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Dr.Reddy's

Whitepaper

Roundtable

Emerging Frameworks in Innovation

May 2024

Chair:

Satish Reddy, Chairman, Dr. Reddy's Laboratories Ltd.

Moderator:

Ms. Anju Ghangurde, Executive Editor (Asia Pacific), Scrip/Pink Sheet, Citeline

Panelists

Professor Jack W. Szostak, Nobel Laureate

Dr. Harish Iyer, Deputy Director, Digital and Health Innovation – India Office, Bill & Melinda Gates Foundation

Dr. Yamuna Krishnan, Professor, Department of Chemistry, University of Chicago

Dr. Shridhar Narayanan, Indian Pharmaceutical Alliance

Dr. Srinivas Oruganti, Director, Dr. Reddy's Institute of Life Sciences

Dr. Murali Ramachandra, CEO, Aurigene Oncology

Dr. Radha Rangarajan, Director, CSIR-CDRI

Dr. Ajit Rangnekar, Director General, Research and Innovation Circle of Hyderabad (RICH), Telangana

Dr. Ravindranathan, Continental Hospitals

Dr. Guru N. Reddy, Founder & Chief of Gastroenterology & Liver Diseases, Continental Hospitals

Dr. Trajko Spasenovski, Vice President, Custom Solutions, Citeline

Overview

New technologies are revolutionizing drug discovery worldwide. However, efficiently exploiting these technological advances to develop new drugs and get them to patients can be extremely challenging. Many stakeholders play significant roles in this complex process, including academic researchers, industry, government agencies, industry, and more.

"Mainstreaming some of the new age therapies and emerging technologies will require the whole ecosystem to go along – integrated data platforms, the funding environment, streamlining regulatory pathways, the patents system, addressing payer dynamics, etc."
– Anju Ghangurde, Citeline

As India strives to become a larger player in the biopharma sector moving from cost-based to value and innovation-based growth, experts are focusing on addressing a variety of issues like collaborative research, funding mechanisms, the regulatory environment, and the clinical trial infrastructure. To focus greater attention and resources, and to generate increased momentum in support of the sector, industry and government leaders have developed long-term targets to promote and accelerate biopharma innovation.

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Context

The second Dr. Anji Reddy Memorial Lecture, delivered by Nobel Laureate Professor Jack Szostak, brought together distinguished leaders representing science, industry, academia, and government. This lecture series was instituted in 2023 to honor the memory of scientist, entrepreneur, and philanthropist Dr. K. Anji Reddy, who founded Dr. Reddy's Laboratories in 1984.

In conjunction with this lecture, a roundtable of leading biopharma experts discussed India's potential to grow the country's pharmaceutical industry from its current level of $50 billion per year to $130 billion annually by 2030. The panelists shared their perspectives on achieving this vision, which will require overcoming various innovation and regulatory challenges with bold thinking and radical steps. They examined the need for greater focus on innovation, transforming the country's biopharma ecosystem, rethinking regulatory frameworks, and creating new incentives for investment.

"The Indian Pharmaceutical Alliance has set out a vision and said that by 2030, the industry should reach $130 billion. It's currently at $50 billion. We have said clearly that only innovation can get us there.... Look at China. They started this innovation game in 2008 or 2010. Look where they are today. It requires a different kind of thinking and bold, radical steps." – Satish Reddy, Dr. Reddy's Laboratories Ltd.

Key Takeaways

The global biopharma R&D pipeline is growing and will yield many near-term assets.

