A Healthy and Sustainable Taiwan: Building a Globally Competitive Clinical-Trial Ecosystem

Final Report
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Notice to readers

The report has been prepared by PricewaterhouseCoopers, Taiwan (PwC Taiwan) for the International Research-Based Pharmaceutical Manufacturers Association (IRPMA). The content is drawn from a range of publicly available data and other sources, as well as a series of structured interviews conducted with key health system stakeholder representatives from policy experts, research institutes, healthcare organisations, patient groups and health industries.

The information used in preparing this presentation has been obtained from a variety of third-party sources. PwC Taiwan has not sought to establish the reliability of those sources, nor has PwC Taiwan verified such information.

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Foreword

Amid ongoing shifts in the global landscape and rapid advances in technology, digitisation and biomedical innovation are speeding up the reshaping of clinical research. Clinical trials, the key route by which new treatments reach clinical practice, are likewise moving towards higher quality and greater efficiency. In the face of this trend, our central concern remains. While protecting participants' rights, research ethics and the security of personal data, we aim to build a clinical trial environment with speed, transparency and predictability, so that patients in Taiwan can benefit earlier from innovative therapies and the overall quality of healthcare can improve.

Taiwan has a strong base and clear strengths in clinical trials: a high-quality health system, ample biomedical talent, solid research capacity, and rich data resources from National Health Insurance and human biobanks. According to the findings of this study by the International Research-Based Pharmaceutical Manufacturers Association, most industry stakeholders recognise Taiwan's international reputation for the quality of its clinical care. In terms of population structure and disease patterns, Taiwan also has unique value as a hub for multi-country, multi-centre trials across the Asia-Pacific region.

Clinical trials power medical progress and are the crucial last mile from innovation to care. IRPMA's white paper diagnoses Taiwan's clinical-trial landscape and recommends a one-stop platform and institutional innovation, aligned with our ministry's aims of administrative efficiency and international competitiveness.

It outlines a clear route to a predictable, high-efficiency clinical-trial hub and serves as a key reference for government–industry collaboration. I fully endorse it and am pleased to recommend it.

The Ministry of Health and Welfare devotes to advance work in health promotion, disease prevention, early diagnosis and precision treatment; bring together the strengths of academia, industry and the medical community; and improve systems and the supply of talent. Building on the international standing of our clinical care quality, we will drive innovation in clinical trials and speed up access to new therapies for the benefit of all. We hope to use this white paper as a blueprint and, working hand in hand with all sectors, move towards a higher-quality, more resilient and more efficient clinical trial ecosystem—realising the vision of a healthy Taiwan and creating new opportunities for our healthcare and biotech industries.

Dr. Chung-Liang Shih
Minister
Ministry of Health and Welfare (MOHW)

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Introduction

Over the past few years, global instability and rapid advances in AI, digitisation, and biomedical technologies have reshaped industries worldwide. While Taiwan's strength has long been in technology, its advantages extend to top-tier biomedical talent and research capacity, a high-quality healthcare system, world-class biobank, and proven resilience during the COVID-19 pandemic. Combining these with AI, big data, and 5G, Taiwan is uniquely positioned to develop decentralised clinical trials (DCT), real-world evidence (RWE), smart wards, and remote monitoring, securing a key role in the global biomedical landscape.

This report highlights clinical trials as a pivotal driver to transform Taiwan's biomedical industry. Establishing a high-quality, predictable trial environment enables the systematic accumulation of credible data and expertise, boosting research capacity, international recognition, and collaboration opportunities. It positions Taiwan as an indispensable node in the global biomedical value chain. Establishing optimized systems, such as a single window for executive processes, streamlined reviews for multicentered IRB mutual recognition, data governance, standardised processes, and talent training, will elevate the entire ecosystem's capabilities.

The report is divided into 3 parts, in which

Part I delivers 3 messages, defining Taiwan's position in the clinical trial industry by comparing international clinical trial indicators, International comparative case studies, and economic impact of clinical trials.

Part II surveyed pharmaceutical companies and CROs to reveal the operating profile, operating cycle times, future investment and opportunities, and strengths and weaknesses of the clinical trial system.

Part III gathered expert perspectives from government, industry, academia, and research, and compiled future directions and recommendation of strategic development .

Introduction

By focusing on speed, quality, transparency, and predictability in clinical trials, Taiwan can attract leading global pharma companies to conduct research locally. Benefits include earlier patient access to innovative therapies, improved treatment quality and affordability, and support for Health Technology Assessment through robust local data. Moreover, trials foster talent development and technological upgrades, raising healthcare standards and clinical research culture.

From industry and national perspectives, clinical trials will catalyse multiregional investment and public-private partnerships, fueling clusters in Contract Research Organisation/Contract Development and Manufacturing Organisation (CRO/CDMO), precision medicine, digital health, and AI startups, and eventually expanding employment and economic resilience. Enhancing public health and national security, clinical trials will strengthen healthcare mobilisation and biomedical defenses, ensuring medicine and technology accessibility and self-sufficiency. This will establish Taiwan as a high level and indispensable hub in the global biomedical industry.

Key Findings

01 Taiwan's clinical trial ecosystem remains competitive but faces an 'advance or fall behind' challenge

- **Taiwan has a high-quality, high-potential clinical trial foundation:** This study indicates that if sponsors set up trial sites in Taiwan, Taiwan is very likely to be among the top 25% of countries in which to start a site, demonstrating the country's competitiveness in medical quality and professional talent.
- **Lagging indicators related to clinical trials:** However, there is still room for improvement in Taiwan's numbers of multiregional trials (mRCTs) and industry-sponsored trials in 2023–2024, compared with those of the UK, Canada, Australia, Japan, and South Korea. Taiwan needs to strengthen its "magnet effect" to attract large international clinical trials. Simultaneously, early-phase clinical trials (Phase I and Phase I/II) are comparable to those in the UK, Canada, and South Korea, but not as strong as those in Australia, which has a similar population size, demonstrating potential for future growth.

02 Industry-sponsored clinical trials conducted in a country affects new drugs approvals and health outcomes

- **Increase new drug approvals:** This study shows the number of FDA novel drug approvals is positively correlated with the number of industry-sponsored drug clinical trials. More industry-sponsored trials help increase the number of new drugs introduced.
- **Improve health outcomes:** The number of industry-sponsored trials is associated with better health indices, such as lower DALYs and higher UHC scores, reflecting how a stronger clinical trial ecosystem improves disease treatment outcomes and medical quality at the national level.

03 Taiwan needs a one-stop, integrated regulatory and administrative system for clinical trials

- **Overcome regulatory obstacles:** This study gathered industry feedback and found that extended startup processes and difficulties in enrollment are the main reasons multinational clinical trials were not conducted in Taiwan.
- **Accelerate administrative procedures:** Taiwan needs a faster contract-signing process to increase willingness to deploy international trials.
- **One-stop platform:** Learn from the models of peer countries; Australia's NOSS, South Korea's KoNECT, and Singapore's CTSG all boost their clinical trial systems through one-stop integrated platforms.

04 Strengthen the application of biobank data and the development of clinical research talent

- **Utilisation of biobank data:** Taiwan possesses world-class biobanks and National Health Insurance (NHI) data. We need to reform regulations and build a more secure environment for Real-World Evidence (RWE) and Decentralised Clinical Trials (DCT) analyses to strengthen its application.
- **Development of research talent:** Increase incentives for principal investigators to participate in trials, improve mechanisms for retaining clinical research talent, and establish mechanisms for quality certification and career development to boost long-term competitiveness.

05 Investment in clinical trial ecosystem is an investment in national health and the biomedical industry

- **Clinical trial development can directly bring economic value**: The annual output value of Taiwan's biotechnology services in 2024 was 14.7 billion TWD. If Taiwan's clinical trial numbers can surpass international peers, it is expected to bring an annual output value of over 33 billion TWD, driving the development of Taiwan's trillion-dollar biomedical industry and creating more than 600 job opportunities with billion-dollar value.
- **Indirect health and economic value:** Introducing new drugs through clinical trials can reduce annual labor-force loss due to illness by improving national health and productivity, potentially adding over 20 billion TWD to Taiwan's annual GDP.

Recommendations and actions

Building a cross-ministry one-stop shop for clinical trials

This report compiled recommendations from cross-sector experts. Experts agreed to build a national-level one-stop model that connects each ministry. This model integrates the entire process, from the entry of international clinical trials into Taiwan, patient enrollment, the import and export of trial materials, contracting and e-signatures, IRB/parallel reviews, disclosure of trial information, new drug approvals, and finally National Health Insurance (NHI) reimbursement, into a single one-stop platform.

01

Reforming the regulatory process and increasing incentives

Coordinate across MOHW, MOEA, NDC, NCC, and their administrative agencies to optimise regulations and processes (including expediting central IRB mutual recognition and timelines, parallel IRB/IND reviews, and administrative procedures). Use policy measures to accelerate new drug approvals and provide tax incentives and subsidies. Unlock the potential of biobank data and clinical talent within a trusted environment to encourage industry sponsors to invest in Taiwan's clinical trial ecosystem.

02

Building national-level CRO quality mechanism and talent pools

Establish a national-level CRO quality mechanism, covering good clinical practice, professional certification, data quality, and cybersecurity, to enhance the reliability and international competitiveness of clinical trials in Taiwan. Focus on courses and training: introducing mandatory clinical trial credits and practical sessions in higher education (for life sciences, medical, nursing, and pharmaceutical majors), while introducing compensation and benefit system to strengthen retention and industry-academic cooperation.

03

Enhancing international visibility and positioning Taiwan as an Asia Pacific pilot study hub

Enhance international visibility through multiple approaches. This includes international health collaboration data exchange, cross-hospital referral and focusing on Phase I/II trials/ oncology/ rare diseases, while highlighting diversification in East Asian ethnicities to position Taiwan as an Asia Pacific pilot study hub. At the same time, reform hospital compensation and benefit mechanisms to increase the participation of research nurses, coordinators, and physicians. Build a international pool for principal investigators.

04

Leveraging AI/Big Data to build Taiwan's trillion-dollar biomedical industry

The clinical trials ecosystem should be deeply integrated with AI, digital tools and AI-driven application to enhance patient enrollment and success rate of trials. This strategy intends to expand participation in mRCT and driving output for precision medicine and digital health to drive Taiwan health industry innovation.

Based on experts' recommendations, we have compiled a **strategy map** and a **goal statement** to present the key strategies, key tasks, and future vision for building this one-stop platform.

Strategy map – Vision and impacts on improving clinical trial ecosystem

Key Strategies

AI/Big Data to surpass peer countries in clinical-trial competitiveness
(Japan, Australia, South Korea)

Refine policies to accelerate access to new drugs Align Taiwan healthcare with global standards

Build clinical-trial competitiveness and let the world embrace Taiwan

Strengthen the biomedical industry to enhance drug supply chain resilience and contribute to global health

Securing Talent Strengthening Quality

Key Tasks

One-Stop Shop
(Inter-ministerial administrative procedures, trial participant recruitment, financial incentives, and project guidance)

Talent development and quality certification
(Talent training, retention systems, feedback mechanisms, and CRO operating quality certification)

Data Management
(Medical information standardisation, electronic signatures, and DCT remote monitoring)

Regulatory optimisation
(IRB review, contracting and administration process)

International strategic alliances
(Interoperability of standards, mutual recognition of data, and regulatory refinement)

Future Vision

Enhance Economic Output

Medical/Bio Talent Retention

National Industry Innovation

Healthy Taiwan Vision

Long term goal – Clinical research as a key driver for Taiwan health industry innovation

Refine role and policies

Establish a cross ministerial one stop platform, strengthen IRB review mechanism for mRCTs and mutual recognition, simplify contracts and administrative processes, provide supporting tax incentives and R&D subsidies, and strengthen data governance and cross-border compliance.

Talent development and industry collaboration

Enhance clinical trial competencies and improve skills and compensation/benefits. Meanwhile, boost synergies across related industries, attract leading global companies to invest in Taiwan, and build biomedical professional capacity.

Industrial expansion and investment

Build Taiwan's clinical trial and data centers, introduce industry certification, trial subsidies, procurement, and expedited review mechanisms to attract global industry and local partnerships. Utilise database from NHI and biobank to advance RWE and DCT research, and spur investment in CRO and CDMO, digital health, and AI startups. Moreover, by combining Taiwan's technological momentum, genomic models are applied to digital health and AI biomedical startups to further drive investment.

Clinical research drives health industry innovation

Set targets for the number of clinical trials and for Taiwan's share of global enrollment; accelerate administrative processes on the one stop platform, and fully implement electronic consent, EHR to eCRF integration, and inter hospital data interoperability. Drive data value creation in the biomedical industry by integrating precision medicine, regenerative medicine, companion diagnostics, and digital health, and aim for building an Asia Pacific trillion-dollar scale biotech island.

Comparison of International Clinical Trial Indicators and Policies

PART I

PART I Background Overview

Part I of this report offers a comprehensive analysis of Taiwan's clinical trial industry environment, structured around 3 key messages: indicator research, case studies, and economic impact assessment.

Within **message 1**, PwC Taiwan analyses data from ClinicalTrials.gov and regulatory sources, focusing on benchmarking Taiwan against seven countries: Australia, Japan, the UK, Canada, South Korea, Israel, and Singapore. The analysis considers regional competition, economic and healthcare standards, population structure, and regulatory leadership, comparing Taiwan's clinical trial data with these nations for a quantitative analysis. We first compared each country's total number of drug clinical trials to gauge overall activity, then examined industry-sponsored trials in both count and share. We then assessed the volume of multiregional (mRCT) trials to indicate global pharma participation. Trial numbers were broken down by phase (I, II, III), with separate comparisons for global and Asian cohorts to improve comparability. We also compiled counts for medical device and diagnostic trials and included a comparison with China. However, due to comparability issues, China data were only shown in the appendix.

To assess the influence of clinical trial activity on marketed new drug approvals, approval efficiency, and care quality, we analysed relationships between industry-sponsored trial volume and indicators such as new drug approval rates, median approval intervals, and disease mortality. These analyses used publicly available country data, including statistics queried from national regulatory agency databases and trial-specific units, which were subsequently compiled and calculated by PwC Taiwan.

*Note: ClinicalTrials.gov is the world's largest clinical trial database, operated by the US National Institutes of Health. The information is voluntarily updated by investigators or sponsors in accordance with local regulations and may differ from figures released by the governments. Nevertheless, the platform remains the primary source used for cross-country comparisons in multinational research.

PART I Background Overview

Message 2 examined government reports and academic research to explore clinical trial improvements in countries including Australia, South Korea, Singapore and Malaysia. This analysis aims to identify success factors applicable to Taiwan and provide reference cases to facilitate cross-ministry communication and build industry consensus.

Message 3 estimates the direct and indirect economic impacts of clinical trials, drawing on studies from European Federation of Pharmaceutical Industries and Associations (EFPIA), the Association of the British Pharmaceutical Industry (ABPI), and PwC UK. Using Taiwanese government public data and adapted international models, we quantified clinical trials' value to Taiwan's economy.

Through systematic international comparisons, benchmark case analyses, and economic impact projections, PwC Taiwan seeks to highlight, with quantitative evidence and practical strategies, the critical value of clinical trials to Taiwan's healthcare and biotech sectors. This work serves as a reference for key stakeholders and a foundation for policy development, aligning with the Healthy Taiwan initiative to establish Taiwan as a key clinical trial hub.

PART I Background Overview

Message 1: International clinical trial indicators comparison

- **Method:** Analyse the trial volume metrics of the United Kingdom, Canada, Australia, Japan, Korea, Israel and Singapore.
- **Purpose:** Quantify the disparities and advantages of Taiwan compared to international standards, providing basis for the future government KPI assessments.

Message 2: International comparative case studies

Overview of each country's clinical trial improvement policies

- **Method:** Compare recent policy directions and analyse successful one-stop platforms such as **Australia's NOSS, South Korea's KoNECT , and Singapore's CTSG.**
- **Purpose:** Offer references for Taiwan's clinical trial ecosystem policy development and aid planning a concrete blueprint.

Message 3: Economic Impact of Clinical Trials

- **Method:** Estimate direct and indirect economic value for clinical trials, including effects on employment, drug introductions and health outcomes.
- **Purpose:** Quantify the economic and societal benefits of clinical trials to raise government attention.

Message 1 : Comparison of International Clinical Trial Indicators

Annual Total Number of Clinical Trials

Number of Industry-Sponsored Trials

Number of multiregional Trials

Number of Phase I/II/III Trials

Impact of Industry-Sponsored Clinical Trial Volume on New Drug Introductions and Disease Treatment in Countries

Observations on the annual number of drug clinical trials conducted in Taiwan and comparator

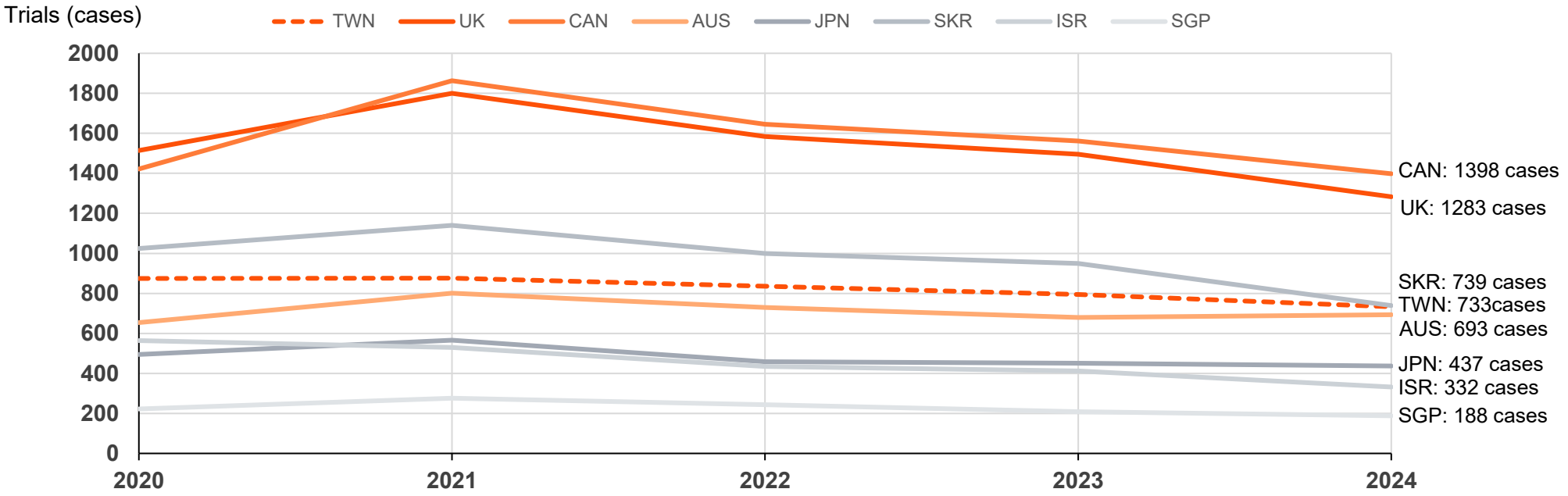
- Taiwan ranks 6th accompany with the 7 peers in **total drug clinical trials**, ahead of only Israel and Singapore; within Asian peers, Taiwan sits around the median. (P.19)
- In terms of the number of **industry-sponsored drug trials**, Taiwan has room for improvement compared with most comparator countries, only ahead of Israel and Singapore. However, as a share of total trials, Israel and Singapore exceed Taiwan. In Japan and Australia, over 90% of trials are industry-sponsored. While Singapore and South Korea previously had trial counts similar to or below Taiwan's, both have surpassed Taiwan in the past two years. (P.21–P.24)
- For **multiregional (mRCT) drug trial applications**, Taiwan recorded 295 cases in 2023 and 315 in 2024, below the highest-volume countries (UK 461, 429; Canada 470, 429; Australia 398, 390). Although the numbers have risen in recent years, Taiwan still has room to improve compared with neighboring countries such as South Korea and Japan. (P.25, P.26)
- Considering the number of clinical trials examining **FDA Novel Drugs (FDA annual report listed 246 new drugs over the past 5 years)** over the past five years, Taiwan recorded 49 trials in 2023 and 54 in 2024—about half the volume of the leading countries (UK 76, 93; Canada 81, 87)—and below South Korea and Japan. (P.27, P.28)
- Taiwan's **early-phase trial** volume (Phase I and Phase I&II) is slightly above the comparable countries, but behind Australia. (P.29)
- **Phase II trial** volume is similar to Japan's but lower than most other comparison countries. (P.30)
- **Phase III trial** counts in Taiwan are lower than in most comparison countries, with 169 in 2023 and 167 in 2024. (P.31)
- Overall, Taiwan's international competitiveness in drug clinical trials have room to improve in **total volume** relative to peers, with particularly significant room to grow in the share of **industry-sponsored trials**.

Taiwan’s total number of clinical trials is at the median among the comparator

Comparing the total volume of clinical trials across countries from 2020 to 2024, including drugs, medical devices, and diagnostics, the chart shows Taiwan in the middle range, reflecting a flat growth. In 2021, trial numbers peaked globally due to post-pandemic recovery and however have since stabilised with a growth trend. Asia's active attraction of clinical trials has led to a decline in some Western regions. To raise visibility and attract more international trial deployments, Taiwan needs to scale up, improve execution efficiency, and strengthen cross center collaboration so it can move from the median to the leading group.

Clinical trial counts by Country

(including drugs, medical devices and diagnostics, medical projects, and academic or research uses, 2020 to 2024)



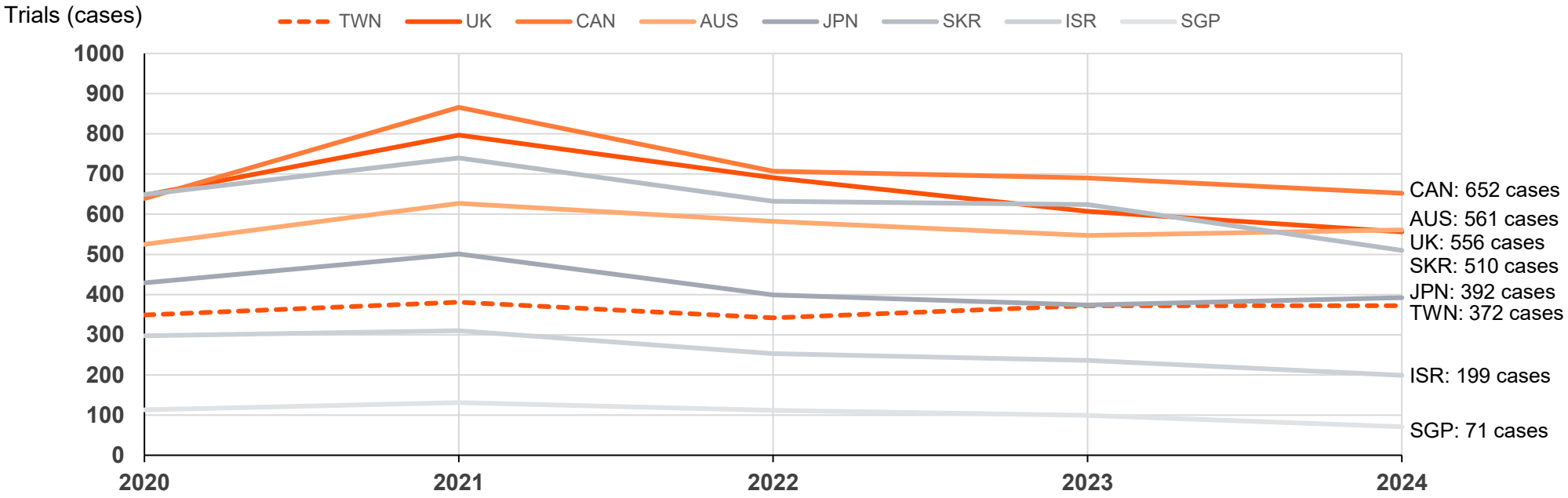
*Note: ClinicalTrials.gov is the world’s largest clinical trial database, operated by the US National Institutes of Health. The information is voluntarily updated by investigators or sponsors in accordance with local regulations and may differ from figures released by the governments. Nevertheless, the platform remains the primary source used for cross-country comparisons in multinational research.
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan ranks 6th accompany with the 7 peer countries in total drug clinical trials

The chart focuses on drug clinical trials and shows that Taiwan ranks about sixth accompany with the 7 peers, with roughly 370 trials annually and a stable capacity. Activity is steady, but the overall scale is modest, indicating room to improve attractiveness for novel drug pipelines and high value research projects. The ranking places Taiwan in the middle tier internationally and suggests it has yet to build clear cluster effects or broader impacts.

Drug clinical trial counts by Country - All phases
(trial counts, drugs, 2020 to 2024)



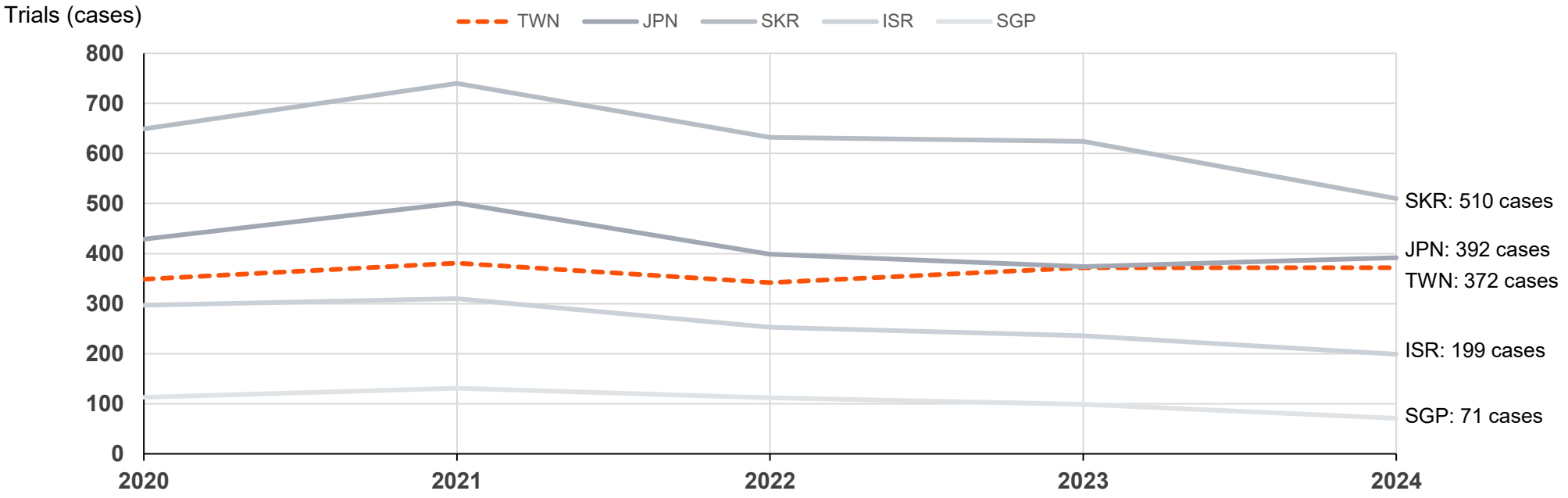
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA statistics

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of drug clinical trials is at the median among Asian comparator

This page builds on the earlier observations and shows that, among Asian comparators, Taiwan's total number of drug clinical trials remains around the median. The pattern suggests a stable clinical foundation and healthcare capacity but not yet a leading regional scale. Further progress will require sustained increases in trial volume, greater diversity in study types, and stronger integration across research center networks.

Drug clinical trial counts across Asian Countries - All phases
(trial counts, drugs, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025) ; TFDA statistics

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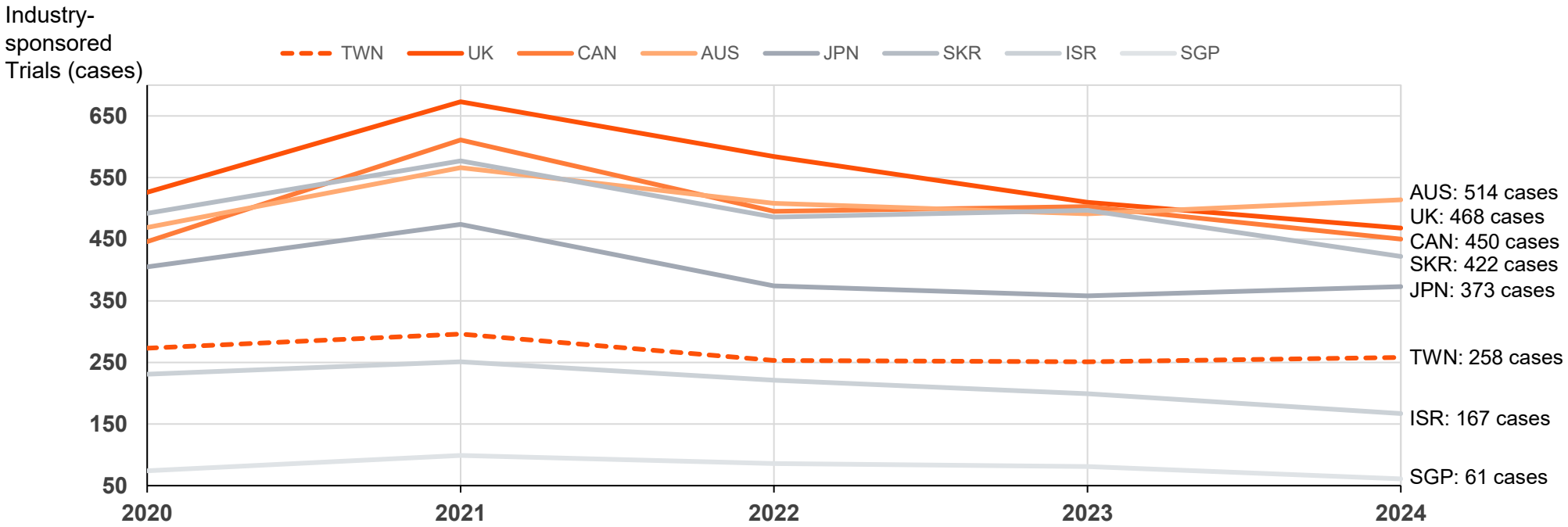
Taiwan's total number of industry-sponsored drug trials is only ahead of Singapore and Israel

This page shows that Taiwan's total number of industry-sponsored drug clinical trials is lower than in most comparators, ranking only above Israel and Singapore. The pattern suggests relatively limited industry. This may weaken Taiwan's visibility and likelihood of being selected for international multicenter research, pivotal trials, and the introduction of advanced therapies.

Industry-sponsored drug clinical trial counts by country
(trial counts, drug only, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

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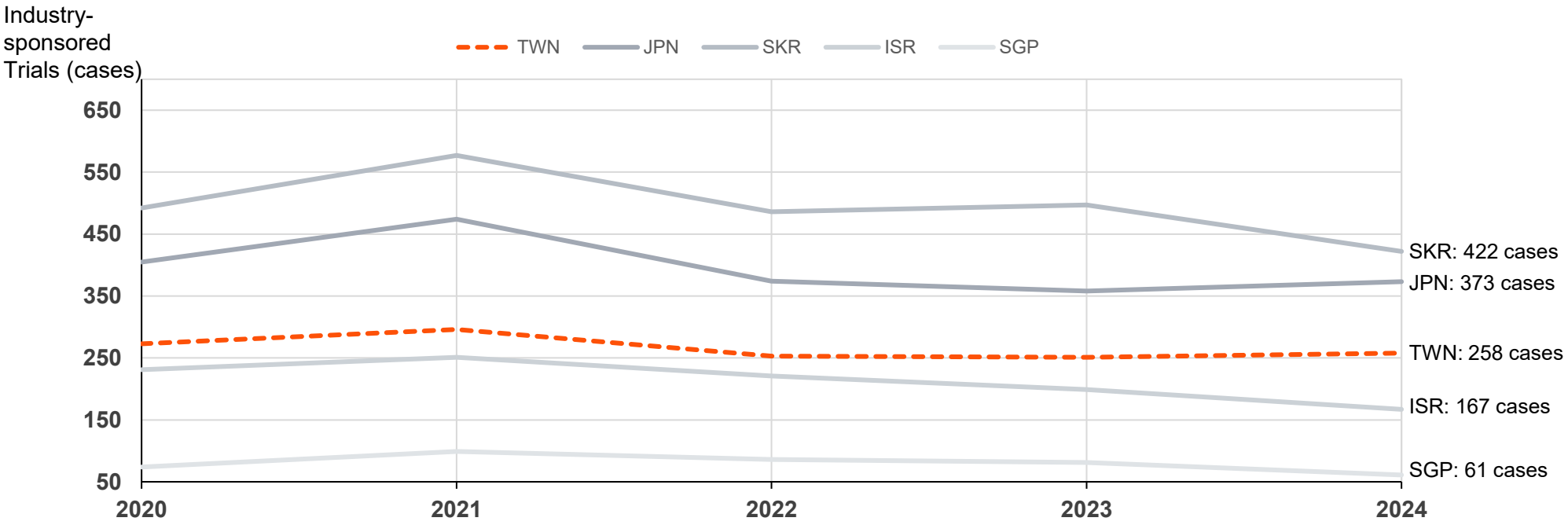
Taiwan's total number of industry-sponsored drug trials is at the median among Asian comparator

Narrowing down to Asia comparative level, Taiwan's number of industry-sponsored drug trials sits around the median. This indicates that Taiwan is not among the top tier in the region for hosting industry led trials, and its weight in site selection by multinational companies is only moderate. To use clinical trials to attract corporate investment in the biomedical sector or to position Taiwan as a regional clinical trial hub, stronger incentives are required.

