

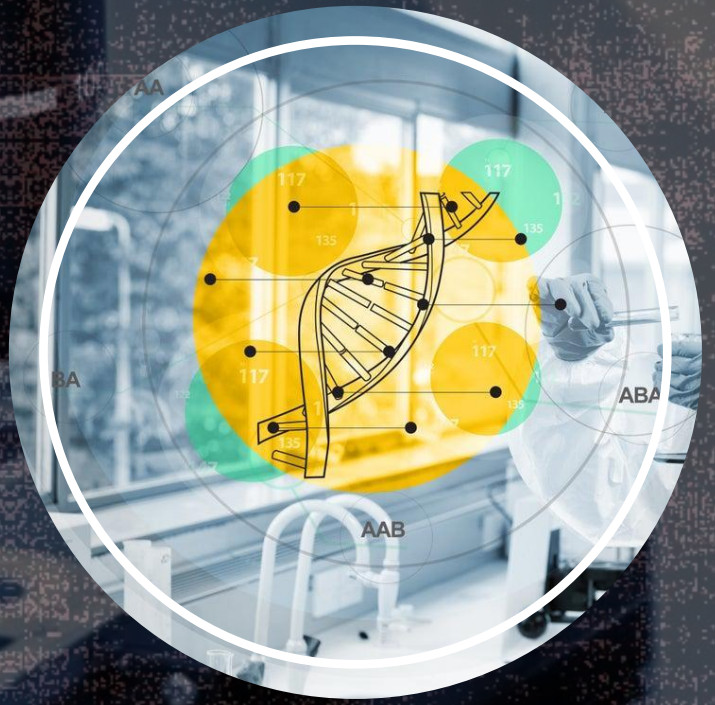

ROADMAP FOR PHARMA R&D: DEVELOPING AN INNOVATION INDEX AS A MONITORING AND EVALUATION METRIC

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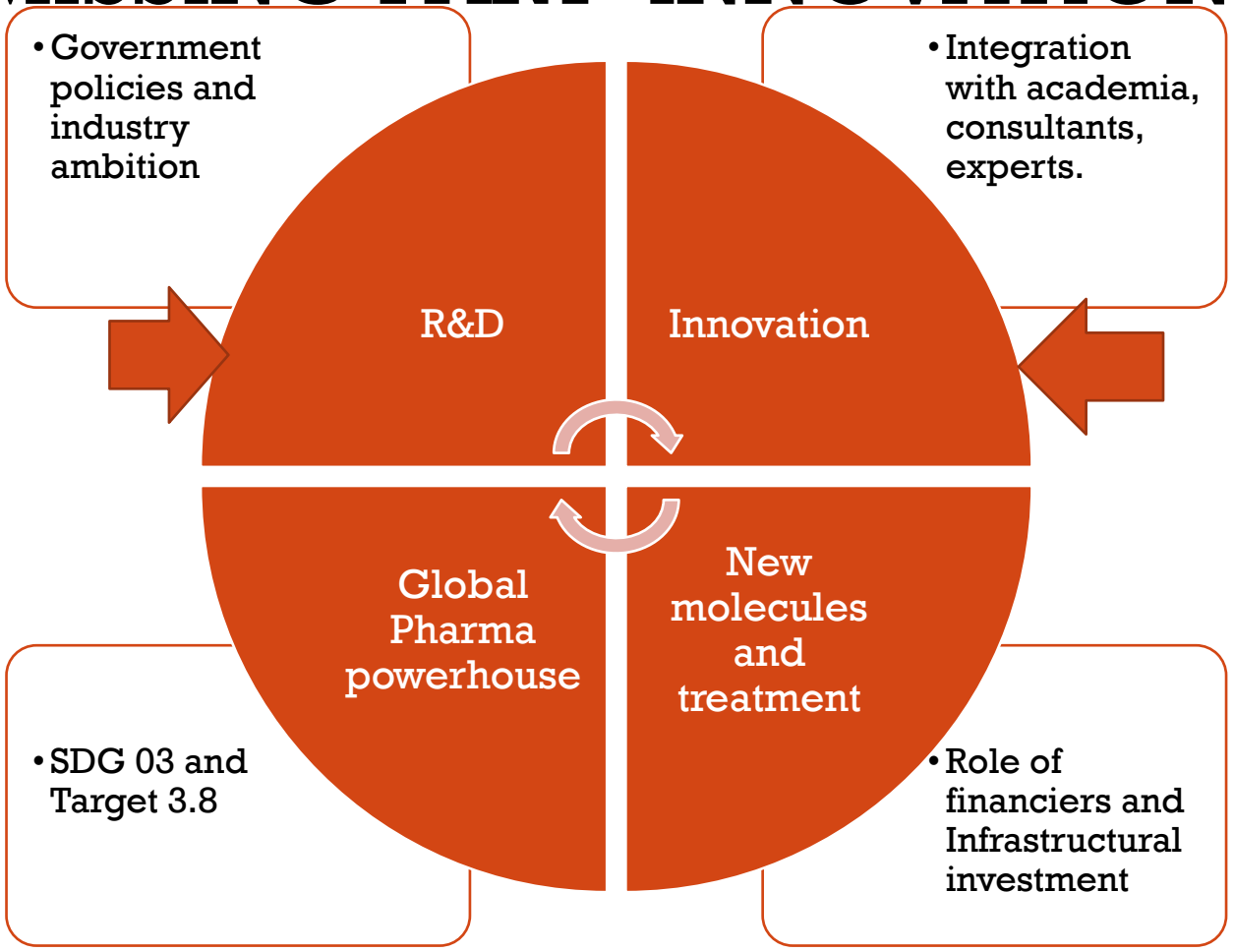
With support from IPA, Invest India and Another Organization

