Tigermed

# Advance Human Health through Delivery Excellence

Global Platform  One Tigermed

# A Global Leading CRO with Global Reach and Proven Expertise

## About Us

Tigermed (Stock code: 300347.SZ/3347.HK) is a leading global provider of integrated research and development solutions for biopharmaceutical and medical device industry. With a broad portfolio of services and a promise of quality, from preclinical development to clinical trial to commercialization, we are committed to moving our customers through their development journey efficiently and cost-effectively. We are devoted to building an integrated platform that enables the boundless possibilities for the healthcare industry, embracing challenges to fulfill our commitment to serving unmet patients' needs, and ultimately saving lives.

www.tigermedgrp.com

Enabling Life-Changing Therapies with Excellence and Commitment.

# Global Platform
# One Tigermed

**10,000+**
Global Employees

**2,700+**
Global Customers

**180+**
Global Locations &
Service Networks

**73**
Innovative Drugs
Supported

**73 Innovative Drugs**
Number of approved Class 1 innovative drugs that Tigermed Group has supported since 2004

**Global Employees**
Number of total employees of Tigermed Group

As of January 2023

# Why Tigermed for Clinical Trials

## Operation Team with Global Efficiency

- A clinical research team with experience in 50+ countries
- Enabled with a Risk-based Quality Management system
- Skilled and well-trained clinical research associates (CRAs)
- Specialized in multiple therapeutic areas

## Customized Strategy & Solutions

- Using real world data and science to optimize protocol design
- Providing customized strategy and analysis before you start
- Evaluating the entire development life cycle for better outcomes

Contributing to Global Health and Well-being

## Capability of Large-Scale Clinical Trials

- Proven track record of large-scale clinical trial operation in APAC, Latin America and China
- Experience of 50+ clinical trials with 1,000+ subjects

## Widespread Collaborative Network

- 1,370+ Collaborative sites
- 4,800+ Principal Investigators
- 30 countries with strategic CRO partners

