# 10 Tips to Successfully Manage Clinical Trials in China

Clinical Development Partner
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## Overview

China has made significant progress in adapting their methodology in conducting clinical trials to meet international standards. However, there are a few unique features warranting consideration to help ensure the successful outcome of these trials in China. Experience managing clinical development at an international level, local team expertise, clear communication, and flexibility are key elements when conducting clinical trials in China, but it is also essential to properly manage China's unique study considerations.

### 1. POPULATION

The National Medical Product Administration (NMPA) regulatory authority can require setting up **specific clinical trials with Chinese populations** (Pharmacokinetic PK trials and /or confirmatory clinical trials) to support the results from ongoing foreign studies, or to validate drugs already approved in markets outside of China.

### 2. FACE-TO-FACE MEETINGS

**Personal interactions are important in China from the cultural point of view**, so it is highly recommended to schedule personal meetings when it comes to critical topics related with the trial. These face-to-face meeting are especially important for site management (there are even sites that does not allow any other form of communication). Visits to institutions (e.g. Human Genetic Resources Administration of China) or Principal Investigators apart from the routine monitoring visits can be frequent.

### 3. REPORTS FROM REGULTORY AND ETHICS COMMITTEES (ECs)

**Official reports can have information that is open to interpretation**, and interpretation of the EC reports can be tricky. It is necessary to check with informal contacts with ECs and the GCP officer.

### 4. TRAVEL

Hospitals in China are spread across thousands of kilometers, **so many sites can be located more than 1,000 km from Beijing**. This is especially important to be aware of with COVID-19 and travel restrictions.

### 5. COVID-19 RESTRICTIONS

Extreme restrictions were applied in the first half of 2020. **Guideline from NMPA**: "Guidelines for the management of drug clinical trials during COVID-19 outbreaks" are to be followed.

### 6. PAYMENTS

Following the contract with the site, sites in China are **paid in advance** meaning patient visits are paid before they are performed. In case of payment delay, sites may stop study activities.

### 7. MEDIA AND PUBLIC OPINION

Clinical trials are followed by media and public opinion depending on the interest of the clinical trial, and this **can impact Principal Investigator(s) willingness to participate** in the study.

### 8. BUDGET

The concept of **out-of-scope costs** are important to keep front of mind and may warrant follow-up, e.g. informing immediately when there are significant out-of-scope costs.

### 9. LANGUAGE

Everything should be translated to Chinese as **English is not commonly spoken** and the Chinese version of the documentation is required by Institutions and ECs.

### 10. TRADITIONAL CHINESE MEDICINE

**Traditional Chinese Medication (TCM) is commonly used**. TCM can often be used as concomitant treatment in the study, and a specific list of TCM that can be used during the clinical trial is appreciated by the Study Investigators.

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