Industry-sponsored drug clinical trial counts across Asian countries
(trial counts, drug only, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

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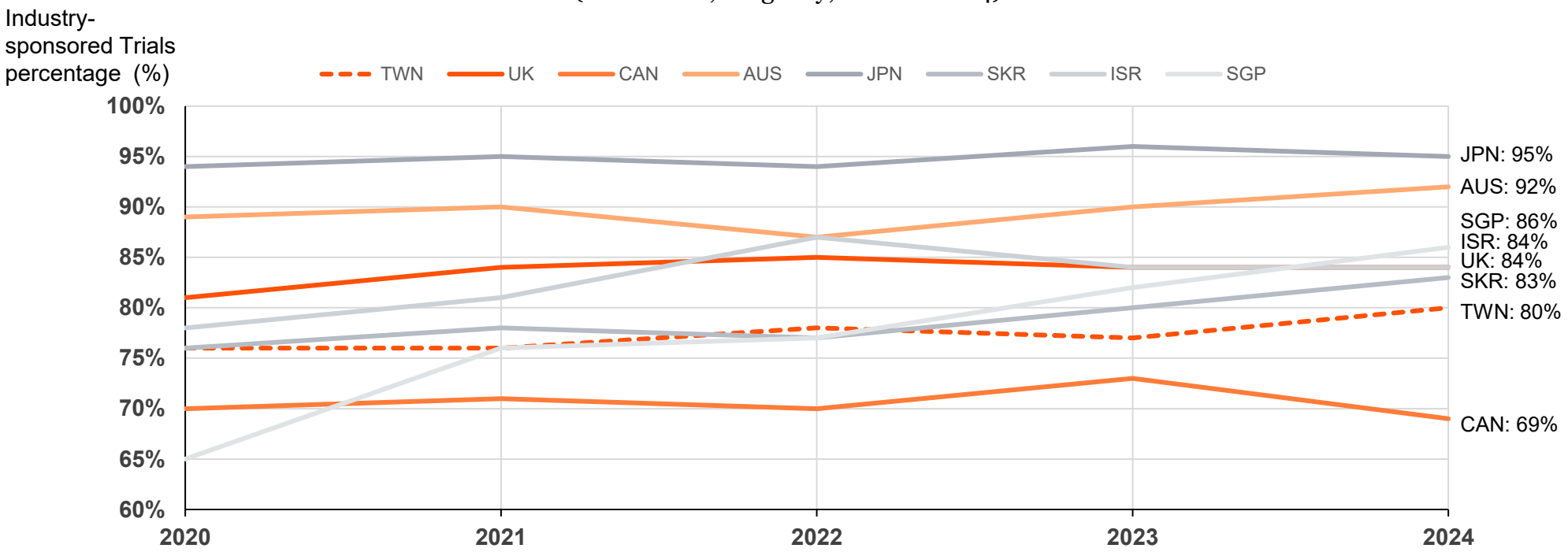
Taiwan's proportion of industry-sponsored drug trials needs to be improved

From a proportional perspective, Taiwan's share of industry sponsored trials is lower than most peers. The chart shows Japan and Australia above 90%, and Singapore and South Korea have recently surpassed Taiwan. Numbers of industry led studies in Taiwan needs to be improved to attract high value, and globally strategic trials.

Industry-sponsored trial share of drug clinical trials by country (sponsored trials / total trials)
(trial counts, drug only, 2020 to 2024)



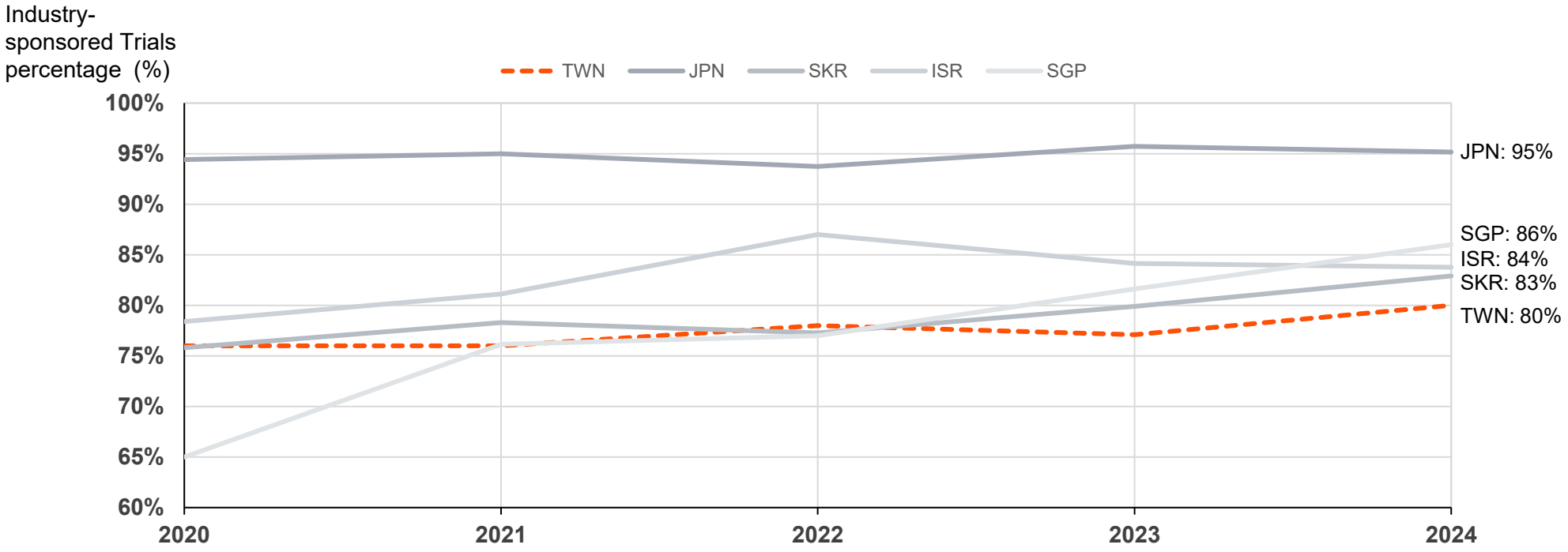
*Since Taiwan's competent authority has not published the proportion of industry-sponsored drug trials, the benchmark for that proportion is based on ClinicalTrials.gov data.Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

In Asia, Taiwan has significant room to grow in the share of industry-sponsored trials.

This page makes clear that, among Asian comparators, Taiwan has a lower share of industry-sponsored trials. This points to priority areas for improvement: need regulation reforms aligned to industry needs, transparency in reviews, faster patient mobilisation, and stronger data quality standards.

Industry-sponsored trial share of drug clinical trials by country (sponsored trials / total trials)
(trial counts, drug only, 2020 to 2024)



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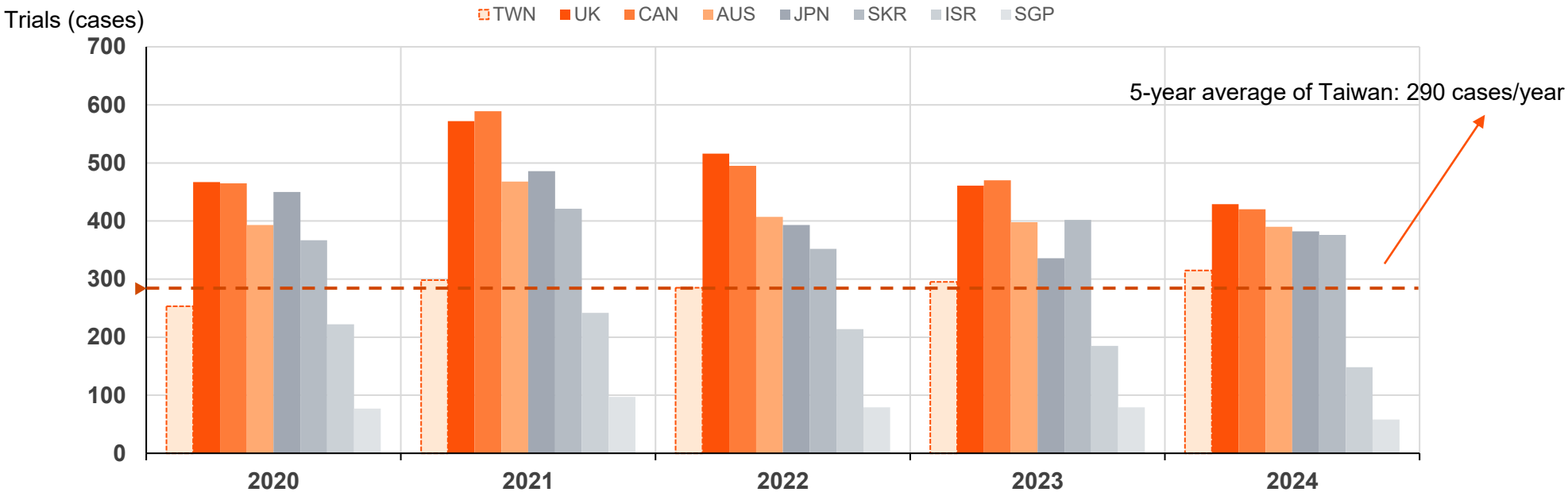
Taiwan's total number of applications for multiregional (mRCT) drug clinical trials has room for improvement

Drawing on statistics from national regulators and clinicaltrials.gov, this page tallies applications for mRCTs by country. Taiwan recorded 295 applications in 2023 and 315 in 2024, below high-volume countries such as the United Kingdom, Canada, and Australia. Although the overall count of mRCTs has edged down, most countries recognise the importance of clinical research and have introduced responsive measures. Taiwan should seise this window of opportunity to close the gap and accelerate.

Drug clinical trial counts by country for mRCTs
(trial counts, drugs only, 2020 to 2024)



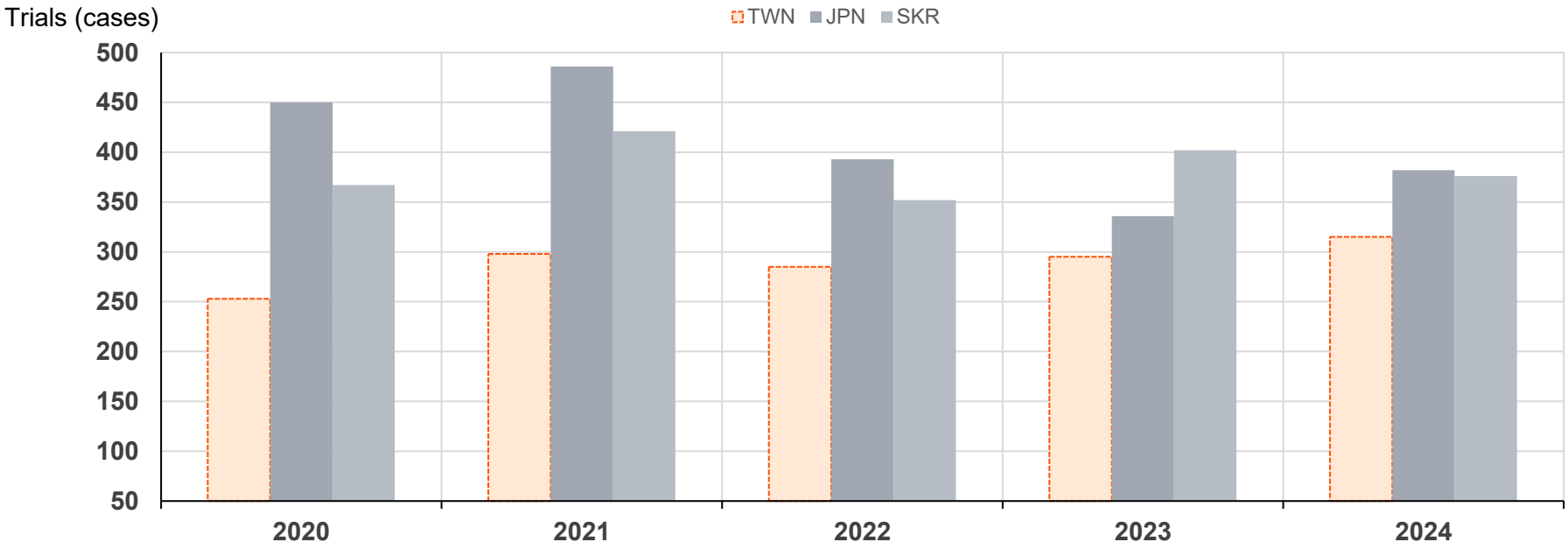
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics; 厚生労働省通知発出の背景及び内容の説明(2025); KONECT (국가임상시험지원재단, Korea National Enterprise for Clinical Trials)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of applications for multiregional clinical trials (mRCTs) remains space to catch up with other Asian countries

Compared with other Asian countries, Taiwan has shown a modest upward trend in recent years, but it does not have a clear advantage over South Korea or Japan. mRCTs require cross-border management, regulatory compliance, and large-scale patient recruitment, therefore Taiwan needs to further strengthen international collaboration and efficiency.

Drug clinical trial counts across Asian countries for mRCTs
(trial counts, drugs only, 2020 to 2024)



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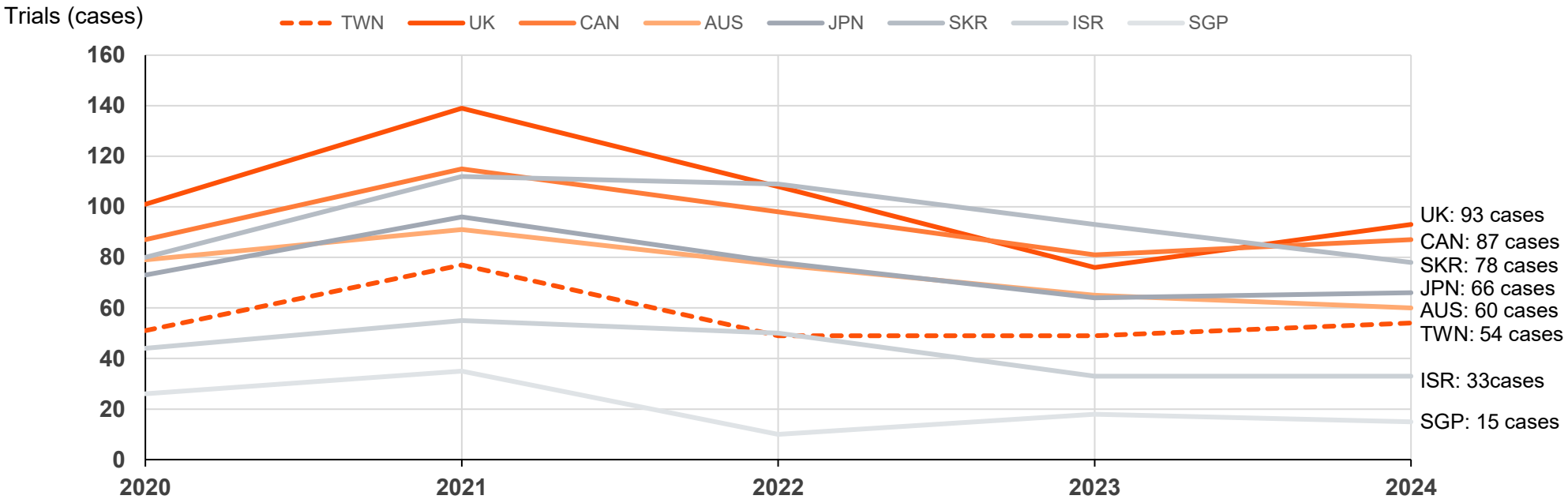
The median number of clinical trials of FDA novel drugs conducted in comparator countries is slightly ahead of Taiwan

Considering the number of trials for US FDA Novel Drugs over the past five years, Taiwan conducted 49 studies in 2023 and 54 in 2024. These figures are less than half of the counts in the highest volume countries such as the United Kingdom with 76 and 93, and Canada with 81 and 87, and they are lower than South Korea and Japan. Factors influencing the choice of clinical trial locations include future market potential, population considerations, trial quality, start-up speed, and administrative costs. This indicates that Taiwan's capacity to host cutting edge innovative drug development has room to improve.

Clinical trial counts by country for FDA-approved novel drugs — all phases
(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

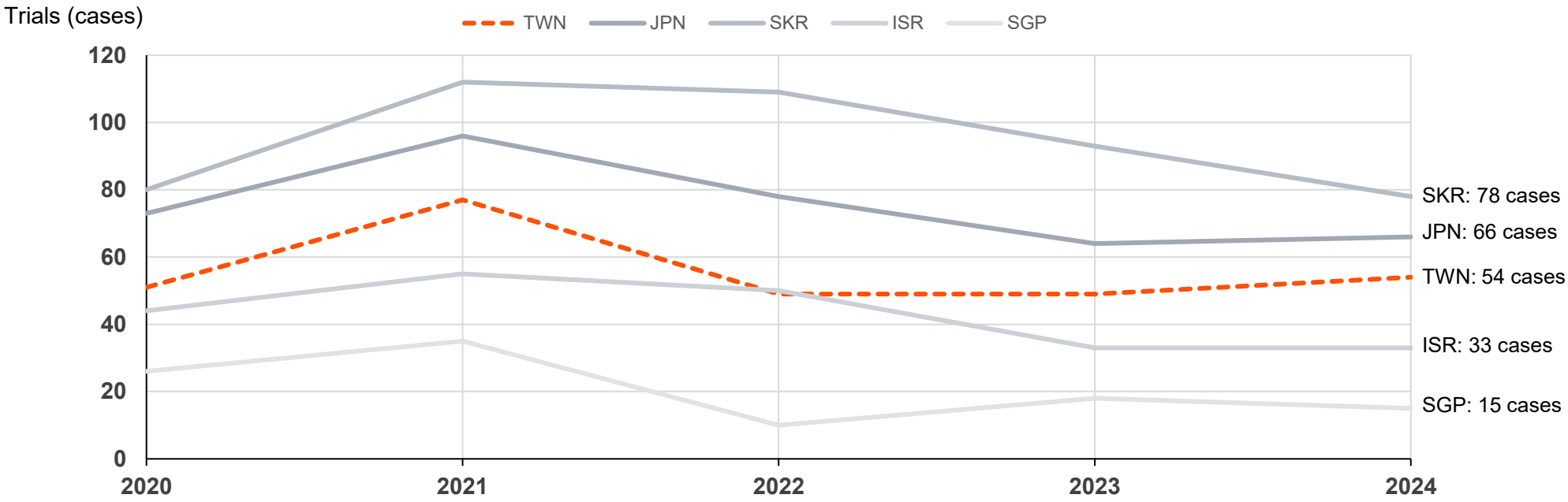
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

The number of clinical trials of FDA novel drugs conducted in Taiwan is roughly around the median of Asian comparator

Comparing the number of US FDA Novel Drug trials across Asian countries over the past five years, Taiwan ranks around the median. Factors influencing the selection of clinical trial sites include future market and population considerations, as well as trial quality, start-up speed, and administrative costs. If Taiwan aims to become an Asian clinical trial hub, it should raise visibility and focus on distinctive study types, but more importantly introduce stronger incentives.

Clinical trial counts across Asian countries for FDA-approved novel drugs — all phases

(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

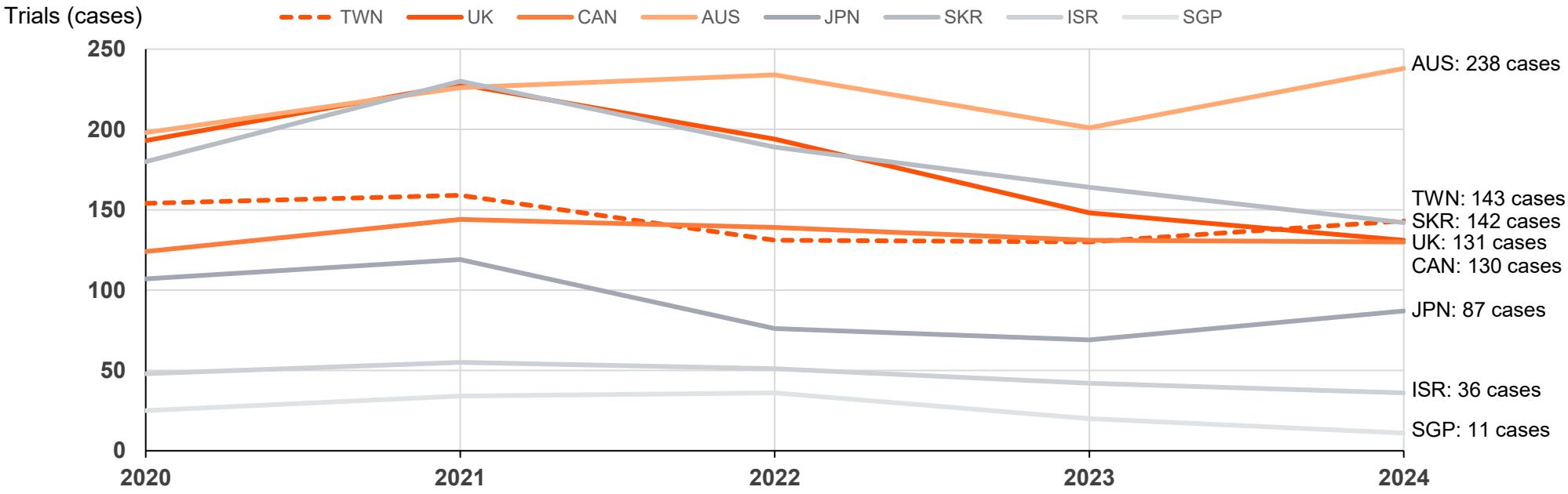
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of early-stage drug clinical trials is slightly above the average of the comparator, yet chasing Australia

Taiwan's Phase I and Phase I/II trial volume is slightly above the comparator average and close to Canada, South Korea, and the United Kingdom. This signals solid early development capacity, including clinical infrastructure, participant management, and safety monitoring. Early phase research is a distinct strength and should be scaled further.

Drug clinical trial counts by country— Early Phase I, Phase I, I&II

(trial counts, drugs only, 2020–2024)



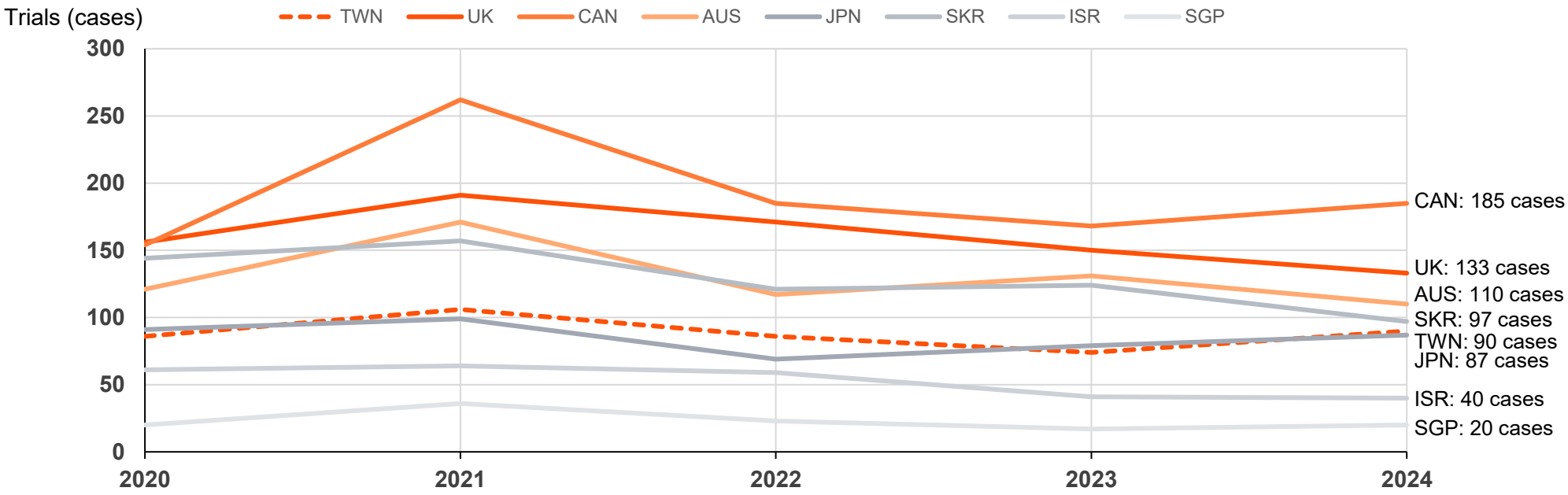
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA statistics

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of Phase II drug clinical trials is similar to Japan's and ahead of Singapore and Israel

Taiwan's Phase II trial volume is similar to Japan but remains lower than most comparators, indicating limited participation in key mid stage work such as efficacy confirmation and dose finding. Phase II trials, proving the effectiveness of the drug, is the critical gate for advancing pipelines, Taiwan should strengthen patient recruitment, increase site diversity, and improve alignment with multinational study designs to gain greater influence in global development.

Drug clinical trial counts by country—Phase II
(trial counts, drugs only, 2020–2024)



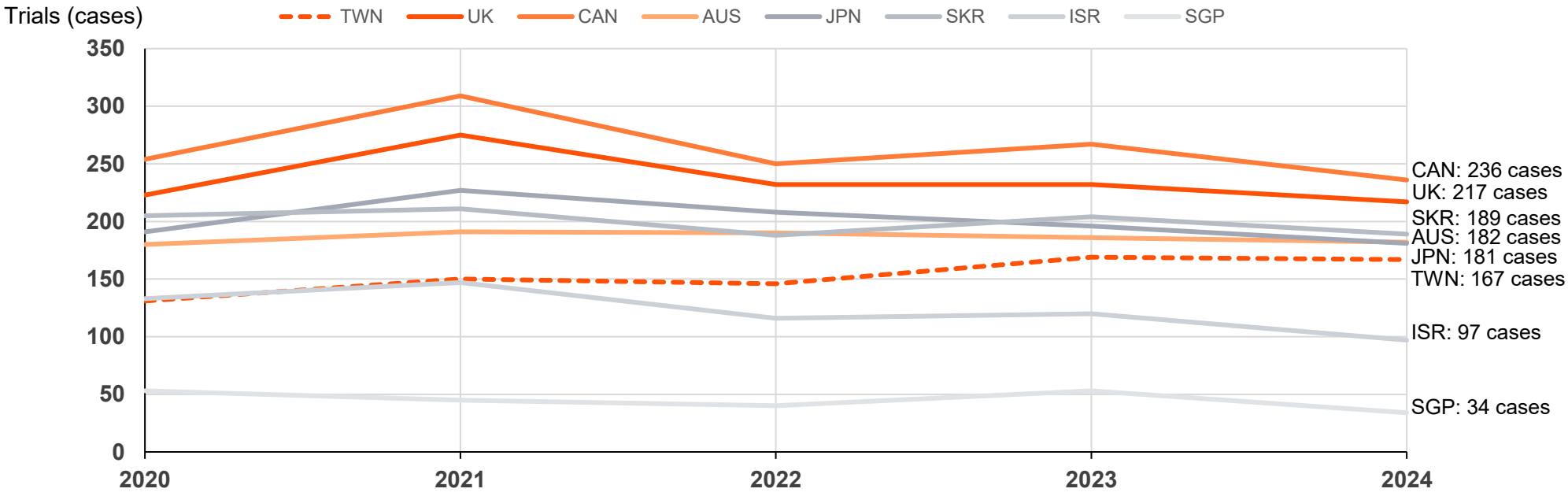
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of Phase III drug clinical trials has potential for improvement

Phase III trial counts in Taiwan were 169 in 2023 and 167 in 2024, below most comparators. Large multicenter trials demand high enrollment and strong data management. While Taiwan's population does not provide a strong incentive, the authorities need to introduce more vigorous measures to increase Phase III trial numbers.

Drug clinical trial counts by country—Phase III
(trial counts, drugs only, 2020–2024)



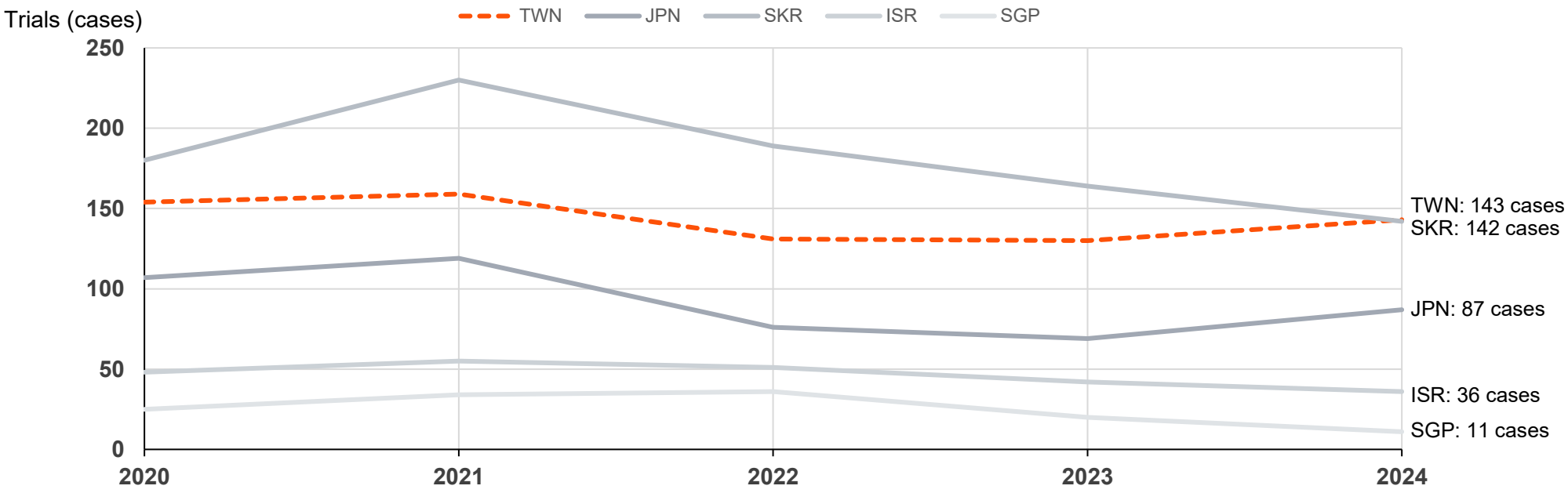
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of early-stage drug clinical trials among Asian countries is competitive

Among Asian comparators, Taiwan leads in the number of early-stage trials, indicating potentials in developing early phase trials. Increasing the share of international collaborations would help consolidate Taiwan's early phase advantage.

Drug clinical trial counts across Asian countries—Phase I, I&II
(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics

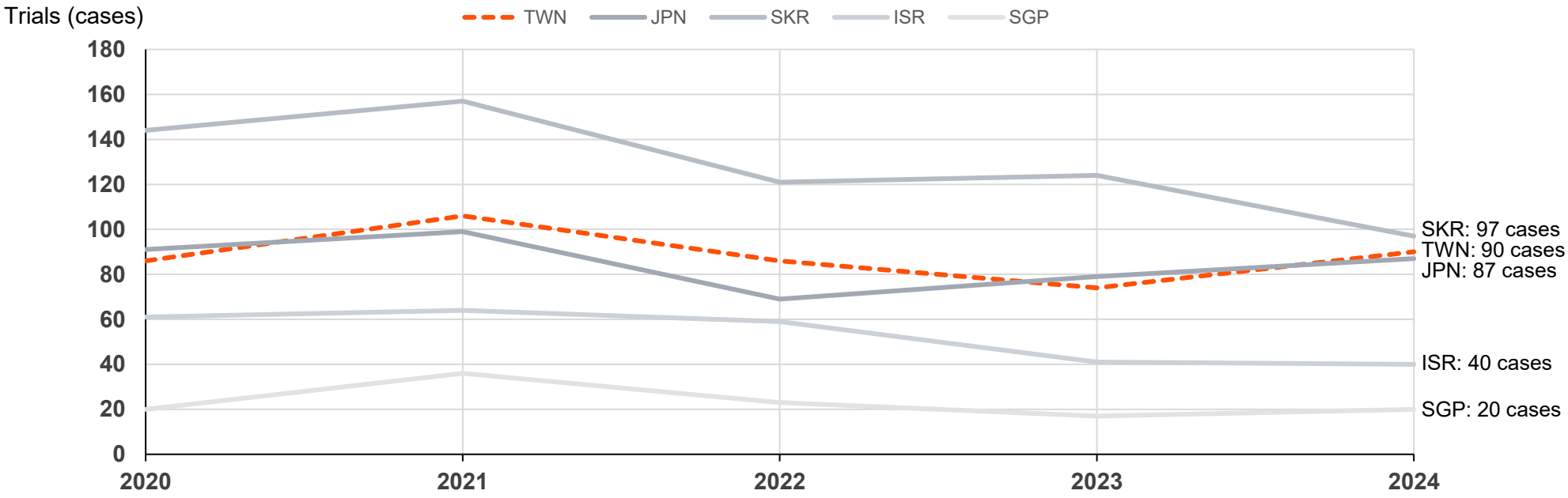
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of Phase II drug clinical trials among Asian comparator possesses strong potential

Among Asian comparators, Taiwan leads in the number of Phase II trials. This stage is pivotal for subsequent Phase III and launch strategies. Taiwan should enhance faster start up, precise recruitment, and stronger quality monitoring to increase the incentive for international trial designs to include Taiwan.

Drug clinical trial counts across Asian countries—Phase II

(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics

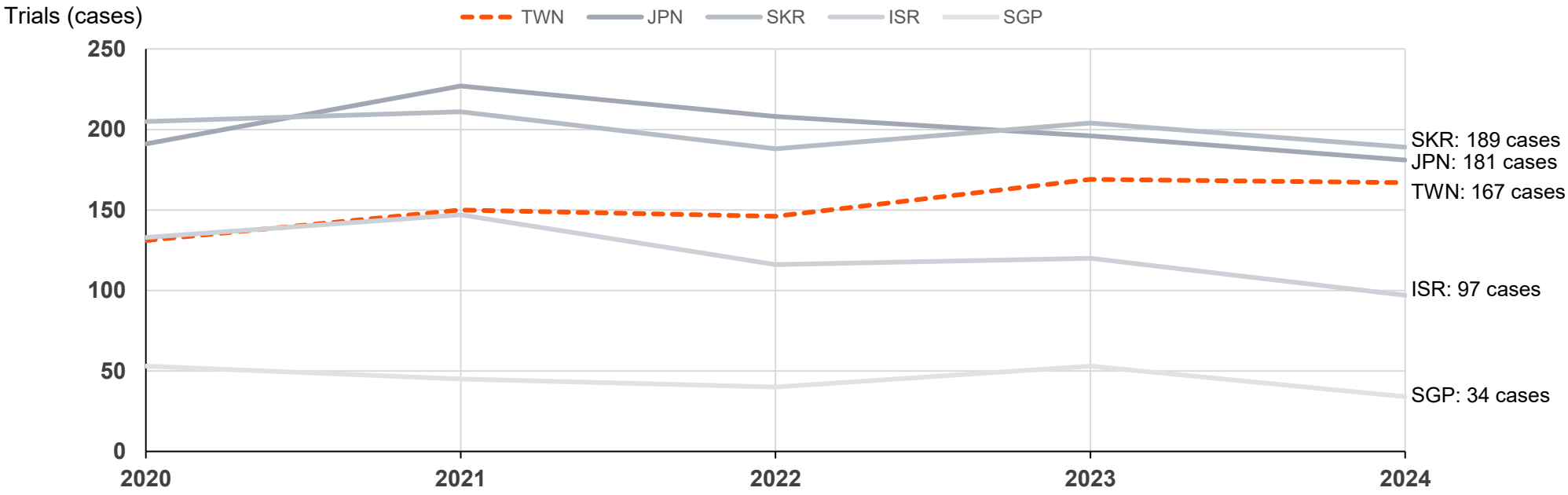
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Taiwan's total number of Phase III drug clinical trials among Asian comparator is competitive

Phase III comparisons place Taiwan around the median, indicating limited participation and visibility in large mRCT studies. This constrains Taiwan's centrality and influence in regional and global evidence generation. Building cross hospital networks, integrating patient pools, and improving data interoperability would strengthen Taiwan's capacity in Phase III trials.

