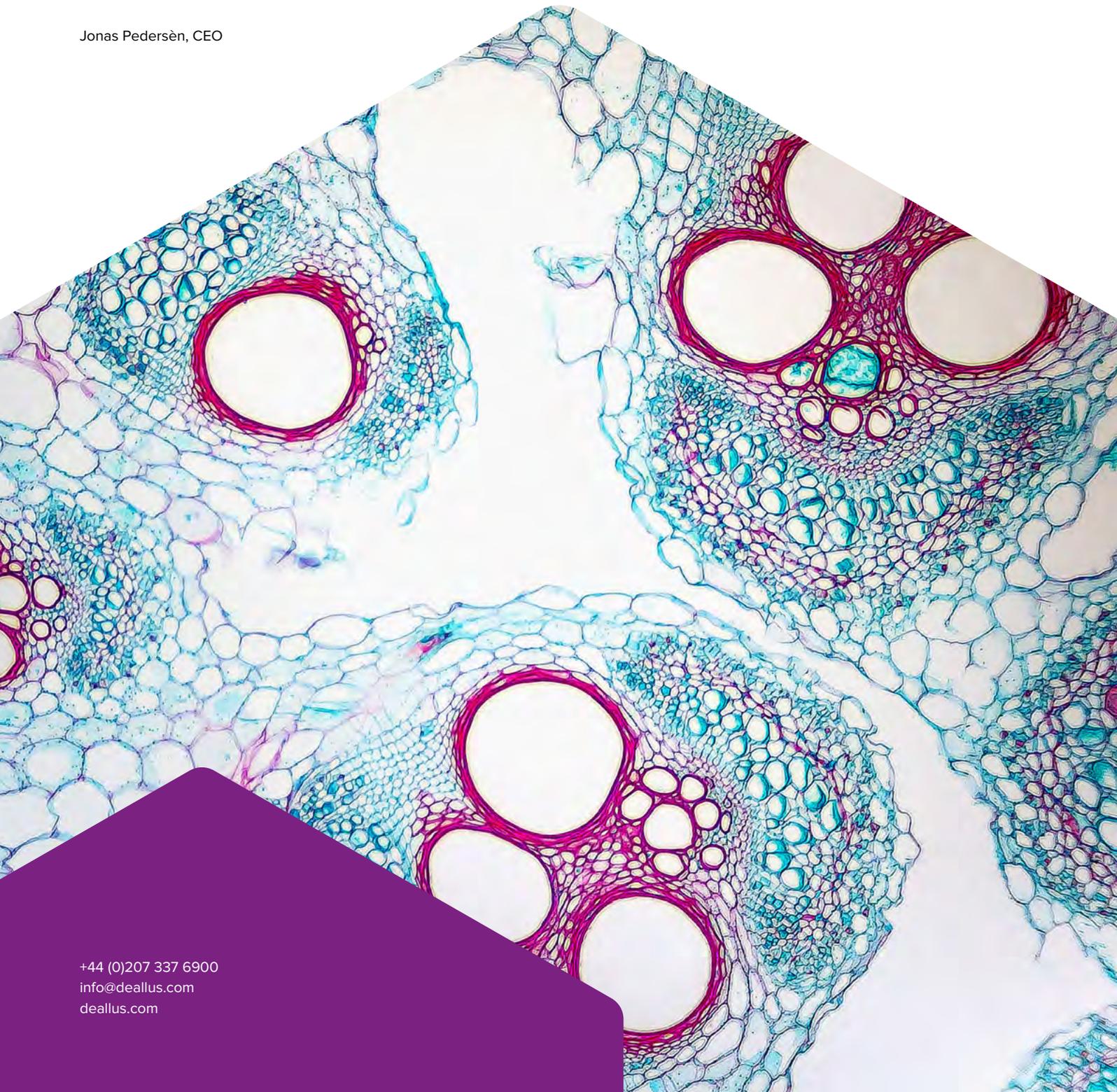


DISRUPTION HAS HIT PHARMA

Are you ready?

