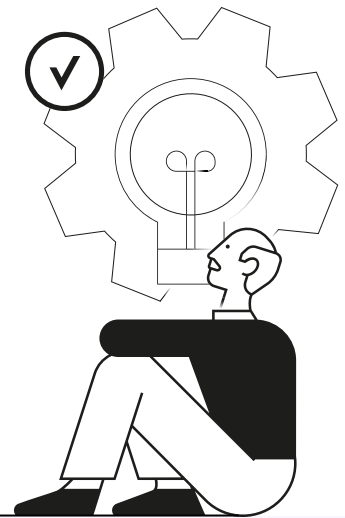


Coordination and Delivery of a Centralised HTA Programme

Case Study | Centralised HTA Programme

Engaging Clarivate's commercial consulting expertise for a gene therapy programme treating Spinal Muscular Atrophy (SMA)



Background

A global top 5 pharma company developed a novel gene therapy for SMA treatment and were seeking support with pan-European HTA submissions.

Clarivate was asked to coordinate and deliver a centralised EMEA (>20-markets) HTA programme to gain market access for the gene therapy.

The Challenge

Orchestrate internal and external stakeholder interactions:

Align functional groups at global-, EMEA- and country-level, including Regulatory Affairs, Clinical Development, Clinical Operations, Medical Affairs, Market Access and HEOR.

Manage external vendors responsible for global activities such as health economic modelling, systematic reviews and country-level HTA dossier submissions.

The Solution

Clarivate Commercial Consulting

Our HTA Centre of Excellence was well positioned to support and provided guidance throughout the entire process to enable the seamless execution of the global submission plan. This included:

- HTA network coordination, including management and tool/training development
- Technical and consistency review of local HTA dossiers
- Coordination of Global HEOR material adaptation
- Core UK market HTA submission development, including full pre- and post-submission support
- Country specific submission development and support
- Global value dossier and HTA objection handler
- Support for global and CEE countries

The Results

A strategic, global partnership driving submissions & reimbursements



23 submissions and/or pre-applications completed to date



Clarivate is seen as a key strategic partner, involved in decision-making at multiple levels



Global support for ex-EU markets, including submission review, HTA assessor responses and ongoing development of HEOR materials



Several global reimbursement successes since programme inception

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