

DISRUPTION HAS HIT PHARMA

We look at key changes in China and global pharma landscape through the lens of strategic intelligence and consider how this powerful tool can help pharma stakeholders grasp the full picture of the competitive environment they intend to enter.

Authors & Contributors



HEAD AUTHOR

Jonas Pedersén, Ph.D., MBA
Advisor



SPONSOR

Jesper Nissen, Ph.D.
Senior Principal, London

Nancy Wang, Ph.D., Senior Manager, London

Flora Tian, MBA, Senior Consultant, Shanghai

Rachel Wang, Ph.D., Senior Associate, Shanghai

YI JIN, MSc, Senior Associate, Shanghai

+44 (0)207 337 6900

global contact:

info@deallus.com

China contact:

shanghai@deallus.com



Strategic intelligence for a fiercely competitive marketplace

In the pharmaceutical industry, change has long been known as the only constant. But the last few years have seen the industry challenged and reshaped by drastic internal disruption and external paradigm shifts.

In major developed markets, the increasing adoption of health economics and outcomes research (HEOR) into payer decision-making means that efficacy and safety alone are no longer enough to launch even the most straightforward small molecule drug directly to profit. The rise of biologicals, biomarker-targeted drugs, gene-specific medications, regenerative medicines (CAR-T therapies), and immune checkpoint inhibitors have provided breakthrough therapies potentially benefitting millions. Whereas in China, social health insurance (SHI) to cover most of these innovative drugs is on the off chance in the short term.

Despite this challenging environment, the China pharma industry continues to grow, expanding steadily over the recent years, is valued at RMB 1,633 billion in 2019, with a year-on-year growth rate of 7%¹. Additionally, under the umbrella of 'Healthy China 2030', the initiation of healthcare reform in 2016 has seen the introduction of multiple policies, such as Generics Quality Consistency Evaluation (GQCE), '4+7' Volume-based purchasing (VBP), diagnosis-related groups (DRGs), prioritizing the launch of innovative medicine, as well as restricting SHI funding on off-patent generics².

The recent 'Two Sessions' held in the country's capital, also known as the 'National People's Congress (NPC) and the Chinese People's Political Consultative Conference

(CPPCC), reiterating the importance of the 14th Five-Year plan³, China's national development blueprint from 2021 to 2025. For the health sector, the next five years will see efforts going into improving healthcare and medical service as aligned with the Healthy China 2030 initiative, such as driving the reform of disease prevention system for future public health emergencies and building a multi-tiered elderly care service system supported by community institutions and professional healthcare business. Most importantly, China will be executing key tasks including promoting the DRG and the diagnosis-intervention packet (DIP) beyond piloting cities⁴, building internet+ hospitals,⁵ and highlighting the continuous focus on VBP on generics and medical devices as a national policy⁶. These policies have influenced many multinational corporates (MNCs) to focus their product portfolio on innovative products, and top-tier domestic pharma are also steering their strategies from imitation-led to innovation-driven.

These market transformations have necessitated changes in the nature and purpose of strategic intelligence (SI). Data or business intelligence, once a challenge to find, now floods us constantly, overwhelming our vision of the market with endless opportunities to second guess ourselves and focus on the wrong things. In this dynamic environment, it is not enough to merely know what the competition is doing, but also what competitors and other key stakeholders' (such as Chinese authorities) intent, for example how they intend to shape the market and why. We need to challenge and make our assumptions about competitors

and stakeholders. To make them evidence based, and hypothesis driven. It is also vital to consider how your competition views you by taking an honest look at your organization's strengths and challenges. SI sees through the data clutter most updated and syndicated data/information clutter and false signals to fully grasp the ramifications of all these elements shifting in and out of play. By keeping firmly grounded in an understanding of the competition and larger market trends affecting each individual market niche, SI offers pharma companies a strategic vision of the choices that competitors have to make, and the options before them, both currently and in the future.

A drug in a pipeline is on a fixed course. Drug pipeline timelines may be shortened by various means, but the course of the drug through the approval process does not allow for quick responses to new competitive realities. Thus, anything less than a full understanding of the multiplicity of variables affecting competitors represents a blind spot that may grow in size and financial risk with every step toward marketability.

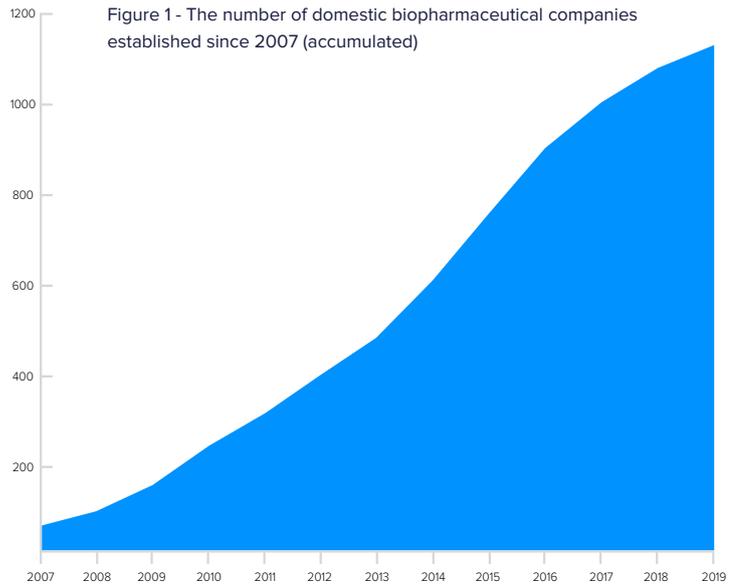
This paper looks at key changes in China and the global pharma landscape through the lens of strategic intelligence and considers how this powerful tool can help pharma stakeholders grasp the full picture of the competitive environment they intend to enter.