Jonas Pedersèn, CEO





DISRUPTION HAS HIT PHARMA

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. 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, and immune checkpoint inhibitors have provided breakthrough therapies potentially benefitting millions. At the same time, insurance to cover these drugs is chaotic in some countries, rigidly stratified by government fiat in some, and nonexistent in others.

Despite this challenging environment, the pharma industry continues to grow. Global revenue grew by 41% from 2003-2015,¹ and the prescription drug market is projected to grow at a compound annual rate of 6.5% from 2016 to 2022, reaching £760 billion.² With drug development becoming ever more expensive, the pressure is on even the most established companies to have winners in their pipelines. Meanwhile, start-ups working at the forefront of medical research may find themselves seeing enormous infusions of cash from established companies, only to have later developments dampen enthusiasm. But when it all comes together - when the drug does what it's meant to do, and the patient improves and is not bankrupted by the cost burden - the rewards for the pharma company, for the patient, and for society in general are potentially greater than ever before. Because of this, the number of stakeholders is growing, specialization is proliferating, and it is becoming increasingly difficult for anyone to have a true holistic understanding of the market in its entirety.

These market transformations have necessitated changes in the nature and purpose of strategic intelligence (SI). Data, 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 they're not doing and why they're not doing it. 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 and false signals in order 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 competitors have to make, and the options before them, both currently and in the future.

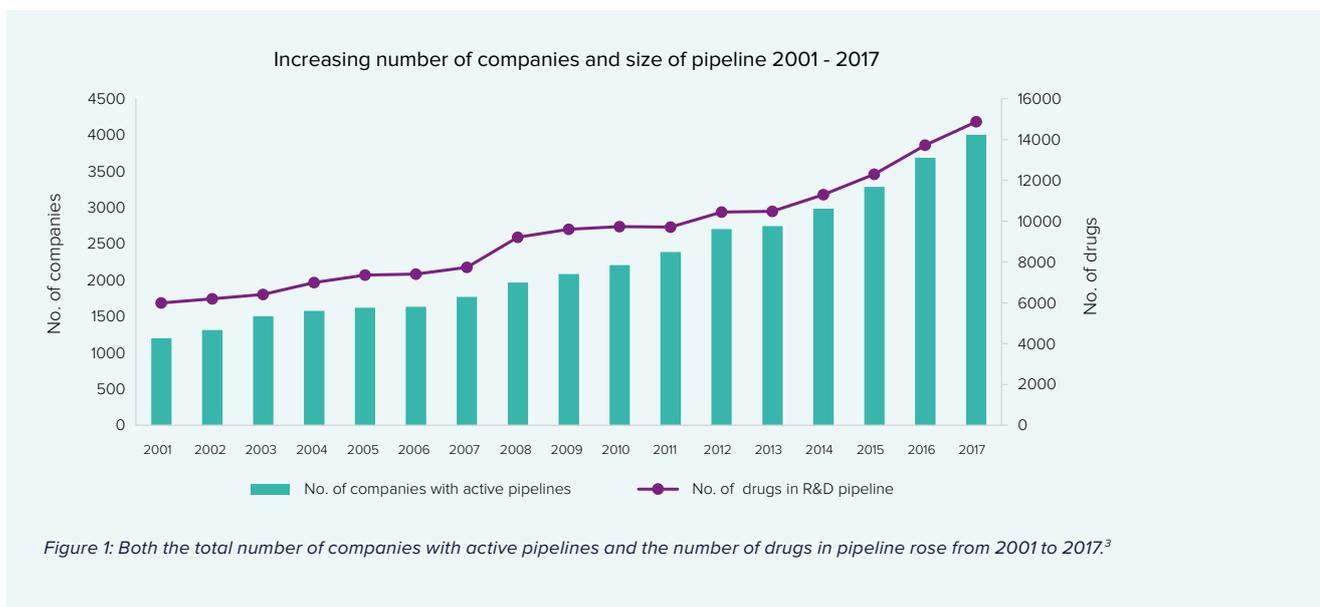
A drug in a pipeline is on a fixed course. Drug pipeline timelines may be shortened by various means, but the course of the drug through the approval process does not allow for quick responses to new competitive realities. Thus, anything less than full understanding of the multiplicity of variables affecting 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 the 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, a market once dominated by a small handful of recognizable corporate names has become diversified by an increasing number of newer players.

