



Advance Human Health through Delivery Excellence



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

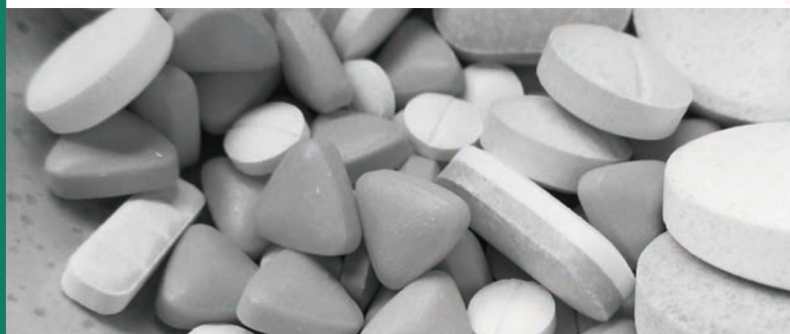
Innovative Drugs in China

Global Footprint

52 Countries with Tigermed Employees

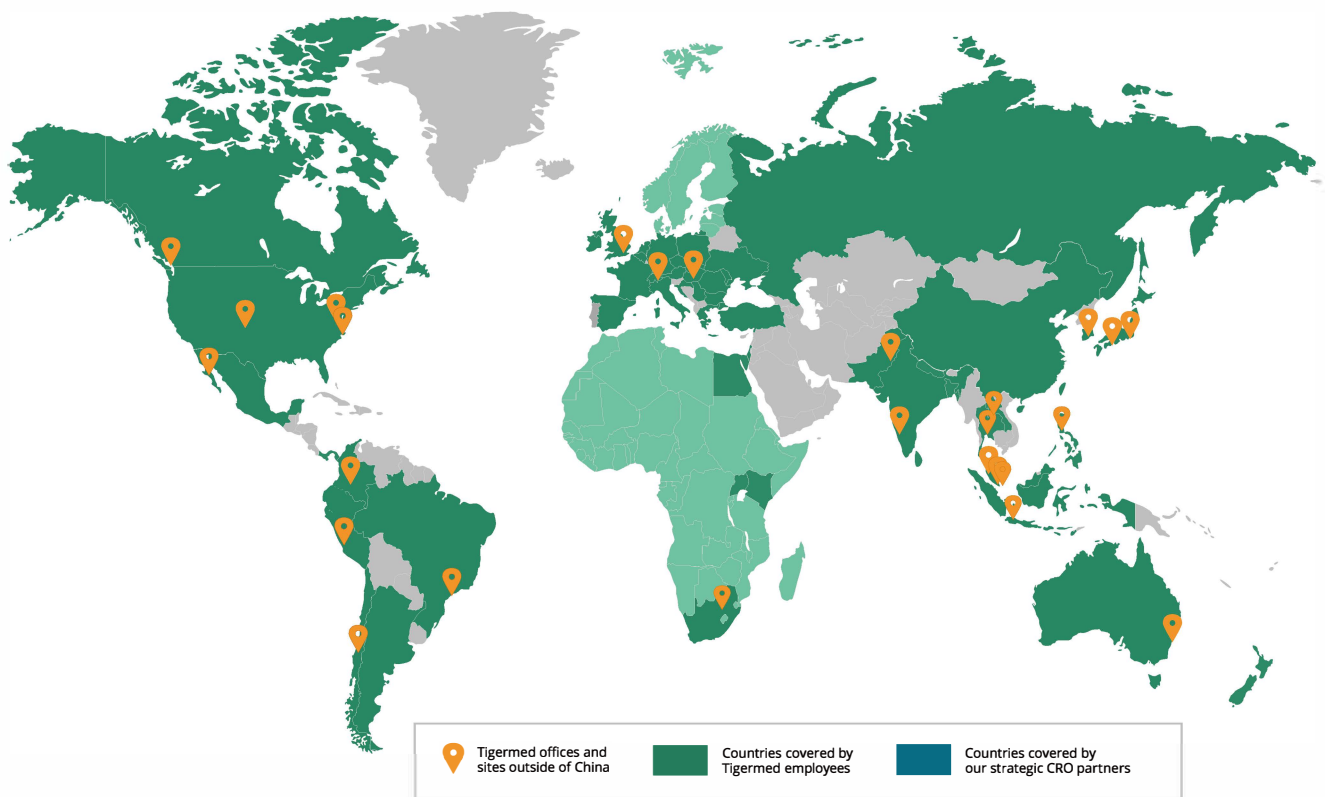
26 Offices & sites outside of China (legal entities)

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



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.



