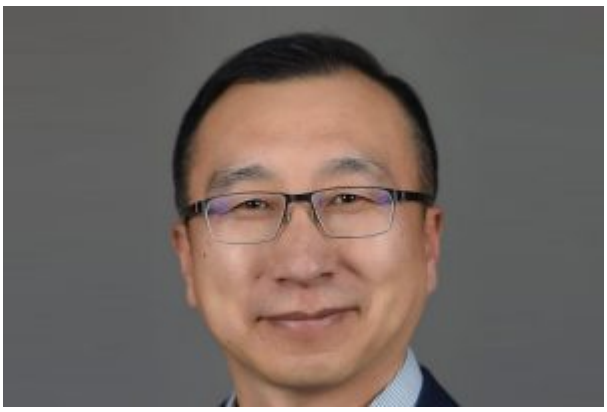
Andy Liu â?? Managing Director China, Novotech



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China is rapidly maturing into a global hub for innovation, offering speed, scale, and cost advantages in clinical trials that few markets can match. Andy Liu, Managing Director China for Novotechâ?? a full-service clinical research organisation (CRO) and scientific advisory company trusted by biotech and small- to mid-sized pharmaceutical companies to guide drug development at every phase â?? is steering the organisationâ??s growth at a pivotal moment, bringing together decades of regional expertise with a strengthened global platform spanning the United States and Europe. By focusing on advanced modalities, rare diseases, and multi-regional development, Novotech is helping both Chinese biotechs and international sponsors turn opportunity into impact.

What is your professional background, and how would you describe Novotechâ??s positioning in the global CRO landscape?

I began my career in engineering, graduating in Electrical Engineering from Tsinghua University, before pursuing an MBA at the University of Chicago Booth School of Business. After returning to Asia, I joined Covance and spent more than a decade in the CRO industry, primarily across the Asia-Pacific region. My last position there was as General Manager of Central Laboratory Services, overseeing operations in Japan, Shanghai, and Singapore, which provided me with valuable experience in managing complex operations that were both regional and global in scope.

In 2021, I assumed the role of Managing Director for Novotech in China. What sets Novotech apart is our strong focus on biotech and small-to-mid-sized pharmaceutical companies, and our expertise in advanced and novel modalities including cell and gene therapies, RNA-based medicines, and antibodyâ??drug conjugates (ADCs). When I first joined, our operations were concentrated in Asia-Pacific, but we have since expanded into the United States and Europe, building on over two decades of regional experience and deep relationships with investigators and regulators. At the same time, we have invested significantly in infrastructure, integrating global platforms such as Veeva Vault EDC and Veeva Study Training to ensure high standards and consistency across all markets. By combining international systems and processes with local agility and knowledge, we have established a position that bridges the scale of large multinational CROs with the flexibility of smaller, more specialised players.

How has Chinaâ??s clinical trial environment evolved over the past decade, and how has Novotech adapted to these changes?

When I returned to China in 2010, the regulatory environment was slow and often discouraging, with approval processes stretching beyond a year. As a result, China was frequently excluded from global multi-regional clinical trials, since other regions could complete recruitment and data collection before Chinese sites had even commenced. The reforms launched in 2015 marked a turning point, introducing faster reviews of INDs and NDAs, acceptance of selected foreign clinical trial data, and more efficient site and ethics approvals. These changes created a markedly more supportive framework for innovation, and many experienced professionals from global CROs and pharmaceutical companies joined us at that time, bringing with them the expertise needed to strengthen capacity in China.

Between 2015 and 2021, Chinese biotechs benefited from abundant, at times excessive, funding, which fuelled an extraordinary wave of activity, particularly in the PD-1 field. Our business during this period was therefore heavily focused on domestic biotech clients, but we also attracted inbound opportunities from US biotechs that had worked with us in Australia and trusted us to guide them in China. This combination of strong local demand and established international partnerships laid the foundation for the merger between Novotech and PPC, a mainland China and Taiwan-based CRO. Completed in 2020, the merger created Novotech Health Holdings, giving us the scale and platform to expand rapidly across Asia-Pacific and positioning us for broader global growth.

How would you characterise the current state of Chinaâ??s clinical trial market, and how is Novotech adapting to multi-regional development?

China has now surpassed the United States in total trial volume, though most studies remain domestically sponsored. The period between 2015 and 2021 was marked by overheated growth, with dozens of PD-1 programmes running simultaneously, but in recent years the market has cooled and become more rational. Biotechs are now more pragmatic, recognising that well-executed China-only data can secure solid out-licensing deals as international acceptance of local data has improved. Many therefore focus on generating rapid proof-of-concept results in China before seeking a partner, rather than committing to expensive late-stage trials in the US. Investors, too, have matured, no longer content with symbolic milestones such as a â??first patient in Australia,â?• but expecting the right geographies and datasets to attract global partners. This shift has driven a rise in domestic requests for proposals alongside increasing inbound interest from US sponsors keen to use China as a development platform.

