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Hangzhou Tigermed Consulting Co., Ltd.

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What have We Seen in an Eventful 2023?

100%

ICH guidelines implementation in China by 2023(1)

Full harmonization of regulatory regime with global standards

A record-high **48** Class-1 innovative drugs approved in 2023(2)

44 of them were launched by China-originated companies

A booming out-licensing partnerships with a total size of **$41+ Billion**(3)

Billion-dollar out-licensing deals kept happening across the year

NRDL 2023 policy tend to support new drug R&D

23 of the 25 innovative drug candidates were add to 2023 NRDL list (4)

Embracing **innovative technologies and reforms** in clinical research

More guidelines issued to demonstrate unwavering support of the adoption of new technology such as DCT etc.

Developing more assets with **global first wave potential**

15% of clinical-stage oncology MoAs(5) are being developing by China-based biotechs

(1) Source: Center for Drug Evaluation of NMPA presentation at DIA China 2023
(2) Source: Center for Drug Evaluation of NMPA. Including emergency approval of COVID-19 related drugs
(3) Source: Citeline Database; total deal size includes milestone and/or royalty payments contingent on future events
(4) Source: National Healthcare Security Administration
(5) Source: McKinsey analysis as of Nov 2023 MoA: mechanisms of action

China Innovative Drug Assets Start to Display a Different Pattern…

China-originated assets started to pursue differentiated innovation and global-competitive modality

Stage 1

Catching Up

2010-2017

- Majority of pipeline are pure followers
- Large gap between global first PoC and China first PoC
- No or limited clinical development strategy
- Accumulating core technology and capability for engineering-based innovation
- Emerging of abundant high-quality talents and suppliers along industry value chain

Stage 2

A Closer Gap

2017-2021

- Leaders started to pursue fast-following strategy with speed and profile differentiation
- Pipeline with a more complexity of modalities
- Strong engineering-based innovation capability
- More savvy on clinical development

Stage 3

Global Recognition

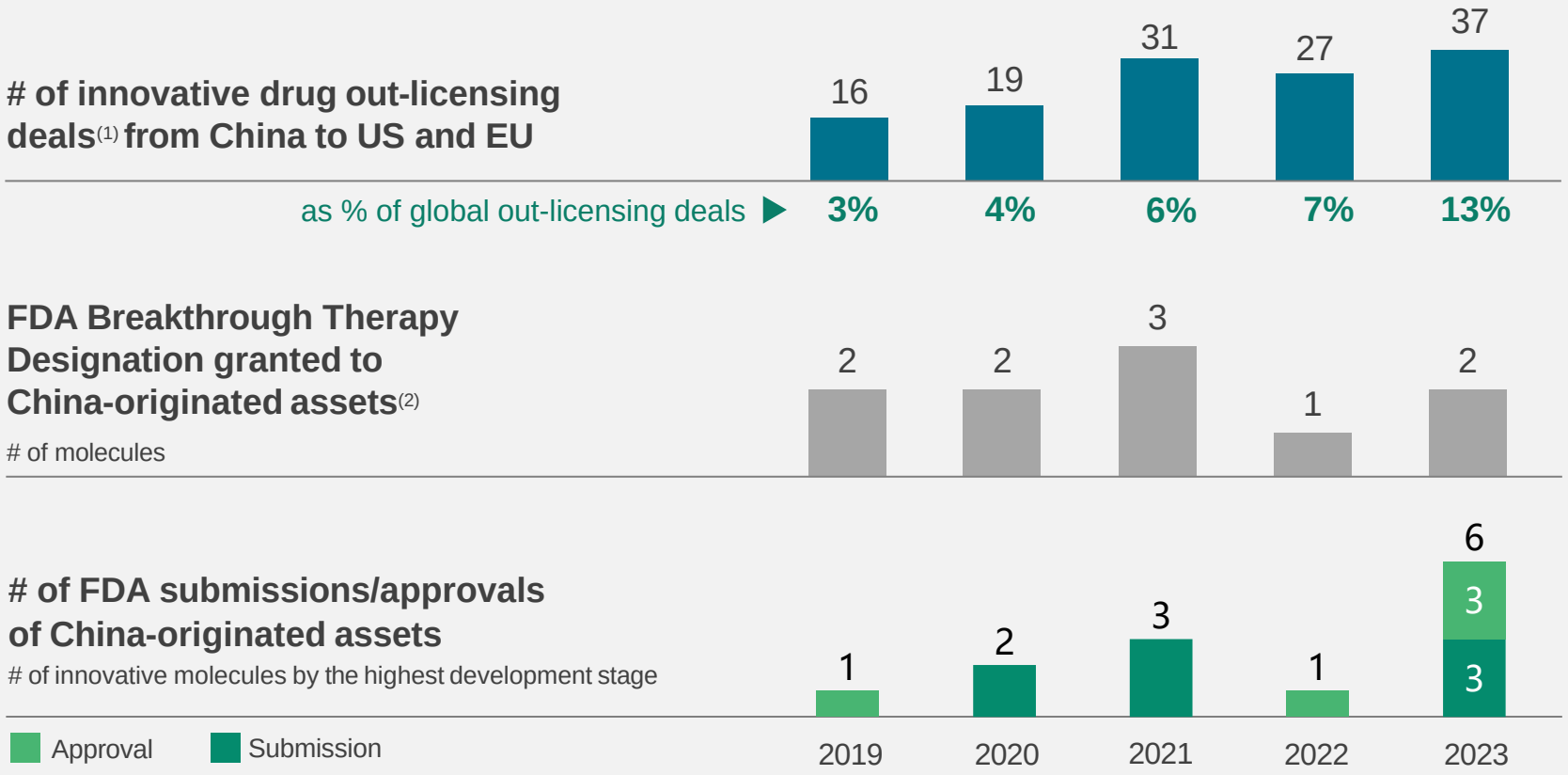
2021 onwards

- Wave of out-licensing transactions to global MNCs:
  - Represents **27%** of global ADC out-licensing deals since 2021(1)
- Co-developments with global leaders in developed markets
- Started to develop assets with global first-wave potential:
  - **15%** of first-in-class MoAs are currently developed by Chinese companies(2)