A changing landscape

From an economic perspective, the China market once dominated by a small handful of recognizable corporate names has become diversified by an increasing number of newer players.

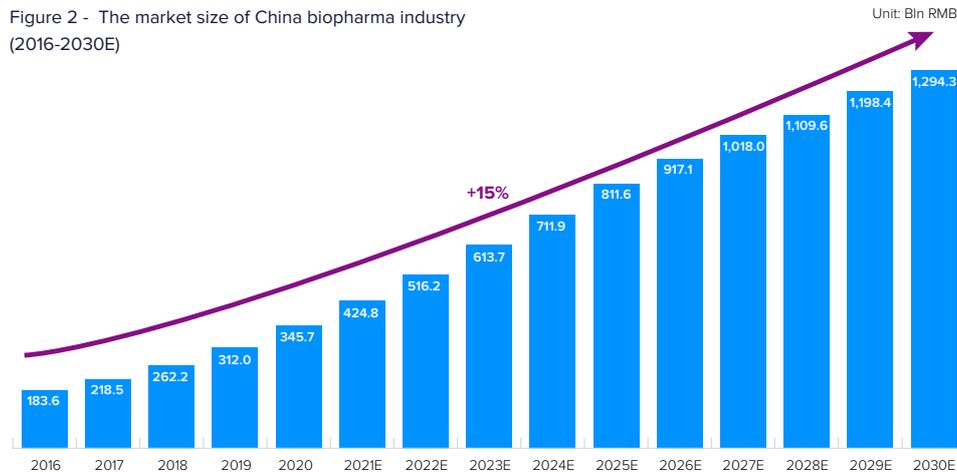
There are numerous newly founded pharmaceutical companies in China each year (see Figure 1).

Data source: Bridge Research; Deallus analysis



A stable increase in the market size of biopharmaceutical companies in China has been observed since 2016, and we estimate that in the next five years, the market size will continue to grow (Figure 2).

Figure 2 - The market size of China biopharma industry (2016-2030E)



Data source: Bridge Research. Accessed by 2020H1; Deallus Analysis

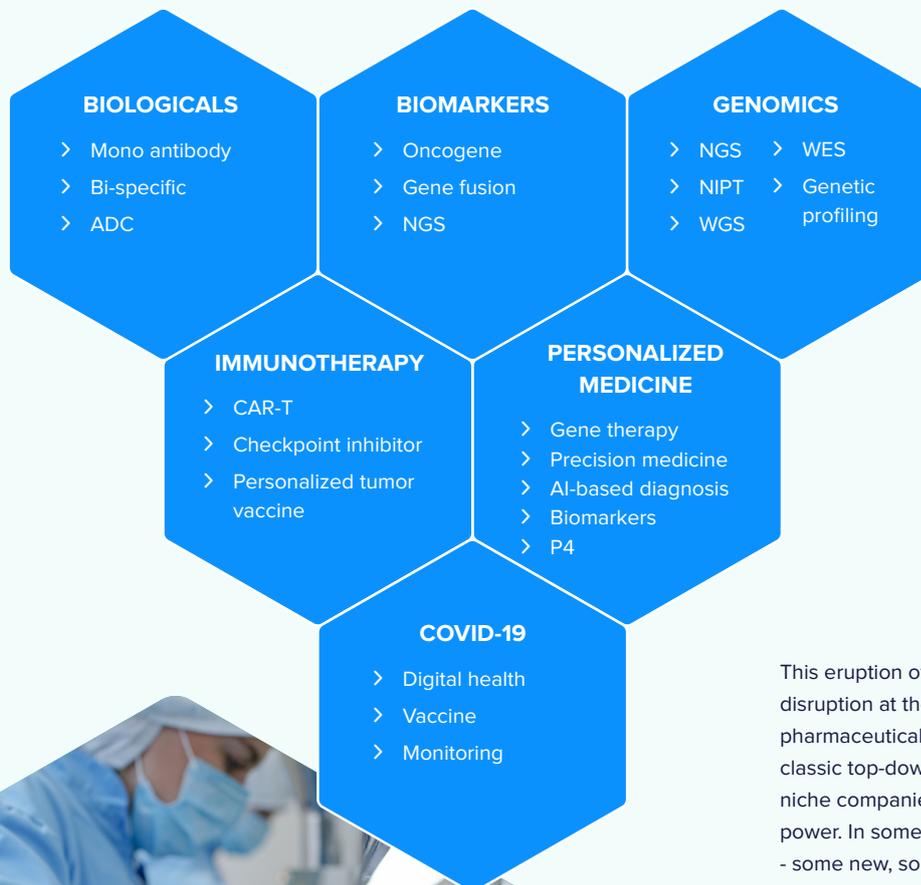


Newer players, narrower indications

A decade ago, most pharma companies were still focused on blockbuster primary care small-molecule drugs (<900 Daltons)⁷. The public hospital market was the main driver for sales⁸, and thus the main focus of the legions of drug representatives sent into doctors' offices by pharma companies. Public hospital market contributed roughly 80% of revenues for most of the big pharma portfolios.

However, gifted with new scientific insights from the revolution in genetics, a groundswell of companies both large and small were creating the explosion of new disease insights, new drug MOAs, and new market opportunities we see today (Figure 3).