To support this evolution, Novotech has expanded into the United States and Europe through acquisitions, extending our capabilities beyond Asia-Pacific. While our US presence is still modest, the trust we have built with biotech clients allows us to grow with them and ultimately deliver global, multi-regional trials that combine our Asia-Pacific expertise with an expanding international footprint. For smaller biotechs, timelines remain critical. Historically, slower start-up times in China made early-phase trials less attractive compared with markets such as Australia, South Korea, or Taiwan. Today, however, regulatory reforms are changing that picture. The National Medical Products Administration (NMPA) is piloting shorter review processes, cutting clinical trial application timelines from 60 to 30 working days in some cases. This progress makes China comparable with the US and, in some instances, faster than Europe or South Korea, reassuring sponsors that data generated here can contribute meaningfully to global programmes without delaying development.

Why has China prioritised shortening trial approval timelines, and what does this mean for sponsors concerned about quality and trust?

The reforms are driven by two main considerations. First, the NMPA is determined to bring Chinaâ??s regulatory framework in line with the US FDA, which remains the global benchmark. This is as much about international competitiveness as it is about regulatory efficiency. Second, the government has invested heavily in clinical trial infrastructure over the past 15 to 20 years, and faster approvals are a way to ensure that this capacity is fully utilised. For large pharmaceutical companies, longer timelines were never a decisive barrier; they came to China regardless, attracted by the patient population and long-term commercial opportunities. For smaller biotechs developing early-stage innovative therapies, however, timelines were critical, and delays in first-in-human or early proof-of-concept studies often discouraged them from considering China. With todayâ??s shorter approval windows, the country has become far more attractive as a market that can be integrated earlier into development strategies.

Concerns around the reliability of data, which were frequently voiced 15 years ago, have also changed. One of Novotechâ??s advantages is that we combine deep roots in China with the global standards expected of Western CROs, giving international sponsors the reassurance that processes and quality are consistent worldwide. At the same time, many leading Chinese trial sites have built strong reputations over the past decade, demonstrating their ability to meet international expectations and earning the trust of global sponsors. While smaller biotechs may still require guidance, large pharmaceutical companies now maintain their own experienced teams on the ground and know the realities of operating here. Even geopolitical tensions, which created hesitation only a few years ago, are no longer the deterrent they once were. Today, as long as the financial and scientific rationale is clear, sponsors are approaching China with much greater confidence.

How interoperable is China-generated data with international standards, and how does Novotech ensure its trials meet global requirements?

For pivotal Phase III trials, sponsors must be cautious, as the FDA has made it clear that data generated entirely in China will not be accepted; there must be contributions from other regions to create the right balance. Early development, however, is a different story. Many biotech companies, including our Chinese clients, conduct Phase I or proof-of-concept studies in China, where they can generate rapid and cost-effective clinical signals to guide decision-making. When these assets are subsequently licensed to US biotechs or global pharmaceutical partners, the responsibility for Phase III development typically shifts to those partners in the United States or Europe, which helps mitigate

geopolitical or data-quality concerns. China is therefore particularly attractive for early-phase research, offering speed, lower costs, and access to advanced modalities such as cell and gene therapies, RNA-based treatments, ADCs, and radiopharmaceuticals, capabilities that were scarcely available a decade ago. With the right strategy, global sponsors can use China to accelerate early-phase development and then transition seamlessly to meet FDA requirements for pivotal studies.

One of Novotechâ??s key strengths is our ability to combine international standards and processes with the agility of a regional partner. Unlike purely domestic CROs, we apply global quality frameworks across all our operations while remaining flexible enough to address the needs of innovative biotech clients. This gives Chinese companies confidence that the data generated through their programmes will be fully aligned with international expectations, positioning them to secure licensing or partnership opportunities with multinational sponsors.

In such a competitive CRO landscape, how does Novotech distinguish itself without resorting to price competition?

Chinaâ??s CRO sector is one of the most competitive in the world. At its peak, hundreds of players, including very small teams, were able to survive on the back of abundant biotech funding, and many even thrived. That dynamic shifted after 2021, when financing tightened and development pipelines were cut back. For Novotech, the merger with PPC in 2020 proved decisive, giving us the scale and platform to compete differently. Rather than entering a race to the bottom on price, we focused on higher-value services with global relevance, such as biometrics, pharmacovigilance, and project management. A clear example was the establishment of our global service centre in Chengdu, which strengthened our biometrics and data capabilities and enabled us to serve both Chinese biotechs pursuing international ambitions and global sponsors conducting studies in China. This strategy has rebalanced our business from being largely domestic to an almost equal split between local and international projects.

In contrast, many domestic CROs relied heavily on underpricing to win contracts, an approach that has proved unsustainable as funding pressures increased, forcing some to restructure or exit the market. Larger players remain resilient â?? WuXi AppTec through its dominance in labs and CDMO services, and Tigermed through its extensive domestic network â?? yet even they face pressure as the market matures and competition globalises. Novotechâ??s strength lies in combining international standards and systems with the agility of a regional partner. Our leadership teamâ??s global experience has made integration and expansion smoother, allowing us to grow rapidly in the United States and Europe through acquisitions such as NCGS in 2022 and EastHORN in 2023. This blend of global reach, robust processes, and local expertise allows us to compete effectively at home and abroad while avoiding the destructive cycle of price competition.

