



MLJC Intelligence™ | Healthcare & Life Sciences
China – The Clinical Trial Overtake and the Structural Reshaping of Global Drug Development
中国 – 临床试验的超越与全球药物开发的结构性重塑

ENGLISH | 中文

Ref No : MLJC/CN/TCTOATSROGDD/2026-10/12/14.30

Date : 12 October 2026

MLJC Intelligence | Healthcare & Life Sciences

China — The Clinical Trial Overtake and the Structural Reshaping of Global Drug Development

A Structural Assessment of Speed, Cost, Volume, Quality and the Geopolitics of Pharmaceutical Innovation



Executive Summary

In February 2025, at Arena International's Outsourcing in Clinical Trials West Coast conference in San Francisco, GlobalData presented a finding that fundamentally reset the industry's mental map: under the GlobalData innovative-drug clinical-trial dataset cited in this analysis, China's share of global clinical trials had reached near-parity with the United States. By 2025, the US share of innovative drug clinical trials had fallen from 46% in 2015 to 33%, while China's share had risen from 4% to 30%—a 42-point gap compressed to just three points. If the observed trajectory persists, China could move into outright leadership in 2026–2027.

The observed shift is consistent with a substantive structural change rather than a simple cyclical fluctuation, although dataset definitions and geographic attribution remain important analytical constraints. GlobalData/PhRMA analysis indicates that Phase I trials conducted in China are approximately 53% shorter than those in the US, with an average cycle time seven months shorter. Phase I work is 30–50% cheaper. China-led innovative drug trials grew eleven-fold from 163 in 2015 to 1,806 in 2024. The quality signal is becoming increasingly difficult to dismiss: China's First-in-Class (FIC) pipeline grew at a 26% CAGR from 2020 to 2025, versus 15% for the US. China's FIC assets rose from 152 to 484—a 3.2-fold increase—while the US went from 1,736 to 3,459, a doubling. By 2025, Chinese companies accounted for approximately 24% of the global FIC pipeline, second only to the United States. However, pipeline classification is not equivalent to regulatory validation or commercial success.

This paper proposes a testable structural hypothesis: China is no longer primarily the world's low-cost testing ground. It is becoming a source of new drugs—and the global pharmaceutical industry is only beginning to adjust.

MLJC Core Structural Hypothesis™

China's clinical-development advantage is increasingly becoming an innovation-system advantage.

The structural significance is not that China is conducting more clinical trials. It is that regulatory speed, patient-access infrastructure, development economics, domestic scale and a rapidly expanding First-in-Class pipeline may be combining to shorten the distance between drug conception, clinical validation and global licensing.

If this transmission continues, China could evolve from a major clinical-development jurisdiction into one of the world's principal sources of new pharmaceutical assets.

The hypothesis remains unproven. The critical test is not trial volume, but translation: FIC pipeline → regulatory approval → global licensing → commercialisation.

MLJC Translation Gap™

Stage Question Current Evidence

1. Trial Volume China runs more trials?
Established
2. Trial Speed China develops faster?
Strong evidence
3. Trial Cost China develops cheaper?
Strong evidence

4. FIC Pipeline China creates more innovative assets? Increasing evidence
5. Regulatory Validation Do major regulators validate these assets? Incomplete
6. Global Licensing Does global pharma acquire/license them? Emerging
7. Commercialisation Do they become global products? Incomplete
8. Economic Capture Does China capture global pharma economics? Not established

MLJC Core Observation:

China has largely closed the execution gap. The innovation-to-commercialisation gap remains open.

MLJC Four-Dimension Leadership Matrix™

Dimension China Current Assessment

Clinical Execution Speed / volume / recruitment Strong

Innovation Generation FIC / novel mechanisms Rapidly strengthening

Regulatory Validation FDA / EMA / global approvals Incomplete

Commercial Capture Global revenue / blockbusters US-led

China may already lead in parts of clinical execution without yet leading the complete pharmaceutical innovation value chain.

Confirmed Facts

Fact 1: Under GlobalData's innovative-drug dataset, China has reached near-parity with the US — February 2025

At the Outsourcing in Clinical Trials West Coast 2025 conference in San Francisco, GlobalData's Global Head of Pharma Research, Analysis and Competitive Intelligence, Revati Tatake, presented data showing that China has reached near-parity with the United States in global clinical trial share, with a 33% US share vs 30% China share as of 2025.

Fact 2: The 42-Point Gap Compressed to Three Points — 2015 to 2025

According to GlobalData analysis cited by the Pharmaceutical Research and Manufacturers of America (PhRMA):

- US share of innovative drug clinical trials: 46% (2015) → 33% (2025)
- China share: 4% (2015) → 30% (2025)
- The gap: 42 points in 2015 → just 3 points in 2025

Sources: GlobalData analysis; PhRMA

Fact 3: Phase I Trials — Faster in China

GlobalData/PhRMA analysis shows that Phase I trials in China are completed approximately 53% faster than in the US, with an average cycle time seven months shorter.

- All indications Phase I duration: US 9–26 months vs China 3–17 months
- Phase II: US 18–38 months vs China 14–30 months
- Oncology Phase I: US 26.2 months vs China 17.2 months
- Oncology Phase II: US 37.6 months vs China 30.2 months

Sources: GlobalData analysis; PhRMA

Fact 4: Phase I Costs — Lower in China

Phase I trials in China cost 30–50% less than in the US:

- Average Phase I cost (US): \$5.8 million
- Average Phase I cost (China): \$3.29 million
- Saving per Phase I trial: \$2.51 million
- Oncology Phase I: 32% lower; Phase II: 25% lower
- Phase II cost savings: 15–30%

Sources: GlobalData analysis; PhRMA

Fact 5: China-Led Innovative Drug Trials — 11-Fold Growth

From 2015 to 2024, China exhibited significant growth in clinical trial activity, with a 36.1% CAGR. China-led innovative drug trials grew from 163 in 2015 to 1,806 in 2024—an eleven-fold increase.

