Case Study



Providing EU5 Market Access Strategy and Reimbursement Support

About the Sponsor

The Sponsor is a specialty pharmaceutical company developing treatments for emergency care and rare diseases. With a diverse portfolio of products, the Sponsor provides critical healthcare solutions for patients worldwide.

Service Line

Market Access

Condition

Treatment Overdose

Drug Type

Investigational

Trial Phase

Phase 2



Challenge

The Sponsor company wanted to secure regulatory approval from the European Medicines Agency (EMA) and launch their product in the EU5 (France, Germany, Italy, Spain and the United Kingdom). However, the Sponsor was not familiar with the regulatory or reimbursement processes in Europe, having no infrastructure in any of the EU5 markets to support or provide guidance for its long term strategy.

Solution

With our experience in rare diseases, pricing, and reimbursement, we were able to help the Sponsor achieve its goals, working cross functionally within the organisation, as an integrated market access partner. Our team provided the Sponsor with a robust market access strategy and developed the Health Technology Assessment & Health Economics dossiers. We also engaged key stakeholders at all levels to ensure the clinical value benefit of the treatment to patients in the specific therapy area was understood.

Outcomes



Secured critical access for patients



Reimbursement was successful in all markets



Orphan Drug Application was approved



Demonstrated value benefit ratios