Drug clinical trial counts across Asian countries—Phase III

(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); TFDA Statistics

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

The number of industry-sponsored clinical trials conducted in a country affects new drugs introduction and health outcomes

- **The share of US FDA Novel Drugs** approved over the past five years is positively correlated with the average **number of industry sponsored drug trials** (R^2 = 0.43). More industry-sponsored trials help increase the number of new drugs introduced. (P.36, 37)

- Countries with a **higher average number of industry-sponsored drug trials** show **shorter approval lag for US FDA Novel Drugs** over the past five years, meaning faster new drug introduction; industry sponsorship improves the efficiency of new drug entry. (P.39)

- Across the comparators, **reductions in disease related disability adjusted life years (DALYs),** are positively correlated with the average number **of industry-sponsored drug trials**. Industry sponsorship supports better treatment outcomes and national health. (P.40)

- Across the comparators**, UHC health indicators** are positively correlated with the average number of **industry-sponsored drug trials** in recent years. Industry sponsorship supports overall national healthcare quality. (P.41)

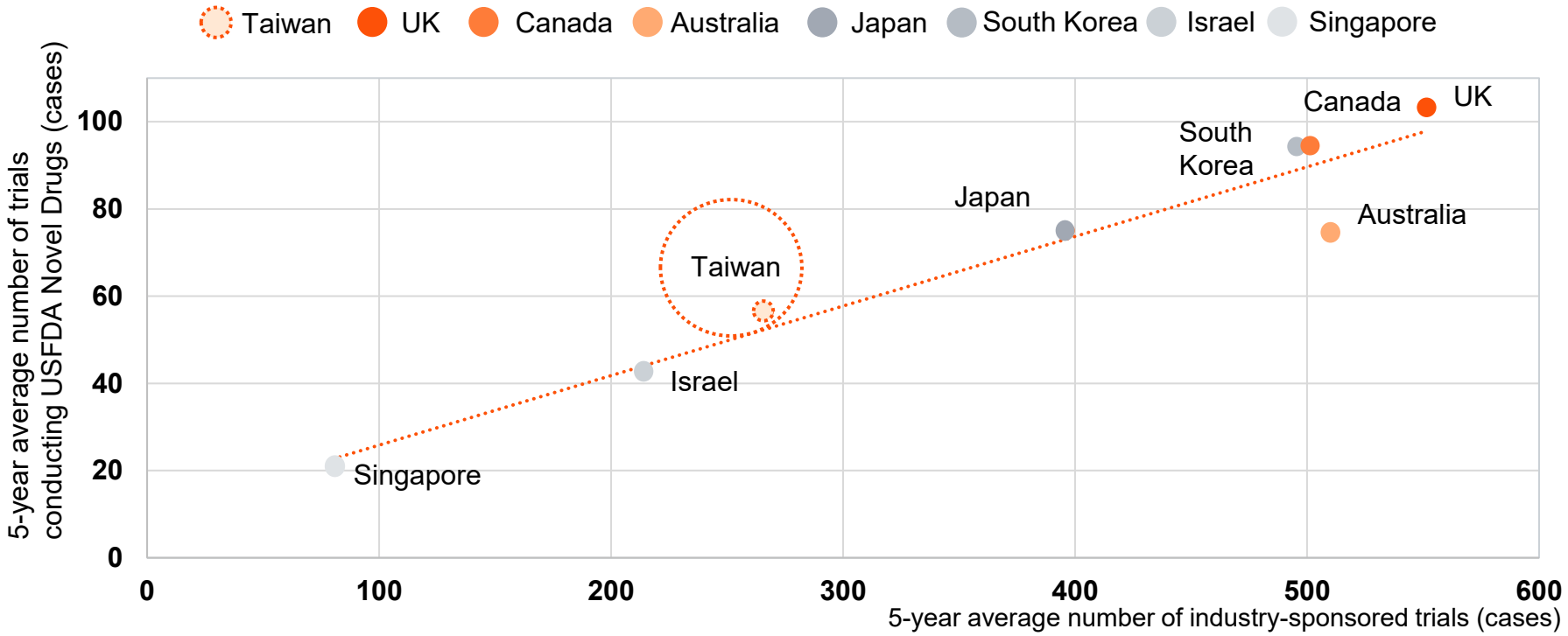
- Overall, a **higher volume of industry-sponsored clinical trials** positively affects **new drug introduction and disease treatment**; if Taiwan does not keep pace with the comparators on this metric, it could lead to delays in **new drug introductions**, adversely **affecting treatment benefits** and the **overall health performance** of the nation.

*Note: This study focuses on the relationship between clinical trials, the introduction of new drugs, and the level of healthcare. However, the number of new drug launches and the waiting time in each country are influenced by multiple factors, such as the drug approval system and the level of market economic development. Some countries allow medicines that have obtained marketing authorization from another country's regulatory authority to undergo a streamlined evaluation process, including waiving certain clinical trial requirements.

The number of industry-sponsored drug clinical trials and the number of trials conducted for US FDA novel drugs is highly correlated

The chart shows a positive correlation between the number of industry-sponsored trials in a country and how often US FDA approved Novel Drugs are used in the studies. Greater industry activity raises the chance of connecting to the global frontline pipeline, giving domestic institutions more opportunities to join high value trials and improving access to new therapies and the visibility of clinical research.

Ratio of industry-sponsored clinical trials to the number of trials conducted for US FDA novel drugs
(trial counts, drugs only, 2020–2024)

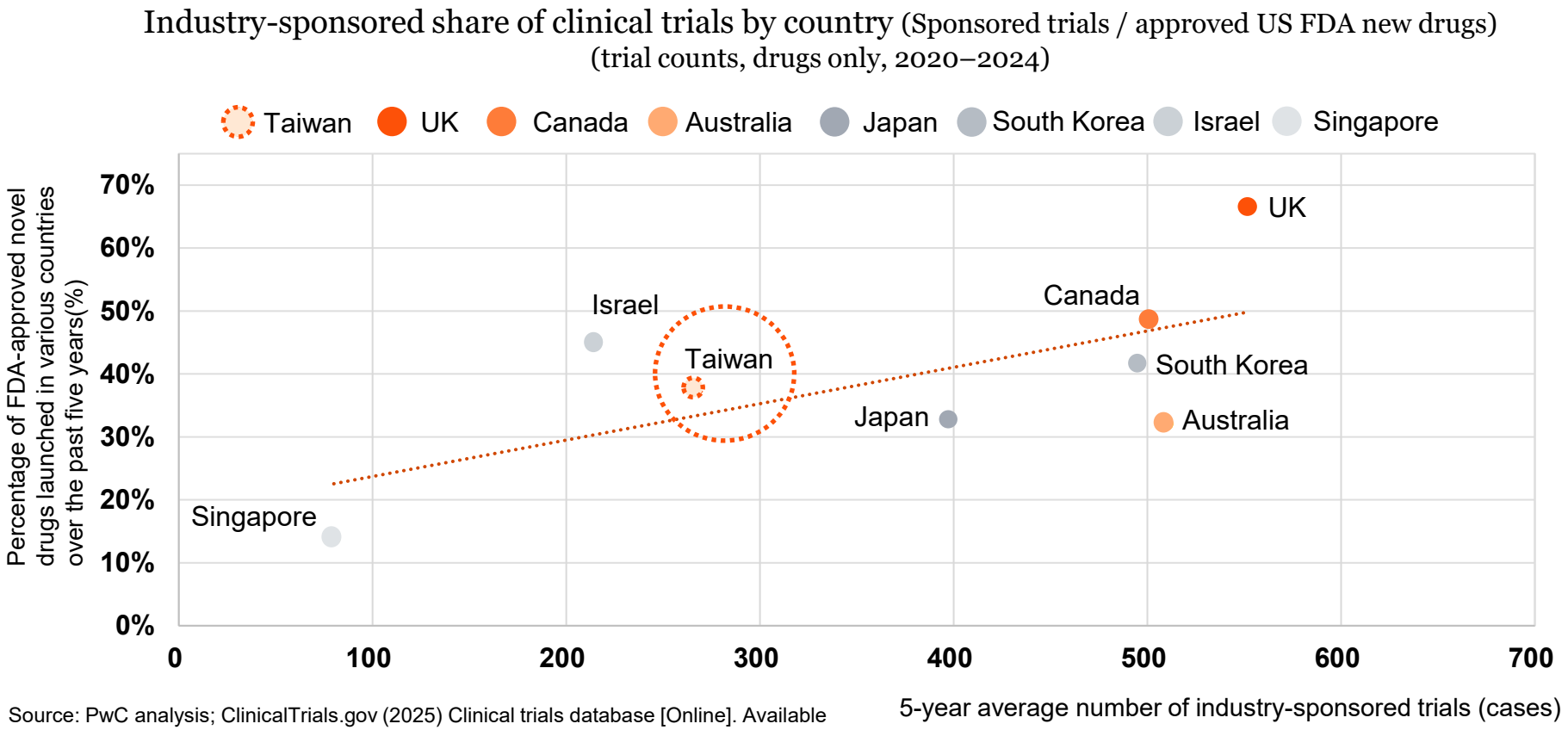


Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); FDA Novel Drug: USFDA annual report

Note: The coefficient of determinant R^2 for the relationship between the number of industry-sponsored drug clinical trials and the number of trials conducted for FDA novel drugs is 0.9309, indicating a high correlation.

The proportion of US FDA “Novel Drugs” approved by a country over the past five years is positively correlated with the number of industry-sponsored drug clinical trials

Comparing the proportion of US FDA “Novel Drugs” approved by a country over the past five years, countries with stronger industry sponsorship tend to have a higher local approval share, showing that clinical trial activity and the pace of new drug introduction are positively correlated. Approval proportions were calculated from national regulatory databases.



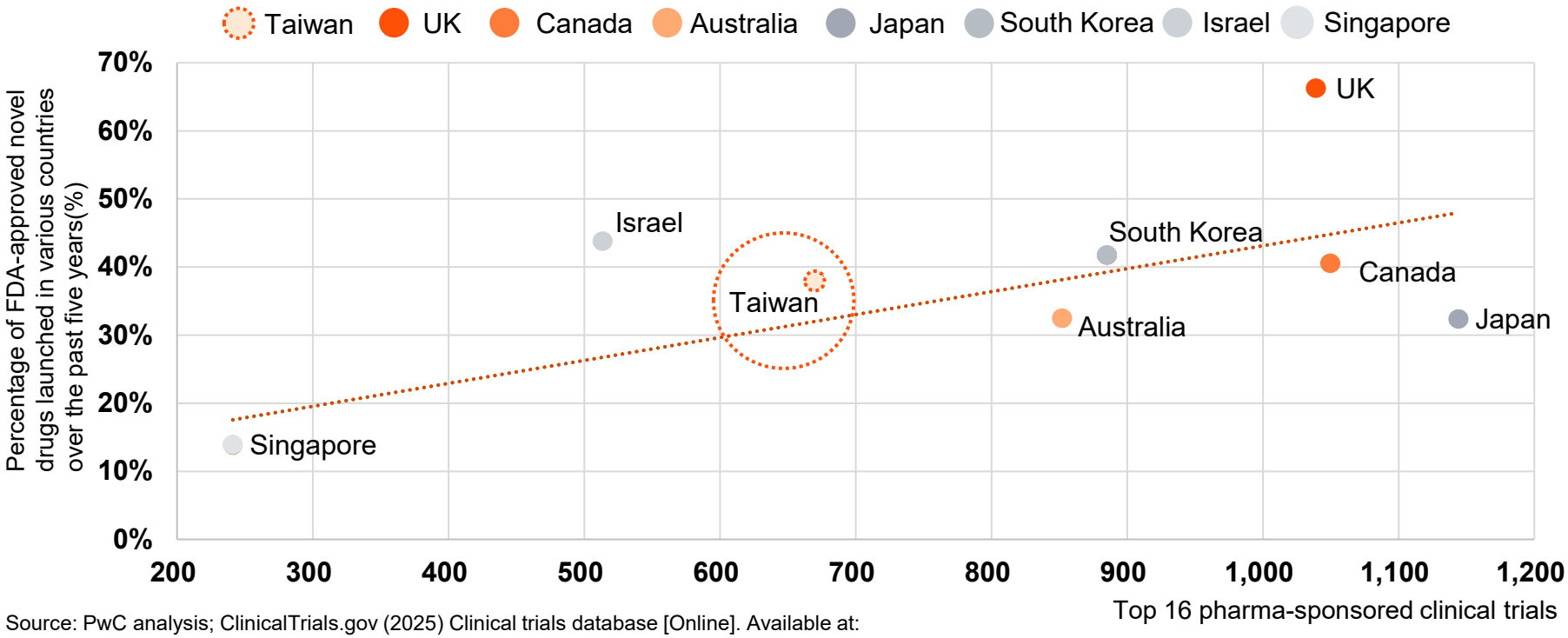
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); New drug approval rate: Statistics from authorities in each countries

Note: Over the past five years, the coefficient of determination R^2 for the relationship between the proportion of US FDA novel drugs and the number of industry sponsored drug clinical trials is 0.4283, indicating a positive correlation. The number of new drug launches and the waiting time in each country are influenced by multiple factors, such as the drug approval system and the level of market economic development.

The proportion of US FDA novel drugs approved by a country is positively correlated with the number of drug clinical trials sponsored by the top 16 pharmaceutical companies

The chart shows a positive correlation that markets with deeper engagement by large pharma tend to have higher local approval shares, suggesting that the depth of collaboration with leading sponsors is closely tied to new drug accessibility and the maturity of regulatory review processes.

Top 16 pharma-sponsored clinical trials by country (Top 16 sponsored trials / approval rate of US FDA new drugs) (trial counts, drugs only, 2020–2024)



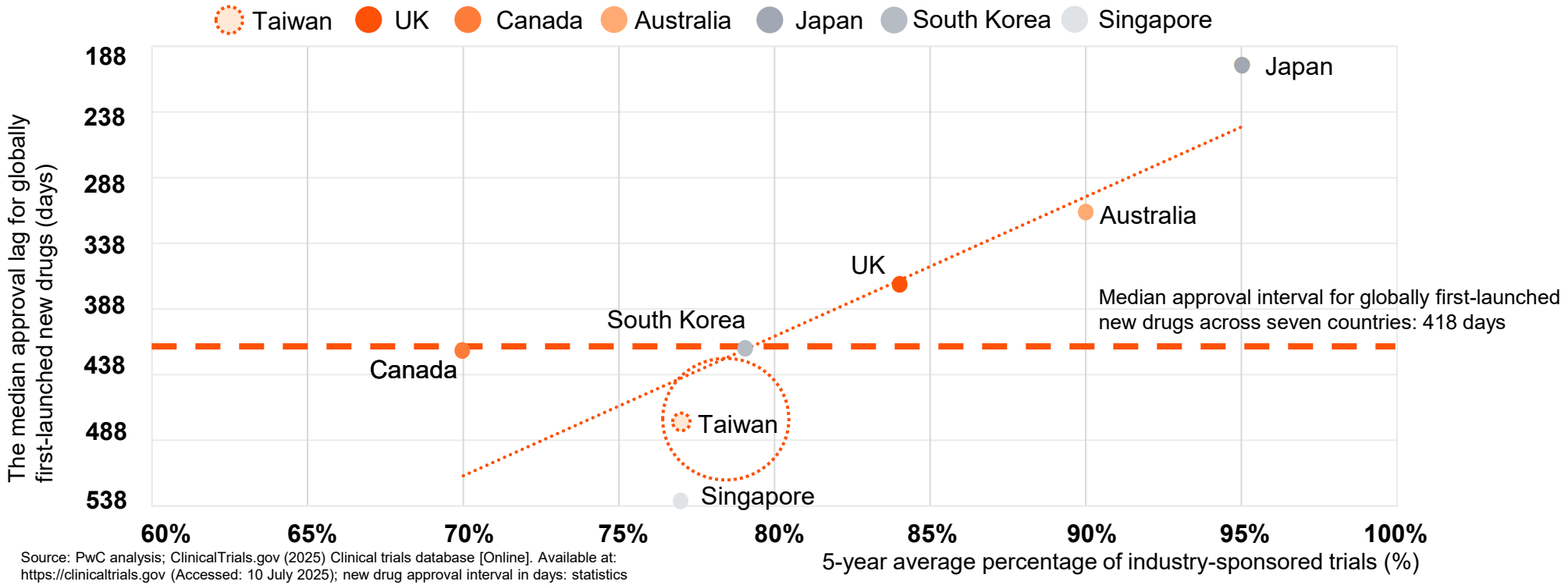
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); Drug approval rate: Statistics from authorities in each countries

Note: The coefficient of determination R^2 for the relationship between the share of US FDA novel drugs among approvals and the number of drug clinical trials sponsored by the top 16 pharmaceutical companies is 0.4384, indicating a positive correlation. The number of new drug launches and the waiting time in each country are influenced by multiple factors, such as the drug approval system and the level of market economic development.

The median approval lag (in days) for globally first-launched new drugs is positively correlated with the average number of industry-sponsored clinical trials

The chart shows that clinical activity intensity and the pace of new drug approvals are highly correlated, reflecting mutual influence among the local clinical ecosystem, regulatory review processes, and corporate investment momentum. These elements should be optimised in a coordinated, system level manner.

Industry-sponsored clinical trials by country (sponsored trials / approval lag days)
(trial counts, drugs only, 2020–2024)



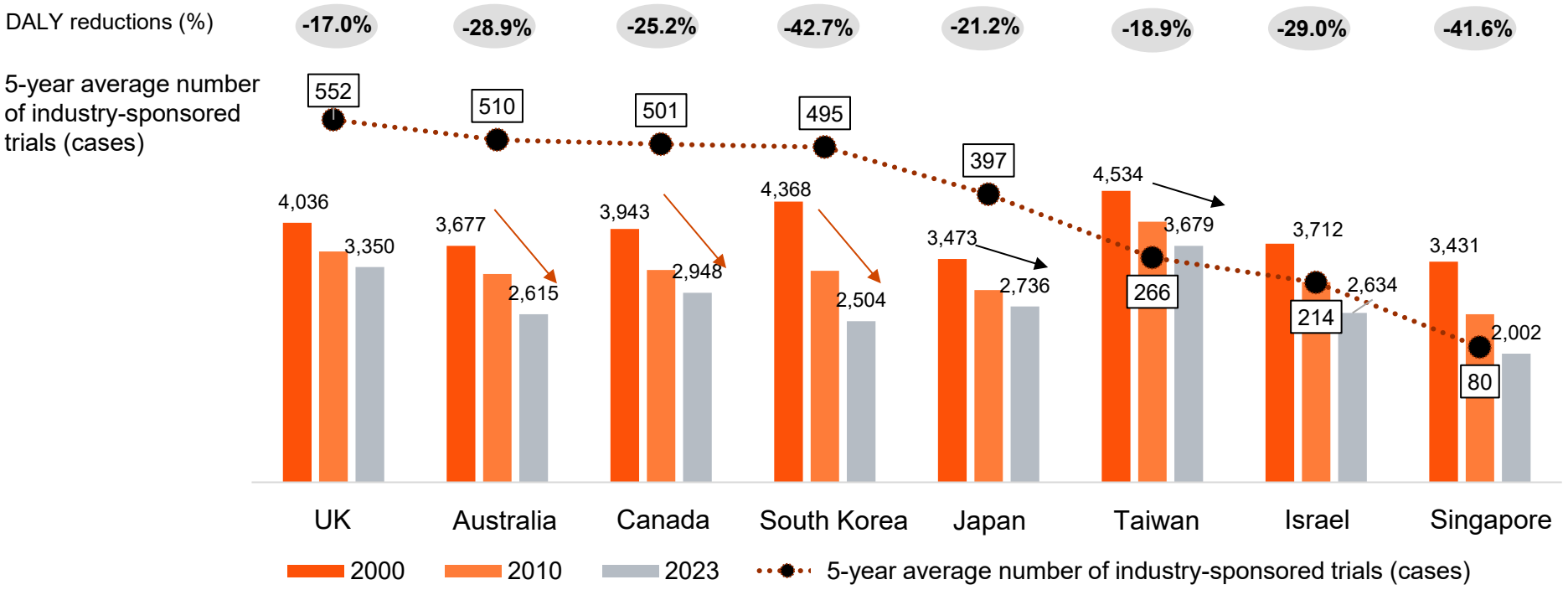
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); new drug approval interval in days: statistics from regulatory authorities in each countries. Note: Israeli regulator does not report exact dates, the approval interval could not be calculated

The calculation method uses the U.S. FDA approval date of novel drugs as the baseline, with the time interval measured from this date to their launch in other countries, presented as a median.
Note: The coefficient of determinant R^2 for the relationship between the median approval interval in days for first in the world new drugs and the average number of industry sponsored clinical trials is 0.7006, indicating a strong positive correlation.

The reduction in disease-related disability-adjusted life years (DALYs) is positively correlated with the number of industry-sponsored drug clinical trials

The chart shows a positive relationship between industry-sponsored and disease-related DALYs. This suggests that industry led clinical research accelerates the introduction of innovative therapies and the accumulation of evidence, which reduces disease burden and improves population health and clinical care outcomes. Taiwan to increase industry sponsored trials could potentially increase health outcomes and surpass peers.

The ratio of industry sponsored clinical trials to DALY reduction by country (sponsored trials / DALYs)
(trial counts, drugs only, 2000–2023)

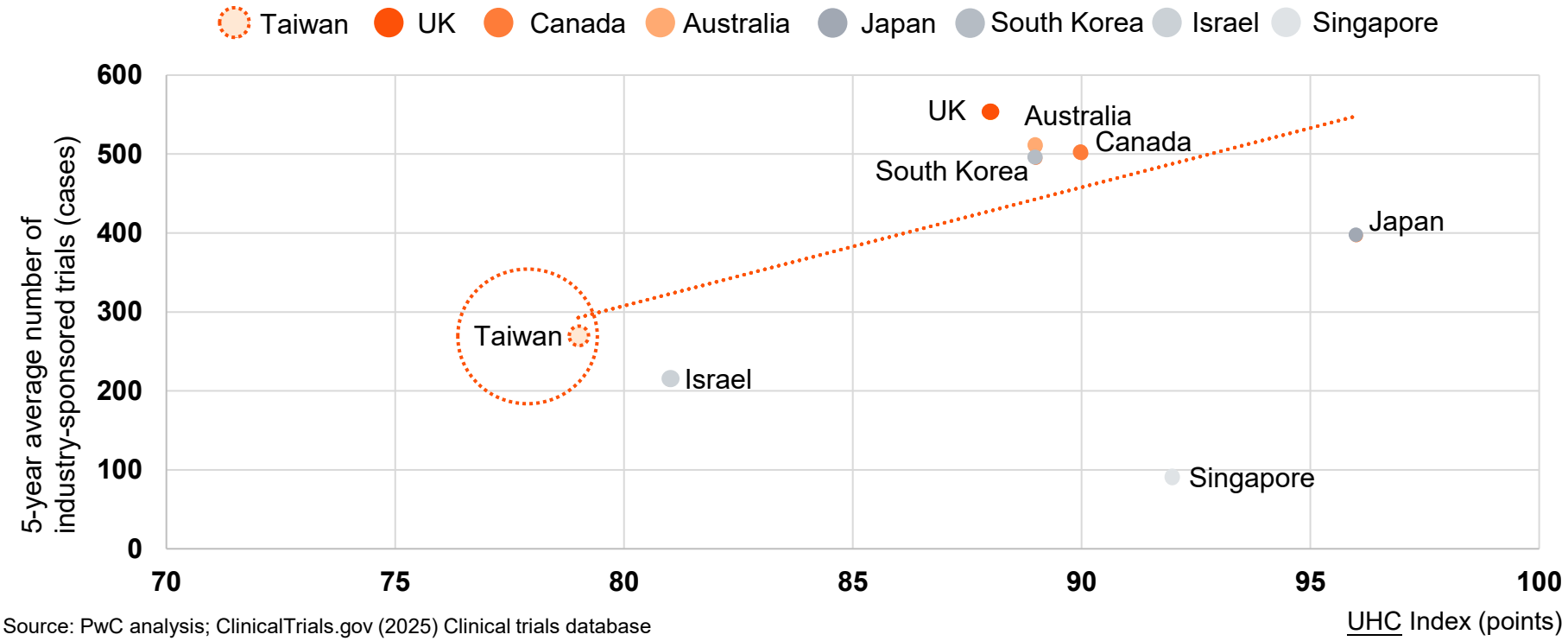


Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); DALY reduction: Lancet Global Burden of Disease

The health indicators calculated under Universal Health Coverage (UHC) are positively correlated with the number of industry-sponsored drug clinical trials

The chart shows that countries with more active industry clinical investment tend to perform better on health system metrics. Beyond improving access to new medicines, industry sponsored trials can raise overall care quality by promoting standardised processes, higher quality requirements to improve the overall health system.

Industry sponsored clinical trials relative to Universal Health Coverage by country (sponsored trials / UHC)
(trial counts, drugs only, 2020–2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); The Universal Health Coverage (UHC) Service Coverage Index

Note: Universal Health Coverage (UHC) is an indicator adopted by the WHO to measure the extent of service coverage and financial protection. It is a United Nations Sustainable Development Goal and is NOT directly related to the National Health Insurance coverage. The coefficient of determinant R^2 for the relationship between Universal Health Coverage UHC related indicators and the number of industry sponsored trials is 0.4269, indicating a strong positive correlation.

Message 2 : International comparative case studies

International Overview

Directions for clinical trial regulation advancements across countries

Australia – Clinical Trial Advancement - NOSS

South Korea – National Clinical Trial Company - KoNECT

UK – VPAG Investment Programme

Hong Kong – Greater Bay Area International Clinical Trial Institute

Singapore – Clinical Trial One Stop Platform

Malaysia – Clinical Research Center by Ministry of Health Malaysia

India – Clinical Trials Registry India

Regulatory Enhancements and Development Directions for Clinical Trials Across Countries

- A review of regulatory reports and policies indicates that many countries are accelerating new rules and systems, investing in streamlined and **expedited review pathways, digitisation, workforce capacity, and cross-ministry one-stop platforms**. (P.44-49)
- Australia, with a population similar to Taiwan's, has historically conducted about twice as many clinical trials and leads in **industry-sponsored** studies. Government investment funds and tax incentives attract international trials. By year's end, a national one-stop clinical trial platform and **cross-government advisory committees spanning industry, academia, and the community** will launch to improve efficiency and bolster Australia's global research standing. (P.50-53)
- South Korea has consistently **led neighboring Asian countries** in total clinical trials, industry-sponsored trials, and mRCT studies. The government established the cross-agency **Korea National Enterprise for Clinical Trials (KoNECT)** to fund drug development, attract international trial resources, support domestic and foreign studies, mobilise investment, train professionals, and strengthen clinical trial data infrastructure. Recent efforts emphasise digitisation (such as remote dispensing and wearable-enabled monitoring) to improve trial efficiency. (P.54-55)
- Singapore, with a smaller population with Taiwan, has historically conducted fewer drug trials. Over the past two years, however, its share of **industry-sponsored trials** has surpassed Taiwan's and is now the highest in Asia, overtaking Korea and Israel. In 2024, Singapore launched the **National Clinical Trials Portal (CTSG)** to connect researchers, academia, and industry, consolidate information on local grants and professional training, and serve overseas users; leveraged with proximity to Malaysia, this positions the Singapore–Malaysia corridor as a preferred **clinical-trial hub in Asia**. (P.59, 60)

International overview – Regulatory Enhancements and targets for each jurisdiction

Jurisdiction	CTA/IND target review time (days)	CTA/IND amendment review time target (days)	Regulatory authority review response format	Regulatory authority requirements during trials
Taiwan	• mRCT drug trials: 15 days • drug trials (including First in Human): 15 days • other drug trials (complicated cases): 120 days	Amendments: 30 days	If approved by TFDA, an approval letter will be issued. If requirements are not met, the application will be rejected.	Sponsors must submit the latest safety reports and report SUSARs (Suspected Unexpected Serious Adverse Reaction). They must notify the regulatory authority in writing when a trial is suspended or terminated. Major changes in information must be reflected by updating the investigator's brochure.
Australia	CTA: targeted 50 days; CTN: N/A, Process within five days of notification	CTA: 50 days; CTN: Process within five days	CTA: approval or rejection letter; CTN: Allow to start trial after notifying sponsor	Follow ICH GCP and the requirements of the study protocol.
South Korea	CTA: 30 workdays (WD)	CTA: 30 WD	Approval; supplement requirement notice; not approved	Notify trial suspension, resumption, completion, and site closure. Sponsors must submit SUSAR reports, urgent safety measure reports, end of trial notifications, and an annual report on trial conduct.
UK	The initial review takes up to 30 days and may extend to 60 days if discussion with the sponsor is needed. For some products such as advanced therapies the period may be extended further.	35 days	Approved; conditional approval; not approved	Sponsors must submit annual safety reports, SUSARs suspected unexpected serious adverse reactions, urgent safety measures, and end of trial notifications.

Source: sources include:Stewart, B. Et al. (2025) 'Requirements and special considerations for drug trials with children across six jurisdictions: 1. Clinical Trial Application Review in the regulatory approval process', Frontiers in Medicine, 12. doi:10.3389/fmed.2025.1542408.; PwC analysis; Due to the limited English-language information published by Israel and the absence of other verifiable public information, Israel data is not provided.

International overview – Regulatory Enhancements and targets for each jurisdiction

Jurisdiction	CTA/IND target review time (days)	CTA/IND amendment review time target (days)	Regulatory authority review response format	Regulatory authority requirements during trials
Canada	30 days beyond receiving full submission	30 days	No Objection Letter, NOL, indicating approval of starting trial; or Not Satisfactory Notice, NSN, for not approved	Notify trial suspension, resumption, completion, and site closure. If the research ethics committee rejects the protocol, this must also be reported. Report serious and unexpected ADR.
China	60 or 30 working days*	Substantial amendments (involving safety): 60-days Non-substantial amendments: Notification or IRB review only	Approve or reject. If no notice is given by the deadline, it is deemed approved.	Notify trial suspension, resumption, completion, and site closure. If the research ethics committee rejects the protocol, this must also be reported. Report serious and unexpected ADR.
Japan	30 days beyond receiving first clinical trial notification	30 days before any amendment	If no response is received within 30 days, the application is deemed approved. If it is not accepted, the authority will require revisions to the study protocol.	Sponsors must report trial suspension, resumption, completion, or site closure, submit annual safety reports, SUSARs, and urgent safety measures, and update the investigator's brochure.
Singapore	CTA: 30 workdays (WD) CTN: 5 workdays, (notify system)	CTA: 15 WD CTN: 5 WD	CTA: approval or rejection letter CTN: If no objection is raised within five days after notification, the trial may begin	Notify trial suspension, resumption, completion, and site closure. Sponsors must submit reports of SUSARs, which are suspected unexpected serious adverse reactions, urgent safety measures, and end of trial notifications.

*Note: For qualifying applications supported by China NMPA—including national priority R&D products, those encouraging early global synchronized development and international multicenter clinical trials, and those serving urgent clinical needs and the development of the national pharmaceutical industry—the review timeline is shortened from 60 working days to 30 working days.

Source: Stewart, B. et al. (2025) 'Requirements and special considerations for drug trials with children across six jurisdictions: 1. Clinical Trial Application Review in the regulatory approval process', Frontiers in Medicine, 12. doi:10.3389/fmed.2025.1542408.; PwC analysis; Due to the limited English-language information published by Israel and the absence of other verifiable public information, Israel data is not provided.

International Overview – Clinical trial review systems and target review time limits

International comparisons show that most countries set clear time limits for clinical trial review and use standardised operating procedures and guidelines to speed timelines while maintaining high quality review. Countries have also developed one stop platforms or parallel review mechanisms that fit their goals and context.

In Australia the Department of Health and Aged Care promotes NOSS, the National One Stop Shop, which integrates the national clinical trial process. It responds to the needs of an aging population and a large territory by linking ethics review, Therapeutic Goods Administration notifications, trial registration and monitoring, and simplified cross state applications through a single platform. The focus is on review efficiency and international competitiveness, with a particular emphasis on early phase trials such as phase I. South Korea established KoNECT, the Korea National Enterprise for Clinical Trial, in 2007 and it was recognised by the Ministry of Health and Welfare in 2014. Under the Special Act on the Promotion of the Pharmaceutical Industry, KoNECT is designated as a national support center. Its mission is to continue building the clinical trial environment, develop professional talent, and promote strategic cooperation at home and abroad. In Singapore, the Singapore Clinical Research Institute launched CTSG to create a nationwide platform that integrates clinical trial information and resources. It provides trial registration, ethics and regulatory guidance, recruitment services, and support for investigators and sponsors, and it enhances research transparency and public engagement.

In Taiwan, the main challenge for review speed lies less in the length of the review itself and more in fragmented administrative procedures. Taiwan has its own, well information-disclosuring one-stop platform, the Taiwan Clinical Trial Consortium (TCTC), but industry generally feels that it has not yet delivered true one stop integration in practice; Reviews, contracts, and trial operations still proceed separately, although the platform performs well in information disclosure and transparency. Building on this foundation, Taiwan can look to international directions and keep improving by setting clear review time limits, standardising processes, enabling parallel reviews across agencies, and consolidating service windows, so that a genuine one stop service can gradually be achieved.

Beyond the abovementioned, UK, Hong Kong, Singapore, Malaysia, and India, etc. are also working to refine their clinical trial systems, in response to the aging population and the technological advancements. The following sections present the directions of regulatory improvements and representative cases from different countries.