Fact 6: First-in-Class Pipeline Growth — China 26% CAGR vs US 15%

Metric China US

FIC pipeline (2020) 152 1,736

FIC pipeline (2025) 484 3,459

Growth 3.2x 2.0x

CAGR (2020–2025) 26% 15%

Sources: GlobalData analysis; PhRMA

By 2025, Chinese companies accounted for approximately 24% of the global FIC pipeline, second only to the United States. China's share of global FIC assets climbed from 8% to 12%.

Fact 7: NME Approvals — China 21% CAGR vs US 9%

New molecular entity (NME) approvals in China grew at a 21% CAGR from 2020 to 2025, more than double the US rate of 9%.

Fact 8: Oncology Trials — China's Share Rises

According to GlobalData's Clinical Trials Intelligence, China's share of global oncology trials reached significant levels in 2025.

Fact 9: WuXi AppTec — US Revenue Surges Despite Geopolitics

In 2025, WuXi AppTec's revenue from US clients reached RMB 31.25 billion (~\$4.52 billion), growing 34.3% year-on-year—a rate far exceeding the company's overall growth. US clients accounted for approximately 72% of revenue from continuing operations.

Sources: WuXi AppTec 2025 Annual Report

Evidence — Observed Signals

1. Volume Signal — The Tipping Point

The compression of the US-China trial share gap from 42 points to 3 points in a decade is not incremental. This signals a structural shift in where global pharmaceutical R&D is being conducted.

2. Speed Signal — The Regulatory Dividend

China's NMPA reform—cutting IND review times from 60 to 30 working days—has created a regulatory environment that matches the FDA in speed. Combined with faster patient recruitment, this creates a durable speed advantage.

3. Cost Signal — The Structural Arbitrage

Phase I cost savings of 30–50% reflect structural differences in labour costs, patient recruitment economics and operational efficiency.

4. Quality Signal — The FIC Inflection

The FIC pipeline data—China's 26% CAGR vs 15% for the US—is the most important quality signal. China is not just running more trials. It is running more innovative trials.

5. Oncology Signal — The ASCO Moment

At ASCO 2026, Chinese sponsors achieved record visibility, with over 90 oncology studies from Hengrui Pharma alone. Chinese-origin oncology assets have become an increasingly important component of global licensing activity, with oncology remaining the dominant therapeutic area for China's out-licensing activity.

6. Geopolitical Signal — The Containment Response

US industry leaders and officials have publicly acknowledged that China has passed the United States in innovative early-stage trials. The policy response—Biosecurity Act restrictions, blocked NIH data access—reflects a risk-containment approach whose long-term competitive implications remain uncertain.

7. Commercial Signal — The WuXi Reality

Despite the Biosecurity Act threats, WuXi AppTec's US revenue grew 34.3% in 2025. Commercial decoupling remains incomplete.

Analytical Boundary

This paper does not interpret China's clinical trial growth as evidence that China has already surpassed the US in overall pharmaceutical innovation, drug discovery capability or biopharmaceutical commercialisation.

MLJC treats the above data as evidence of a structural shift in the global clinical trial landscape, not as a comprehensive assessment of the entire biopharmaceutical value chain.

The clinical-trial overtaking is no longer the central question. The central question is whether China's execution advantage can compound into innovation, and whether innovation can ultimately compound into global economic capture.

Structural Interpretation

MLJC Assessment — Structural View

Five structural forces are converging to reshape global drug development.

Layer 1: The Regulatory Reform Dividend

China's 2015 regulatory reforms were a step-change, not an incremental adjustment. The NMPA's IND review timeline was cut from 60 to 30 working days, aligning with the FDA.

Layer 2: The Patient Recruitment Advantage

China's large, hospital-centric medical system enables faster patient recruitment than in the US or Europe.

Layer 3: The Cost Arbitrage

Phase I cost savings of 30–50% reflect lower labour costs, lower site fees and more efficient patient recruitment.

Layer 4: The Scale Effect

China's domestic market of 1.4 billion people generates vast patient pools for clinical trials.

Layer 5: The Quality Catch-Up

The FIC pipeline data—26% CAGR vs 15% for the US—is the most important signal.

Causal Hypothesis

[MLJC Causal Hypothesis — To Be Tested]