(1) Source: McKinsey analysis as of Nov 2023. ADC deals from China only include out-licensing transactions to US and EU markets; acquisitions excluded
(2) Source: McKinsey analysis as of Nov 2023. Including MoAs at Phase I–III clinical and pre-NDA stages. MoA numbers are counted by modality and target pairs, i.e. for small molecule, ADC, and mAbs, the MoA is counted by targets; for multivalent mAbs and CGT, the MoA is counted by combinations

…And Start to Show Impact on Global Stage…

"In China For China" story no longer the only priority



(1) Innovative asset-based deals with licensor being companies headquartered in China and deal rights territory including US and EU
(2) Assets developed by China-originated biopharma

Source: McKinsey, Insight Database

…With Recognition by Global Market Leaders

In 2023, transactions involving China innovative drug assets continued to heat up and hit a record high, reflecting a greater influence in the global biopharma industry and a higher recognition from global market leaders

A record-breaking out-licensing deal from China biotech to MNC

SystImmune (China) and BMS announce in Dec 2023 a global strategic collaboration agreement for the development and commercialization of BL-B01D1(1)

Upfront payment
$800 million

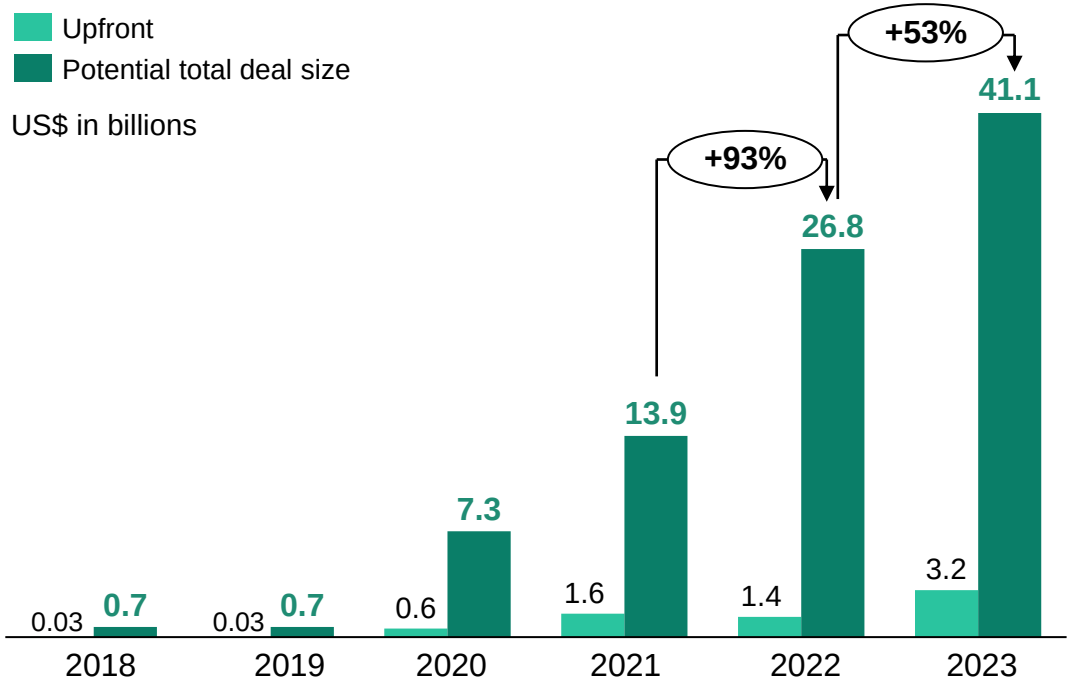
Total potential deal size
$8,400 million

The first listed China-originated biotech to be fully acquired by MNC

Gracell Biotechnologies (China) announced in Dec 2023 to be acquired by AstraZeneca, furthering cell therapy ambition across oncology and autoimmune diseases(2)

Total transaction size
$1,200 million

A significant growth of drug out-licensing upfront and potential total deal size (2018-2023)



(1) Source: BMS Press Release
(2) Source: Gracell Press Release

Source: Tigermed Analysis, Insight Database

Select US$1Bn+ Out-Licensing Deals from China Biopharma in 2023

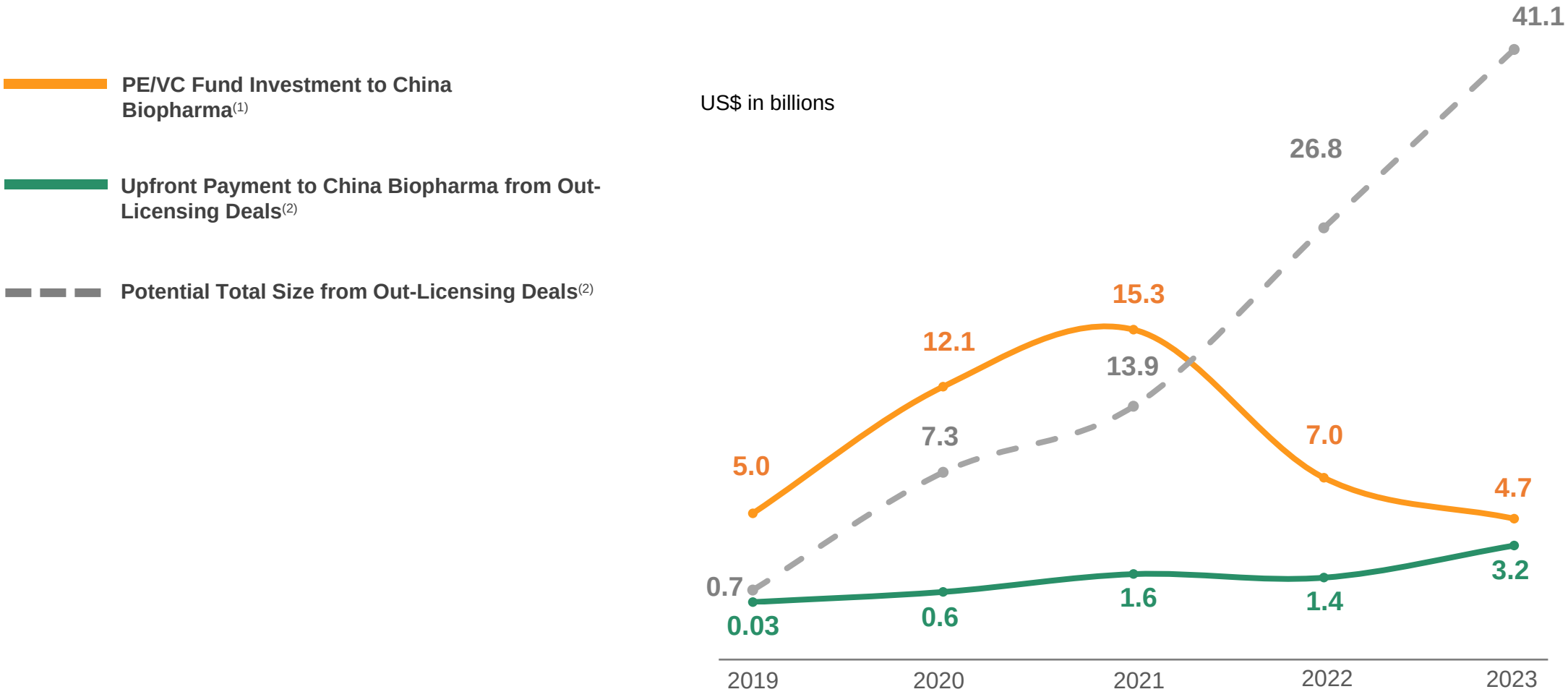
Mostly focus on advanced therapies (e.g. ADC and CGT, etc.)

