

Pharmacovigilance

China's new frontier: Seizing opportunities, overcoming obstacles



China's expansive regulatory overhaul is expanding opportunities for pharma and biotech companies to launch clinical trials and fast-track new drug application approvals in this burgeoning global market.



CHALLENGE:

Navigating the complexities of language, culture, regulatory requirements and provincial policies presents a host of challenges that can delay or derail your program's success. You need on-the-ground experts who understand the impact of new regulations on your specific program and who can quickly enact effective strategies for overcoming barriers along the way.



SOLUTION:

PPD's China Pharmacovigilance team comprises experienced, local experts who tailor a solution that complies with both the Chinese regulatory requirements and with global PV-industry best practices. Our PV model incorporates efficient procedures, systems, and quality & compliance programs to help you effectively monitor and manage innovative therapy safety profiles during the clinical development phase and beyond.

China is the world's second largest pharmaceutical market. Exhaustive regulatory reforms in China have paved the way for drug companies to expand their footprint in this vast and rapidly expanding global market. New regulations are designed to:

- Improve the drug review process through shortened IND and NDA review timelines to speed approvals
- Encourage new drug innovation
- Accelerate market authorization of medical innovations

OUR EXPERIENCE

6,000+

ICSRs submitted to the NMPA* for more than ten clinical studies

*National Medical Products Administration

18+ years

of clinical development experience in China

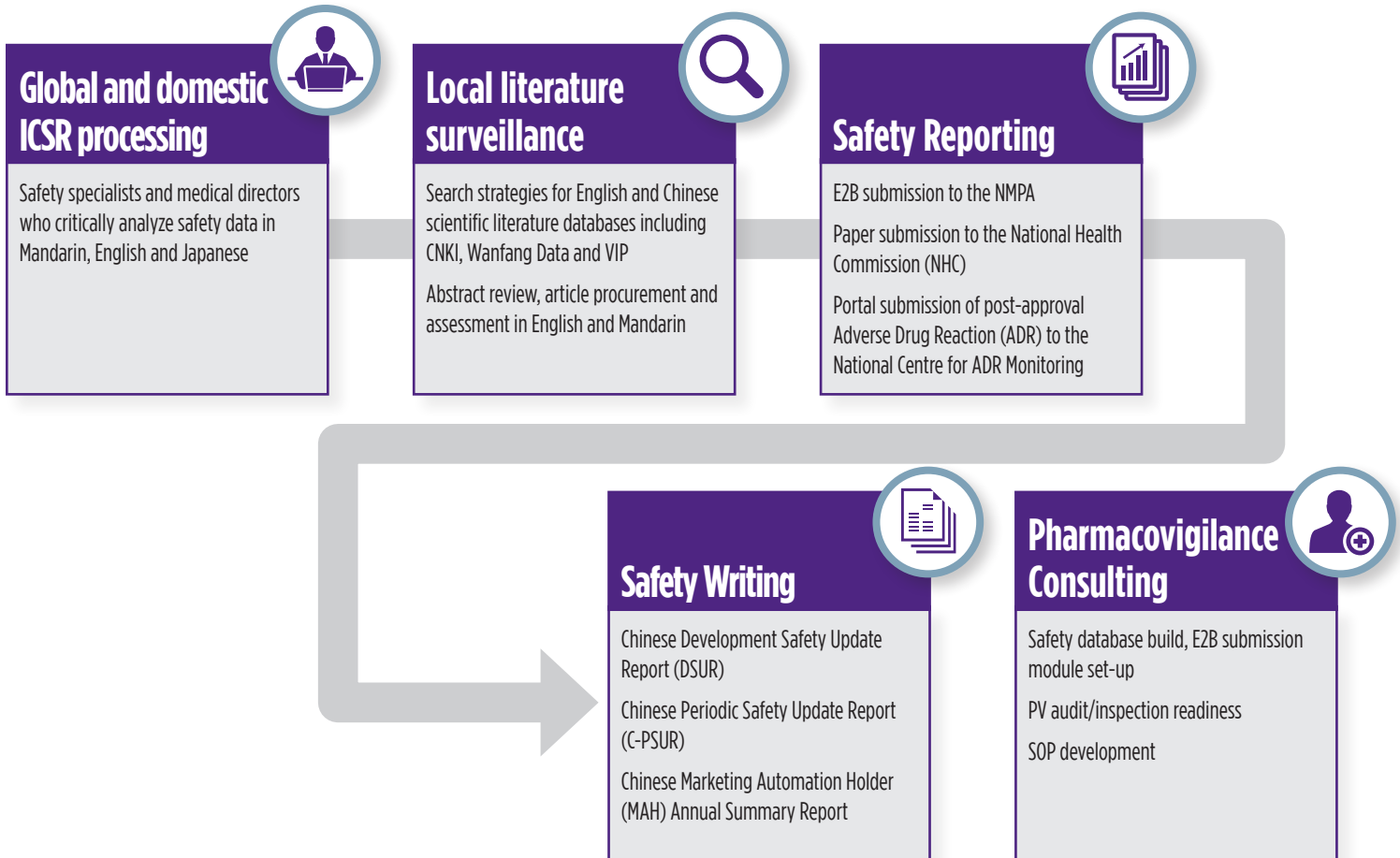
80+

local and global clinical trials safety management in the past 5 years

5 years'

average experience in pharma and CROs across our China PV team

OUR CAPABILITIES



OUR SOLUTIONS

- Full PV global capabilities with extensive knowledge of China's evolving PV regulations
- Deep experience in Oracle's Argus Safety and ArisGlobal's LifeSphere Safety MultiVigilance (formerly ARISg) safety databases, including implementation and management of ARISc (Chinese-language safety database)
- Integrated global drug safety system that is designed to capture China-specific data elements and safety reporting requirements defined by the Centre for Drug Evaluation (CDE) and the National Medical Products Administration (NMPA)
- Local safety specialists and medical directors, fluent in English and Mandarin, who review safety data in both languages and effectively communicate with the NMPA, local, and global customers
- PV teams based in Shanghai, Beijing and Shenyang provide business continuity, flexible pricing and potential cost savings
- Adherence in China to the same stringent global SOPs, procedures and quality standards as other countries

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