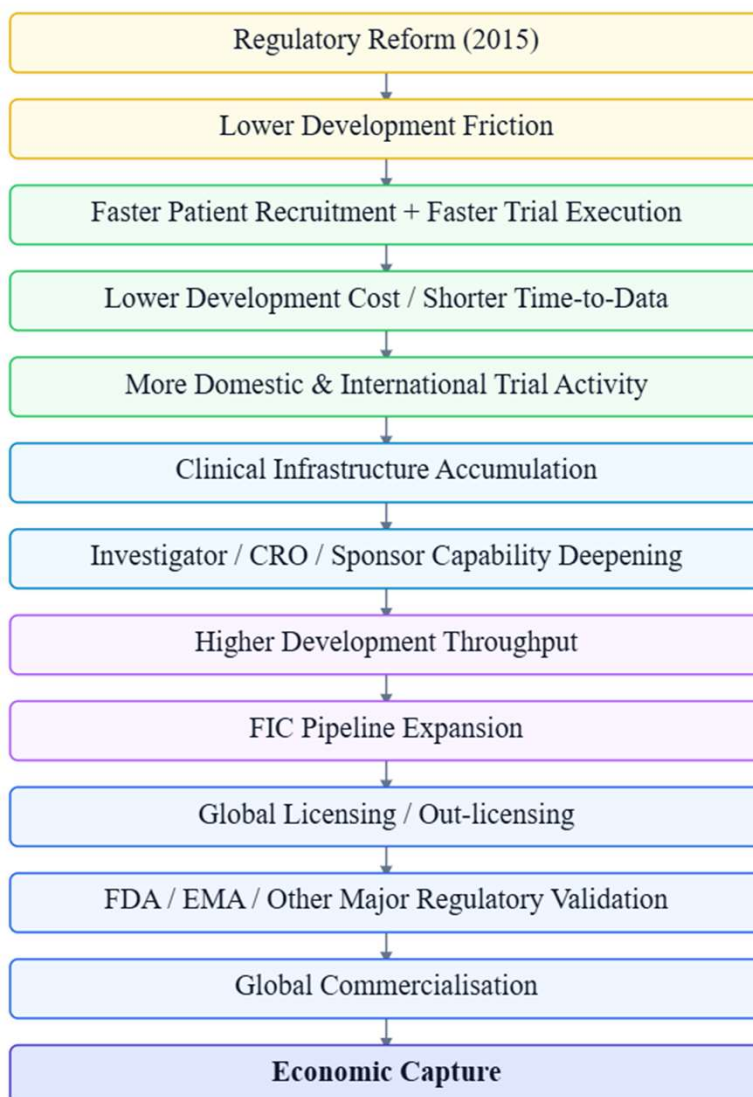
The above observations are consistent with the following structural hypothesis:

1. China's regulatory reforms created a step-change in trial initiation velocity.
2. Structural advantages in speed, cost and scale are mutually reinforcing.
3. The quality catch-up—evidenced by FIC pipeline growth—is real and accelerating.
4. US policy responses are unlikely to fully reverse the structural trend, as they do not address the underlying cost, speed and scale advantages.
5. The commercial reality—exemplified by WuXi AppTec's US revenue growth—continues to pull US pharmaceutical companies toward China.

This hypothesis is falsifiable and testable through the monitoring framework below.

Transmission Architecture

[MLJC transmission mechanism — to be tested; each arrow represents a transmission node requiring verification]



Transmission Risk Gates:

Transmission Node Current Confidence
Regulatory reform → Lower friction High
Faster recruitment → Faster completion High
Lower costs → More attractive to global pharma High
More trials → More infrastructure/expertise High
Volume → Quality improvement Medium–High
Quality improvement → FIC pipeline growth High
FIC pipeline growth → Global approvals Medium
Global approvals → Commercialisation leadership Low–Medium

Cross-Market Implications

Pharmaceutical Industry: The structural shift in clinical trial activity will reshape global pharma R&D strategies. Companies that fail to incorporate China into their early-stage development plans risk falling behind on speed and cost.

Biotech Investment: Biotechs with Chinese clinical operations may command valuation premiums for faster, cheaper development paths.

Contract Research Organisations (CROs) : Chinese CROs are gaining share globally. US and European CROs face structural pressure.

Healthcare Infrastructure: China's hospital-centric medical system is a structural asset for clinical research.

Geopolitics: The Biosecurity Act represents a risk-containment approach whose long-term implications remain uncertain.

Capital Markets: The shift in clinical trial activity will eventually translate into shifts in drug approval, commercialisation and revenue.

Market Perception Risks

1. Underestimating the structural nature of the shift

The compression of the US-China trial share gap is often attributed to "China catching up." MLJC's hypothesis is that this is a structural realignment.

2. Overestimating the effectiveness of containment

Commercial incentives may continue to offset part of the geopolitical pressure.

3. Underestimating the quality dimension

The FIC pipeline data—26% CAGR vs 15% for the US—directly contradicts the "volume, not quality" narrative.

4. Misattributing the driver

The driver is not "cheap labour." It is a system—regulatory reform, patient recruitment infrastructure, hospital networks, government support and scale.

Headwind Case (Significant risk) Biosecurity Act passes with severe restrictions; global pharma reduces China exposure; quality concerns limit global approvals of Chinese data. China's clinical trial growth slows; US maintains leadership in approvals and commercialisation; structural shift delayed.

Scenario Analysis

[MLJC subjective scenario assessment, not a statistical forecast, does not constitute investment advice]

Scenario Key Drivers Outcome

Base Case (Highest probability) China maintains speed/cost advantages; FIC pipeline continues to grow; US containment measures are partial; global pharma continues to deepen China presence. China becomes the undisputed global leader in clinical trial volume by 2027; Chinese-origin assets account for increasing share of global licensing deals; US pharma adapts.

Acceleration Case (Lower probability) US containment measures backfire; European pharma intermediates Chinese assets; China's regulatory approvals gain global recognition. China becomes a primary source of new drug candidates for global pharma; European firms become intermediaries.