Date	Licensor	Licensee	Asset	Type	Upfront (US$ in millions)	Total Potential Size (US$ in millions)
January	**HutchMed**	Takeda	Fruquintinib	Chemical	400	1,130
February	**Keymed and Lepu Biopharma**	AstraZeneca	CMG901	ADC	63	1,188
April	**Duality Bio**	BioNTech	DB-1303，DB-1311	ADC	170	1,670
April	**GeneQuantum**	Pyramid Biosciences	GQ1010	ADC	20	1,020
May	**BlissBio**	Eisai	BB-1701	ADC	N/A	2,000
August	**Hengrui**	Aiolos Bio	SHR1905	mAb	25	1,050
October	**Medilink**	BioNTech	HER3 ADC	ADC	70	1,000+
October	**Hansoh**	GSK	HS-20089	ADC	85	1,570
October	**KBP Biosciences**	Novo Nordics	KBP-5074	nsMRA	N/A	1,300
October	**Hengrui**	Merck KGaA	HRS-1167, SHR-A1904	ADC	160	1,400
November	**Biotheus**	BioNTech	PM8002	BsAb	55	1,055
November	**Eccogene**	AstraZeneca	ECC5004	Chemical	185	2,010
November	**Legend Bio**	Novartis	CAR-T	Cell therapy	100	1,110
December	**Biokin Pharmaceutical**	BMS	BL-B01D1	ADC	800	8,400
December	**Hansoh**	GSK	HS-20093	ADC	185	1,525

May Not Be Exhaustive

Funding Environment and Sentiment Remains Weak

Divergence of the trend between PE/VC investment and out-licensing transactions



May Not Be Exhaustive

(1) Source: PharmaCube
(2) Insight Database

Potential Future Trends for China-based Innovative Drug Assets

"Made for China and made from China"

From Biopharma/Big Pharma

- Fast follow for local commercialization
- IP licensing/acquisition (both local and global opportunities)
- Concentrated clinical programs in developed markets with indication differentiation preferred

Clinical Value-Oriented
Science and Innovation

From Biotech/Start-up

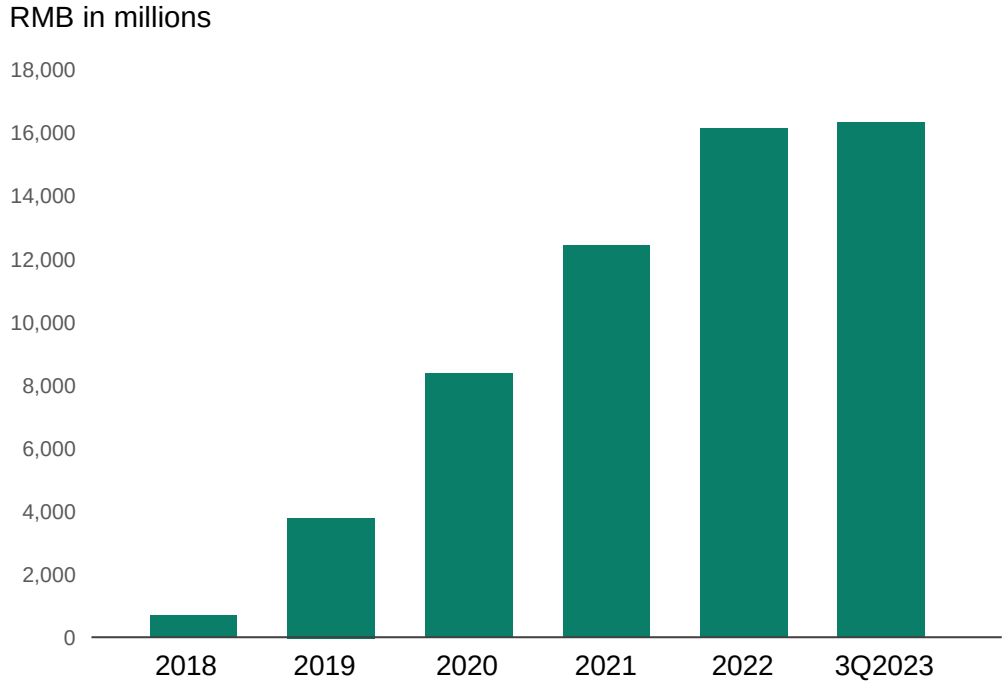
- Fast following with speed and differentiation after clinical validation in developed markets with big global TAM
- TA bets for Chinese market
- Riskier MoA bets for global markets
- Translation from academia

