

# Advance Human Health through Delivery Excellence



# 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.

99

Enabling
Life-Changing
Therapies with
Excellence and
Commitment.





10,000+

Global Employees

2,700+

**Global Customers** 

180+

Global Locations & Service Networks

73

Innovative Drugs Supported

# 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



#### Our Mission

Advance human health through delivery excellence



#### Our Vision

To be recognized as the leading global CRO

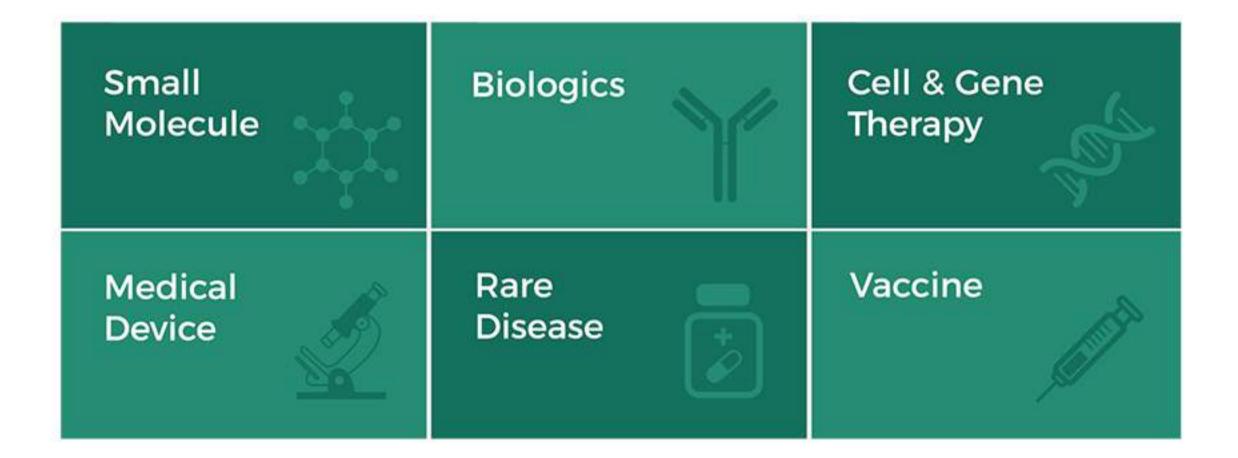
#### Our Values

Integrity & Honesty
Open & Inclusive
Collaborative & Accountable
Professional & Innovative



# 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.



# Global Footprint



1,350+

29 Offices & sites outside of China

50 Countries with Tigermed employees 30+
Countries with strategic CRO partners

of China

# 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

Post-market Research

Real World Study

Investigator-Initiated Trial



# 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 Submission 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



# 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

Delivery with High Quality and Data Integrity



28+

NDA/BLA Submissions to FDA with new indications





1,000+

Global Biometrics Experts



- 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



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

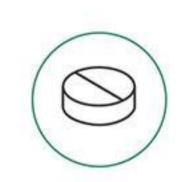
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Estimating the risks of amendment and delays

# Pharmacovigilance (PV) and Clinical Safety



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**

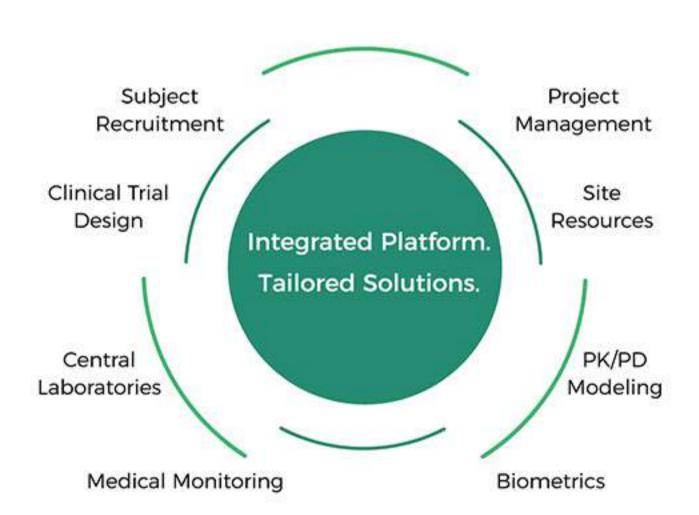
A dedicated team to deliver the right combination of in-house resources, tools and expertise.

