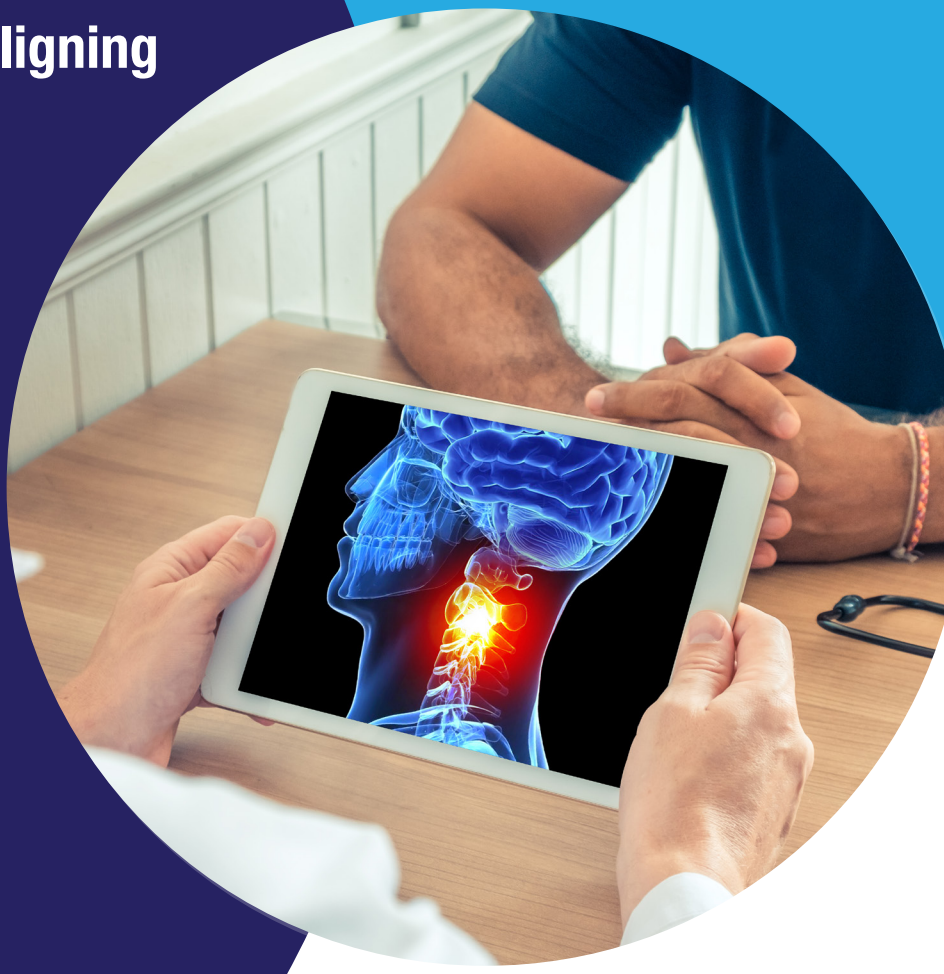
CASE STUDY

Oncology Developer Utilizes Integrated Scientific Advice to Optimize Phase III Trial, Aligning Regulator and HTA Needs

Evidera's Value & Development Consulting team leverages our Integrated Scientific Advice (ISA) offering to provide feedback to drug developers to optimize their evidence generation plans and satisfy stakeholder requirements



65+

Integrated regulatory and HTA advice engagements and supporting 15+ companies

30+

Indications worked across in ISA engagements

Key Takeaways

Received positive feedback and alignment on the client's the Phase III trial design, including the choice of endpoints, comparator, and study inclusion criteria

Modified the early economic model to one with a structure more aligned with the expected clinical outcomes based on feedback from NICE

Revised the label indication to ensure the consistent definition of appropriate comparator therapy in all future HTA engagements

Successfully out-licensed the product to a top 10 biopharmaceutical company with exclusive worldwide commercial rights worth approximately €1 billion, exclusive of royalty payments

Objective

A mid-sized biopharmaceutical client was in the planning stages of a Phase III clinical trial for a new locally advanced head and neck cancer therapy and was seeking ways in which integrated scientific advice (ISA) could be used to optimize the trial to satisfy both regulatory and HTA requirements in Europe. ISA, a multi-stakeholder advice process that brings together regulators, HTA bodies and patients, allows for better alignment of evidence needs for both regulatory approval and market access.

Challenges

The client had limited awareness of various ISA options, including the advantages and disadvantages of each option and the value of engaging early with HTA bodies alongside regulators. Additionally, after deciding to pursue EMA-EUnetHTA Parallel Consultation procedure, which allows for drug developers to receive feedback from regulators and HTAs at the same time, the client was rejected due to EUnetHTA resource capacity constraints. This rejection expedited the need to implement an alternative ISA option to obtain regulatory and HTA feedback on the clinical and evidence development plan.

Strategy

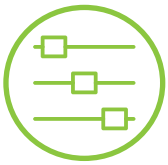
Our Value & Development Consulting team worked to implement an ISA plan to provide external validation of the client's clinical development plan to potential out-licensing partners. Specifically, our experts advised the client to pursue two individual ISA routes, selecting both G-BA and NICE-EMA concurrent advice to provide insights for Europe. At the time, the NICE-EMA concurrent advice pathway was a newly launched service that allows drug developers to obtain concurrent EMA regulatory and NICE advice, complementing the EMA-EUnetHTA Parallel Consultation procedure.

To support this, our team:

- Provided rapid implementation of briefing book changes
- Crafted a timely response to the list of issues
- Supported preparation meetings
- Attended two advice meetings

Results

- Our VDC experts guided the company through a new NICE and EMA concurrent advice pathway, which involved several key methodological differences versus established pathways
- Client gained valuable insight from a regulatory and HTA perspective for their pivotal trial design and overall evidence generation strategy
- Product's regulatory label wording was refined to clarify the target patient population, which prevented an unfavorable comparator treatment from being included in future HTA appraisals



4 areas of discussion with HTA bodies had a high degree of alignment, validating the client's clinical development plan

Client out-licensed product in a **worldwide commercial deal worth approximately €1 billion**

Evidera's Integrated Scientific Advicec (ISA) offering provides feedback to companies to help optimize their evidence generation plans to develop robust evidence that is relevant to all stakeholders and supports timely patient access. Our integrated team provides evidence-based support combined with tailored project management to ensure timely delivery of a robust HTA package to maximize the efficiency, quality, and impact of ISA engagement.

Visit evidera.com/ISA to learn more about Integrated Scientific Advice™