

# MEDPACE CHINA

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## Resources and Experience

- Office established in 2007
- Laboratory established in 2008
- General Manager – over 8 years experience in international pharma companies, medical device companies, and CROs
- Country Manager – over 10 years clinical research experience in China and Singapore at pharma companies and CROs
- Data Manager – 6 years experience at international pharma companies and CROs
- Laboratory Director – experienced laboratory professional with MD and PhD in Pathology and Immunology
- Clinical Research Associates – average of 3 years experience in China at pharma companies and CROs
- Senior Laboratory Technician – 6 years experience in clinical laboratory
- Laboratory Technicians – well-educated staff with degrees in clinical laboratory and systematic training in first-class hospitals

## Therapeutic Expertise

Medpace China employees have collective experience in the following therapeutic areas and types of trials:

- Phase I-IV
- Oncology – breast, lung, colorectal, leukaemia, anaemia caused by solid tumor
- Anti-infection – fungals, hepatitis B, hepatitis C, influenza
- Cardiovascular – hypertension, congestive heart failure, thrombosis, CHD, ACS
- CNS – Alzheimer's disease, antidepressant
- Metabolic – diabetes, weight-reducing aid
- Epidemiology – cerebrovascular for neurology
- Gynecology – vaginal dryness syndrome

## Services

### Site Monitoring

- Perform site evaluation, initiation, routine monitoring, and closeout visits
- Ensure drug accountability
- Collect and maintain essential documents
- Perform data and safety monitoring, including EDC and CRFs

### Regulatory

- Submit regulatory submissions and ongoing reports to authorities
- Correspond with ethics committee and central and local IRBs, as appropriate
- List and maintain trial details on National Research Register

- Export permit application and renewals for international material transfer
- Prepare, distribute, and track essential trial documents and master file

### Project Management

- Ensure feasibility and protocol compliance
- Perform site identification and evaluation
- Coordinate local investigator meeting, if applicable
- Negotiate and manage investigator agreements and payments
- Oversee clinical trial supply importation and distribution
- Manage audits
- Manage archival of trial materials

### Data Management

- Develop and maintain DM-related documents
- Follow patient CRF and data query filing procedures
- Coordinate communication with external database providers for data transfers
- Coordinate clinical coding procedures and dictionary transfers
- Imaging

### Central Laboratory

- 600 square meters in laboratory area, including main laboratory, logistics, and archive area
- Equipments and instruments: Olympus AU2700 analyzer, Dade Behring BN II system, Beckman LH750, Clinitek Atlas Urinalysis analyzer, Roche cobas e411, Sysmex CA-1500 coagulation analyzer, Tosoh G7 HbA1c analyzer, Eppendorf 5810R centrifuge, and Millipore Elix 70 clinical water purification system
- Industry-appropriate quality assurance and accreditation: certificate of lipid standardization program and NGSP (level I) laboratory certification
- Secure on-site archival storage of specimens
- Process samples related to hematology, biochemistry, lipid profile, urinalysis, immunoassays, and thyroid function

## Why China?

- Large population, 1.3 billion
- Prevalence of many types of disease
- Most big public hospitals have advanced equipment
- ICH GCP compliant CA and IRB approval processes
- Approximately 10 years of GCP clinical trials
- Experienced trial sites, participating in global trials
- Competitive pricing
- Often one of the highest recruiting countries in most indications on global trials
- Most investigators English-speaking
- Excellent support infrastructure – air/rail/road network, telecommunications, IT, etc.
- Rapidly growing market