Monitoring Dashboard

Variable Current Signal Direction Importance

US vs China clinical trial share US 33% vs China 30% (2025) China gaining Primary volume indicator

Phase I cycle time gap China 7 months faster China widening Speed advantage sustainability

Phase I cost gap China 30–50% cheaper Stable Cost advantage sustainability

FIC pipeline CAGR China 26% vs US 15% China widening Quality catch-up indicator

China FIC share of global 8% (2020) → 12% (2025) Rising Quality translation indicator

Oncology licensing deals Increasing Chinese-origin share Rising Commercial relevance indicator

WuXi AppTec US revenue growth 34.3%
YoY (2025) Strong Commercial
decoupling reality check

Biosecurity Act status Pending To be
observed Policy containment effectiveness

Falsification Conditions

The structural assessment in this paper
would be revised if:

1. China's share of global clinical trials stagnates or declines for two consecutive years.
2. China's FIC pipeline CAGR falls below 15% for three consecutive years.
3. US policy measures materially reduce US pharma engagement with Chinese CROs and clinical sites, with measurable impact on trial volume.
4. Global regulatory bodies (FDA, EMA) significantly restrict the use of Chinese clinical data for global approvals.
5. Chinese regulatory environment tightens materially, reversing the 2015 reforms.



MLJC Assessment

What we know

- Under GlobalData's innovative-drug dataset, China has reached near-parity with the US in clinical trial share: 30% vs 33%
- Phase I trials in China are faster (53% shorter) and cheaper (30–50% lower) than in the US
- China's FIC pipeline grew at 26% CAGR from 2020–2025 vs 15% for the US
- WuXi AppTec's US revenue grew 34.3% in 2025 to RMB 31.25 billion

What we infer

- China's clinical trial advantages—speed, cost, scale—are structural and durable
- The quality catch-up, evidenced by FIC pipeline growth, is real and accelerating
- Commercial incentives may continue to offset part of the geopolitical pressure

What remains uncertain

- Whether FIC pipeline growth will translate into global NME approvals and commercial-stage assets at scale
- Whether US policy measures will materially slow the trend or merely create friction
- Whether the European intermediation channel will become significant

What would change our view

See "Falsification Conditions" above.

MLJC Core Proposition™

China's pharmaceutical rise is no longer primarily a story of clinical-trial volume. It is becoming a test of whether execution advantage can compound into innovation advantage.

China has built measurable advantages in clinical development speed, cost, patient recruitment and trial scale.

Its First-in-Class pipeline is expanding rapidly.

The unresolved question is whether these advantages will consistently translate into global regulatory approvals, licensing transactions and commercial-stage medicines.

The next phase of China's pharmaceutical rise will therefore be measured not by how many trials China runs, but by how much globally validated pharmaceutical value those trials produce—and how much of that value China captures.

MLJC Structural Rating

Observation MLJC Rating

China clinical-trial activity has rapidly expanded High Confidence

China possesses meaningful speed advantage High Confidence

China possesses meaningful cost advantage High Confidence

Patient recruitment is a structural advantage Medium–High

China's FIC pipeline is expanding rapidly High Confidence

China is moving up the pharmaceutical value chain Medium–High

FIC growth will translate into global approvals Medium / Unresolved

Chinese-origin assets will capture increasing licensing share Medium / Testable

China will achieve global commercialisation leadership Unestablished

China will become the world's leading pharma innovation ecosystem Testable
Structural Hypothesis

China — The Clinical Trial Overtake and the Structural Reshaping of Global Drug Development

CHINA

China's biotech surge sparks US security concerns as drug trials break records in 2025

Saturday, 27 Jun 2026 | 8:02 PM MYT

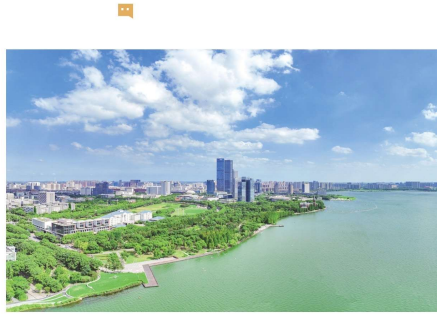


BUSINESS / ECONOMY

Systemic leap: How China's innovative drug industry is shaping the future

By Wu Wei

Published: Aug 06, 2026 07:43 PM



Aerial view of Suzhou Industrial Park in Suzhou, East China's Jiangsu Province, where biomedicine stands as one of the park's signature industries. Photo: VCG

Analyst Comment

China's rapid rise in drug development casts a long shadow over US oncology

China is rapidly overtaking the US in global oncology clinical trials, accounting for more than half of late-stage study activity by 2025.

GlobalData | GlobalData Healthcare | July 24, 2026

Share



China's role in global oncology clinical research has expanded dramatically. Credit: MMD Creative via Shutterstock.com.

CMoney 投資網誌

台股 美股 研究報告 理財達人 新手入門 生活理財

跟著達人學投資 > CMoney 研究員 > 美股

臨床試驗版圖大逆轉：中國加速崛起、美歐資金緊縮，AI 成藥界新...



CMoney 研究員

2026-05-20 15:00 更新：2026-05-20 15:00

美股, 美股新聞快訊, 美股精選新聞

收藏



Clinical Trials Day 2026: 'Research Rising' theme reflected in Q1 study growth

As China continues to inch ahead of competition in terms of trial initiations, immunology and metabolic disease trials attract sponsor eyes.

Annabel Kartal Allen | May 20, 2026

Share



In Clinical Trial Supply Leadership

By Dan Leonard, executive director, We Work For Health



Any driver knows the feeling of being passed on a highway.