Sales of Domestic Innovative Drugs in China Continued to Ramp up in 2023

Top China innovative drugs approved between 2018-2022 by domestic sales in 3Q2023

Company	Product	Target
BeiGene	Tislelizumab	PD-1
ChiaTai Tianqing	Anlotinib	VEGF
Innovent	Sintilimab	PD-1
Hansoh	Almonertinib	EGFR
BeiGene	Zanubrutinib	BTK
Allist	Furmonertinib	EGFR
Akeso	Cadonilimab	PD-1/CTLA4
Henlius	Serplulimab	PD-1
Hutchemd	Fruquintinib	VEGFR
TopAlliance	Toripalimab	PD-1

Historical sales of select domestic innovative drugs in China(1) (2018-3Q2023)



May Not Be Exhaustive

(1) Selected domestic innovative drugs include: Tislelizumab, Anlotinib, Sintilibab, Almonertinib, Zanubrutinib, Furmonertinib, Cadonilimab, Serplulimab, Fruquintinib, Toripalimab

Source: PharmaCube, company announcement, press release

Regulatory Environment Further Enhanced for Clinical Development

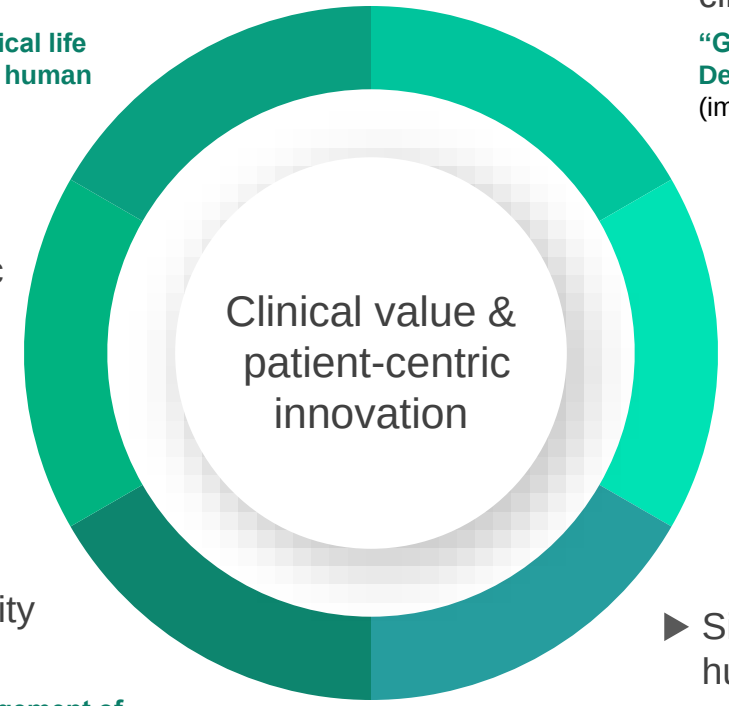
Select key regulations by NMPA and related authorities in 2023

- Protecting patients' rights regarding ethical management

  "Regulations to ethical review of biomedical life sciences and medical research involving human beings" (implemented, Feb 27, 2023)

- Promoting patient-centric practice in clinical research

  "Guideline on Patient Centric Clinical Trial Design/ Implementation/ Benefit-risk assessment " (implemented, Jul 23, 2023)



- Accelerating approval process for pediatric drugs and orphan drugs

  "Regulations of accelerating the review of market approval applications for innovative drugs" (implemented, Mar 31, 2023)

- Encouraging DCT in rare disease clinical trials

  "Technical guideline on utilizing decentralized clinical trials in rare disease clinical research" (solicit public opinion, Nov 24, 2023)

- Continually improving trial quality and site supervision

  "E6 (R3) Specifications for quality management of drug clinical trials" (solicit public opinion)

  "Regulations for supervision and inspection of drug clinical trial site" (to be implemented, Mar 1, 2024)

- Simplifying regulation process on human generic resources

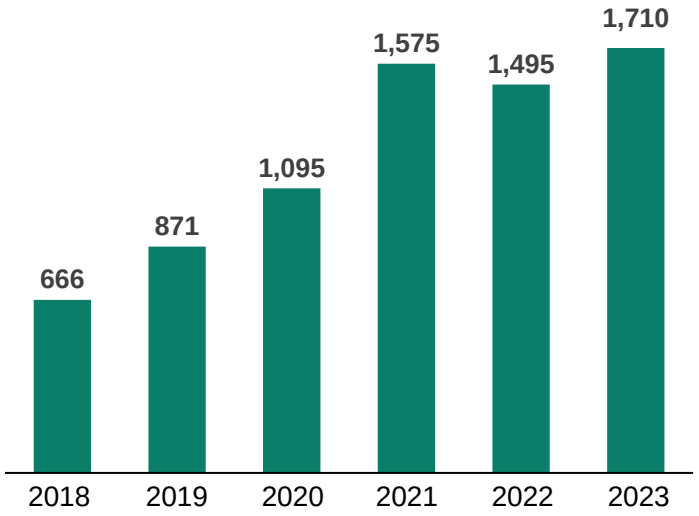
  "Regulation and specifications for the management of human generic resources" (implemented, Jul 1, 2023)

Source: Center for Drug Evaluation of NMPA, National Health Commission, Tigermed Analysis

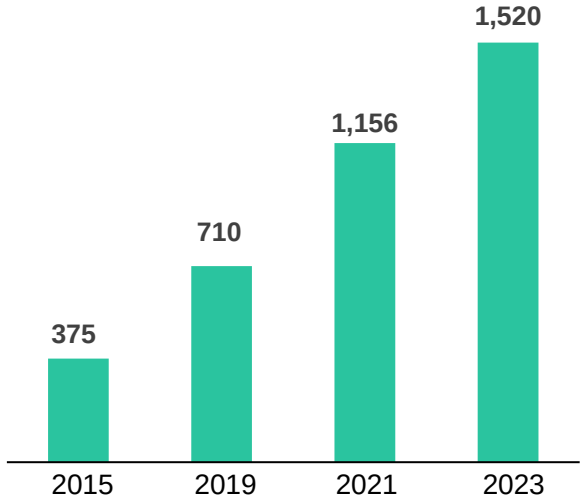
Clinical Development Pipeline and Resources are Growing in China

