Building a Unified Ecosystem:

The Founding Mission and Next Steps for TACTC

Dawn Chen, Vice Dean of the Office of Human Research
Taipei Medical University

Tina Sun, Chairman of Taiwan Clinical Research Association
Site Management & Monitoring (SMM) Country Head
/ Development Country Coordinator (Taiwan)
Novartis

SCRS
Society for Clinical Research Sites

TACTC
TAIWAN ALLIANCE OF
CLINICAL TRIAL CENTERS

Building a Unified Ecosystem

The Founding Mission and Next Steps for TACTC

SCRS 2026 Ambassador Symposium / Asia
August 15, 2026

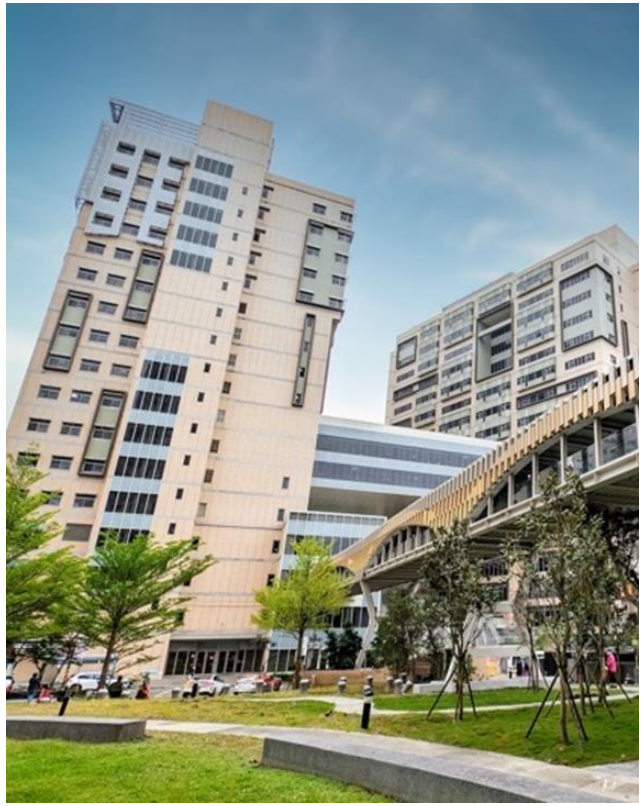
Together | Better | Stronger

Smart Infrastructure.

Zero Guesswork.

Redefining Trial Start-Ups.

Taiwan: A World-Leading Clinical Trial Hub



Qualified Sites with Proven Track Record

145
Clinical Trial Sites

2,000+
Top Principal Investigators

14
Disease-Specific Consortia

27
Medical Centers

100%
International Accreditation

350-400
IND Applications each year

A Foundation of Uncompromising Quality

Global Acceptance

Quality results accepted by key regulators (e.g. FDA & EMA)

Experienced Investigators

A network of over 2,000 PIs via the TPIDB platform.

Highest Global Standards

AAHRPP, SIDCER-FERCAP, and JCI accreditations across medical centers.

Digital Maturity

Secured clinical data flows (e.g. HIMSS EMRAM Stage 7 validations).

The Friction of Traditional Trial Start-up

Administrative Bottlenecks

Redundant feasibility surveys.

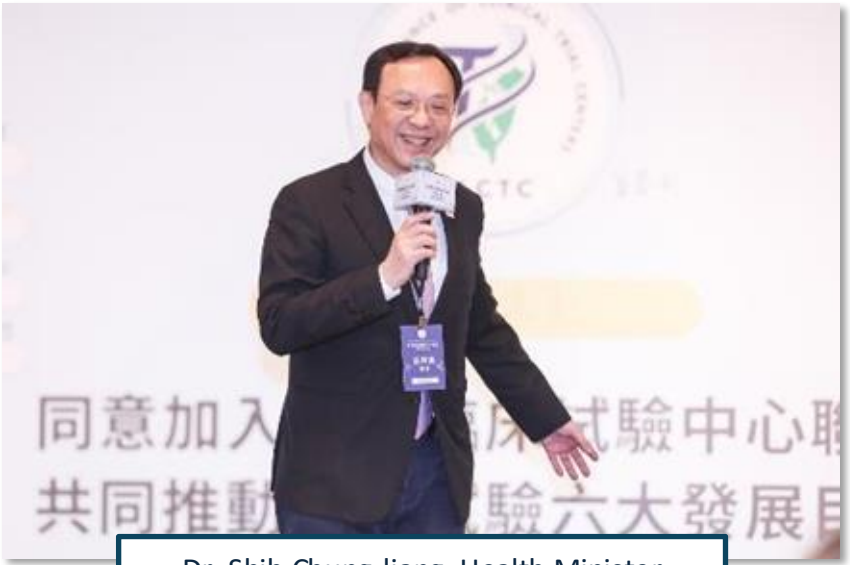
Unsynchronized IRB submissions.

Deadlocked contract negotiations.

Unpredictable Execution

Inconsistent patient recruitment pools across disconnected networks.

