Case Study

Accelerating a US IND Submission for a China-Originated Asset

Ulcerative colitis is a chronic inflammatory bowel disease that affects millions of patients worldwide and continues to drive demand for innovative treatment options. An emerging, investment-backed biopharmaceutical company acquired a promising product developed in China and sought to advance the asset into US clinical development. However, significant differences between Chinese and US regulatory requirements created challenges for IND preparation. The sponsor engaged MMS to conduct a regulatory gap assessment, support protocol development, provide medical writing and regulatory operations expertise, and prepare the submission within an aggressive, investor-driven timeline.

The Challenge

The sponsor's development package had been assembled for the Chinese regulatory environment and was not submission-ready for the US. MMS identified several critical gaps, including missing study datasets, incomplete supporting documentation, untranslated reports, and content required for US regulatory compliance that had not been generated during the original Chinese development program.

Compounding these challenges, the sponsor was operating under a compressed timeline linked to investor milestones while simultaneously building its internal team. The project scope evolved throughout execution, including a substantial protocol redesign that expanded a single protocol into a master protocol with two intervention-specific subprotocols. Additionally, key CMC content was still being developed only days before the planned submission.

The Solution

MMS conducted an in-depth regulatory assessment to identify submission gaps and provide a clear roadmap to US IND readiness. The team worked closely with the sponsor to determine which materials could be obtained from the original development partner and which would need to be newly developed.

To address missing datasets without jeopardizing timelines, MMS collaborated with regulatory operations specialists to create simplified trial summary files while supporting efforts to obtain additional source datasets from the sponsor's Chinese partner. MMS also guided the sponsor through formal translation and certification requirements to ensure documentation met FDA expectations.

Beyond submission support, MMS provided medical writing expertise for nonclinical summaries and protocol development while helping the sponsor create a content strategy for Module 3 documentation. As project requirements shifted and new stakeholders joined the program, the MMS team remained flexible, continuously adapting plans and deliverables to maintain progress toward the submission milestone.

The project also incorporated AI-assisted quality control, with MMS working alongside the sponsor to apply AI-supported review processes as an additional layer of document quality assurance.

The Result

MMS successfully helped the sponsor transform a China-focused development package into a US IND submission package despite extensive content gaps, evolving study requirements, and compressed timelines. Through integrated regulatory strategy, medical writing, regulatory operations, and submission support, MMS provided the structure, expertise, and flexibility needed to keep the program aligned with its critical investment milestone.

The project demonstrated MMS's ability to support sponsors bringing China-originated assets into the US market, navigate complex regulatory differences, and adapt quickly to changing program needs without compromising submission quality.

Key Success Factors

- Early identification of US regulatory gaps
- Integrated regulatory, medical writing, and submission expertise
- Flexible approach to evolving project requirements
- Innovative use of AI-assisted quality control
- Strong cross-functional coordination under aggressive timelines
- Strategic support for emerging sponsors with limited internal resources

Let's Talk!

If you'd like to discuss this case study further or learn more on how our technology enabled services can support your development project, please visit **mmsholdings.com** or get in touch **info@mmsholdings.com**