Clinical trial activities remain strong and the number of clinical trials in China tops the world for three-consecutive years

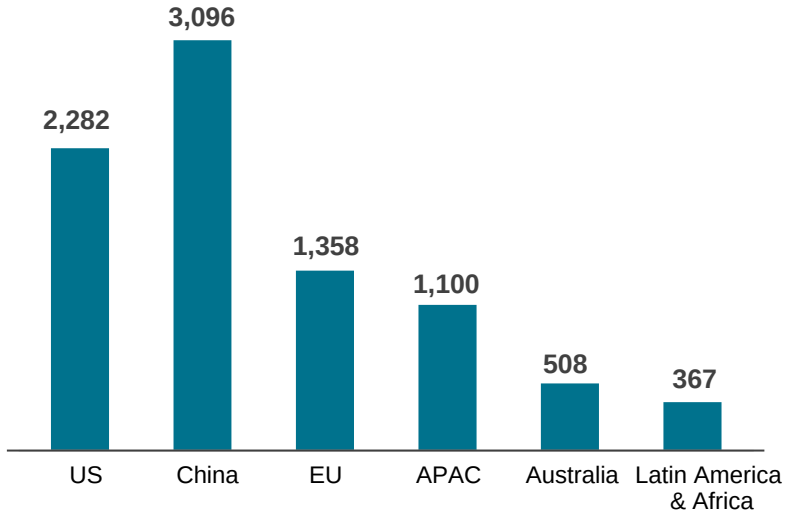
Newly started innovative drug clinical trials in China[1] (2018-2023)



Number of certified clinical trial sites in China[2] (2015-2023)



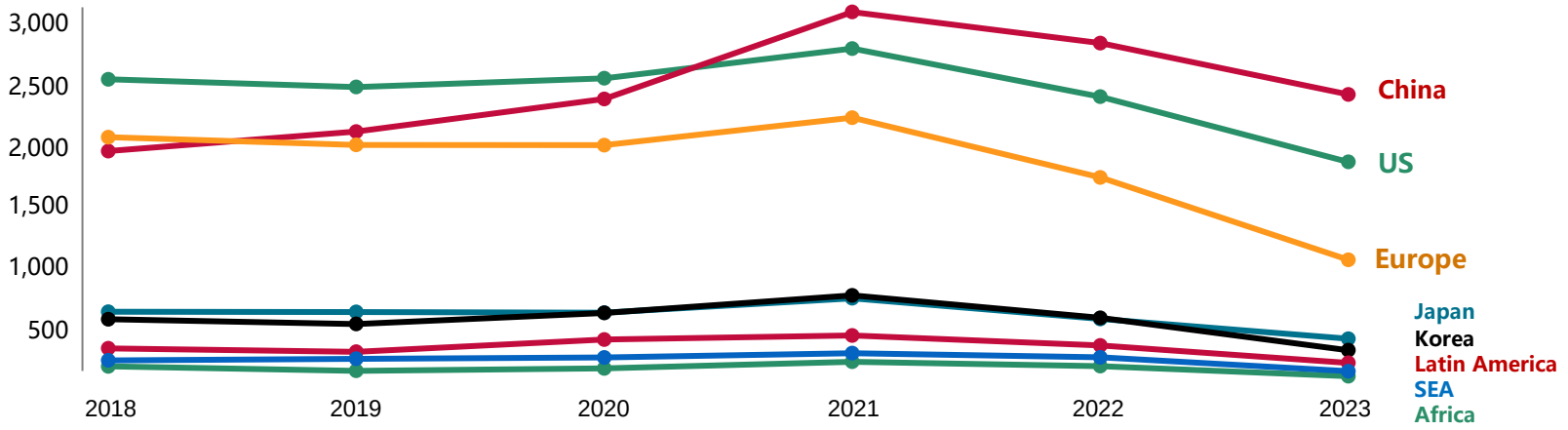
Total number of all newly started clinical trials by country/region in 2023[3]



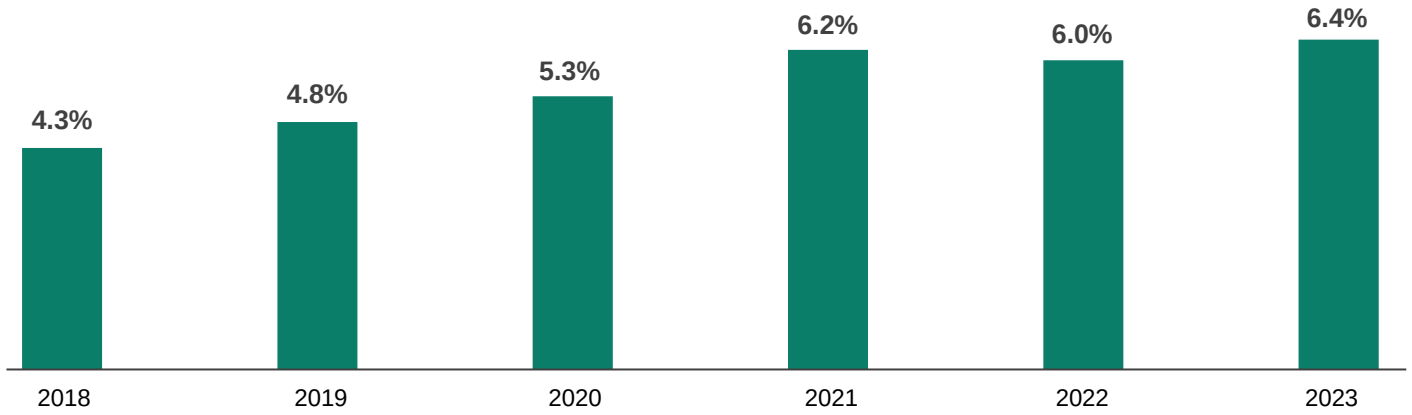
(1) Source: Center for Drug Evaluation of NMPA
(2) Source: PhRDA, NMPA
(3) Source: Citeline Database