2026年上半年临床试验：中国、资金和技术主导议程

H1 2026 clinical trials: China, funding and technology set the agenda - Clinical Trials Arena

环球医讯 / AI与医疗健康

来源: www.clinicaltrialsarena.com 英国 - 英语

2026-05-24 23:51:14 - 阅读时长5分钟 - 2017字

2026年上半年临床试验领域呈现三大主导趋势：中国影响力持续扩大，临床试验发起比例从2015年的4%升至2025年的30%，且I期试验周期仅需7个月，成本比美国低32%-52%；美国早期生物科技融资环境严峻，NIH资金缩减导致风险投资更倾向后期低风险资产；人工智能技术正从实验阶段融入临床试验全流程，在方案开发、患者招募、风险监测等方面发挥重要作用，但人类监督仍不可或缺。同时，适应性试验设计和去中心化试验模式正推动研究更加以患者为中心。





MLJC Intelligence™ | Healthcare & Life Sciences
China – The Clinical Trial Overtake and the Structural Reshaping
of Global Drug Development
中国 – 临床试验的超越与全球药物开发的结构性重塑

MLJC Intelligence | 医疗与生命科学

中国——临床试验的超越与全球药物开发的结构性重塑

速度、成本、规模、质量与医药创新地缘政治的结构性评估



核心摘要

2025年2月，在旧金山举行的Arena International Outsourcing in Clinical Trials West Coast 会议上，GlobalData展示了一项从根本上重置行业认知地图的发现：根据本分析所引用的GlobalData创新药临床试验数据集，中国在全球临床试验中的份额已接近与美国持平。到2025年，美国在创新药物临床试验中的份额已从2015年的46%下降至33%，而中国的份额则从4%上升至30%——一个42个百分点的差距被压缩至仅剩3个百分点。如果观察到的趋势持续，中国可能在2026至2027年跃居绝对领先地位。

观察到的转变与实质性结构性变化一致，而非简单的周期性波动，尽管数据集定义和地域归属仍是重要的分析约束条件。

中国——临床试验的超越与全球药物开发的结构性重塑

GlobalData/PhRMA 分析显示，在中国开展的I期临床试验比美国短约53%，平均周期缩短七个月。I期工作成本低30%至50%。中国主导的创新药物试验从2015年的163项增长至2024年的1,806项，增长了十一倍。质量信号正变得越来越难以忽视：中国的First-in-Class（FIC）管线在2020至2025年间以26%的复合年增长率增长，而美国为15%。中国的FIC资产从152项增至484项——增长3.2倍——而美国从1,736项增至3,459项，增长一倍。到2025年，中国公司约占全球FIC管线的24%，仅次于美国。然而，管线分类并不等同于监管验证或商业成功。

本文提出一个可检验的结构性假设：中国不再主要是全球低成本试验场。它正在成为新药的来源——而全球制药行业才刚刚开始调整。

MLJC核心结构性假设™

中国的临床开发优势正日益转化为创新体系优势。

其结构性意义不在于中国正在进行更多临床试验，而在于监管速度、患者可及性基础设施、开发经济学、国内市场规模以及快速扩张的First-in-Class管线可能共同缩短从药物概念到临床验证再到全球授权的距离。

如果这一传导持续，中国可能从一个主要的临床开发管辖区演变为全球新药资产的主要来源之一。

该假设尚未被证实。关键检验不是试验数量，而是转化：FIC管线 → 监管批准 → 全球授权 → 商业化。

MLJC转化差距™

阶段 问题 当前证据

1. 试验数量 中国开展的试验更多？ 已确立
2. 试验速度 中国开发更快？ 强证据
3. 试验成本 中国开发更便宜？ 强证据
4. FIC管线 中国创造更多创新资产？ 证据增强中
5. 监管验证 主要监管机构是否验证这些资产？ 不完整
6. 全球授权 全球制药公司是否收购/授权它们？ 正在形成
7. 商业化 它们能否成为全球产品？ 不完整
8. 经济捕获 中国是否捕获全球制药经济价值？ 尚未确立

中国——临床试验的超越与全球药物开发的结构性重塑

MLJC核心观察：

中国已基本缩小了执行差距。但创新到商业化的差距仍然存在。

MLJC四维领导力矩阵™

维度 中国 当前评估

临床执行 速度/数量/招募 强

创新生成 FIC/新机制 快速增强中
监管验证 FDA/EMA/全球批准 不完整

商业捕获 全球收入/重磅药物 美国领先

中国可能在临床执行的某些部分已经领先，但尚未在整个制药创新价值链中占据领导地位。

已确认事实

事实一：根据GlobalData创新药数据集，中国已与美国接近持平——2025年2月

在旧金山举行的Outsourcing in Clinical Trials West Coast 2025会议上，GlobalData制药研究、分析与竞争情报全球负责人Revati Tatake展示的数据显示，中国在全球临床试验份额中已与美国接近持平，截至2025年美国占33%，中国占30%。

事实二：42个百分点差距压缩至3个百分点——2015年至2025年

根据PhRMA引用的GlobalData分析：

- 美国在创新药物临床试验中的份额：46%（2015年）→ 33%（2025年）
- 中国份额：4%（2015年）→ 30%（2025年）
- 差距：2015年42个百分点 → 2025年仅3个百分点

来源：GlobalData分析；PhRMA

事实三：I期试验——中国更快

GlobalData/PhRMA分析显示，在中国开展的I期试验完成速度约快53%，平均周期短七个月。

- 所有适应症I期持续时间：美国9-26个月 vs 中国3-17个月
- II期：美国18-38个月 vs 中国14-30个月
- 肿瘤I期：美国26.2个月 vs 中国17.2个月
- 肿瘤II期：美国37.6个月 vs 中国30.2个月