Figure 3 - New market opportunities



This eruption of knowledge has led to disruption at the leading edge of the pharmaceutical industry as it realigns from the classic top-down model to one in which smaller niche companies often hold considerable power. In some cases, these niche companies - some new, some with longstanding if unexceptional histories - have been able to bring medical products to market. In others, traditional large pharmaceutical firms have monitored smaller companies as they succeed and fail, and then purchased the winners and added them to their ongoing pipelines.



But what we see across the board are these new opportunities shaking up big pharma's hold on the marketplace and disrupting its traditional routes to profitability. Within the China market, we have seen many MNCs and domestic pharma active in building partnerships (Figures 4 and 5): the equity-based investment made by Pfizer to the Suzhou-based CStone Pharmaceuticals, and the Novartis-BeiGene deal focused on the global out-licensing agreement on BeiGene's anti-PD-1 antibody tislelizumab, both have reported collaboration expansion in 2021, with additional assets included in the partnerships indicating the strategic viability of these decisions.

The global equity-based partnership between Amgen and BeiGene. Additionally, leading domestic biopharma including Innovent and Junshi Biosciences explored various product in-licensing collaboration with global and local innovators to enrich their pipelines or creating add-on values with existing products. Building the right partnership for portfolio expansion or organization diversification will well prepare the pharma companies for the upcoming fierce competition in China.

Figure 4 - Number of BD cross-border Partnerships in China Biopharmaceuticals (2012-2021)

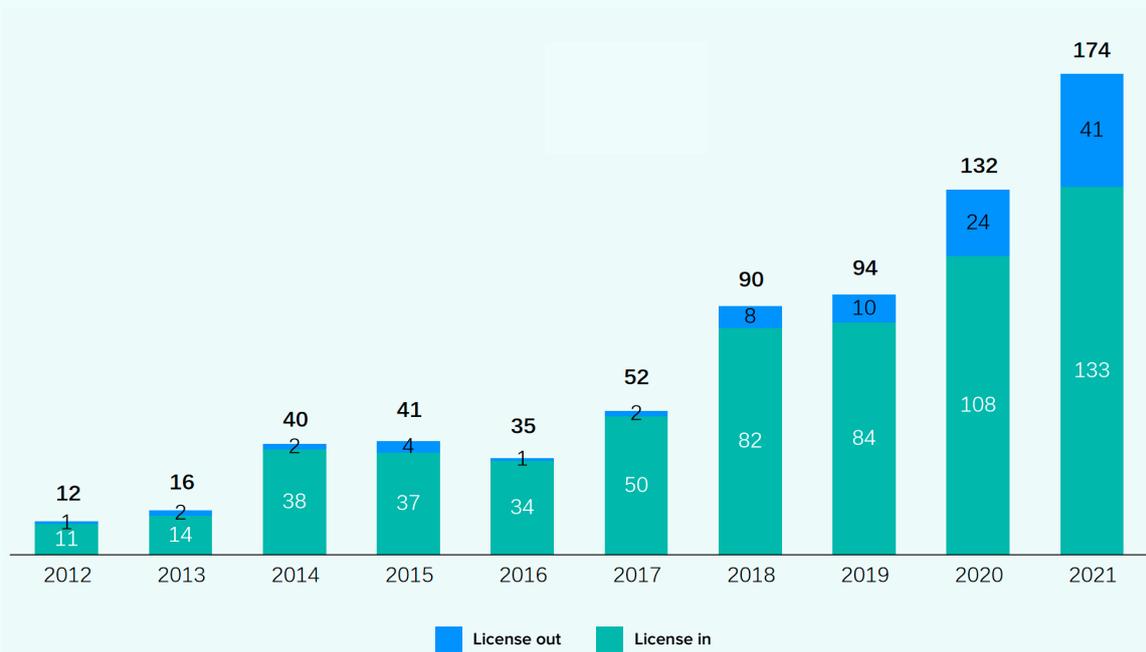
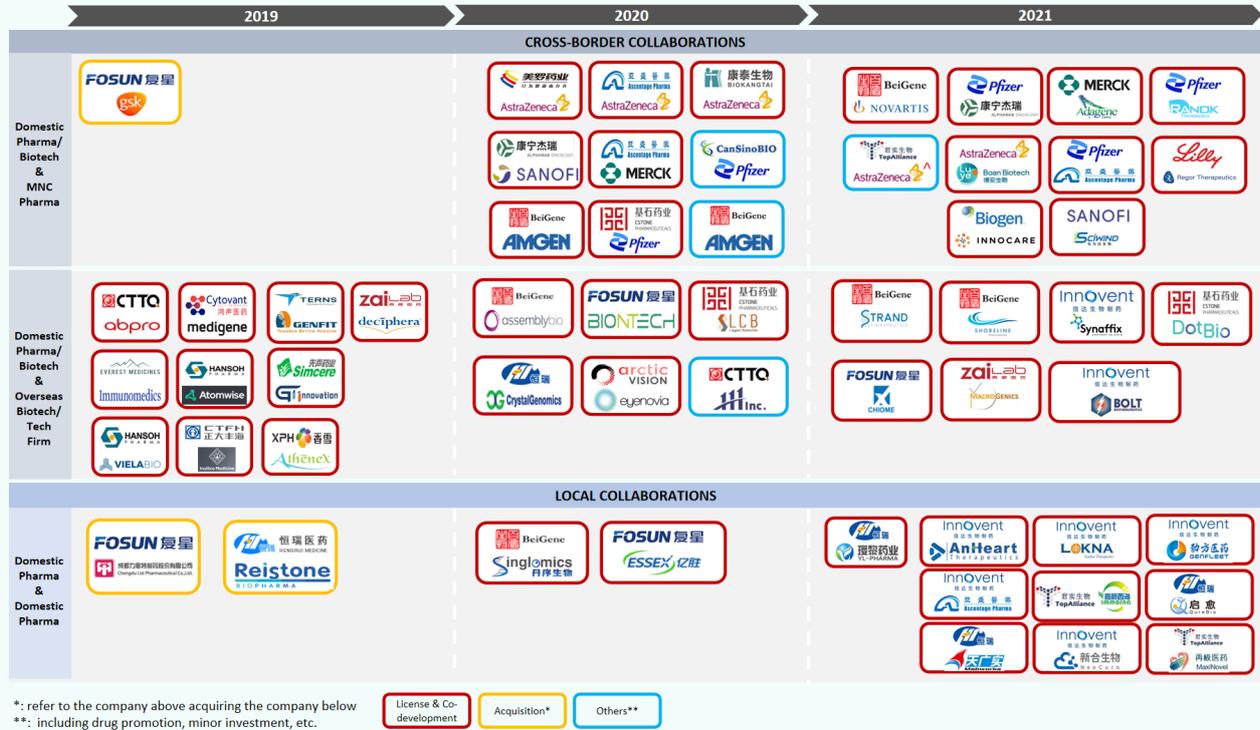