# A Shared Passion For Pursuing Excellence

Solutions

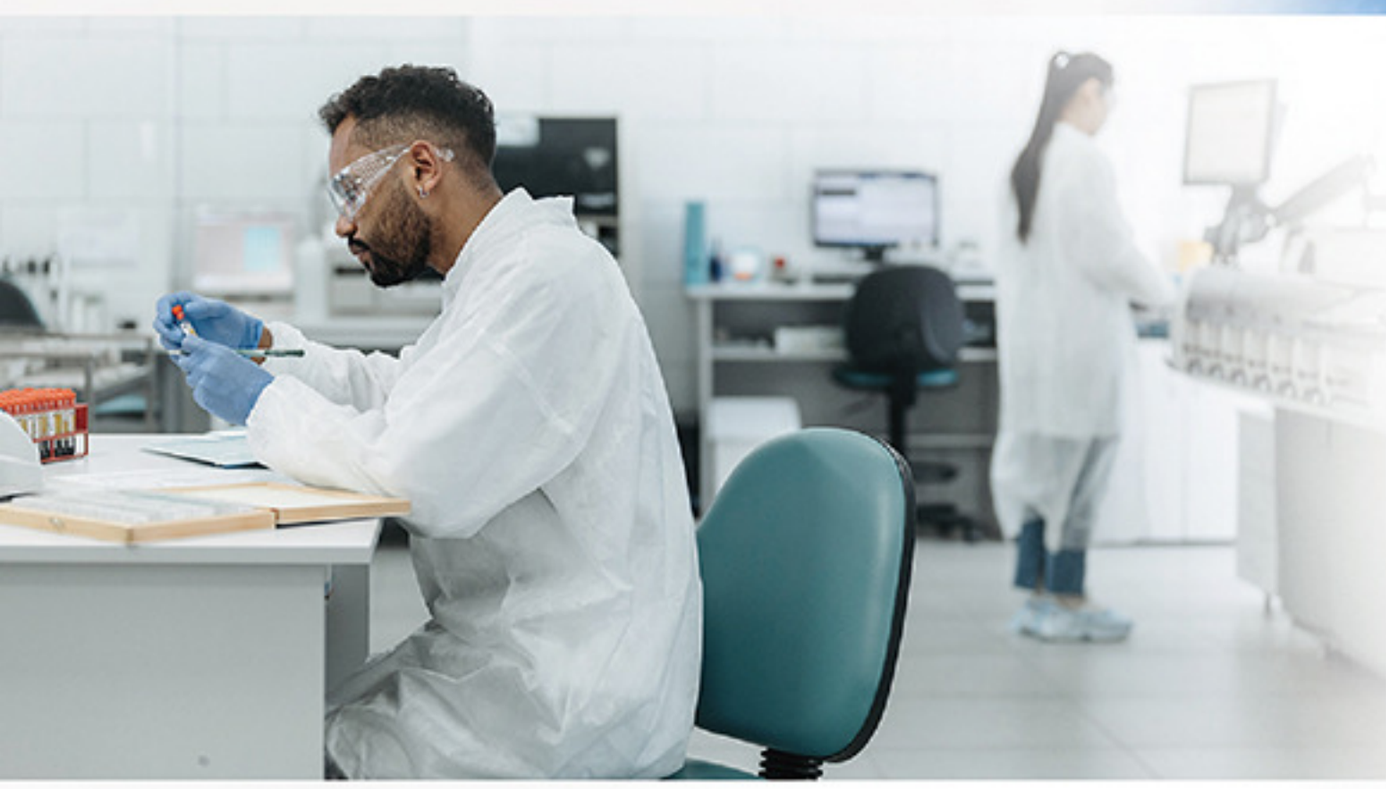
Brand Identity

## Tigermed – Passion for Innovation

Global Excellence, China Expertise

Our Mission

## Advance human health through delivery excellence



Our Vision

## To be recognized as the leading global CRO

Our Values

## Integrity & Honesty

## Open & Inclusive

## Collaborative & Accountable

## Professional & Innovative



As of January 2023

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# Delivering Tailored Solutions across Full Range of Healthcare Innovation

Whether you are developing small molecules or biologics, vaccines or medical devices, we have tailored solutions to move your research forward.

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

## Global Footprint


**1,350+**
Employees outside of China

**29**
Offices & sites outside of China

**50**
Countries with Tigermed employees

**30+**
Countries with strategic CRO partners

# A Full Suite of CRO Capabilities

Integrated Platform with End-to-End Service Offerings

## Pre-clinical

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

## Phase I-III

- Medical Science & Strategy
- Regulatory Affairs
- Global PM & Operations
- Clinical Monitoring
- Biometrics
- Site Management (SMO)
- Subject Recruitment
- Medical Device & IVD
- Vaccine

## Integrated Services

- Medical Imaging
- Pharmacovigilance
- Medical Translation
- Third Party Audit
- GMP Consulting
- Functional Service (FSP)
- Central Lab Services
- Pharmaceutical Supply Chain
- Remote Follow-up Center

## Phase IV & RWS

- Post-market Research
- Real World Study
- Investigator-Initiated Trial

As of January 2023


# Competitive Edges that Set Us Apart

Harnessing Our Passion and Expertise

## Industry-Leading Quality Standard

Synchronized quality system and SOPs

## Extensive Project Experience

Demonstrated track record of excellence

## Tailored Solution for Customer Needs

Providing customized solutions with science-driven approaches

## Global Network and Expertise

Unique global scale and capabilities with localoperation teams in 50+ countries

## Highly Talented Teams

Dedicated to supporting and developing life-saving treatment

## Full Life Cycle of Clinical Development

From laboratory to clinical research to post-market

# Regulatory Affairs

Drive Your Products on the Right Track

## Full Regulatory and Sub-mission Services

Global regulatory services for innovative drugs & generics, including chemical drugs and biologics products, IND / CTA / NDA, supported with eCTD submission.

## Expertise with Global Reach

Nearly 60 highly-experienced experts with in-depth knowledge of regulatory reforms of FDA, NMPA, and Europe healthcare authorities.