Source: Stewart, B. et al. (2025) 'Requirements and special considerations for drug trials with children across six jurisdictions: 1. Clinical Trial Application Review in the regulatory approval process', Frontiers in Medicine, 12. doi:10.3389/fmed.2025.1542408.; PwC analysis

International Overview – Directions for clinical trial regulation advancements

Jurisdiction	Clinical trial regulation advancements
Taiwan	**Emphasis administrative process** • 2023: Guidance issued on decentralised execution measures for drug clinical trials. • 2024: Guidance on computerised systems and electronic data in drug clinical trials published; a fully online application mechanism will be adopted in 2025. • From 2025: The push for complete paperless operations enables all drug clinical trial cases, including new and amended applications, to be processed online via the ExPRESS platform, including online submission of applications for the import and export of trial drugs, streamlining these processes and improving efficiency. • August 4, 2025: Announce streamlined review procedures for multinational, multicenter drug trial protocols. • September 1, 2025: Broadened in the criteria for hospitals eligible to conduct mRCT drug clinical trials, no longer limiting participation to medical centers only. • September 25, 2025: Announce reference document for adopting decentralised approaches in trials. TFDA further expanded eligibility for hospitals to conduct mRCTs, no longer limiting it to medical centers.
Australia	**Government subsidy** • Since 2016, Australia has advanced a clinical trials initiative, established the MRFF to boost national trial activity, and strengthened tax incentives to attract foreign sponsors to conduct studies in Australia. **Established one stop platform** • In 2024, the federal government committed AUD 18.8 million to build a national one-stop clinical trials platform. • Advancing digital trial applications to shorten start-up timelines.
South Korea	**National clinical trial enterprise** • Established in 2012 with South Korean government funding, promoting new drug development and attracts international clinical trial activity to Korea. • Measures include mobilising domestic and foreign investment, training professionals, and collecting clinical trial data. **Strengthened digital and tele-technology for DCTs** • 'Electronic Informed Consent Guidelines' issued to support decentralised/remote trials, specifying eICF technical requirements by 2023. • KoNECT launched a national decentralised clinical trial (DCT) pilot across seven hospitals by 2023. • Developed frameworks for direct-to-patient drug shipment and wearable-enabled remote monitoring.

Source: Regulatory authorities from each countries; PwC analysis

International Overview – Directions for clinical trial regulation advancements

Jurisdiction	Clinical trial regulation advancements
UK	**Risk-based classification and streamlined IRB procedures** The revised clinical trial regulations will take effect in April 2026. Including: • Risk-based oversight: controls calibrated to trial risk; a notification regime for low-risk studies to streamline certain applications and amendments. • Combined Review: a single submission to obtain both ethics approval (REC/IRB) and regulator approval (MHRA). • Mandatory registration and results disclosure: all UK trials must be registered in a WHO-recognised public registry and publish a summary of results within specified timelines.
Canada	**Accelerate low-risk clinical trials** • Drafts amendments adopt a risk-based approach, including a notification regime for low-risk studies. • Formalise design standards for decentralised trials to provide flexibility while safeguarding participant safety and data quality, strengthening trial implementation.
China	**Risk-based, tiered on-site inspections** • 2023 Measures for the 'Supervision and Inspection of Drug Clinical Trial Institutions (provisional)' took effect on 2024-03-01, introducing a graded, risk-based on-site inspection regime. • Draft Guideline on the 'Use of DCT Technologies in Rare Disease Drug Development' released for comment; will refine DCT procedures, including remote informed consent and direct-to-patient drug shipment. • Draft 'Guideline on Safety Information Reporting and Risk Communication in Clinical Trials' released for comment, detailing how parties must report safety information during drug trials in November,2023. **Cross-border data sharing and Review Facilitation** • In 2024, Shenzhen and Hong Kong joined forces to share clinical trial data, streamline several cross-border administrative processes, and establish a centralised platform to coordinate resources. • In September 2025, under the 'Opinions of the General Office of the State Council on comprehensively deepening reform of drug and medical device regulation and promoting high quality development of the pharmaceutical industry', an announcement was issued to speed up IND approval from previously 60 days to 30 days.

Source: Regulatory authorities from each countries; PwC analysis

International Overview – Directions for clinical trial regulation advancements

Jurisdiction	Clinical trial regulation advancements
Japan	**Currently in planning, with an emphasis on reporting obligations** • The Clinical Trials Act (No. 16 of 2017) has been in force for over five years and is slated for amendment. • Proposed changes include easing certain requirements (e.g., conflict-of-interest disclosures and reporting obligations) and streamlining review processes.
Singapore and Malaysia	**Relax clinical workforce constraints** Issued digital/hybrid clinical trial guidelines. • Effective October 1, 2021, the clinical trial regulations were amended to strengthen informed consent requirements for collection of human tissue from participants, relax investigator qualifications, and allow qualified pharmacists to serve as principal investigators (PIs) for trials of marketed therapeutic products to expand clinical researcher capacity. • In 2024, the Singapore Clinical Research Institute (SCRI) launched a national clinical trials information platform that consolidates trial information for patients and researchers to search.
India	**Prospective registration and life cycle oversight** • The CTRI provides free search and registration and requires all trials conducted in India to be registered before the first participant is enrolled; it covers post marketing surveillance, BA/BE studies, and trials undertaken as part of postgraduate theses. • In 2019, the 'New Drugs and Clinical Trials Rules' established a comprehensive framework for marketing authorisation and post marketing surveillance, strengthening quality and ethics. • In September 2025, an amendment changed CTA and IND from an approval system to a notification system, reduced the statutory processing time from 90 days to 45 days, and exempted some BA/BE studies from licensing, streamlining procedures and shortening startup timelines to enhance India's attractiveness for clinical research and pharmaceutical R&D.

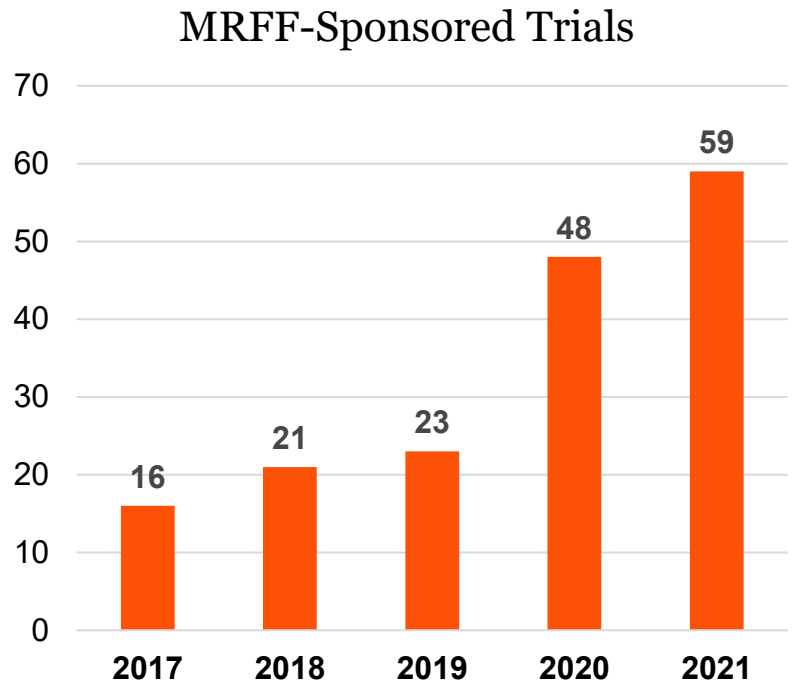
Source: Regulatory authorities from each countries; PwC analysis

Australia

1. Clinical Trials Activity initiative

Established in 2016, the Clinical Trials Initiative aims to bring international trials to Australia, expand patient participation, and strengthen the evidence base for clinical care. Funded by the Medical Research Future Fund (MRFF), it supports national trial activity, with AUD 750 million committed for 2024–25 through 2033–34. Australia also offers an R&D tax incentive for clinical trials, allowing eligible companies to claim back up to 43.5% of qualifying R&D expenditure.

Pilot studies	Clinical Trials
Fund pilot studies to evaluate the feasibility of clinical trials of novel therapies or care strategies addressing rare cancers, rare diseases, and/or unmet medical needs.	Fund clinical trials to evaluate therapies or care-based interventions for rare cancers, rare diseases, and/or unmet medical needs.
Comparative Effectiveness Research (CER)	**Science Trials**
Fund CER to assess the relative benefits of two or more health interventions for disease treatment, provide evidence and reduce unnecessary or ineffective interventions.	Fund science trials to identify the most effective strategies for preventive measures, screening or diagnostic tests, therapeutics, medical technologies, or models of care that are not yet in routine use in Australia.



Source: National Science and Technology Council, NSTC Australia; PwC analysis

Australia

2. Consideration of establishing “The National One Stop Shop, NOSS”

The National Health and Medical Research Council (NHMRC), and the Department of Health and Aged Care (DHAC), gathered experts and proposed 5 key points to establish NOSS in order to promote national clinical trial ecosystem.

01 **Establish a single national high quality one stop platform**
Accelerate completion of the NOSS and the public-facing National Clinical Trials Portal to avoid states duplicating staffing and resources to build separate systems.

02 **Establish a long-term cross-departmental managing framework for platform execution**
Establish cross-departmental advisory committees comprising industry, research, and community stakeholders. Governments are expected to sign intergovernmental agreements (e.g., “Encouraging More Clinical Trials in Australia”) to balance responsibilities across jurisdictions, manage clinical trial activities through a unified platform, and extend access to healthcare and aged-care providers to enable seamless, consistent operations.

03 **The platform should meet the requirements identified and validated during consultations**
It must provide robust governance, strong cybersecurity controls, and high quality of data-privacy.

04 **Establish an open-to-public database**
The platform should offer an internationally searchable public database to help foreign clinicians and the public identify suitable clinical trials and to encourage overseas sponsors to apply to conduct studies in Australia.

05 **Parallel communication strategy and education campaign to the public**
Develop a strategic communication and education campaign to increase public awareness and trust in clinical trials and strengthen support for research and public health policy.

Source: National Science and Technology Council, NSTC Australia; PwC analysis

Australia

3. Functions of the national one stop clinical trial platform

In 2024 the federal government announced an investment of 18.8 million Australian dollars to build a national one stop clinical trial platform. Through a nationwide review and data system it streamlines research, making it easier for sponsors researchers and patients to find and join trials in Australia, improving efficiency and raising Australia's standing in global clinical research. The platform will allow all public private and nonprofit organisations as well as universities and aged care institutions that conduct medical research to use NOSS to access clinical trial information.

Participants of the platform:

Researchers
Submit clinical trial applications, seek ethics approval, choose a human research ethics committee, register clinical trials, and publish clinical trial results.

Clinicians
Find suitable clinical trials for patients and provide clear trial information to support discussion with them.

Health Facilities
Assess and manage research performance indicators, fulfill reporting obligations under the National Clinical Trials Governance Framework (NCTGF), and demonstrate capability to sponsors and medical institutions to attract clinical trial studies.

Trial Sponsors
Accelerate clinical trial applications and strengthen recruitment for industry sponsored trials; through a single clinical trial window, trials can begin within four to eight weeks.

Patients
Find clinical trials suitable to your condition and register to receive clinical trial information.

Source: National Science and Technology Council, NSTC Australia; PwC analysis

Australia

AI expediting clinical trials

Australia is actively integrating AI into clinical trials, enabling remote access to EHRs and patient data and using AI to identify eligible participants. Since enrollment shortfall is the main reason to delay studies and undermine data quality, the Australia government launched AI-assisted matching for lung cancer trials and achieved roughly 92% accuracy and 94% specificity.

In addition, the Queensland Government is partnering with multiple AI clinical-trial companies to accelerate the conduct of clinical trials:

Company	Contents
Opyl.ai	Develop TrialKey, an AI-based SaaS for clinical trial design and prediction that trains on historical trial data to simulate workflows, optimise designs, and reduce failure rates.
Clinials	Use AI to convert clinical trial documents into plain-language summaries and regulator-compliant reports, reducing review time by 40% and accelerating trial processes, communication, and execution.

Australian Tele trial Program

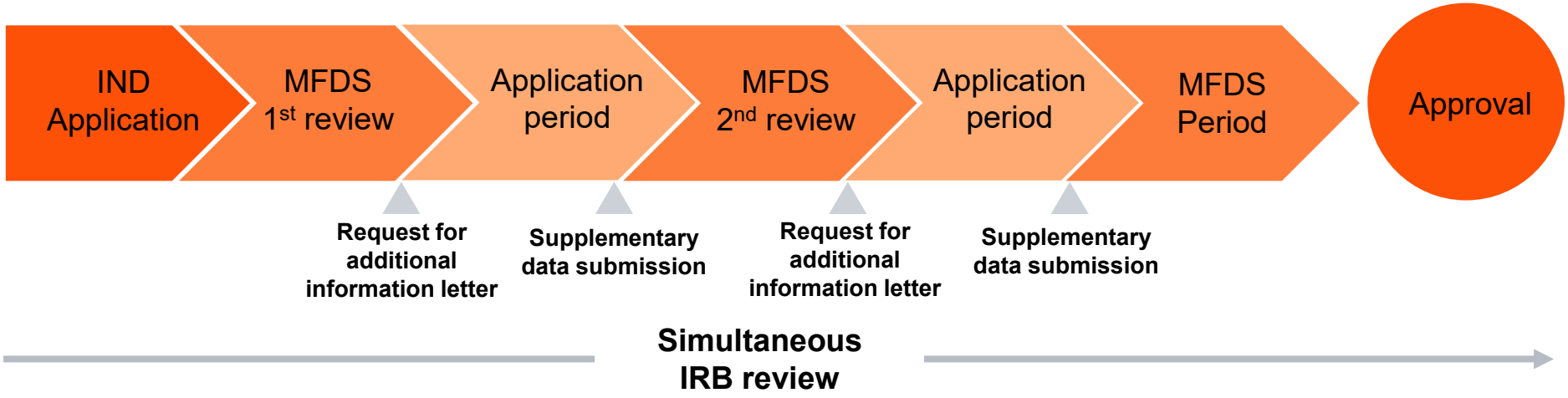
Australia is advancing decentralised clinical trials, including tele trials, to improve access for rural and remote populations where healthcare access and life expectancy lag; about 88% of trials occur in cities, limiting exposure to innovation. The 'Australian Tele trial Program' uses digital communication to link regional sites and researchers to primary trial centers, enabling participation outside urban hubs. Funded by the MRFF, it has invested AUD 75 million over the past five years in infrastructure to support tele trials.

Source: National Science and Technology Council, NSTC Australia; PwC analysis

South Korea

South Korea has introduced major measures to streamline clinical trial regulation, align internationally, and reduce IND review timelines to 30 days.

Trials require MFDS IND approval and IRB review, with IRB typically taking three weeks. For products targeting serious public-health threats, MFDS can designate them as “prophylactic crisis-response medical products” to accelerate IND processing, and IND and IRB reviews may run in parallel to further shorten timelines.



MFDS provides pre-submission consultations to companies developing innovative medical products, enabling them to assess the adequacy and suitability of data before filing an IND or NDA. Starting June 2025, MFDS has launched the’ Navigator Program for Innovative Products (혁신제품 길잡이 프로그램)’, selecting 20 promising innovations, including breakthrough drugs, cell and gene therapies, and novel medical devices, and assigning project managers to offer clinical and regulatory guidance throughout review to improve approval and launch success.

Source: South Korea (보건복지부 · The Ministry of Health and Welfare); PwC analysis

South Korea

1. Establish National Enterprise (국가임상시험지원재단 – Korea National Enterprise for Clinical Trials, KoNECT)

Designated in 2014 by the South Korean government under the 'Special Act on the Promotion of the Pharmaceutical Industry', KoNECT was established with public funding as a national support center. Its mission is to promote new drug development and attract international clinical trial activity to Korea. KoNECT drives domestic and overseas trials by mobilising investment, training professionals, and building clinical trial data resources. It also oversees several initiatives and programs, including:

Encourage and support international clinical trial initiatives in South Korea:

KoNECT convenes APAC and global stakeholders through the KoNECT-DIA conference, promotes technical exchange, and elevates Korea's clinical research profile. With the government, it drives accelerated and priority reviews and offers end-to-end support (design, monitoring, data) to aid execution. Funding and policy incentives attract multinational trials, advancing new drug and biotech development.

Regional Clinical Trial Centers (RCTC), initiative:

KoNECT has already set 8 RCTCs in Seoul, 3 RCTCs in Busan, and 3 RCTCs in other areas of South Korea. The added 15 RCTCs have handled over 60% of clinical trials in South Korea.

KoNECT clinical trial training academy:

KoNECT provides GCP training for investigators, CRCs, clinical trial pharmacists, CRAs, data managers/biostatisticians, and clinical pharmacologists. It is participating in the government's Smart Clinical Trials R&D program to deploy international best-practice technologies—digital tools for DCT, digital therapeutics, advanced medical products—and to integrate trial data, building a smart clinical trial environment in Korea.

Source: South Korea (보건복지부, The Ministry of Health and Welfare); PwC analysis

South Korea

2. Five-Year Comprehensive Plan for Clinical Trial Development (임상시험 발전 5개년 종합계획)

To promote the development of clinical trials in South Korea, strengthen global competitiveness, and realise a patient-centred vision for a leading nation in innovative drug R&D, the Ministry of Food and Drug Safety (MFDS) announced a five-year "Five-Year Comprehensive Plan for Clinical Trial Development" in 2019. The plan has three major goals:

Its 3 main objectives are:

Establish a clinical trial safety management system:
Develop measures to safeguard trial participants' safety and rights, improve the quality and management of clinical trials, and strengthen the independence and governance of clinical trial oversight.

Enhance the international competitiveness of clinical trials:
Improve the clinical trial review system, develop clinical trial guidelines aligned with international standards for innovative medicines, and strengthen the professional workforce through clinical trial execution support organisations (Site Management Organization, SMO).

Expand opportunities for patient treatment and establish a communication system:
Improve patient-centred review mechanisms for clinical-trial medicines. Work with KoNECT to co-host international conferences, broaden and strengthen international collaboration, and increase patients' opportunities to access medicines under development overseas.

3. Financial incentives to support the conduct of clinical trials

Tax incentives and pricing premiums for innovative new medicines

The 2016 tax amendments made Phase III clinical trial costs conducted in South Korea eligible for New Growth R&D tax credits. In 2023, Korea expanded National Strategic Technologies to cover certain biopharmaceutical innovations (including clinical-stage work), with R&D tax credit rates up to 20–40% for large and middle-market companies and 40–50% for SMEs. Separately, MOHW's 2016 pricing reform allows a "global innovative new drug" that shows improved clinical benefit and meets conditions (e.g., domestic trials and R&D investment) to receive up to a 10% premium over the highest-priced comparator and a faster listing/reimbursement timeline.

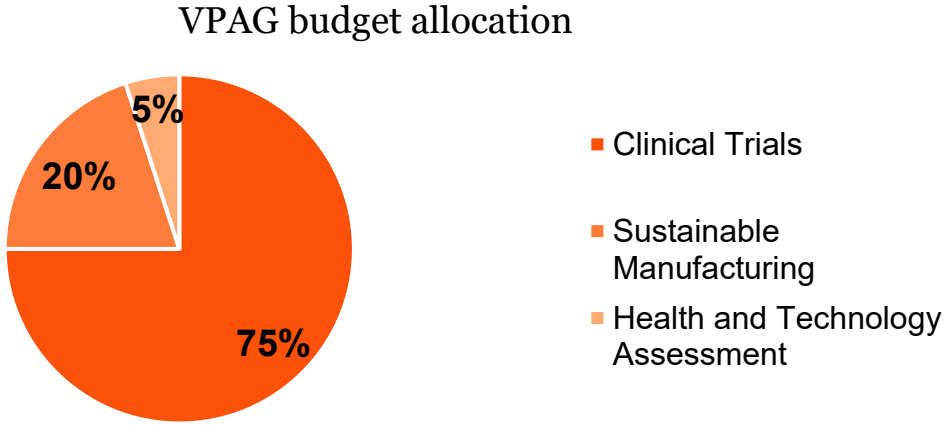
Source: South Korea (보건복지부 · The Ministry of Health and Welfare); PwC analysis

United Kingdom

VPAG investment programme (Voluntary Scheme for Branded Medicine Pricing, Access and Growth investment programme)

In 2024, the UK government and industry representatives agreed on the Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG). Under VPAG, an investment programme of up to £400 million will be delivered over five years. The programme is funded primarily by contributions from the pharmaceutical industry and is reinvested to support sector development, helping to maintain the UK's attractiveness as a destination for innovative-medicine clinical trials.

The VPAG Investment Programme will invest mainly in clinical trials, sustainable pharmaceutical manufacturing, and health technology assessment (HTA). Around 75% (approximately £300 million) will be allocated to expanding the UK's capacity and capability to deliver industry-/commercially sponsored clinical trials. The programme is expected to establish up to 18 new Commercial Research Delivery Centres (CRDCs), increasing opportunities for patients to participate in clinical trials. Researchers will also be able to access the latest equipment and technologies to design innovative studies across hospitals, community settings, and care facilities, improving the accessibility of clinical trials.



Note: Commercial Research Delivery Centres (CRDCs) support the decentralisation of clinical trials by extending studies to smaller hospitals and primary care facilities, improving patient recruitment and trial start-up efficiency in the UK.
Source: Department of Health and Social Care; PwC analysis

Hong Kong SAR

Establish One stop supporting service – Greater Bay Area International Clinical Trial Institute (GBAICTI)

Under China NMPA, Hong Kong seeks to accelerate the clinical trial industry to become an international authority in drugs and medical devices and to build a healthy Hong Kong, with a special focus on Phase I trials. The Greater Bay Area International Clinical Trial Institute GBAICTI, drawing on Malaysia's CRM as a primary liaison platform, provides coordinated resources and has independent operating funds to promote collaboration between sponsors or contract research organisations (CRO) and the Hospital Authority (醫管局), for example by coordinating ethics review applications and developing standard clinical trial agreements.

Establish a real-world research and application center and clinical research support office

Partner with Guangdong Province to run real world studies in the Greater Bay Area under the 'Hong Kong and Macao access policy (港澳藥械通)', and open data sharing to speed registration in Hong Kong, mainland China, and overseas.

'1+' mechanism for expediting new drug review

- Integrate review platforms and accelerate reform of approval systems for new drugs and medical devices.
- Allow conditional registration in Hong Kong for drugs treating serious or rare diseases with one reference approval from a recognised regulator, such as the NMPA from China, once local data and expert endorsement are met.

Visitor entry facilitation program

Using a 'one zone two parks' model, the institute will develop in tandem with Shenzhen and build a Greater Bay Area platform for clinical trial collaboration. It will support drug research and development at home and abroad and promote cross-border trials that meet international standards.

CRI Academy – bridge professionals to the industry

The institute partners with universities and hospitals, provides accredited training for clinical research coordinators, and offers consulting to specialty hospitals and university research centers.

Source: Greater Bay Area International Clinical Trial Institute (https://gbaicti.hk/), Hong Kong Science and Technology Parks Corporation(https://www.hkstp.org/en/), (Lau et al., 2023); PwC analysis

Singapore

One stop platform for clinical trial - National Clinical Trials Portal (CTSG)

In 2024 Singapore's CTSG was established by the Singapore Clinical Research Institute SCRI as a one stop platform that consolidates clinical trial information in Singapore. It is designed for patients, caregivers, clinical researchers, and companies. The platform explains the clinical trial process and the regulatory framework that safeguards patient safety and supports efficient trials. It makes information easier to access and understand and promotes innovation and better patient outcomes.

Patients:

Users can search clinical trials by specific health condition, quickly find relevant studies, and learn about the trial process, eligibility, and the benefits and risks of participation. The site is open to overseas patients. Those who wish to join a trial in Singapore can consult their physician and then use the contact details on the site to reach the trial team.

Clinical Research Professionals:

The platform connects clinical researchers, academic institutions, and industry partners, and provides information on local research grants and training opportunities for clinical research professionals.

Bio Database:

Clinical researchers can search for and apply to access samples relevant to their studies. The integrated database contains local and overseas specimens and imaging data, with collections dedicated to cardiovascular and oncology research. The large volume of data supports clinical research.

Source: Clinical Trials Singapore; PwC analysis

Malaysia

Ministry of Health of Malaysia clinical research center - Clinical Research Malaysia, CRM

CRM was established in 2012 by the Malaysian Ministry of Health as a one stop clinical research center management organisation. It provides comprehensive clinical research support services and aims to make Malaysia the preferred clinical trial hub in Asia.

Feasibility studies and researcher matching services

Assess studies referred by pharmaceutical companies or contract research organisations and forward them to investigators.

Budget consulting and management

Manage clinical trial budgets with full transparency and provide regular reports.

Clinical trial contracts review service and confidentiality agreements

CRM has a professional legal team that assists investigators and pharmaceutical companies with CTA and NDA reviews.

Expand the number of investigators and trial centers

Continuously cultivate potential investigators and trial sites to expand the clinical research network.

Training and allocation of CRCs

Recruit suitable candidates and provide training for qualifying research coordinators, then assign them to trial sites to assist investigators in conducting clinical trials.

Clinical research training

Plan subsidised training courses for investigators to improve their ability to conduct IITs.

Raise public recognition about clinical trials

Partners with patient groups and non-governmental organisations to promote clinical trials through advertising and positive media coverage and to support participant recruitment.

Industrial one stop service

Assist industry partners in resolving obstacles with government agencies and regulatory authorities that may impede the clinical trial review process.

Clinical trial promotion

Social media promotion to reach the target population precisely. People can complete a personal information form and submit it to CRM for screening.

Source: Ministry of Health of Malaysia; PwC analysis

India

Clinical Trials Registry- India (CTRI)

The Clinical Trials Registry of India is hosted by the National Institute of Digital Health and Data Science under the Indian Council of Medical Research (ICMR). It was formally launched in 2007 as a free online system for registering clinical trials conducted in India. Its mission is to ensure that every clinical trial in India is prospectively registered before the first participant is enrolled. Post marketing surveillance studies, bioavailability and bioequivalence studies, and clinical research conducted as part of a postgraduate thesis should also be registered in the registry. Its vision is to ensure that every trial in the region is prospectively registered and that all trial data items are fully disclosed. Although the registry is intended mainly for trials conducted in India, it also accepts trials from other countries in the region that do not yet have a primary registry of their own.

New Drugs and Clinical Trials Rules (NDCT), 2019

To promote domestic clinical research, raise trial quality and ethical standards, and accelerate drug development, India's Ministry of Health and Family Welfare issued the 'New Drugs and Clinical Trials Rules' in 2019. These rules establish the regulatory framework for new drugs in India, whether for research or sale, investigational new drugs, clinical trials, bioequivalence and bioavailability studies, the process for marketing authorisation applications, and the requirements for post marketing surveillance.

Beginning in September 2025, to simplify CTA and IND procedures for clinical trials, the ministry amended the NDCT, shifting from an approval system to a notification system and reducing the statutory processing time from 90 days to 45 days. At the same time, some bioavailability and bioequivalence studies are exempt from licensing requirements, aiming to enhance India's attractiveness as a preferred location for clinical research and further consolidate its position as a global hub for pharmaceutical research and development.

Source: Clinical Trials Registry- India, Central Drugs Standard Control Organization; PwC analysis

Message 3 : Economic Impact of Clinical Trials

Direct and indirect economic impacts from conducting industry-sponsored clinical trials for new drugs in Taiwan

Direct economic impact and investment

Indirect economic impact: reduce the annual loss of workers due to illness and restore the labour force

Direct and indirect economic impacts from conducting industry-sponsored drug clinical trials in Taiwan.

- **Industry sponsors in Taiwan have invested significant fundings** in equipment, talent, R&D, supply chain and software/hardware. (P.64)
- The **direct economic impact** brought by Taiwan's **biotechnology services sector**, including contract research organisations and contract manufacturing organisations, has an annual output of NT$14.72 billion and drives NT$700 billion a year in the biomedical industry. If Taiwan raises its clinical trial activity to surpass the level of Australia and South Korea, output could double, and more jobs would be created. (P.65)
- Clinical trials generate **indirect economic benefits**. In a breast cancer case, a new drug tested in Taiwan was then introduced faster and covered by National Health Insurance. As its indication expanded to include early-stage patients, this group saw **annual QALY gains** and many returned to work. Trials by a single new drug can raise annual GDP by **more than NT$100 million.** (P.66-67)
- It is found that introducing new drugs through clinical trials may reduce the annual loss of workers to illness. By restoring **labour capacity**, this could increase Taiwan's annual GDP by **more than NT$20 billion**. (P.68)
- Industry sponsored clinical trials speed the introduction of new medicines. They spur direct economic growth and deliver indirect gains. By aligning Taiwan's treatment practices with international standards, they improve **public health and productivity** and create a virtuous cycle.

Investments in clinical trial by sponsors in Taiwan

The six most active sponsors in Taiwan have invested over NT$8 billion in clinical trials over the past five years. Their resources extend across areas adjacent to clinical trials, the actual contribution far exceeds the headlines. These investments include funding in-hospital trial-related equipment, promoting talent development and international exchange, supporting early-stage research and innovation programs, strengthening the local supply chain and logistics, and introducing software and hardware for digital and wearable technologies that accelerates Taiwan's clinical R&D capacity.

Training programs

- Establish cooperation agreements with multiple universities to train future CRA.

Hospital partnerships

- Conduct clinical trials.
- Assist hospitals with talent development and international exchanges.
- Invest in in-hospital, trial-related equipment.

Research → **Training** → **Procurement** → **IT** → **Clinical setting**

Invest in early-stage research and innovation programs.

Provide R&D incentives to academic and research institutions to procure clinical trial reagents

Investment in digital

- Introduction of digital wearable devices
- Promote employment in software and hardware sectors

Source: public information from companies and business associations

Direct economic impacts and investment from industry-sponsored clinical trials

Clinical trials in Taiwan have driven growth in the biomedical industry and created economic output:

Taiwan's biomedical industry has an annual output of **700 billion New Taiwan dollars.**(1)

Biotechnology services total **14.72 billion New Taiwan dollars.**(1)**(including CRO&CMO)**

6.7%(1) **CAGR** **of biotechnology services industry**

If Taiwan surpass Australia and South Korea in the number of industry-sponsored clinical trials, doubled output is expected and more jobs will be created.

Over **5,800 PIs**(2)

and co-investigators of clinical trials across Taiwan in the past five years

Nearly **10 billion New Taiwan dollars** (3)

Economic output generated by research personnel due to increased clinical trial activity.

Source: (1) The Act for the Development of Biotech and Pharmaceutical Industry 2024, MOEA; (2)Taiwan clinical trial consortium, TCTC. https://www.taiwanclinicaltrials.tw/tctc
(3)PwC analysis

Indirect economic impacts – Economic model of productivity gains from new drugs

The model for disease-specific economic benefit is used to quantify the added value new drugs create for Taiwan by selecting several drugs with trials conducted in Taiwan, focusing on their different indications, and using QALYs to gauge their overall contribution to the economy.

Expected QALY gain per patient

HTA/literature reports

Extract QALYs for specific drug treatments from HTA assessments or clinical trial literature.

X

GDP Per Capita

IMF /Directorate-General of Budget, Accounting and Statistics

Use GDP per capita to quantify the economic value of each QALY.

X

Working age share of disease

GBD/Disease statistics report

Use the share of working age patients in this disease to estimate the actual rate of return to the labour market.

X

Expected number of benefited patient

IQVIA/MoHW /CDE data

=

Estimated productivity gain.

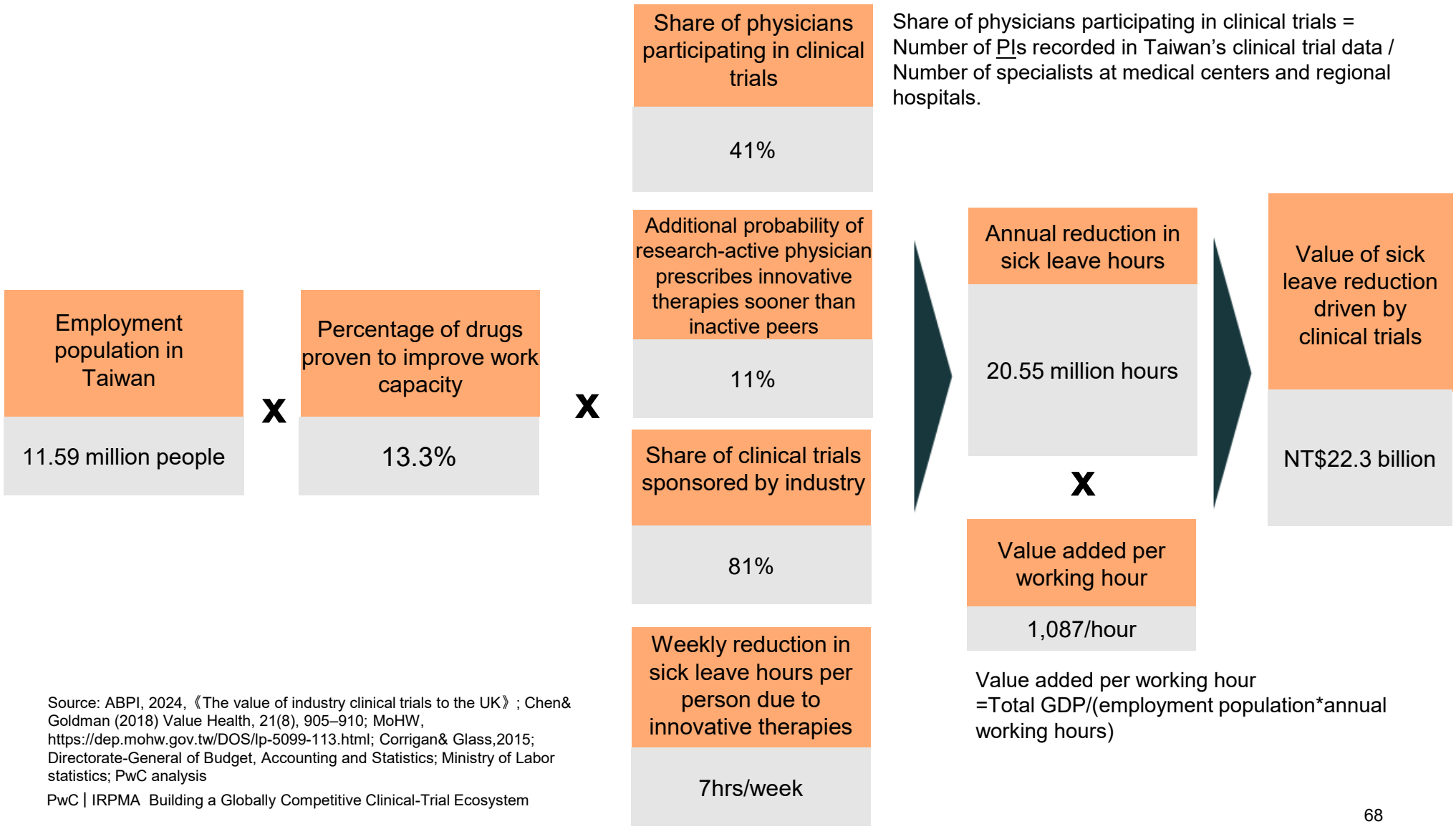
Source: PwC UK《Economic and societal footprint of the pharmaceutical industry in Europe》, 2019, PwC Taiwan analysed

Indirect economic impacts – Sponsor funding offsets for drug costs and increased productivity

The model for disease-specific economic benefit is used to quantify the added value new drugs create for Taiwan. Sponsors provide additional funding to healthcare costs, and recovered patients return to work and increase productivity.