To set the stage for the roundtable discussion, Trajko Spasenovski from Citeline reviewed the current state of biopharma innovation worldwide. Highlights include:

- Between 2001 and 2023, the size of the global biopharma R&D pipeline had a compound annual growth rate of 5.9%. Currently, there are 21,292 drugs under development by approximately 5,500 companies. Of these new drugs under development, 41% are anti-cancer, 20% are for rare diseases, and 14% are neurologicals.
- R&D and innovation are highly diffused, as big pharma increasingly sources its portfolio from external partners. Big pharma's share of innovation continues to decline as mid-size companies contribute to overall R&D growth. The Top 10 pharma companies' share of the global biopharma pipeline decreased from 13.4% in 2011 to just 4.1% in 2023. It is platform biotech companies that are now producing new drugs at scale.
- Major themes of key drug launches in 2024 include oncology and novel modalities. The pipeline is set to deliver 69 key launches across 65 discrete drugs in 2024. Of these key launches, 42% are expected to be practice changing. Oncology is leading the way with 29 expected launches.
- Nearly one-quarter of global biopharma R&D activity is occurring in China. China is the #2 location for active R&D, behind the US, with 24% of the industry pipeline and 5,033 assets under development.

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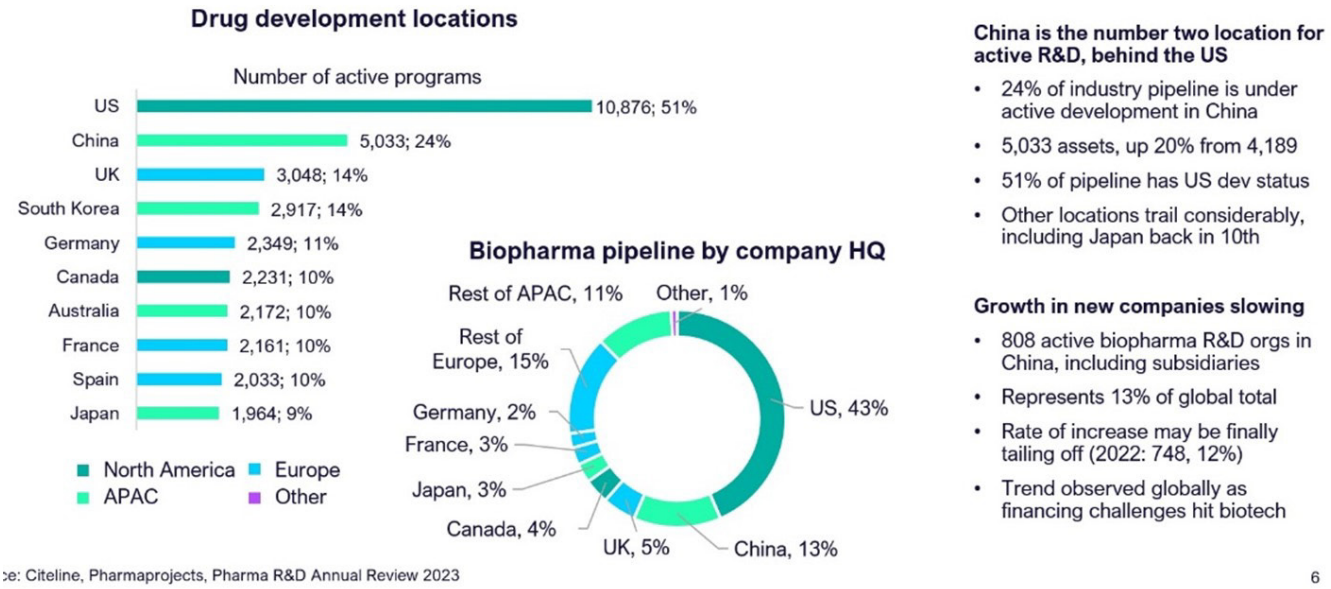
Figure 1: Leading Locations for Biopharma R&D



"The productive pipeline is growing and there is still a lot of R&D…. Innovation is still there and there is a lot of potential for companies like Dr. Reddy's and a lot of Indian companies to tap into these innovative markets." **– Trajko Spasenovski, Citeline**

Access to patient data is key to future drug discovery and development work.

Historically, biopharma companies have developed pathways and molecules in the lab and then demonstrated them in a human context. Now, there is tremendous capacity to measure samples directly from patients.

"Academia will be facing the clinic more because that's where the human patient samples are coming from. Every single thing is getting measured – proteomics, genomics, metabolomics, and more. Nature is already doing the experiment. What we're doing is finding out what the experiment is. I'm excited about the shift of getting the clue first from the model organism and then going to humans." **– Yamuna Krishnan, University of Chicago**

With AI, researchers can identify patterns using large volumes of patient data, build hypotheses, model organisms, and test their hypotheses with data.