## Feasible Regulatory Strategy

Providing feasible submission strategies and proactive planning, applying up-to-date, robust regulatory intelligence.

## Demonstrated Track Record

We have successfully supported thousands of regulatory approvals globally, including MRCT approvals of COVID-19 vaccines in Africa, Europe and APAC.

**2,400+** Drug registration projects

**640+** Global drug registration customers

As of January 2023

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# Medical Translation

- **20+ Years in Medical Translation**
- **Expertise of 80+ languages**
- **Online Platform YXC-TP**
- **Professional Certification**
  - — Translation management system accredited by ISO9001, ISO17100, ISO27001 and ISO14001.
  - — Ranked 57th in Global Language Service Provider by CSA Research
- **Therapeutic Depth**

**350M+**
Words translated per year

**20,000+**
Translation projects

**400+**
Full-time translator

**630+**
Global customers

# Medical Writing

Medical writing services spanning from individual documents to extensive medical writing programs.

**1,700+**
Including drug and medical device development protocols and CSR, etc.

- **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**

# Biometrics

Delivery with High Quality and Data Integrity

**28+**
NDA/BLA Submissions to FDA with new indications

**4,500+**
Biometrics Projects

**1,000+**
Global Biometrics Experts

**600+**
CDISC Projects

- Teams in APAC and US for global customer reach
- Excellent tracking record of quality and on-time deliverables
- 100+ employees capable of using Medidata Rave, Clinflash EDC and Oracle Clinical
- Well known industry reputation for being highly reliable and trustworthy
- Deep understanding of therapeutic areas like Oncology, Immunology, Endocrinology, Neurology, Infectious Diseases, etc.

# Site Management (SMO)

End-to-End CRC Services with Proven Quality and Efficiency

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

**Flexible Clinical Trial Support with Knowledge and Expertise**

- Studies cover Phase I - IV and 50% of which are sponsored by MNCs.
- Indications include oncology, hematology, diabetes, cardiology, infectious disease and nephrology, etc.

**140+**
Cities with Tigermed CRCs in China

**1,300+**
Clinical trial sites under collaboration

**2,460+**
Full-time clinical research coordinators (CRCs)

**2,600+**
Site management projects

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# Medical Science and Strategy Consulting

1

Providing customized and insightful study designs

2

Identifying product value, market access and positioning

## A Competitive Protocol Design that Benefits Your Entire Product Development Life Cycle

5

Improving your protocols with up-to-date market and regulatory intelligence

3

Evaluating the possibility of exceeding study timelines

4

Estimating the risks of amendment and delays

www.tigermedgrp.com

# Pharmacovigilance (PV) and Clinical Safety

Solutions

Pharmacovigilance Operations for Clinical Trials

Post-Marketing Pharmacovigilance Operations

Pharmacovigilance Consulting

Pharmacovigilance Data Security

- A complete portfolio of PV solutions for **drugs, devices, vaccine and cosmetics**
- Over **150** PV experts across China and Europe
- **100+** global partners with **700+** projects
- Enabled **36** Class I innovative drugs in China
- Highly experienced in Oracle Argus, Clinflash, etc.
- Expertise in the E-reporting process for application in **China, the US and Europe.**

# Early Phase Development

Move Your Research from First-in-Human to Proof-of-Concept

### Customized Strategy

Providing tailored development strategy and protocol design to fit your scientific and regulatory needs.