China Sites Play a Bigger Role in Global Clinical Trials

Global clinical trials by destination country/region
2018-2023



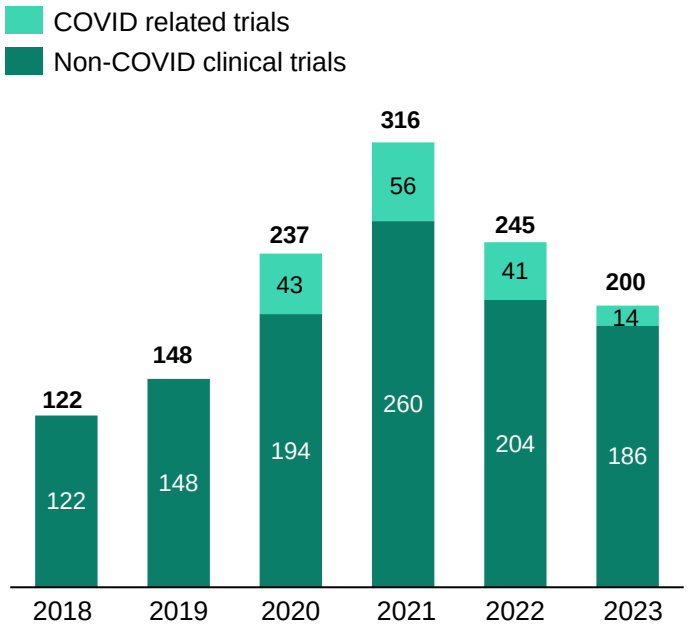
% of China site involvement in global clinical trials
2018-2023



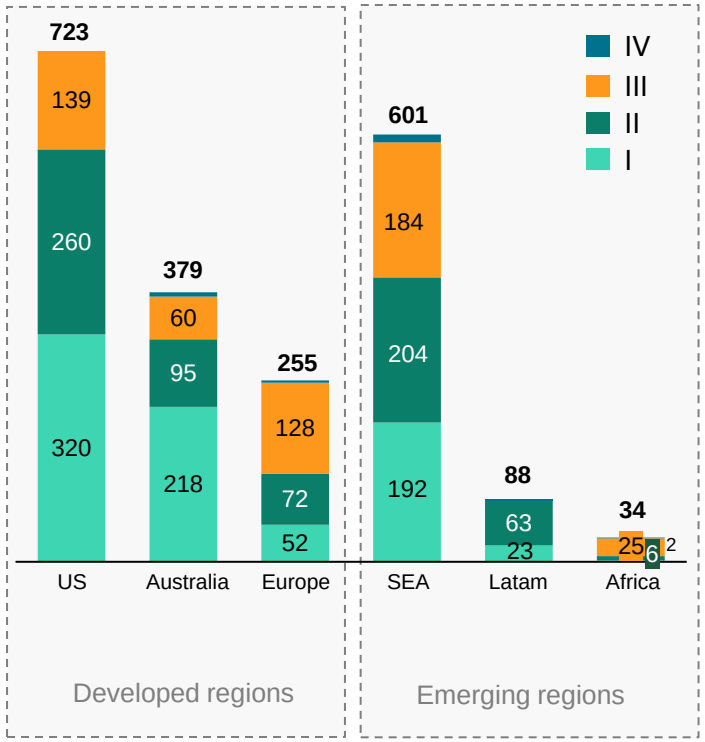
Source: Insight Database, Tigermed Analysis

Chinese Companies are Pursuing Clinical Trials Globally

Clinical trials initiated by Chinese companies in overseas countries[1] (2018-2023)



Clinical trials initiated by Chinese companies in overseas countries by country/region[2] (2018-2023)



Building global clinical capabilities with local team and more overseas trial experiences

12+

Chinese PIs led global Phase II or Phase III MRCTs (including site in the US) since 2019[3]

85%+

of these MRCTs focus on Oncology (lung, liver, nasopharynx) given unmet needs and patient base in China[3]

1 Chinese Clinical CRO

1 Chinese clinical CRO (Tigermed) among global Top 10 with 1.5% market share[4]

(1) Source: Insight Database, Tigermed Analysis
(2) Source: Insight Database, Tigermed Analysis
(3) Source: McKinsey
(4) Source: Frost and Sullivan

Real World Evidence to Play an Increasingly Important Role in China

Real World Evidence (RWE) to play a growing role to secure registration and become a new pathway to access vast Chinese market

Regulatory Support

Guidelines and technical principles have been issued continually for clinical practices

Feb 2023
Technical guideline for communication of real-world evidence support to drug registration applications

Feb 2023
Guideline for Real-World Research Design and Protocol Framework for Drugs

Apr 2022
Technical Guideline for Communication under Registration Review Evidence System Based on "Three Combinations"

Jan 2022
Guideline for the Application of Patient-reported Outcomes in Drug Clinical Studies

Unique opportunity

Using RWE to support regulatory decisions and gain accelerated approval in China

- China has introduced Boao Lecheng (Hainan) the only region in China that can use licensed drugs approved in other countries but not registered in China, led to an opportunity to gain faster market access to China by leveraging RWE
- Regulatory authorities, partnering with industry, academia and medical institutions, are positively driving forward the application of RWE

Success Story

First NDA in China by using real world evidence

The NDA of Isatuximab injection formally accepted by China National Medical Product Administration (NMPA) in December 2023

1st

the first hematologic oncology treatment to have its market approval application accepted by NMPA by using RWE from Boao Lecheng

SARCLISA® (isatuximab-irfc)

Source: Center for Drug Evaluation of NMPA

Embracing Decentralized Clinical Trials (DCTs) – Swift and Bold

Decentralized clinical trials are becoming an increasingly important part of the clinical research landscape in China

Regulatory Support

Intensive regulations on encouraging DCT model in clinical research were implemented in 2023

General Guidelines

July 2023
Technical Guidance for the Design of Patient-Focused Clinical Trials (by CDE, NMPA)
July 2023
Technical Guidance for the Implementation of Patient-Focused Clinical Trials (by CDE, NMPA)
July 2023
Technical Guidance for Benefit-Risk Assessment of Patient-Focused Clinical Trials (by CDE, NMPA)

