Tigermed

Global Excellence
China Expertise

Advance Human Health through Delivery Excellence

Tigermed Group
www.tigermedgrp.com

Tigermed

Enabling Life-Changing Therapies with Excellence and Commitment

We are a full-service global CRO committed to supporting biopharmaceutical and medical device innovation in the best possible way. With a broad portfolio of services and a promise of quality, from preclinical development to clinical trial to commercialization, we are devoted to moving our customers through their development journey efficiently and cost-effectively. Tigermed currently represents a worldwide network of more than 100 subsidiaries and 170 offices and sites, with over 8,800 employees across 52 countries in Asia Pacific, Europe, North & South America and Africa.

8,800+
Global Employees

2,500+
Global Customers

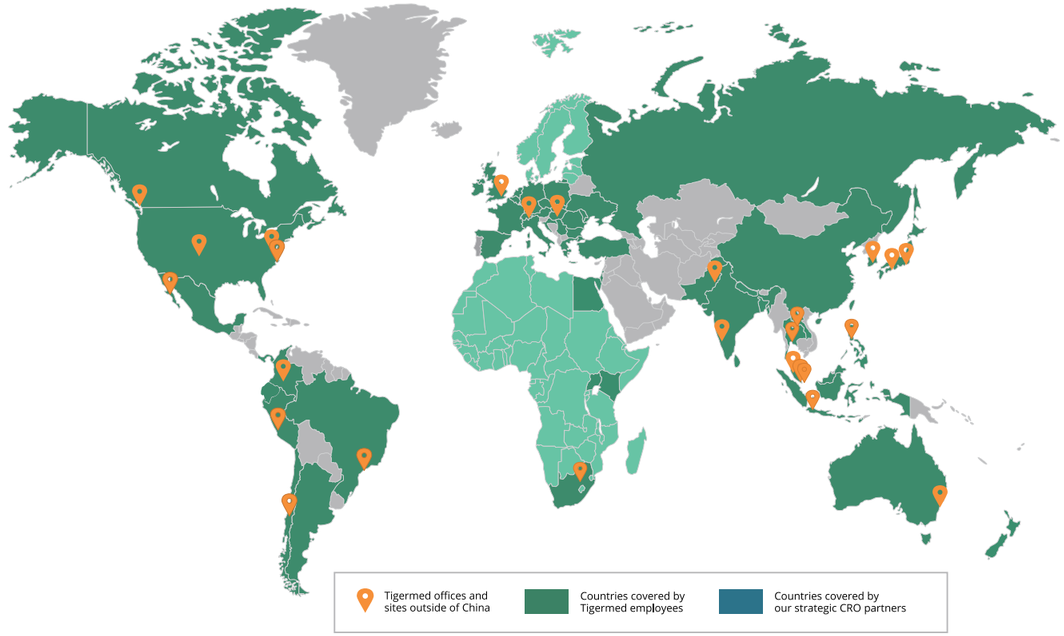
179
Global Offices & Service Locations

59
Innovative Drugs in China

Global Footprint

52 Countries with Tigermed Employees
26 Offices & sites outside of China (legal entities)

- **Tigermed Australia** — Sydney, Australia
- **DreamCIS** — Seoul, South Korea
- **Tigermed Malaysia** — Puchong Selangor, Malaysia
- **Tigermed Asia Pacific** — Singapore
- **Tigermed Singapore** — Singapore
- **Tigerise** (Tokyo) — Tokyo, Japan
- **Tigerise** (Osaka) — Osaka, Japan
- **PT Tigermed Indonesia** — Jakarta, Indonesia
- **Tigermed India** — Karnataka, India
- **Tigermed Philippine** — City of Makati, Philippine
- **Tigermed Thailand** — Bangkok, Thailand
- **Tigermed Lao Sole** — Vientiane, Laos
- **Tigermed Pakistan** — Lahore, Pakistan
- **Tigermed America** — Fort Collins, Colorado, US
- **BDM Consulting** — Somerset, New Jersey, US
- **Frontage Lab** — Exton, Pennsylvania, US
- **Tigermed Canada** — Vancouver, BC, Canada
- **Tigermed Columbia** — Medellin, Columbia
- **Tigermed Mexico** — Tijuana, Mexico
- **Tigermed Chile** — Santiago de Chile
- **Tigermed Brazil** — San Paulo, Brazil
- **Tigermed Peru** — Lima, Peru
- **Opera CRO** — Timisoara, Romania
- **Tigermed Swiss AG** — Zug, Switzerland
- **Tigermed UK** — London, United Kingdom
- **Tigermed South Africa** — Gauteng, South Africa



