Roadmap for Pharma R&D: Developing an Innovation Index as a Monitoring and Evaluation Metric



Executive Summary

From humble beginnings in 1969, when foreign firms supplied 95 percent of medicines in India, indigenous pharma firms now manufacture and sell 85 percent of medicines in India. However, while the opportunity in the generic space may still be large, an even larger opportunity awaits in being able to come up with new molecules and treatments for different therapy areas. India has witnessed some early success with 5+ NME launches already and 12-15 assets in the pipeline; nevertheless, the overall scale of innovation is still not comparable to countries such as the US, China and Israel. One of the key policy measures to achieve the objective of making India a global powerhouse in pharmaceuticals is to increase attention to R&D and innovation. The journey to increasing R&D and Innovation requires goal definitions and measurement of where one is at a given point in time and whether there is progress in the desired direction. It should be managed as a project which includes the process of tracking and reviewing the project's progress to satisfy the project management plan requirements and to achieve stakeholder satisfaction.

Monitoring and evaluating progress in R&D and Innovation in the Indian pharma industry, thus, requires the presence of a metric that can be used as a measurement tool. It is in this context that the Innovation Index in this note has been constructed. The index is composed of:

- a) a qualitative part that is based on a perceptual survey of leaders in industry, academia and PE/VC firms and
- b) a quantitative part that is based on reputed secondary data sources.

Compared to a US benchmark of 8 (on a scale of 1 to 10), the calculated Pharma Innovation Index for India has improved from 3.08 in 2018 to 3.78 in 2021. The qualitative part of the index suggests that the three areas requiring more improvement are outcomes (number of patents), integration with global practices (global trials) and capability, infrastructure and talent. The quantitative part of the index suggests that the three areas requiring the most improvement are in output (# of new NMEs), in # of quality STEM graduates and in funding. The index is still, however, a work in progress and will become more granular over time.

I would like to thank Indian Pharmaceutical Alliance, Invest India and others in the preparation of this Report. This research has benefited from excellent inputs from stakeholders across sectors, including government officials, government scientists/professionals, industry captains, IPA, OPPI and IDMA industry organizations, and academia. I appreciate all the stakeholders' contributions to the production of this study. Without their participation and commitment, none of this would have been possible. I also want to express our gratitude to the IPA Executive Council for their unwavering support and leadership during this process.

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1. Why Innovation Index

a. The Indian Context

India has improved its ranking in the Global Innovation Index (GII) 2021 to 46th among 132 economies, up from 48 in the previous year's ranking, as per the World Intellectual Property Organization (WIPO).¹ It was ranked second among economies from lower middle- income countries. It is commendable that the country is progressing in the right direction, as innovation is the key to progress; according to Peter Drucker, a nation has to innovate continuously or it will die.

And yet a Global Innovation Index rank while nice to know, does not provide actionable insights especially at the industry level and at more granular levels of areas of focus within an industry. This is particularly germane to the pharmaceutical industry in India which is on the cusp of significant change. From humble beginnings in 1969, when foreign firms supplied 95 percent of medicines in India, by 2018, 85% of medicines in India are manufactured and sold by local pharma firms. In addition, India supplies generic medicines to the world. In developed markets, India caters a significant part of prescriptions. India has helped improve access globally by supplying ~60% of global vaccine supply,20-22% of generic exports, enabling access to anti-retroviral treatment to 37% of people living with HIV in Africa in 2009 compared to just 2% in 2003 and by being the 2nd largest exporter of Ayurveda and alternative medicine in the world. The industry has also contributed significantly to India's economy by providing employment to 2.7 Mn people, generating USD13 Bn in trade surplus every year, and USD 2 Bn in FDI inflows to pharmaceutical industry in the period 2015 to 2018. The focus on high quality is borne out by the presence of largest number of USFDA accredited manufacturing plants outside of the US.