来源：GlobalData分析；PhRMA

中国——临床试验的超越与全球药物开发的结构性重塑

事实四：I期成本——中国更低

中国的I期试验成本比美国低30%至50%：

- 美国平均I期成本：580万美元
- 中国平均I期成本：329万美元
- 每次I期试验节省：251万美元
- 肿瘤I期：低32%；II期：低25%
- II期成本节省：15-30%

来源：GlobalData分析；PhRMA

事实五：中国主导的创新药物试验——增长十一倍

2015年至2024年，中国临床试验活动显著增长，复合年增长率36.1%。中国主导的创新药物试验从2015年的163项增长至2024年的1,806项——增长十一倍。

事实六：First-in-Class 管线增长——中国复合年增长率26% vs 美国15%

指标 中国 美国

FIC管线（2020年） 152 1,736

FIC管线（2025年） 484 3,459

增长 3.2倍 2.0倍

复合年增长率（2020-2025年）
26% 15%

来源：GlobalData分析；PhRMA

到2025年，中国公司约占全球FIC管线的24%，仅次于美国。中国在全球FIC资产中的份额从8%上升至12%。

事实七：NME批准——中国复合年增长率21% vs 美国9%

2020年至2025年，中国的新分子实体（NME）批准以21%的复合年增长率增长，是美国9%增长率的两倍多。

事实八：肿瘤试验——中国份额上升

根据GlobalData临床试验情报数据，中国在全球肿瘤试验中的份额在2025年达到显著水平。

事实九：药明康德——尽管地缘政治紧张，美国收入激增

2025年，药明康德来自美国客户的收入达到312.5亿元人民币（约45.2亿美元），同比增长34.3%——远超公司整体增速。美国客户约占持续经营业务收入的72%。

来源：药明康德2025年年度报告

证据——观察信号

1. 数量信号——临界点

中美试验份额差距在十年内从42个百分点压缩至3个百分点，并非渐进式变化。这标志着全球制药研发活动地点的结构性转变。

2. 速度信号——监管红利

中国的NMPA改革——将IND审评时间从60个工作日缩短至30个工作日——创造了一个在速度与FDA相当的监管环境。结合更快的患者招募，这形成了持久的速度优势。

3. 成本信号——结构性套利

I期成本节省30%至50%反映了劳动力成本、患者招募经济学和运营效率的结构性差异。

4. 质量信号——FIC拐点

FIC管线数据——中国26%的复合年增长率对比美国15%——是最重要的质量信号。中国不仅在开展更多试验，而且在开展更具创新性的试验。

5. 肿瘤信号——ASCO时刻

在2026年ASCO年会上，中国申办方取得了创纪录的能见度，仅恒瑞医药一家就有超过90项肿瘤研究。中国来源的肿瘤资产已成为全球授权活动中日益重要的组成部分，肿瘤仍是中国对外授权活动的主导治疗领域。

6. 地缘政治信号——遏制反应

美国行业领袖和官员已公开承认中国创新早期试验方面已超越美国。政策回应——生物安全法限制、NIH数据访问封锁——反映了一种风险遏制路径，其长期竞争影响仍不确定。

7. 商业信号——药明康德现实

尽管面临生物安全法威胁，药明康德在美国收入在2025年仍增长了34.3%。商业脱钩仍不完整

分析边界

本文不将中国的临床试验增长解释为中国已在整体制药创新、药物发现能力或生物制药商业化方面超越美国的证据。

MLJC将上述数据视为全球临床试验格局结构性转变的证据，而非对整个生物制药价值链的全面评估。

中国——临床试验的超越与全球药物开发的结构性重塑

临床试验的超越已不再是核心问题。核心问题在于中国的执行优势能否复合为创新，而创新又能否最终复合为全球经济捕获。

结构性解读

[MLJC评估——结构性观点]

五重结构性力量正在汇聚，重塑全球药物开发格局。

第一层：监管改革红利

中国2015年的监管改革是一次阶跃变化，而非渐进式调整。NMPA将IND审评时间从60个工作日缩短至30个工作日，与FDA看齐。

第二层：患者招募优势

中国以医院为中心的大型医疗体系实现了比美国或欧洲更快的患者招募。

第三层：成本套利

I期成本节省30%至50%反映了更低的劳动力成本、更低的研究中心费用和更高效的患者招募。

第四层：规模效应

中国14亿人口的国内市场为临床试验提供了庞大的患者池。

第五层：质量赶超

FIC管线数据——26%对比15%的复合年增长率——是最重要的信号。

因果假设

[MLJC因果假设——待验证]

