

BUSINESS CASE

Case Study: Externalization of Publishing Operations for a Global Multinational



CHALLENGE



Seeking a provider to **fully outsource all eCTD publishing activities** for their global portfolio.



The increased workload surpassed internal capacity, requiring **rapid and flexible allocation of resources**.



Developing a high-level **global roadmap** to optimize both resources and timelines.



Four distinct headquarters with diverse operational procedures.



SOLUTION

- **Eight dedicated FTE experts**, led by a client-appointed accountable manager.

- **Flexible invoicing modality** based on actual monthly time dedication.

- Developed a **global feasibility study** and aligned all headquarters on **standardized operational practices**.



OUTCOME

Handled the publication of **200+ dossiers** across major markets including the EU, US, Canada, UK, Switzerland, Australia, and other RoW countries

- Management of new drug applications, variations, renewals, and pre- and post-approval activities.
- Continuous **training** on regulatory operations guidelines and updates in the regulatory landscape.
- **Efficient Alignment** with Regulatory Expectations and Optimized Management of **Resources and Timelines**.