Although the generic offers huge opportunity, there is a greater opportunity that lies ahead in the innovation with new molecules and treatments for different therapy areas. India has seen early launch of 5+ NME while about 12-15 assets in pipeline. Yet India's overall scale of innovation remains at a nascent stage in comparison to US, China and Israel.² And leadership in the pharma industry, like any other, will flow from research and innovation that leads to new molecules and treatment avenues. Increased emphasis to R&D and innovation is part of essential governmental initiatives and relevant industry actions to attain the goal of making India a worldwide powerhouse in medicines. Increasing attention to R&D and innovation is vital policy measure that will make India a global hub in pharmaceuticals. The sector objectives can contribute to achieving SDG 03 namely "Ensure healthy lives and promote well-being for all at all ages" and specifically the Target 3.8. "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." The Parliamentary Standing Committee in its 46th Report on 'Promotion and

¹ <u>https://www.livemint.com/news/india/india-improves-ranking-in-global-innovation-index-11632145244382.html</u>

² Department of Pharmaceuticals (DoP) (2020) Catalyzing the Pharma MedTech Innovation Eco-system in India

coordination of basic, applied and other research in areas related to the Pharmaceutical Sector' in July, 2018 recommended institutionalizing 4 inter-departmental coordination mechanism: enhancing academia-industry linkage, boosting infrastructure, enhancing budgetallocation for Pharmaceuticals and medical devices Research & Development, and concentrating on future areas of research.

The journey to increasing R&D and Innovation requires goal definitions and measurement of where a country is at a given point in time and if it is progressing in the desired direction. It should be managed as a project which includes the process of tracking and reviewing the project's progress to satisfy the project management plan requirements and to achieve stakeholder satisfaction.³

The Innovation Index should indicate on where more work is required – together with the R&D Policy, it may provide guidance on which areas a country should pursue in R&D and Innovation in the future. It is in this context that the leading industry body, Indian Pharmaceutical Alliance, has worked with the Indian Institute of Management, Ahmedabad, and Invest India to develop the industry's first Innovation Index to be better able to assess current position and monitor progress. A robust Innovation Index that has acceptance from all stakeholders (industry, academia, government and financiers) also becomes a tool that enables more productive conversations that are data based. The R&D Policy that has just been released explicitly mentions an implementation framework and monitoring and evaluation for Innovation Index becomes a part of the Monitoring and Evaluation Framework for the Government and for the industry.

b. Role in Enhancing R&D and Innovation

It is known that where the underlying research support eco-system is underdeveloped, active support from the university system and/or government and industry is an important contributor to the increase in innovation output.⁴ Arguably, while the generic R&D eco- system in India is reasonably well developed, the NCE, NBE, IND, genomics, space for R&Dand innovation and go to market (clinical trials) in India still has some distance to traverse before it can be considered to be in the same league as innovation and R&D in developed markets. One of the key drivers for the industry to achieve a target of the Indian pharma industry growing to US\$120-130bn size by 2030 would be expansion of its industry's presence in the innovation space which continues to account for 2/3rd of the global pharmaceutical opportunity. Building this presence can also generate substantial health benefit for India by enabling development of drugs for India-specific ailments which do not get adequate attention globally. It is in this context that a tool to measure, monitor and

³ Acebes, et. al. (2021), *Central European Journal of Operations Research*, Project risk management from the bottom-up: Activity Risk Index

⁴ Breznitz, O'Shea and Allen (2008), *Journal of Product Innovation Management*, University Commercialization Strategies in the Development of Regional Bioclusters.

evaluate progress on innovation would be very useful; this is consistent also with the Government's focus on creating appropriate metrics (DoP 2020; p.29).⁵

c. Other Indices

Other geographies have constructed indices of different kinds to help monitor and progress performance on innovation (and other areas).⁶ For example, the HealthTIES indicators and indexes in the European Union provide useful practical tools for the measurement and benchmarking of university–industry–government innovation in European medical and life science clusters.⁷ In doing so, such approaches follow now well established "triple helix" model of university–industry–government relations based on the theoretical insight that universities, industry and government are becoming increasingly interdependent and co-evolving, while retaining their institutional identities in contributing to innovation.⁸ To this trinity, we add the presence of funding which has become increasingly important in pharma and healthcare research.