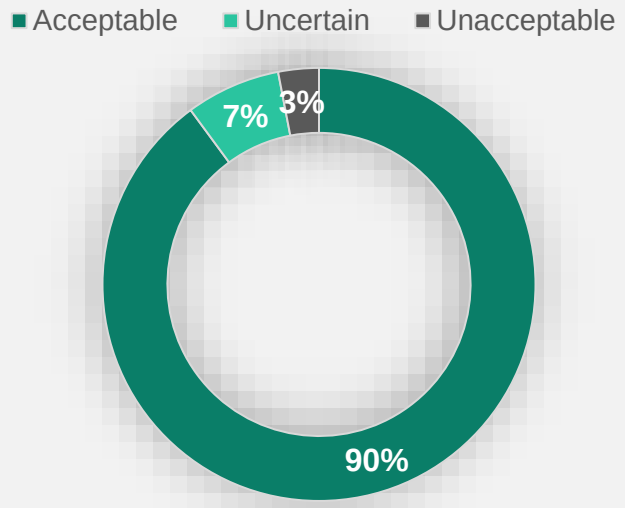
Implementation in Beijing

Oct 2023
Beijing Municipal Medical Product Administration officially announced implementation plan of DCTs in clinical trials

Patient Acceptance

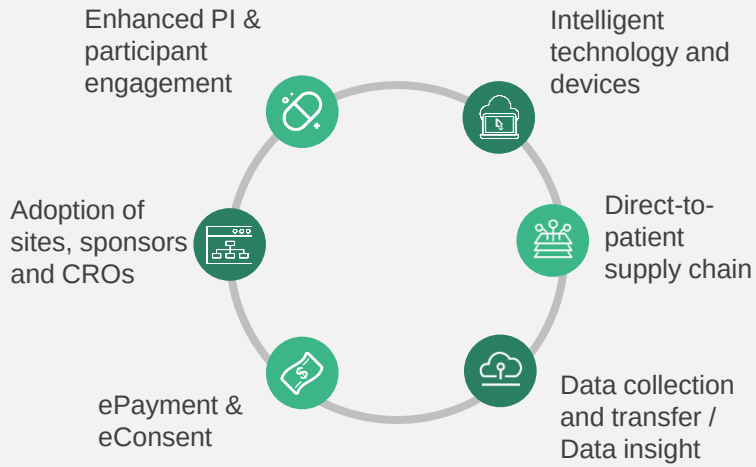
Acceptance of overall decentralized clinical trials concept by participants

Survey of 685 respondents from West China Hospital, Sichuan University



Ecosystem is forging

A vibrant ecosystem from virtual technology to data collection and online platform is quickly forging

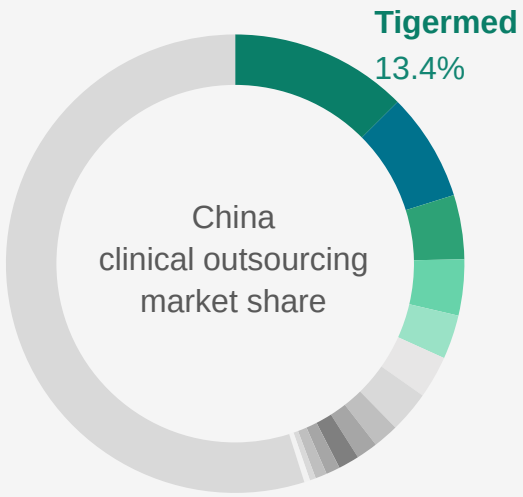


Source: Center for Drug Evaluation of NMPA, Beijing Municipal Medical Product Administration

Tigermed: Leader and Key Enabler of China Innovative Drug Research

The Leading Clinical Research Service Provider in China in both Scale and Market Share

Tigermed has the largest market share of **13.4%** in China's clinical outsourcing market in 2022(1)



Leveraging unique global layout to deliver clinical studies for customers worldwide

10,000+
global employees

180+
locations and service networks

30+
countries

China Innovative Drugs We Served

92

Provided services to the development of 92 approved Class 1 Innovative drugs in China since 2004(2)

Influence on China's Innovative Drug Research

63%

Delivered or supported the development of 63% of China Class 1 innovative drugs since 2004

