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"TOO MANY COMPANIES WITH THE FINANCIAL STRENGTH TO WEATHER THE STORM ARE SIMPLY PLANNING TO WAIT IT OUT."

LINGSHI TAN, DMED

CORONAVIRUS

# China offers forward-thinking biotechs much more than an opportunity to get delayed clinical trials back on track

BY LINGSHI TAN, DMED GLOBAL

Weiji (危机), the Chinese term for crisis, combines the characters for "danger" and "opportunity," an apt description of the challenge posed by COVID-19.

While most of the world struggles with pandemic containment and 're-opening,' China, the world's second largest pharmaceutical market, is nearing return to pre-pandemic operations, and the country's effective COVID management and revamped clinical trial infrastructure can offer Western companies a destination for resuming studies.

Seizing that opportunity now could create strategic opportunities to enhance competitiveness and create significant value in the long term.

## Beyond crisis management

Forced by the pandemic to seek innovative pathways to keep development programs on track, Western biotech companies are beginning to appreciate the impact of China's progressive policies on the potential of China to enhance the value of their assets.

This realization not only represents the road out of the current disruption caused by the pandemic, it also represents a path to more efficient, less expensive clinical trials over the longer term.

Dated views of China still prevent some, however, from seeing the country's evolution into a viable, global drug development contender.

The traditional view of China centers on two conflicting ideas. On one hand, China has the essentials for drug development: three to four times the number of patients in key indications

(e.g., NSCLC, diabetes), six times the number of hospitals and overall costs up to about 65% less than the West. On the other hand, complex rules, understaffed regulatory agencies and quality concerns give many biotechs pause.

A closer look at today's reality, however, reveals that China has dramatically improved its operating environment and is quickly becoming an appealing option for clinical development. Key advancements include reduction of Clinical Trial Authorization (CTA) timelines from 12 months to 60 days, acceptance of foreign clinical data, a six-fold increase in government agency review staff, and NDA approvals coming within 6-12 months of submission. All of this is occurring as IP protection and data quality continue to improve.

While there is undoubtedly work left to do, China is now able to be considered in the context of a global development strategy -- especially during the current pandemic crisis.

Almost all biotechs have been impacted by the pandemic. Those without studies in the clinic are assessing how long they can delay, while firms with ongoing studies are scrambling to ensure patients are not harmed and study disruption is minimized. Enrollment has declined industry wide by almost 70%, with cardiovascular studies suffering a 95% decline versus last year.

In this uncertain environment, China provides a practical and accessible alternative for an industry now forced to move in slow motion. Chinese society is almost back to full operation with manufacturing, education and transportation sectors planning to hit that mark in June. Medidata reports that Chinese sites resumed adding more patients per site as of February.

Combined with the evolution of the clinical development landscape, China's swift post-pandemic emergence offers drug developers a productive environment for their programs.

Unfortunately, this opportunity is overshadowed by other concerns.

The majority of pharmaceutical leaders I have recently spoken to in China and the West say their daily focus is maintaining some level of operational status quo. When innovative alternatives are discussed, adoption of telehealth/telemedicine is the main topic.

Remote technologies may be a critical component of the pandemic response for some trials, but their rapid implementation does not come without immediate challenges. On both fronts -- tapping China's rapidly developing clinical infrastructure and adopting remote technologies -- many companies are avoiding change if they can.

In short, too many companies with the financial strength to weather the storm are simply planning to wait it out until they can regain their original trajectories.

I argue this is a short-sighted way of thinking that will lead them to miss valuable opportunities.

## "A THOUGHTFUL CHINA STRATEGY TO MITIGATE THE IMPACTS OF THE PANDEMIC TODAY CAN BE BUILT INTO A LONG-TERM CHINA STRATEGY FOR TOMORROW."

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### The Opportunity

The COVID-19 crisis should be viewed as an opportunity to adopt new strategies, different ways of thinking and long-term solutions. Companies that merely weather the storm may have the resources to restart their original plans, but those that think strategically and act with foresight are more likely to emerge from this crisis in a leadership position.