Figure 5 - Landscape of Key Partnerships in the China Biopharmaceutical Market



Another trend currently changing the game has to do with the business models behind these advanced-technology companies becoming increasingly reliant on highly nuanced distinctions in seemingly similar NMPA drug indications. For example, to date there are eight PD-1/PD-L1 drugs that have been launched in China, with four from MNCs and four from domestic companies with multiple indications have been approved or under regulatory review (as of March 2021). Consider the market fight going on right now between these PD-1/PD-L1 assets (Figure 5).

Obviously, MSD, BMS, Roche and AstraZeneca entered the market knowing they had a dogfight on their hands. In the race to be first, many of them were able to truncate the timing of the NMPA approval process by being awarded various combinations of priority review or conditional approval designations. In addition, the jammed PD-1 market in China is further crowded with >50 ongoing clinical trials targeting several types of cancers, which may pose challenges on patient recruitment. The successful inclusion of Tyvyt in NRDL in 2019 and 2020 has also made other PD-1/PD-L1 assets face challenges in NRDL negotiation⁹.

In the recent NRDL negotiation in December 2020, other three domestic PD-1/PD-L1 assets, TouYi™ of Junshi, BaiZeAn™ of BeiGene, and AiRuiKa™ of Hengrui have also been successfully included in NRDL, while all of the four MNC assets (Keytruda of MSD, Opdivo of BMS, Tecentrique of Roche, and Imfinzi of AstraZeneca) failed in the negotiation.

What were once incentive programs has become a strategic business imperative, another consideration for any company attempting to shape the market in their favour.

Which speaks to the high degree of knowledge each of these companies must have to launch drugs with overlapping indications in what used to be a single therapeutic area. Not only must they know their product, patients, and positioning, they must also be keenly aware of their competitor's current actions and future intent.

Figure 6 - PD-1/PD-L1 Landscape in China

	Innovent 信达生物制药 达伯舒® Tyvyt (Sintilimab)	BeiGene 百泽安® BaiZeAn™ (Tislelizumab)	君实生物 TopAlliance 拓益 Tuo Yi™ (Toripalimab)	恒瑞 艾瑞卡® AIRuIKa™ (Camrelizumab)	AstraZeneca IMFINZI® durvalumab	Roche TECENTRIQ® atezolizumab	MERCK KEYTRUDA® (pembrolizumab) Injection 100mg	Bristol Myers Squibb® OPDIVO® (nivolumab)
Melanoma			☑ Dec 2018 ⊕ 2020, 62.3%				☑ Jul 2018	
Urothelial carcinoma		☑ 2019 ⊕ 2020, 79.5%	☑ Apr 2021					
Classical Hodgkin lymphoma	☑ Dec 2018 ⊕ 2019 & 2020, 63.7%	☑ 2020 ⊕ 2020, 79.5%		☑ May 2019 ⊕ 2020, 85.2%				
Hepatocellular carcinoma	⌘ Jan 2021	⌘ Jul 2020		☑ Mar 2020 ⊕ 2020, 85.2%		☑ Oct 2020, Avastin combo		
Non-small-cell lung cancer	☑ Feb 2021 nsqNSCLC ¹ ⌘ Aug 2020 1st line sqNSCLC ² ⌘ Jan 2021 2nd line sqNSCLC ²	⌘ Apr 2020 sqNSCLC ⌘ Jun 2020 nsqNSCLC		☑ Jun 2020 ⊕ 2020, 85.2%	☑ Dec 2019, stage III		☑ Apr 2019 nsqNSCLC ☑ Sep 2019, Metastatic NSCLC ☑ Nov 2019 sqNSCLC	☑ Jun 2020
Esophageal squamous cell carcinoma				☑ Jun 2020 ⊕ 2020, 85.2%			☑ Jun 2020, 2nd line	
Small-cell lung cancer					⌘ Jul 2020, ES-SCLC	☑ Feb 2020, ES-SCLC		
Nasopharyngeal carcinoma			☑ Feb 2021					
Head and neck squamous cell carcinoma							☑ Dec 2020	☑ Oct 2019
Colorectal cancer							⌘ Nov 2020	
Esophagogastric junction adenocarcinoma								☑ Mar 2020

☑ Approved indication ⊕ NRDL inclusion and time with % of price drop as compared to pre-NRDL inclusion ⌘ NDA submitted

¹ nsqNSCLC: non-squamous non-small-cell lung cancer; ² sqNSCLC: squamous non-small-cell lung cancer; not exhaustive

In a market where a product's success depends on how expertly its strategy carves a niche, not knowing a competitor's moves and motives can end with your product getting carved out.