From 2001 - 2018, both the total number of pharmaceutical companies with active pipelines, as well as the annual number of pipeline drugs, have tripled.³



¹ Goldsmith AD, Varela FE. Fragmentation in the biopharma industry. Drug Discovery Today. 2017;22:433-439.

² EvaluatePharma®. World Preview 2017, Outlook to 2022. EvaluatePharma®, Evaluate Ltd., 2017.

³ Lloyd J. Pharma R&D Annual Review 2018. Pharmaprojects, Pharma intelligence. Informa, 2018.



Newer players, narrower indications

A decade ago, most pharma companies were still focused on blockbuster primary care small-molecule drugs (<900 Daltons).⁴ The primary care channel was the main driver for sales,⁵ and thus the main focus of the legions of drug representatives sent into doctors' offices by pharma companies. Primary care drugs contributed roughly 80% of revenues for most of the big pharma portfolios.⁶

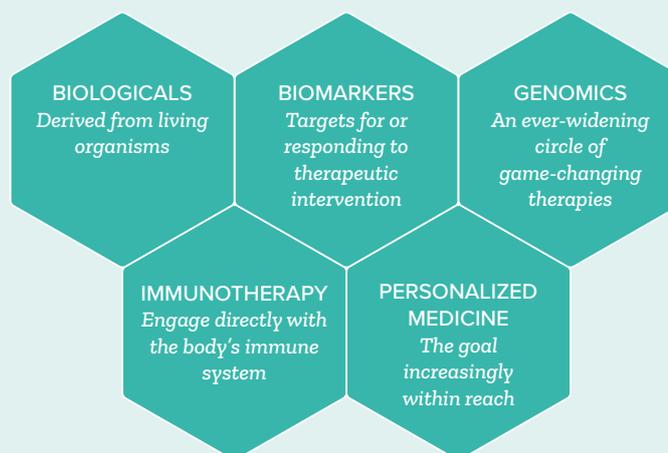
However, gifted with new scientific insights from the revolution in genetics, a groundswell of companies both large and small were creating the explosion of new disease insights, new drug MOAs, and new market opportunities we see today (please see figure 2).

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.

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 FDA drug indications. Consider the market fight going on right now between these three drugs:

- Pfizer's Ibrance (palbociclib), a CDK4/6 inhibitor, approved by the FDA in March, 2017 for first-line treatment of HR+ HER2-metastatic breast cancer⁷
- Novartis' Kisqali (ribociclib), a CDK4/6 inhibitor, approved by the FDA in March, 2017 for first-line treatment of postmenopausal women with HR+ HER2-breast cancer⁸
- Lilly's Verzenio (abemaciclib), a CDK4/6 inhibitor approved by the FDA in September 2017 for first-line treatment of postmenopausal women with HR+ HER2-breast cancer⁹

Figure 2: Disruptors in Pharma



Obviously, Pfizer, Novartis, and Lilly entered the market knowing they had a dogfight on their hands. In the race to be first, all three were able to truncate the timing of the FDA approval process by being awarded various combinations of fast-track, breakthrough, and priority review designations - expanded programs of the sort originally developed to incentivize orphan drug research. What was once an incentive program 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. 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 CD4/6 inhibitor story unfold will tell us much about which teams prioritized strategic intelligence, and which did not.

⁴ The FDA Group. A brief guide to small-molecule compounds and FDA regulations. <http://www.thefdagroup.com/thefdagroup-blog/2014/10/small-molecule-compounds/>. Accessed May 23, 2018.

⁵ National Health Service. Primary care. <https://digital.nhs.uk/PC>. Accessed May 23, 2018.

⁶ Gautam A, Xiaogang P. The changing model of big pharma: impact of key trends. *Drug Discovery Today*. 2016;21:379-384.