#### 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.



# 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:





APAC

Taiwan China
Philippines
Thailand
Singapore
Pakistan
Australia
Nepal
Vietnam
Malaysia
Indonesia
Laos

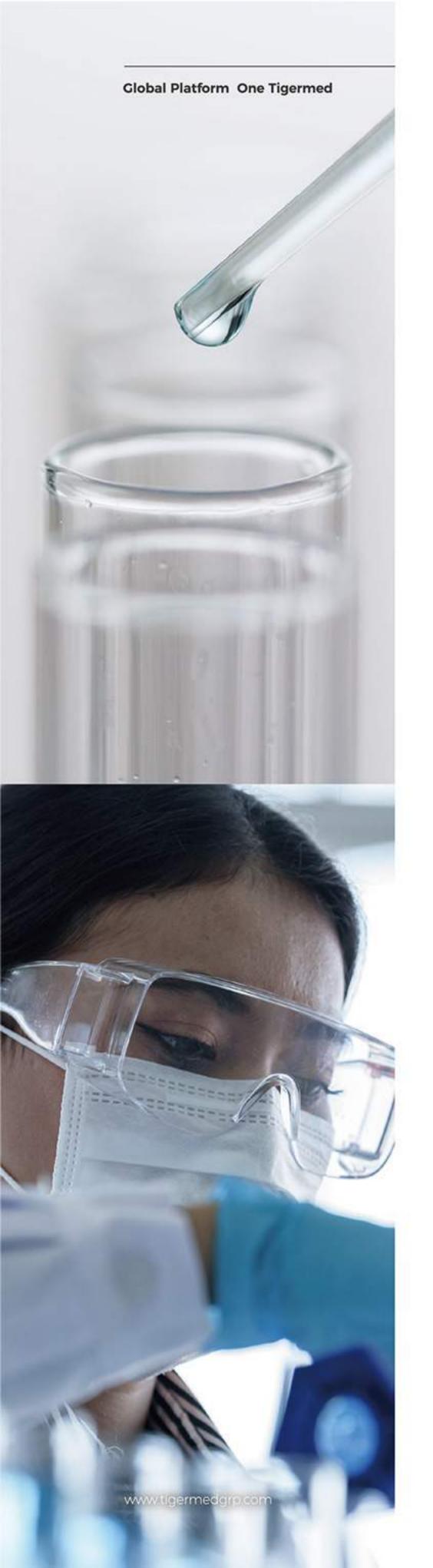
India

UAE

Hong Kong China

Korea

Japan



# 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**+

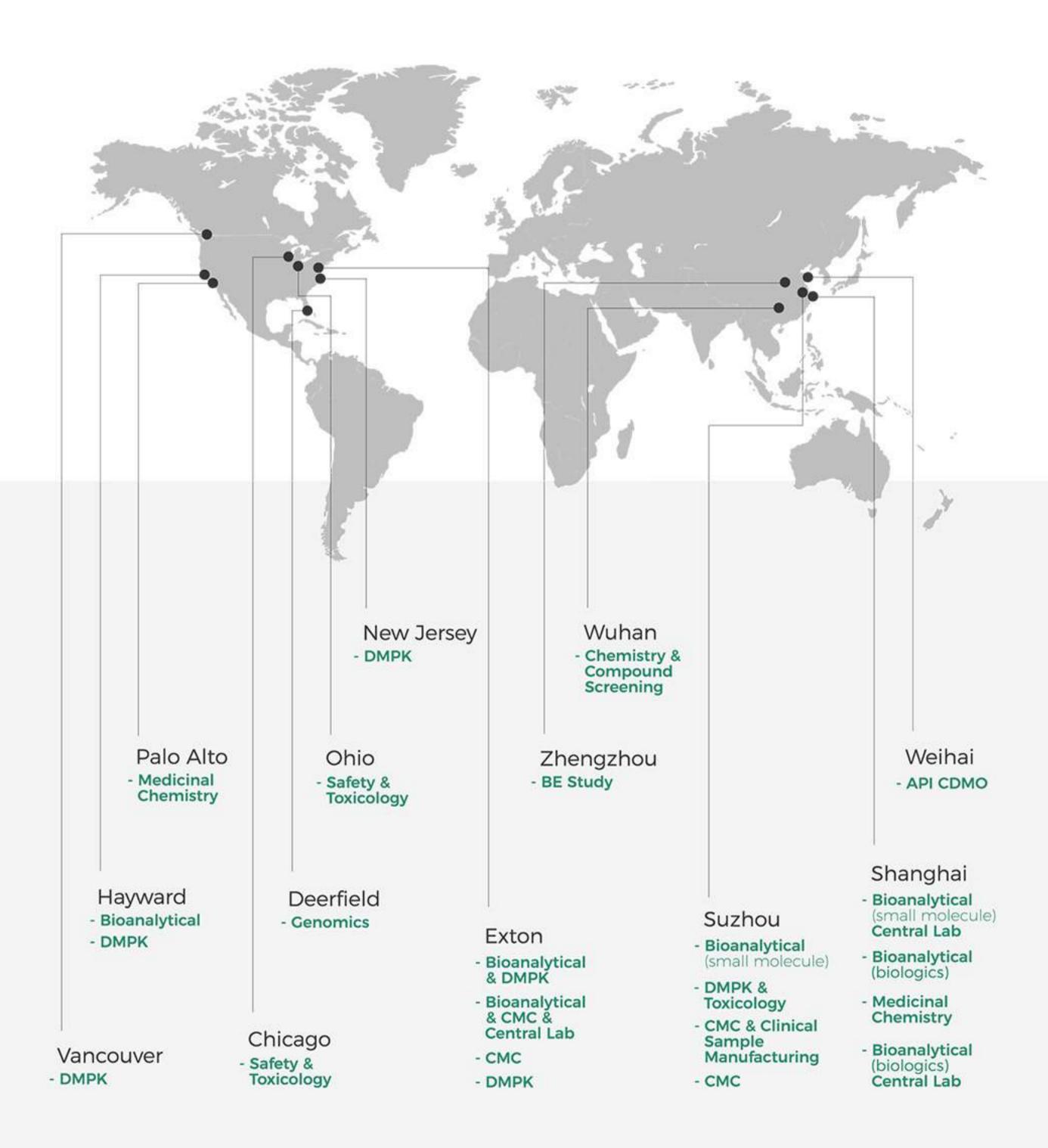
Global customers