"Continental Hospitals sees four lakh [400,000] patients a year. We have 3.5 to 4 lakh [350,000 to 400,000] of patient data. We have used electronic medical records since Day 1. I'm very optimistic for India." **– Guru N. Reddy, Continental Hospitals**

While there are many patients in India with a wide variety of diseases, one limitation for biopharma research is that very little data is available from public resources. The National Digital Health Mission is a promising start, but it's unclear whether public hospitals will adhere to its guidelines.

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"There has been exponential growth in the number of startups over the last seven years, which is very exciting. A lot of the work we are doing will be based on data. The lack of available data will be one of our biggest problems. Most public and many private hospitals still use paper records for outpatients." **– Ajit Rangnekar, RICH, Telangana Government**

Funding is a perennial concern for drug discovery and development.

In the United States and other Western countries, new drug development has been accelerated by large-scale government investments and investments by venture capital firms. One challenge is that most venture capitalists have historically avoided investing in India due to concerns about the regulatory process.

Given the level of resources needed to develop and commercialize drugs, Aurigene Oncology has used a different model. It has worked in collaboration with other major pharma companies. This enabled the company to develop an internal ecosystem. Employees were exposed to how leading pharma companies run programs. By adopting best practices and training large numbers of scientists on the various steps in drug discovery, Aurigene Oncology gained the confidence to start its own drug discovery programs.

"What accelerates drug development a lot is large-scale investments by the government. Another thing that has a lot of history in the United States is large investments by venture capital firms. VC investments are kind of a mixed bag. Sometimes they have a short-sighted view of things, but on the other hand, they can really catalyze development. It would be exciting if you could expand the inputs of financial resources from those two sources in India." **– Jack Szostak, Nobel Laureate**

Although high costs are an obstacle to clinical drug development in India, AI provides a promising solution.

India is well positioned to do early drug discovery work. However, many companies hit a bottleneck when they encounter the cost of clinical drug development. To have a sustainable drug development model, costs must decrease dramatically.

AI is showing promise for iteratively evaluating compounds, making small changes, and then looking for corresponding changes in effect. By embedding AI into drug discovery processes, this cycle can be accelerated. One challenge is that AI platforms are becoming proprietary. India's Central Drug Research Institute (CDRI) is collaborating with multiple institutions to build an open AI platform.

"With AI, we are seeing some early success in drug discovery. For example, In silico Medicine was able to go from zero to a Phase I-ready compound in 18 months for a serious unmet need – idiopathic pulmonary fibrosis. Now they are in Phase II." **– Radha Rangarajan, CSIR-CDRI**

A more robust clinical trial infrastructure in India can help advance biopharma in the country.

The number of Indian patients available for clinical trials is a boon for drug discovery and development. With the right infrastructure in place, clinical trials in India could be easier, faster, and cheaper than anywhere else in the world.

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"Having been in the industry for the last 20 years and doing nothing but drug discovery, I think India has so much opportunity to offer. Due to our large population, we have numerous patients across different diseases, including some of the rare diseases. I think this will make conduct of clinical trials in India easier, faster, and cheaper than anywhere else in the world." – Shridhar Narayanan, Indian Pharmaceutical Alliance

However, many large pharma companies are hesitant to do first-in-human studies in India today because they aren't comfortable with safety management practices. More work is needed to develop additional sites to conduct clinical trials effectively.

"The major thing is how to safely do first-in-human studies in India. Five or six sites aren't good enough for a country of India's size. If innovation is to be scaled up, we need many more sites to do trials effectively." – Murali Ramachandra, Aurigene Oncology

In addition, perceptions about participation in clinical trials need to change among Indian patients. Many people are hesitant to enter clinical trials and there is little public awareness that clinical trials with innovative drugs could be beneficial for patients. This is slowly starting to change. Aurigene Oncology, for example, has seen many individuals volunteer for its CAR-T trial.