2. Index Components and Methodology

We develop the index components using inputs from the relevant research literature. First, national-level research and development (R&D) data are used to characterise national contexts and inputs into the innovation process as well as innovation activities.⁹ Second, patents and citations relevant to the pharma space provide insights into the invention process.¹⁰ Third, bibliometrics help understand and forecast the scientific process underpinning inventions.¹¹ Fourth, we rely on expert opinion to assess technological change and its policy implications (this leads to the development of the perceptual survey of leaders in industry, academic and the investment community).¹² Fifth, topic-specific databases and innovation surveys provide statistics on collaboration, commercialisation, financing and otherinnovation activities and opportunities.¹³ Sixth, we are consistent with earlier efforts by the government in this area (DoP 2020, p.8).¹⁴ Finally, composite synthetic indicators use a

⁵ Department of Pharmaceuticals (DoP) (2020) Catalyzing the Pharma MedTech Innovation Eco-system in India

⁶ Acebes, et. al. (2021) Ibid.

⁷ Edmunds, et. al. (2019), *Health Research Policy and Systems*, New indicators and indexes for benchmarking university– industry– government innovation in medical and life science clusters: results from the European FP7 Regions of Knowledge HealthTIES project

⁸ Etzkowitz and Leydesdorff (2000), *Research Policy*. The dynamics of innovation: from National Systems and "Mode 2" to a Triple Helix of university–industry–government relations.

⁹ OECD. Frascati Manual: Guidelines for Collecting and Reporting Data on Research and Experimental Development. http://oe.cd/frascati. Accessed Ocotber 31, 2021.

¹⁰ Acs, Anselin and Varga.(2002), *Research Policy*, Patents and innovation counts as measures of regional production of new knowledge.

¹¹ Watts, Porter and Newman (1998). Competitive Intelligence Review, Innovation forecasting using bibliometrics

¹²Grupp. (1994), *Research Policy*, The measurement of technical performance of innovations by technometrics and itsimpact on established technology indicators.

¹³ Eurostat. Community Innovation Survey (CIS). https://ec.europa.eu/eurostat/ web/microdata/community-innovationsurvey. Accessed October 31, 2021.

¹⁴ Department of Pharmaceuticals (DoP) (2020) Catalyzing the Pharma MedTech Innovation Eco-system in India

variety of data sources to assess innovation capabilities and performance,¹⁵ which is what we do in this exercise in both the perceptual survey and the quantitative data, as below.

a. Items in Qualitative Component and Rationale

The first part of the index uses perceptual data on 6 dimensions from leaders in industry, academia, and PE/VC firms. These six dimensions are detailed in the figure below.

Figure 1

The survey has questions across 6 key dimensions . The respondents were asked to rate India across the dimensions on a scale of 1-10, assuming that the US scores 8 on every dimension for the years 2018 (3 years back) and today (2021)							
Dimension	Sample Survey Questions						
Regulatory landscape	End to End timeline for approval	Ease of submission					
	Clarity of guidelines and requirements	Transparency					
Policy	Effectiveness of current IP policies	Resolution of complaints regarding IP infringement					
Funding	• Ease of getting capitals through Govt., Debt, PE/VC						
	ROI of innovation in Industry						
Capability, Infrastructure and	Quality of Indian R&D talent	Quality of infrastructure					
talent	Ease of access to data	Industry Academia Collaboration					
Global Collaboration	India Out-licensing to Global Partners						
	 India In-licensing from Global Partners 						
Output Dimension	Level of Novelty of Innovative pipeline						

Items in Quantitative Component and Rationale

The second part of the index uses quantitative data from a variety of sources (WIPO, CTRI, Company websites, US Government data, IPA data, National Center for Education Statistics, All India Survey on Higher Education, PCT data, H-Index from Scopus, etc.) on 5 dimensions. These five dimensions are detailed in the figure below.