TACTC: Establishment & Government Support



Dr. Shih Chung-liang, Health Minister

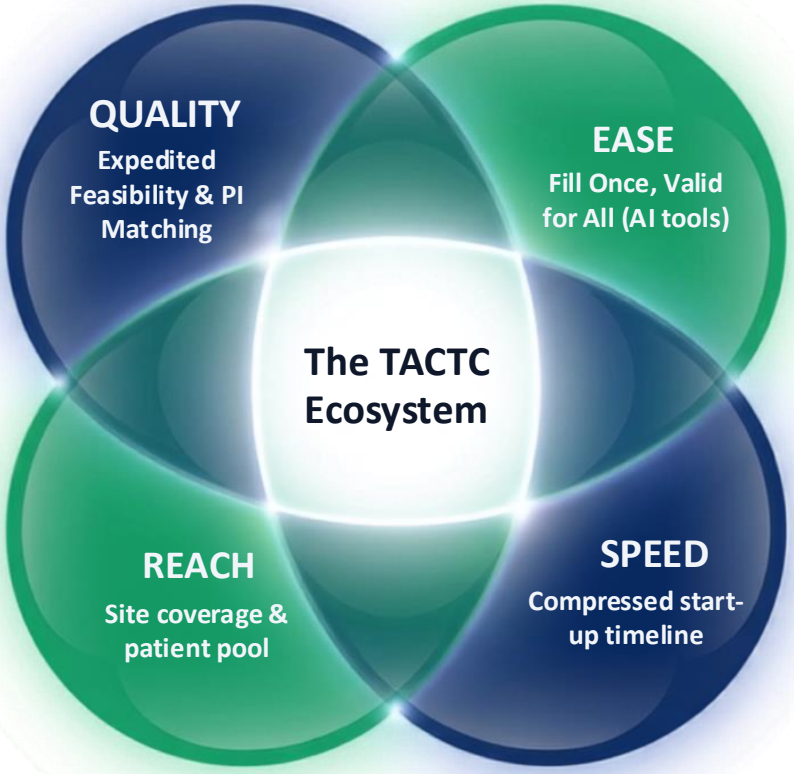
32 Leading Institutions (Alliance Members)

23 Medical Centers

>90% of Taiwan's total medical center capacity represented

- **Founded in December 2025**
- **First General Assembly held in April 2026**
- **Supported by Taiwan's Ministry of Health and Welfare (MOHW)**
- **National platform for clinical trial coordination and integration**

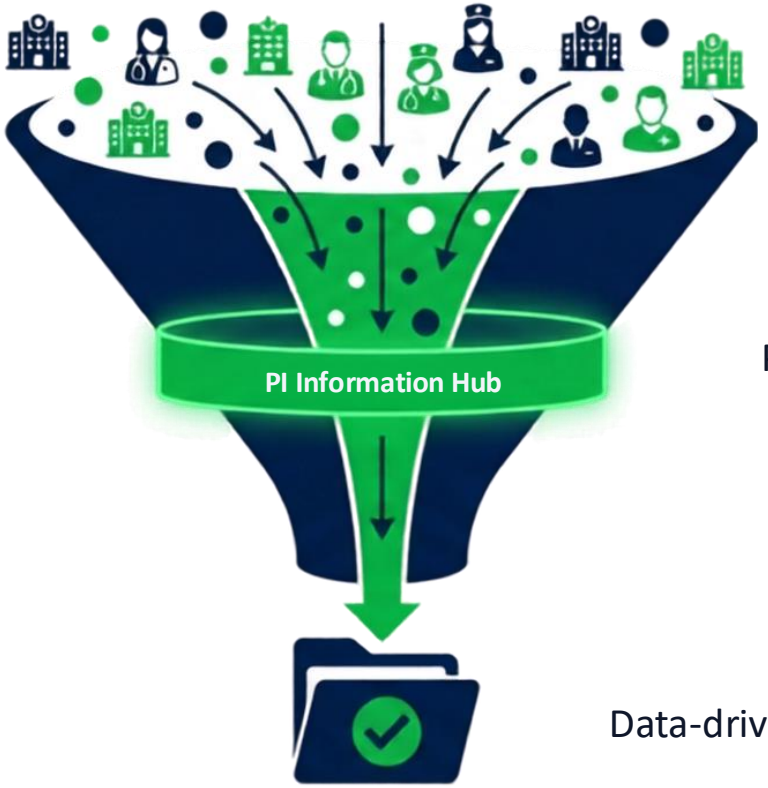
The National Team for Global Medical Innovation



Eliminating the traditional trade-off between rapid site activation and rigorous clinical excellence.