China can serve as a key component of such strategies.

The resumption of enrollment represents the immediate opportunity. With trials in the West significantly delayed, China is perhaps the only near-term buffer from the COVID-19 storm.

Integrating China into a COVID response can take many forms, and a number of innovative biotechs are evaluating alternative solutions. Whether the goal is to fill possible gaps in the U.S. or Europe by adding China sites to an existing program or to accelerate development of a second indication by launching a global trial first in China, a growing number of fresh solutions are increasingly attractive.

Selecting the best path means tailoring the regulatory and development strategy to each company and drug candidate or portfolio, leveraging both a deep understanding of China and global clinical development.

For those seeking to do more than simply overcome their current delays, China can be used to build long-term competitive advantage.

While the enrollment benefit is clear, what may be less apparent is how a drug developer can accelerate their program in the current environment. The Chinese government has stepped up efforts to encourage foreign development. For drugs targeting unmet needs in China, a priority review process exists to fast track approval. A silent approval process also allow trials to begin 60 days after placing a new drug application, if no objection is raised by the Center for Drug Evaluation (CDE).

By homing in on the correct sequence and objectives, a development program with a strong strategy can significantly speed the time to launch in China, while contributing to global registrational data.

As delays continue in the U.S. and Europe, the right strategy in China can unlock market access and meet patient needs. An early China launch can create ROI while generating real-world evidence that can be used to augment filings, expand indications and generate the insights needed for stronger launches in the U.S. and Europe.

As more insular developers follow the status quo in the West, innovators can use the pandemic's disruption to pivot and strengthen their overall position.

Longer term, China can be used to maximize an asset's global value. A thoughtful China strategy to mitigate the impacts of the pandemic today can be built into a long-term China strategy for tomorrow.

FDA's acceptance of China data in granting breakthrough designation and subsequent approval of Brukinsa zanubrutinib from BeiGene Ltd. (NASDAQ:BGNE; HKEX:6160) proves China is ready to take the lead in global programs. Such inclusion means a parallel U.S.-China approval strategy can be executed and years of missed market opportunity eliminated.

Some have even gone so far as to prioritize China market access. SVB Leerink's analyst Geoffrey Porges predicts Evrenzo roxadustat from FibroGen Inc. (NASDAQ:FGEN) may generate up to $1 billion in revenue in China alone by 2025, highlighting the opportunity that is possible by accessing the world's second largest pharmaceutical market as early as possible.

## Being Successful

Capturing the China opportunity is not without risk. Chinese staff with global experience, China and U.S. regulatory expertise and the ability to bridge the numerous cultural differences between China and the West are all critical capabilities for an organization to develop and deploy strategies that leverage China's unique advantages.

Most organizations struggle in one or more of these critical areas. Global CROs often lack the deep regulatory expertise needed to navigate what remains a complex pathway to market. Local China CROs are often unable to bridge the divide between China and the West.

In the light of rapidly changing needs, drug developers motivated to capture the China opportunity during this crisis must seek out the next generation of development partners that can bring deep regulatory expertise and global, innovative drug experience in a single package. A next-generation development partner will have resources in China and the West that can operate efficiently in a global model. It will have the technology platforms needed to facilitate remote monitoring and paperless trials. Most essentially, a partner must offer the flexibility needed to rapidly adjust its approach to the specific, unique needs of each company and molecule.

With access to these critical capabilities, forward-thinking companies can emerge from the pandemic in a stronger position than their more complacent competitors. Such re-examination should not stop at the protocol. A clinical program's ecosystem of support, especially development partners, must be looked at anew to understand if the capabilities required for success in this crisis exist. In normal times, such rapid change and re-evaluation would be almost unthinkable. With the pandemic, they are essential.

*Lingshi Tan is founder, chairman and CEO at dMed.*

*Signed commentaries do not necessarily reflect the views of BioCentury.*

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