¹⁵ Grupp and Schubert (2010), *Research Policy*, Review and new evidence on composite innovation indicators for evaluatingnational performance

Quantitative Dimensions

Dimension	Indicator					
Regulatory landscape	 Regulatory Approval for different modalities timelines – CT/IND/NDA/NBE 					
Funding	Total Private capital for R&D					
	Direct Govt. Funding					
	Primary Funding through PE/VC					
Capability, Infrastructure	• # of at scale innovation Hub					
and talent	# of Publications and citations in International Journals					
	• # of PCT patents filed					
	# of Quality STEM graduates					
Global Collaboration	# of cross border deals on drug R&D					
	# of global trials					
Output Dimension	 # of New molecular entities (NME's) registered from India 					

Where required, each of the above metrics is scaled appropriately. For example, the number of PCT patents filed is divided by the amount of R&D expenditure (corrected for PPP); the total private capital expenditure for R&D is taken for the top 15 firms in the country is scaled by the revenue of the firm; the number of NMEs for a country is scaled by the GDP of the nation.

b. Putting together the two components for a Composite Index

We then combine the qualitative and quantitative dimensions to form a composite index which indicates where Indian Pharma Innovation is relative to the US. We assign a rank of 8/10 to innovation in the USA and then calculate the relevant index numbers for India for 2018 and 2021 and assess how much progress the Indian pharma industry has made in that period in developing R&D based innovations in NCE, NMEs, NBEs, genomics, etc. While the Global Innovation Index is computed by taking a simple average of scores in two sub- indices, the Innovation Input Index and Innovation Output Index, which are composed of five and 40% to the qualitative part premised on (a) the Einhorn and Hogarth thesis on overconfidencein judgment and (b) inputs from individual interactions with stakeholders. As the index matures, the weights that are used in the calculation of the Indian Pharma Innovation Index may change.

 ¹⁶ https://www.globalinnovationindex.org/userfiles/file/reportpdf/gii-full-report-2015-v6.pdf;

 https://en.wikipedia.org/wiki/Global
 Innovation
 Index.

3. Data Collection

Data were collected in two parts.

The first was perceptual data gathered from leaders in industry (pharma, CRO, medtech), academia, and PE/VC firms. As a part of this process, personal interviews were held with key policy makers and industry stakeholders:

The key takeaway from these conversations was that there was a need for developing the index and that the Indian pharma industry needs to be able to invest more in new drugs, clinical trials and to move up the value chain. There was a universal recognition that:

- Doing business as usual on the back of generics in regulated markets would not provide a leadership to Indian pharma in the future as technology accelerated the change; also, that technological change (to genomics, computational biology, proteonomics, molecular biology, and so on) would provide new opportunities to Indian firms.
- That R&D and innovation that leads to NCEs / NBEs, etc. can only scale if it was not solely driven by the passion of a few individuals but also includes an eco-system element along with the mechanisms and incentives that motivate more activity in R& D and Innovation.

The survey was sent to 142 leaders across industry, academia, government, and PE/VC firms in India.

The quantitative data accessible from various sources on the dimensions indicated in Section #2 constituted the second component of data collecting

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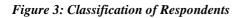
- Doing business as usual on the back of generics in regulated markets was not going to provide a leadership to Indian pharma in the future as technology accelerated the change; also, that the change in technology (to genomics, computational biology, proteonomics, molecular biology, etc.) would provide new opportunities to Indian firms.
- That R&D and innovation that lead to NCEs / NBEs, etc. can only scale if it was not primarily driven by the passion of a few individuals but also had an eco-system element along with the mechanisms and incentives that motivated more activity in R& D and Innovation.
- The index was seen as a good metric to measure and drive performance.

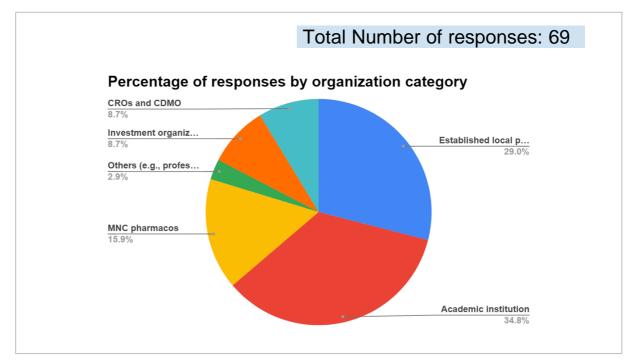
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The second part of data collection was quantitative data available from different sources on the dimensions identified in Section #2.

a. Survey Data

A total of 72 respondents and 8 personal interviews provided data between September 21 and October 31 after multiple follow ups from the team at IIM, Ahmedabad and Indian Pharmaceutical Alliance. The distribution of respondents is as per Figure 3 below.