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



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

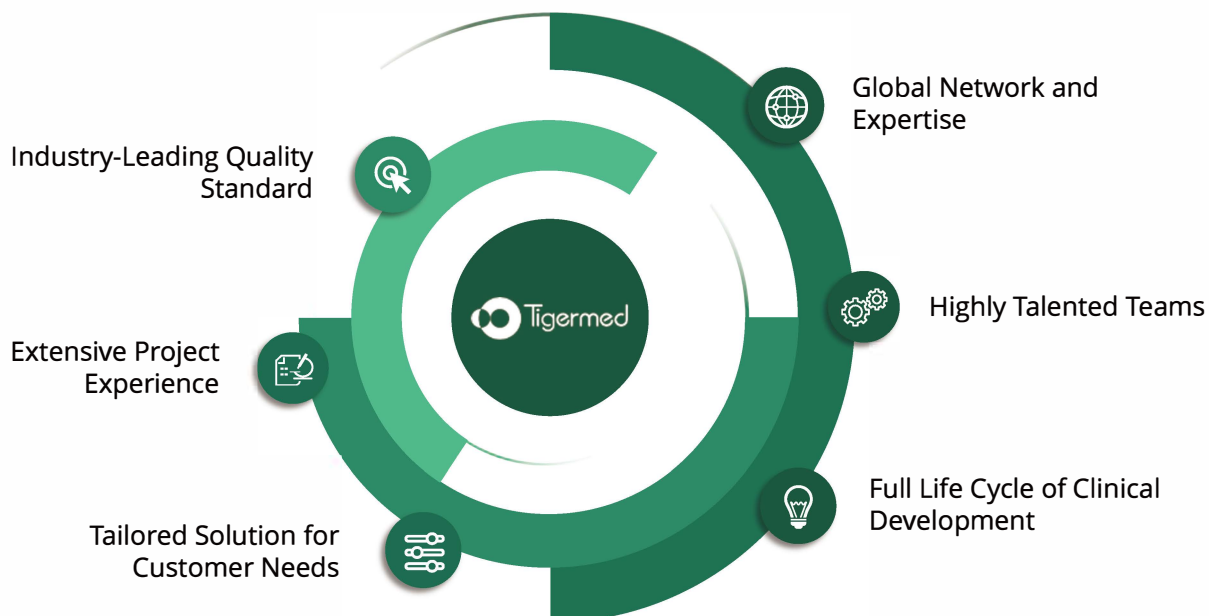
Since 2004, Tigermed Group has supported 527 Class 1 innovative drug research projects in China. ⁽¹⁾

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)



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

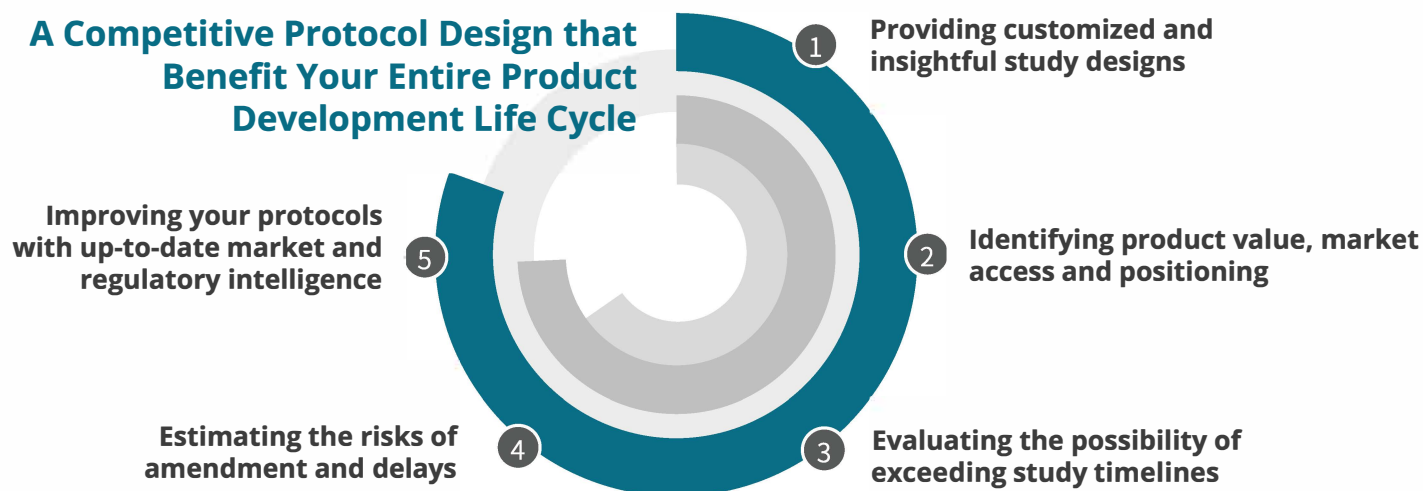


Clinical overview (module 2.5), Clinical summaries (module 2.7), Integrated summaries of safety and efficacy, RMP.