Drug name	Estimate of sponsors' funding to offset healthcare costs	Estimate of productivity gains from patient recovery	Reference for QALYs
Durvalumab	**NT$1.36 billion+ (Data from 54 clinical trials)**	Small cell lung cancer (Over NT$1.5 billion)	**Liu K, Zhu Y, Zhu H el. Translational Lung Cancer Research. 2025;14(8):2942-2953.** Assess the cost effectiveness of durvalumab consolidation for limited-stage SCLC (LS-SCLC) patients without progression after concurrent chemoradiotherapy, using ADRIATIC phase 3 survival data, versus placebo or observation.
Pembrolizumab	**NT$1.32 billion+ (Data from 99 clinical trials)**	Early triple negative breast cancer (Over NT$2.1 billion)	The HTA for Keytruda Injection cites early TNBC evaluation data.
Olaparib	**NT$190 million+ (Data from 6 clinical trials)**	BRCA(+) early breast cancer adjuvant therapy (Over NT$150 million)	**Journal of Clinical Oncology 40, 6593-6593(2022)** Compare the cost-effectiveness of adjuvant Olaparib with standard adjuvant therapy without Olaparib in early breast cancer with germline BRCA mutation.
Dupilumab	**NT$52 million+ (Data from 9 clinical trials)**	Severe asthma patients (Over NT$3.2 billion)	**Health Economics Review vol 14: 67 (2024)** Using LIBERTY ASTHMA QUEST data, assess the cost effectiveness of adding dupilumab to standard therapy versus standard therapy alone in Korean patients aged 12 or older with uncontrolled severe asthma.

Indirect economic impact - Restore in workforce and reduce in workforce loss generating more than NT$20 billion to Taiwan's GDP each year



Share of physicians participating in clinical trials = Number of PIs recorded in Taiwan's clinical trial data / Number of specialists at medical centers and regional hospitals.

Value added per working hour =Total GDP/(employment population*annual working hours)

Source: ABPI, 2024,《The value of industry clinical trials to the UK》; Chen& Goldman (2018) Value Health, 21(8), 905–910; MoHW, https://dep.mohw.gov.tw/DOS/lp-5099-113.html; Corrigan& Glass,2015; Directorate-General of Budget, Accounting and Statistics; Ministry of Labor statistics; PwC analysis

PART II

Current Status of Clinical Trials in Taiwan

–Analysis of Taiwan's Clinical Trial Industry

Taiwan's clinical trial environment – Competitiveness, cycle times, and opportunities

Taiwan was once a leading country in Asia for clinical trials but is now gradually being surpassed by other countries across various indicators. In response to this challenge, this study surveyed 16 pharmaceutical companies that conduct trials in Taiwan and abroad and 5 contract research organisations (CROs). It examines the competitiveness of Taiwan's clinical trial industry, the cycle times at each stage relative to international benchmarks, and issues related to investment and employment opportunities in clinical trials in Taiwan.

The survey asked these 16 pharmaceutical companies and 5 CROs about the strengths of Taiwan's clinical trial environment, the difficulties and challenges they face, and their recommendations. The findings aim to provide more comprehensive guidance for policy makers. This part presents 3 areas of discussion, an overview of industry operations, an analysis of industry competitiveness, and directions and strategies for industry development.

Based on the survey results, we proposed key challenges in Taiwan's clinical trial environment and proposed strategic recommendations to improve trial quality, enhance policy predictability, and expand international collaboration and investment.

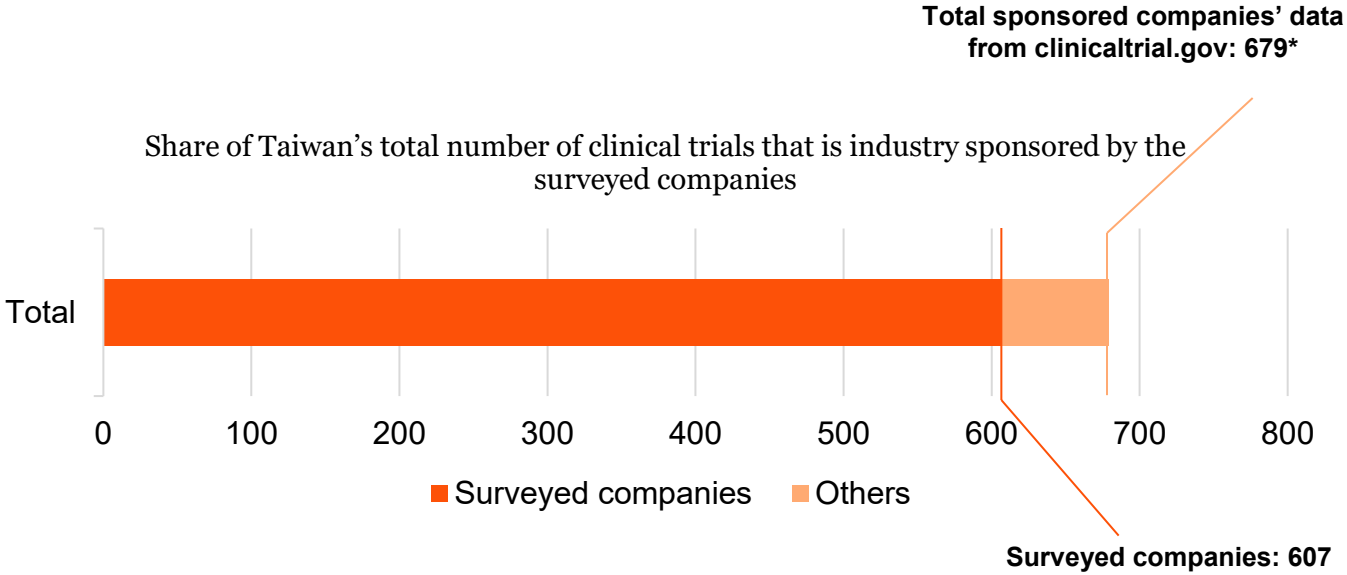
Clinical Trial Industry Competitiveness

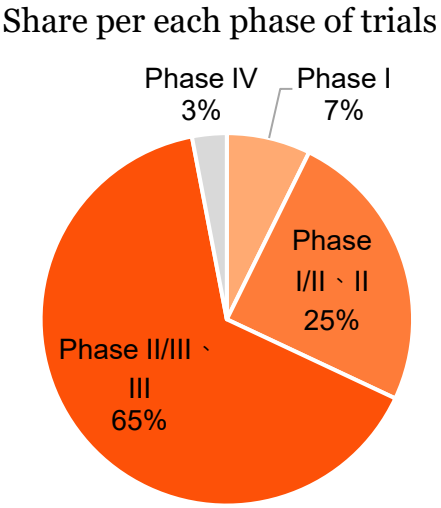
Operating Cycle Time

Investment and Opportunities

Current Taiwan clinical trial environment – Survey of pharmaceutical and CRO companies

Companies surveyed in this study are sponsoring over 600 ongoing clinical trials, accounting for about 90% of industry-sponsored drug trials in Taiwan, showing a representative sample. Although information provided by the companies and data from external databases may differ due to variations in trial categorisation or data entry methods, trend observations show that the distribution of clinical trial types and the number of trials in Taiwan have not changed significantly over the past three years (2023–2025). Of these, Phase I–Phase II trials account for about 30%, while Phase II/III and Phase III trials account for over 60%.



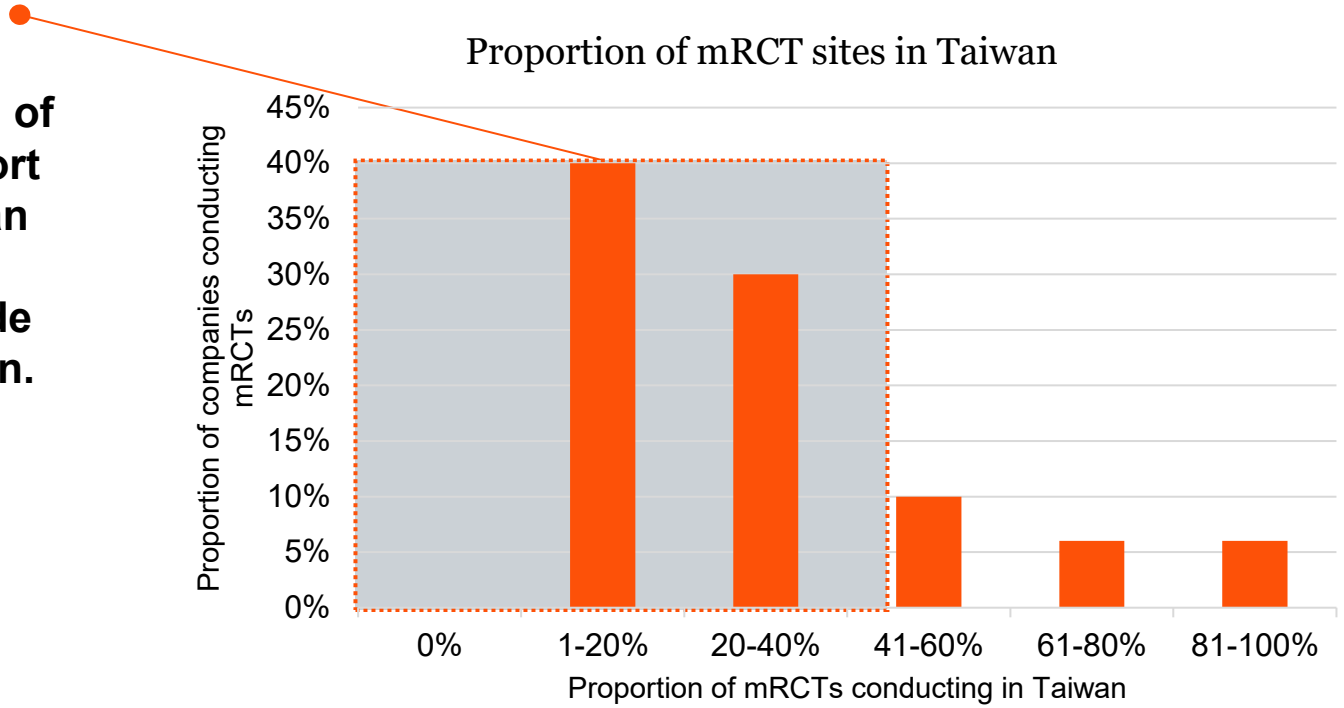


*Total sponsored companies' data refers to ClinicalTrials.gov
Source: PwC questionnaire; PwC analysis; MoHW website

Industry competitiveness overview – Proportion of mRCTs clinical trials with sites in Taiwan

Survey results indicate that for more than 70% of pharmaceutical companies and CROs, fewer than 40% of their mRCTs include sites in Taiwan. Although some sponsors attribute this to market size, evidence from Part I shows that countries with populations comparable to or smaller than Taiwan, such as Australia, Singapore, and Israel, have a higher share of mRCTs among all trials. Sponsors most often cite three reasons for not placing studies in Taiwan: limited numbers of eligible participants, no plan to launch in Taiwan, and complicated start up and contracting processes. A detailed breakdown of these reasons appears later in the report. (Reasons for not conducting trials in Taiwan)

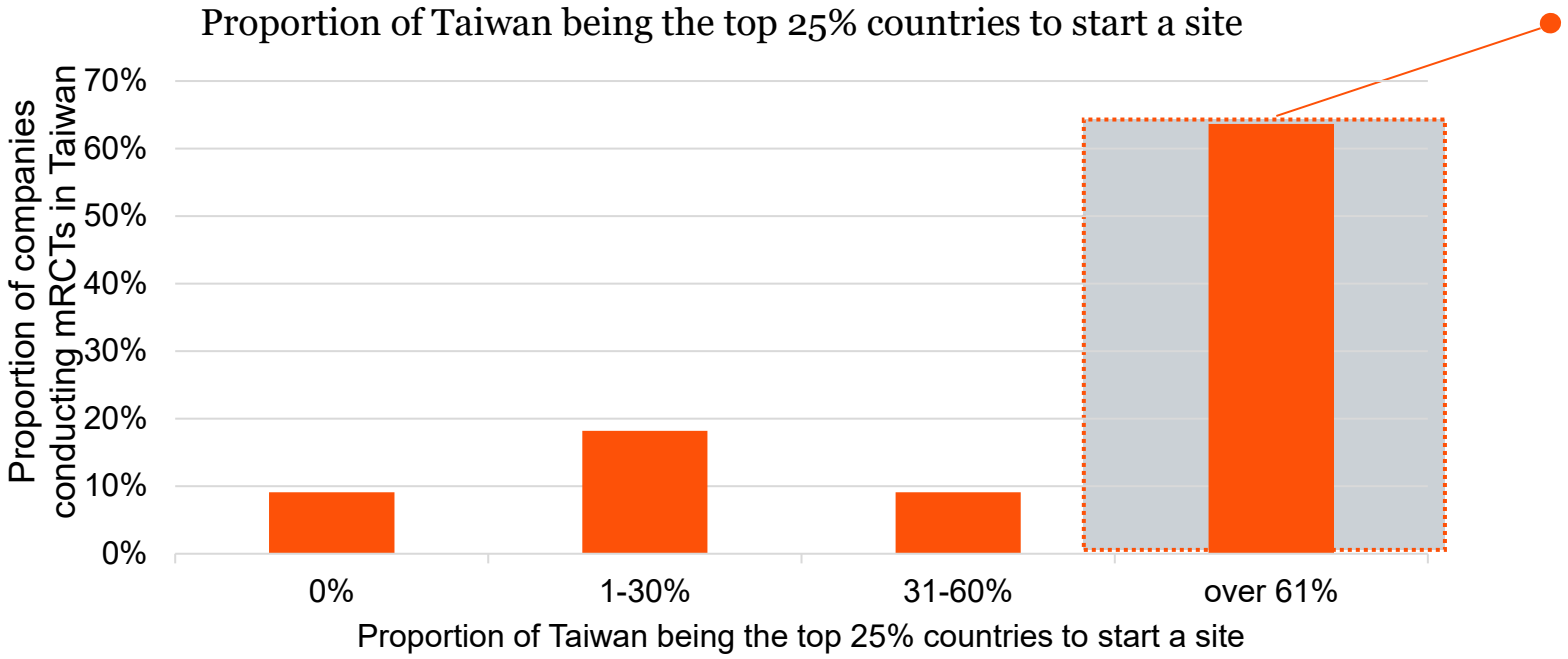
More than 70% of sponsors report that fewer than 40% of their mRCTs include sites in Taiwan.



Source: PwC questionnaire; PwC analysis

Industry competitiveness overview – The proportion of Taiwan ranked in the top 25% countries to start a site

A majority (nearly 70%) companies conducting mRCTs in Taiwan reveals that in over 60% of these trials, Taiwan ranked in the top 25% countries to start a site. This indicates that, given Taiwan's strengths in a high-quality healthcare system, and cross-sector advantages, it is highly attractive for multiregional clinical trials.



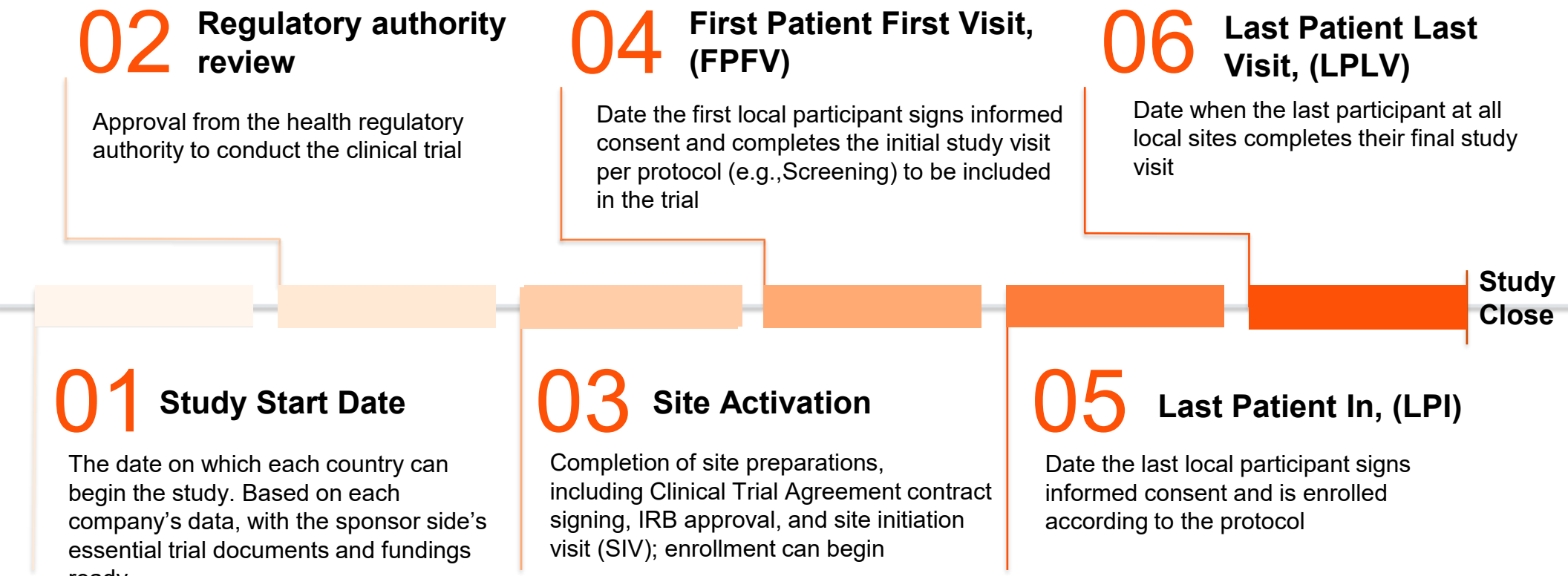
Taiwan is likely (more than a 60% chance) to be in the top 25% countries to start a site, revealed by a majority of companies

Source: PwC questionnaire; PwC analysis

Industry competitiveness overview – Operating cycle time milestones

Each stage of a clinical trial carries distinct significance. Start-up time not only directly affects how quickly patients can access new medicines, but also a key factor sponsors consider when selecting trial sites. Start-up typically hinges on administrative procedures such as regulatory review, contracting processes, and enrollment speed.

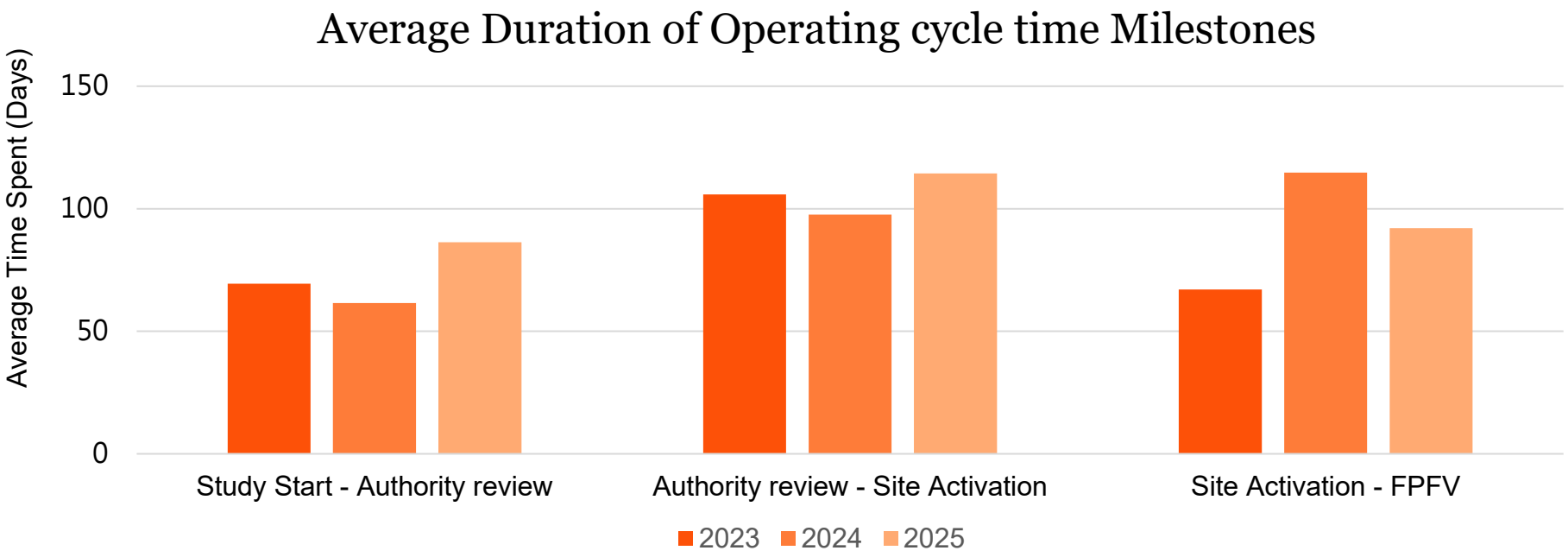
To better analyse the time required at each step, we divided the total duration from trial initiation to completion into six segments. We surveyed sponsors on the time spent in Taiwan, across the Asia-Pacific region, and globally for each segment, and compared the past three years of durations to identify Taiwan's relative advantages and disadvantages.



Note: Study closeout is defined as the completion of local database lock (DBL), followed by statistical analysis, report writing, QA approval, finalization of the clinical study report, and submission of the final report to the regulatory authority. Source: PwC questionnaire; PwC analysis

Average time spent on clinical trial start-up milestones – Trend in Taiwan from 2023 to 2025

Due to that the timeline after the enrollment of participants are greatly varied by disease type, this section focuses on the time spent before a trial begins. The full trial cycle is presented in the Appendix. We examine the average time spent at each milestone in the Taiwan clinical trial start up cycle and how it changed from 2023 to 2025. The time required at each milestone in Taiwan remained steady. However, comparing the timing of each step with global and Asia Pacific trends, we further analyse the key bottlenecks to strengthen Taiwan's clinical trial process.

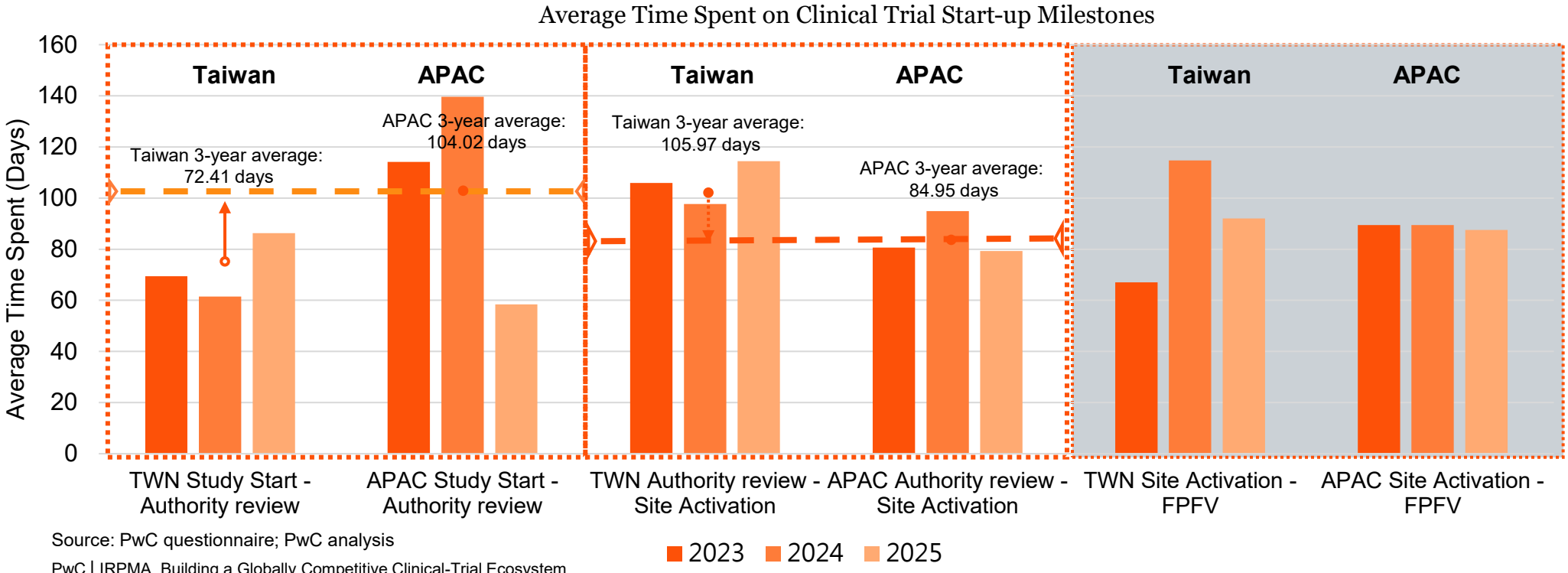


This study reports both the mean and the median; either measure shows the same trend. The mean is presented here primarily to reflect the impact of longer waiting times on the overall efficiency of clinical trials. Source: PwC questionnaire; PwC analysis

Average time spent on clinical trial start-up milestones – Taiwan vs. Asia-Pacific Comparison, 2023 to 2025

First, we compare the time spent at each milestone in Taiwan (TWN) and in the Asia Pacific (APAC). The figure shows the time from study start to health authority review, from authority review to site activation, and from site activation to FPFV, which is the first patient first visit.

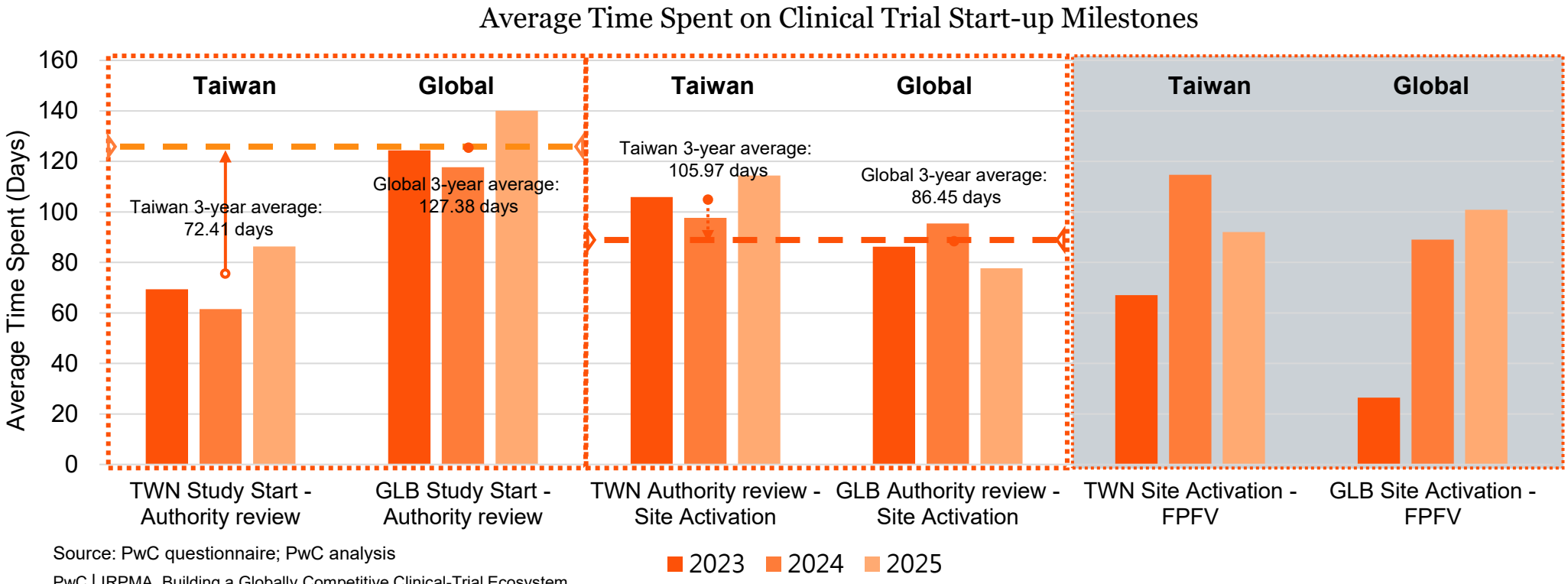
Over the past three years Taiwan has had a shorter interval from study start to health authority review than the Asia Pacific average, but a longer interval from authority approval to site activation. The Asia Pacific has recently shortened health authority review times, reflecting a regional push for faster trial start up to attract international studies.



Source: PwC questionnaire; PwC analysis

Average time spent on clinical trial start-up milestones – Taiwan vs. Global Comparison, 2023 to 2025

We then compare the same time window for Taiwan and the global average. Taiwan has a considerable advantage in the time from study start to health authority review, whereas the time from health authority approval to site activation is longer. This can be attributed to mature and international regulations in Taiwan. Taiwan should enhance this strength and accelerate the site activation process to gain attractiveness.



Source: PwC questionnaire; PwC analysis

Investments and opportunities – Clinical trials industry in Taiwan can scale NT$30 billion annually

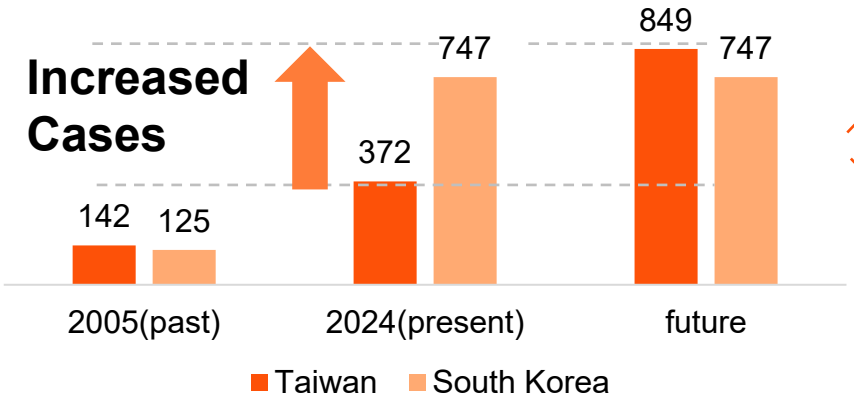
In the PwC questionnaire, we compiled statistics on the composition of core personnel positions required for clinical trials, as reported by various trial sponsors. It summarises how clinical trials not only drive the development of new drugs but also help retain professional talent and the economic value of high-value-added services locally. Back in 2005, according to clinicaltrials.gov, Taiwan surpassed South Korea in drug clinical trial numbers (142 vs 125), and by percentage of 14.5%. Taiwan has the potential to surpass Asia peer countries (like South Korea) and reaching over 800 clinical trial numbers per year, generate job value for NT$1.2 billion, and generate more than NT$33 billion in additional direct output and biotech jobs.

Taiwan surpassed South Korea by 13.6% 20 years ago

Now South Korea surpasses Taiwan

Goal: Surpass peer countries and establish Global Clinical Trial Hub

Annual mRCT applications



Industrial benefits

Value of clinical trial services

NT$ 14.72 billion in 2024

Reach 800+ clinical trials annually
Benefit Economic Growth

Increase in job opportunities

600+ jobs

Employment benefits*

Expected Industry benefits

NT$ 33 billion+ annually

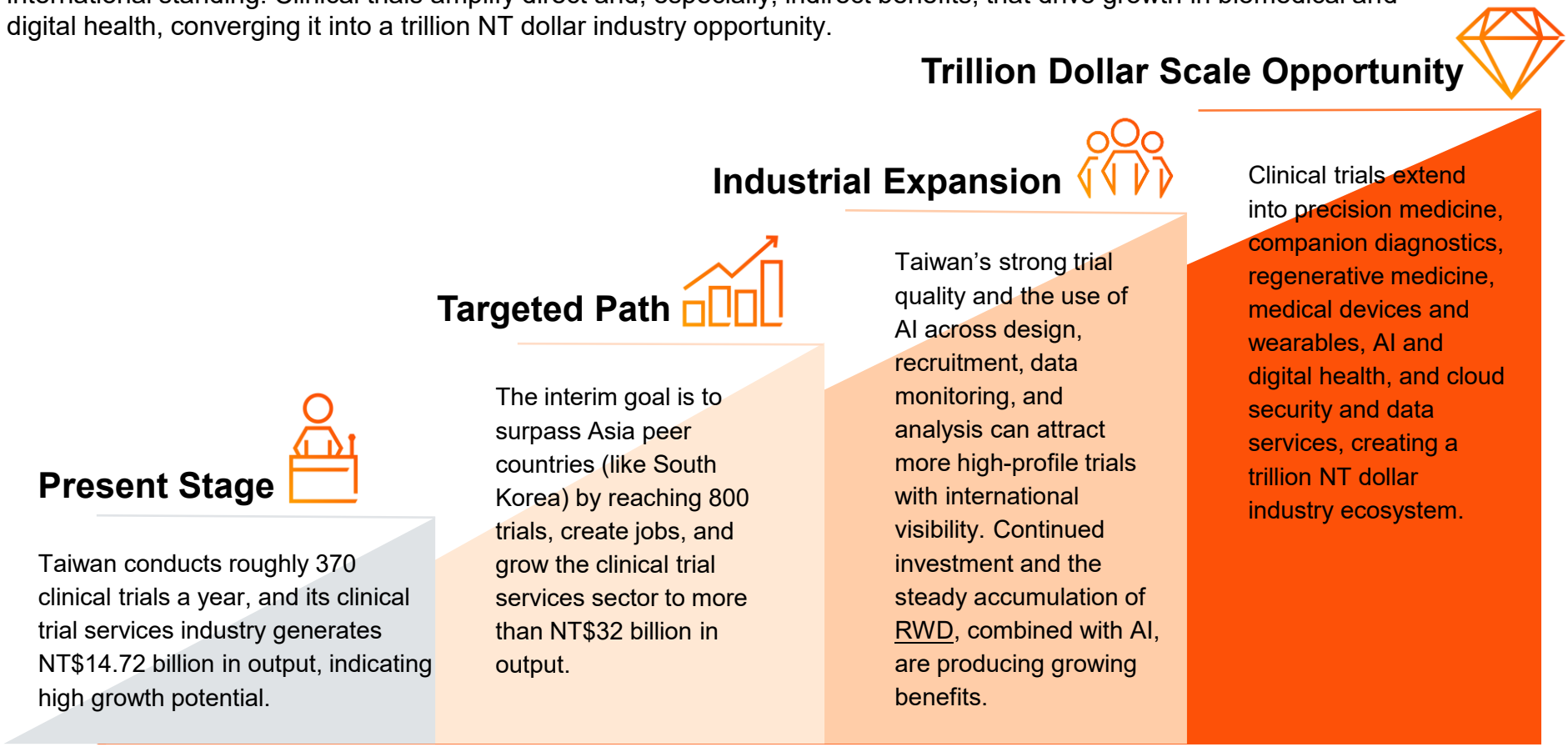
Job Value

NT$ 1.2 billion+ annually

*Note: Estimates of employment benefit and core value is listed in the appendix;
Figures for Korea's 2024 clinical trials are based on the latest data released by KoNECT, including cases currently under application.
Source: 2025 Yearbook of applied biotechnology industry; ClinicalTrials.gov; KoNECT; PwC questionnaire; PwC analysis

Investments and opportunities – Amplified billions of NT dollars output scaling trillion NT dollars of opportunity

Clinical trials are knowledge and data intensive, generating clinical evidence assets trusted by regulators and markets worldwide. They advance precision medicine, companion diagnostics, regenerative medicine, medical devices and wearables, and data and RWE products, strengthening Taiwan's industry from R&D to commercialisation and its international standing. Clinical trials amplify direct and, especially, indirect benefits, that drive growth in biomedical and digital health, converging it into a trillion NT dollar industry opportunity.