THE GOAL: A $120 BILLION PHARMA INDUSTRY: THE MISSING PART- INNOVATION METRICS



Results

Expansion of Industry's presence in the innovation space

Development of new drugs at scale

R&D Monitoring and Evaluation Framework

Develop metrics

Innovation Index

Indian Pharma Alliance & Large Org.

INVEST INDIA
NATIONAL INVESTMENT PROMOTION & FACILITATION AGENCY

THE PROCESS-1 - PEOPLE

- Getting the people on board
  - IPA
  - Invest India
  - IIM, Ahmedabad
  - Others
- Coordination – Thanks to Covid everyone was comfortable working digitally

THE PROCESS-2: DATA COLLECTION, ANALYSIS & APPROACH

Data collection

Survey data – From industry leaders, academia and PE/VC firms

Quantitiative Data:
From Relevant Secondary Sources

Approach

Qualitative Survey :

- Perception of respondents on a scale of 1 to 10 assuming US at 8 in 2018 and 2021.
- Mean of these perceptual scores based on each of the six dimensions
- Weighted average of the mean scores

Quantitative Survey :

- The actual quantitative data for India and US is scaled to a 1-10 scale with the number for US taken as 8 to make it consistent with qualitative part.
- Index number for India for each of the five components of the quantitative part is then derived

Analysis

* Generalized view of the calculations is taken (Exhibit 1)
* This index is taken with a 60:40% weight
* This is then merged into a composite Pharma Innovation Index with a 60:40% weight to both qualitative and quantitative parts

