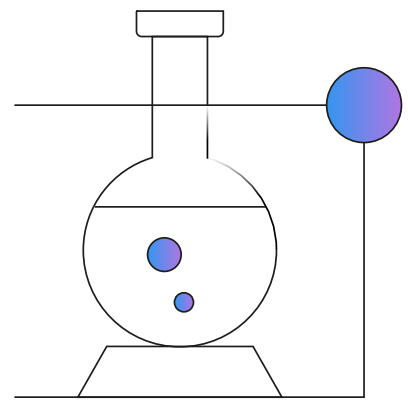


Adapting Global HEOR Models

Case Study | HEOR Models

Adapting Global HEOR Models to Support US Launch Readiness for an SMA Therapy



Background

A biopharmaceutical company preparing for the US launch of a therapy for spinal muscular atrophy (SMA) required health economic evidence to support payer engagement and commercial strategy. While global cost-effectiveness and budget impact models had been developed for the UK, these models did not reflect US payer requirements or launch-phase needs.

The Challenge

The client needed to rapidly adapt existing global HEOR models to the US context while ensuring regulatory and compliance readiness.

Key challenges included:

- Aligning global cost effectiveness and budget impact models with US methodological requirements
- Identifying and incorporating appropriate US specific clinical, cost, and epidemiological inputs
- Updating documentation and outputs for payer facing and field team use
- Ensuring models were compliant, approved, and suitable for US launch activities

Expert technical oversight was required to minimize risk and maintain model integrity.

The Solution

Clarivate's health economics experts delivered a structured, collaborative model adaptation programme to support US launch readiness.

Key elements included:

Model assessment and adaptation planning:

Review of existing global models and development of a detailed US specific adaptation plan covering methodology and data requirements.

US focused model adaptation:

Updating the cost effectiveness and budget impact models with relevant US inputs while ensuring functionality, consistency, and robustness.

Collaborative execution:

Close coordination with the client and the original model vendor throughout development to align key changes.

Launch ready outputs:

Updating technical reports and developing clear model summary slides to support payer engagement and internal use.

Compliance support:

Ongoing guidance to ensure adapted models were approved and appropriate for use by US field teams.

The Results

Clarivate successfully delivered US ready HEOR models and supporting materials to enable confident launch execution.

Outcomes included:

- Adapted cost effectiveness and budget impact models for the US SMA market
- Transparent, US specific technical reports and summary slides
- Models approved for use in US payer engagement and launch activities
- Expert guidance that streamlined adaptation and reduced execution risk

This work enabled the client to leverage global evidence efficiently while meeting US payer expectations and supporting a successful product launch.