Pillar 1: Quality

Expedited Feasibility & PI Matching



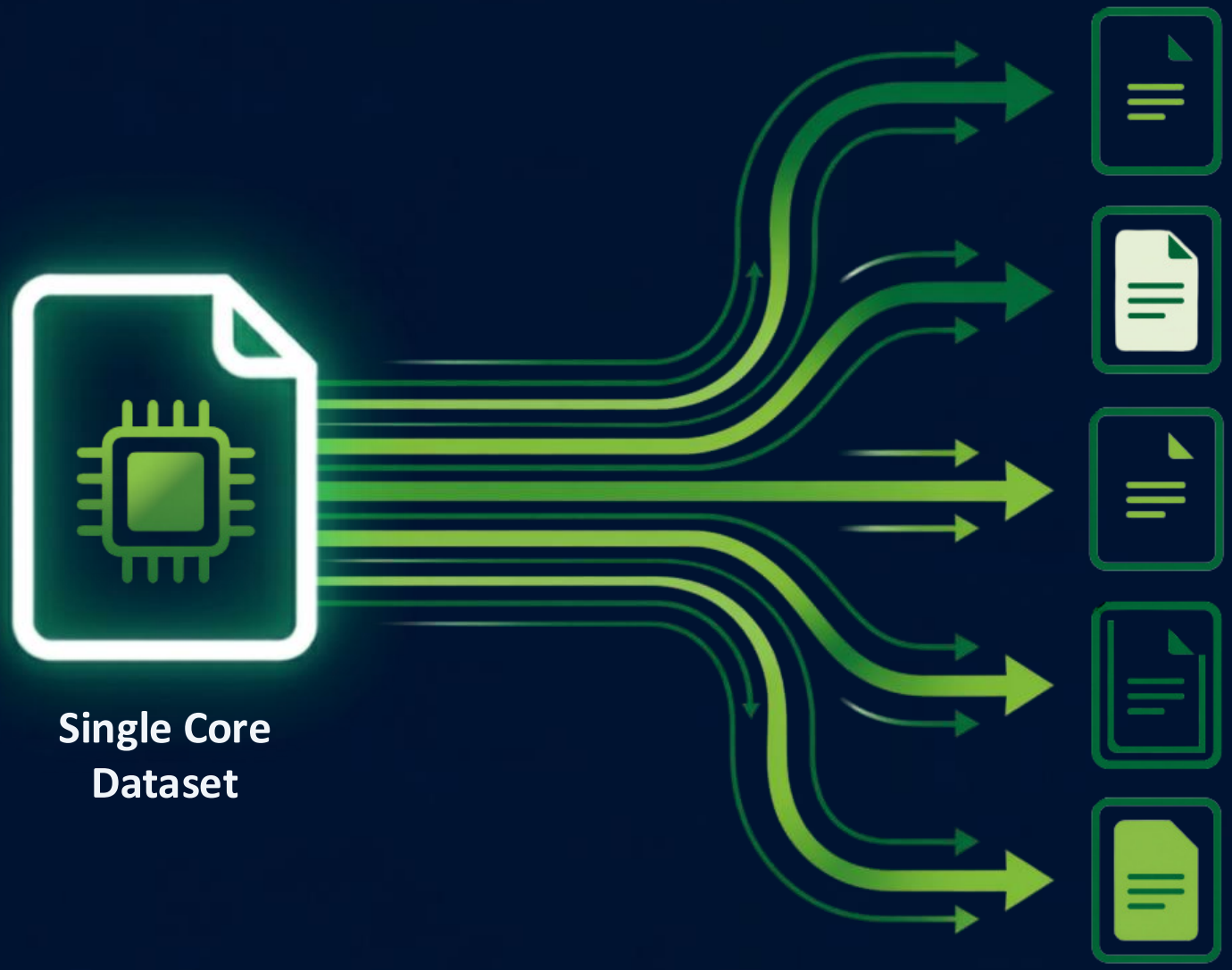
Inputs
Rapid feasibility survey across TACTC's 30+ sites.

Filter
Precision matching of qualified PIs based on therapeutic specialty and site capacity.

Output
Data-driven, consolidated site selection report to the sponsor.

