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. 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 needed an experienced partner and chose Fortrea to help support their efforts. This case study shares how Fortrea provided a regulatory strategy and facilitated interactions with the National Medical Products Administration (NMPA) in China.

Driving a tight timeline for regulatory interaction

As an emerging company, the sponsor did not have in-house expertise on NMPA regulation and needed to navigate a very tight timeline. They turned to Fortrea to set up and facilitate a consultation with the NMPA on their behalf.

The typical NMPA protocol response time to sponsor meeting requests takes approximately 15 working days after a request is submitted, at which time proposed meeting dates are provided. In this case, the NMPA reviewers had a very high workload and the process was delayed. After nearly two months of persistent communication from the Fortrea regulatory strategist, the NMPA finally offered to schedule the meeting in three weeks. Because this milestone fell outside of the sponsor's desired timeline, Fortrea 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 NMPA

Gathered multiple subject matter experts to prepare sponsor's presentation to the NMPA

Secured a priority and fast-track review to advance the sponsor's study of this unique treatment in China

The sponsor was pleased with this outcome, but the Fortrea leads now needed to gather the cross-functional team that was familiar with the meeting materials, Chemistry, Manufacturing and Controls (CMC) package and nonclinical package to rehearse their presentation to the NMPA reviewers. These materials needed to consider 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 NMPA only uses Mandarin and Fortrea needed to have materials translated to involve the sponsor's team in the meeting.

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Gathering an international team to deliver the presentation

With a date set with the NMPA, the Fortrea regulatory strategy team had to first ensure that all available team members from Fortrea 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, Fortrea 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.

Fortrea led the team in a review of the materials to familiarize them with the meeting contents and rehearse their presentation to prepare for the NMPA consultation. Fortrea 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 pharmacokinetic (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.

Guiding the sponsor to receive a fast-track review

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

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

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

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