synteract®

Broad Regulatory Affairs Knowledge Internationally

Working with Seasoned Regulatory Affairs Experts Gives Confidence

Having supported 240+ product approvals, Synteract can help to define the most comprehensive regulatory strategy for your product. Whether your new product is a drug, biologic, device, or even a combination of them, we understand the nuances of regulatory requirements and have the resources and proven expertise to address your specific needs, in whichever country you are applying.

Our regulatory affairs experts can help guide you throughout the full continuum of clinical development, whether it is preparing the IND or IDE, providing regulatory services across the project life cycle for each clinical trial, or preparing the NDA, BLA, MAA, or PMA.

Complying with the World Regulatory Bodies, One Country at a Time

With the capabilities to support you with regulatory services internationally, we provide up-to-date global know-how coupled with local experience to manage complex, ever-evolving environments and requirements. Our experts also are well-versed in the new European Clinical Trials Regulation currently being implemented.

Our Global Regulatory Affairs Strategy and Consulting Services Include:

- Drug development plans
- Regulatory registration strategy
- Pediatric study plans (PSPs) and pediatric investigation plans (PIPs)
- Orphan drug designation applications
- Breakthrough designation
- PRIME eligibility request
- Partnership and support for regulatory authority meetings and communication
- US agent or act as sponsor representative
- INDs, CTAs - both initial application and ongoing management
- NDAs, BLAs, MAAs - initial application and ongoing management

We know that taking new products successfully through clinical development, submission, and approval can be a difficult, expensive, and lengthy process. Contact us to get the support you need from our highly-responsive and experienced regulatory affairs experts.

Contact us to learn more about leveraging our Regulatory Affairs expertise and experience.

Ludwig Baumann, Executive Director, Regulatory Affairs

- Provides regulatory strategy, guidance, and consultation
- Provided support for and attended authority meetings with EMA and national competent authorities
- Supported preparation of PIPs and PSPs, orphan designation, and PRIME eligibility requests
- Experienced in writing and assessing quality documentation for submissions

CASE STUDY

Synteract Helps Company Obtain Orphan Drug and First PRIority MEdicines (PRIME) Designation in Europe

A clinical-stage biopharmaceutical client obtained orphan designation in the U.S. for its lead product and wanted to also obtain the designation in Europe. The respective rare disease can cause pain, leading to physical disabilities, organ damage, and early death. Orphan designation in Europe can provide development and commercial incentives, market exclusivity for a period of time, product consultation from the EMA, and lower, or reduced, regulatory fees. However, the client did not have a presence in the region.

Challenges

- To be accepted for orphan designation and the PRIME scheme in Europe, a therapy must demonstrate the potential to benefit patients with unmet medical needs through early clinical data. However, calculation of the prevalence in this case across Europe was not easy to determine, as it is less widespread in the region and significant differences exist between EU member states.
- Although the disease in question is a known rare disease and orphan designations have been granted in the past, Synteract recognized the client's application needed to be supported by solid data on the nature of the disease, available therapies, whether they are considered satisfactory or not, and justification on how the intended product meets an unmet need, or could be a significant benefit to existing treatment alternatives.

Our Solutions

- Synteract acted as sponsor for the orphan designation request and encouraged the client to participate in a pre-submission meeting with the EMA to ensure a smooth process and understanding of requirements. Synteract experts emphasized that while a more thorough procedure around submission preparation could extend timelines, having all requirements properly addressed could shorten back and forth communication between the client and the Committee for Orphan Medicinal Products (COMP) overall and be more likely to ensure success.
- Synteract leveraged its regulatory experience to calculate detailed information on prevalence of the disease in the EU and potential benefits of the drug for patients with unmet medical needs.
- Synteract provided strong medical and regulatory leadership throughout the process and performed a final regulatory review of the complete package before it was submitted to make sure it included all information required by authorities.

Program Success

- Recommendations from the pre-submission meeting played a large role in creating a meaningful submission, and providing information upfront, eliminating the need for COMP members to raise questions afterwards.
- The European Commission (EC), acting on a positive recommendation from the COMP, designated the drug an orphan medicinal product with no comments, signifying that the opinion was unanimous amongst the 36 members of the COMP and Eurordis reviewers.
- Synteract is the official holder of the orphan drug designation in the EU for this product on behalf of the client.
- Based on the availability of early clinical data, the potential to significantly address an unmet medical need was appropriately justified. Synteract acted successfully as applicant for the PRIME eligibility request on behalf of the client and access to the PRIME scheme was granted.

Medicines eligible for PRIME can also expect to be eligible for accelerated assessment at the time of MAA. As of May 2018 only 40 medicines out of 145 applications have been granted access to the PRIME scheme.