### One-stop Solutions

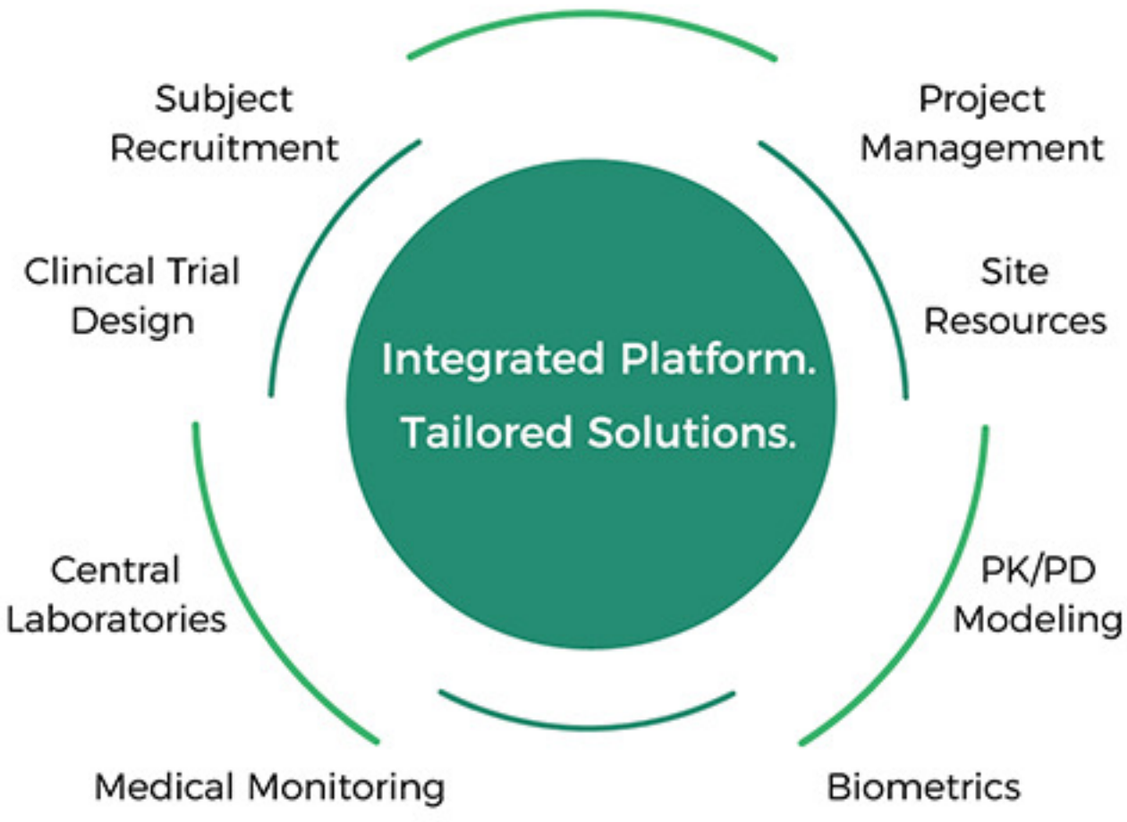
A dedicated team to deliver the right combination of in-house resources, tools and expertise.

### Capabilities & Experience

We have brought over 400 studies with scientific excellence in early-phase clinical development in the last 5 years.

### PK/PD Modeling & Simulation

50+ professionals in pharmacokinetic and pharmacodynamic modeling and simulation.