30,000+

Compounds delicered

# Laboratories in US & China

# Quality, Scientific Integrity, Regulatory Compliance



# 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

600 +

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

320+

Inspection consulting and testing projectsv

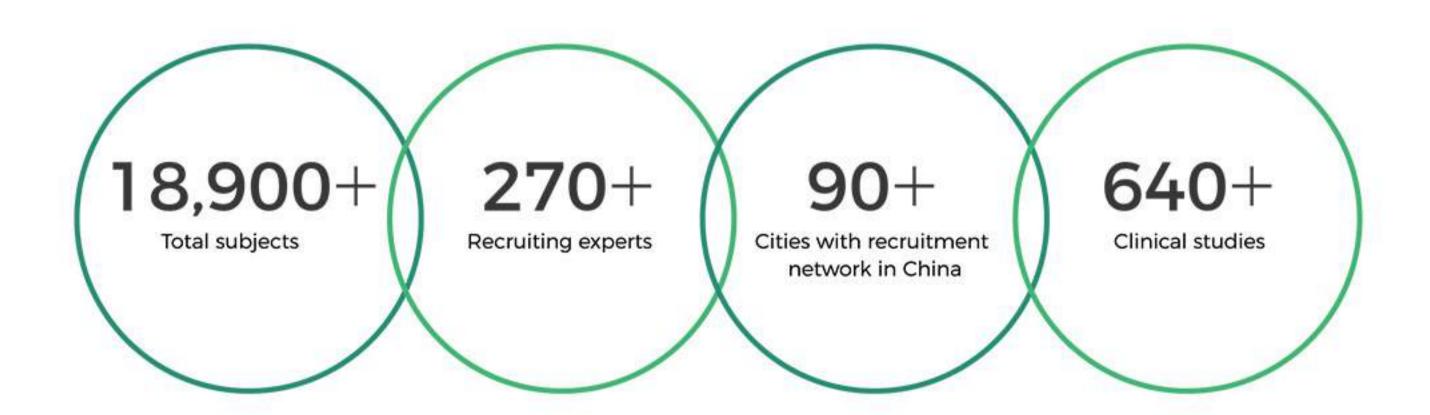
**30**+

Consulting experts in EU, US and China

For more information: www.china-canny.com