Pillar 2: Ease

Fill Once, Valid for All

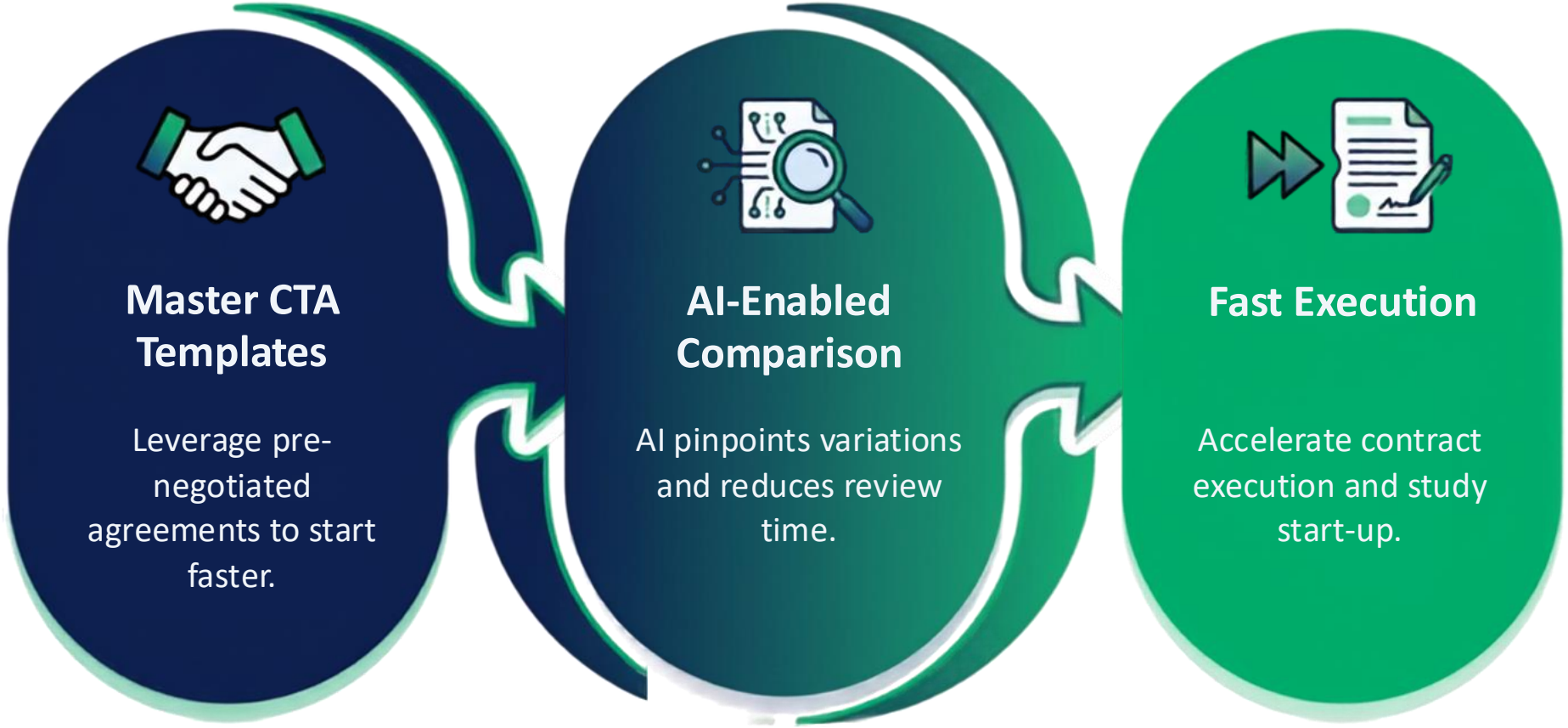


Single Core Dataset

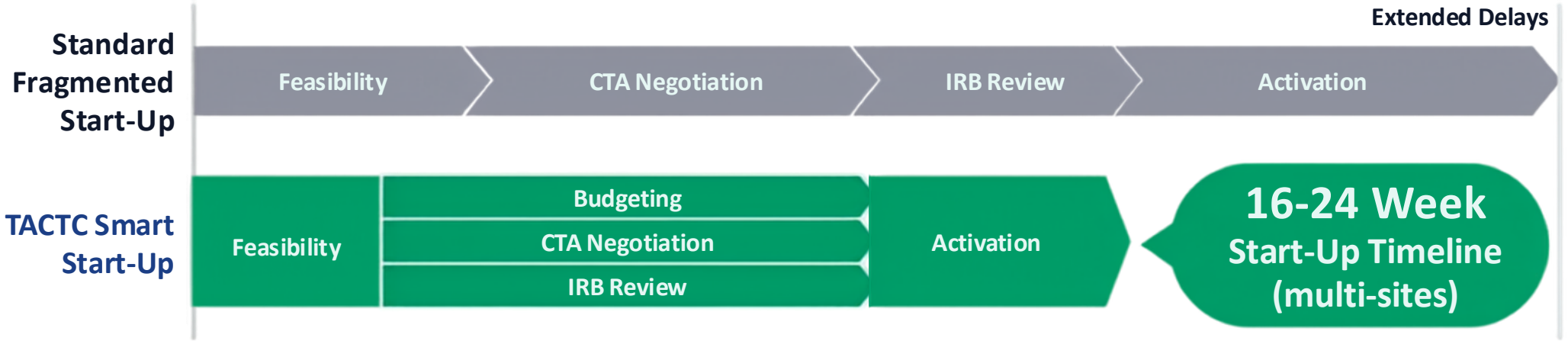
AI-Driven IRB & Ethics Applications

*Localized IRB documentation from a single master dataset, eliminating repetition & errors to support **simultaneous activation** across multiple sites.*