Premier Clinical Research Network in China

Best-in-class site relationships in China with therapeutic depth and expertise.

101
Subsidiaries and Joint-Ventures in China

153
Offices and service locations in China

1,280
Clinical trial sites in collaboration

Delivering Tailored Solutions across Full Range of Healthcare Innovation

Whether you are developing a small molecule or biologic, a vaccine or medical device, we have tailored solutions to move your research forward.

Small Molecule | **Biologics** | **Cell & Gene Therapy** | **Medical Device** | **Rare Disease** | **Vaccine**

Serving China Healthcare Innovation

Innovative Drugs Supported

Since 2004, Tigermed Group has supported the development of 59 approved Class 1 Innovative drugs in China. (1)

59

Innovative Projects Participated

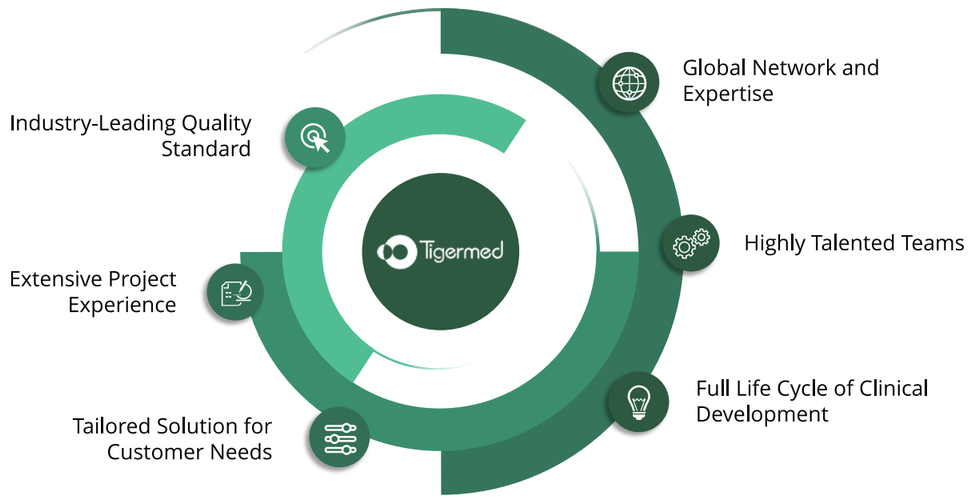
Since 2004, Tigermed Group has supported 527 Class 1 innovative drug research projects in China. (1)

527

(1) Class 1 innovative drug projects include clinical operations, imaging analysis, SMO, biometrics, central lab, EDC, PV, etc.

Harnessing Our Passion and Expertise

Competitive Edges that Set Us Apart



Proven Track Record of Project Delivery

Innovative Drug Clinical Projects 527	**Multi-region Clinical Trials** (MRCT) 88	**Clinical Operations Projects** 3,000+	**Medical Device Clinical Trials** 590+
Biometrics 3,400+	**Site Management** (SMO) 2,300+	**Pharmacovigilance** 560+	**Medical Imaging** 150+
Medical Device Registration 5,800+	**Drug Registration** 1,870+	**Medical Writing** 1,440+	**GMP Consulting** 600+