Source: Qualitative Survey

Exhibit 2 gives a list of the organizations that provided responses to the questionnaire for the perceptual survey.

b. Quantitative Data

To supplement the qualitative survey and to make the index more robust, Quantitative data were gathered from the following sources as given in the Table 1 below.

Theme	Index constituent	Source			
Regulatory	Recombinant Vaccine	From CDSCO, IPA and Industry			
landscape Timelines	Non-Recombinant Vaccine	sources			
	NCE				
	NBE				
	Biosimilar				
Funding	Total private capital for R&D (Top 15 by revenue) (In \$ million)	Annual Reports and Public Disclosures of top 15 Pharmaceutical firms (By revenue) in India and the USA			

Table 1: Quantitative Data and Source

Theme	Index constituent	Source			
	Direct Government funding (In Rs. Crore and \$ billion)	Annual Reports and Public Disclosures of DBT, ICMR and CSIR; Union budget allocations. USA federal spending categories: NIH funding data			
	Primary funding through VC/PE (In \$ million)	Pitchbook			
Capability, Talent and Infrastructure	# Publications in international journal	SCImago Journal and Country reports; Data Source: SCOPUS			
	# of average citations	SCImago Journal and Country reports; Data Source: SCOPUS			
	# of patents filed	WIPO			
	# of STEM Postgraduates and PHDs	India: AISHE (All India Survey on Higher Education) report by Ministry of Education, GOI USA: NCES (National Centre for Education Statistics)			
Global	# of cross border deals on Drug R&D	Pharmadeals			
Collaboration	# of global trials	India: CTRI database; USA: Clinicaltrials.gov			
Output Dimension	# of New molecular entities (NMEs, NBEs) registered from India	USFDA database			

The original items on # of industry academic research collaboration and # of clusters were dropped as the data available were index data rather than hard data and /or the data were not meaningful.

4. Data Analysis Approach and Analysis

a. Approach

In the qualitative survey, we asked the respondents to share with us their perception of where a particular dimension (that is relevant to pharma innovation e.g., capability, infrastructure and talent, regulatory landscape, output, policy, funding, etc.) is in India on a scale of 1 to 10, assuming that the US is at 8 in the year 2018 and in the year 2021. The mean of these perceptual scores on each of the 6 dimensions are then taken as where innovation in India is on that dimension compared to the developed world as proxied by the US. A weighted average of the mean scores on the 6 dimensions is then taken to arrive at the qualitative dimension of the Innovation Index.

For the quantitative part, a similar approach is followed. The actual quantitative data for India (e.g., the number of PCT patents filed scaled by the R&D expenditure; the time taken for regulatory approvals in different categories (e.g., NBA, NDE, IND, etc) and the US is scaled to a 1-10 scale with the number for US being taken as 8 to make it consistent with the

qualitative part. The index number for India for each of the five components of the quantitative part is calculated for 2018 and 2021 and given in the Section 5 of this report.

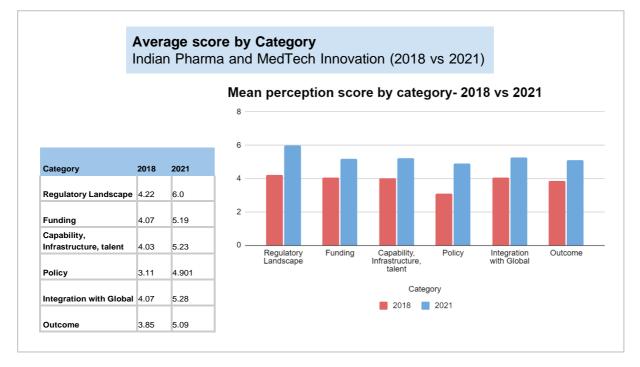
b. Analysis

A birds-eye view of the calculations for the quantitative part of the index is given in Exhibit 1. While the approach in the Global Innovation Index development,¹⁷ would have suggested a composite Pharma Innovation Index with a 50% weight to both the qualitative and quantitative parts, we have given a higher weight of 60% to the quantitative part of the index, premised on (a) the Einhorn and Hogarth view on overconfidence in judgment and (b) one on one interactions with stakeholders and their view of the perceptual surveys.