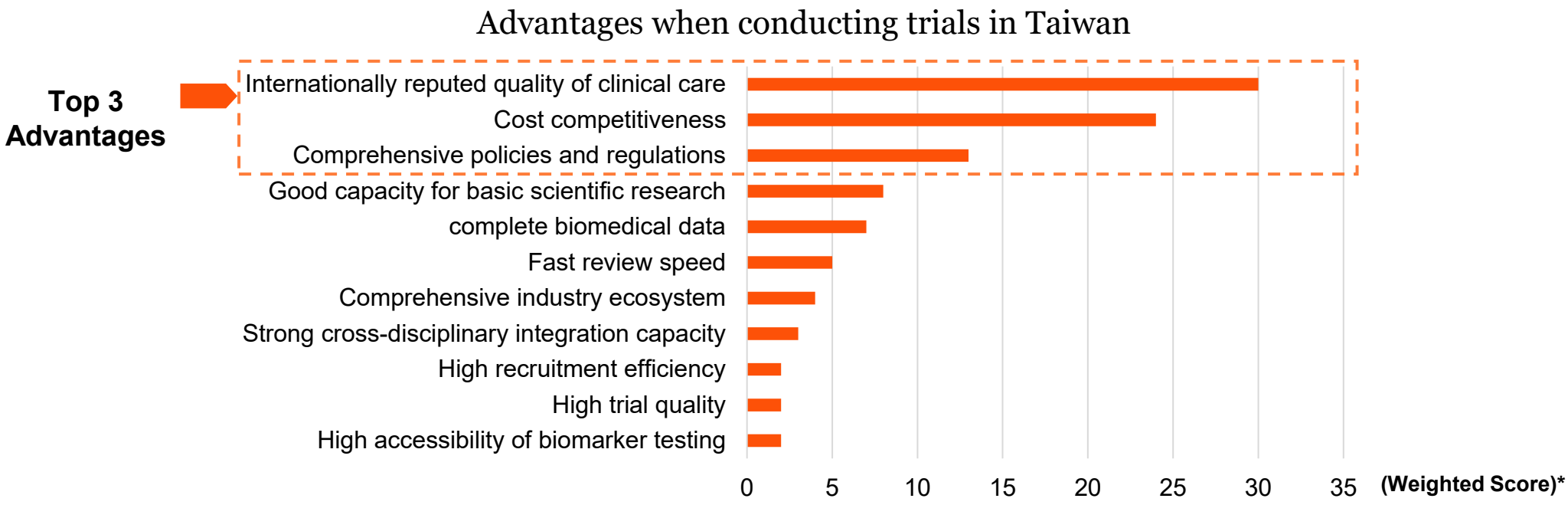


Source: abpi (2025), Creating the conditions for investment and growth ; PwC questionnaire; PwC analysis

Industrial analysis – Advantages when conducting trials in Taiwan

This study compiled industry respondents' answers on the advantages and disadvantages of conducting clinical trials in Taiwan to understand how trial sponsors decide where to conduct trials. The rank order of responses (first-, second-, and third-ranked advantages) was used for weighted calculations*.

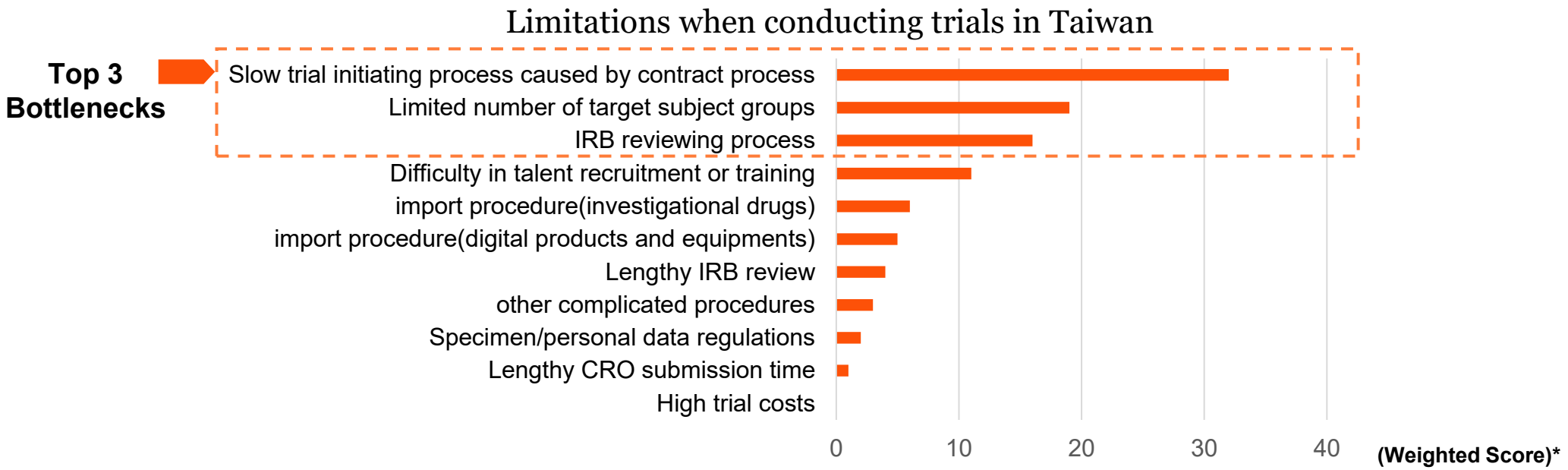
Over ninety percent of sponsors identified Taiwan's international reputation for the quality of clinical care as the top advantage, and over sixty percent regarded it as the single most prominent strength. More than sixty percent consider trial costs to be strongly competitive, which ranked second after weighting. The third ranked advantage was Taiwan's well developed regulatory policies for the clinical trial industry, with thirty percent of sponsors viewing regulatory strength as the principal source of competitiveness.



*Note: Weighted scores for each item are calculated based on the top three rankings. First place receives 3 points, second place receives 2 points, and third place receives 1 point. No rankings receive 2 points.
Source: PwC questionnaire; PwC analysis

Industrial analysis – Limitations when conducting trials in Taiwan

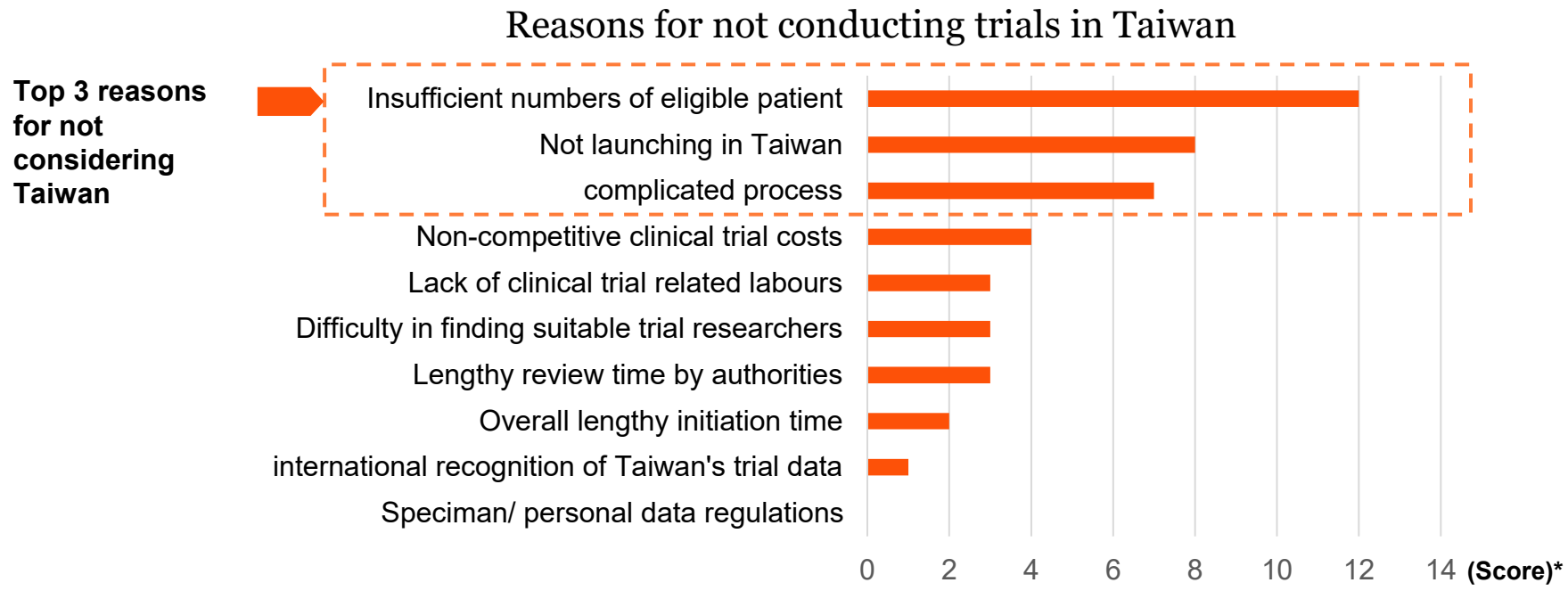
In our survey of industry bottlenecks, sponsors identified three main weaknesses in Taiwan's clinical trial environment: slow initiation process caused by contract process, limited numbers of target participants, and lengthy IRB review. 90% cited complicated contracting as a bottleneck, about half cited insufficient participants, and 40% pointed to IRB review. Several sponsors added that for the Taiwan market, an accumulation of complicated procedures is a major barrier, including the lack of automatic mutual recognition in the central IRB system, which forces sponsors to resubmit to secondary reviewing hospitals and causes delays. Other complicated steps include approvals from biosafety and radiation protection committees, hospital administrative procedures, permits for importing and exporting specimens and test reagents, and processes under the NCC and BSMI, all of which create significant friction. Therefore, the greatest obstacle in Taiwan's clinical trial system is the complexity of administrative procedures, rather than demographic factors. Timelines at each stage are longer compared with the Asia-Pacific region and even globally. Taiwan should leverage its advantage of faster early-stage trial initiation and address shortcomings in administrative processes to make the overall clinical trial environment more attractive.



*Note: Weighted scores for each item are calculated based on the top three rankings. First place receives 3 points, second place receives 2 points, and third place receives 1 point. No rankings receive 2 points. Source: PwC questionnaire; PwC analysis

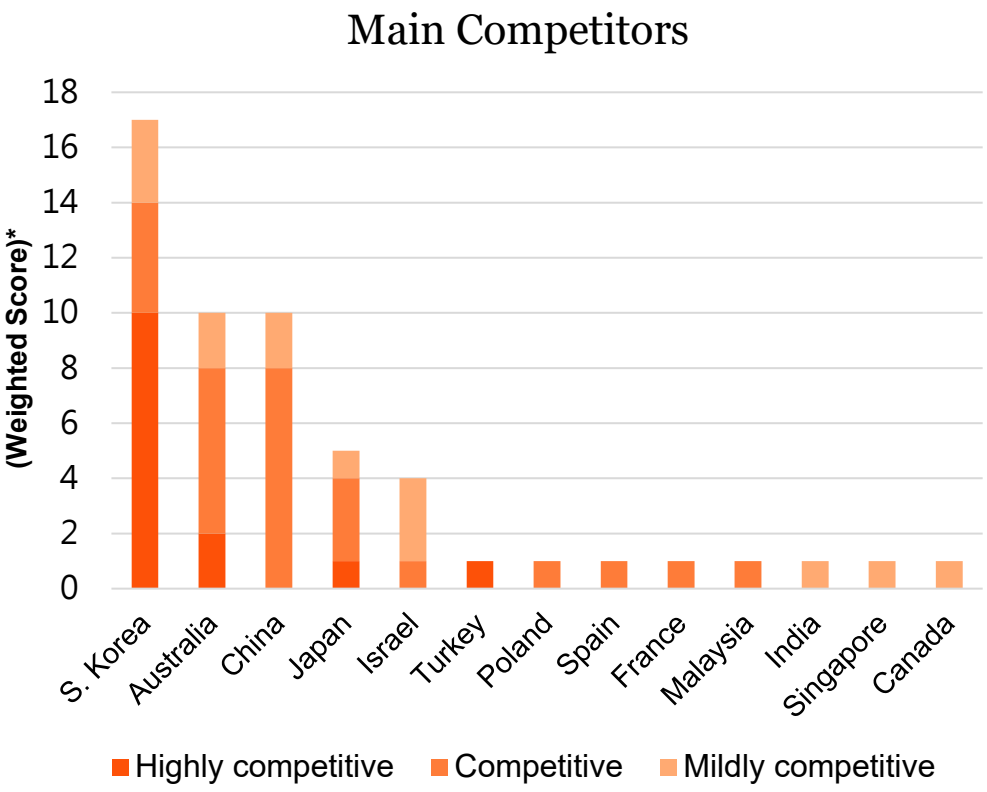
Industrial analysis – Reasons for not conducting trials in Taiwan

The survey of weaknesses examined why sponsors are reluctant to run clinical trials in Taiwan or find it hard to win trials. The top reasons, in order, are insufficient numbers of eligible patients, not launching in Taiwan, and complicated process. Besides Taiwan's population size and disease prevalence, decisions of not launching including regulatory and reimbursement timelines, uncertainty in HTA and drug pricing, acceptance of cross-border data, and supply and commercial footprint. Therefore, the policy makers should focus on building a single window with standardised review models and budget negotiation, defined IRB timelines, electronic approvals and streamlined import and export procedures, and stronger data governance with predictable international inspections. When start up speed, process transparency, and compliance quality improve markedly, Taiwan’s site attractiveness in mRCT trials can rise even with a limited patient base and launch decisions driven by commercial considerations.



*Note: Cumulative score for multiple-select questions.
Source: PwC questionnaire; PwC analysis

Industrial analysis – Key competitors for mRCTs in Taiwan



Note: Weighted scores for each item are calculated based on the top three rankings. First place receives 3 points, second place receives 2 points, and third place receives 1 points. No rankings receives 2 points.

Source: PwC questionnaire; PwC analysis

In comparing to future competitors, pharmaceutical companies and CROs broadly identify South Korea as the main competitor, with about seventy percent viewing it as the primary competitor; about sixty percent consider Australia a competitor, and roughly sixty percent of those rank Australia second; about fifty percent see China as a competitor; others also point to Canada, Turkey, India, Poland, and Spain. Evaluation criteria extend beyond population size and ethnic comparability to include ethics and regulatory processes, government measures and subsidies, cross hospital collaboration, and patient enrollment capacity.

Refer to PART I - Message 2 : International comparative case studies, major competitor countries have strengthened their clinical trial environments through clear policy actions. South Korea and Australia have used strong incentives such as tax credits, trial grants, and single window services to keep companies and trials local. If Taiwan does not respond in time and scale up, international projects and high value trials may shift abroad, leaving the country at risk of declining share and reactive competition over the next three to five years. This demands serious attention.

To compete globally, Taiwan can leverage its high diversification in East Asian ethnicities and high clinical trial quality, combined with strong digital capabilities, to achieve differentiation and maintain and improve international competitiveness in clinical trials over the next three to five years.

Industrial analysis – Key challenges for Taiwan's clinical trial industry

Based on the survey, the key challenges in Taiwan's clinical trial environment identified by pharmaceutical companies and CROs are outlined below as reference points for regulatory improvement:

1. Regulation and processes

- Import procedures for investigational drugs, test reagents, and equipment are lengthy and require multiple approvals.
- Despite a c-IRB system, review process remains time-consuming. Inspection standards should be more closely aligned with international practice*.
- Processes involve many checkpoints, including the biosafety committee, the radiation safety committee, and agencies such as the NCC and BSMI.

2. Hospitals and execution aspects

- Clinical trials are concentrated in teaching hospitals and are hard to extend to the community.
- Principal investigators have difficulties balance between clinical workload and clinical trial.
- Administrative and contract processes are not streamlined, hospital IRB and contract reviews are lengthy, and hospital budgeting and payment procedures vary widely.

3. Participant sources and social aspects

- Small population base, limited eligible participants, and lack of referral mechanisms.
- Public awareness and participation rates of clinical trials are low.
- Limited outreach reduces acceptance.

4. Data and technology

- The NHI database and the cancer registry provide a foundation, but RWD integration and legal authorisation are insufficient.
- Electronic signatures and digital applications have low adoption, and AI use remains limited.

5. International visibility and talent

- Taiwan is often seen as a support market and has not yet become an international hub; there is still great potential to increase enrollment numbers.
- Taiwan should have more next generation young principal investigators with international standing.
- Study nurses and research staff talent shortage.
- Collaboration among industry, government, and academia and global visibility need to be strengthened.

*For example, under Australia's National Approach to Single Ethical Review, ethical review is provided by only one National Human Research Ethics Committee using certified ethical review processes. Each institution collaborating in a multi-centre project utilising the outcome of a single ethical review must individually authorise the commencement of research at their institution.

Industrial analysis – Strategic countermeasures for challenges

Based on current challenges, the following are key strategic recommendations in response:

One-Stop Platform

- Establish a single communication window
- Raise the level and clearly define services and lines of responsibility and jurisdiction.
- Managed by PM specialties

Legal regulation

- Use AI to assist pre review of IND and IRB documents and speed the process.
- Strengthen the quality of clinical trial operation by the CROs.
- Consider clinical trial review timelines in hospital accreditation.

Hospital Side

- Dedicate hospital revenue from clinical trials to support internal trial development, including staff pay increases, funding for IITs, and upskilling of regulatory affairs staff.
- Relax pay rules in public hospitals.

Talent & Education

- Design a national clinical research training program.
- The government should actively attract key talent in regulatory and health technology assessment.
- Professional societies should run courses that grant continuing education credits.

Patient Recruitment Platform & Referral Mechanism

- Integrate patient data within each institution to quickly generate candidate lists.
- Use disease alliances or cross hospital referral platforms so each hospital can see potential recruits in real time.
- Consent forms for trials and patient information should state the purpose and use digital signatures, with de identification and controlled relinking for traceability.

Data Interoperability

- Set data exchange standards for hospital eCRF connection

International Recognition Strategy

- Build leading research units and talent and leading therapeutic areas.
- Emphasize the advantages of doing trials in Taiwan as a microcosm of East Asia, with low costs, high quality data, and high-quality medical care.

New Drug Reimbursement

- Raise the effective reimbursement price for investigational drugs
- Increase new drug investment

Tax Incentives

- Tax refund or fiscal subsidy for trial sponsors

PART III

Future Visions and Strategic Recommendations for Clinical Trials

KOL perspectives

To assess the opportunities and challenges for Taiwan clinical trial ecosystem comprehensively, we interviewed 35 experts spanning healthcare institutions, policymakers and implementers, professional societies, patient groups, researchers, and industry. We examined five core themes—current perspectives, key bottlenecks, strengths, weaknesses, and concrete recommendations. This multi-stakeholder panel is designed to capture a broad range of views and to generate practical, feasible proposals for improving policy and the industrial environment.

Beyond highlighting Taiwan's latent competitiveness, the findings offer actionable guidance for government decision-making to accelerate the development of the biomedical industry. Taiwan's robust healthcare system, extensive National Health Insurance data, and strengths in IT provide a strong foundation. By further developing the clinical-trial ecosystem, Taiwan can unlock substantial gains in R&D investment, job creation, and economic output.

01

Taiwan's current challenges and opportunities

02

Taiwan's clinical trial regulatory framework and enhancing efficiency

03

Taiwan's clinical trial leadership talents and professional ecosystem

04

Taiwan's industrial collaboration strengths and international cooperation

05

Clinical trials as a national strategic investment for a Healthy Taiwan.

KOL perspectives – Challenges and development of Taiwan's clinical trial industry

Taiwan's clinical trial volume, especially industry sponsored and early phase (Phase I and Phase II) studies, has room to improve to compare with peer countries such as Australia and South Korea. This shows underinvestment in health research and development. Key obstacles include slow startup caused by complex administrative process, pressure from the hospital global budget system, weak financial rewards for physicians, and shortages and high turnover of SCs, CRAs, and investigators. Experts recommend treating clinical trials as a strategic national investment by introducing strong fiscal incentives such as tax refund, creating a high level cross ministerial one stop platform, enabling the secondary use of National Health Insurance data and effective utilisation of biobank data, and standardising EMR formats. Using Taiwan's information technology strengths to improve speed and efficiency would help attract first wave multinational multicenter trials and strengthen international competitiveness.

Administrative and legislatives

The process need a high level one stop service, assist cross ministerial administrative integration, such as the Customs and the NCC. In addition, IRB review needs speed up and integration. The contract review standards and budgeting processes need further improvements.

Healthcare management

The current national health budget system need to be revised to unlock hospitals' potential for clinical studies. Further needs a cross-hospital referral system to enhance enrollment efficiency.

Talent development and investment

Talents need to be fully utilised, including through funding for investigator-initiated trials (IITs), intellectual property protection, and salary rewards. Clinical trial coordinator staffing and compensation structures need to be refined. The government should view clinical trial spending as an investment rather than an expense.

KOL Perspectives – Taiwan's Clinical Trial Regulation Structure reform and efficiency optimisation

01 Establish a high-level coordination mechanism and a one-stop platform, and reform the hospital's financial and administrative systems

Taiwan has the potential to reform its clinical trial ecosystem. The main hurdles include slow contracting, fragmented administrative and regulatory processes, multiple review checkpoints, and a lack of effective financial incentives for researchers, foreign companies, and pharmaceutical firms. The biotechnology sector also needs more resources and talent and urgently requires institutional reform.

Several recommendations focus on institutional reform and improving efficiency:

1. Establish a high-level coordination and integrated one stop platform

- A high-level coordinator (e.g., Executive Yuan) must be appointed to promote the establishment of the "Taiwan Clinical Trial One Stop Shop". This platform will integrate the entire process including IND, IRB and contract management and provide trial sponsors with a transparent timeline.
- Learn from international experience. Taiwan should enhance multi-centered IRB review cases and formulate a standardised contract review format to accelerate contract negotiations across hospitals.

2. Reform financial and administrative systems

- Raise the level of Clinical Trial Centers (CTCs) in hospitals and establish them as formal units to enhance their resource allocation and decision-making authority.
- Digital infrastructure should be strengthened, with the National Health Insurance Administration leading the promotion of a unified electronic medical record (EMR) format and integrating existing information platforms into the "My Health Bank" to facilitate patient recruitment and information flow.

KOL Perspectives – Taiwan's Clinical Trial Regulation Structure reform and efficiency optimisation

02 Learn from successful international models to enhance Taiwan's global attractiveness for clinical trials.

Since most of Taiwan's challenges are fundamental structural issues, experts recommend learning from successful international cases and emulating suitable models to improve Taiwan's clinical trial environment across institutional design, execution, and financial incentives.

1. International models for institutional reform

- Learn from Japan's experience to build a clear, rigorous, industry-wide framework, and recruit experienced industry professionals and experts to bring fresh perspectives and enhance resilience.
- Learn from the United States' national strategy: maintain a consistent stance on strategic priorities and a clear roadmap for clinical trial development to boost biotechnology innovation.

2. International models for executional reform

- Learn from South Korea's KoNECT model to establish an integrated clinical trial "enterprise" that supports cross-institutional enrollment, and upgrade digital platforms to provide comprehensive data, enable end-to-end integration, and accelerate administrative processes.
- Learn from Singapore's CTSG. Despite a smaller population, Singapore is actively building a one stop system with a clear goal to become the Asia Pacific clinical trial hub. Taiwan should set clear targets that leverage its unique genomic data and industry strengths, for example as a center for high value trials or for specific disease areas.

3. International models for fiscal reform

- Learn from Australian model and offer more attractive incentives. The Australian government invests significant fundings for clinical trials and provides cash tax refund incentives for spending on industry sponsored trials. This is more appealing than Taiwan's current income tax R&D credit, which only profitable firms can claim, and it is especially helpful for new drug developers that are not yet profitable.

KOL Perspectives – Taiwan Clinical Trial Leadership Talent Establishment and Professional Training System

03 Establish industry talent training programs and courses, promote investigator-initiated trials, and increase investigator retention.

Only with sufficient talent can Taiwan unlock its competitiveness in clinical trials. Current challenges include shortages and high turnover among study coordinators and study nurses. Incentives for principal investigators should be increased, and early-career physicians should have more opportunities to serve as principal investigators.

Reform should focus on systemic incentives and industry certification:

1. Industry certification and global attention

- Taiwan should establish a CRO quality evaluation system, and the government should enhance quality management for sponsors and CROs to ensure sponsors' responsibilities are properly executed, thereby strengthening clinical trial execution quality.

2. Talent acquisition and training

- The government should promote clinical trial training to expand the workforce and increase talent and introduce a professional certification system to raise standards and ensure quality.
- Universities should add clinical trial courses to nursing, pharmacy, and life science programs to build a stable talent pool and address shortages of study coordinators and clinical research associates. Singapore’s approach can be a model to draw more science and biology graduates into the study coordinator and clinical research associate field.
- Create incentive and reward programs for hospitals and companies that invest in talent development to support long term growth.

KOL Perspectives – Taiwan Clinical Trial Leadership Talent Establishment and Professional Training System

03 Establish industry talent training programs and courses, promote investigator-initiated trials, and increase investigator retention.

3. Talent retention and application

- The government should actively support investigator-initiated trials and provide a sustainable funding platform.
- Refine benefits and compensation systems and ensure reasonable workloads to retain clinical research talent.
- Provide appropriate benefits and academic recognition to teams participating in international multi-regional clinical trials (mRCTs) to motivate physicians to engage in research..

KOL Perspectives – Taiwan's Industry Strengths, Collaboration, and International Cooperation

04 Taiwan clinical trial digital transformation and data transparency: accelerate AI regulations and EMR utilisation to maximise health data value

Taiwan's clinical trials have unique strengths in digital and AI use, such as TPMI's genomic data and National Health Insurance electronic medical record data. They also face fragmented systems, conservative data privacy rules, and limited infrastructure. These strengths should be turned into an advantage for international collaboration.

Recommendations should focus on regulation, data standardisation, and AI applications:

1. Expedite regulation amendments with resilience

- The government should enhance effective use of genomic and electronic medical record data to support clinical trial. For AI applications, accelerate work on AI regulation and use the European Union AI Act as a reference.
- For emerging therapies such as gene therapy, traditional trial rules do not suit patients in urgent need, so regulations should offer more flexible pathways.
- Revise regulations such as pharmacist regulations to support low risk telemedicine and decentralised clinical trials. For example, allow delivery of investigational drugs to patients' homes with proof of receipt.

2. Strengthen digital infrastructure and data standardisation

- Taiwan's NHI electronic medical record EMR data is a unique global asset. The NHI should lead further EMR standardisation and integrate EMR data into clinical-trial use.
- Create a standardised framework that lets patients consent at admission to use of their data for screening while keeping the right to withdraw later. Integrate existing clinical trial information platforms, for example into the 'My Health Bank', so patients can get information and take part in recruitment.

KOL Perspectives – Taiwan's Industry Strengths, Collaboration, and International Cooperation

04 Taiwan clinical trial digital transformation and data transparency: accelerate AI regulations and EMR utilisation to maximise health data value

1. **Conditionally open national databases**
   - Enhance national databases for secondary use under regulatory compliance, including TPMI genomic data and the NHI database.
2. **AI and digital application**
   - Recommend AI use in clinical trials at the early stage, establishing a dedicated unit to plan AI applications and strategy, and standardising medical record formats across hospitals.
   - Recommend integrating medical records and linking to eSource applications, such as using QR codes or iPad cloud storage for electronic informed consent in clinical trials.
3. **Strategy for international co-operation**
   - Taiwan should coordinate across hospitals so principal investigators can boost enrollment for gaining global traction.
   - Highlight Taiwan's advantage as representative of Asian population. Trials run in Taiwan provide insight into East and Southeast Asian markets and should be used to attract sponsors.
   - Leverage the strong performance of Taiwan principal investigators in fields such as hepatology and lung cancer to draw more international trials.
   - Enhance international medical service and mutual recognition of trial data.
   - Cultivate physicians to serve as global leading PI or steering committee members and secure roles in protocol design and data analysis to raise visibility and attract external resources.

KOL Perspectives – Clinical Trials as a National Strategic Investment for a Healthy Taiwan

05 Reshape priorities with a focus on cost-effectiveness and enhance the industry's health economic impact

Taiwan need to develop a cost-effectiveness perspective. A comprehensive strategic reform is needed view clinical trial spending as an investment rather than an expense.

1. Direct economic impact and investment

- The government should consider bringing in external investment funds to support high value clinical trials.
- Increase the National Health Insurance budget and adjust allocation so the CRO industry chain can grow its direct output and amplify its impact, with total Taiwan biotech industry output to reach NT$700 to 800 billion.
- Include clinical trials KPI's in medical center accreditation to enhance investment of resources.

2. Indirect economic impact and investment

- Investing in clinical trials will speed the introduction of new medicines and let patients access them two to three years earlier.
- Strengthen the link between trials and the downstream market, including pricing and reimbursement speed. Tie National Health Insurance reimbursement prices to new drugs and set rules to fast-track coverage after approval, so Taiwan is not placed last in global launches due to low prices or long reimbursement timelines. Overall, we should focus more on the national health budget and regard it as a key investment in "Healthy Taiwan."

Strategic recommendations to strengthen Taiwan's clinical trial environment

1. Policy and regulatory optimisation

- Draw on the experience of neighboring countries to create an environment that attracts foreign investment.
- Introduce regulatory relaxations favorable to novel therapies (e.g., cell and gene therapies).
- Streamline review and contracting processes to accelerate clinical trial start-up and patient enrollment.
- Offer supportive policies such as tax incentives, R&D subsidies/grants, and expedited reviews.
- Advance national-level initiatives such as the "Biomedical Industry Innovation Promotion Program" and the "Asia Clinical Trial Center"

2. Data and digital development

- Leverage the National Health Insurance (NHI) claims database and electronic medical records (EMRs) to support patient screening, real-world evidence (RWE) studies, and long-term follow-up.
- Introduce AI and big data analytics to rapidly identify suitable participants and accelerate enrollments.
- Promote health information standards, establish harmonized electronic health records (EHRs), and integrate them with clinical trial case report forms (CRFs).
- Promote e-signatures and digital tools to support decentralised clinical trials (DCTs).
- Utilise telemedicine and digital trial models to improve efficiency and patient participation, aligning with the ICH E6 (R3) trend.

3. International positioning and competitiveness

- Build an international brand for Taiwan's clinical trials and become an Asia–Pacific hub.
- Focus on areas of strength such as rare diseases, oncology, and special areas for Asian populations.
- Seek mutual recognition/acceptance of data with ICH, the US FDA, and the EMA to enhance international value.

4. Precision medicine and patient engagement

- Expand advanced clinical trials in precision medicine, gene therapy, and cell therapy.
- Leverage Taiwan's East Asian genetic profile to enhance diversity in international research.
- Build on local medical R&D strengths to attract more early-phase clinical trials to Taiwan.
- Establish patient registry platforms and educational resources to improve public awareness and participation.
- Utilise the National Health Insurance (NHI) database to support trial site selection and strengthen enrollment competitiveness.

Short term → **Mid term** → **Long term**

Future Vision and Recommendation – Building a practical one-stop platform for clinical trial

One-Stop Platform

Cross-Ministry cooperation and information sharing platform

National Communication Commission

- ✓ Approval for the importation of regulated telecommunications radio-frequency equipment

National Science and Technology Council

- ✓ Provide development resources for CROs, data platforms, logistics, academic/research institutions, and digital medical devices

National Development Council

- ✓ Attract multinational pharmaceutical companies to invest in clinical trials
- ✓ Integrate and oversee the clinical trial industry development plan

Ministry of Economic Affairs

International Trade Administration

- ✓ Approval for the importation of biological products and medical devices manufactured in Mainland China

Bureau of Standards, Metrology and Inspection

- ✓ Application for exemption from inspection for equipment used in drug clinical trials

Ministry of Health and Welfare

TFDA

- ✓ Review of clinical trial protocols; approval for the importation of investigational drugs and trial-use medical devices

CDC

- ✓ Approval for export infectious specimens

NHIA

- ✓ Incentivise local clinical trials through drug price add-ons

Department of Medical Affairs

- ✓ Develop workforce development policies for clinical-trial-related healthcare professionals

Department of Information Management

- ✓ Promote standardisation of EHR data fields and cross-hospital interoperability; integrate e-platforms

National Health Research Institutes

- ✓ Promote a smart collaboration network for early-phase clinical trials

CDE

- ✓ Promote standardisation of IRB review criteria and mutual recognition among IRBs

Joint Commission of Taiwan

- ✓ Develop reference guidelines for clinical trial contracts
- ✓ Include start-up speed as a reference indicator in accreditation

Definition and Vision of a One-Stop Platform

Integrate resource and process:

The platform will integrate sourcing, patient recruitment, import and export of investigational drugs and materials, contract standardisation and electronic signatures, IRB/regulatory reviews, information disclosure, and facilitate drug approval and health insurance reimbursement.

