2020 African American genomes

A genomic sequencing initiative to help understand and eliminate the causes of cancer health disparities in the African American/black population was launched in March. The death rate for all cancers combined is 25% higher in African American/black people than in white people, according to the US National Cancer Institute. To address this public health challenge, the American Association for Cancer Research (AACR) and its collaborators will sequence both tumor and normal tissue from 2,020 consenting African American/black cancer patients by 2020. The AACR will make the results from the project, known as "2020 by 2020," freely available to academic and industry researchers to accelerate discovery, and enhance cancer diagnosis and treatment in this medically underserved population. The AACR will partner with Pelotonia, a nonprofit organization that raises money for cancer research through bike rides, The Ohio State University Comprehensive Cancer Center informatics company M2Gen, based in Tampa, Florida, and the Oncology Research Information Exchange Network (ORIEN). To facilitate data sharing, leaders of the project have selected a common protocol from the Total Cancer Care Protocol at Morehouse School of Medicine, Atlanta. The genomic data will be added to the AACR Project GENIE (Genomics Evidence Neoplasia Information Exchange) registry, and then made available to public cancer genome registries. Some analyses have revealed a racial bias and a lack of diversity in genome-wide association studies (*Nature* **538**, 161–164, 2016). A 2017 study of lung tumor and normal tissue samples in African Americans and European Americans found differences in gene expression in the two groups (*Clin. Cancer Res.* doi:10.1158/1078-0432.CCR-17-0527, 2017).

"When you understand the underlying biology of the disease and design clinical programs around that, you're going to have a much higher success rate rather than when you just threw therapies against the wall." Adam Stone of Perceptive Advisors tells an audience of investors in New York in early April why investors are bullish on biotech. (*STAT*, 9 April 2018)

"These kinds of cases, where they just ask for an unduly high price…that has to stop. The magisterial preparation of CDCA can be a first domino stone that triggers a movement." Carla Hollak, professor of metabolic diseases at the Academic Medical Center (AMC) in Amsterdam, refers to a scheme in The Netherlands in which AMC will manufacture several high-priced drugs; CDCA, a drug for treating the rare hereditary disease cerebrotendinous xanthomatosis, which costs as much as €220,000 ($272,000) per patient per year, will cost €25,000 ($31,000). (*nrc.nl* 5 April 2018)

Indian biotech sector readies for liftoff

The Indian government has unveiled bold plans to rekindle its homegrown biotech industry, allocating Rs. 24 billion ($372 million) for 2018–2019, the Department of Biotechnology (DBT) announced on February 1. The new spending will support 300 to 500 startups a year—aiming to reach 2,000 by 2020—two bioclusters, 15 bioincubators and three regional entrepreneurship centers. The earmarked funds will also help support 150 technology transfer offices and 20 'Bioconnect' offices dedicated to providing access to incubators, mentors, investors, know-how and connections with the international market.

This should be good news, but many in India's scientific community feel let down by what they see as a paltry 6.2% rise in biotech-related spending by DBT. Even so, others see the government's plan as feasible; startups have mushroomed across India since 2012 when the DBT created the Biotechnology Industry Research Assistance Council (BIRAC), specifically to nurture young companies.

The sector's growth has been dramatic, according to the white paper 'India's Biotechnology Start-up Ecosystem' published by the Association of Biotechnology Led Enterprises (ABLE), a 400-member organization representing the biotech sector. A measure of that progress can be gleaned from the fact that in the six years since BIRAC was established, 1,022 new companies were started by 3,000 entrepreneurs with a total investment of Rs. 187 ($2.8) billion. Of note, one-third of the entrepreneurs are women and 57% of the new companies are biopharma startups, including diagnostics and medical device firms.

The local biopharma industry certainly welcomes the cash injection, modest though it may be. "[It] is still significant," Villoo Patell, founder of Avesthagen, a Bangalore-based life sciences company says. Nilay Lakhar, founder of SynThera Biomedical in Pune, Maharashtra, a company developing bioactive glass products for bone graft substitutes, says the government's backing has been vital. Academic scientists wanting to start a business feel more sure-footed than in the past, thanks to this support, says Sangeeta Naik, director of Cleanergis Biosciences, a firm developing bioremediation technology for processing industrial waste water. "The atmosphere for biotech startups has become very conducive and more friendly than before," she says. For instance, the National Bio Entrepreneurship Competition last December attracted over 1,500 registrations from aspiring entrepreneurs.

For startups, BIRAC does much of the hand-holding, from financial support to mentorship and advice, throughout product development. "BIRAC has not only ignited the ecosystem but is today poised to revolutionize the biotech startup sector," says Renu Swarup, secretary of the Department of Biotechnology (DBT). Since its inception, BIRAC has supported over 650 projects, 500 startups which have generated 150 patents and brought to market over 100 products and technologies. It is notable that most Indian start-ups do not prioritize patent filing as an early-stage activity, instead waiting for an idea to be reduced to practice before filing intellectual property (IP). Swarup, who is also senior advisor at DBT. "The ecosystem is ready, the policies are in place, the key players and stakeholders are all on board. Now our emphasis is on scaling these innovations through a clear market-driven pathway." BIRAC will set up a fund this year dedicated to product commercialization. The "Make in India" action plan, introduced by Prime Minister Narendra Modi in 2014, could even attract more funds, Swarup says, as the budget acts as "a catalyst to mobilize other investment opportunities. Panchapagesa Murali, until recently President of ABLE points out, however, "we need more industry participation" to implement the proposals. Murali admits finding risk capital for early-stage life science ventures remains an issue. "This space is still not filled. Currently, a lot of early stage is still government funded," he says. Hard-core classic biotech areas whose products have a 10--15 year gestation before they are approved for commercialization don't have many takers," he adds.

