Tina Sun – President, Taiwan Clinical Research Association (TCRA)

We aspire to become the pre-eminent Asian clinical research hub, yet we face formidable competition

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As President of the Taiwan Clinical Research Association (TCRA), Tina Sun brings 25 years of pharmaceutical industry experience to bear on the evolution of Taiwan's clinical research ecosystem. This interview explores TCRA's pivotal role in harmonising regulatory frameworks, fostering cross-stakeholder collaboration, and positioning Taiwan as a competitive clinical trials hub within the increasingly dynamic Asia-Pacific landscape, whilst addressing persistent operational challenges that require strategic resolution.

Could you introduce TCRA to our global readers and outline your role within the organisation?

The Taiwan Clinical Research Association was formally established in 2006, evolving from the Medical Affairs Association, which had encompassed both clinical operations and regulatory affairs. The transformation coincided with Taiwan’s publication of its first Good Clinical Practice guidelines – aligned with ICH GCP standards introduced internationally in 1996 – demonstrating the government’s commitment to cultivating a robust clinical trials environment.

Today, TCRA operates as a volunteer-driven, non-profit organisation representing approximately 200 individual members from roughly 93 companies: 40 percent from pharmaceutical companies, 36 percent from contract research organisations, 20 percent from biotechnology firms, and Six

hospitals. This voluntary foundation – where members contribute expertise without obligation – creates genuine engagement and enables collaborative problem-solving to supersede individual corporate interests.

Our mission focuses specifically on clinical trial operations within Taiwan. We work to accelerate clinical trial processes, evolve the research ecosystem, attract increasing volumes of international clinical trials, and ultimately expand patient access to innovative therapies through enhanced clinical research infrastructure. This collective approach advances Taiwan's clinical research community more effectively than any single organisation could achieve independently.

How would you characterise Taiwan's development as a clinical research hub over the past two decades, and what contribution has TCRA made to this progress?

Having worked in this field for 25 years, I have witnessed Taiwan's clinical research evolution firsthand. The journey began with regulatory harmonisation: when ICH GCP was published internationally in 1996, Taiwan responded that same year with its first Traditional Chinese-language GCP guidance. This pattern continued when ICH GCP E6 R2 version emerged in 2016, and by 2018, Taiwan achieved formal recognition as an ICH GCP member country.

Over the past two decades, we have developed regulations paralleling international best practices. A particularly instructive example occurred during the COVID-19 pandemic: when Denmark published the first decentralised clinical trial guidance, the Taiwan Food and Drug Administration immediately prepared a Traditional Chinese-language version. By 2023, Taiwan became the first Asian nation to publish comprehensive DCT guidance, demonstrating both regulatory agility and strategic foresight.

Beyond regulatory evolution, Taiwan has cultivated a sophisticated stakeholder ecosystem. The government invested substantially in establishing eight major clinical trial centres within leading medical institutions, whilst the Taiwan IRB Association represents institutional review boards nationwide. TFDA has actively facilitated knowledge transfer by sponsoring study tours for clinical trial centre representatives to Singapore and Australia, enabling institutions to observe international best practices.

The second critical evolution involves stakeholder collaboration. Taiwan's unique geopolitical circumstances – persistent political tensions and our historical struggle for international recognition – have fostered a collaborative mindset where collective action generates substantial impact. The

relationship between TCRA and the Taiwan IRB Association exemplifies this model. We regularly convene joint workshops bringing together IRB members and industry representatives to examine real-world scenarios and address mutual pain points.

These workshops prove remarkably productive. When stakeholders from different perspectives convene in person, dialogue shifts dramatically. Participants recognise that divergent viewpoints stem from organisational positions rather than fundamental disagreement, and through face-to-face engagement, mutual understanding emerges. This collaborative capacity represents one of Taiwan's most distinctive competitive advantages in the Asian clinical research landscape.

Could you walk us through the regulatory pathway for clinical trial approval in Taiwan – from CDE evaluation to TFDA approval and site initiation? How does Taiwan balance speed with quality and safety?

Taiwan hosts two distinct categories of clinical trials: international pharmaceutical trials and locally initiated research studies. Academic medical centres conduct substantial volumes of investigator-initiated research, but for international pharmaceutical trials, the government has implemented several mechanisms to facilitate rapid approval for multinational studies.

The most significant mechanism is the MRCT process – Multi-Regional Clinical Trial review. If your clinical trial is conducted in Taiwan with the same approved IND protocol number and conducted simultaneously in one of the 10 reference countries ("A10 countries" according to the Regulations for Registration of Medicinal Products) you qualify for the MRCT pathway. The critical advantage is that this route eliminates the comprehensive scientific review typically conducted within TFDA. Instead, sponsors provide approval documentation from a reference country along with relevant supporting materials, and TFDA conducts an administrative review.