Sustainable operation:

The platform should be granted legal authority and integrated with government policies, with long-term planning and KPI management to address issues of fragmented resources and project discontinuity, ensuring the platform's operational stability and sustainability.

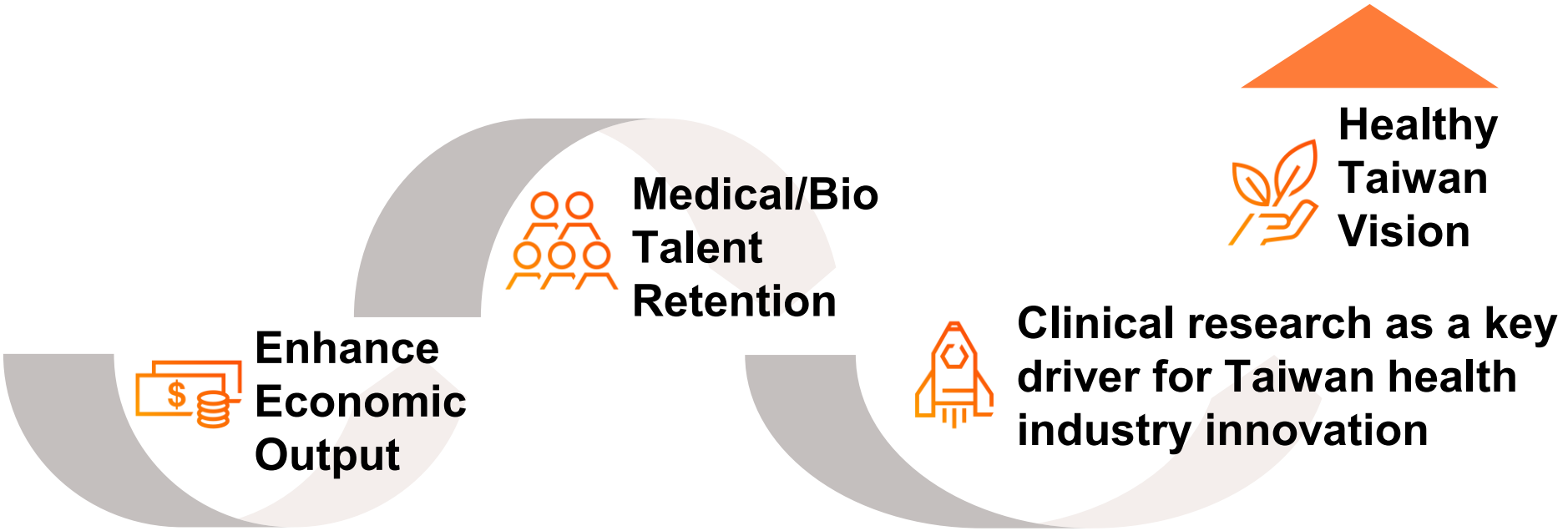
Responsible governance:

The platform should be run by a dedicated and sustainable unit to effectively connect government policies and achieve the "Healthy Taiwan" goals.

Conclusion

Taiwan has a high-quality healthcare system, comprehensive health insurance data, strong AI/IT capabilities, and clinical talent—forming a solid foundation for developing clinical trials. The priority now is to turn these advantages into scalable capabilities by integrating data, processes, and labour to achieve speed, quality, and predictability of clinical trial ecosystem.

International competitors are ahead of Taiwan, with regulations and technologies changing rapidly; if supporting measures and applications do not keep pace, Taiwan's competitiveness will quickly fade. Taiwan's appeal lies in healthcare quality and digital capabilities; these should be leveraged to attract external investment and high-value trials while safeguarding the financial sustainability of the National Health Insurance, cultivating talent, and strengthening drug supply resilience. Aligned with the vision of "Healthy Taiwan", Taiwan can enhance international impact by positioning itself as a benchmark destination for pilot studies—such as early-stage trials (Phase I, Phase II), first-in-human (FIH) studies, and Asian market entry. In doing so, foster a new generation of industries that supports the country's economy, improve access to care, and reinforce long-term national health benefits.



Glossary of acronyms

ADR	Adverse Drug Reactions
AI	Artificial Intelligence
APAC	Asia Pacific Region
BA/BE	Bioavailability/ Bioequivalence test
CAGR	Compound Annual Growth Rate
CDMO	Contract Development Manufacturing Organisation
c-IRB	Collaborative Institutional Review Board
CMO	Contract Manufacturing Organisation
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Clinical Trial case report forms
CRO	Clinical Research Organisation
CTA	Clinical Trial Application
CTC	Clinical Trial Center
CTN	Clinical Trial Notification
DALY	Disability-Adjusted Life Year
DCT	Decentralised Clinical Trial
ECG	Electrocardiogram
eCRF	electronic case report form
EDC	Electronic Data Capture system
EHR	Electronic Health Record
eICF	electronic Informed consent form
EMR	Electronic Medical Record
FeNO	Fractional Exhaled Nitric Oxide
FHIR	Fast Healthcare Interoperability Resources
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GVA	Gross Value Added
HTA	Health Technology Assessment
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IITs	Investigator-Initiated Trial
IND	Investigational New Drug
IRB	Institutional Review Board
KoNECT-DIA	Korea National Enterprise for Clinical Trials Drug Information Association
mRCT	Multi Regional Clinical Trial (Multinational-multicentered Clinical Trial)
MRFF	Medical Research Future Fund
NCTGF	National Clinical Trials Governance Framework
NDA	New Drug Application
NDCT	New Drugs and Clinical Trials Rules
NOL	No Objection Letter
NSN	Not Satisfactory Notice
PI	Principal Investigator
PM	Project Manager
QALY	Quality-Adjusted Life Year
RCTC	Regional Clinical Trial Centers
REC/IRB	Research Ethics Committee/ Institutional Review Board
RWD	Real World Data
RWE	Real World Evidence
SaaS	Software as a Service
SC	Study Coordinator
SCLC	Small Cell Lung Cancer
SMO	Site Management Organisation
SUSAR	Suspected Unexpected Serious Adverse Reaction
TNBC	Triple Negative Breast Cancer
TPMI	Taiwan Precision Medicine Initiatives
UHC	Universal Health Coverage
VPAG	Voluntary Scheme for Branded Medicine Pricing, Access and Growth investment programme

Glossary of acronyms – Organisations

ABPI	The Association of the British Pharmaceutical Industry
BSMI	Bureau of Standards, Metrology and Inspection
CDE	Center of Drug Evaluation
CRM	Clinical Research Malaysia
CTRI	Clinical Trial Registry
CTSG	National Clinical Trials Singapore
DHAC	Department of Health and Aged Care
EFPIA	European Federal Pharmaceutical Industrial Association
EMA	European Medicines Agency
GBAICTI	Greater Bay Area International Clinical Trial Institute
ICMR	Indian Council of Medical Research
IMF	International Monetary Fund
IMF	International Monetary Fund
KoNECT	Korea National Enterprise for Clinical Trials
MFDS	Korean Ministry of Food and Drug Safety
MHRA	Medicines and Healthcare Products Regulatory Agency
NCC	National Communication Commission
NHI	National Health Insurance
NHMRC	National Health and Medical Research Council
NMPA	China National Medical Products Administration
NOSS	The National One Stop Shop
SCRI	Singapore Clinical Research Institute
TCTC	Taiwan Clinical Trial Consortium
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration
US FDA	U.S. Food and Drug Administration
WHO	World Health Organization

Notes – Reference of Regulatory Authorities from each Jurisdiction

Taiwan	Food and Drug Administration (Taiwan)	https://www.fda.gov.tw/
Australia	Human Research Ethics Committees	https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees
South Korea	Ministry of Health and Welfare (Korea)	https://www.mohw.go.kr/
UK	Medicines and Healthcare Products Regulatory Agency	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Canada	Health Canada	https://www.canada.ca/en/health-canada.html
China	National Medical Products Administration (China)	https://www.nmpa.gov.cn/
Japan	Pharmaceuticals and Medical Devices Agency	https://www.pmda.go.jp/
Singapore	Singapore Clinical Research Institute	https://www.scri.edu.sg/
Malaysia	Ministry of Health (Malaysia)	https://www.moh.gov.my/
India	Central Drugs Standard Control Organisation	https://cdsco.gov.in/

Appendix

1. Acknowledgement
   Interviewee list and Editorial Team
2. Appendix charts

APPENDIX

Acknowledgement
Interviewee list and Editorial Team

Thanks to the following companies for providing valuable suggestions

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Amgen Taiwan Limited	台灣安進藥品有限公司
Astellas Pharma Taiwan, Inc.	台灣安斯泰來製藥股份有限公司
AstraZeneca Taiwan Limited	臺灣阿斯特捷利康股份有限公司
Biogen Taiwan Limited	台灣百健有限公司
Bristol-Myers Squibb (Taiwan) Ltd.	台灣必治妥施貴寶股份有限公司
Chugai Pharma Taiwan Ltd.	台灣中外製藥股份有限公司
Daiichi Sankyo Taiwan Ltd.	台灣第一三共股份有限公司
Eli Lilly and Company (Taiwan), Inc.	台灣禮來股份有限公司
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Novo Nordisk Pharma (Taiwan) Ltd.	台灣諾和諾德藥品股份有限公司
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Parexel International Co., Ltd.	百瑞精鼎國際股份有限公司
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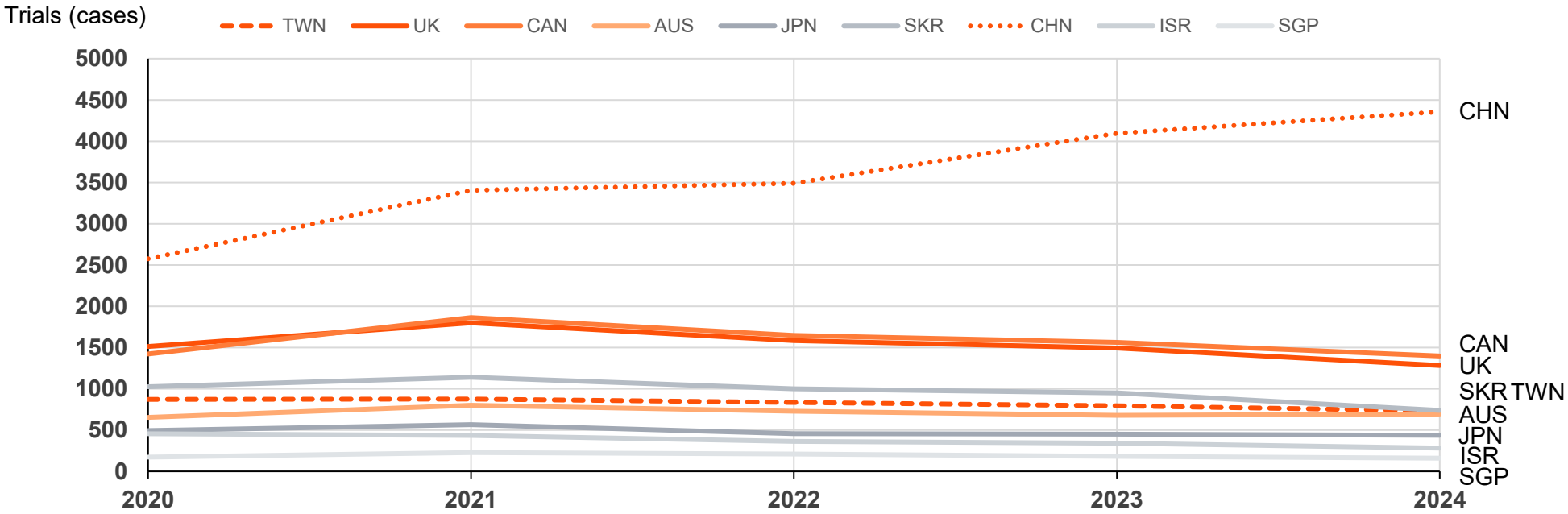
Appendix charts

Appendix – PART I – Clinical trial numbers by territory, including China, covering drugs, medical devices and diagnostics, medical procedures, and academic research use

China has a total number of clinical trials exceeds those of all other countries, due to its large population.

Clinical trial counts by territory - Including China

(including drugs, medical devices and diagnostics, medical projects, and academic or research uses, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

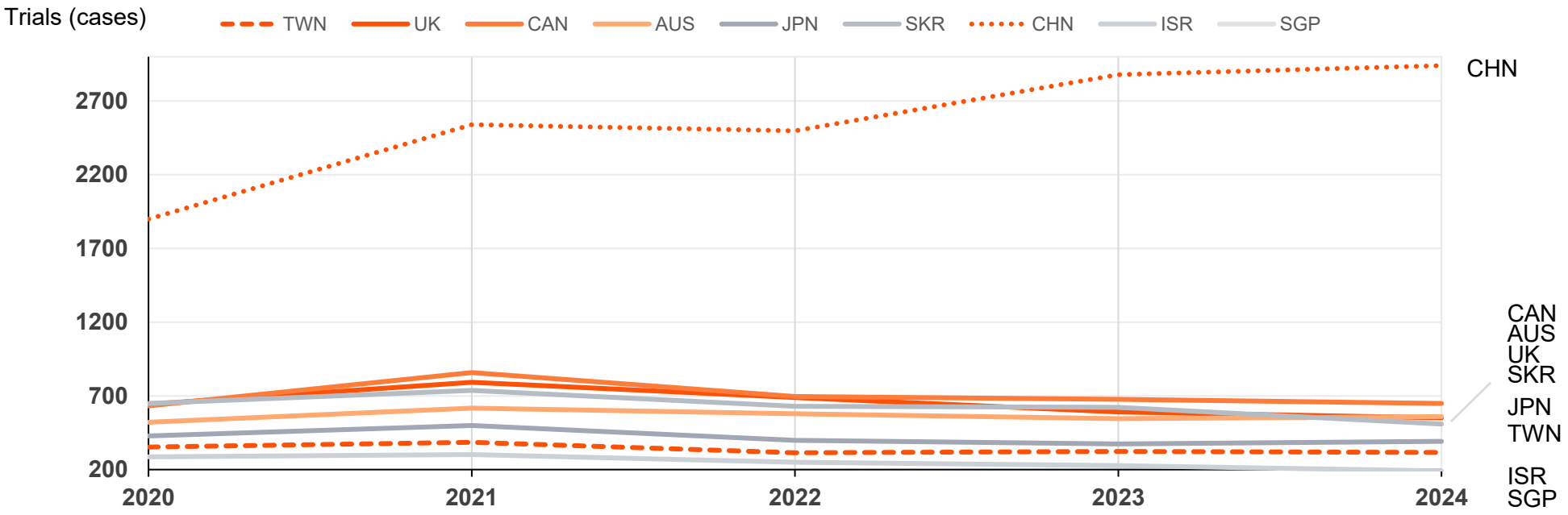
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I – Drug clinical trial numbers by territory, including China

China has a total number of drug clinical trials exceeds those of all other countries, due to its large population.

Drug clinical trial counts by territory - Including China

(trials counts, drugs only, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

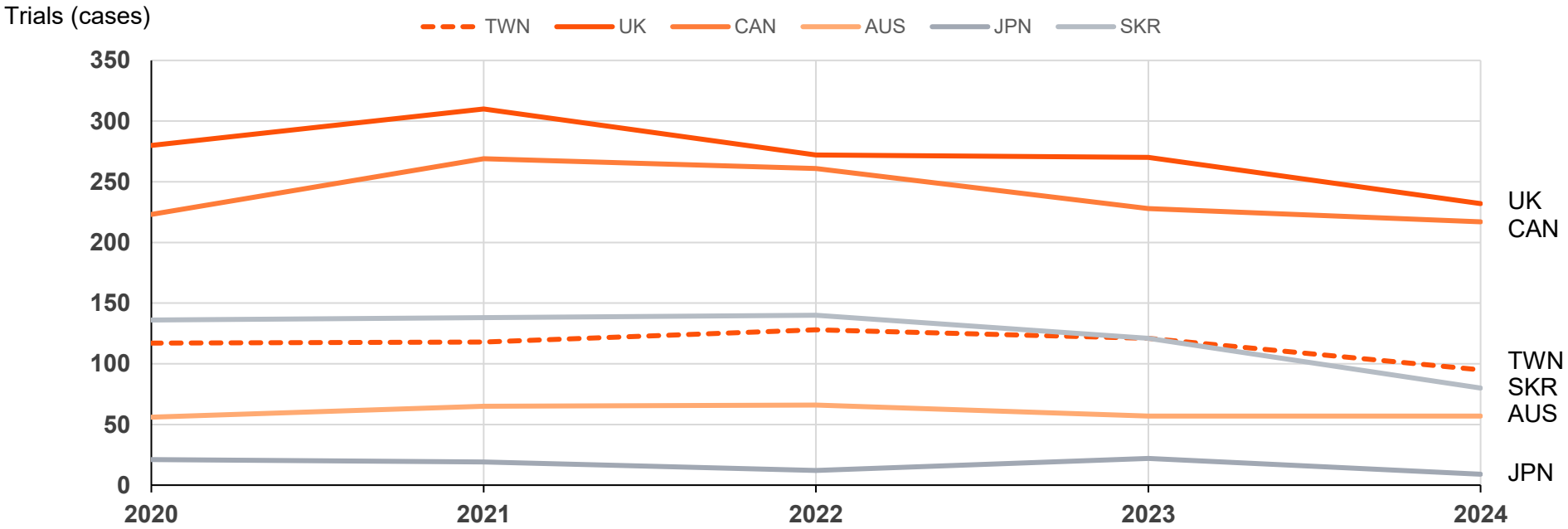
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I – Clinical trial numbers by territory, for medical devices and diagnostics

For medical device and diagnostic trial counts, Taiwan ranks near the middle among peer countries.

Clinical trial counts by territory - medical devices and diagnostics

(trials counts, medical devices and diagnostics, 2020 to 2024)

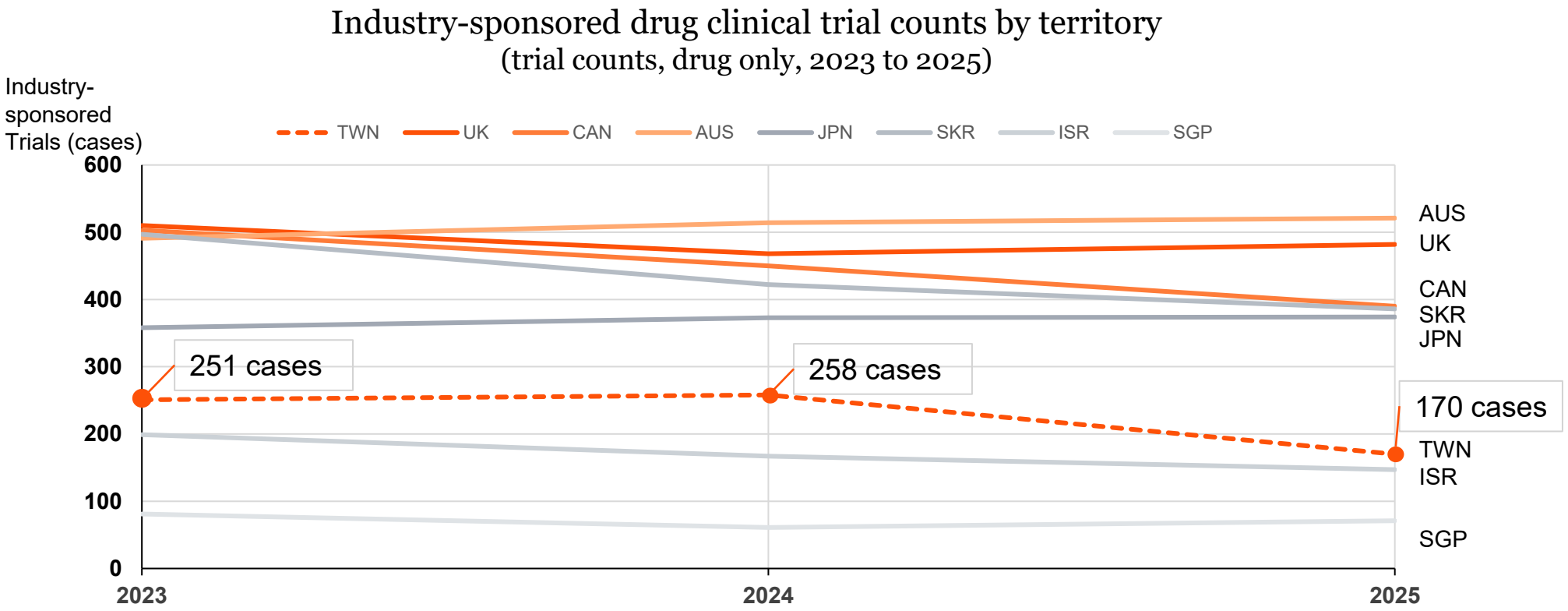


Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I –Number of industry-sponsored drug trials in Taiwan – Total of 679 trials throughout 2023-2025

According to the clinicaltrials.gov website, the total number of industry-sponsored drug clinical trials conducted in Taiwan in 2023, 2024, and 2025 are 251, 258, and 170, respectively, with a combined total of 679 trials over the three years.



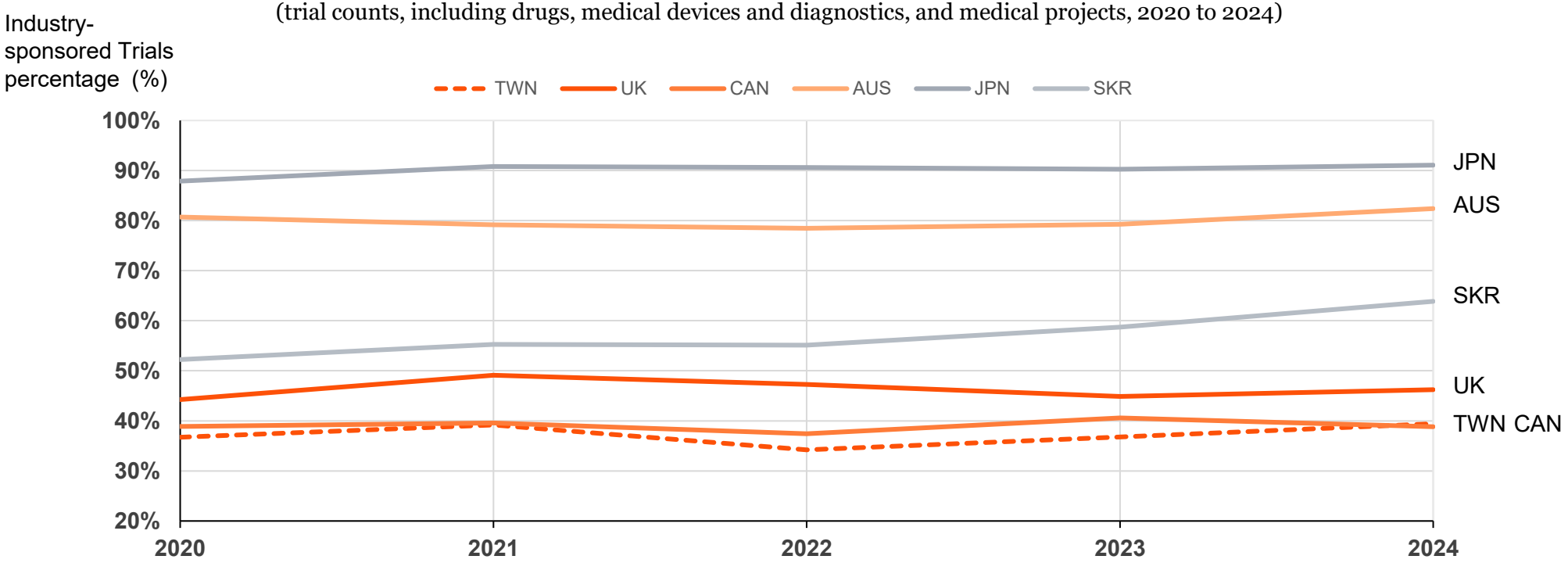
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP

Appendix – PART I – The proportion of industry-sponsored clinical trials in Taiwan (including drugs, medical devices and diagnostics, and medical projects)

Even when broadening the scope to include drugs, medical devices and diagnostics, and medical projects, Taiwan still has a lower share of industry sponsored clinical trials than most countries. This indicates Taiwan needs actions to attractive trial sponsors.

Industry sponsorship share of clinical trials by territory (sponsored trials / total trials)
(trial counts, including drugs, medical devices and diagnostics, and medical projects, 2020 to 2024)



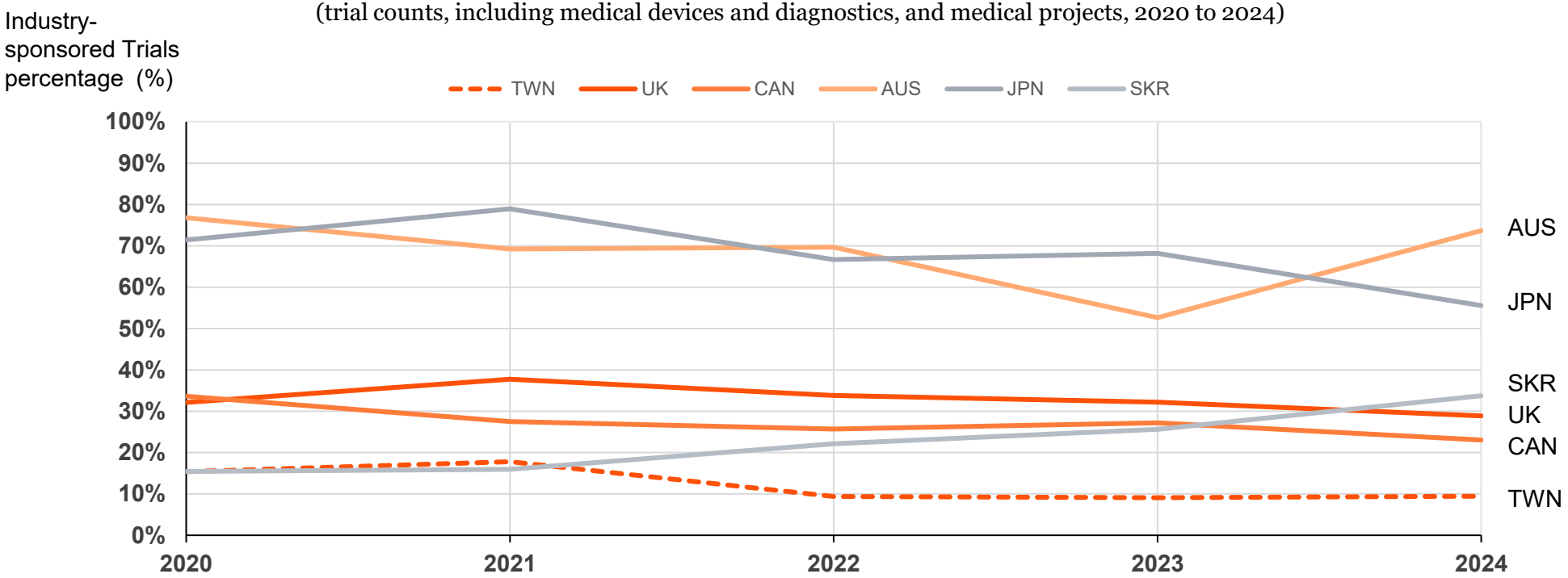
Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I – The proportion of industry-sponsored clinical trials in Taiwan (including medical devices and diagnostics, and medical projects)

From 2020 to 2024, Taiwan industry sponsored trial share dips around 2022 and then rises slightly.

Industry sponsorship share of clinical trials by territory (sponsored trials / total trials)
(trial counts, including medical devices and diagnostics, and medical projects, 2020 to 2024)



Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

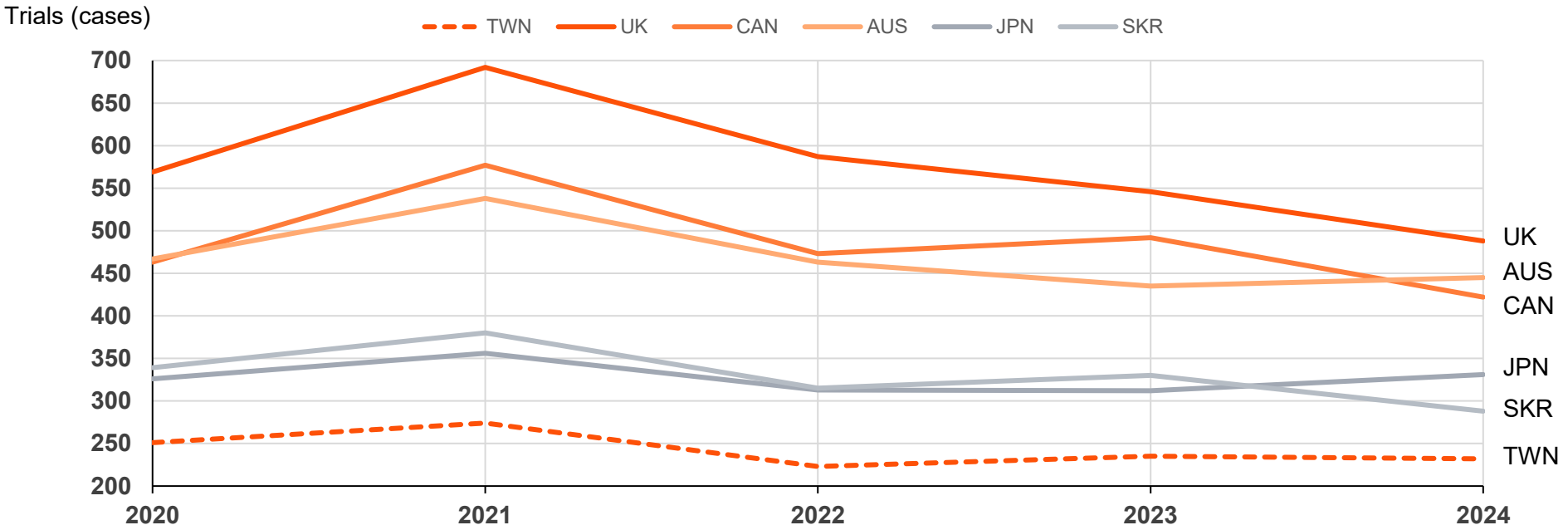
Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I – Clinical trial numbers by territory for mRCTs, including drugs, medical devices and diagnostics, medical projects, and academic research

The chart shows Taiwan at the bottom in mRCT counts from 2020 to 2024, dipping around 2022 and only slightly recovering by 2024. The UK and Canada lead, and Australia, Japan, and South Korea remain well above Taiwan throughout. This confirms that we rank lower not only in drug mRCTs but also in other types of clinical trials included here. The evidence signals a need to focus more on strengthening Taiwan's performance in mRCTs.

Clinical trial counts by territory - mRCT trials

(trial counts, including drugs, medical devices and diagnostics, and medical projects, and academic research 2020 to 2024)

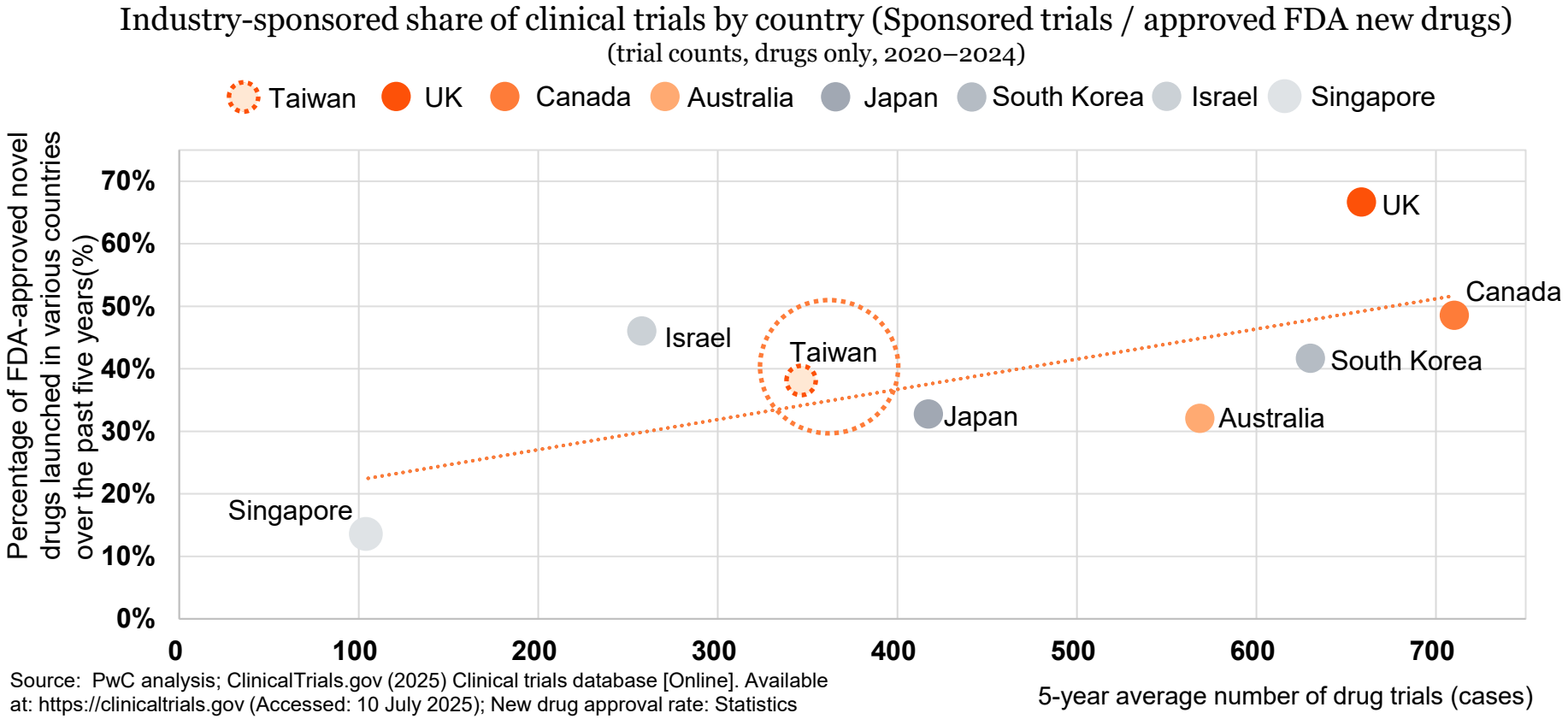


Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025)

Notes: Taiwan – TWN, United Kingdom – UK, Canada – CAN, Australia – AUS, Japan – JPN, South Korea – SKR, Israel – ISR, Singapore – SGP, China – CHN

Appendix – PART I – The proportion of U.S. FDA “Novel Drugs” approved by a country is positively correlated with the number of all drug clinical trials (including industry-sponsored &IITs)

Across industry- and non–industry–sponsored studies, countries with greater overall trial volume tend to have higher local approval shares, indicating that broader clinical research intensity co-varies with approval activity. Approval proportions were calculated from national regulatory databases.