But will this be enough to transform India into a global biotech hub by 2020, and a $100-billion biotech industry by 2025, as announced by the government? Unlikely, says Arumugam Muruganandam, managing director of Bangalore-based startup Affigenix Biosolutions, a company developing novel biologics. The $372 million allocated to biotech enterprises "is peanuts," he says, conducive only to setting up a company, but not enough to support product development once the seed fund is exhausted.

Swarup dismisses these fears. Although the agency's budget covers operational and entrepreneurial activities only, companies can access a further Rs. 2,492 ($38.4)-million fund from DBT's private-public-partnership scheme for startups. In addition, "We have excellent partnership programs with

CyCa OncoSolutions

Nusrat Sanghamitra, founder and CEO of CyCa OncoSolutions of Bhubaneswar, India. Her company's CyCa drug delivery device has funding from SOS Ventures, Cork, Ireland.

Wellcome Trust, the Bill and Melinda Gates Foundation and USAID, which bring in matching contributions, and we also hope to attract a number of angel funds," says Swarup. In fact, many startups seeded by BIRAC are also successful in raising investor capital. A case in point is Bangalore-based Pandorum Technologies, a company developing three-dimensional (3D) printed liver tissue and bioengineered human corneas, which recently raised $3.6 million from four investors, including the Indian Angel Network and the Karnataka Information Technology Venture Capital Fund.

The digital healthcare space is a sweet spot for India's IT expertise. In February, the government allocated Rs. 30.7 billion ($474 million) to its Digital India program. This is a boon for startups such as Merkel Haptics, incubated at the Indian Institute of Technology Madras (IIT-M). The company, founded by Muniyandi Manivannan, develops simulators for helping doctors to learn *in vitro* fertilization and laparoscopic technique using virtual reality and haptics (interaction involving the sense of touch).

The nanotech space is also proving enticing to India's entrepreneurs. A spin-off from the Indian Institute of Science (IISc) in Bangalore, i2n Technologies has launched a scanning tunneling and atomic force microscope and a 3D printer for use in research. UE LifeSciences, in Mumbai, founded by medtech entrepreneur Mihir Shah, is developing a portable, handheld, battery-powered, breast tissue imaging device that could slash scan costs to $1. UE has announced that its early-detection kit, currently available in India, Myanmar and Botswana, will be commercialized in more than 25 countries across South Asia, Southeast Asia and Africa in partnership with GE Healthcare.

As for reversing India's IT 'brain drain', especially towards Silicon Valley, the government hopes at least to engage Indian émigrés' expertise in collaborations. "We will soon be working with experts from leading biotechnology conglomerates and startups in South San Francisco," Mohanasankar Sivaprakasam, head of the Healthcare Technology Innovation Centre at IIT-M says. Bangalore–Boston Biotech Gateway to India brings together institutes in Boston (including Harvard and MIT) and Bangalore to share ideas and mentor entrepreneurs in the areas of genomics, computational biology, drug discovery and new vaccines. DBT has also signed a Memorandum of Understanding with Heidelberg University, Germany, for a joint graduate program on big data research and computer vision. The formal launch of the German-Indian Startup Exchange Program took place in Delhi on February 23. India is already building cross-border partnerships with other thriving startup ecosystems in Israel and Japan.

Getting industry, academia and government to collaborate on biotech startup opportunities has taken some time to ramp up. Under the DBT's "startup action plan," announced in January 2016, the government assigned up to Rs. 100 ($1.53) million to support academia-industry tie-ups for nurturing innovations in academic institutions, but this never quite took off. Now, the bioincubator approach is an opportunity to accelerate these collaborations. Avesthagen's founder Patell welcomes academic tie-ups with her company as an opportunity to further develop its rather large pipeline with young entrepreneurs worldwide in exchange for a modest licensing fee and stock with royalty upon success. Their 'Avestagenome' project, she says, is India's answer to that started by deCODE Genetics of Reykjavik, Iceland.

So far, the government's incentives have helped swell biotech's startup ranks. Govindarajan Padmanabhan, BIRAC's innovation adviser, says, "One needs to wait and examine as to how well these indigenous technologies survive in the market." Encouraged by the progress in the sector, the government sanctioned Rs.15 billion ($250 million) to support the National Bio-Pharma Mission—the biggest cash injection into the biopharma sector yet, signed in June 2017. The mission brings industry and academia together to produce at least five locally manufactured biopharmaceuticals within five years. To run this ambitious project, India has taken a $125-million loan from the World Bank aims "to make the Indian biotech industry globally competitive over the next decade," says Swarup. Currently India has only a 2.8% share in the global biopharma market.

BIRAC can already claim a string of success stories. One company that stands out is Strand Life Sciences, a spinoff from IISc, which provides genetic-testing-based diagnostics in cancer detection to more than 300 large hospitals and recently raised $13 million from a healthcare-focused private equity investor. Will there be more exciting global businesses emerging out of today's startups in India? Vijay Chandru, who founded Strand Life in 2000, says, "there are many hidden champions." Nilay Lakhar of SynThera Biomedical agrees. "Of course this requires continued timely efforts from all the major stakeholders, but we are confident that slowly but surely India will make its mark as an innovation powerhouse on the global stage."

According to ABLE, the total biotech investments by startups in the country is estimated to be more than Rs. 187 ($2.8) billion between 2012–2016. This includes private equity, grants and loans from families and friends. Of this, Rs. 18 billion ($265 million) is the BIRAC investment.

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