# Subject Recruitment

Accelerating Enrollment Speed by Proven Data and Analytics



# Third Party Audits

Supporting You with All Aspects of the Audit Process

## Wide Coverage

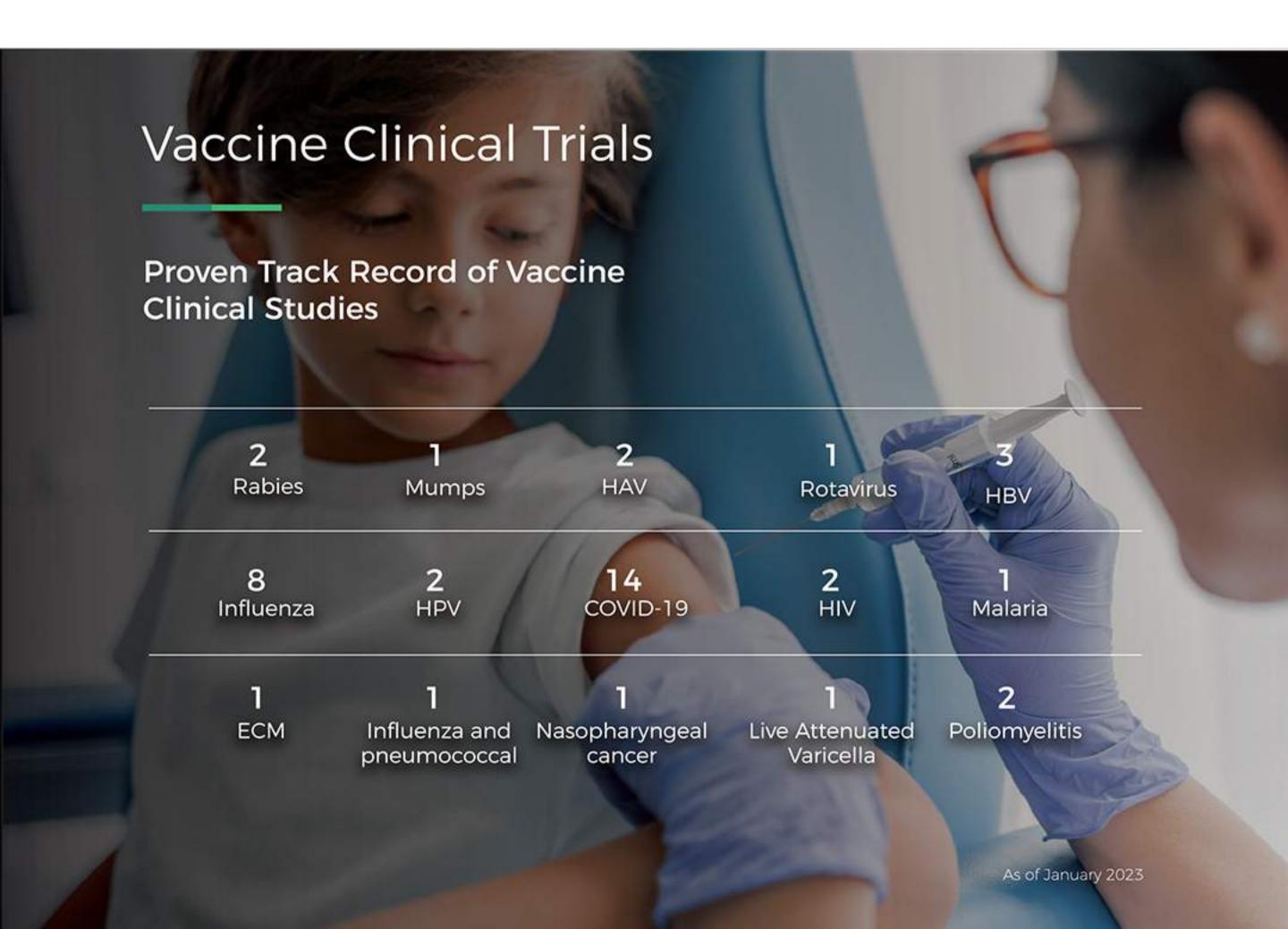
- Audit services for Phase I-IV clinical trial, medical device clinical trial,
   IVD, BE study, PK study, data management, TMF, etc.
- Audit services for external vendors and NMPA onsite inspections
- GCP/GLP/GMP audits

