Pharma Intelligence
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China's Challenges and Opportunities in the Wake of COVID-19

COVID And Beyond: China Urged To Address Chronic Disease, Improve Access

Issues Laid Bare By Coronavirus

Executive Summary

Facing the aftermath of coronavirus disruption and supply chain reorganization, executives of multinational drug firms in China say the government needs to do more to help address a flurry of issues laid bare by the public health crisis.

In its latest advocacy effort, the R&D-based Pharmaceutical Association Committee (RDPAC) in China has called upon the Chinese government to invest more in public health, prioritize chronic care, increase access to innovative new drugs and support the digital health push.

Member companies and executives of RDPAC, which represents big pharma in China, advocated for the industry during China's annual National People's Congress in Beijing, the so-called "Two Sessions", which had been delayed two months from March to late May because of the pandemic.

In an RDPAC statement, Sanofi China president Pius Hornstein called on Beijing for more government funding devoted to health, especially chronic diseases as the attention on coronavirus is abating. China has the largest number of people with chronic respiratory diseases, hypertension and diabetes, due to smoking, lifestyle factors and its huge population.

During the outbreak, chronic disease has taken a back seat and even before COVID-19, China was prioritizing cancer and major infectious diseases. But the current crisis has exposed the risks associated with a large population with underlying health issues. People with the chronic conditions are likely to develop more severe symptoms and have higher death rates when infected with the coronavirus, several studies show.

Sanofi suffered a 14% sales drop in China in the first quarter, impacted by the expansion of centralized procurement schemes which saw domestic companies' products win bids, hitting several of the French company's large-selling products such as Plavix (clopidogrel), which dropped 53%. One bright spot, however, is vaccines, a sector where Sanofi grew 15% in China in the quarter.

Outside centralized procurement, Sanofi reported Lantus (insulin glargine) benefited from the allowance of large refilled prescriptions during the outbreak.

Access, Reimbursement Policy

Increasing vaccination rates and improving reimbursement for rare disease treatments are also listed high on executives' minds. Since China is increasingly focusing on innovative new drugs and off-patented drugs have seen their prices free-falling, R&D-based firms are looking to market access issues and protection of intellectual property rights.

One Achilles heel exposed by the coronavirus outbreak is the seemingly large but insufficient coverage for patients who needed care, a shortcoming acknowledged by health policy makers in China.

"China should increase public health and overall health infrastructure buildup," urged Julio Gay-Ger, the China president of Lilly Research Laboratories, who joined other senior executives to voice concerns and push for policy support for the pharma sector.

The heavy focus on oncology should be offset by increasing attention to chronic conditions such as diabetes, he urged. "Increasing access to innovative new drugs, especially for patients in grassroots clinics, so the products can better [help] patients with diabetes and cancer," is necessary, added the executive.

Lilly reported its first-quarter sales in China increased by 30%, driven by anti-PD-1 antibody Tyvyt (xintilimab), jointly developed with Chinese company Innovent Biologics Inc.. Tyvyt is the first PD-1 immuno-oncology drug to be covered by China's National Reimbursement Drug List, a factor which really contributed to Lilly's local revenue growth.

China amid coronavirus outbreak has tightened grip over Hong Kong, passing National Security Law and essentially ending the "one country, two systems" the island city has enjoyed since 1997 when was handed over from UK, and the US has decided to revoke special status, the sudden change is likely to impact many companies' decision in the city (Also see "China's New Hong Kong Security Law To Derail Biotech IPOs?" - Scrip, 29 May, 2020.)

Digital Health Push

Other multinationals such as Novartis AG and AstraZeneca PLC are leaping into the digital health domain in post-coronavirus China, renewing their focus to offset the impact the outbreak has had on restricting face-to-face physician visits.

Novartis has implemented a multi-channel sales strategy involving physicians and healthcare professionals, which includes web-based conferences and social media outreach activities and helped drive quarterly sales up by 18%.

AZ increased its quarterly sales in China by 17%, after it set up information portals for physicians. Based on diseases rather than products, these attracted millions of doctors even during a time when many were staying at home and there were few other ways to get medical information.

"There should be more investment in and support for smart healthcare, encouraging the integration of Internet of Things, artificial intelligence, big data and 5G [mobile networks] with health care," proposed Leon Wang, executive vice-president, International for the UK-based firm.