As of January 2023

# Multi-Region Clinical Trial (MRCT)

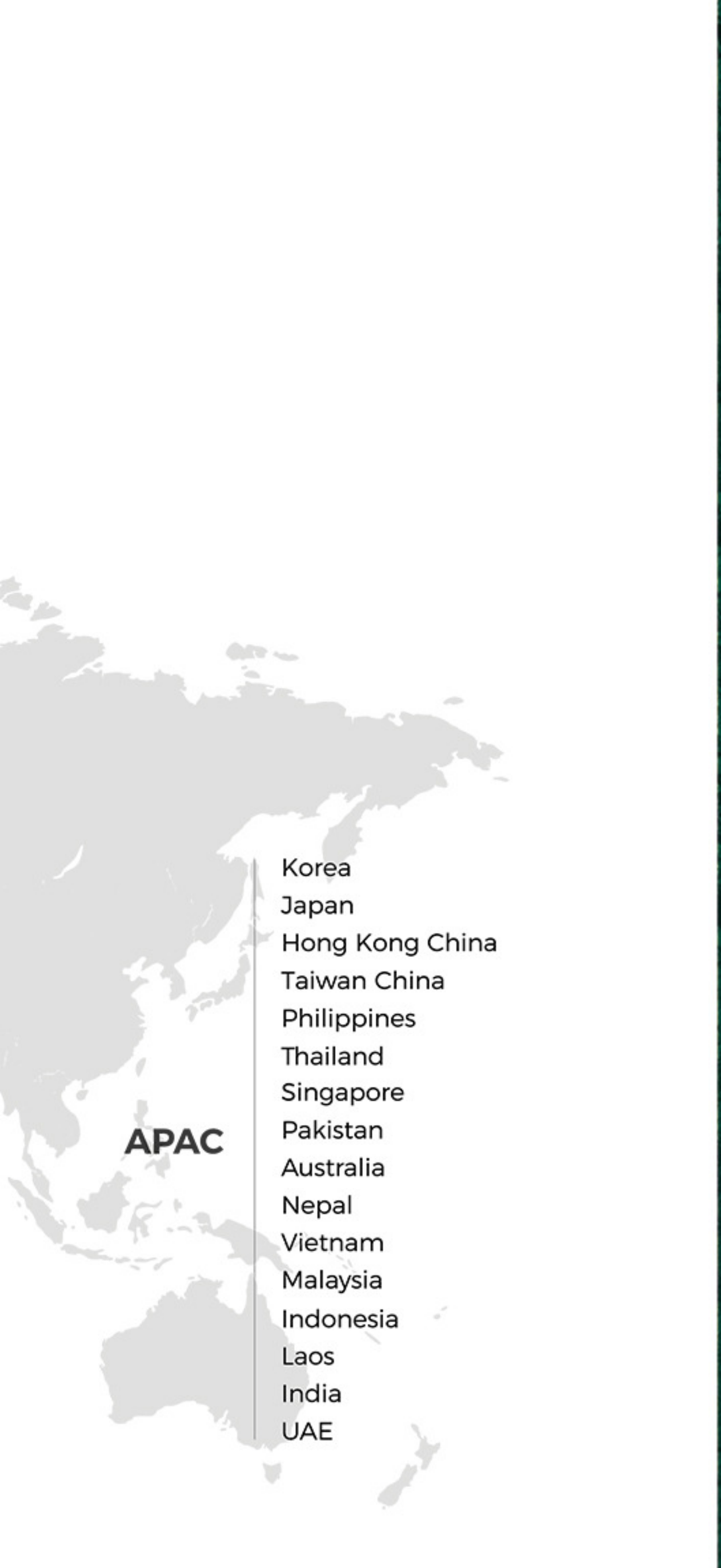
With our global PM team and local operation team, we support our partners' MRCT projects in 49 countries and regions:

**North America**
- United States
- Canada
- Mexico
- Panama

**Europe**
- Germany
- Hungary
- Romania
- Ukraine
- Poland
- Serbia
- Spain
- Latvia
- Sweden
- Italy
- Russia
- Turkey
- UK
- Austria
- Belgium
- Bulgaria
- Czech
- Switzerland

**Latin America**
- Argentina
- Chile
- Peru
- Colombia
- Brazil
- Ecuador

**Africa**
- South Africa
- Kenya
- Ghana
- Egypt
- Tunisia




## Solutions

### Countries and Regions

**49**

Compliant with ICH-GCP and local GCP requirements.