A Full Suite of CRO Capabilities

Pre-clinical

- **Medicinal Chemistry**
- **Compound Screening**
- **DMPK**
- **Safety & Toxicology**
- **Bioanalysis**
- **CMC**
- **Central Laboratories** (Frontage)

Phase I-III

- **Medical Science & Strategy** (Tigermed)
- **Regulatory Affairs** (Tigermed)
- **Global PM & Operations** (Tigermed)
- **Clinical Monitoring** (Tigermed)
- **Biometrics** (Tigermed / Macrostat)
- **Site Management (SMO)** (SIMO)
- **Subject Recruitment** (Rzmed)
- **Medical Device & IVD** (Tigermed Jyton)
- **Vaccine** (Tigermed / Rzmed)

Integrated Services

- **Medical Imaging** (Fantastic)
- **Pharmacovigilance** (IntelliPV)
- **Medical Translation** (Yaxincheng)
- **Third Party Audit** (TLT)
- **GMP Consulting** (Canny)
- **Functional Service** (Tigermed)
- **Central Laboratories** (Teddy Lab)
- **Call Center** (Tigermed)

Phase IV & RWS

- **Post-market Research** (Tigermed / Rzmed)
- **Real World Study** (Tigermed)
- **Investigator-initiated Study** (Tigermed / Rzmed)

Note: names in (GREEN) represent subsidiary companies who provide corresponding service
As of March 2022

Regulatory Affairs

Full Regulatory and Submission Services
Regulatory services for innovative drugs & generics globally, including chemical drugs and biologics products, IND/CTA/NDA, supported with eCTD submission.

Expertise with Global Reach
60+ experts with years of working experiences with FDA, NMPA, and EU health authorities, and a deep understanding of ongoing regulatory reforms worldwide.

Feasible Regulatory Strategy
We can provide you with feasible submission strategies and proactive planning which applying up-to-date, robust regulatory intelligence.

1,870+
Global drug registration projects

5,50+
Drug registration customers

Medical Translation

350 M+
Words/ year

380+
Full time employees

20,000+
Translation projects

600+
Global customers

20+Years in Medical Translation
The largest medical translation service provider in China, with twenty years' dedicated experience.

Deep Expertise in Translation
Dealing with 4 million Chinese characters and 50 projects daily, expertise in CN, EN, Japanese, German, French, Korean, Spanish, etc.

Online Platform YXC-TP
TPM System achieving dynamic tracking during full paperless translation process.

Therapeutic Depth
Expertise includes human drugs (chemicals, biologics, pharmaceuticals, etc.), medical devices (including diagnostic reagents) and other medical products.

Global GMP Consulting

GMP and Regulatory Compliance

As a leader in GMP compliance consulting, we offer a full range of services in GMP compliance from development through commercialization, and help you design or adapt your quality and safety processes to minimize the risks involved in (bio) pharmaceutical production.

We provide comprehensive consulting services to ensure US cGMP, EU-GMP, WHO GMP and Chinese GMP compliance. Our services cover the entire life cycle of the GMP regulatory system.

- GMP Compliance (China and Overseas)
- GMP Auditing – Mock Inspections
- Factory Compliance
- Laboratory Quality System Compliance

600+
GMP compliance cases globally, incl. 100+ cases for EU/FDA/TGA inspections

1,000+
China and global customers & partners

24 Years
24+ years in medical consulting

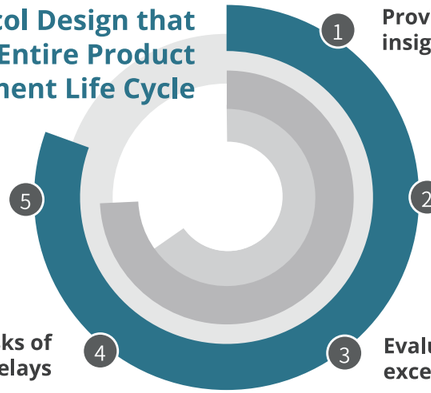
80+
Professional consultants

60+
Successful onsite inspections by US FDA

Medical Science and Strategy Consulting

- Phase I-IV drug and medical device protocols
- Clinical study reports (Phase I-IV)
  Patient narratives /appendices /publishing /basic results disclosure /lay summaries /redaction
- Informed consent forms
- Clinical development plan
- Investigator brochures
- Clinical overview (module 2.5), Clinical summaries (module 2.7), Integrated summaries of safety and efficacy, RMP.
- Investigator meeting materials