Digital health will not only bring convenience to more patients but allow medical resources to be equally allocated and relieve the pressure on large hospitals, Wang added.

Making quality health care accessible to more people is a key policy goal within the Chinese central government's Healthy China 2030 plan.

Published online in Scrip, 02 June 2020

Lessons From COVID-19: How Pharma Supply Chains Must Evolve Before Next Disaster

Executive Summary

Experts describe the agile, localized supply chains that will emerge, only perhaps to be forgotten just-in-time for the next crisis.

The COVID-19 pandemic has forced a reckoning for a global pharmaceutical supply chain that in recent years has grown more efficient than resilient, supply chain experts say.

Companies are compensating for the lack of resiliency by communicating constantly, finding new ways to complete routine tasks and collaborating like never before to keep the supply chain from breaking. (Also see "How Some Manufacturers Are Navigating COVID-19 Pharma Supply Chain Challenges" - Pink Sheet, 14 Apr, 2020.)

As the coronavirus crisis subsides, the industry is sure to fortify the supply chain. But a panel of experts warned a recent International Society for Pharmaceutical Engineering webinar that the resiliency companies add may well erode under pressure for efficiency as memory of the pain diminishes.

"While we thought we had really good business continuity plans, I guarantee that we – and everyone, probably – are going to look at those plans in hindsight and see if they make sense," Jen Trone, managing director of sales, UPS Supply Chain Solutions Inc., told the 2 April pandemic supply chain webinar. "Reflection is going to be a significant activity that we're all going to see when this is all over."

So Many Supply Chain Challenges

In fact, the reflection already is beginning.

"There are a lot of weaknesses in the supply chain being exposed right now," said Robert Handfield, executive director of the Supply Chain Resource Cooperative and professor of supply chain management at North Carolina State University.

He said some of those weaknesses are around clinical trials, vaccines, personal protective equipment, active pharmaceutical ingredients and contract development and manufacturing organizations.

There is the challenge of export restrictions, which 24 countries are imposing on other countries to retain domestic supplies of personal protective equipment, medical devices and pharmaceuticals.

There is the problem of global supply chains that have become highly dependent on sourcing from China, compounded by the problem that much PPE was consumed in China where the outbreak started.

By outsourcing to low-cost countries like China, global manufacturers have lost much of the flexibility they need to confront the pandemic, he said.

A Black Swan Moment

The supply chain challenge with the COVID-19 pandemic, as Handfield had discussed in a paper on the 2003 severe acute respiratory syndrome (SARS) epidemic, is "how to deal with these kinds of black swan events that occur simultaneously around the globe."

Such events drive home the need for local supply sources and local manufacturing. And in the wake of the COVID-19 pandemic, "I think we're going to see the opposite of what happened a few years ago where a lot of big pharma companies were shutting down local supply and local sites and moving to global sites. I think that may be changing in the future."

How Just-In-Time Delivery Is Not Dead

In Handfield's view, the pandemic will not put an end to the just-in-time delivery philosophy of cutting costs by trimming inventories.

"I think the issue is not so much do we keep less inventory, but where do we keep the inventory?"

In Handfield's view, it's all about localizing the supply chain, much as the automotive industry does. And that's not just to reduce inventories – it's also about communicating more effectively and increasing the velocity of material movement.

Nations will rethink their approach to stockpiles and companies will rethink their business continuity plans.

"It's difficult before a pandemic to say, 'what's the ROI on keeping a bunch of material in a stockpile?' Well, that becomes very clear when you have an event like this."

Why Agility Matters More Than Models

Joydeep Ganguly, senior VP, corporate operations, Gilead Sciences Inc., shared a similar point of view. The JIT philosophy is not dead because of the coronavirus. In this chaotic environment, "there isn't a supply chain model that we can say is dead."

Even though the supply chains that were pillories for bloated inventories in the high-efficiency industrial 4.0 era now are being touted as super-resilient, the supply chain of the future won't necessarily differ by having greater inventories, in Ganguly's view. But it definitely will be more agile.

"What I think we can learn from this right now is our ability to react to the next crisis that will occur will be less a function of the dominant supply chain model we've chosen, but it truly will be our culture of agility, and our culture of innovation and our culture of driving change and expecting change and reacting appropriately."

Just In Time For The Next Disaster

The panelists agreed that the industry is going to get much more serious about risk management and preparedness for major crises like pandemics – but there were concerns that the readiness might not last.