This expedited process can compress approval timelines to approximately two weeks, with optimal cases achieving approval within ten days. In practical terms, large pharmaceutical companies conducting multinational trials typically reference US FDA procedures. After submitting an IND to the US FDA and receiving an acknowledgement letter with no review comments – which functions effectively as approval – we compile documentation for TFDA submission, including the US FDA acknowledgement letter confirming protocol submission, Form 1571 evidencing the US FDA submission, and indication that we are pursuing the MRCT pathway. TFDA then reviews primarily Taiwan-specific elements: the informed consent form, investigational medicinal product information, and similar localised components, without conducting in-depth scientific protocol

review.

By contrast, the standard IND approval process involves referral to the Centre for Drug Evaluation, where scientists conduct comprehensive scientific review generating substantial queries. The standard timeline is 45 calendar days, though certain indications now qualify for expedited 30-working-day review, translating to approximately one to two months total. For large pharmaceutical companies conducting international multi-centre trials, the MRCT pathway has become standard practice, offering significant timeline advantages.

Phase III studies are particularly prominent in Taiwan. Is attracting more early-phase research also a strategic priority?

Taiwan accommodates diverse trial phases, including early-phase studies and even cell and gene therapy trials. Any trial type conducted globally can be executed in Taiwan. However, one category remains relatively uncommon: healthy volunteer phase one studies.

Large pharmaceutical companies typically conduct first-in-human healthy volunteer trials at specialised centres in the US, Europe, or Japan. Such trials are generally uncommon across Asia. Whilst some large pharmaceutical companies have conducted phase one healthy volunteer trials in Taiwan historically, these remain exceptional rather than routine.

The majority of clinical trials in Taiwan span phase two through phase three, with particular concentration in pivotal studies. Phase one oncology trials are also very common in Taiwan. Additionally, we observe post-approval commitment trials – studies TFDA may require as a condition of accelerated approval, mandating risk management plans or post-marketing trials before licence renewal.

Regarding healthy volunteer trials specifically: whilst large pharmaceutical demand remains limited, Taiwan maintains several qualified phase one centres. These facilities primarily conduct bioavailability/bioequivalence studies or support local biotechnology companies' first-in-human trials. The clinical trial volume for phase one and BE studies remains robust, though driven primarily by these alternative applications rather than multinational pharmaceutical first-in-human studies.

Which further regulatory alignments with global standards is TCRA currently advocating?

TCRA does not engage directly with individual pharmaceutical companies on regulatory matters. Rather, we function as a collective industry voice coordinating with other associations. In Taiwan, we also have the IRPMA. Given my company's involvement in regulatory affairs, I serve as a member of IRPMA's clinical research task force, creating substantial overlap between our memberships.

Taiwan's relatively modest market size means industry professionals often hold memberships in multiple associations whilst maintaining close collegial relationships. We are not merely association members but professional colleagues who know one another quite well.

Our organisational model emphasises that we serve collective industry interests rather than individual companies. However, company representatives participating in board meetings can advocate for their organisations' needs and seek alignment across membership. When we achieve consensus that a particular issue represents a shared priority, we can advance it as a collective goal and engage various stakeholders more effectively.

This collective approach proves far more influential than individual company advocacy. A single hospital or regulatory authority might dismiss concerns raised by one company. However, when an association representing dozens of organisations presents a unified position supported by multiple member companies, the message carries substantially greater weight and commands serious attention.

What is the balance between multinational and local CRO participation within TCRA, and how do their priorities differ?

Our focus on accelerating clinical trial processes, streamlining start-up timelines, ensuring regulatory awareness, and communicating hospital policies and IRB requirements benefits all members equally, regardless of whether they represent pharmaceutical companies or CROs.

However, most board members represent pharmaceutical companies, as pharmaceutical organisations typically offer greater flexibility for personnel to dedicate volunteering time to external associations. CRO organisations often face resource constraints that limit board participation. We may invite senior CRO executives to present at workshops or provide commentary, but they less frequently assume formal board positions.

CRO member companies and local biotechnology firms participate primarily through our monthly meetings, often rotating representatives from month to month. These meetings follow a consistent structure: the first segment provides regulatory updates and environmental developments; the second segment features special topics with invited speakers addressing current issues.

For CRO and local biotechnology participants, the primary value proposition lies in knowledge sharing and learning from global pharmaceutical best practices. Large pharmaceutical companies conducting international trials in Taiwan consistently strive for operational consistency across all countries, and we have a vested interest in elevating Taiwan's clinical trial practices to global standards. When large pharmaceutical companies introduce innovative approaches, other stakeholders can observe and learn from these practices, and once the broader community recognises the value of a particular innovation, local companies and CROs benefit substantially from this knowledge transfer.