Watching the PD-1/L1 inhibitor story unfold will tell us much about which teams prioritized strategic intelligence, and which did not.



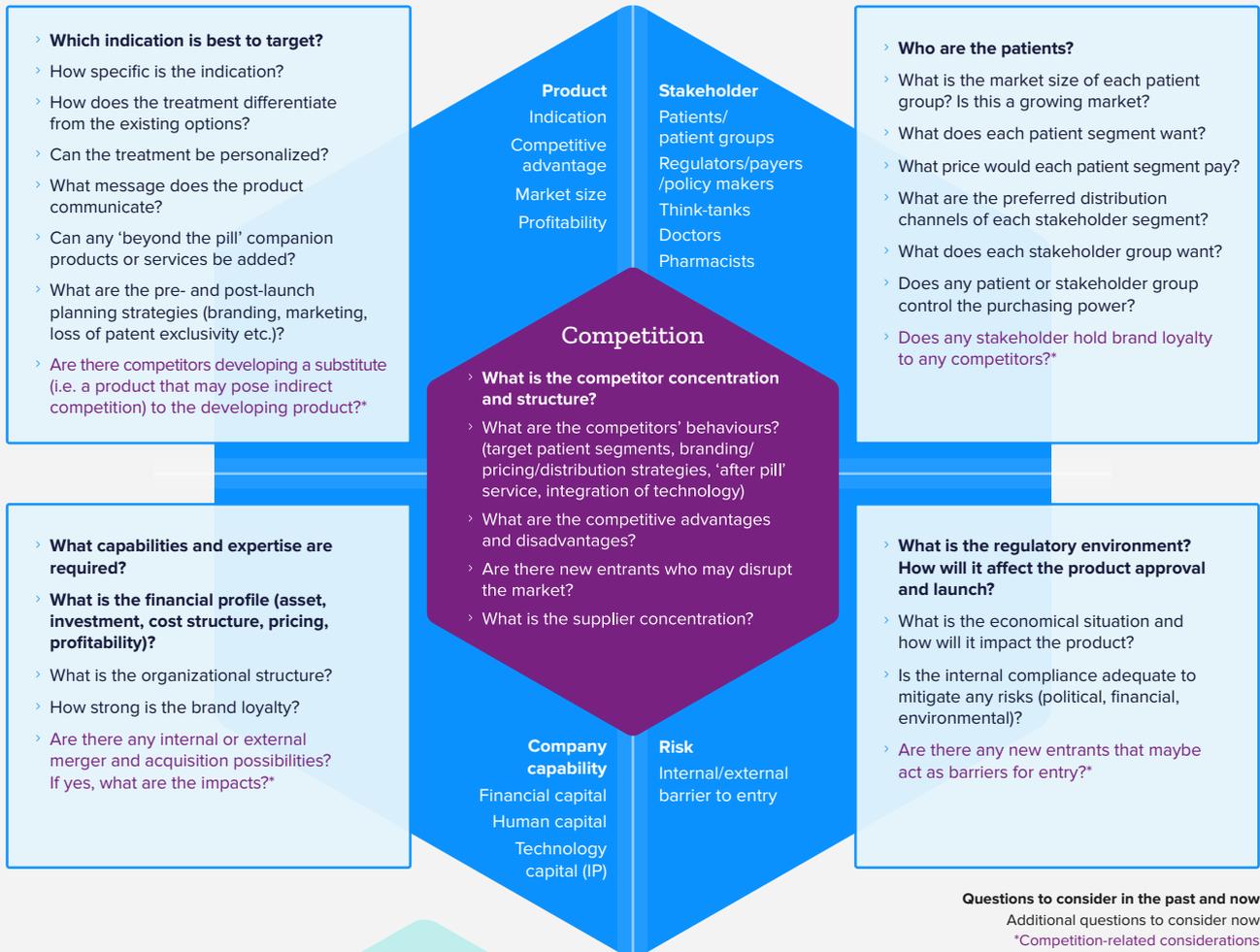
A new rulebook for pharma

As we've seen, new technology, new biotech start-ups capable of attracting venture capital, new business models for more rapid approval, and increasingly fragmented indications all translate into enormous pressure on pharma executives to get things right. When critical information is absent, unseen, or unprioritized, the consequences can be marketing failure on a global scale.

Competition: The key to decision-making

Consider an asset for a cancer indication. The key questions pharma executives asked a decade ago would differ significantly in the present (Figure 7).

Figure 7 - Questions pharma executives might consider for a potential asset, two decades ago versus now



Questions to consider in the past and now

Additional questions to consider now

*Competition-related considerations

The questions have become increasingly complex, and the answers even more so - with more niches capable of supporting products, more competitors for those niches, and more stakeholders looking at new paradigms to supplant the niche entirely, success is labyrinthine.

