OVERVIEW OF CLINICAL TRIAL APPLICATION (CTA) IN CHINA

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Definition and Scope of CTA in China

In China, a Clinical Trial Application (CTA) should be submitted to the National Medical Products Administration (NMPA), to request the authorization to administer an Investigational Drug to humans. CTA can be submitted to NMPA for Phase I through Phase IV clinical trials, including bioequivalence trials, that are conducted in China. Sponsors should receive CTA approval and a CTA certificate before starting their clinical trial in China. CTA certificate has 3 years validity.

Foreign sponsors, with no presence in China, should appoint a local representative in China, called Marketing Authorization Holder (MAH), that should submit the CTA to NMPA on their behalf and provide the appropriate support till CTA approval.

Content of CTA in China

CTA includes Module 1, Module 2, Module 3, Module 4 and Module 5 has shown below. The content of CTA should be translated in Chinese language.

Module 1

- Administrative information (Application form)
- Overall Investigational Plan
- Investigator's Brochure
- Informed consent
- Clinical Study Protocol
- Product labeling
- Risk management if available
- Feedback on consultation meeting with NMPA

Module 2

- Summary of pharmacology studies
- Summary of toxicology studies
- Summary of pharmacokinetic studies
- Individual study reports

Module 3

- 3.2 S Drug Substance: Description of drug substance characteristics and properties, synthesis process, specifications, analytical methods and their validation, manufacturing process and its validation, container closure system and stability studies.
- 3.2 P Drug Products: Description of the drug product and its presentation, pharmaceutical development, specifications, justification of specifications, analytical methods and their validation, manufacturing process and its validation, container closure process, and stability studies.

Module 4

- Pharmacology, toxicology and pharmacokinetic studies reports

Module 5

- Existing clinical data from previous clinical studies (domestic /Overseas) if available that shows the efficacy and or safety of the drug product in the proposed indication to be investigated.
- Data from published literature data related to the safety and or efficacy of the of the study drug.

CTA Review Process in China

Before submitting a CTA to NMPA for review, it is highly recommended to have a pre-consultation meeting with NMPA, to confirm the information and data to be included in the clinical trial application and the feasibility of the clinical trial in China.

The review process of CTA by NMPA normally takes 65 days, excluding the clock stops due to NMPA queries (Figure 1). Sponsors not receiving feedback from NMPA after 65 days, can consider their CTA approved and can start the conduct of the clinical trial in China after receiving the approval from the ethic committee (EC).

Figure 1: CTA Review process

NMPA Fees for CTA in China

Origin of Investigational Drug	FEES (CHINESE RMBS)
Domestic drug CTA	192,000 RMB
International drug CTA	376,000 RMB
Generic drugs made in China	318,000 RMB
Generic drugs made outside China	502,000 RMB

NMPA Timelines for CTA Review in China

NMPA Review	Working Days
NMPA administrative review	5 days
NMPA technical review	60 days
Issue of CTA approval Certificate	10 days

Main Differences Between CTA in China, EU and USA

Comparative criteria		China CTA	US IND	EU CTA/IMPD
CTA Content	Module 1	Country specific	Country specific	Country specific
	Module 2	Complete 2.3.S and 2.3.P	Introduction only 1 to 2 pages	Introduction only 1 to 2 pages
	Module 3	Similar between the 3 countries		
	Module 4	Similar between the 3 countries		
	Module 5	Similar between the 3 countries		
Review timelines		60 days	30 days	30 days
HA fee		See fees below	No fees	Vary depending on country

About the Author

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Dr. Suzan Davis is the founder, president and CEO of Global Regulatory Partners. Inc, (GRP), that is a Group of companies that provide clinical development, regulatory affairs, quality and pharmacovigilance services to pharmaceutical and medical device companies globally.

GRP Group includes 6 companies located in Brazil, China, Mexico, Japan, USA and South Korea.

Dr. Suzan Davis has more than 35 years of experience in clinical development, regulatory affairs, and compliance. Over her carrier, she has supported more than 70 clinical development programs and registered more than 50 news drugs and biologics from different therapeutic areas, in USA, Europe, Latin America and Asia, especially in China, Japan and South Koreas. Before GRP, Suzan assumed many leadership and executive responsibilities in small and large pharmaceutical and biotech companies, such as GSK, Pfizer, Genzyme, EMD Sereno, Takeda, Merk, in United States, Europe, Latin America and APAC. Suzan received a Pharm.D from pharmacy college (Université Paris 1 Panthéon-Sorbonne) in Paris, a Master in Regulatory Affairs (MRA) and an Executive Master in Business Administration (EMBA) from Northeastern University in Boston. She is also certified as a quality auditor, certified in US regulatory affairs, European regulatory affairs and international Regulatory Affairs.