⁷ Drugs.com. Ibrance approval history. <https://www.drugs.com/history/ibrance.html>. Accessed May 24, 2018.

⁸ Drugs.com. Kisqali approval history. <https://www.drugs.com/history/kisqali.html>. Accessed May 24, 2018.

⁹ Drugs.com. Verzenio approval history. <https://www.drugs.com/history/verzenio.html>. Accessed May 24, 2018.

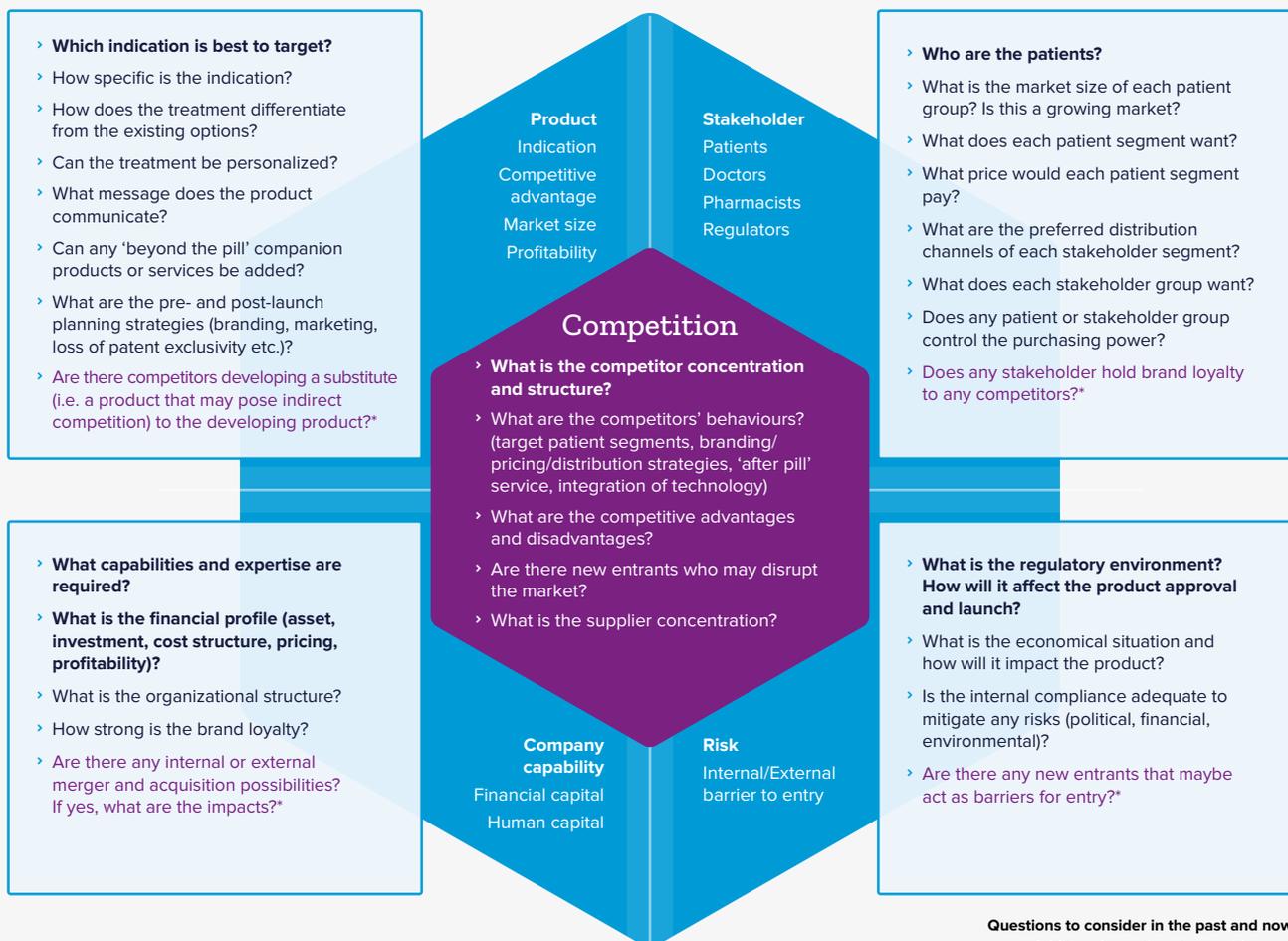
A new rulebook for pharma

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 3: 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 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 strategy-focused projects have increased at twice the rate of traditional competitive intelligence assignments. Our user profiles have also diversified, and now include portfolio strategic leadership, senior management, market access stakeholders, and business development. This trend is a reflection of 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. Which brings us back to the point: Raw data without interpretation is simply not useful without segmentation, prioritization, and skilful 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.