How is Novotech engaging with advanced therapeutic modalities such as cell and gene therapies, RNA-based treatments, and ADCs?

Advanced modalities hold enormous potential, and for CROs that establish themselves early, they provide an opportunity to move ahead of competitors. Novotech has a strong track record in this space. Our predecessor company supported Chinaâ??s first CAR-T trial through audit, inspection, and approval, and we were also among the first to build medical and regulatory expertise in ADCs. When I joined in 2021, we continued to invest in this field, hosting an ADC Forum in China to showcase our capabilities and bring together emerging biotech leaders. Taking such steps early was a calculated risk, but it underscored our long-term commitment to supporting innovation in advanced

therapies.

These early steps established our reputation in areas such as cell and gene therapy, ADCs, and radiopharmaceuticals, which now gives us a clear advantage when biotechs developing next-generation therapies are selecting partners. In China, we have also been able to draw on global expertise and apply that knowledge locally to support domestic sponsors. Advanced therapies, particularly in rare diseases, carry significant risk, but by investing early we have built credibility and positioned ourselves strongly for their growth. By combining international experience with local execution, Novotech has become a trusted partner for biotechs working at the forefront of science.

What opportunities and challenges do rare disease trials present in China, and how do cultural and cost factors influence the countryâ??s role in global development?

Rare disease trials in China present both promise and complexity. On the commercial side, policymakers must still weigh whether such therapies can be sustainably funded within a state-led healthcare system, even as efforts continue to expand the role of commercial insurance. From a development perspective, however, China offers clear advantages: a large pool of potential patients, robust screening capabilities, and a clinical research infrastructure that has been built up over the past 50 years. These factors make the country an attractive location for rare disease studies, provided sponsors work with trusted partners to help them navigate a system that can remain challenging. Crucially, the quality of clinical research in China has advanced considerably over the past decade and is now broadly comparable with international standards.

Cultural dynamics also play a part. Historically, Chinese KOLs were less outspoken than their Western counterparts, which sometimes limited open dialogue during trials. This is steadily changing. The growing number of â??returneesâ?• â?? professionals who spent years working or studying abroad before returning to China â?? has helped bridge communication gaps, while many Chinese KOLs are now internationally recognised, presenting confidently at global conferences and serving as lead investigators in multi-regional studies. At Novotech, we see value in connecting sponsors with these investigators and guiding them through cultural nuances while enabling access to Chinaâ??s broad therapeutic expertise. Cost remains another important factor: trials in China are still significantly cheaper than in the United States, often around half, although this may not hold indefinitely. For now, the combination of speed, patient access, and cost efficiency makes China an opportunity that global sponsors and investors cannot afford to overlook.

Looking ahead, what are Novotechâ??s priorities for the mid-term, and how do you see the company positioned for 2025â??2026?

We are in the midst of executing a new three-to-five-year strategic plan, underpinned by fresh investment from GIC and Temasek earlier this year as well as continued support from TPG Asia. This capital is dedicated to accelerating our international growth, particularly in the United States and Europe. While geopolitical tensions in recent years made some sponsors cautious about their engagement in China, sentiment is now shifting. Regulatory reforms, rising market demand, and improved infrastructure are restoring confidence, and we believe Novotech is well positioned to capture these opportunities.

Our priorities over the next two years are clear. Domestically, Chinese biotechs are regaining access to funding and showing greater confidence in the value of China-only trial data for licensing purposes. We are strengthening our local team and capabilities to meet this demand while carefully

tracking how these companies approach overseas development. Some may still turn to Australia, where Novotech has long-standing expertise, or to the United States, but we expect a sharper focus on proof-of-concept studies before seeking partners. For many, survival will depend on generating early clinical signals quickly and cost-effectively, even if that means out-licensing earlier than planned. Our role is to provide solutions that make this possible, reinforcing our base in China, leveraging our strength in Australia, and responding to the growing volume of inbound requests from US biotechs. Already, we are seeing more proposals than last year, which reflects Novotechâ??s rising profile as a trusted partner in global development.

As a final thought, what message would you like to share with global sponsors as they consider China in their development strategies?

I am truly encouraged by how far Chinaâ??s clinical research landscape has come over the past 15 years. The governmentâ??s sustained investment in infrastructure is now delivering real value, not only for Chinese biotechs, which benefit from faster, more cost-efficient trials and a wider range of opportunities, but also for global sponsors who can increasingly leverage these advantages. Ongoing regulatory reforms are designed to make participation more straightforward and to integrate China more closely with the international ecosystem, forming part of a broader economic strategy to maximise the return on this national investment.

For US biotechs and multinational sponsors, the message is clear: China represents an opportunity that should not be overlooked. While complexities remain, the combination of speed, scale, and cost efficiency offers a compelling platform for development, provided companies work with partners they can trust. At Novotech, we bring both deep local knowledge and international standards, enabling us to guide sponsors through this environment and help them realise the full potential of their programmes in China.

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