CASE STUDY

Early economic modelling to inform Phase 3 design in treatment-resistant depression

An EU pharmaceutical company developing a new therapy for treatment-resistant depression (TRD) needed to understand its economic potential with only early-phase data. We designed a flexible early cost-effectiveness model (CEM) that tested value across different treatment positioning and trial-design scenarios, and fed back strategic recommendations into Phase 3 planning.

KEY RESULTS

HTA-ready foundation

A model concept and early CEM as an initial step towards producing an HTA-ready model

Early EJP estimates

Early indications of an economically justifiable price (EJP)

Phase 3 guidance

Strategic recommendations on Phase 3 design, plus a prioritised list of further research activities

AT A GLANCE

CLIENT
Biopharmaceutical company

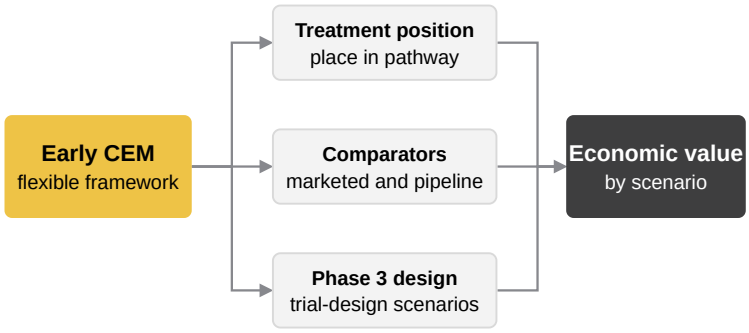
THERAPY AREA
Treatment-resistant depression

SERVICE
Health economics: early cost-effectiveness modelling

MARKETS
Global, with EU and US HTA in view

STAGE
Early clinical development, Phase 2

AUDIENCE
Global market access, HEOR and clinical development teams



One flexible framework tests the economic case across each plausible future treatment landscape at launch.

The challenge

The client had a promising therapy in TRD at an early stage of clinical development. Only early-phase data were available, and the product's eventual place in the treatment pathway was still undecided. Phase 3 design decisions were approaching, and those choices would shape the evidence available to payers and HTA bodies at launch.

Framing the economic case was complex, the depression pathway involves many lines of therapy and possible comparators, and TRD has no single agreed definition. Early trials were also likely to exclude people with the most severe illness, leaving a gap between trial populations and the patients HTA bodies are likely to assess.

The risk was clear. A Phase 3 programme designed without an economic lens could generate evidence that struggles to support a credible value case at HTA.

CEM, cost-effectiveness model; EJP, economically justifiable price; HTA, health technology assessment; TRD, treatment-resistant depression.

Our approach

We built the CEM with flexibility in mind, enabling a single framework to test the therapy's economic case across each plausible future treatment landscape at launch.

1

Reviewing precedent CEM

We began with a review of published cost-effectiveness models and HTA appraisals in depression and TRD. This showed how others had structured the pathway, defined TRD and selected comparators, and where those choices had drawn scrutiny. A systematic review identifying 20+ economic evaluations in TRD was critically appraised, and three additional economic evaluations were identified and examined in further detail to inform the model design.

2

Designing flexible CEM for future treatment landscape

With the timing of launch undecided, we specified a model structure that could incorporate data from comparators still in development as well as comparators already on the market. The client could evaluate the economic case against each comparator using the best available data while retaining flexibility to incorporate future data readouts as competitors progressed towards launch.

3

Turning analysis into recommendations

We worked closely with the client's HEOR and biostatistics teams to pressure-test the findings and shape them into strategic recommendations on Phase 3 design, considerations for the future HTA-ready model structure, and a detailed list of further research activities.

The outcome

The client now has an early CEM ready to develop into an HTA-ready model as clinical evidence matures, and early EJP estimates. The early CEM sets out the potential economic value of the therapy under alternative future treatment landscapes at launch and different Phase 3 design scenarios.

The work gave clinical development and market access teams a shared basis for Phase 3 decisions. Our recommendations on trial design, and the list of further research activities, give the client a clear route to stronger evidence for future HTA submissions.

Early CEM
Ready to develop into an HTA-ready model as evidence matures

EJP estimates
Early indications of an economically justifiable price

Recommendations
Phase 3 design advice and a prioritised research list

RELATED WORK

Flexible model build | Absence of trial data for a non-drug intervention | Health Economics services

WORK WITH US

If you need to understand the economic potential of an asset before Phase 3 decisions are fixed, our health economics team can help.

Talk to our health economics team

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