Data without interpretation - raw data - is simply not useful without segmentation, prioritization, and skilful strategic analysis against a backdrop of deep market understanding.

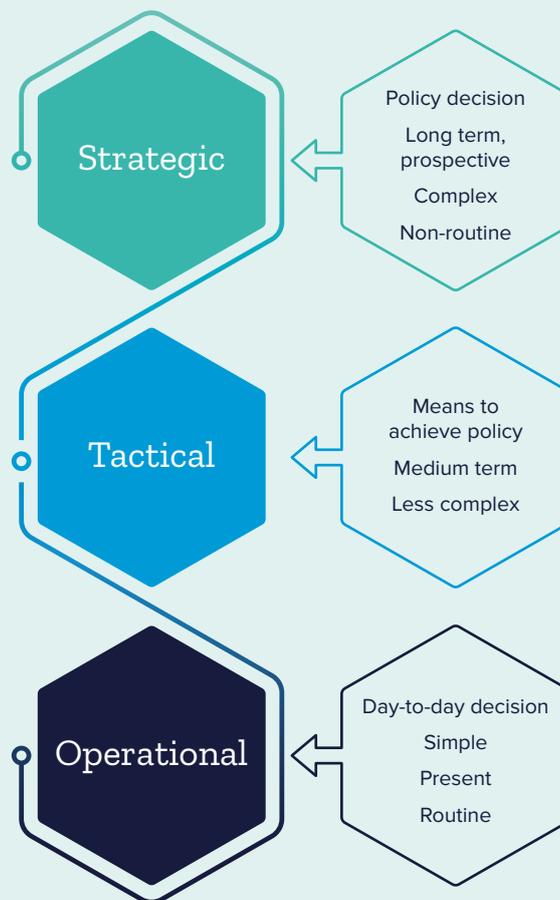
Intelligence for the 21st century: Strategic foresight

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 strategists.¹⁰

At Deallus, we define strategic intelligence as data-driven wisdom and insights that generate executable, future-focused strategies steeped in a deep understanding of competitor actions and intent. 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 operational.¹¹ 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 4: The three levels of business decisions.



¹⁰ Central Intelligence Agency. The state of strategic intelligence. <https://www.cia.gov/library/center-for-the-study-of-intelligence/csi-publications/csi-studies/studies/vol51no2/the-state-of-strategic-intelligence.html>. Accessed June 16, 2018.

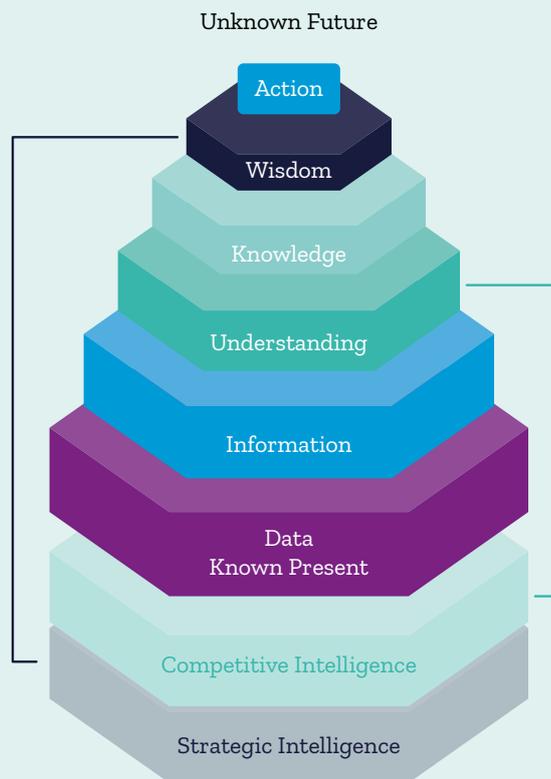
¹¹ British Broadcasting Corporation. Business Management: decision-making in business. http://www.bbc.co.uk/bitesize/higher/business_management/business_enterprise/decision_making_business_revision/1/. Accessed April 4, 2018.