For anyone wanting to stay on top, the role of strategic intelligence takes on tremendous importance - but what is needed from SI has changed as well. In the competitive arena, simple raw data or information isn't as valuable as it once was. The demand for data-driven insights that can support competitive strategy, meanwhile, has surged.

Deallus has seen this change up close: our global strategy-focused projects have increased at twice the rate of traditional competitive intelligence assignments. Our user profiles have also diversified, and now in addition to CI and Market

Research and Business Insights managers, also include brand strategy leads, portfolio strategic leadership, senior management, market access stakeholders, commercial and innovation stakeholders, and business development.

This trend reflects market competition at every step of the product life cycle. Every time your company makes a critical decision - from how best to shape phase one testing to allow for future indications, to launch marketing, to patent extension, to planning around expiry - new complexities arise, leading to more questions, more room for ambiguity, and greater uncertainty. And in a somewhat ironic twist, more information is pouring in on these questions than ever before thanks to the accessibility and immediacy of raw data/information. Which brings us back to the point: Raw data/information without interpretation is simply not useful without segmentation, prioritization, and skillful strategic analysis against a backdrop of deep market understanding.

For Deallus, this transition into strategic intelligence is now complete; every interaction with every client is rooted in a holistic understanding that the competitor may be the question, but the market is the context.



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Intelligence for the 21st century: Strategic foresight

In the military setting, strategic intelligence is defined as the collection, processing, analysis, and dissemination of intelligence necessary for forming policy and plans to equip leaders to be effective strategists¹⁰.

At Deallus, we define strategic intelligence as evidence-driven wisdom and insights that generate executable, future-focused strategies steeped in a deep understanding of competitor actions and intent (Figure 8). The result is a way forward strong enough to shape markets and avoid being shaped by your competitors within them.

Adopted from military theory, business management divides business decision-making into three levels: strategic, tactical, and operational¹¹. Strategic decision is at the highest level, determining the overall commercial policy; inputs are often complex, prospective or future-focused and lack certainty. Since strategic decision oversees the overall direction and drives the ultimate actions to make a change, it is critical to prioritize it from the start, and keep it firmly in mind even as tactical and operational tasks commence.

Figure 8 - The three levels of business decisions

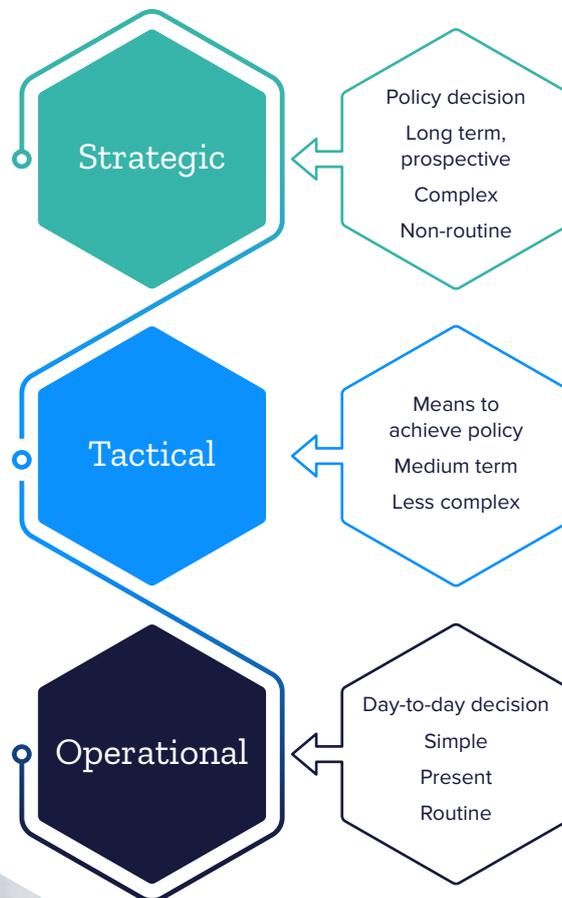
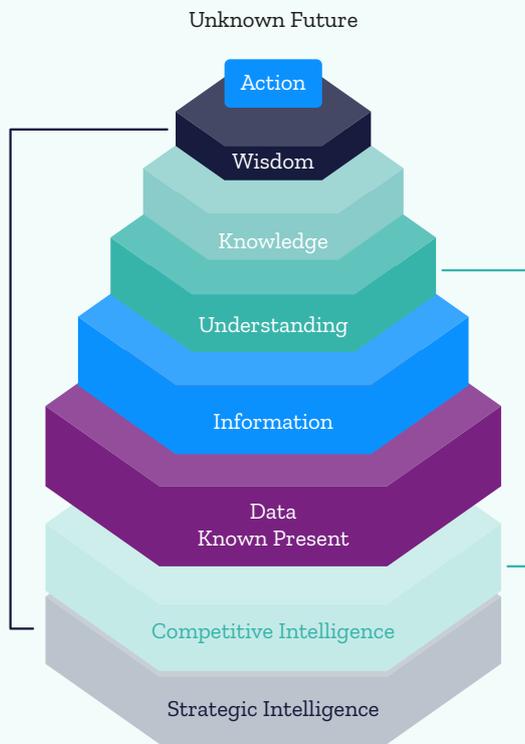


Figure 9 - The hierarchy of intelligence¹²

Consider the hierarchy of intelligence, as illustrated in Figure 8 - in the first three tiers, the raw data of competitors' actions is processed into useful information which leads to the understanding of a threat or opportunity. In the past, most tasks our clients requested went no further than this, without deeper strategic analysis and contextualization. Awareness of a new competitor coming to market in your space is valueless without knowing how their timelines, product, and positioning stack up against not only your product, but all competitor products vying for market share. Contextualizing facts into their larger landscape is the only way to truly understand what this information means for you and your own strategy.