A Competitive Protocol Design that Benefit Your Entire Product Development Life Cycle



1. Providing customized and insightful study designs
2. Identifying product value, market access and positioning
3. Evaluating the possibility of exceeding study timelines
4. Estimating the risks of amendment and delays
5. Improving your protocols with up-to-date market and regulatory intelligence

Vaccine Clinical Trials

Vaccine MRCT projects cover 10+ countries in APAC, Europe, Latin America and Africa with 140,000 subjects enrolled.

Vaccine Clinical Research Process

- Team Organization
- Documents and SOP Preparation
- Base Setup
- IEC reviewing
- HGRAC & Agreement
- Site Initiation
- Enrollment & Monitoring
- Data clean & Database Lock
- Site Close Out

Proven Track Record of Vaccine Clinical Trial Deliveries

9 COVID-19			2 Rabies
3 HBV		2 HPV	1 Mumps
8 Influenza			2 HIV
2 HAV	1 Nasopharyngeal cancer	1 Rotavirus	1 Malaria
2 Poliomyelitis	1 Influenza and pneumococcal		

Clinical Operations

From start-up to close-out, our experienced clinical operation teams ensure efficient site support, patient safety and data monitoring through a complete project management system and effective relationships with widely distributed study sites. Our wide network of clinical experts ensures global consistency and high standards that meet ICH-GCP guidelines, wherever we manage your clinical trials.

Medical Science

With a sound quality management and quality control system, and a proven track record in obtaining high-quality clinical research data, we are committed to ensure the compliance with both ICH-GCP and Chinese GCP requirements during your clinical trials.

Early Stage Clinical Development（Phase I & IIa）

By leveraging our many clinical facilities, biometrics capabilities, PK/PD study experts, and project management experience, we collaborate closely with you to develop tailored roadmaps for your study and aim to maximize efficiency, anticipate challenges, and mitigate risk.

Late Stage Clinical Development（Phase IIb & III）

By making use of our robust in-house quality management system, well-developed SOPs, extensive experience in international project management, we have executed numerous large-scale trials efficiently and cost-effectively.

Medical Monitoring

Our Medical Monitoring team is composed of clinical physicians with specific expertise and abundant experience in clinical trials. Regarding to ICH-GCP and Chinese GCP regulation, we have a well-established medical monitoring management system to ensure the subject safety, the medical compliance with the protocol and ICH GCP requirement.

Project Management

Besides our experience in various projects, we also apply our company values in our project management. We aim to be flexible, innovative, respectful, and honest. By doing so in all our activities globally and in a broad spectrum of therapeutic areas, we help you to successfully navigate any hurdle in clinical development.

Biometrics

850+
Global Biometrics Experts

3,400+
Clinical Projects

160+
Global Customers

19
NDA/BLA Submissions to FDA with new indications

- Teams in APAC and US for global customer reach
- Deep understanding of therapeutic areas like Oncology, Immunology, Endocrinology, Neurology, Infectious Diseases, etc.
- Well known industry reputation for being highly reliable and trustworthy
- Excellent tracking record of quality and on-time deliverables

Data Management

- Data capture and management using EDC systems
- CRF/eCRF design
- Database design, development, and maintenance
- Data validation specifications and edit check programming & testing

Biostatistics

- Randomization schedule development
- Statistical Analysis Plan (SAP) and TFL Shells development
  Data Monitoring Committee, Evaluation Committee and Interim
- Analysis support
- Integrated summary of efficacy and safety (ISE/ISS)
- Statistical analysis report

