Regulatory Strategy

Comprehensive Assessments and Innovative Solutions

Synchrogenix provides global regulatory strategy consulting harnessing all of Certara’s capabilities, and leveraging our technologies and domain expertise.

- Regulatory gap analysis of development programs and global dossiers to increase probability of success for approval and patient access
- Agency engagement preparation, communications, and leadership
- Review of Agency correspondence, analysis of relevant regulatory guidelines and precedent
- Competitor labeling assessment to identify opportunities for competitive differentiation; labeling preparation and negotiations
- Proactive stakeholder consultation to achieve alignment
- Modification of development plans to incorporate Agency advice, including innovative approaches to address divergent regional perspectives or requirements
- Consideration of expedited regulatory pathways
- Integration of Health Economics Outcomes Research (HEOR), risk mitigation, modelling and simulation approaches, and post-authorization activities into drug development and regulatory strategies
- Due diligence assessments for in-licensing and partnering, including proposals to increase value proposition
- Applications; dossier preparation; and submission leadership
- Incorporation of regional regulatory requirements (United States, European Union, Asia-Pacific, Latin America)

For more information, visit our website at www.synchrogenix.com or email contactus@synchrogenix.com.