### Global MRCT Projects

**110+**

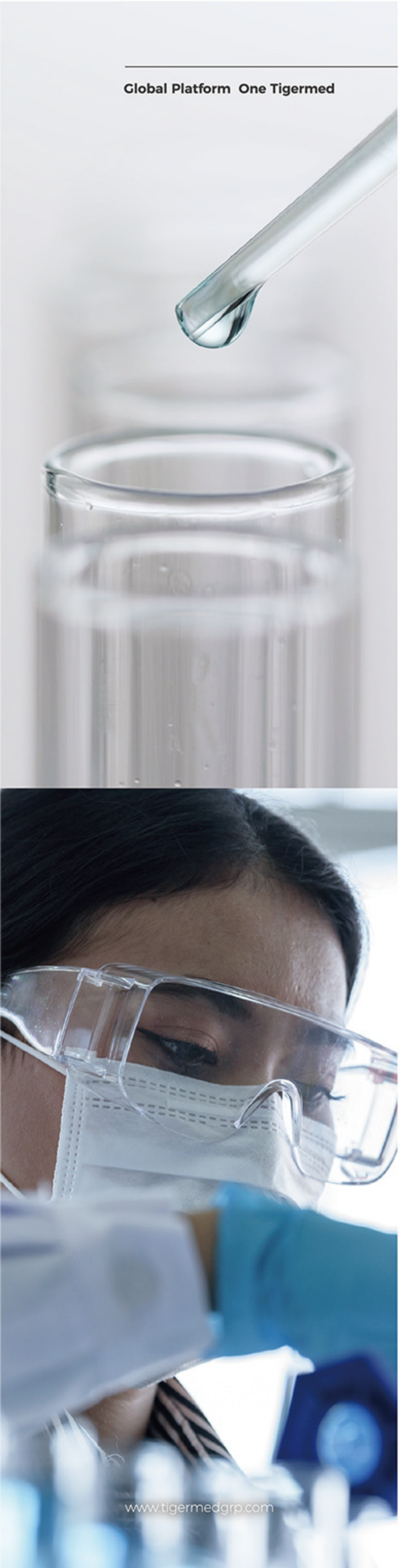
Cross-Functional Full Services with GPD / GPM Leadership

### Therapeutic Areas

**17**

Oncology, Vaccine, Respiratory, Cardiovascular, RA, Infectious, etc.

As of January 2023




# Preclinical & Laboratory Services

- Operating in China and US with synchronized SOPs and quality standards
- 100,000+ m2 lab space globally, services ranging from drug discovery to IND enabling package
- Strong track record of successful regulatory inspections by the US FDA, NMPA, WHO and US EPA, etc.
- Extensive experience in GMP, GLP, GCP
- AAALAC accredited animal facilities

Medicinal Chemistry

Compound Screening

CMC
(Chemistry, Manufacturing and Control)

DMPK

Safety & Toxicology

Bioanalytical

Central Laboratories

**140+**
Bioanalytical lab inspections by NMPA

**60+**
Lab inspections by US FDA

**700+**
Global customers

**30,000+**
Compounds delicered

# Laboratories in US & China

## Quality, Scientific Integrity, Regulatory Compliance

**Vancouver**
- DMPK

**Hayward**
- Bioanalytical
- DMPK

**Palo Alto**
- Medicinal Chemistry

**Chicago**
- Safety & Toxicology

**Deerfield**
- Genomics

**Ohio**
- Safety & Toxicology

**New Jersey**
- DMPK

**Exton**
- Bioanalytical & DMPK
- Bioanalytical & CMC & Central Lab
- CMC
- DMPK

**Zhengzhou**
- BE Study

**Wuhan**
- Chemistry & Compound Screening

**Suzhou**
- Bioanalytical (small molecule)
- DMPK & Toxicology
- CMC & Clinical Sample Manufacturing
- CMC

**Weihai**
- API CDMO

**Shanghai**
- Bioanalytical (small molecule) Central Lab
- Bioanalytical (biologics)
- Medicinal Chemistry
- Bioanalytical (biologics) Central Lab

As of January 2023

# Global GMP Consulting

GMP and Regulatory Compliance

**25** Years

Consulting experience in healthcare and pharmaceutical

- GMP Compliance (China and Global)
- Factory Compliance
- Verification and Testing
- GMP Auditing – Mock Inspections
- China MAH Service

**1,000+**
China and global customers & partvners

**320+**
Inspection consulting and testing projectsv

**600+**
GMP compliance cases in EU, US, UK, Germany, Australia, China, etc.

**30+**
Consulting experts in EU, US and China

For more information： www.china-canny.com

# Subject Recruitment

Accelerating Enrollment Speed by Proven Data and Analytics

**18,900+**
Total subjects

**270+**
Recruiting experts

**90+**
Cities with recruitment network in China

**640+**
Clinical studies

www.tigermedgrp.com

# Third Party Audits

Supporting You with All Aspects of the Audit Process

## Wide Coverage

- Audit services for Phase I-IV clinical trial, medical device clinical trial, IVD, BE study, PK study, data management, TMF, etc.
- Audit services for external vendors and NMPA onsite inspections
- GCP / GLP / GMP audits

## Complete Process

- We design a complete workingprocess and give you a clear pathway for a successful audit
- Full audit service including preparation, onsite inspection, report writing, CAPA planning, etc.