Statistical Programming

- Development of submission -ready datasets and supporting documents in CDISC format: Annotated CRF, SDTM, ADaM, Define.xml and Reviewer's Guide
- Generation of Analysis Datasets

Pharmacovigilance (PV) and Clinical Safety

A Full Suite of PV Services at Your Disposal

Pharmacovigilance Operations for Clinical Trials

- PV system introduction
- Preparation: Review protocol; Review investigator brochure; Review CRF; Draft safety management plan; database setup
- Case management
- Meetings such as safety review committee
- Draft/Review DSUR
- Draft/Review risk management plan

Post-Marketing Pharmacovigilance Operations

- Call center
- Literature search
- Case management, including cases from Health Authority and oversea serious adverse reaction cases
- Draft/Review PSUR
- Draft Annual Report
- Signal detection
- Draft/Review risk management plan

Support Services Outsourcing

- Pharmacovigilance Audits
- Training
- Pharmacovigilance system outsourcing

Data Security

- Tigermed's SOP and relevant guides have been updated according to EU General Data Protection Regulation.
- Procedures for regular testing, assessment and evaluation control objectives.

150+
Global Customers

6,000+/Year
Retrieval Quantity
In EN and CN

400+
Total Projects

40+
Multi-Region Clinical Trial Projects

10,000+/Year
PV Case Report

Site Management

End-to-End Onsite CRC Services for Clinical Development

- Exemplary quality and deliverables
- On-time and on-budget approaches
- Global standard + strong customer service orientation
- Flexibility for workload and timeline fluctuation

2,900+
SMO total employees
Including 2,700 full-time CRCs

1,280
Clinical sites in collaboration

150+
Cities with Tigermed CRCs in China

25
Branches in China
Headquartered in Hangzhou

Flexible Trial Support with Knowledge and Expertise

- 2,300+ Site management projects
- Studies cover Phase I - IV and 70% of which are sponsored by global pharma companies
- Indications include: oncology, hematology, diabetes, cardiology, infectious disease and nephrology, etc.

SMO Service with Proven Quality and Efficiency

- Provided Phase I-IV site management services to innovative drug companies, biotechs and Top20 global pharms.
- Supported by 270+ project managers (PM) and 150+ line managers (LM) who are experienced with GCP compliance.
- CRC team provides day-to-day management, project management, training, QA and emergency intervention during clinical trials at clinical trial sites.
- One of the largest patient and healthy volunteer recruitment teams in China offering support from Phase I to IV.

Subject Recruitment

Strength and Advantages

- Recruiting service cover all major cities and surrounding regions in China
- Extensive experience in recruiting patient population for multiple TA like oncology, cardiovascular disease, infectious disease, etc., ranging from phase I to IV
- Strong network of clinical resources and disease experts, and online promotional & educational channel to support fast and efficient enrollment

Recruitment Center

- Patient recruitment
- Patients health education
- Academic meetings
- Medical mobile APP business expansion
- Recalling the long-lost patients

Third Party Audits

Effective Audit Services for Quality and Compliance

Wide Coverage · **Team of Experts** · **Complete Process**

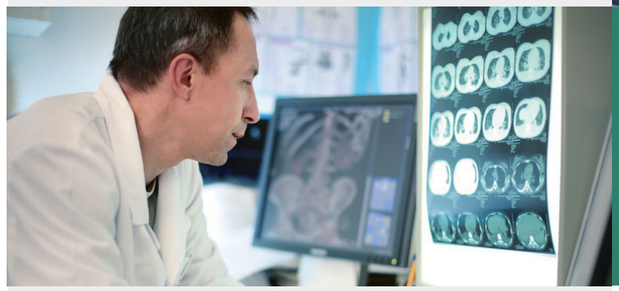
Audit Projects
400+

Onsite Audits
1,200+

- Audit services for Phase I-IV clinical trial, medical device clinical trial, IVD, BE study, PK study, data management, TMF, etc.
- **30+** professional auditors, **15** experts in key areas like bioanalysis, biometrics, protocol, pharmacovigilance, medical imaging, IT, etc.

