

Case Study

How Citeline Services Help Sponsor with Global Clinical Trial Disclosure

The challenge

A large global pharmaceutical sponsor in the rare disease space sought regulatory writing expertise for global clinical trial submission.

The sponsor was in need of a partner with specific expertise to:



Lead and support the Clinical Overview and Summaries for submission to multiple health authorities



Integrate seamlessly into the Medical Writing group and cross-functional teams



Confidently lead cross-functional discussion and moderate study team decisions



Work within the confines of established company processes



The solution: Citeline Regulatory & Medical Writing Services

Citeline was able to understand and implement the client's requirements, providing a tailored approach to help the client reach by:

- Providing writers, with expertise in the specific challenges encountered during a global submission for a high-profile product, and were dedicated to doing everything possible to help make the drug available to vulnerable patients as early as possible
- Acting as an extension of the medical writing team to expand the team's knowledge and experience base
- Taking an agile approach that enabled the writing team to adapt to both client and regional-specific regulatory requirements

Outcomes & Success



Repeatedly pushed regulatory documents “across the finish line” successfully and on time



Secured document approval in multiple countries



Executed within confined processes to help the client achieve approval



Assigned a lead writer to learn client business processes to support future projects

“The team is professional and is always willing to take on more responsibility; this has led them to become a **trusted partner**.”

— Head of Clinical Trial Transparency

[Learn more](#) about how TrialScope Regulatory Writing Services can help support your regulatory and compliance efforts.