上述观察与以下结构性假设一致：

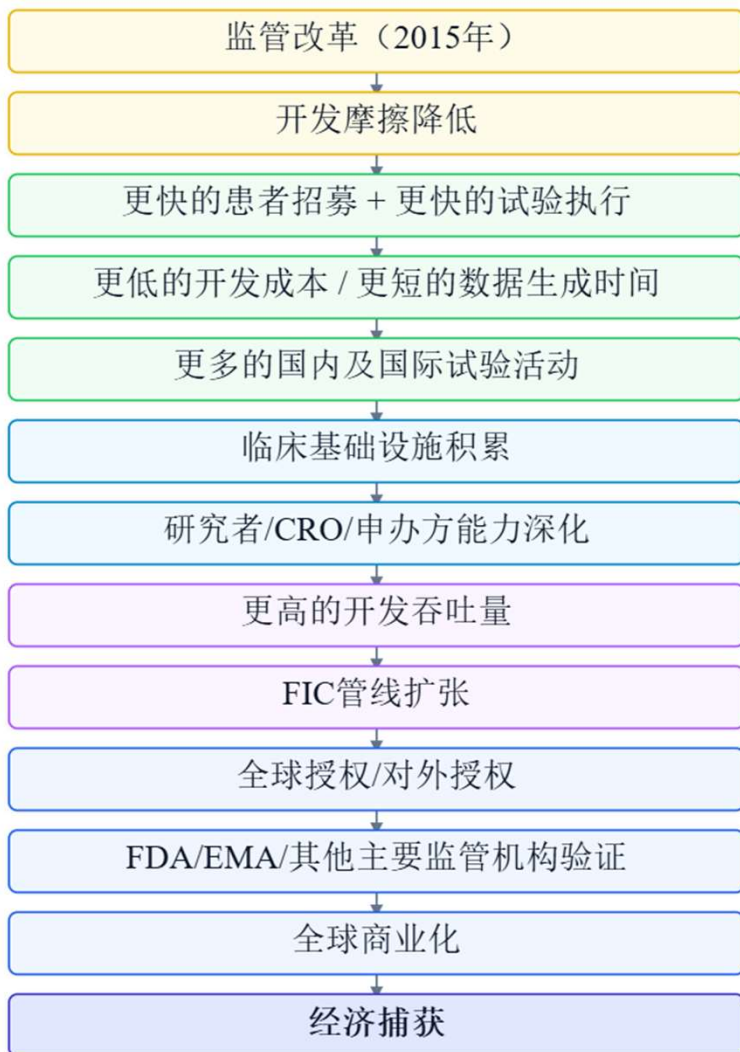
1. 中国的监管改革创造了试验启动速度的阶跃变化。
2. 速度、成本和规模的结构性优势相互强化。
3. 质量赶超——以FIC管线增长为证——是真实且加速的。
4. 美国的政策回应不太可能完全逆转这一结构性趋势，因为它们并未解决中国在成本、速度和规模方面的根本优势。
5. 商业现实——以药明康德美国收入增长为例——继续将美国制药公司拉向中国。

该假设可证伪，可通过下文监测框架进行检验。

中国——临床试验的超越与全球药物开发的结构性重塑

传导架构

[MLJC传导机制——待验证；每个箭头代表需要验证的传导节点]



传导风险门控：

传导节点 当前置信度

监管改革 → 降低摩擦 高

更快的招募 → 更快的完成 高

更低的成本 → 对全球制药更具吸引力 高

更多试验 → 更多基础设施/专业知识 高

数量 → 质量提升 中高

质量提升 → FIC管线增长 高

FIC管线增长 → 全球批准 中

全球批准 → 商业化领导地位 低至中

跨市场含义

制药行业：临床试验活动的结构性转变将重塑全球制药研发战略。未能将中国纳入早期开发计划的公司面临在速度和成本上落后的风险。

生物技术投资：拥有中国临床运营的生物技术公司可能因更快、更便宜的开发路径而获得估值溢价。

合同研究组织（CRO）：中国CRO正在全球范围内获得份额。美国和欧洲CRO面临定价和数量上的结构性压力。

医疗基础设施：中国以医院为中心的医疗体系是临床研究的结构性资产。

地缘政治：《生物安全法》代表了一种风险遏制路径，其长期影响仍不确定。

资本市场：临床试验活动的转变最终将转化为药物批准、商业化和收入格局的转变。

市场认知偏差风险

1. 低估转变的结构性本质
中美试验份额差距的压缩常被归因于"中国正在追赶"。MLJC的假设是，这是一次结构性调整。
2. 高估遏制的有效性
商业激励可能继续抵消部分地缘政治压力。
3. 低估质量维度
FIC管线数据——中国复合年增长率26%对比美国15%——直接反驳了"只有数量、没有质量"的叙事。
4. 误判驱动因素
驱动因素不是"廉价劳动力"。它是一个体系——监管改革、患者招募基础设施、医院网络、政府支持和规模效应。



情景分析

MLJC主观情景评估，非统计预测，不构成投资建议

情景 关键驱动因素 结果

基准情景（最高概率） 中国保持速度/成本优势；FIC管线持续增长；美国遏制措施部分实施；全球制药继续深化中国布局。到2027年，中国成为全球临床试验数量无可争议的领先者；中国来源资产在全球授权交易中占比增加；美国制药企业适应新格局。

加速情景（较低概率） 美国遏制措施产生反效果；欧洲制药企业充当中国资产的中介；中国监管批准获得全球认可。中国成为全球制药新药候选分子的主要来源之一；欧洲企业成为中介方。

阻力情景（显著风险） 《生物安全法》以严格限制条款通过；全球制药减少中国敞口；质量问题限制中国数据的全球批准。中国临床试验增长放缓；美国在批准和商业化方面保持领先；结构性转变延迟。

中国——临床试验的超越与全球药物开发的结构性重塑

监测仪表板

变量 当前信号 方向 重要性

中美临床试验份额 美国33% vs 中国30% (2025年) 中国上升 主要数量指标

I期周期时间差距 中国快7个月 中国扩大 速度优势可持续性

I期成本差距 中国低30-50% 稳定 成本优势可持续性

FIC管线复合年增长率 中国26% vs 美国15% 中国扩大 质量赶超指标

中国FIC全球份额 8% (2020年) → 12% (2025年) 上升 质量转化指标

肿瘤授权交易 中国来源占比上升 上升 商业相关性指标

药明康德美国收入增长 2025年同比增长34.3% 强劲 商业脱钩现实检验

《生物安全法》状态 待定 待观察 政策遏制有效性

证伪条件

如果出现以下情况，本文的结构性评估将被修正：

1. 中国在全球临床试验中的份额连续两年停滞或下降。
2. 中国FIC管线复合年增长率连续三年低于15%。
3. 美国政策措施实质性减少美国制药与中国CRO和临床中心的合作，对试验数量产生可衡量影响。
4. 全球监管机构（FDA、EMA）显著限制使用中国临床数据进行全球批准。
5. 中国监管环境实质性收紧，逆转2015年改革。

