies. Learn more at certara.com. | certara.com/services/model-based-meta-analysis