BUSINESS CASE

Case Study: Global Submission Strategy

CHALLENGE

A European pharmaceutical company was developing a novel fixed dose combination product, which was already registered in the FDA, aiming to secure global marketing authorization without the need for additional clinical trials. The objective was to design a phased global submission strategy aligned with regulatory expectations across key markets.

The project faced the following challenges:

- Identify countries that could accept the existing clinical dossier without requiring local data.
- Evaluate the global acceptability studies conducted without local subject inclusion.
- Design a phased regional rollout plan grounded in regulatory feasibility and strategic priorities.
- Determine where prior regulatory engagement would be critical before submission.
- Deliver a high-level global roadmap optimizing both resources and timelines.

SOLUTION

Asphalion provided strategic regulatory consultancy, developing a Global Regulatory Assessment Report that mapped out the client's international expansion plan.

- **Global Feasibility Analysis**: Identified countries where the Marketing Authorisation Application (MAA) could be submitted without additional clinical trials and assessed regulatory acceptance of non-local clinical data.
- **Clinical Package Review**: Evaluated the adequacy of existing studies and regional data requirements.
- **Regulatory Clusters: Territories were divided into three groups**:
  - Group A (low-barrier markets) accepted the current dossier with minimal adjustments
  - Group B (moderate-barrier markets) required additional justification or limited new data
  - Group C (high-barrier markets) recommended early dialogue with Health Authorities due to stringent requirements or reference country status.

Comprehensive Report: Delivered a region-specific report covering submission feasibility, market warnings, expected timelines, and tailored regulatory recommendations.

OUTCOME

Development of a Global Submission Strategy in a 5-Stage Regulatory Planning for Expedited Market Entry

The client received a customized 5-stage global submission strategy, designed to expedite market entry with a projected 5-year timeline. This strategy was delivered on time and within the agreed budget, including the following key outcomes:

STRATEGY:
Clear, phased regulatory pathway for submission across key markets.

COMPLIANCE:
Efficient Alignment with Regulatory Expectations

EFFICIENCY:
Optimized Resource and Timeline Management

www.asphalion.com
info@asphalion.com
+34 93 238 59 45