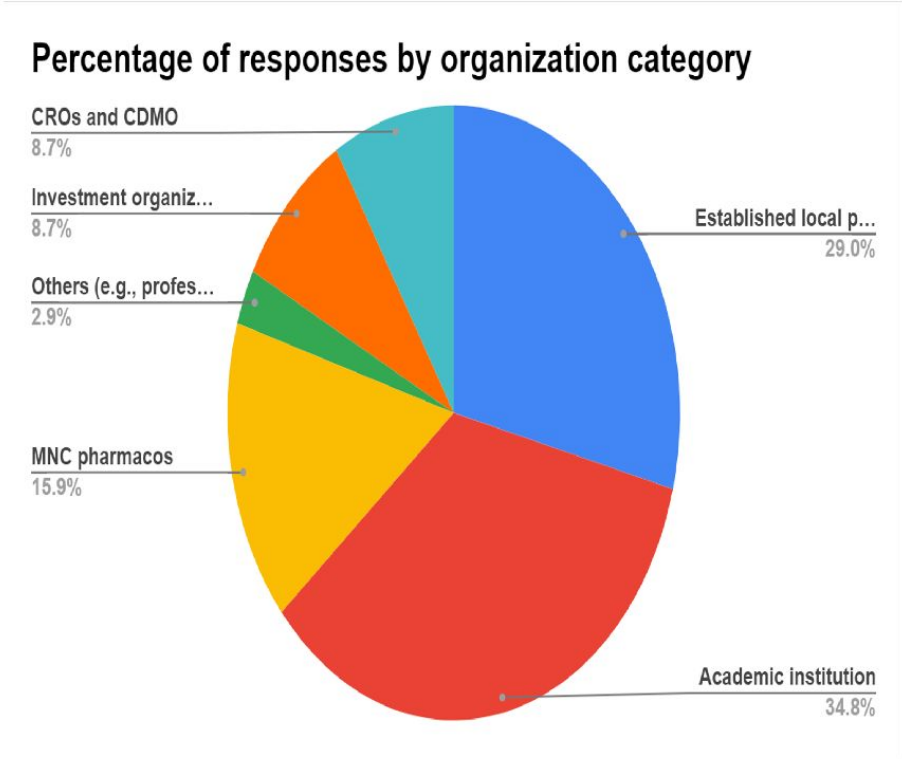
QUALITATIVE SURVEY

Qualitative Survey Dimensions

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 talent	• Quality of Indian R&D talent	• Quality of infrastructure
	• 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	