5. Results and the Index

The components of the perceptual index based on the survey are provided below in Figure 4





Source: Qualitative Survey

Clearly, there is improvement across all parameters between 2018 and 2021. Taking the weights and putting it all together, the qualitative index is calculated at **5.26 in 2021** as compared to 8 for the US, which is an improvement from **4.02 in 2018**. The three areas requiring more improvement are outcomes (number of patents, etc.), integration with global practices (global trials, etc) and capability, infrastructure etc.

^{17 &}lt;u>https://www.globalinnovationindex.org/userfiles/file/reportpdf/gii-full-report-2015-v6.pdf;</u> <u>https://en.wikipedia.org/wiki/Global_Innovation_Index.</u>

The quantitative part of the index is given below in Figure 5

	Dimension	Indicator	Index Value (2018)	Index Value (2021)
1	Regulatory Landscape	Regulatory Approval for different modalities	3.41 5.00	5.09
		timelines – CT/IND/NDA/NBE	2.42 2.07	6.83
				4.94
			2.57	2.50
				3.94
2.	Funding	• Total Private capital for R&D	3.53	2.76
		Direct Govt. Funding Primary Funding through	1.92	1.84
		PE/VC	0.59	1.39
3.	Capabilities, Infrastructure	# of Publications in International Journals	1.91	2.21
	and Talent	# of citations # of Quality STEM	3.80	4.08
		 # of Quality STEM graduates 	4.82	4.85
		• # of PCT patent filed	5.84	5.89
4.	Global Cooperation	 # of cross border deals on drug R&D 	0.37	0.10
		• # of global trials	3.63	4.13
5.	Output Dimension	 # of New molecular entities (NME's) registered from India 	0.52	0.27
			Composite Index Value	
			2.46	2.79

Figure 5: Components of the Quantitative Index (based on secondary data)

As with the perceptual survey, on the basis of quantitative data too, **India has also made an improvement from Index score of** <u>2.46 in 2018</u> **to Index score of** <u>2.79 in 2021</u>, an **improvement of 13% over three years**. *However, expectedly, the overall scores are lower than the qualitative component of the index, since perceptions are subject to the*

overconfidence effect.¹⁸ The areas requiring the most improvement are in output (# of new NMEs), global collaboration, international publications and funding.

Combining the two indices into a composite Pharma Innovation Index for India is calculated as index score of 3.08 in 2018 and 3.78 in 2021, indicating progress, but still some distance to go.

6. Next Steps

The Pharma Innovation Index is a significant first step in being able to measure and facilitate progress towards a more intensive R&D and Innovation performance in the Indian ecosystem. We think that this will contribute to the implementation and monitoring framework for the Government and Industry to assess the status at any given point in time and to work on the necessary steps in the appropriate areas to enhance R&D and Innovation output and productivity in India.

The following points emerge as takeaways to do from the exercise.

- a. Conduct the Indian Pharma Medtech innovation index exercise on an annual basis that allows the industry and government to monitor progress on an ongoing basis.
 - i. The perceptual survey for 2021suggests that three areas requiring more improvement are outcomes (number of patents, etc.), integration with global practices and capability, infrastructure and talent.
 - ii. The quantitative survey in 2021 suggests that the greatest effort required are in industry academic collaboration, funding and output of new NMEs.
- b. Doing business as usual on the back of generics in regulated markets would not provide leadership to Indian pharma in the future as technology and burgeoning research using a variety of approaches accelerated the change; also, the change in technology (to genomics, computational biology, proteonomics, molecular biology, etc.) would provide new opportunities to Indian firms.
- c. R&D and innovation that lead to NCEs / NBEs, etc. can only scale in India if it was not primarily driven by the passion of a few individuals but also added an eco-system element along with the mechanisms and incentives that motivated more activity in R& D and Innovation.
- d. Regulatory Capacity Building: If India is to become a global leader in innovation, the regulatory office must be strengthened, the regulatory office needs to be strengthened with more "in-house" expertise medical experts, statisticians, regulatory scientists, pharmacologists etc. We are today, to a large extent, dependent on external expertise / invited experts. This will surely take time but we must start the process ASAP.