The value of strategic intelligence lies in building a truly three-dimensional view of your competition. Strategic intelligence provides the 'know-how' to solve immediate and pressing problems, and couples it with wisdom to forecast prospective opportunities and threats. The output is an executable action plan robust enough to anticipate competitors' potentially market-shaping actions, and thereby circumvent them.

Companies often become invested in ideas that their competitors have rendered invalid. As a pharma executive, consider the scope of your responsibilities. Can you see your competitor's next move? You may have a strong understanding of your niche of the market as it relates to your drug - but do you understand how the niche your competitor is aiming for might cut across yours?

Strategic intelligence offers insights into your competitor's plans, range of options, strengths and weaknesses, and projected future moves. No other technique provides a clearer path to maximizing opportunities, mitigating potential problems, and converting threats into opportunities.

Ask yourself

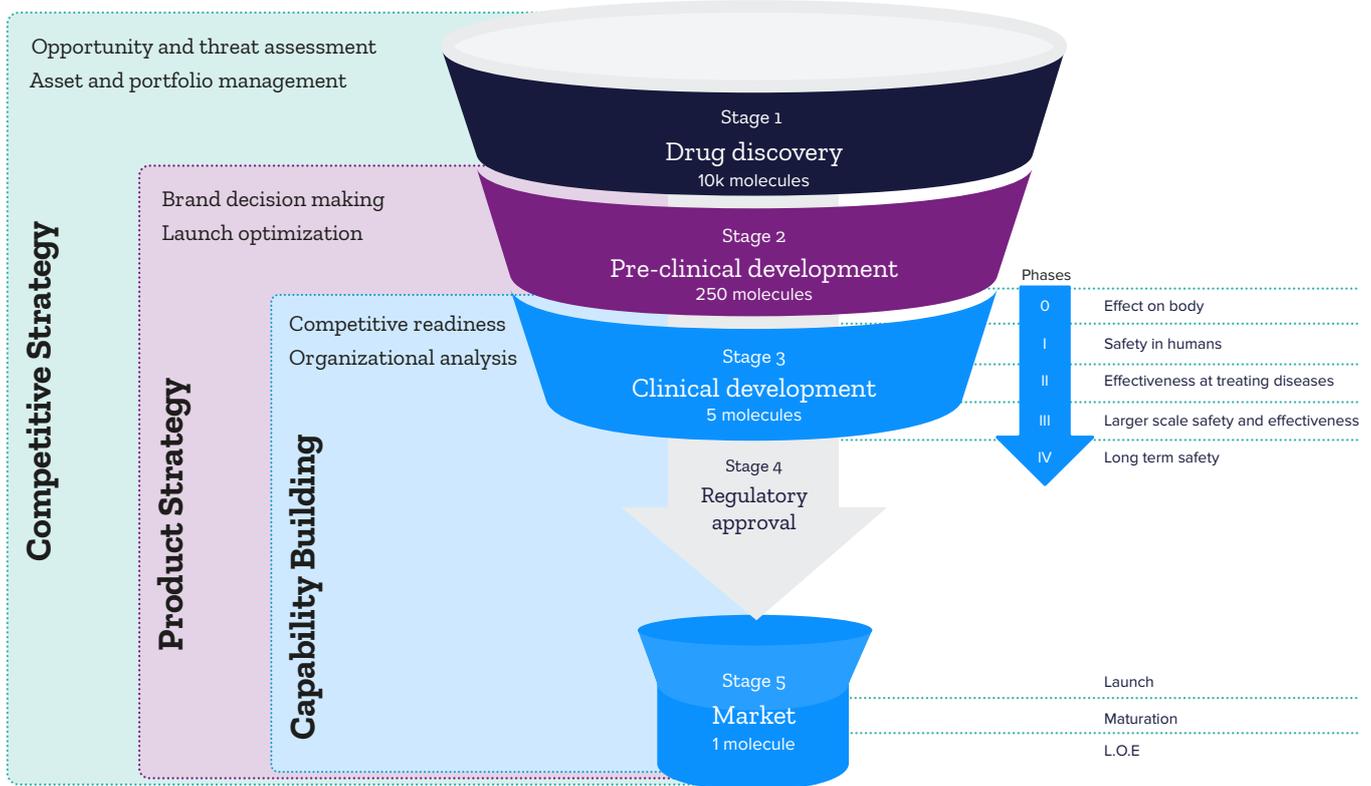
- > Do you discuss and analysis, as a cross-functional team, how the market is likely to take shape in the next few years and why?
 - > Or, does your market focus aligns with the healthcare macro-environment and is prepared for the next five years?
 - > Does your organization collaborate efficiently and be agile in facing potential challenges?
- > Do you understand not only your competitors' current actions, but also their strategy, objectives, and future intent?
 - > Or, does your focus remain on answering questions limited to competitors' news or initiations but lacking understanding of its rationale behind?

Strategic intelligence: Creating real-world value

One of the tasks of strategic intelligence is to ensure a company's success by taking a long, hard look at the competition, not forgetting to take an equally deep look at the environment within the company itself.