Pillar 3: Speed
Compressed Multi-sites Start-up



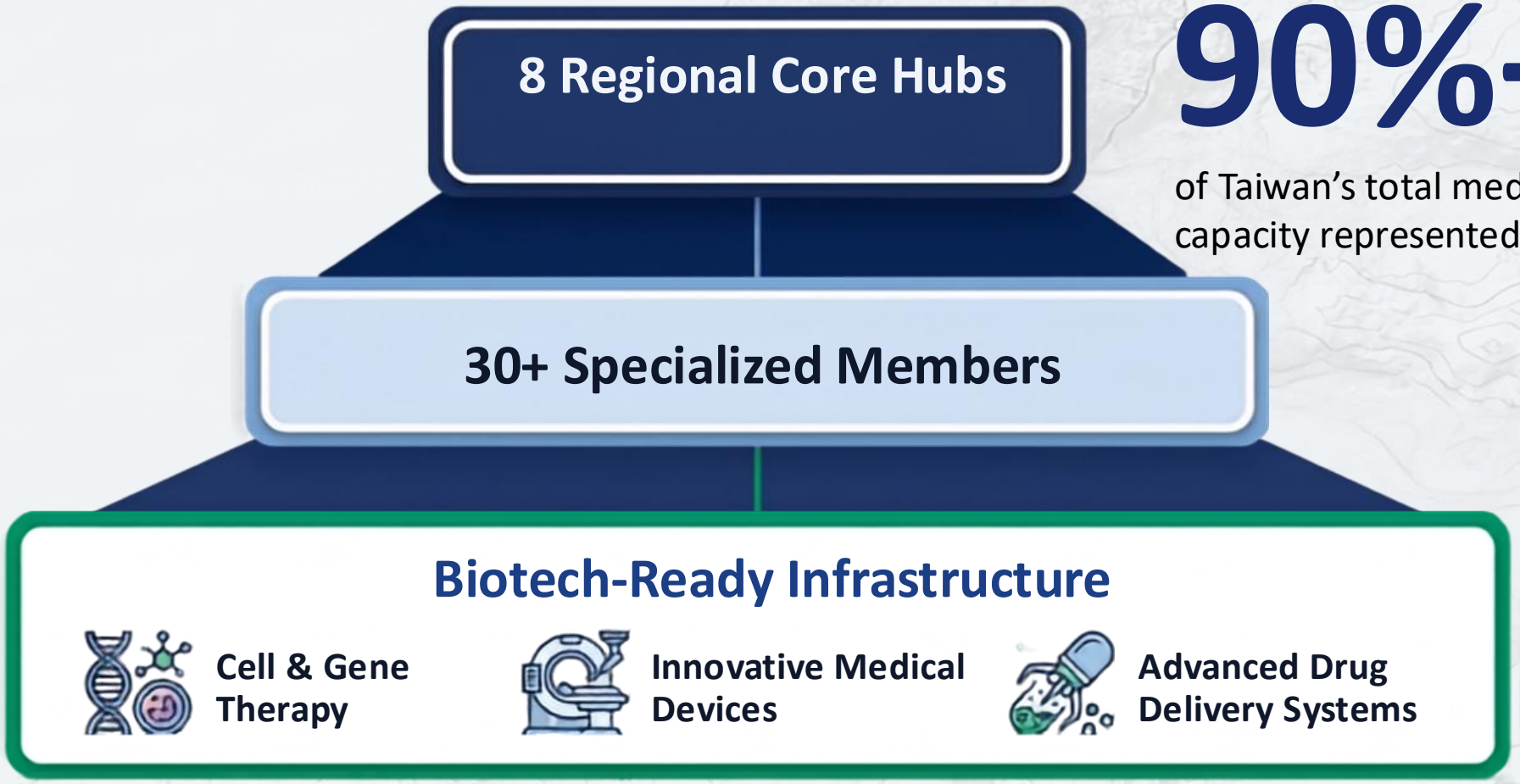
The Result: Timeline Compression



By executing feasibility, ethics, and contracts in parallel at multiple sites, TACTC delivers unmatched speed to site activation.

Pillar 4: Reach

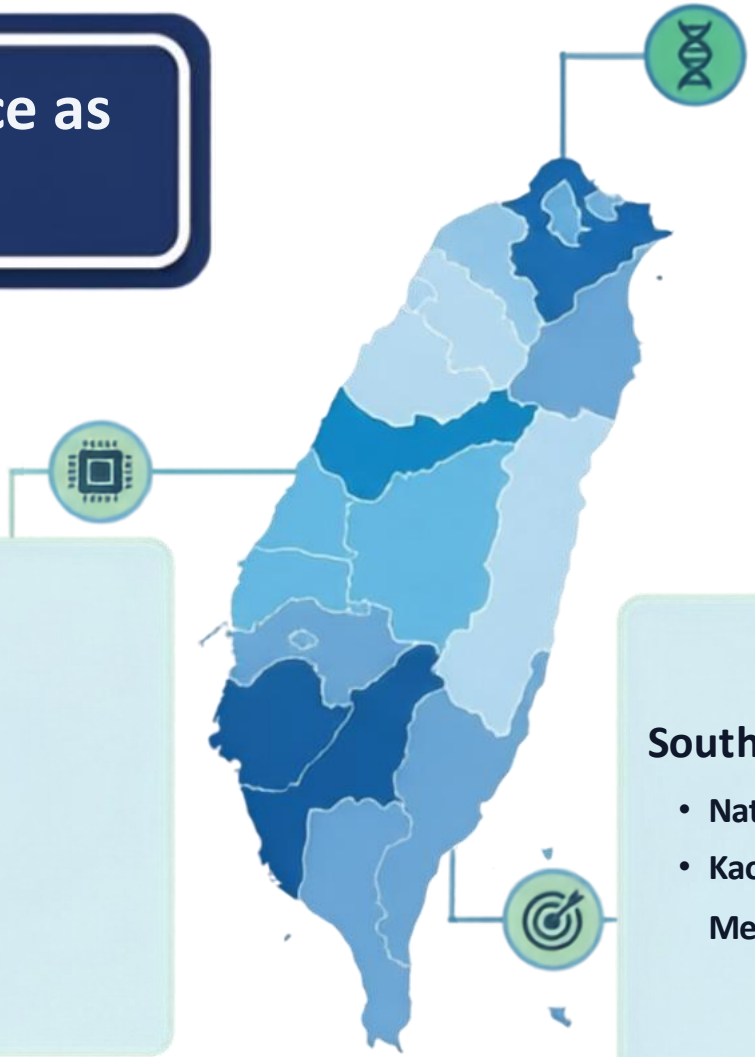
Extensive coverage & diverse patient pool



90%+

of Taiwan's total medical center capacity represented

8 Centers of Excellence as Regional Hubs



Northern Region

- National Taiwan University Hospital
- Taipei Veterans General Hospital
- Taipei Medical University Healthcare System
- Linkou Chang Gung Memorial Hospital

Central Region

- China Medical University Hospital
- Taichung Veterans General Hospital

Southern Region

- National Cheng Kung University Hospital
- Kaohsiung Medical University Chung-Ho Memorial Hospital

Integrated Patient Recruitment Ecosystem

Unified App Integration

Direct reach to trial participants through TACTC sites' **mobile apps & websites**.

National Platform

Light2Health: Taiwan Clinical Study Volunteer Registry powered by the sponsors

Homegrown Database

Access to sites' **bio database** to identify potential candidates across Taiwan.

Expedited recruitment to shorten trial period.

Taiwan: Your Strategic Asia-Pacific Hub

Japan / Korea
REACTA (Asia)
NCCJ/JIHS (Japan)
KONECT (Korea)

ASEAN
CRM (Malaysia)
CRIS (Singapore)

ANZ
AusTrade / CROs

Global Credibility

Clinical data quality seamlessly accepted by FDA and EMA.

Strategic Location

The geographic and operational bridge connecting Northeast Asia, Southeast Asia, and Oceania.