Incentives for biopharma research collaboration could jumpstart innovation in India's biopharma sector.

Collaboration is often discouraged in India's academic research community. When Yamuna Krishnan, professor in the Department of Chemistry at the University of Chicago, returned to India as an academic, for example, she was advised not to collaborate with other scientists as it could prevent her winning awards in her name. She did not accept this advice, did the exact opposite, and still received considerable recognition for her work.

"We need to change the way funding is made available for academia for specific targets and problems. If the collaborative mechanisms catalyzed by COVID could be put on steroids, you would see more people come out of their shells." – Yamuna Krishnan, University of Chicago

Incentives for research collaboration could change this culture and foster greater innovation in the biopharma sector. A precedent was set during COVID-19 when many government grants required collaboration.

COVID-19 saw the power of science and innovation and collaboration across industry and across disciplines. There is a need to entrench some of the frameworks more effectively in the Indian innovation ecosystem to accelerate the speed and overall impact of research from lab to the clinic and onward, said the moderator.

"Many papers are published by multiple authors and different people take credit, which is great. If we fund projects and push for collaboration, the large prizes in the world will end up with large collaborations. The Indian Space Research Organization is an example of what's possible if you incentivize collaboration." – Harish Iyer, Bill & Melinda Gates Foundation

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The Indian regulatory framework for drug discovery and commercialization must be further streamlined.

The panelists made several observations about the regulatory environment for drug development in India and offered recommendations for changes that could enhance biopharma innovation in India:

- Committee-based decision-making has disadvantages. A lot of government decision-making is done by committees, which is slow and often leads to the most conservative outcomes. Ideally, committees will take reasonable risks and move forward quickly.

"A lot of decision-making for government and VC funding is done by committees, which leads to the most conservative possible outcomes. How do you get committees to be responsible and take reasonable risks, but not too many and also move forward quickly? It's a difficult challenge." **– Jack Szostak, Nobel Laureate**

- The steps for drug approval must be clarified. In India, more detail and clarity are needed on how to take a drug from preclinical to clinical and through regulatory toxicity studies. The existing regulation reads like a list that is open to interpretation. The US FDA is a good model for clear industry guidance.

"The US FDA uses a consultative approach. They try to encourage scenarios where there is an unmet medical need and they give a lot of feedback to industry. That's something we don't have in India." **– Srinivas Oruganti, Dr. Reddy's Institute of Life Sciences**

- Additional technical expertise is needed within the Indian regulatory system. Many employees in the Indian regulatory organization view themselves as licensers, focusing largely on the completion of checklists, rather than a deep dive into what drug data shows.
- The Indian regulatory system needs to strengthen institutional capacity with enhanced expertise around interpreting toxicology information, evaluating what an adverse effect means, and more, though it is encouraging to see recent government policy efforts that aim to build and expand in-house expertise in new biological entities, new chemical entities, biologics, imaging medical technologies and AI/ML-based innovations, among other areas.
- The responsibilities of India's central drug regulators and state regulators are not well defined. At the state level, biopharma expertise is also generally sparse.
- Regulatory vision is required to create safe, accelerated drug development pathways in India. The US FDA, for example, has created the limited population antimicrobial drug (LPAD) pathway to bring antibiotics to market with only one Phase III trial. This sort of regulatory vision would be beneficial in India. Key questions for developing safe, accelerated drug development pathways include whether the drugs need to be indication-specific or based on the urgency of a clinical need.

"We need an innovation ecosystem if we want to do early trials in India. That's where it's imperative that our regulators and clinical centers are top notch. There needs to be a lot of exchange of ideas between industry, clinical centers, academia, and government."
– Murali Ramachandra, Aurigene Oncology

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Replicating China's drug discovery and development model will not work in India, but certain elements can be imitated.

China's recent track record in biopharma research and development is impressive. As a democratic nation, India would be unable to implement China's strict, top-down drug discovery and development model. The panelists discussed, however, whether certain aspects of China's approach could be emulated in India, though there were diverging views.

