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Whiteboarding Ideas From Novartis, Novo To Address India's Elephants In The Room, 'On Streets'

Biome In India Set Back By COVID-19

by **Vibha Ravi**

Senior VPs from Novartis and Novo Nordisk offered suggestions ranging from protecting IP and fixing the perception of “elephants roaming the streets,” to “fit for purpose” global development plans to improve the research landscape in India, during a recent webinar, which also saw academia weighing in on various issues.

[Novartis AG](#) and [Novo Nordisk A/S](#) have long recognized India's potential in research and development, the former running its collaborative innovation program “Biome” here and Novo a R&D unit, one among 12 set up globally.

A recent webinar organized by industry bodies Indian Pharmaceutical Alliance (IPA) and Confederation of Indian Industry (CII), in partnership with India's Department of Pharmaceuticals (DoP), had Novartis's senior vice-president and India head for global drug development Sadhna Joglekar and senior vice-president Robin Evers offer views on what it takes to build early-stage drug discovery partnerships.

With the Indian government set to introduce a research-linked incentive scheme on the lines of the production-linked incentive schemes it has already rolled out, the ground is being laid in earnest for drug discovery efforts in the country. (Also see "[Will The \\$3bn Stimulus Amid COVID-19 Place Indian Cos Among Goliaths?](#)" - Scrip, 12 Mar, 2021.)

These efforts assume significance against the backdrop of growing complaints about the UK government's pharma industry policies, which prompted [AstraZeneca PLC](#)'s CEO Pascal Soriot to

say companies would be forced to invest elsewhere and [GSK plc](#)'s CEO Dame Emma Walmsley warn the environment could hit a "tipping point" if a number of factors are not addressed. (Also see "[UK Launches Inquiry Into Its Clinical Trials Problems After Pharma Outcry](#)" - Scrip, 21 Feb, 2023.)

With the Inflation Reduction Act introducing pricing uncertainty in the US and an increasing awareness of the need to look for opportunities outside US and EU markets, India's efforts to draw investments in research could pay off if it plays its cards right. (Also see "[First Drugs That Could Be Picked For Price Negotiation Showcase Longevity Of Some Brands](#)" - Scrip, 30 Mar, 2023.)

A national policy on R&D is close to finalization and will focus on strengthening the regulatory framework to facilitate innovation, incentivizing investment in innovation through a mix of fiscal and non-fiscal measures and creating a facilitatory ecosystem including setting up frameworks for interdepartmental coordination, Rajneesh Tingal, joint secretary at the DoP in the Ministry of Health and Family Welfare, said during the virtual event.

Elephant In The Room, On Streets

Both Evers and Joglekar mentioned the elephant in the room – intellectual property (IP) protection – while highlighting the importance of correcting perceptions as India promotes the country as an R&D destination.

"I think it's time that we fix a few things and not just fix but let the whole world know that we fixed them. Otherwise, the perceptions remain. Perceptions are still that elephants roam around on the streets of India, right?" Joglekar quipped.

Referring to the IP protection landscape, she said "everybody is worried about what happens to the IP if a drug or a molecule is discovered in India. So, we shouldn't have any ambiguity...because that deters people from making those investments." (Also see "[Pendulum Swings Again: Entresto Patent In India Restored, For Now](#)" - Scrip, 20 Jan, 2023.)

A bit more circumspect, Evers said India needs to build an ecosystem of facilitating research and supporting nascent IP. "I think the money is there, the will is there and certainly we get attracted

BioAsia 2023: Focus Research Outside US, Take 'One Health' Approach To Prevent Next Pandemic

By [Vibha Ravi](#)

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Speakers from BMS, Takeda, UNICEF and more discussed how a shift in R&D focus, free flow of data on animal and human health, public sector investment and higher regulatory flexibility are key to make 'One Health' work and prevent future pandemics

[Read the full article here](#)

to the science. [But] It's not just about a bilateral collaboration between [global] large pharma and Indian pharma, I think the rest of the ecosystem also needs to be there in terms of the support from financial institutions to be able to grow those companies over time," as well as a favorable tax regime.

Novo's Indian R&D unit delivers data management, biostatistics and programming, medical writing, publishing, safety surveillance and medical communication for clinical trials and marketed products. The company has 300 clinical sites in the country.

During the discussion moderated by IPA's senior technical advisor Shridhar Narayanan, Evers also pointed to the need for India to showcase its talent and opportunities via events like the J.P. Morgan Conference, which build "the collaborative network by which the science gets discussed." (Also see "[The Best Of J.P. Morgan – Valuations, Deals And The IRA](#)" - Scrip, 16 Jan, 2023.)

While smaller events are organized in the country, like BioAsia which was held in Hyderabad last month, global events of the scale of JPM "become really important opportunities for local industry to be able to showcase their science and allow partnerships to be forged."