Regional Synergy

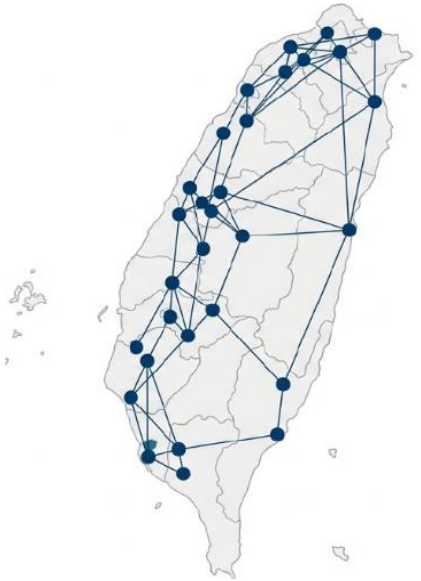
Expanding cross-border collaborations to anchor multi-national APAC trials.

The One-Stop Platform for All

Global Sponsors / CROs

TAIWAN ALLIANCE OF CLINICAL TRIAL CENTERS

TACTC



30+ sites

Single Window

A single point of contact for national coordination

National Capacity

Quality
Ease
Speed
Reach

Comprehensive Coverage

Together | Better | Stronger

Partner with TACTC Today

Moving from fragmented site management to a unified national ecosystem.

tactc@tactc.tw

www.tactc.tw

Together | Better | Stronger

Partnering with TACTC: Operationalizing a Unified Clinical Trial Ecosystem

- *This session is presented from the perspective of the Taiwan Clinical Research Association (TCRA), addressing how the professional and industry community can collaborate with TACTC to shape and optimize Taiwan's clinical trial environment — through alignment on operational and regulatory standards, professional training and talent development, and sustained industry–academia–government dialogue. Together, these efforts define the next steps toward pilot implementation and regional collaboration to advance site excellence across Asia.*

SCRS
Society for Clinical Research Sites

OUTLINE

TCRA at a glance:

- History, structure, and the five task forces, with C&C and EC working closely with TACTC

Stakeholder consensus:

- Key insights from IRPMA's 2026 report “A healthy and Sustainable Taiwan: Building a globally competitive clinical trial ecosystem”

Near-term TCRA-TACTC collaboration:

- Accelerating contract execution and IRB review timelines

Taiwan Clinical Research Association (TCRA)

- The Taiwan Clinical Research Association (TCRA) was established on 26 August 2005 with the mission of advancing Taiwan's clinical research environment and new drug development, to encourage and elevate the quality and standard of clinical trials and align them with international practice.
- **The Association currently comprises 28 pharmaceutical companies, 33 contract research organizations (CROs), 19 biotechnology companies, and 6 hospital member organizations, with approximately 189 members in total.**
- Working through member-driven taskforces, TCRA strengthens trial execution capabilities via shared learning and sustained engagement with regulators, hospitals, and peer associations — raising Taiwan's clinical trial standards and connecting them with the world.

Five taskforces drive the association's work

GA

Government Affairs
Bridge between industry and regulators; consolidates industry input to improve the regulatory environment

EC

Ethics Committee
IRB / EC engagement and collaboration with TAIRB

C&C

Center & Contract
Clinical trial site operations and trial contract practices

EDU

Education & Training
GCP / ICH guideline courses; academic and practical exchange

BTT

Branding & Communication
Social media (Facebook, IG, LinkedIn) and event promotion