^{▶ &}lt;sup>18</sup> Einhorn and Hogarth (1978), *Psychological Review*, "Confidence in Judgment."

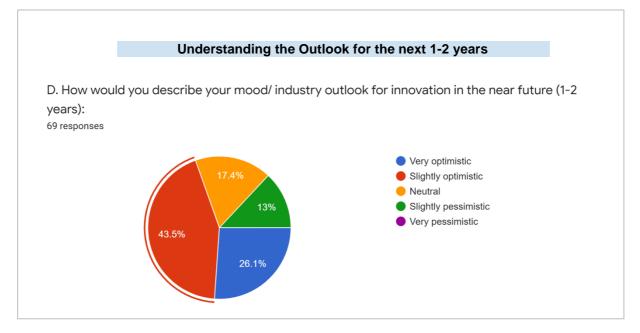
- e. Phase 1 and First in Human Studies: While the index does include phase 1, for future reference, the index must also explicitly mention FIH as that is where the disconnect is unless we take this step and allow FIH studies, even for entities researched abroad, we will always be trailing behind the regulators can begin by allowing such studies only in accredited centers which have passed through stringent assessments
- f. Lack of encouragement for corporates and hospitals for doing research no special tax structure / accreditation – thus providing no motivation to engage in R&D and innovative activities. A government functionary also mentioned that pharma corporates need to be prepared to take more risks.
- g. Functioning of SECs remains a major bottleneck today for clinical research and drug development. The experts should be oriented on the requirements of global regulatory and drug development norms. Some of the key challenges here are :
 - i. Asking for India specific changes in global protocols without any scientific rationale
 - ii. Timelines

iii. Lack of transparency of review and decision making process¹⁹

- h. Interestingly, while 62% of the respondents on the qualitative survey cited infrastructure and R&D ecosystem as the single biggest hurdle in achieving greater scale and output in pharma R&D, 75% also said that the industry needs to work on many different dimensions simultaneously (functional capabilities, organizational readiness, breakthrough science capabilities, etc.) to be able to achieve the stretch goals that the industry was capable of.
- i. Finally, a significant majority of the polled respondents were either slightly or very optimistic about the innovation outlook for the Indian pharma industry over the two years to 2023. (See Figure 6 below). This bodes well for the future of R&D and Innovation in Indian pharma, provided one sustains the momentum.

¹⁹ These points are extracted from Email responses from some participants on the perceptual survey.

Figure 6: Innovation Outlook



Source: Qualitative Survey

A final caveat. The very nature of this exercise means that many indicators that are potentially informative were subsequently not used (e.g., the number of pharma innovation clusters; industry academic collaboration) because of the lack of data availability and / or a consequent lack of meaningfulness). There are therefore limitations to the index that we have developed which is based on what can be measured, rather than on all of what should be measured. Within these limitations, however, we believe the Innovation Index as currently developed is a good starting point for providing an important input in the monitoring and evaluation framework that can be used both by the government and the industry to monitor progress towards the goal of being a world leader in pharma innovation. It provides granular insights into areas where actions are more required and areas where there can, potentially, be greater impact in helping India to further improve its performance on R&D and innovation in pharma.