References

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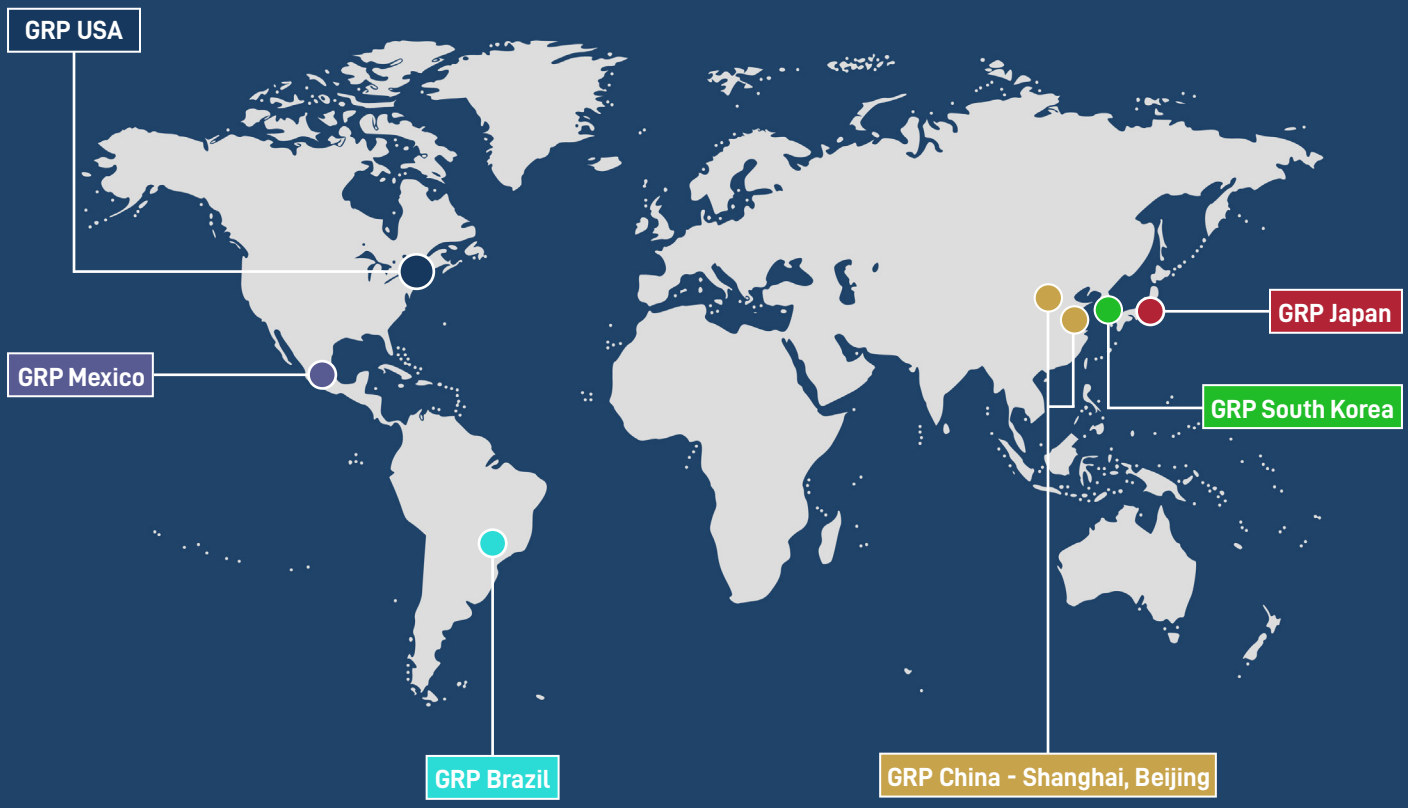
GRP LOCAL BRANCHES



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ABOUT
GLOBAL REGULATORY PARTNERS, CHINA

Global Regulatory Partners China (GRP-China) has two offices in China (Shanghai and Beijing) with local teams of Regulatory Affairs, Clinical, Pharmacovigilance and quality professionals, who support foreign pharmaceutical and medical device companies access the Chinese market.

Global Regulatory Partners China services include:

- Market access
- Pre-consultation meeting with NMPA,
- Preparation and submission of CTA to NMPA,
- CTA maintenance,
- Feasibility studies in China
- Medical writing and translation,
- Investigational drugs importation, testing and supply chain management in China,
- Clinical studies conduct and management in China.
- Clinical development
- Drugs and biologics registration and lifecycle maintenance.

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