Medical Imaging Services

Technology-driven Imaging Evaluation to Support Your Decision-Making.



One-Stop Imaging Evaluation Services

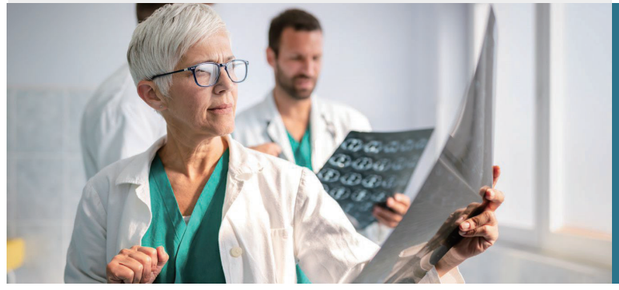
Validated imaging system / Protocol design & consultation / Imaging acquisition / Image read & adjudication / Project management / Technology consulting

Clinical medical imaging projects
150+

Global customers
60+

Projects successfully submitted to FDA/NMPA
20+

Imaging experts
100+



Scope

Clinical trial: Phase I-IV

Therapeutic areas: cardiovascular disease, oncology, medical device, CNS and pain, rheumatology, hematology, etc.

Diagnostic modalities: CT, MRI, PET, PET/CT, SPECT, X-Ray

Clinical Trial System Solution

Clinflash EDC

Your Reliable and Trusted EDC System

3,000+
Total studies

200+
Studies submitted to NMPA

100+
Studies approved by NMPA

- Clinflash aims to help pharmaceutical companies improve R&D effectiveness and efficiency by providing first-class IT solutions.
- Collaborated with more than 300 global healthcare companies and CROs to enable 2,000+ clinical trial projects.

Clinflash® EDC
Electronic Data Capture

Clinflash® IRT
Randomization and Trial Supply Management

Clinflash® Safety
Pharmacovigilance safety database

Clinflash® ePRO
Electronic patient reported outcome

Clinflash® CTMS
Clinical Trial Management System

Clinflash® eTMF
Electronic trial master file

Clinflash® eCTD
Electronic Common Technical Document

Pre-clinical Services and Solutions

- Medicinal Chemistry
- CMC
- Safety & Toxicology
- Bioanalytical
- Compound Screening
- DMPK
- Central Laboratories

120+
Bioanalytical lab inspections by NMPA

50+
Lab inspections by US FDA

700+
Global customers

25,000+
Compounds delivered

- Operating in China and US with synchronized SOPs and quality standards.
- A comprehensive portfolio of laboratory services ranging from drug discovery to IND enabling package
- Strong track record of successful regulatory inspections by US FDA, NMPA, WHO and US EPA, etc.
- Extensive experience in GMP，GLP，GCP
- AAALAC accredited animal facilities

Central Laboratories

In-house Central Lab Services with Global Reach

- Lab Services
- Flow Cytometry
- Anatomic Pathology
- NGS
- Bioanalysis
- Companion Diagnostics

One-Stop Platform to Meet Diverse Clinical Needs

2,000+
Test items

6,500+ m^2
Laboratory space

98%
On-time delivery rate

CAP
Accredited

- Infectious Disease
- Immuno-Oncology
- Hematology
- Endocrinology
- Inflammation
- Precision Medicine

Medical Device & In Vitro Diagnostics

As the largest Medical Device/ IVD regulatory and clinical trial CRO service provider in China, Tigermed has over 300 full-time experienced medical device clinical researchers. We have established long-term cooperative relationships with over 2,100 manufacturers from more than 30 countries in the last 20 years.

As always, Tigermed's priority is to assist your activities in Medical Device/In Vitro Diagnostic development and manufacturing process, to cope with the ever-changing regulatory requirements globally.