#### 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



# 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+

2,100+

**30**+

**Global Clients** 

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

 $10,000+m^2$ 

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

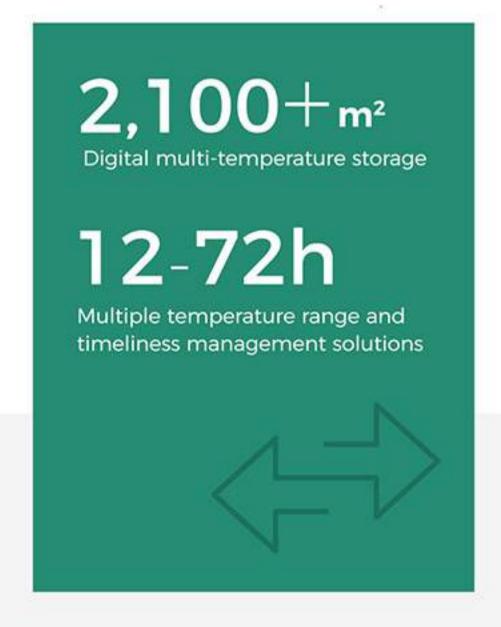
"direct drug procurement" model

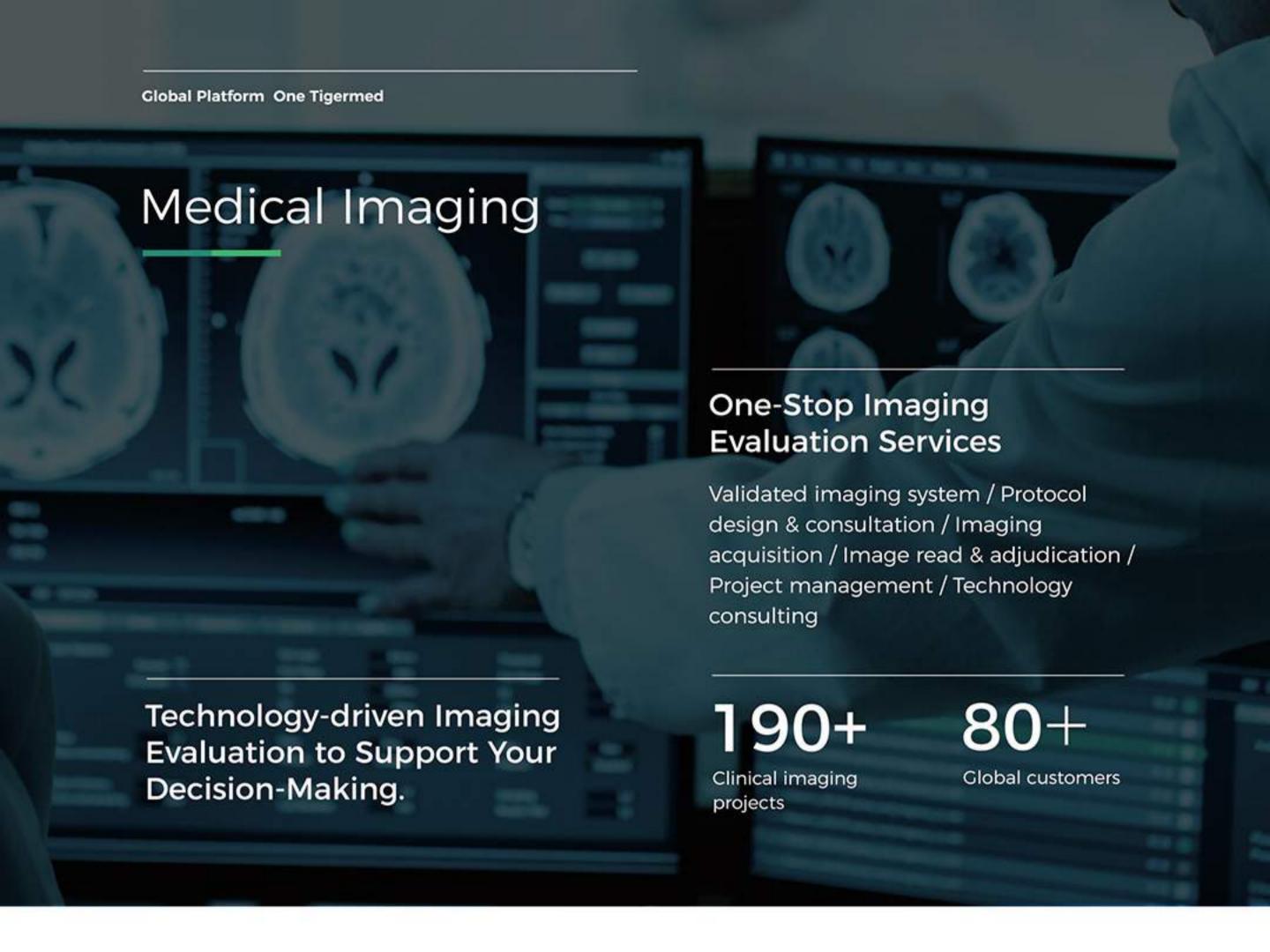
GMP & GDP Certification and Medical Equipment Trading Enterprise Permit

Comparator Procurement 30+30+

Self-operated outlets

Self-operated network in China





# 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)

# Real World Study (RWS)

Solutions

# **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.







**Study Design** 







Data Management



Statistical Analysis



KOL Network



System and Technology

# A Leading Provider of Innovative Clinical Research Solutions