Ganguly expects to see "a general appreciation for risk processes, risk management, risk governance, not to paralyze an organization but to have a healthy appreciation for that, and make sure we don't forget this during times when there isn't a crisis."

Timo Usinger, VP for customer project management/procurement at Vetter Pharma-Fertigung GmbH, agreed that "everybody is talking about this now, and the sustainability of the supply chain, of supplier risk management will be increased in the future."

Companies have learned from fire disasters, supplier bankruptcies, volcanic eruptions and nuclear disasters, but then slowly forgot what they learned.

Usinger said he hopes the industry will remember the way today's pandemic is disrupting the global pharmaceutical supply chain and prepares better

for the next challenge and remains prepared.

But he worries that within four years, "everybody is asking again what is your cost per unit, and bring them down, and we have the just-in-time principle in place again."

Published online in Pink Sheet, 15 April 2020

China Turns COVID-19 Crisis Into A Global Health Care Opportunity

China's ability to push back digital boundaries position it well in the ongoing transformation of health care delivery

Executive Summary

Another important step has been taken under the Healthy China initiative, with the implementation on June 1 of a basic law on access to health care. This provides additional tailwind for a health system that appeared to efficiently contain its coronavirus outbreak and is now making further structural improvements.

- Better health care in line with standards delivered in other markets is increasingly demanded in China, where the use of digital technologies is both higher and better accepted than in many other parts of the world.
- Renewed attention to primary care needs has resulted in a long-overdue law on promoting basic medical and health care needs, which continues the momentum started in 2016 with the Healthy China 2030 Vision for Health Care.
- China's impetus toward ensuring greater access to health care comes as it seeks to eliminate COVID-19 within its borders, having at one time seemed likely to suffer a long-term and much more costly episode of infection.

Amidst the frequent criticism of how China dealt initially with the outbreak of coronavirus in early 2020, and the uncertainty in many quarters over the precise origins, timings and sequence of events in 2019 that led to the pandemic, one thing is certain: China's decisive action in and beyond Wuhan in late January could have been a lesson to economies yet to be hit by COVID-19.

Many countries where infection spread did not use Wuhan as a blueprint for action, or not fast enough, which is one reason why global infections have continued to rise. In early June, the infection rate was nearing seven million, and deaths 400,000 globally. In China, the respective figures on 31 May were 83,000 and 4,600, as claimed officially in the State Council Information Office of the People's Republic of China's report, Fighting Covid-19 – China in Action.

The report was published in the first week of June. The 73rd World Health Assembly meeting of the WHO concluded not three weeks earlier, with no promise that China would approve an independent investigation into COVID-19, as demanded by the EU and Australia. Instead, President Xi Jinping listed 11 internal proposals and measures in his speech opening the WHA. These are a focus of the official report, which congratulates the Chinese people for joining together as one to contain the spread of the virus.

Viewed from outside, while China praises its efficient system and central authorities for exercising overall command, there is a broad international consensus that the county's very early handling of the outbreak locally was poor. Some viewed China as slow to react, according to Nick Beckett, co-head of the Life Sciences & Healthcare Group and managing partner in Beijing at global law firm CMS. Beckett commented that China's administration felt it had done a good job responding, if perhaps not quickly enough.

In fact, once the machinery of government got going, it made good progress and was impressive in successfully isolating the first novel coronavirus strain on 7 January, locking down in Wuhan on 23 January and quarantining 50 million people rapidly in Wuhan and surrounding cities, and building a 1,000-bed Huoshenshan Hospital in just 10 days, for instance. The renewed concerns over virus spread in Beijing in mid-June are apparently being addressed in a similarly focused manner.

In addition, the National Medical Products Administration (NMPA) fast tracked the approval of four novel coronavirus test kits from four local companies to boost capacity for producing virus nucleic acid test kits. In hindsight, the massive testing program, hospital building and control actions show China, in all, did an effective job, especially when viewed against the performance of the US, say, in attempting to control the infection, Beckett notes.

In addition, many countries have valued China's sharing of its knowledge of novel coronavirus and its experiences. The country's exports of personal protective equipment (PPE) have been both significant and positively received. China's COVID-19 focus is now on preventing renewed spikes of the kind seen in Shulan in mid-May; and on developing a vaccine, where it is reported that Chinese researchers are progressing well on two coronavirus vaccine candidates.