Novartis's India Biome Setback

Sharing experiences from Novartis setting up a Biome in Hyderabad, Joglekar admitted it hasn't delivered to expectations on account of COVID-19-related setbacks, but three projects have highlighted its potential.

Sandoz, Novartis's generics and biosimilars business, worked with partners to develop in silico, simulated development "especially in the formulation development space." Novartis itself has partnered a leading medical hospital to develop an ophthalmology diagnostic tool to help diagnose a few eye conditions in a "much more" efficient manner.

The third example she mentioned was in manufacturing. "There's something that's being worked on in the logistics space using digital technology. These have all completed the pilot phase and the next phase, of course, is to take it to scale."

India's Top Deck Backs Patent Box Policies, Four-Prong Strategy

By [Vibha Ravi](#)

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C-suite executives from Sun Pharma, Zydus, Dr Reddy's, Biocon, Piramal and Bharat Serums discuss future growth drivers as the generics opportunity shrinks. Favorable patent box policies, open-source innovation and areas like gene therapy and orphan diseases feature among ideas thrown up.

[Read the full article here](#)

Set up in February 2020, the India Biome aimed to leverage the fast-growing digital ecosystem and capital in the country. “So, while India was envisaged to be the external face of the Novartis soul, of the innovation engine, the idea was to look at some of the biggest healthcare challenges that the Novartis internal ecosystem cannot address” and see if a partner could help solve them.

“I think it's time that we fix a few things and not just fix but let the whole world know that we fixed them.” - Sadhna Joglekar, Novartis SVP and India head for global drug development

Novartis roped in the reputed Indian Institutes of Technology (IITs) and Indian School of Business as academic partners and The National Association of Software and Service Companies (NASSCOM) as a digital partner. (Also see "[Novartis Logs Into India With Digital Innovation Hub](#)" - Scrip, 20 Feb, 2020.)

“We have strategic partners too, but most importantly, we also have venture capitalists. So, if there is a requirement for funding, for research brainstorming, for some academic inputs, all these people can convene together at the site or virtually,” she pointed out.

In 2021, the company launched a Biome in Brazil and another one in sub-Saharan Africa. In California, its partner the University of California, San Francisco Health’s Center for Digital Health Innovation and BeeKeeperAI (a spinout of CDHI) has helped the company’s commercial team validate a digital solution to detect patients with a rare disease.

The Novo Prescription

Asked by the chair of CII’s National Committee on Biotechnology and MD of [Panacea Biotec Ltd.](#), Rajesh Jain, what India could do to strengthen the ecosystem to attract companies like Novo Nordisk to invest in preclinical research in the country, Evers said globally such collaboration and partnerships work well where a strong academic foundation is coupled with a strong interest in fundamental biology research.

“So, we ourselves have located our activities where we see a nascent, but emerging and/or dominant research led activity in terms of academic research like exploring novel biology, targets, computer-enhanced or imaging activities, supporting that research and the spin out of those small companies, which are then willing to partner and join us.”

Novo Nordisk has made strategic investments in places like Oxford, UK and Boston, US and other

academic centers “where academic researchers also provided the framework or their own innovations to be spun out into smaller scale companies that will then grow over time.” (Also see "[Tech Transfer Roundup: Novo Nordisk Foundation, Broad Institute Team On Genomic Drivers Of Disease](#)" - Scrip, 29 Oct, 2021.)

“I think the conditions can exist within India, but it comes from strong academic skills,” Evers added.

The IPL Model, Bayh-Dole Act

George Patani, director Inga Laboratories, drew an analogy from cricket, India’s most popular sport, to illustrate a way to build the requisite skill set.

Giving an example of the Indian Premier League (IPL), a cricket league held annually in India, he said “We know what IPL did to Indian cricket, Indian cricket has been at the top for the last couple of years. And how they did that was they brought international talent as coaches, they brought them as players and they made them play with our talent.”

"The question is 'have we tried and failed enough?'" - NIPER Mohali director, Dulal Panda

Similarly, India has a large pool of talented scientists and those at the masters and PhD levels should be given the opportunity to work alongside and learn from international talent brought into the country, which in turn will lead to a change in “the way we think in India.”

To a suggestion that India should have legislation along the lines of Bayh Dole Act, Patani responded: “We keep trying to ape the west. Most of the research in the US is funded by the NIH [National Institutes of Health] and basically this Act allowed the universities to sell the intellectual property that they developed from this research.” (Also see "[India Proposes Faster Approvals, Bayh-Dole-Like Policy To Spur Innovation](#)" - Pink Sheet, 2 Nov, 2021.)

India doesn’t need the Bayh Dole Act, he reasoned as “there is nothing stopping our research institutions from selling their intellectual property to the industry. Our government is funding so many schemes, but they are free. They have said that you can patent whatever invention you have.”