One limitation exists: if board members from large pharmaceutical companies do not conduct certain trial types in Taiwan – such as highly sophisticated decentralised trial components that exceed Taiwan's current infrastructure capabilities – CRO members cannot benefit from associated expertise, and the association cannot provide direct support.

Nevertheless, as long as topics represent common interests across substantial portions of our membership, we commit resources to collaborative problem-solving. We maintain an important principle: any member can raise questions or propose topics requiring solutions, provided at least three member companies endorse the issue. This threshold ensures we address genuinely widespread challenges rather than company-specific concerns. Upon confirming widespread impact, our task forces mobilise to identify solutions, ensuring we allocate resources towards maximum collective benefit.

How well integrated are digital tools, decentralised trial approaches, and real-world data within Taiwan's current clinical research and post-marketing environment?

Integration of these elements varies considerably by company. Some organisations embrace digital tools and real-world data extensively; others less so. Within TCRA, we have not focused substantially on real-world data or real-world evidence research – our primary interest centres on prospective clinical trials.

However, we have invested considerable effort in promoting decentralised clinical trial concepts. DCT has emerged as a critical topic globally, and we have worked diligently to advance DCT adoption in Taiwan. Over recent 2 years, I have personally visited numerous hospitals to introduce DCT concepts, aiming to educate investigators and institutional leadership.

Our educational messaging emphasises several core principles: DCT represents a fundamentally patient-centric approach to trial design; DCT implementation requires thoughtful strategic consideration rather than ad hoc adoption; protocol design must drive DCT element selection, as one size decidedly does not fit all. Initially, hospitals possessed minimal DCT knowledge. Today, several institutions demonstrate genuine enthusiasm for these approaches.

Taichung Veterans General Hospital and Taipei Medical University exemplify institutional leadership in this domain. Taipei Medical University hosted a DCT conference in October 2025, featuring speakers from Japan and Korea to share international perspectives. Taichung Veterans General Hospital, has championed specific DCT elements – electronic consent, for instance. Whilst we might debate whether consent captured via tablet truly constitutes authentic electronic consent, the institutional commitment to exploring technological solutions represents meaningful progress.

We have also invited hospital superintendents to present at TCRA monthly meetings, describing their institutions' digital transformation initiatives. Taichung Veterans General Hospital, now position themselves as "smart hospitals," implementing comprehensive digital infrastructure across operations. These developments suggest growing institutional sophistication regarding digital clinical trial capabilities.

How is Taiwan positioning itself in next-generation modalities such as regenerative medicine, cell and gene therapy, mRNA, and precision oncology?

These represent extraordinarily popular topics in Taiwan, with widespread enthusiasm for next-generation therapeutic modalities. However, I must acknowledge limited personal expertise in this domain, as my company's portfolio does not extensively engage all of these areas. My knowledge derives primarily from observing industry trends rather than direct operational involvement.

Nevertheless, I can confirm these represent priority areas for Taiwan. Hospitals actively pursue capabilities in next-generation therapies, including next-generation sequencing applications. Taiwan's National Health Insurance programme has allocated dedicated funding for NGS testing, enabling hospitals to build sophisticated capabilities. Major medical centres have made substantial

investments in this infrastructure and conduct extensive internal research programmes.

Taiwan generates remarkable volumes of academic clinical trials. Examination of ClinicalTrials.gov reveals substantial Taiwanese trial registration – a significant proportion representing investigator-initiated academic research. Academic medical centres pursue these trials partly because career advancement and professorial appointments require robust publication records. Given physicians' demanding clinical schedules, investigator-initiated trials represent an efficient pathway to generating publications.

Consequently, whilst precise statistics lie beyond my expertise, I am confident that Taiwan's academic physicians – particularly at major medical centres – possess sophisticated capabilities in next-generation sequencing and advanced therapeutic modalities. These capabilities, however, manifest primarily through academic research rather than industry-sponsored trials.

Against regional competitors such as China, Singapore, Korea and Japan, where does Taiwan currently stand as a clinical trials destination?

This question strikes at the heart of our strategic challenges. We aspire to become the pre-eminent Asian clinical research hub, yet we face formidable competition. Historically, Korea has demonstrated considerable strength. China, previously characterised by protracted IND review timelines, has achieved dramatic improvements recently – multiple companies report China now completes reviews within four months, a remarkably competitive timeline that intensifies regional rivalry.

Taiwan has experienced certain setbacks this year, However, we now observe renewed momentum. Clinical trial centres have demonstrated heightened eagerness to improve performance metrics. Through our collaboration with the Taiwan IRB Association, we have identified specific pain points requiring resolution and are collectively committed to accelerating start-up processes.