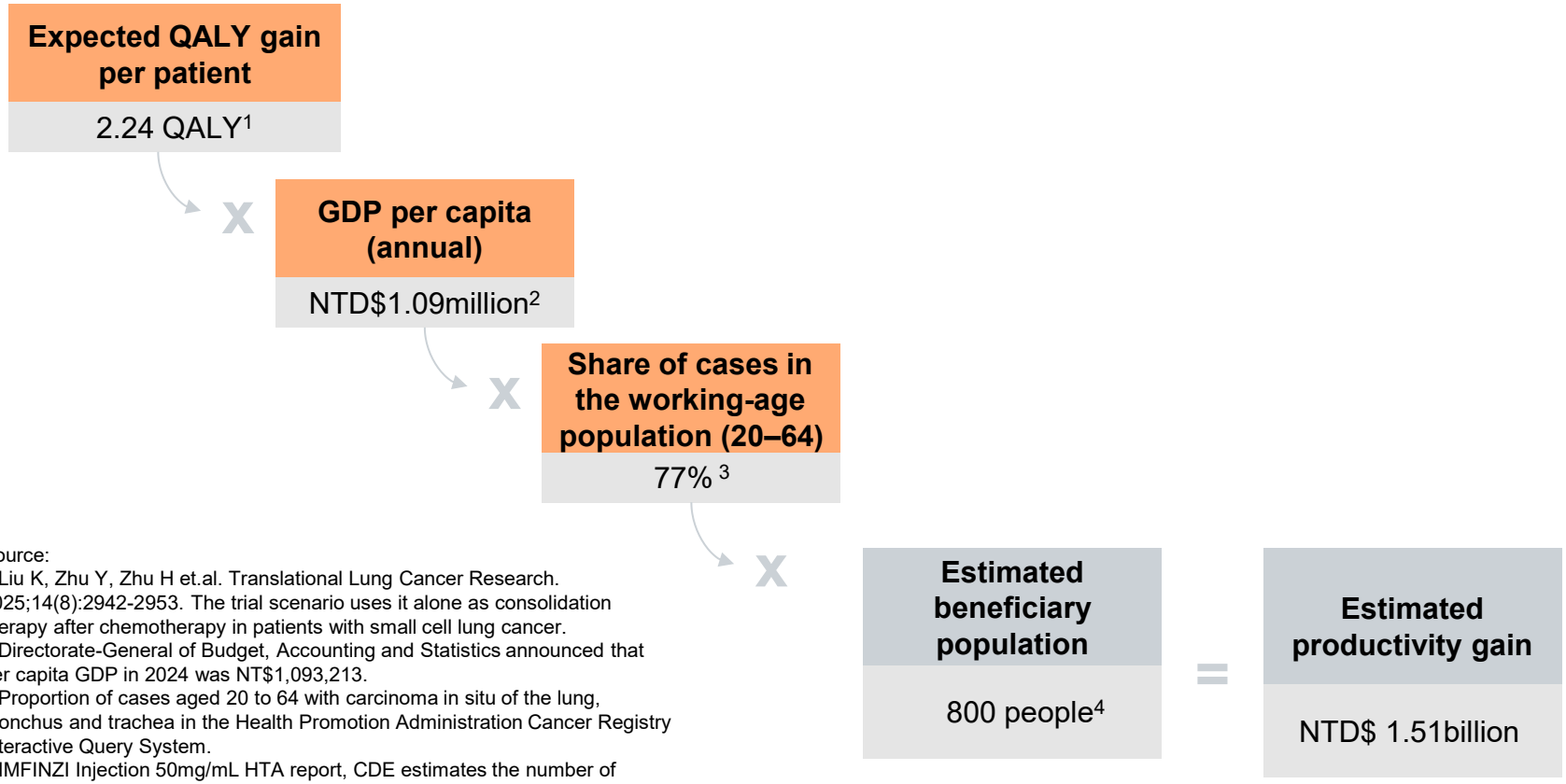


Source: PwC analysis; ClinicalTrials.gov (2025) Clinical trials database [Online]. Available at: https://clinicaltrials.gov (Accessed: 10 July 2025); New drug approval rate: Statistics from authorities in each countries

Note: Over the past five years, the coefficient of determinant R^2 for the relationship between the proportion of US FDA novel drugs and the number of drug clinical trials is 0.4728, indicating a positive correlation.

Appendix – PART I – Model estimation: using Durvalumab for small cell lung cancer as an example of benefit

According to the TCTC, Durvalumab (MEDI4736) has 54 trials directly sponsored by the originator company, covering indications such as cholangiocarcinoma, non small cell lung cancer, and small cell lung cancer. Among these, phase 1/2a and phase 3 trials for small cell lung cancer were all conducted in Taiwan. As a result of these clinical trials,, Durvalumab has become a new treatment option for small cell lung cancer in Taiwan and is expected to deliver a direct productivity gain of NT$1.51 billion.



Source:
1 Liu K, Zhu Y, Zhu H et.al. Translational Lung Cancer Research. 2025;14(8):2942-2953. The trial scenario uses it alone as consolidation therapy after chemotherapy in patients with small cell lung cancer.
2 Directorate-General of Budget, Accounting and Statistics announced that per capita GDP in 2024 was NT$1,093,213.
3 Proportion of cases aged 20 to 64 with carcinoma in situ of the lung, bronchus and trachea in the Health Promotion Administration Cancer Registry Interactive Query System.
4 IMFINZI Injection 50mg/mL HTA report, CDE estimates the number of people who will benefit from use in small cell lung cancer over the next five years, calculated using the fifth year.

Appendix – PART I – Trial value estimates: Durvalumab trials—examples of drug cost-sharing

Taiwan enrolment: 1334 participants; 54 trials directly sponsored by the originator company.

	Experiment (Exp)	Control	Saving Estimates[1]
Lung Cancer (NCT03003962)	Durvalumab 1500mg Q4W , median treatment duration 7 cycles	Platinum-based SoC Q3W (Pemetrexed or Gemcitabine) Concurrent (Cisplatin or Carboplatin), median treatment duration 4 dose	Average medication cost savings per trial participant[2]: **NT$ 511,822**
Breast Cancer (NCT06112379)	Datopotamab deruxtecan Q3W +Durvalumab 1120 mg Q3W (Pre-op: 8 cycles; Post-op: 7 cycles**)**	Pembrolizumab Q3W+Chemo (Pre-op **8 cycles,** Post-op **9 cycles)**	Average medication cost savings per trial participant per trial participant: **NT$ 2,088,106**
Liver Cancer (NCT03298451)	**Arm 1** Durvalumab 1500 mg Q4W , median treatment duration 5.5 cycles **Arm 2** Tremelimumab 75 mg ×4 doses + Durvalumab 1500 mg Q4W , median treatment duration 4.6 cycles **Arm 3** Tremelimumab 300 mg ×1 dose + Durvalumab 1500 mg Q4W **,** median treatment duration 5.5 cycles	**Arm 4** Sorafenib 400 mg BID · median treatment duration 4.1 months	Average medication cost savings per trial participant: **NT$ 785,253**

Based on the actual enrolment proportions for each indication[3], the weighted-average medication cost is about NT$1.02 million per person, and the total company-sponsored medication cost across these clinical trials is about NT$1.36 billion.

Notes 1: In 2025, the per course cost of Durvalumab is NT$136,818; the NHI price for Tremelimumab 300 mg per vial is NT$350,000; Sorafenib 200 mg is NT$856; Gemcitabine plus cisplatin or carboplatin has an NHI price of about NT$12,588 per person every three weeks; Pemetrexed plus cisplatin or carboplatin has an NHI price of about NT$52,893 per person every 3 weeks; Pembrolizumab has an NHI price of about NT$143,046 per person every 3 weeks.
Notes 2: Assume the experimental and control groups have the same participant ratio. For urothelial carcinoma Arms 1, 2, 3 and 4, use the real global trial scenario for calculation: 389, 153, 393 and 389 participants.
Notes 3: The clinical trial participant counts for lung, breast and liver cancer are 338, 222 and 260 respectively.

Appendix – PART I – Model estimation: using Pembrolizumab for early triple-negative breast cancer as an example of benefit

Expected QALY gain per patient

1.57 QALY

(Treatment: 9.33 QALY)
(Control: 7.76 QALY)

X

Estimated value (productivity and household work loss)

2-fold GDP per capita increased per 1 QALY gain

GDP per capita (annual)

NTD$ 1.09million[2]

X

Share of disease in employment age(20-64)

72.4% [3]

X

Estimated beneficiary population

856 people[4]

=

Estimated productivity gain

NT$ 2.13billion

According to TCTC, Pembrolizumab has 99 trials directly sponsored by the originator company. Many clinical trials for new indications were conducted in Taiwan. As a result of these clinical trials, Pembrolizumab has become a a new treatment option for early triple-negative breast cancer (TNBC) in Taiwan and is expected to deliver a direct productivity gain of NT$2.13 billion.

Source:
1 Keytruda Injection HTA reports use data from the early TNBC assessment report.
2 From a societal perspective, including patient productivity and carer loss, the avoidable lifetime loss versus the standard of care is about two times per capita GDP.
3 Directorate-General of Budget, Accounting and Statistics announced that per capita GDP in 2024 was NT$1,093,213.
4 Health Promotion Administration Cancer Registry Report, year 111 (2022).
5 Keytruda Injection HTA report supplementary data estimates number of beneficiaries of the new indications was calculated for the fifth year.

Appendix – PART I – Trial value estimates: Pembrolizumab trials—examples of drug cost-sharing

Taiwan enrolment: 2200 participants; 99 trials directly sponsored by the originator company.

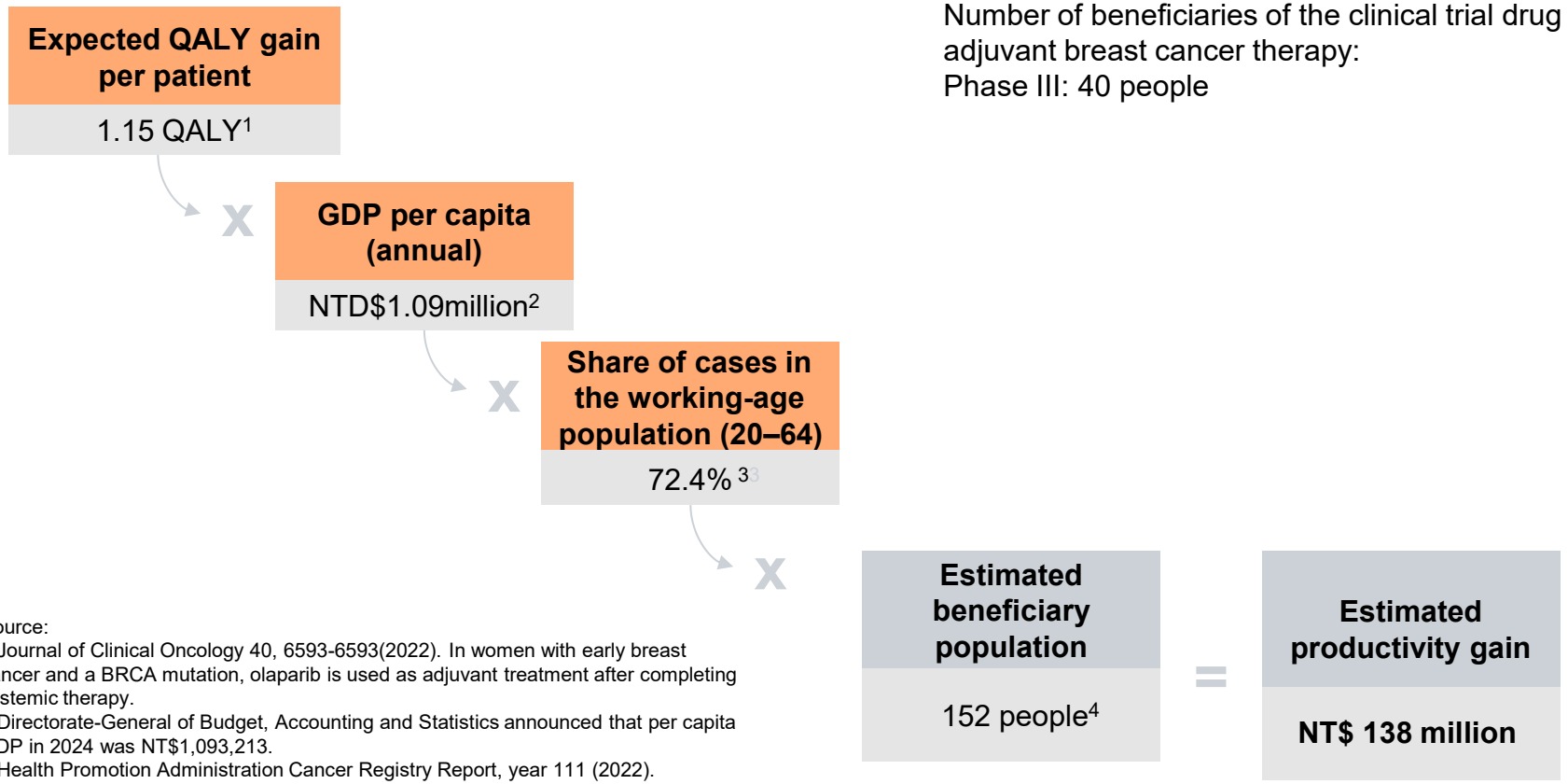
	Experiment (Exp)	Control	Saving Estimates[1]
Breast Cancer (NCT02555657)	Pembrolizumab: 200 mg Q3W, median treatment duration 3 cycles (62 days)	Chemo Capecitabine/ Eribulin/ Gemcitabine/ Vinorelbine, median treatment duration 3.4 cycles (73 days)	Average medication cost savings per trial participant[2]: **NT$ 265,585**
Lung Cancer (NCT03066778)	Pembrolizumab 200 mg Q3W + EP chemotherapy (etoposide + platinum) during the first four cycles; median treatment duration: 7 cycles	Placebo+ EP chemotherapy (etoposide + platinum) during the first four cycles, median treatment duration 6 cycles	Average medication cost savings per trial participant: **NT$ 521,273**
Urothelial carcinoma (NCT02853305)	**Arm 1** Pembrolizumab 200 mg, Q3W **+** chemo (Gemcitabine + Platinum)**,** median treatment duration 11 cycles **Arm 2** Pembrolizumab 200 mg, Q3W, median treatment duration 7 cycles	**Arm 3** Placebo+chemo (Gemcitabine + Platinum), median treatment duration 6 cycles	Average medication cost savings per trial participant: **NT$ 956,528**
Gastric Cancer (NCT03675737)	Pembrolizumab 200 mg, Q3W, Concurrent Chemo (FP or CAPOX), median treatment duration 10 cycles (6.7 months)	Placebo + Chemo (FP or CAPOX), median treatment duration 8 cycles (5.6 months)	Average medication cost savings per trial participant: **NT$ 848,610**

Based on the actual enrolment proportions for each indication[3], the weighted average medicine cost is about NT$600,000 per person, and the total company sponsored medicine cost for the clinical trials is about NT$1.32 billion.

Notes 1: Pembrolizumab costs NT$143,046 per cycle; capecitabine, eribulin, gemcitabine, and vinorelbine cost about NT$9,360, NT$76,290, NT$20,700, and NT$13,686 per cycle; carboplatin and etoposide cost NT$3,863 and NT$1,290 per cycle respectively; FP costs about NT$1,344 per cycle; CAPOX costs about NT$14,820 per cycle.
Notes 2: Assume the experimental and control groups are the same size; for urothelial carcinoma Arms 1, 2 and 3, the allocation is 1:1:1.
Notes 3: The clinical trial participant counts for breast, lung, urothelial and gastric cancer are 203, 515, 158 and 204 respectively.

Appendix – PART I – Model estimation: using Olaparib for early breast cancer as an example of benefit

According to TCTC, the originator company has directly sponsored 6 clinical trials of Olaparib (AZD2281) . Among these, phase 2 and phase 3 trials for breast cancer were conducted in Taiwan, enabling earlier reimbursement and faster patient access. As a result of these clinical trials, Olaparib has become a new adjuvant option after surgery for early breast cancer with BRCA mutation in Taiwan, bringing a direct productivity gain of NT$138 million.



Number of beneficiaries of the clinical trial drug for adjuvant breast cancer therapy:
Phase III: 40 people

Source:
1 Journal of Clinical Oncology 40, 6593-6593(2022). In women with early breast cancer and a BRCA mutation, olaparib is used as adjuvant treatment after completing systemic therapy.
2 Directorate-General of Budget, Accounting and Statistics announced that per capita GDP in 2024 was NT$1,093,213.
3 Health Promotion Administration Cancer Registry Report, year 111 (2022).
4 The National Health Insurance Administration estimates the number of beneficiaries for olaparib's new early breast cancer indication, calculated for the fifth year.

Appendix – PART I – Trial value estimates: Olaparib trials—examples for drug cost-sharing

Taiwan enrolment: 237 participants; 6 trials directly sponsored by the originator company.

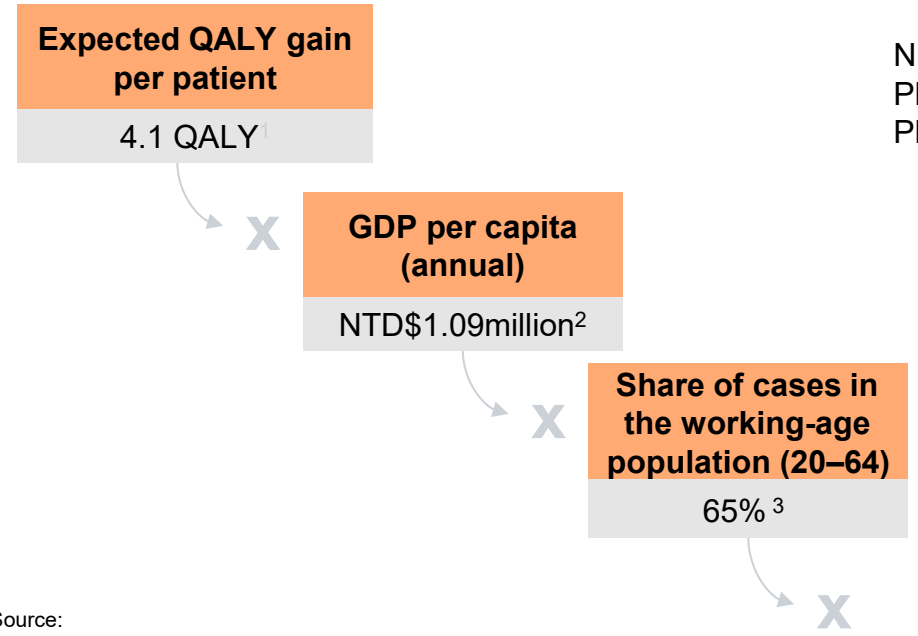
	Experiment (Exp)	Control	Saving Estimates[1]
Breast Cancer (NCT02555657)	Olaparib 300 mg BID, median treatment duration 8.2 months	Chemotherapy: capecitabine, eribulin, or vinorelbine (Q3W); median treatment duration: 3.4 months (5 cycles).	Average medication cost savings per trial[2] participant: **NT$ 869,980**
Gastric Cancer (NCT01924533)	Olaparib 100 mg BID; median treatment duration: 111 days + paclitaxel (80 mg/m², D1/8/15, 28-day cycle), 4 cycles.	Placebo + paclitaxel (80 mg/m², D1/8/15, 28-day cycle); median treatment duration: 82 days (3 cycles).	Average medication cost savings per trial participant: **NT$ 247,254**
Urothelial carcinoma (NCT03459846)	Olaparib 300 mg BID median treatment duration 112 days + Durvalumab 1,500 mg Q4W, 5.0 cycles	Placebo+ Durvalumab 1,500 mg Q4W · median treatment duration : Durvalumab 3.5 cycles; Placebo 3.0 cycles	Average medication cost savings per trial participant: **NT$939,877**

Based on the actual enrolment proportions for each indication[3], the weighted average medicine cost is about NT$815,000 per person, and the total company sponsored medicine cost for the clinical trials is about NT$190 million..

Notes1: Olaparib 100 mg per tablet NT$1,500; 150 mg per tablet NT$1,600. Durvalumab costs NT$136,818 per course. Capecitabine, eribulin, and vinorelbine cost about NT$9,360, NT$76,290, and NT$13,686 per course respectively. Paclitaxel costs NT$22,644 per 28-day course.
Notes 2: Assume the experimental and control groups are the same size.
Notes 3: The clinical trial participant counts for breast, lung, urothelial and gastric cancer are 76, 35 and 125 people.

Appendix – PART I – Model estimation: using Dupilumab for severe asthma as an example of benefit

According to the TCTC, Dupilumab has 9 trials directly sponsored by the originator company. A phase 3 trial for persistent asthma was conducted in Taiwan, enabling earlier reimbursement and faster patient access. As a result of these clinical trials, Dupilumab has become a treatment option for severe uncontrolled asthma in Taiwan, bringing a direct productivity gain of NT$3.26 billion.



Number of beneficiaries of the clinical trial drug (for severe asthma):
Phase III: 50 people
Phase IV: 5 people

Estimated beneficiary population		Estimated productivity gain
1123 people[4]	=	**NT$3.26 billion**

Source:
1 Health Economics Review vol 14: 67 (2024). This trial is for patients aged 12 and above with uncontrolled severe asthma; relative to background treatment, QALYs rise from 3.93 to 8.03.
2Directorate-General of Budget, Accounting and Statistics announced that per capita GDP in 2024 was NT$1,093,213.
3 According to the Taiwan Association of Asthmatics, about 10 per cent of adults and about 20 per cent of children in Taiwan have asthma. Use these prevalence rates multiplied by the population in each age group to derive the estimates.
4 Dupixent® HTA reports estimates the number of beneficiaries of the new indication, calculated for the fifth year.

Appendix – PART I – Trial value estimates: Dupilumab trials—examples of drug cost-sharing

Taiwan enrolment: 122 participants; 9 trials directly sponsored by the originator company.

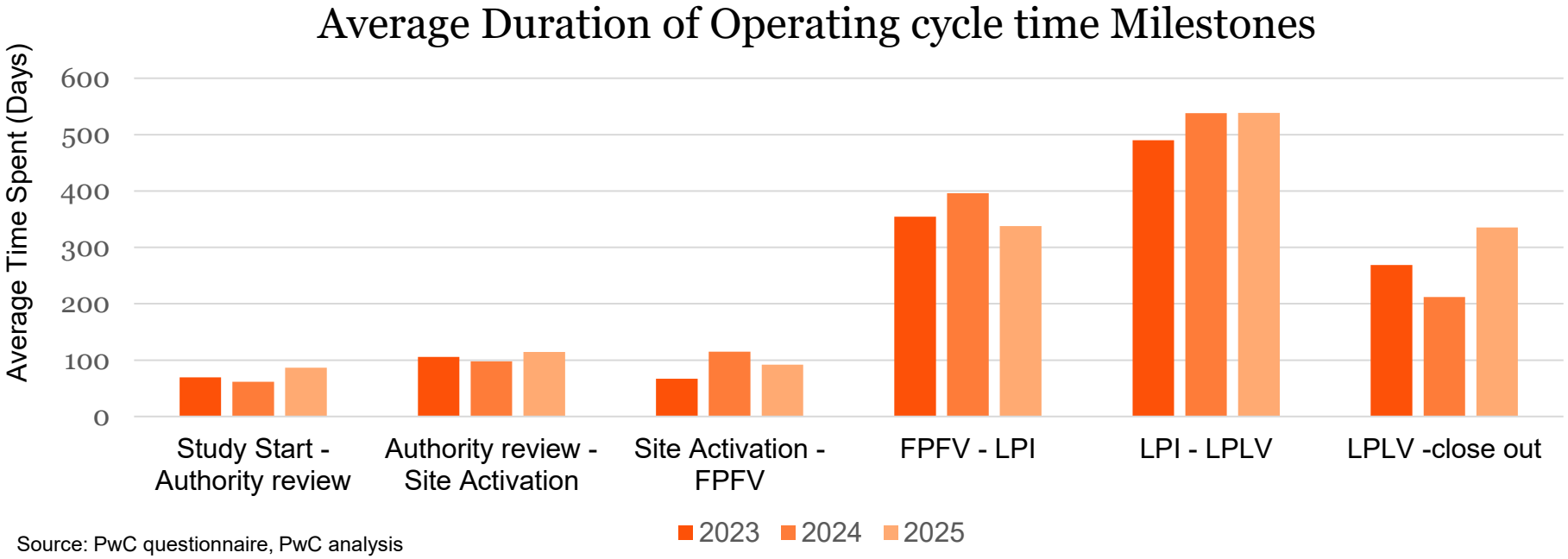
	Experiment (Exp)	Control	Saving Estimates[1]
Asthma (NCT02414854)	Exp A: Dupilumab 200 mg Q2W Exp B: Dupilumab 300 mg Q2W One year of dosing, 27 cycles, plus standard background treatment(ICS/LABA/LAMA/SABA)	Placebo for 27 cycles(1 year). + standard background therapy (ICS/LABA/LAMA/SABA)	**Average medication cost savings per trial participant: NT$ 380,862**
	Both groups undergo the relevant examinations **Spirometry/FEV_1**: NT$2,000 each × 21 times per person FeNO: NT$1,000 each × 21 times per person Biochemistry and blood tests: NT$2,500 each × 18 times per person **12-lead ECG**: NT$200 each × 8 times per person Outpatient consultation: NT$500 each × 28 times per person		**Average examination cost saving per trial participant: NT$123,600**
Pruritus (NCT04202679)	**Dupilumab loading dose: 600 mg**; then Dupilumab 300 mg every 2 weeks for 12 cycles, plus standard background treatment (low to medium potency TCS or TCI)	Placebo + Standard background treatment (low to medium potency TCS or TCI)	**Average examination cost saving per trial participant: NT$138,116**

Based on the actual enrolment proportions for each indication[3], the weighted average medicine cost is about NT$425,000 per person, and the total company sponsored medicine cost for the clinical trials is about NT$51.84 million.

Notes 1: Dupilumab 200 mg NT$16,428 every two weeks; experimental group B: Dupilumab 300 mg NT$19,738 every two weeks. Gold guideline background triple therapy (for example ICS with LABA and LAMA, LABA with LAMA, or ICS). Combination therapy with ICS, LABA and LAMA that replaces delivery via more than two devices is priced by market share, giving an estimated standard background treatment cost of NT$55,368 per year.
Notes 2: Assume the experimental and control groups are the same size; the three asthma treatment groups are allocated 1:1:1.
Notes 3: Asthma and prurigo nodularis counts are 83 and 23 people respectively.

Appendix – PART II – Average time spent on full clinical trial cycle milestones – Trend in Taiwan from 2023 to 2025

Examining the 2023 to 2025 changes in the average time spent at each milestone of Taiwan's clinical trial startup cycle, we find the timelines remain steady. Compared with timing changes across steps worldwide and in Asia Pacific, we further analyze the key bottlenecks Taiwan must address to strengthen its clinical trial process.

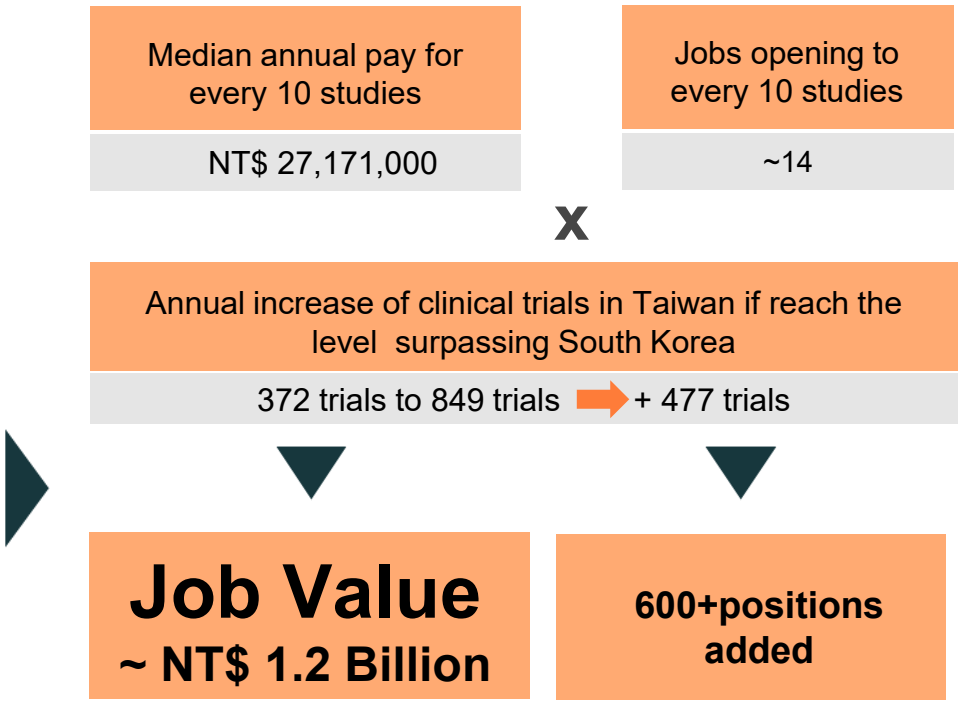


Source: PwC questionnaire, PwC analysis

Appendix – PART II – Annual estimate of the job value created by clinical trials

We estimate annual pay levels and total payroll for the staff needed to launch each type of trial, as a measure of the value of trials adds to Taiwan's labour market and wages. The continued growth of clinical trials brings substantial new jobs and lifts overall payroll, creating broad opportunities across healthcare, R&D, regulatory, and supply chain roles. This estimate is based on core personnel data from dozens of sponsors conducting trials in Taiwan.

Labour composition	Annual salary range
Quality Assurance	NT$1075000－1620000
Manager	NT$1660000－2585000
CTA	NT$520000－1170000
Other CT related jobs	NT$780000－1300000
Administrative, interns	NT$564000－650000
CRA	NT$1300000－1950000
Legals (IND only)	NT$900000－1300000
Project Manager	NT$1800000－2700000
Pharmacovigilance	NT$900000－1300000
Medical Science Liaison	NT$1300000－1900000
Data Management	NT$780000－1560000
Statistician	NT$715000－1300000

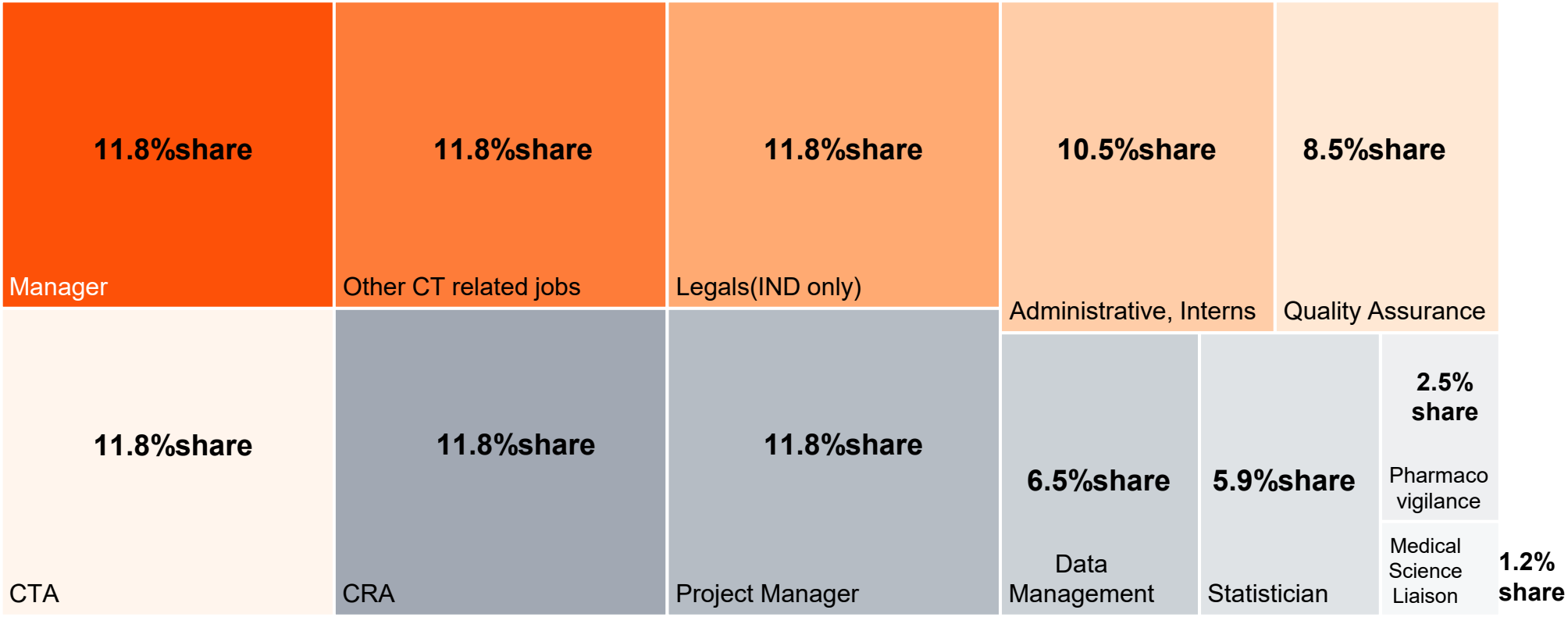


Source: 1 payment data: MichaelPage 2025 Taiwan salary report for medical and life sciences, Adecco Taiwan Salary Guide 2025, Persol Taiwan Salary Guide 2025, Directorate-General of Budget, Accounting and Statistics; 2.clinical trial counts: Food and Drug Administration, MOHW statistics; PwC questionnaire, PwC analysis

Appendix – PART II – Annual estimate of the job value created by clinical trials

Based on annual pay levels and total payroll for the personnel required to launch each type of trial, we gauge the value each new batch of trials adds to Taiwan's labor market and wages. We then estimate the percentage breakdown of job opportunity amounts above one billion, covering all roles involved in clinical trials.

Salary composition



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