However, trust is critical. Likening a partnership between industry and institution to a marriage,

Patani said “The two heads of the two groups need to trust each other's capabilities first. Drug discovery always doesn't go how you want it to go. So, you need to trust each other's capability.”

Sharing Resources – The DNDi Example

Also participating in the discussions were officials from India’s premier research institutes, National Institutes of Pharmaceutical Education and Research (NIPER) and Translational Health Science and Technology Institute (THSTI).

THSTI’s executive director Pramod Garg highlighted the institution’s efforts to develop a pan-beta coronavirus vaccine in association with clinical development partner Panacea Biotech and funding partner CEPI, saying “this is the way we can develop partnerships between academia and industry.”

Academic institutions are already building a collaborative, fostering network, he added. For example, in Delhi, multiple institutions like THSTI are working with the Department of Biotechnology to develop a National Science Cluster.

“If we can organize such mechanisms where different institutions share their resources and also share their knowledge, then I think drug discovery should not be that difficult,” he added.

Notably, the South Korean drug industry has increased joint financing and collaboration efforts as it tries to optimize costs and harness innovation talent with the goal of transforming local companies into global giants. (Also see "[How KIMCo Is Orchestrating Korean Pharma Collaborations](#)" - Scrip, 13 Mar, 2023.)

Citing the example of the dengue project under The Drugs for Neglected Diseases initiative (DNDi), a non-profit drug research and development organization, Garg said it involves four countries and seven institutions.

Different teams – preclinical, clinical, epidemiological, fundraising advocacy, biomarker diagnostics team and PK/PD (pharmacokinetics/pharmacodynamics) - and a joint study committee to oversee the teams, work together to leverage each one’s strengths and formulate joint solutions.

CEPI Partners Panacea, THSTI For Pan Beta Coronavirus Vaccines

By [Vibha Ravi](#)

22 Feb 2022

CEPI will provide up to \$12.5m funding for Panacea Biotech and THSTI’s pan-beta coronavirus vaccine candidate, currently in the preclinical stage. Meanwhile, Panacea’s dengue and pneumococcal vaccines are on track for a 2023 launch.

[Read the full article here](#)

DNDi itself has forged a diverse range of alliances and research collaborations with over 200 partners and service providers in over 40 countries to drive patients' needs-driven projects.

However, Garg pointed out that the Indian industry's appetite for risk "is much less when it comes to investment in R&D and I think that has to go over a period of time." The dengue vaccine candidate hasn't received external funding so far but it's "not waiting for funds to come."

Building Infra Brick-By-Brick

NIPER Mohali director Dulal Panda said India has just started its early drug discovery journey and is at a nascent stage in building the infrastructure required to produce the desired results.

"We've just started five to six years back. We are building start-ups and incubation centres. We are now valuing the industry and they have started coming for industry-academia partnerships." Efforts to strengthen drug discovery skills include a revision of curriculums and exposure of students to real-life problems in the industry, he added.

However, while Inga's Patani said it's critical to introduce specialization at the bachelor's level and continue with specialized curriculums at the Master's and the PhD level, Panda differed saying it's also important to provide "holistic academics" to students.

The NCE Maker's View

Recounting *Zydus Lifesciences Limited's* varied experience of working with academic institutions in India was its president and head of non-clinical R&D, Mukul Jain, who said while collaborating with professors at a personal level "to understand some aspect of science or publish work" has been fruitful, drug discovery efforts at the institutional level haven't yielded the desired results.

"I think the academic organizations we worked with didn't have an understanding of the end-to-end discovery process at the time, so they did something that was possible for them, but did not pursue it the way industry pursues it. So unfortunately, those did not give us any positive outcomes. But no regrets about that," he said.

Zydus Cadila Turns DNA Pioneer With COVID-19 Vaccine Approval

By **Vibha Ravi**

24 Aug 2021

With an emergency approval, Zydus Cadila has commercialized the world's first plasmid DNA vaccine for human use and the first COVID-19 vaccine for use in adolescents in India. Will efficacy against the Delta variant help tide over hesitancy towards a new technology or a lack of publicly published data hamper acceptance?

[Read the full article here](#)

However, Zydus has recently had a rewarding collaboration for its plasmid DNA-based COVID-19 vaccine, first in the world to be successfully commercialized, with the Indian Council of Medical Research, Jain added.

The company has in the past successfully worked with institutions in Switzerland and US to accelerate its drug discovery process, allowing it to be one of the few companies from India to have developed a New Chemical Entity.

Zydus' saroglitazar has been commercialized for use against non-alcoholic steatohepatitis (NASH), non-alcoholic fatty liver disease (NAFLD), diabetic dyslipidemia and hypertriglyceridemia in India while it has moved to Phase II clinical trials in the US for NASH, NAFLD and primary biliary cholangitis.