Consider the hierarchy of intelligence, as illustrated in Figure 5 - 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, the majority of 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?

Figure 5: The hierarchy of intelligence.¹²



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 maximising opportunities, mitigating potential problems, and converting threats into opportunities.

¹² The Managing Research Library. The Multiverse Lexicon Bibliography. <https://managingresearchlibrary.org/glossary/intelligence-hierarchy>. Accessed April 4, 2018.

Are you seeking and generating intelligence that will help you shape your market, or merely reacting to how your competitors are shaping it for you?

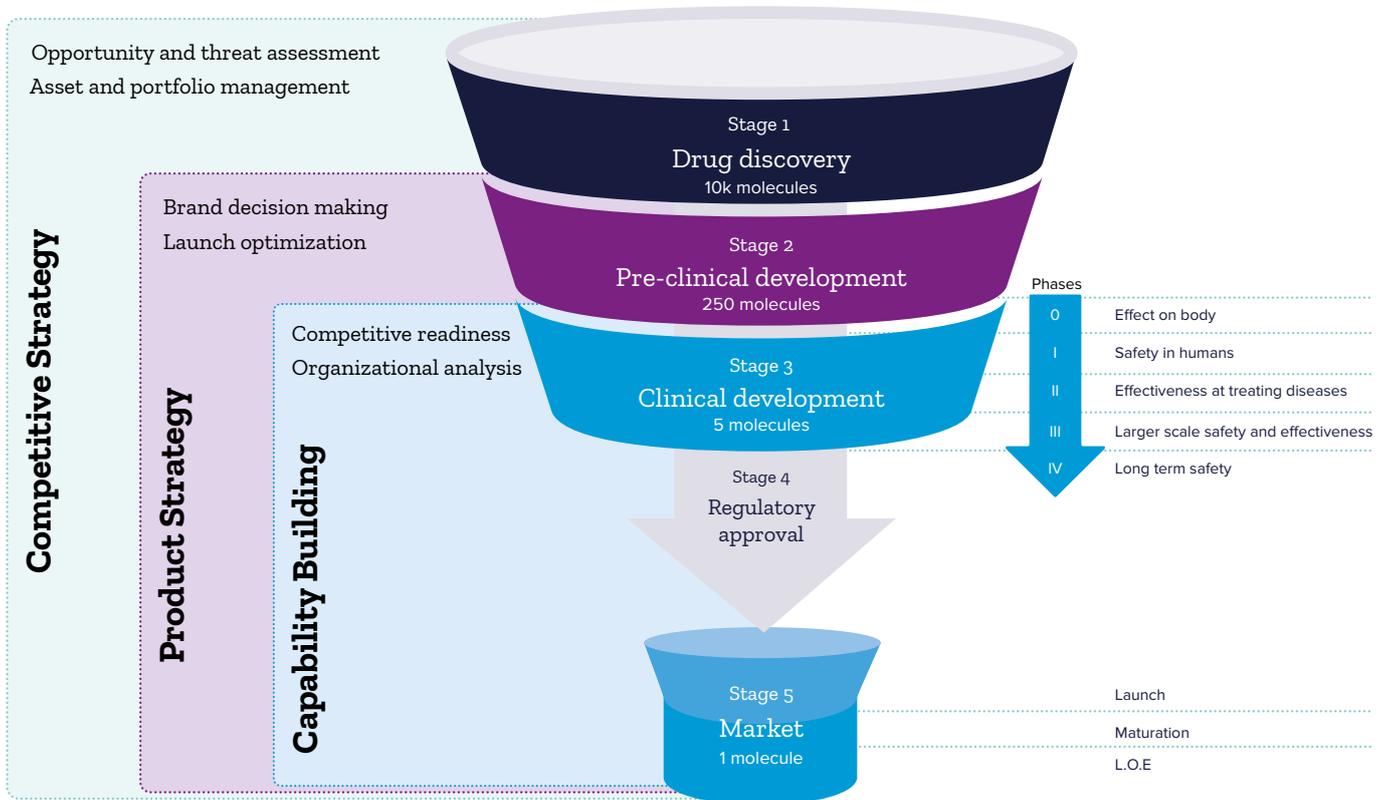
Ask yourself

- › Do you discuss and analyse, 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 rarely extend past the previous or current quarter's events?
- › 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 current threats, and gathering bits of urgent but disparate info?

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 6: Strategies in a drug development cycle



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 and real-world results

Case study 1: Preparation for loss of exclusivity in an orphan disease medication

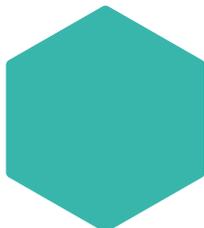
The situation: As LOE approached, our client was unable to move forward because of an internal debate. Some executives worried that the first wave of generic competitors would wipe out their hold on their market overnight. Others suspected that no one would actually bother with the expense and effort of producing a generic for their disease state. The questions of what, if any, resources to commit post-expiry were unresolvable.

Methodology: Deallus analyzed the strategic options of target manufacturers, specifically to characterize their short and long-term intent.

Findings: Under the lens of strategic intelligence, consideration of competitor end-goals, personalities of key personnel, and various other factors, a number of hidden truths were made plain.

- The number of generics manufacturers with intent to supply was limited and manageable
- For many of these, the generic version of our client's drug was likely going to be their only portfolio product
- If our client could ride out the situation longer than their generic contenders, there would be continued opportunity in the mid-term
- One particularly feared competitor was in fact moving forward with a generic with the intention of using its approval to show operational proof of concept ahead of an IPO. They actually had no compelling long-term manufacturing or marketing plans for the drug