## Team of Experts

- **40+** auditors, **15** experts in key areas like bioanalysis, biometrics, protocol, pharmacovigilance, medical imaging, IT, etc.
- **60%** of our auditors have 6+ years of auditing experience

# Vaccine Clinical Trials

## Proven Track Record of Vaccine Clinical Studies

| | | | | |
|---|---|---|---|---|
| 2 Rabies | 1 Mumps | 2 HAV | 1 Rotavirus | 3 HBV |
| 8 Influenza | 2 HPV | 14 COVID-19 | 2 HIV | 1 Malaria |
| 1 ECM | 1 Influenza and pneumococcal | 1 Nasopharyngeal cancer | 1 Live Attenuated Varicella | 2 Poliomyelitis |

As of January 2023

# Medical Device & In Vitro Diagnostics

Bring Your Medical Device Product to Market with Speed and Efficiency.

- Testing Services
- Quality Consultation
- Clinical Operations
- Clinical Evaluation
- Medical Device Audit
- Regulatory Affairs
- Proxy Services
- Global Certification

Tigermed, as the largest Medical Device (MD) / IVD regulatory and clinical trial CRO service provider in China, 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 top priority is to assist your Medical Device/In Vitro Diagnostic development and manufacturing process, to cope with the ever-changing regulatory requirements globally.

**6,100+**
MD Regulatory Projects

**780+**
MD Clinical Trials

**2,100+**
Global Clients

**30+**
Countries of business coverage

# Central Lab Services

One-stop Central Lab Solution to Support Clinical Studies with High Compliance

- Bioanalysis
- Routine/Safety tests
- Flow Cytometry
- Anatomic Pathology
- Mol. Pathology (NGS)
- Biomarker/Companion Diagnostics

**2,000+**
Test items

**CAP**
Accredited

**550+**
Projects

**10,000+ m²**
Laboratory space

**GLP/GCP**
Compliance

# Pharmaceutical Supply Chain Management

Clinical Trial Sample Managerial Integration

## Advantage

One-stop pharmaceutical supply chain management

Professional project management team

"direct drug procurement" model

GMP & GDP Certification and Medical Equipment Trading Enterprise Permit

**2,100+ m²**
Digital multi-temperature storage

**12-72h**
Multiple temperature range and timeliness management solutions

**800+**
Comparator Procurement

**30+**
Self-operated outlets

**30+**
Self-operated network in China

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# Medical Imaging

## One-Stop Imaging Evaluation Services

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

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

**190+**
Clinical imaging projects

**80+**
Global customers

# Clinflash: Clinical Trial System Solution

The leading provider of cloudbased solutions and professional services in Clinical Trials Systems.

- Clinflash aims to help the biopharmaceutical industry improve R&D effectiveness and efficiency by providing world class data & information solutions.
- Collaborated with more than 800 global healthcare companies and CROs to enable 3,000+ clinical trial projects.

**4,000+**
Total studies

**1,000+**
Global customers
(Pharma, Biotech, CRO, etc.)

**100+**
Phase III clinical trials
(60% are oncology trials)

For more information: www.clinflash.net
www.tigermedgrp.com

# Real World Study (RWS)



## Expertise on RWS

retrospective/prospective RWS, post-marketing new drug safety monitoring, health economics outcome research, real-world patient management.

## One-Stop RWS Solutions

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

## Full Suite of RWS Service

Under China NMPA real-world study regulations and guidelines, we offer one-stop high-quality services.

- Consulting
- Study Design
- Project Management
- Study Execution
- Data Management
- Statistical Analysis
- KOL Network
- System and Technology

As of January 2023

A Leading Provider of
Innovative Clinical Research Solutions

Tigermed

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