A Health Care System In Need Of Attention

The performance was more remarkable as China's health care system has widely recognized difficulties and problems within it, Beckett said in an interview with In Vivo. These are notably the lack of primary care, the absence of GPs and hugely over-crowded hospitals. In times of public health crises, when resources are stretched, such inadequacies are highlighted. With no system of GPs or pharmacists to cope with minor health care issues, all patients gravitate towards hospitals, using up the capacity that is needed desperately in a pandemic.

These underlying issues create a health care system with structural difficulties and challenges. The latest WHO Global Health Observatory (GHO) data show that while Germany has 4.2 doctors per 1,000 of population, the UK 2.8 and the US 2.5, in China the rate is just 1.78 per 1,000 of population.

In many ways the structures in China have simply not caught up with other markets, and not just in primary care doctor numbers. There is no proper training system, no major medical specialty institutions, no regular fora of experts coming together to discuss topics in modern medicine, and no pooling of intellect and talent. All the learning happens in the field and on the job. It is both a waste of opportunity and misuse of skills, when qualified cardiologists, for instance, are having to spend 30% of their time dealing with minor ailments.

A New Law To Bring Overdue Change

But the ground has now been laid for change, following the implementation on 1 June of China's first fundamental and comprehensive law on basic medical and health care. The law was approved during a bimonthly session of the National People's Congress Standing Committee in December 2019. It aims to promote medical and health care matters, improve access to basic medical and health care services and build a "healthy China."

Empowering medical institutions, upgrading professional training, and providing accurate health care information to the public are other elements of the law. Furthermore, medical workers who choose to work in local communities

and poorer, remote areas will qualify for higher remuneration and allowances, and greater career development opportunities. The law also encourages improved health education at schools and universities. Medical and health care education has long been a missing part of the picture in China.

Both the government and the public have been pushing for more holistic health care, from prevention to detection to treatment, as well as the provision of a better all-round education in health matters. This law on promotion of basic medical and heath speaks very much to those needs," said Beckett. While a lot of the domestic focus to date has been investing in biotech and pharma R&D – and less so in medtech – there has been little focus on "health care."

Overseas specialists will have an ongoing role in helping China meet these newly identified and acknowledged needs. Just as China wants its own talent to return and help build such systems, so it also sees the need to leverage western knowledge and talent to help in that task. The increasing use of English, in the main cities at least, is down to children being taught it much earlier, as well as to the younger population being more receptive to western influences. There has been a relaxation over time of restrictions on certain elements of English language culture.

Digital Upsurge In An Already Receptive Population

One very clear positive to emerge from the pandemic is a wider recognition of the value of telecare and telemedicine, said Beckett. In China, the JD.com online retailer's JD Health platform has seen daily online consultations increase from 10,000 in the pre-COVID period to 150,000 in its post-pandemic recovery period. Patients are increasingly comfortable accessing health care online, a trend now also being exploited by rival platforms from Tencent Holdings and Alibaba Inc.

They are following the trend set by WePay and Alipay, China's leading online banks, the success of which in revolutionizing banking in the early 2000s has seen credit cards bypassed. Just as online banking has supplanted much of the traditional banking activity, so virtual health care has evolved to fill the gaps in traditional health care, such as the lack of primary care. These private company platforms are tending to fulfil the role of what would be the GP in other markets, with much of their care being delivered through artificial intelligence tools.

The result has been a "tech savvy" audience that is receptive to the delivery of health care, and diagnostic and treatment services though online means, even if the patient-user knows there is not a human at the other end. "In that, they are receptive in a way that other markets may not be," Beckett said.

A recent example is the COVID-19 contact tracing system put in place in China in February in Hangzhou, headquarters city of Alibaba, and quickly rolled out to the all 200 cities in China. To prove their disease status, individuals had to download an app, hosted by Alibaba, Tencent and Baidu, which displayed their status. This was determined after they had input information, including close contacts. In turn, this gave them a QR code; and to be able to move around, a green code ("disease free") was required to be shown to the authorities at checkpoints.

This QR color-coded system was seemingly well received by the Chinese, who have become used to such technologies. No one complained about privacy or the government overreaching its powers, Beckett observed. Going beyond

coronavirus, there are notions that the same QR technology will be used to create permanent health trackers, which will integrate with other parts of the system. This is more ambitious and could be seen as more personally invasive. But equally, the Chinese people might accept it without too great a concern.