MLJC评估

我们所知道的

- 根据GlobalData创新药数据集，中国在临床试验份额上已与美国接近持平：30% vs 33%
- 中国的I期试验更快（短53%）且更便宜（低30-50%）
- 中国FIC管线在2020-2025年间以26%的复合年增长率增长，美国为15%
- 药明康德2025年美国收入增长34.3%至312.5亿元人民币

中国——临床试验的超越与全球药物开发的结构性重塑

我们所推演的

- 中国的临床试验优势——速度、成本、规模——是结构性和持久的
- 质量赶超——以FIC管线增长为证——是真实且加速的
- 商业激励可能继续抵消部分地缘政治压力

仍不确定的

- FIC管线增长能否大规模转化为全球NME批准和商业化阶段资产
- 美国政策措施是会实质性减缓这一趋势，还是仅仅制造摩擦
- 欧洲中介渠道是否会变得重要

会改变我们判断的

参见上文"证伪条件"。

MLJC核心命题™

中国医药产业的崛起已不再主要是临床试验数量的故事。它正成为一场关于执行优势能否复合为创新优势的检验。

中国已在临床开发速度、成本、患者招募和试验规模方面建立了可衡量的优势。

其First-in-Class管线正在快速扩张。

尚未解决的问题是，这些优势能否持续转化为全球监管批准、授权交易和商业化阶段药物。

因此，中国医药产业下一阶段的衡量标准，将不再是"中国开展了多少试验"，而是"这些试验产生了多少经过全球验证的医药价值——以及中国捕获了多少这种价值"。

观察 MLJC评级

中国临床试验活动快速扩张 高置信度

中国拥有显著的速度优势 高置信度

中国拥有显著的成本优势 高置信度

患者招募是结构性优势 中高

中国FIC管线快速扩张 高置信度

中国正在医药价值链上攀升 中高

FIC增长将转化为全球批准 中/未解决

中国来源资产将捕获更多授权份额 中/可检验

中国将实现全球商业化领导地位 尚未确立

中国将成为全球领先的制药创新生态系统 可检验的结构性假设

中国——临床试验的超越与全球药物开发的结构性重塑

CHINA

China's biotech surge sparks US security concerns as drug trials break records in 2025

Saturday, 27 Jun 2026 | 8:02 PM MYT

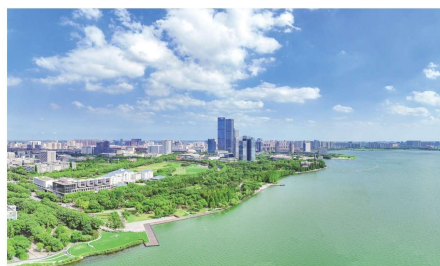


BUSINESS / ECONOMY

Systemic leap: How China's innovative drug industry is shaping the future

By Wu Wei

Published: Aug 06, 2026 07:43 PM



Aerial view of Suzhou Industrial Park in Suzhou, East China's Jiangsu Province, where biomedicine stands as one of the park's signature industries. Photo: VCG

Sign in | Q
Subscribe

Analyst Comment

China's rapid rise in drug development casts a long shadow over US oncology

China is rapidly overtaking the US in global oncology clinical trials, accounting for more than half of late-stage study activity by 2025.

GlobalData | GlobalData Healthcare | July 24, 2026

Share



China's role in global oncology clinical research has expanded dramatically. Credit: MMD Creative via Shutterstock.com.

CMoney 投資網誌

台股 美股 研究報告 理財達人 新手入門 生活理財

跟著達人學投資 > CMoney 研究員 > 美股

臨床試驗版圖大逆轉：中國加速崛起、美歐資金緊縮，AI 成藥界新...



CMoney 研究員

2026-05-20 15:00 更新：2026-05-20 15:00

美股, 美股新聞快訊, 美股精選新聞

收藏



Clinical Trials Day 2026: 'Research Rising' theme reflected in Q1 study growth

As China continues to inch ahead of competition in terms of trial initiations, immunology and metabolic disease trials attract sponsor eyes.

Annabel Kartal Allen | May 20, 2026

Share



In Clinical Trial Supply Leadership

By Dan Leonard, executive director, We Work For Health



Any driver knows the feeling of being passed on a highway.

家医大健康 familydoctor.cn

2026年上半年临床试验：中国、资金和技术主导议程

H1 2026 clinical trials: China, funding and technology set the agenda - Clinical Trials Arena

环球医讯 / AI与医疗健康

来源: www.clinicaltrialsarena.com 英国 - 英语

2026-05-24 23:51:14 - 阅读时长5分钟 - 2017字

2026年上半年临床试验领域呈现三大主导趋势：中国影响力持续扩大，临床试验发起比例从2015年的4%升至2025年的30%，且I期试验周期仅需7个月，成本比美国低32%-52%；美国早期生物科技融资环境严峻，NIH资金缩减导致风险投资更倾向后期低风险资产；人工智能技术正从实验阶段融入临床试验全流程，在方案开发、患者招募、风险监测等方面发挥重要作用，但人类监督仍不可或缺。同时，适应性试验设计和去中心化试验模式正推动研究更加以患者为中心。