Taiwan Clinical Research Association 台灣藥物臨床研究協會

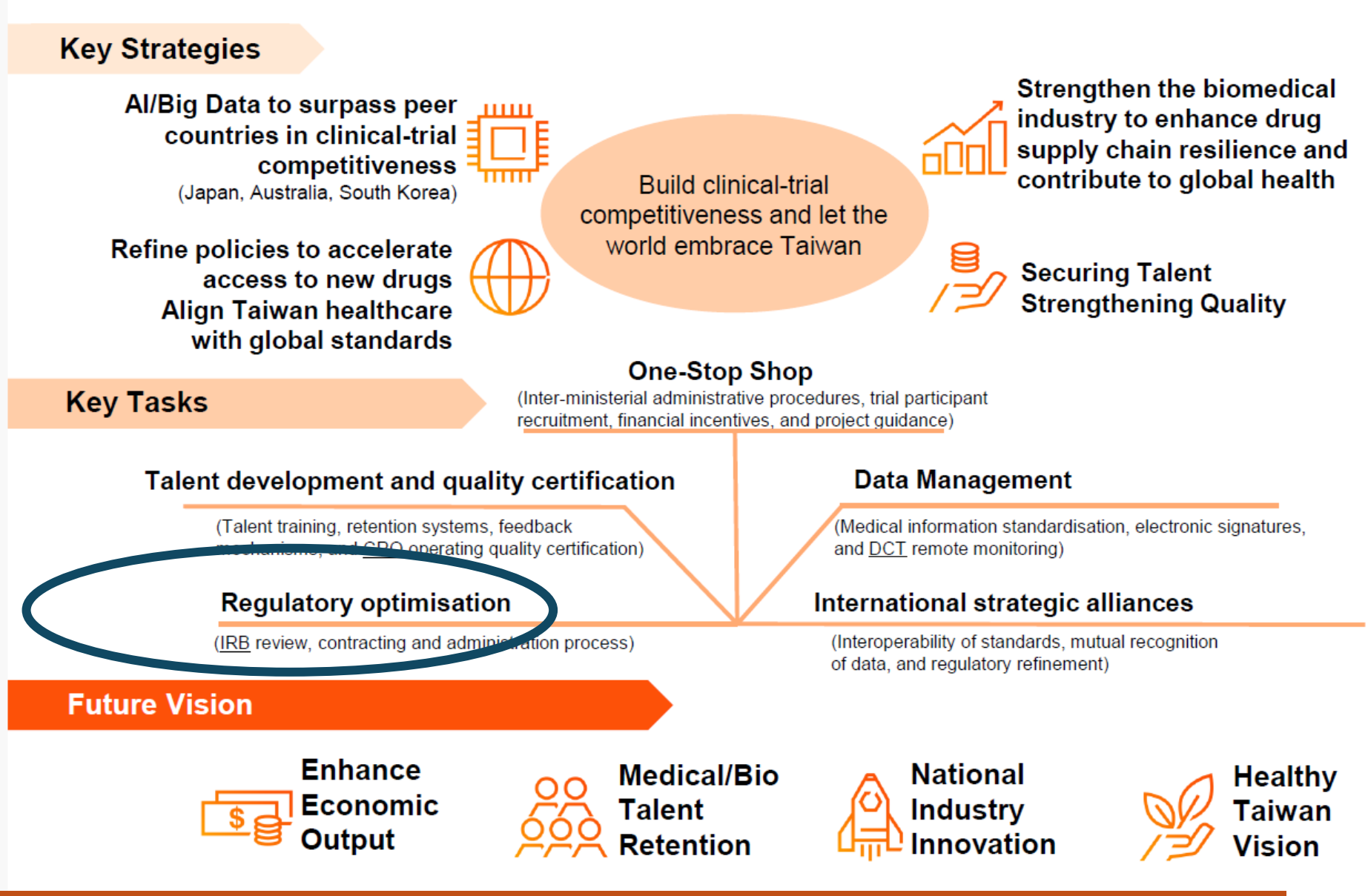
臉書粉絲專頁 QR Code

IG粉絲專頁 QR Code

SCRS Society for Clinical Research Sites

Stakeholder consensus & Strategy map:

Team Taiwan's roadmap to global trial competitiveness



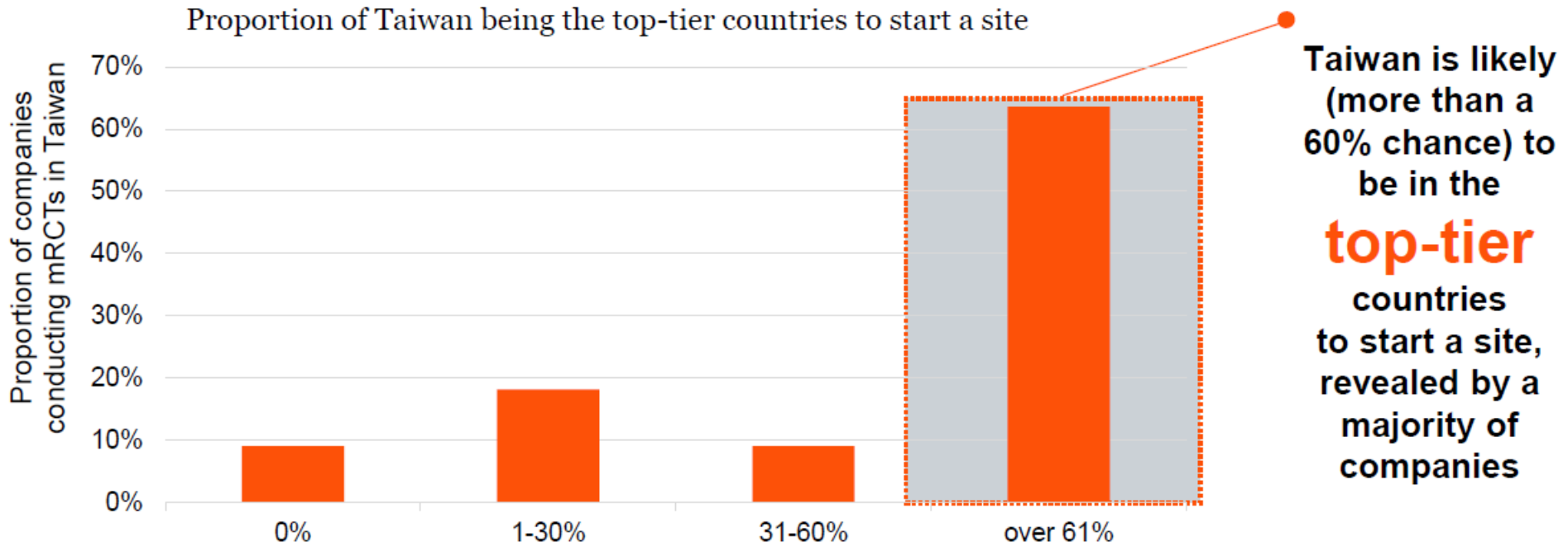
Source: A Healthy and Sustainable Taiwan: Building a Globally Competitive Clinical-Trial Ecosystem

SCRS
Society for Clinical Research Sites

Building on existing strengths:

Enhancing site start-up competitiveness

A survey of companies conducting multiregional clinical trials in Taiwan found that in more than 60% of these studies, Taiwan was placed in the top-tier countries for site initiation. In addition, nearly one third of respondents reported that Taiwan was designated as a top-tier country in more than 70% of their company's trials. These findings suggest that Taiwan is consistently viewed as a priority market for trial start up and remains highly attractive for multiregional clinical research.