Chinese Lessons

In all, it seems COVID-19 has taught China many things. The country has learnt that it could do better, and this is broached in specific measures in the law on basic medical and health care access. People are ever more aware that basic medical care provisions and the need to guarantee drug supplies are not high enough up the domestic agenda. Alongside the law, certain lower level guidances on building intelligent hospitals, and spot checks on medical devices, in line with concerns over the quality of some PPE and face masks, are being proposed.

On the other hand, there is considerable pride locally, and the administration's successful testing of some 10 million people in and beyond Wuhan in a mere few days is one source of that. In May, the government announced it was able to perform over 1.5 million COVID-19 serology tests per day. The achievement of the local industry in being able to mobilize rapidly to produce millions of pieces of PPE daily is similarly impressive. It is all part of the China model, says Beckett. "When China sets itself a task, it does it very effectively, be it in locking down businesses, municipalities, provinces or even the country. And it can re-open at the same speed and get business going again," he said.

During COVID-19, the life sciences industry held up well in China's eyes, so any financial support and grants largely went to other industries.

But the government has introduced a program whereby companies are not required to pay national insurance, a scheme that applies to all industries.

Getting Back To Normal

Attention now turns to bringing elective care back to more normal levels. There was sharp decline in certain elective procedures, and a consequent decline in procurement of medical devices during the outbreak in China: interventional device procurement shrunk 40-80% in Q1 2020. But a gradual recovery is underway in the procurement of medical devices, although Beckett does not believe a full catch-up of the lost volumes will be achieved this year. "In some areas of high-volume consumables, there is an expectation of a continued contraction of perhaps 20% for the whole year," he ventured.

This is compounded by expected short-term declines in health care budgets. GDP is expected to grow by between 1% and 2.3% in 2020, down from 6% last year, so health care will have lower spending. Medical device prices will come under pressure as a consequence. But there should be a relatively short-term effect, with improvements expected in 2022.

This should not alter perspectives about China as a market. While there have been notable changes in trade flows in health care and medtech, COVID-19 is a global issue. The world is still trying to cope with seeing supply chains disrupted in a major way. The rest of calendar 2020 will be challenging for all medtechs globally, partly because of turmoil in their own markets. But China is coming out of the turmoil more quickly than others, and as a destination market for medtechs, it presents the same if not better opportunities in areas like telehealth.

An Attractive Market In Waiting

"The Chinese market is still just as attractive to multinational companies, although it may take businesses a year to get themselves back to a position of normality in their own markets and regarding their own workforces, in order to be able to seize these opportunities," said Beckett.

Certain macro issues, such as the ongoing trade dispute with the US, the latter's claims about the outbreak of COVID-19, China's refusal thus far to open up the issue to an independent investigation, its apparent bid to end the "one China, two systems" policy in the case of Hong Kong, and its activity in the South Sea, observed nervously from afar, obviously engender feelings of unease in the business community.

But at a commercial level, China still incentivizes multinationals to fairly access its market. Moreover, it knows that western companies would find it difficult to consider not going there, in view of its lucrative and growing market in life sciences.

China also, usually, takes a long-term and pragmatic, big picture view of what it does. The US threat to withdraw funding and its membership of the WHO – with which it "terminated" its relationship on 29 May, has opened up the path for China to assume the putative lead role on global health care matters. "For China, being seen as a leading force in health care globally would be very important," said Beckett.

Back on the domestic front, the beginnings of a move to a better system for the delivery of basic health care will be welcomed by a large and often underserved population. COVID-19 has shone a powerful light on telemedicine and digital capabilities generally, and these are areas where China has both the technology and a receptive market.

Similarly, its readiness to embark on app-based health care delivery puts it in a good position as needs continue to evolve and grow. China has achieved a lot in a relatively short time, but as the administration might agree, more still needs to be done.

Published online in In Vivo, 23 June 2020

Global Promise, Local Challenges: Can China Deliver First COVID Vaccines To World?

Executive Summary

A rare look at China's regulatory push to get the first vaccines for SARS-CoV-2 ready for both its 1.4 billion people and supply to the world, in a move for "global public good" promised by president Xi Jinping.