Innovative Drug Clinical Studies

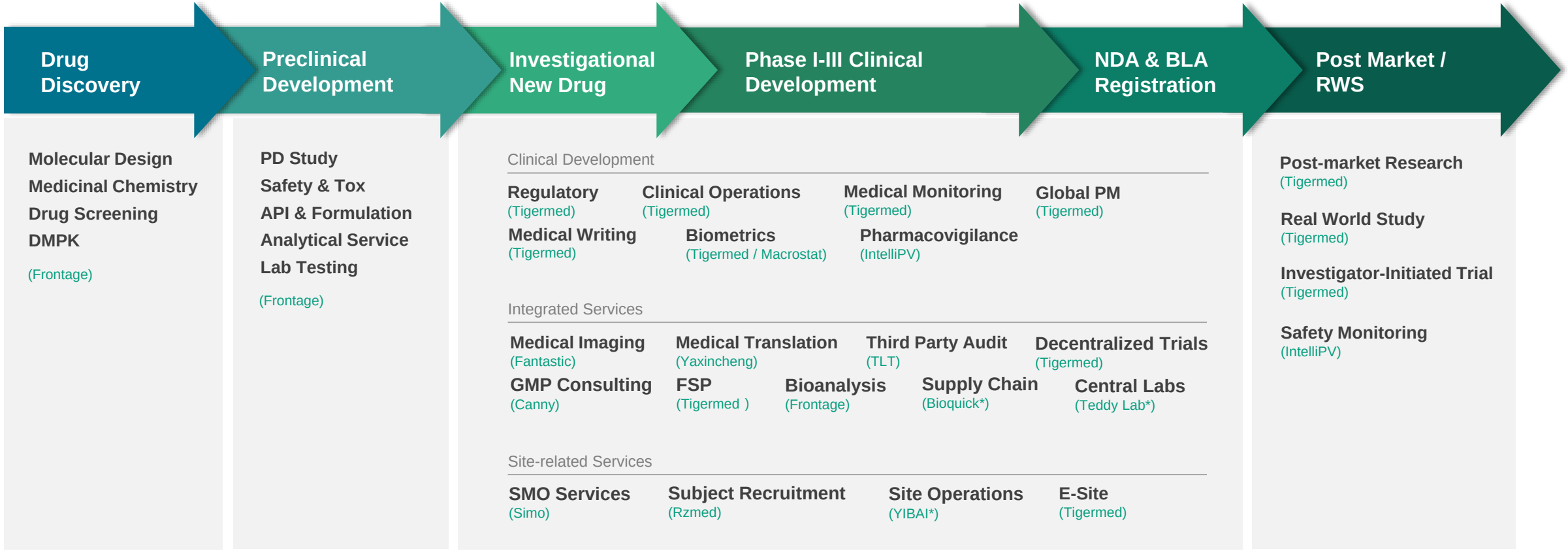
745

Since 2004, Tigermed has participated 745 Class 1 innovative drug research projects in China(2)

As of Oct 2023

(1) Source: Frost & Sullivan
(2) Services for Class 1 innovative drug studies include clinical operations, imaging analysis, SMO, biometrics, central lab, EDC, PV, etc.

Tigermed: End-to-End Service Offerings from Lab to Clinical



End-to-End Service Offerings for Drug R&D

Names in (GREEN) represent controlling subsidiaries or joint ventures providing corresponding services
Company marked as* represents non-controlling subsidiary of Tigermed

Tigermed: Strategically Located with Global Operation and Local Expertise

North America Team: 850+

- Laboratory facilities in 8 cities across North America
- Partnering with over 100 sites across 33 States in US
- Local expertise in clinical monitoring / PM / biometrics / regulatory, etc.

China Team: 7,900+

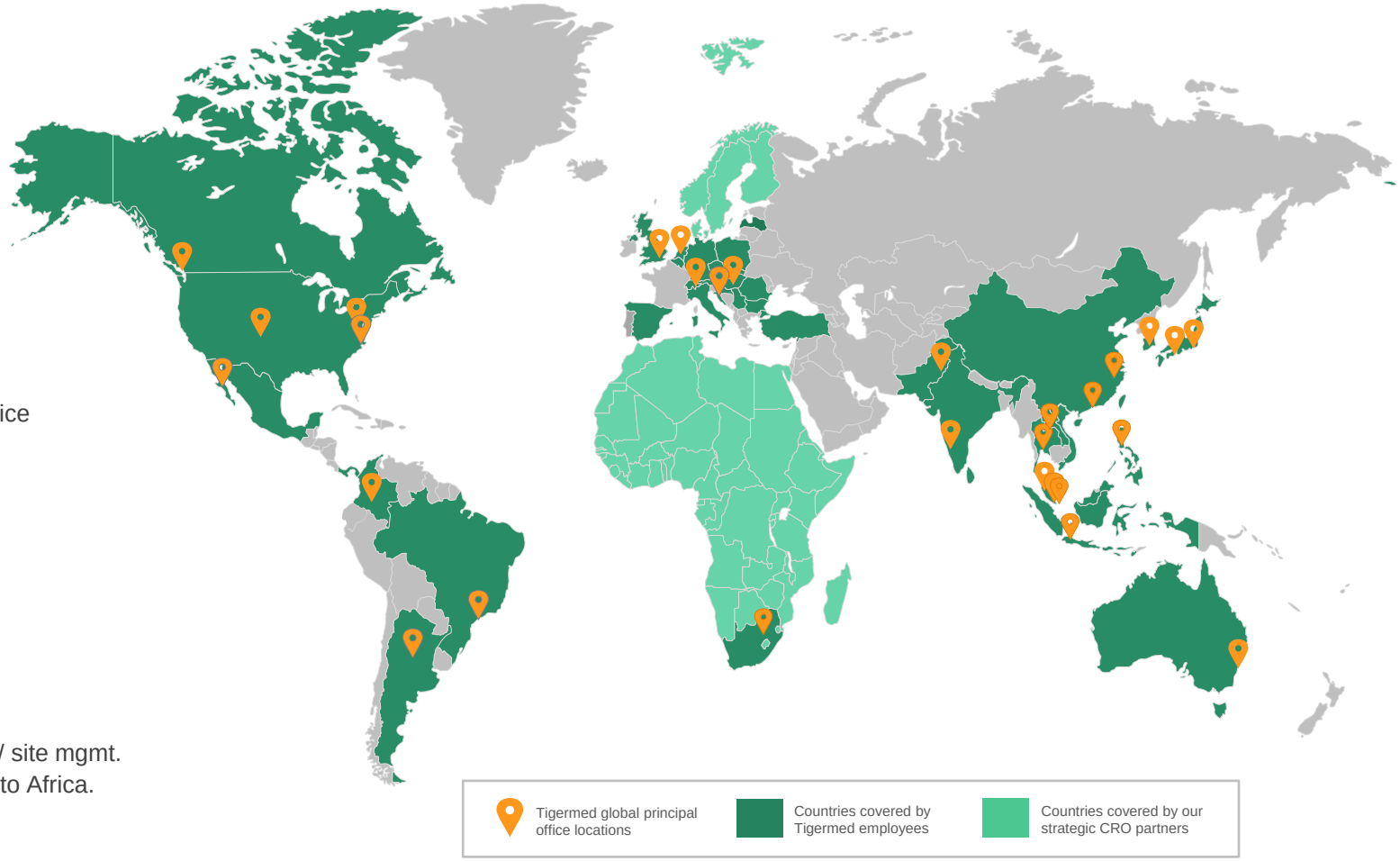
- Engaging with 1,300+ clinical sites in China
- Full contract research services for pharma, biotech and medical device

APAC Team: 550+

- Offices in Japan, Korea, Australia and South East Asia
- Experienced in large-scale clinical studies
- Local expertise in clinical operation / PM / biometrics, etc.

EMEA Team: 80+

- FTEs in 15 countries across Europe in clinical ops / regulatory / PV / site mgmt.
- Localized knowledge spans from Eastern through Western Europe, to Africa.



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