Exhibit 1: Calculation Sheet of the Innovation Index

Theme	Index constituent	Normalizing factor	India (2020/21)	USA (2020/21)	Innovation Index (2020/21)	India (2018/19)	USA (2018/19)	Innovation Index (2018/19)	Details	
	Recombinant Vaccine		27.5	17.5	5.09	41	17.5	3.41		
Regulatory	Non-Recombinant Vaccine	-	20.5	17.5	6.83	28	17.5	5.00	For USA, the timlines are same	
landscape Timelines	NCE		23.5	14.5	4.94	48	14.5	2.42	for both years.	
rimennes	NBE		56	17.5	2.50	67.5	17.5	2.07		
	Biosimilar		35.5	17.5	3.94	54.5	17.5	2.57		
			1	Mean	4.66	M	ean	3.09		
	Total private capital for R&D (Top 15 by revenue) (In \$ million)	Revenues	1705	80708	2.76	1777	66878.4	3.53	The value for USA is 2020 and India 2021 due to different method of financial years	
Funding	Direct Government funding (In \$ billion)	GDP	0.91013204	43	1.35	0.81378719	27.0	1.84	NIH funding for USA and ICMR, NIPER,DBT and CSIR data are taken	
	Primary funding through VC/PE (In \$ million)	GDP	707.3	32551.2	1.39	221.0	22836.2	0.59	The year considered is 2020.	
			1	Mean	1.83	М	ean	1.99		
	# Publications in international journal	None	37159	134775	2.21	30420	127346	1.91	Latest year 2020	
C 132	# of average citations	By publications	31950	227373	4.08	166879	1472240	3.80	Latest year 2020	
Capability, Talent and Infrastructure	# of STEM Postgraduates and PHDs	Total Population	451628	177870	4.85	422957	169710	4.82	The STEM data for USA for the year 2020 are projected basis 10 year history.	
	# PCT patents filed	R&D Spend	475	9042	5.89	462	7722	5.84	PPP scaling done based on PPP rates of respective years.	
			1	Mean	4.26	M	ean	4.09		
a 1.1.1	# of cross border deals on Drug R&D	None	5	413	0.10	17	369	0.37	2019 and 2021 values taken	
Global Collaboration	# of global trials	None	5031	9749	4.13	3855	8488	3.63	CTRI data with quality multiple and Clinicaltrial.gov data for USA	
80			1	Mean	2.11	М	ean	2.00		
Output Dimension	# of New molecular entities (NMEs, NBEs) registered from India	None	1	29	0.27	2	31	0.52	The NME are allocated to the country where the parent organisation is from.	
				Mean	0.27		ean	0.52		
				Index Value	2.79			2.46		

Weightage for themes calculating the final Quantitative Index

Theme	Weightage
Regulatory landscape Timelines	22.3%
Funding	19.1%
Capability, Talent and Infrastructure	22.5%
Global Collaboration	18.8%
Output Dimension	17.3%

Exhibit 2: List of Participating Organizations in the Qualitative Survey

Estal	blished local pharma (29%)	Academic Institutes (35%)			
11. 12. 13. 14. 15. 16. 17. 18. 19.	Ajanta Pharma Limited Alkem Laboratories Ltd Biocon Limited Cadila Healthcare Itd Cadila Pharmaceuticals Limited CuraTeQ Dr.Reddy's Emcure Glenmark Pharmaceuticals Ltd. Lupin Mankind Pharma Ltd Micro Labs Limited, Bangalore Natco Pharma Ltd Panacea Biotec Ltd. Sun Pharmaceutical Industries Ltd. Unichem Laboratories Limited USV Private Limited Cipla Ltd. Torrent Pharmaceuticals Ltd Intas Pharmaceuticals Ltd		AMTZ Limited BIRAC CDSA CDSA-THSTI CSIR CSIR Indian Institute of Chemical Technology INST OF MICROBIAL TECH National Brain Research Centre Delhi Institute of Pharmaceutical sciences and Research IISER Mohali NIPER Hyderabad	13. 14. 15. 16. 17. 18. 19.	PSGIMSR Swami Rama Himalayan university University Institute of Pharmaceutical Sciences, Panjab University National Institute of Pharmaceutical Education and Research (Retired) NIPER Ahmedabad NIPER-Ahmedabad NIPER-Ahmedabad NIPER-GUWAHATI Pharmacy Council of India THSTI

Investment Organizations (9%)	CROs and CDMO (9%)	MNC Pharma (16%)	Others (3%)		
 Apax Edelweiss IIFL Securities Ltd Baring Private Equity Partners (India) Brookfield Asset Management Independent Consultant 	 CDSA Emmes corporation ProClin Research Private Limited Veedà Clinical Research Ltd Vibrance Clinical Research Pvt Ltd Xyz 	 Abbott Healthcare Bayer Ferring Pharmaceuticals India Pvt Ltd ICon Merck Healthcare India MSD Novonordisk Otsuka Pharmaceutical India Pvt Ltd SANOFI Serdia Pharmaceuticals TOSK Inc 	 Bioquest Solutions Indegene 		