Outcome: Information garnered from the strategic analysis provided confidence that the fight was winnable, and gave the company a clear path forward with actionable strategy, tactics, and target goals. The company injected new meaning, and invested new resources, into creating a marketing plan for their generics. What had been a problem became an opportunity through strategic intelligence.



Case study 2: Overcoming a safety differentiation challenge

The situation: Our client had a best-in-class nutraceutical indicated for a variety of clinically significant healthcare contexts. The nutrient at the heart of the intervention was essentially a commodity - it is the delivery matrix that differentiates their product from the competition. Also, this niche has a history of products being withdrawn because of hypersensitivity reactions, and customer perceptions still linger.

Methodology: Deallus initiated a marketplace landscape and competitor threat assessment.

Findings: Through strategic intelligence we isolated a credible marketplace threat.

- We identified a fairly innocuous poster from an academic center highlighting a higher-than-expected incidence of adverse events (AEs) with our client's product
 - We conjectured that the academic center - being in Denmark - was probably working with a Danish manufacturer
- In parallel, we identified that the Danish competitor intended to differentiate along the lines of safety (leveraging highly-sensitized customer perceptions)
- We proactively identified that a more robust head-to-head trial was planned well in advance of its formal announcement

Outcome: We prepped our client so they could prepare a counter-case, including:

- Overall communications strategy and guidance - down to the level of specific terminology
- Evidence generation into the clinical significance of the AEs in question
- Timely deployment of reactive messaging with the field force

Through a robust engagement with strategic intelligence, threats were identified and responded to with agility. Strategic intelligence enabled the company to determine a path forward that allowed our client to defend their niche before the competitor was able to redefine it to their own advantage.

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, corner drugstores supplied, and each individual illness was treated more or less 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 more sure 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?

Strategic intelligence allows you to confidently answer these questions. It is the best tool we have to 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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