Regulatory Case Study

PROVIDING REGULATORY SUPPORT IN CHINA FOR A NEW COMPOUND

A small to mid-size pharmaceutical company in India was developing a new combination treatment for complicated Urinary Tract Infection (cUTI). They were starting studies in the U.S. and EU but also wanted to evaluate their treatment in China with a Phase III trial. They chose Covance to support their efforts, provide a regulatory strategy and facilitate interactions with the China Food and Drug Administration (CFDA).

The Challenges: Driving a tight timeline for regulatory interaction

As a smaller company, the sponsor did not have in-house expertise on CFDA regulation. Covance was asked to set up and facilitate a consultation with the CFDA on behalf of the client and work around the client's tight timeline.

Typical CFDA protocol response times to sponsor meeting requests take approximately 15 working days after such requests are submitted, at which time proposed meeting dates are provided. In this case, the CFDA reviewers had a very high workload and the process was delayed. After nearly two months of persistent communication from the Covance regulatory strategist, the CFDA finally offered to schedule the meeting in three weeks. Because this milestone fell outside of the sponsor's desired timeline, Covance negotiated a much earlier meeting time that was scheduled for just one week away.

Key Takeaways

- Worked around extremely tight timelines to set up a consultation with the CFDA
- Gathered multiple subject matter experts to prepare sponsor's presentation to the CFDA
- Secured a priority and fast-track review to advance the sponsor's study of this unique treatment in China

While the sponsor was pleased with this outcome, the Covance leads now needed to gather the cross-functional team that was familiar with the meeting materials, CMC package and nonclinical package to rehearse their presentation to the CFDA reviewers. These materials needed to take into account the sponsor's Phase III protocol design and previous studies that supported a submission package, as well as the clinical development plan. A language barrier presented an additional challenge, as the CFDA only uses Mandarin and Covance needed to have materials translated to involve the sponsor's team in the meeting.

The Action: Gathering an international team to deliver the presentation

With a date set with the CFDA, the Covance regulatory strategy team had to first ensure that all available team members from Covance and the sponsor could attend the planning meetings, along with the local and global medical teams to provide input on the study. Many team members had to quickly secure travel visas and meet in Beijing on short notice. Due to the short timeline, Covance also assisted the sponsor with applying for travel visas, securing hotel rooms and booking the rehearsal meeting room as well as arranging for ground transportation.

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Covance led the team in a review of the materials to familiarize them with the meeting contents and rehearse their presentation to prepare for the CFDA consultation. Covance advised the sponsor on potential questions that may be asked and what the reviewers would need to approve the study. From the CMC work to the nonclinical package and PK bridging study and Phase III study along with inclusion/exclusion criteria, the team worked diligently to ensure all components of the study package were thoroughly reviewed before the consultation.

The Results: Guiding the sponsor to a successful outcome

The meeting with the CFDA was very successful. The CFDA reviewed the package provided by Covance and agreed with the proposal that the treatment addressed an unmet medical need in China. They also recommended that Covance submit an IND application as soon as possible and offered to process the application with priority and fast-track review. The CFDA also concurred with the protocol design and agreed to the proposal from Covance to run the PK bridging study in parallel with the Phase III study.

The sponsor was delighted with the outcome of the CFDA consultation and has asked Covance to support additional clinical studies in China along with the IND submission services.

The Lessons Learned: Being nimble and prepared for anything at any time

The Covance team's thorough understanding of the sponsor's compound and experience with global regulatory processes helped prepare the study design and communications for the CFDA review team. Because CFDA practices can change quickly, a proactive partner that can keep up with regulatory shifts is necessary to support successful studies in China.

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