Several critical challenges span regulatory and operational dimensions. Whilst we have implemented the MRCT process and achieved substantial regulatory harmonisation with global standards, certain requirements remain uniquely burdensome. The investigational medicinal product, lab kits and medical device import permit represents a particularly striking example – no other country imposes Taiwan's requirement for sponsors to submit import permits with 100 percent reconciliation for both investigational products and laboratory kits. This regulation creates

genuine operational pain. Currently, every company must dedicate one to two full-time equivalents exclusively to managing laboratory kit and IMP import permit processes – a profoundly inefficient resource allocation that generates minimal value.

The government has established a Central IRB process designed to streamline ethics review. The conceptual framework is sound: once the primary IRB grants approval, subsequent IRBs should provide tacit approval. In practice, however, individual IRBs maintain institutional reputations and professional standards, leading them to conduct independent reviews and generate additional queries, undermining the intended efficiency. Clinical trial centres are working to establish genuine mutual recognition of IRB approvals across institutions.

Individual sponsors have established unique contractual templates with individual hospitals, creating a labyrinth of varying agreements that introduces substantial complexity, particularly as trial designs become increasingly sophisticated. Payment processes exemplify this: in many countries, sponsors simply remit payment to hospitals, receive invoices, and complete transactions. In Taiwan, hospitals require study coordinators and sponsor clinical research associates to collaboratively verify individual expense line items before the clinical investigator drafts and approves the invoice, and only then can sponsors release payment. This process consumes disproportionate time and resources, representing another area demanding reform to enhance Taiwan’s competitive position.

How do Taiwan’s cycle times and recruitment performance compare with neighbouring countries?

Performance varies considerably. In certain cases, we achieve exceptional speed – Taiwan has secured global first patient enrolment in multiple trials. However, examining median cycle times reveals we cannot consistently maintain competitive performance due to persistent bureaucratic obstacles.

Achieving first-patient-first-visit status in Taiwan requires dedicated project management and intensive monitoring of each procedural step. Global company strategy plays a critical role: if a company designates Taiwan as a tier-one priority country, they will prepare required regulatory documentation at the earliest possible stage, enabling accelerated submission. The MRCT process discussion illuminates this dynamic. If TFDA did not impose comprehensive import permit and laboratory kit requirements, we would not need to request these detailed specifications from global teams at early stages. Laboratory kit details typically constitute final documentation elements

rather than initial submissions, yet these additional requirements delay our submission timelines.

When global companies prioritise Taiwan for first patient enrolment, they invest extraordinary effort to ensure documentation readiness. By contrast, countries like Singapore and Australia – which do not require such extensive ancillary documentation – can achieve first patient enrolment consistently without comparable global investment.

Success requires both local operational excellence and global resource allocation. Certain pharmaceutical companies operating in Taiwan consistently achieve first patient enrolment, likely through substantial dedicated investment and through well-established local processes and highly efficient operation team. By contrast, my company conducts cell therapy, gene therapy, and radioligand therapy trials – highly innovative modalities where protocol design, procedures, and front-loading documentation requirements prove substantially more complex. For innovative, first-in-class therapies, achieving first patient enrolment in Taiwan presents considerably greater challenges.

This reality underscores our advocacy for TFDA and IRB process evolution and regulatory reform. We must reduce bureaucratic friction to enable Taiwan to compete effectively for cutting-edge clinical research.

Looking ahead five years, what are your expectations for Taiwan's clinical research ecosystem? What message would you convey to global stakeholders considering establishing clinical trials in Taiwan?

On behalf of TCRA, I must acknowledge I have not formulated an exhaustive long-term strategic vision, partly because association leadership rotates biennially. Nevertheless, certain trajectories are clear.

We remain firmly committed to evolving Taiwan's clinical trial ecosystem. We have not achieved our ultimate objectives, but cross-functional cooperation positions us to collectively elevate Taiwan's standing and establish Taiwan as a genuine biotechnology hub.

TCRA's primary focus addresses international clinical trials, yet we maintain meaningful engagement with local biotechnology companies through our membership structure. Taiwan's domestic biotechnology sector demonstrates remarkable strength. These companies benefit substantially from TCRA participation, as we provide education – particularly for clinical research associates – and disseminate best practices across the community.

Local biotechnology companies often possess compelling intellectual property and strategic vision but lack clinical development expertise. Many newly established Taiwanese biotechnology companies join TCRA specifically to access this knowledge. They learn from global pharmaceutical company practices shared through our programmes.

TCRA may not single-handedly transform Taiwan’s clinical research environment, but we function as a meaningful catalyst – one engine among several driving continuous improvement in speed, efficiency, and quality.

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