590+
MD Clinical Trials

5,800+
MD Regulatory Projects

30+
Countries of business coverage

2,100+
Global Clients

TECH-NICAL	R&D Path & Plan	Tests for Safety/ Consistency/ Reliability	Third Party Inspection		
	R&D Outsourcing	Process Improvement; Prototype Modification	Technological Innovation	Animal Experiments	
CLINICAL	Filing & Approval	Experiments & Evaluation	Post Marketing Clinical	Adverse Reaction Monitoring	
LEGAL	Chinese Patent Application	Innovation Channel Application	Registration Inspection	Advertising Approval	
	NMPA Registration	MD GMP/QMS Establishing	QMS Pilot Test	QMS Modification	Overseas Certification
	MD-MAH	MD-GSP			

Product Development → Design Verification → Product Listing

Real World Study (RWS)

One-Stop RWS Solutions
Our competitive solution is based on our strong clinical operation capabilities, innovative technologies adopted, rich local expertise and experience.

Expertise on RWS
Retrospective/prospective RWS, post-marketing new drug safety monitoring, health economics study, real-world patient management

Full Suite of RWS Service
Under China NMPA real-world study regulations and guidelines, we offer one-stop high-quality services.

Consulting
Research strategy consultation, feasibility assessment, regulatory affair service

Study design
Provide RWS and IIT study design and consultation

Project management
Provide comprehensive project management to ensure expected project schedule, quality and budget

KOL network
Wide network with KOL and research associations to provide scientific advisory and innovation support

Study execution
Provide on-site and remote CRC management , CRA inspection, medical and follow-up services

Data management
Perform data cleaning, auditing and coding, coordinate database setup and locking, internal and external data transmission

Statistic analysis
Develop SAP and statistical report, or conduct data mining and analysis for existing database

System and technology
Empower clinical research using innovative technologies such as block chain, big data and artificial intelligence, as well as other conventional systems such as EDC, ePRO

Call Center Services

Hotline
400/800 hotline, including medical information service/ patient education service/ pharmacovigilance service, etc., to answer questions from patients, to collect drug AE and to process customer complaints; based on WeChat APP/ mini programs, to provide Human-Machine Coupling online customer service.

Patient Follow-up
Follow-up service for clinical research and studies, including pre-clinical studies, post-market studies, real-world studies, and investigator-initiated studies. AI-assisted customer services can provide reminders for the doctor visit, data collection, data analysis.

Market Survey
Market survey, including customer satisfaction survey, drug usage survey, and disease burden survey through phone, APP, mini programs.

Clinical Trial Supplies and Logistics Service

98%
Service coverage of China administrative counties

2000+ M^2
Digital multi-temperature storage

30+
Self-operated outlets

Solutions
- Temperature controlled transportation solutions
- Temperature control service
- Cold chain transportation
- Warehouse management system
- Information Supervision System

Temperature control program

Drug transportation

Equipment leasing

Warehouse management

Global storage and transportation

Drug & sample management

Specimen transportation

Multi-Region Clinical Trial (MRCT)

Tigermed supported our partners for their MRCT projects in **30** countries and regions around the world.