Many agreed that one of the best things that China did was to attract scientific talent back from the West through the Thousand Talents Plan. In the biopharma sector, these individuals were some of the most senior people at the most successful companies. This gave them instant credibility and connections at high levels in big pharma almost immediately, making a huge difference.

"While funding and all the other things came in place these talents were not only at the highest level in pharma companies but also at regulatory bodies – pretty much everything that's needed to support the ecosystem. They could place people who had already done it well in the West successfully." **– Murali Ramachandra, Aurigene Oncology**

The Chinese government also backed scientists with funding and set them up with great labs, though the academic side of things in the country can tend to be rather bureaucratic at times, the roundtable heard.

"You have to stand in alliance with China to pick up the good things they have done. They are efficient. They put their heart into something, and it happens."
– Dr. Ravindranathan, Continental Hospitals

Another successful aspect of China's biopharma strategy has been setting a clear vision. Indian experts recognize the power of creating a mission and are establishing biopharma industry goals for the country.

"Flattery is the food of fools. But I would also say that flattery should be the food of geniuses. Imitation is the best form of flattery. Let's imitate any other country to the extent we can and adapt some of their practices." **– Guru Reddy, Continental Hospitals**

But India has not lagged China on all fronts – areas like vaccines, among others, have seen the huge impact that Indian companies have made. Besides, the Indian government machinery is also thinking "big picture," though allocating large funding in the sector will also need buoyant economic growth alongside, panelists noted.

To galvanize biopharma innovation in the public and private sectors, India is creating a long-term vision and targets.

Today, the pharmaceutical industry in India is $50 billion. The Indian Pharmaceutical Alliance has established a vision, saying that by 2030, the industry should reach $130 billion. In addition, by 2047, the 100th year anniversary of India's independence, the Alliance has set a target of $500 billion for the pharmaceutical industry.

To achieve these goals, innovation will be essential, as will collaboration. The private sector could look to government and academic institutions as laboratories to potentially test out some radical ideas, one panelist suggested.

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Success also relies on government collaboration. With the right targets in place, the Indian government has shown that it can achieve meaningful goals in the biopharma sector. The government has developed a rotavirus vaccine and the nation is close to eliminating leishmaniasis. In addition, malaria and tuberculosis cases are decreasing in India.

"We need a long-term plan, consistent funding, and consistent leadership. And we need to fix targets. The government has enormous scope to make change and there has been success. One example is the rotavirus vaccine. Another is that we are close to eliminating Leishmaniasis in this country. These have happened because the government put a date on achieving targets."
– Radha Rangarajan, CSIR-CDRI

Glimpses from the Roundtable

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Conclusion

This roundtable highlighted India's long history of biopharma pioneers like Dr. Kallam Anji Reddy, founder of Dr. Reddy's Laboratories, who set an example about the importance of innovation and the tremendous future opportunity for India in the biopharma industry. Dr. Reddy's was the first domestic company to out-license a new molecule, an insulin sensitizer, to Novo Nordisk, way back in 1997, charting a path for many other Indian firms to emulate.

The roundtable also identified India's many strengths and capabilities in this sector, along with the challenges faced.

To strengthen India's position in this industry, the government has enacted schemes focused on transforming India into a high-volume, high-value player in the global market for pharmaceuticals, meeting the quality, accessibility, and affordability goals. India has launched its National Policy on Research and Development and Innovation in the Pharma-MedTech Sector and also proposed a PRIP (Promotion of Research and Innovation in Pharma MedTech Sector) scheme with a budget outlay of INR5000 crores, among a string of initiatives to bolster the sector's growth.

Key strategies include encouraging creation of an ecosystem to support innovation, creating a regulatory environment that expands on the objectives of safety and quality to also facilitate innovation and research in product development, and incentivizing private and public investment in innovation through a mix of fiscal and non-fiscal measures. As part of India's funding strategy, the country needs to explore options like joint funding, in addition to VC funding.

These strategies and others can strengthen India's biopharma ecosystem and help India achieve its bold vision and goals.

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Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance. For more information, log on to: **www.drreddys.com**

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About Citeline

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