Why, out of five coronavirus vaccines under clinical development in China, four are based on the inactivated virus? What are Chinese regulators doing to speed up development, which usually takes longer than novel drugs? And while state-owned biotech giants are hastening development, what about the smaller developers in China?

In a rare inside peek into the policies behind the vaccines race in China, the Center for Drug Evaluation (CDE) under the National Medical Products Administration has published two interview articles on its push to get the first such products launched in the country, and answering some of these pressing questions.

After the coronavirus first hit Wuhan, the nation's efforts to develop a virus have been swift.

Like its approaches towards treating the outbreak, China has resorted to something familiar - vaccines based on the inactivated virus. The country has already built a solid foundation for this established technology, which was natural to pursue this time.

"Vaccine testing cycles take longer than drugs," Xiang JinZhong, chief reviewer at the CDE's biologics section, said in the articles. To that end, the center has quickly established links with other centers, for clinical samples and other testing and quality standards reviews, to save time, he added.

Regulatory High Gear

Four months in, a total of five vaccines are now in clinical development in China, four based on the inactivated virus and one an adeno-associated virus (AAV) product. By July, Phase II clinical trials are set to be complete, noted the CDE.

Another regulatory official, Li Changgui of the National Institute of Food and Drug Inspection, said that his team used their technical skills to provide antibodies from animals and providing the virus's spike protein to developers of inactivated vaccines to establish antigen testing methods and thus accelerate R&D.

Since setting a goal to launch the first COVID-19 vaccine globally, China has kicked the race into high gear and initiated a process of urgent inspections which would usually take months to complete.

Developing vaccines requires testing at Protection 3 level lab, but the limited number of such domestic facilities is unable to meet the sudden surge for testing needs from developers. "Before, early-stage testing required lab testing and high biosecurity risks. After joint efforts between the regulatory team and the developers, we set up testing on immunized mice and settle on a testing system that requires no P3 lab testing," noted Li.

Since mid-March, when Sinovac Biotech Ltd. started testing its CoronaVac vaccine candidate, the institute has tested 36 batches of vaccines

based on the inactivated virus. This accounts for 44% of all batches of coronavirus vaccines so far in China, laying the foundation for global leadership, noted the CDE.

However, industry experts say the fact that four out of the five leading Chinese vaccines are inactivated may not actually indicate a leadership position. "Vaccines based on the inactivated virus is an outdated approach, developed decades ago," Ke Wu, CEO of Wuhan-based BravoVax told the Pink Sheet. "If you look around outside China, there are few vaccine developers using this method to develop coronavirus vaccines right now."

SOE Dominance

State-owned firms are also taking a notable lead among the multiple vaccine developers in China. Sinopharm Group Co. Ltd.'s China Biologics Products Group is out front in the inactivated space, while Tianjin CanSino Biotechnology Inc., although not a state-owned enterprise but closely aligned with the China Academy of Medical Science, is pushing ahead with its AAV-based vaccine.

Smaller developers like BravoVax have seen an uneven playground in the race, Wu said. The company, established in 2013, couldn't even get approval from local authorities to resume its operations until late March, while state-owned companies could work right through the outbreak, he observed.

When it comes to testing vaccines at a P3 lab, the chances for smaller developers are essentially nonexistent when SOEs are rushing to get theirs into the system, Wu added.

Another privately-owned vaccine firm, Shanghai-based Stemirna Therapeutics, has been developing a mRNA-based vaccine for the pandemic. While the company's overseas rival in this sector, Moderna Inc. of the US, is entering its mRNA vaccine into Phase III, Stemirna recently sold the rights to its preclinical candidate to Tibet Pharma, a generics firm, in a CNY35m ($4.9m) deal.

It was already challenging for smaller companies such as Stemirna and BravoVax to raise money prior to the outbreak and the policy prioritization for large, state-owned companies is further worsening prospects for raising much-needed funds to accelerate development, Wu stressed.

Published online in Pink Sheet, 18 June 2020

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Accurate and timely intelligence about the drug development pipeline is vital to understanding the opportunities and risks in today's biopharmaceutical marketplace—whether you are targeting an unmet medical need, investigating promising new therapies or researching drug development historical trends and treatment patterns. If you are providing contract research or other services in the pharma industry, you need to stand out. A solid understanding of your potential clients' pipelines and competition will help you leave a lasting impression.

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