30 Countries and regions

16

MRCT项目覆盖的
疾病领域（个）

88

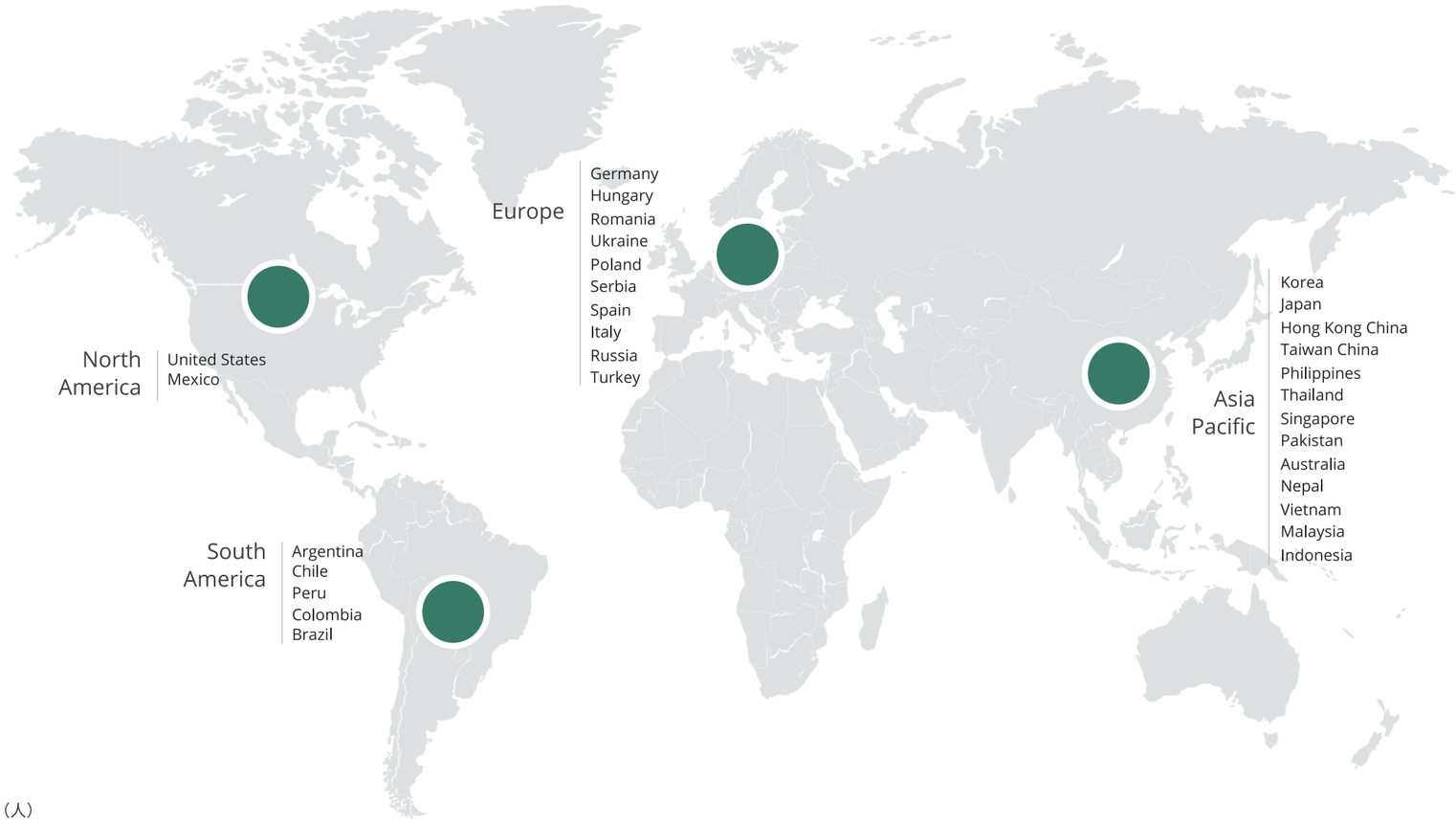
国际多中心临床
运营项目经验（项）

600+

海外的MRCT及项目
管理和运营团队[1]（人）

43

GPM国际项目管理团队（人）



Delivered first China-initiated phase III vaccine clinical study in Feb 2021 covering multiple continents, including Asia, Europe, and Latin America. (CanSino Ad5-nCoV vaccine)

Cross-Functional Full Services with GPD / GPM Leadership

Globalized project management unit + localized operation team (CPM,CRA)

Global SOPs and budget protocol, localized contracting process, country level site contract template

Centralized service hub in China including MW, MM, CTA, DMBS, PV, Central Lab, Central Imaging, etc.