Source: PwC questionnaire; PwC analysis

PwC | IRPMA Building a Globally Competitive Clinical-Trial Ecosystem

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

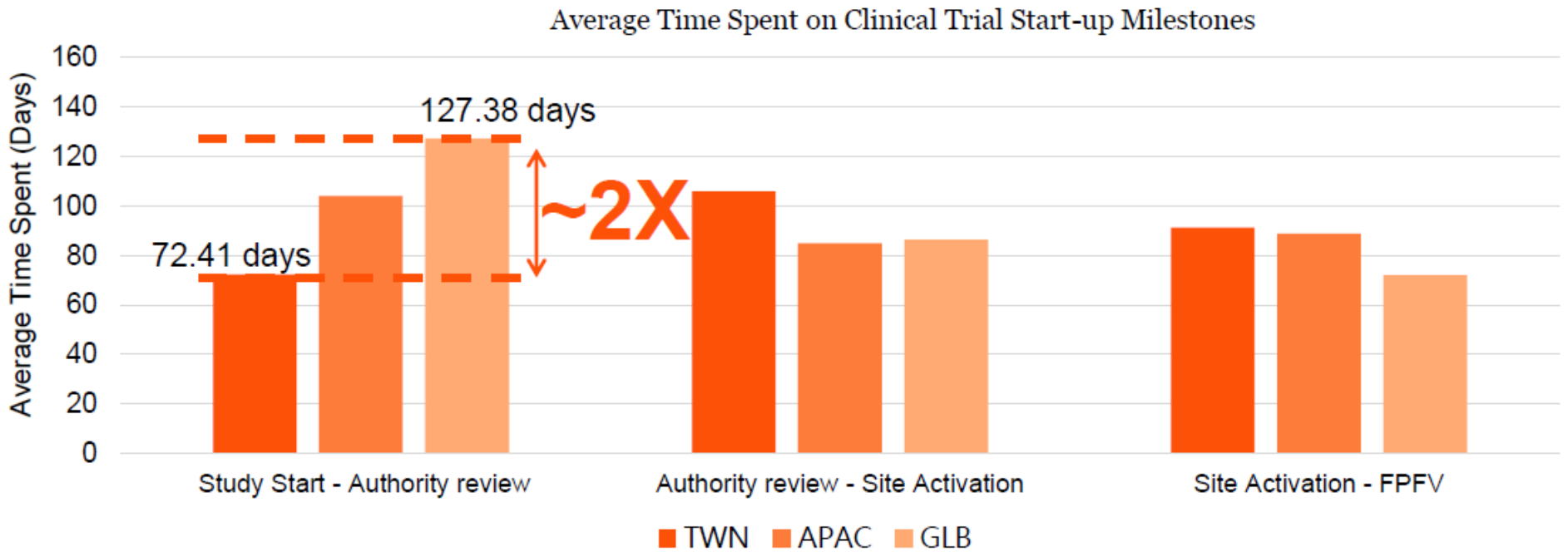
SCRS Society for Clinical Research Sites

Opportunity of site activation acceleration:

IRB turnaround is the decisive lever for competitiveness

The report segmented the clinical trial timeline into six milestones, from study start to authority review, authority review to site activation, site activation to FPFV, FPFV to LPI, LPI to LPLV, and LPLV to close out. Of these, the most meaningful indicators of system efficiency are the two early intervals, from study start to authority review and authority review to site activation, because they are less affected by external factors that influence later trial execution.

Taiwan's strongest advantage lies in the study start to authority review phase. In this interval, Taiwan is nearly twice as fast as the global average and about 1.6 times faster than the Asia Pacific average, making it a clear competitive strength. This demonstrates Taiwan's efficiency at the front end of trial initiation and supports its position as an attractive location for early phase clinical research.



Source: PwC questionnaire; PwC analysis

*Note: FPFV- First Patient First Visit; LPI- Last Patient In; LPLV-Last Patient Last Visit
TWN-Taiwan; APAC- Asia Pacific; GLB-Global

TACTC: A Step Toward a More Integrated National Clinical Trial Ecosystem

The Taiwan Alliance of Clinical Trial Centers (TACTC) marks an important step toward a more integrated and sponsor-ready clinical trial ecosystem in Taiwan.

TACTC was formally established by 33 member institutions and entered its next phase at its Kick-off on 8th Dec 2026.

The alliance is designed to strengthen cross-institutional collaboration and enhance Taiwan's clinical trial capacity through more consistent feasibility assessment, IRB review, contracting and budgeting processes, talent development, and participant recruitment support.

Looking ahead, TACTC aims to build a streamlined, people-centered, and internationally competitive **One-Stop ecosystem** in Taiwan by advancing AI-enabled parallel review, strengthening talent development and patient recruitment, and expanding Asia-Pacific strategic collaboration.

33
Member Institutions

1

Patient-Centered Recruitment
Building trial success through structured CRC/SMO training and a national participant recruitment platform.

2

AI-enabled Parallel Review
AI integration streamlines parallel review processes, enabling c-IRB, Master CTA, and a standardized budget framework to advance simultaneously.

3

Global Strategic Alliances
Strengthening global collaboration through strategic partnerships, cross-border research, and international engagement.

Near-term TCRA-TACTC collaboration: CIRB & Contract Process

- Leverage TCRA's established taskforce structure to contribute professional perspectives on EC and contract matters
- Collaboration between TCRA and TACTC to strengthen the international competitiveness of clinical trials in Taiwan, advance a domestic IRB mutual-recognition mechanism, and share implementation approaches to international single-review systems
- Streamline hospital administrative review processes and simplify contract application forms, for example:
  - CDE to provide a checklist of contract mandatory items for sponsors' reference
  - Set master agreements between sponsors and hospitals to a term of at least five years, and shorten master agreement negotiation timelines to improve efficiency

Thank You

Tina.sun@novartis.com