Strategic intelligence uses the knowledge gained from this process to evaluate competitive, product, portfolio, and company capability-building strategies. Because of its fundamentally forward-looking focus, SI should be a consideration at every critical decision inflection point along the pharma pipeline (Figure 10).

Figure 10 - Opportunity and threat assessment and portfolio management



In the case studies to follow, Deallus was able to leverage strategic intelligence to discover hidden wisdom that led to the creation of value.

Case studies

Case 1: China macro industry trends and analysis of multinational and domestic pharma competitor dynamics

The situation

Our client was a global brand team of a large multinational (MNC) and wanted to understand how the competitive situation will further evolve in China, as the importance of China pharmaceutical market has increased significantly in recent years following Chinese government's ambition to further reform healthcare. The client also wanted to broaden their understanding of macro-level trends, including healthcare policy and the regulatory ecosystem to identify potential market opportunities and threats.

Methodology

Deallus conducted a systematic secondary research deep-dive in both English and Mandarin, to develop a robust understanding of government and industry-led market trends. The team also conducted gap analysis and targeted primary research to track market trends and developed a forward-looking view of how opportunities and threats are likely to evolve in China and impact the RoW.

Findings

- We successfully identified the trends for our client that Volume-based Purchasing expansion coupled with NRDL updates is redirecting SHI funding from off-patent drugs towards innovative medicine.
- We recommended our client to consider voluntarily opt out of Volume-based Purchasing scheme because the significant price cut may not be able to compensate by guaranteed market share, and seek ex-hospital channels such as retail pharmacies and online drug stores for their off-patent originators.

Outcome

Insights, critical analyses and the 'so what' implications generated from the project helped our client to prioritize the most crucial elements of China's healthcare policy dynamics and safeguard a successful China market strategy.

Case 2: Competitive simulation workshop supporting China launch planning for a CNS asset

The situation

Our client is a global multinational company (MNC) based in Europe and was preparing to launch a CNS asset into the China market, with no significant prior experience in this space in China. The client needed to stress test their launch strategy and accompanying assumptions around market dynamics and competitor activities.

Methodology

Deallus led the whole process of a cross-functional competitive simulation workshop.

Deallus conducted systematic secondary research and targeted primary research to develop a package of comprehensive yet easily digestible workshop briefing materials.

Findings

- Through strategic intelligence we built comprehensive market landscape and identified challenges and threats to our clients
- We built the market and competitive landscape in China and deep dive into each competitor to produce comprehensive yet easily digestible briefing materials. Our findings significantly elevated our client's understanding of competitor activities and strategic intent, thereby ensuring that discussion during the workshop was as informed as possible.
- We identified potential challenges to our client and proposed a feasible action plan to help client better prepare for uncertainties and threats.

Outcome

According to client feedback the workshop was of great value since it helped the global team to align and understand the unique dynamics of the China market as well as the current and likely future strategies and tactics of their key competitors.

The workshop also highlighted remaining knowledge gaps and an action plan was developed to ensure the team was prepared.



Strategic intelligence, competitive advantage

There used to be constants in pharma. Large companies sold small-molecule drugs and had pipelines filled with more. Doctors prescribed, public hospital pharmacy supplied, and each individual illness was treated the same way, regardless of its individual nuances.

That world is gone, disrupted by paradigm-changing scientific discoveries. From those have arisen a burgeoning wealth of start-ups promising innovative therapies even as pharma giants turn to buying their pipelines rather than growing them. Biomarker targeting, genetic therapies, and new insights into the biomechanics of disease variants will inevitably lead to increasingly nuanced medicines, with pharma companies investing heavily to reach smaller and smaller segments of the population. And what we have discussed here are only a handful of the trends currently shaping these complexities, with surer to come in the next few years.

It is clearly an exciting time for the science and practice of medicine, and a challenging time to be a pharma executive. In an environment rapidly becoming more complex and nuanced while simultaneously exploding with data, not backing your team's critical decision-making with the authority strategic intelligence provides can result in marketing failure on a global scale.



So, ask yourself: What edge does your competitor have that you don't? What do they see that you haven't? What strategy are they planning that will undercut your position in the market?

How will macro-level dynamics including regulation and policy changes impact your business development in China? What are the implications of these changes? How can you cope with the ever-changing industry?

Strategic intelligence allows you to confidently answer these questions. It is the best tool we must pierce the fog surrounding the intentions of your competitors and lay bare the situation they face and the choices they are considering.

Strategic analysis, and the knowledge it brings, allows for new levels of insight that validate action plans no matter how unpredictable the environment. It drives decisions that keep products, portfolios, and companies surging ahead. And most importantly, it helps you define your market, and your competitors, before they ever get a chance to define you.



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About the authors



HEAD AUTHOR

Jonas Pedersén, PhD, MBA
Advisor
Jonas.Pedersen@deallus.com



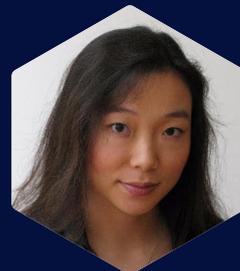
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Jesper Nissen, PhD
Senior Principal, London
Jesper.nissen@deallus.com



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Rachel Wang, PhD
Senior Associate, Shanghai
Rachel.wang@deallus.com



RESEARCHER

Yi Jin, MSc
Senior Associate, Shanghai
Yi.jin@deallus.com

To learn more about this topic, or to find out about ways in which Deallus can help you, please get in touch.

+1 646 553 4280

Global contact:

info@deallus.com

China contact:

shanghai@deallus.com