Investigator meeting materials

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





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

9	C OVID- 19	2	Rabies
3	HBV	2	HPV
		1	Mumps
Proven Track Record of Vaccine Clinical Trial Deliveries			
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 overseas 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

Pharmacovigilance Services

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

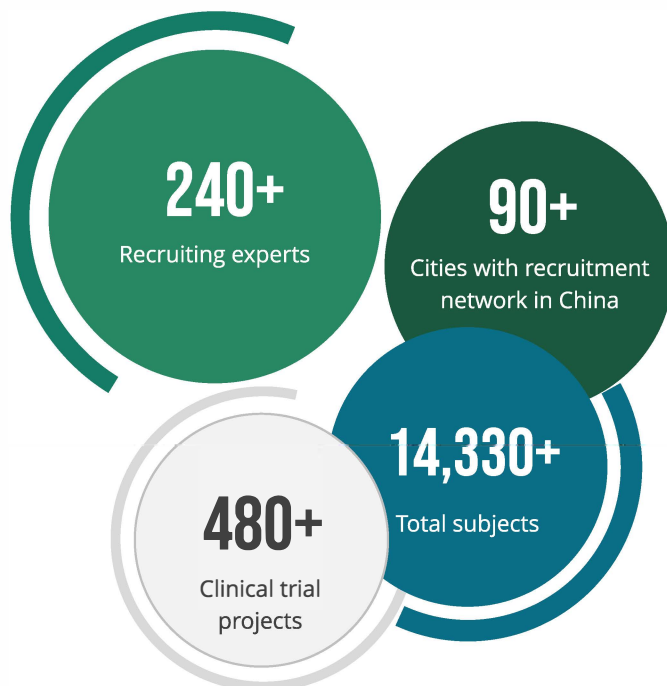
Flexible Trial Support with Knowledge and Expertise

- **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, biotech 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





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

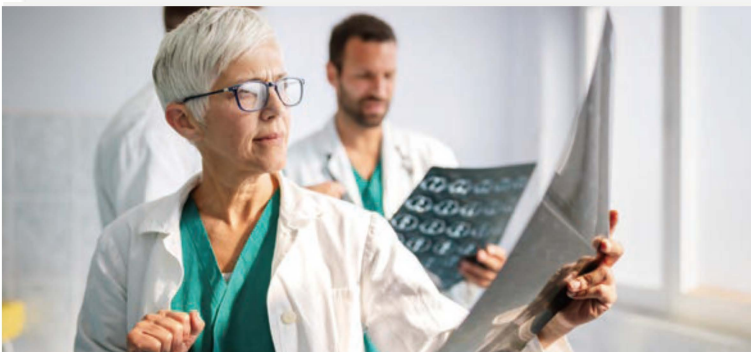
60+

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



Total
studies



Studies submitted
to NMPA



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+ m²

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

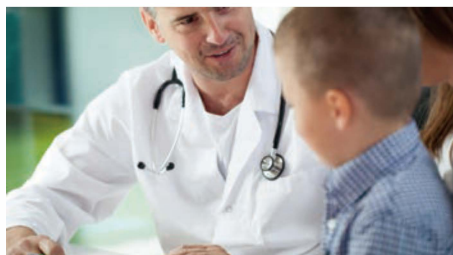


Design Verification



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

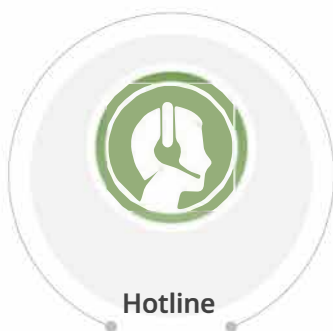
Statistic analysis

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



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.



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, 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+ M²

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 Therapeutic Areas

88

Global MRCT Projects

600+

Overseas Operation Professionals

43

Global Project Manager / Director





Asia Pacific

- Korea
- Japan
- Hong Kong China
- Taiwan China
- Philippines
- Thailand
- Singapore
- Pakistan Australia
- Nepal
- Vietnam Malaysia
- Indonesia



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 I maging, etc.

A Leading Provider of
Innovative Clinical Research Solutions



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