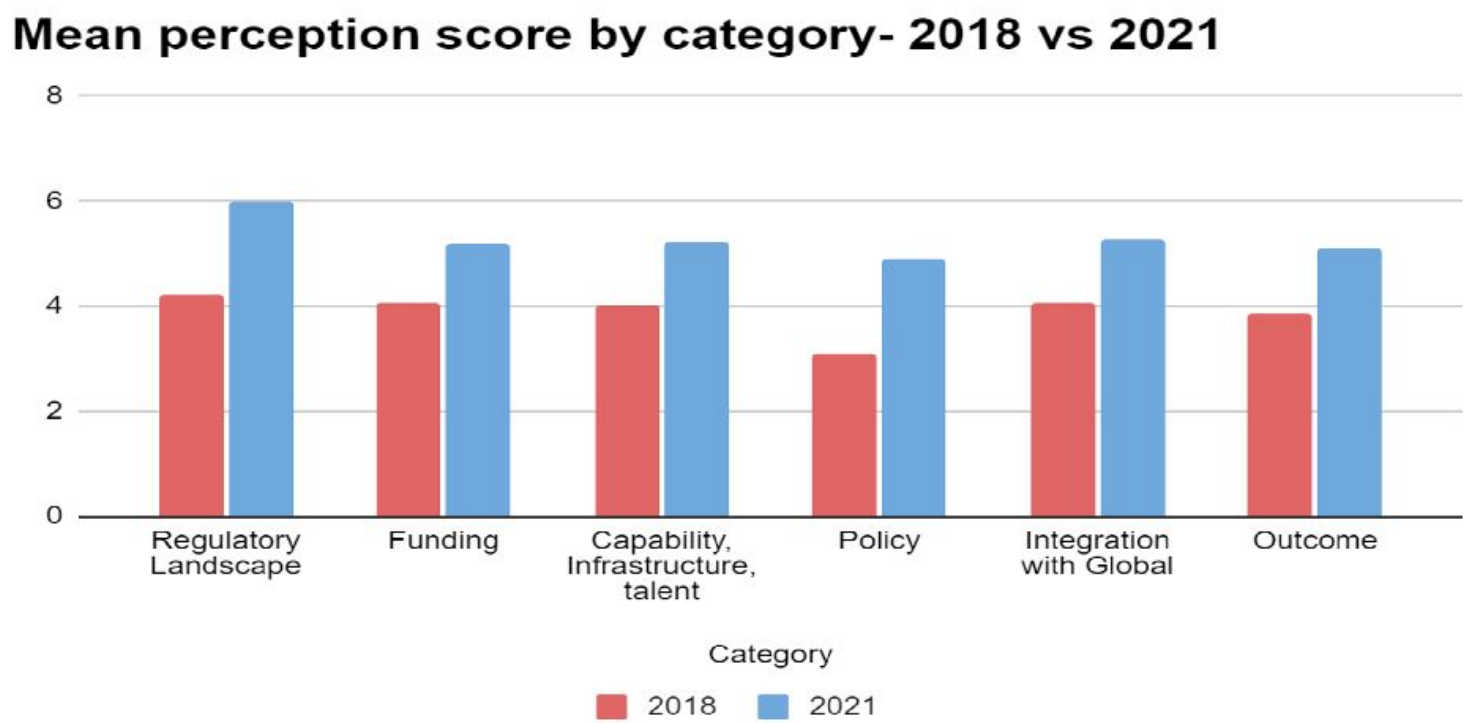
Total Number of responses: 69



RESULTS

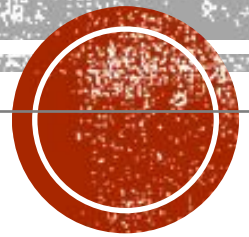
Average score by Category
Indian Pharma and MedTech Innovation (2018 vs 2021)

Category	2018	2021
Regulatory Landscape	4.22	6.0
Funding	4.07	5.19
Capability, Infrastructure, talent	4.03	5.23
Policy	3.11	4.901
Integration with Global	4.07	5.28
Outcome	3.85	5.09



Quantitative Dimensions of the Index

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 and talent	• # of Publications in International Journals • # of citations in International Journals • # of Quality STEM graduates • # of PCT patent filed
Global Collaboration	• # of cross border deals on drug R&D • # of global trials
Output Dimension	• # of New molecular entities (NME's) registered from India



eme	Index constituent	Source
gulatory landscape Timelines	Recombinant Vaccine	From CDSCO, IPA and Industry sources
	Non-Recombinant Vaccine	
	NCE	
	NBE	
	Biosimilar	
nding	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
	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
pability, 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
	# PCT 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)
obal Collaboration	# of cross border deals on Drug R&D	Pharmadeals
	# of global trials	India: CTRI database; USA: Clinicaltrials.gov
tput Dimension	# of New molecular entities (NMEs, NBEs) registered from	USFDA database

RESULTS

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

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
Regulatory landscape Timelines	Recombinant Vaccine	None	27.5	17.5	5.09	41	17.5	3.41	For USA, the timlines are same for both years.
	Non-Recombinant Vaccine		20.5	17.5	6.83	28	17.5	5.00	
	NCE		23.5	14.5	4.94	48	14.5	2.42	
	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	
				Mean	**4.66**		**Mean**	**3.09**	
Funding	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
	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.
				Mean	**1.83**		**Mean**	**1.99**	
Capability, Talent and Infrastructure	# Publications in international journal	None	37159	134775	2.21	30420	127346	1.91	Latest year 2020
	# of average citations	By publications	31950	227373	4.08	166879	1472240	3.80	Latest year 2020
	# 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.
				Mean	**4.26**		**Mean**	**4.09**	
Global Collaboration	# of cross border deals on Drug R&D	None	5	413	0.10	17	369	0.37	2019 and 2021 values taken
	# of global trials	None	5031	9749	4.13	3855	8488	3.63	CTRI data with quality multiple and Clinicaltrial.gov data for USA
				Mean	**2.11**		**Mean**	**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**		**Mean**	**0.52**	
				Index Value	**2.79**			**2.46**	

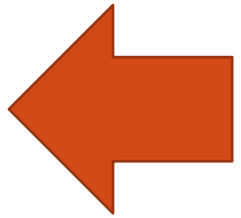
A rank is assigned 8/10 to USA pharma R&D and innovation

Weights (60% and 40%) are assigned to Quantitative and Qualitative dimensions

Quantitative index based on secondary data (2.46 and 2.79 in the year 2018 and 2021 respectively

Qualitative index is derived based on dimensions (4.02 and 5.26 in the year 2018 and 2021 respectively

Deriving the Composite Pharma Innovation Index for India by combining the two indices calculated as index score 3.08 in 2018 and 3.78 in 2021



DERIVING COMPOSITE PHARMA INNOVATION INDEX

CAVEAT IN THE INDEX CALCULATION

Many informative indicators not used- e.g. # of clusters due to unavailability of data and lack of meaningfulness

Innovative Index developed, is based on what can be measured, rather than on all of what should be measured.

Assuming a commitment to R&D to move up the value chain

Indian Pharma Innovation index exercise to be conducted annually – as a part of self monitoring, to engage with government and check direction

Commit to a few moonshot areas – computational biology? Genomics?

Get more scientists to operate out of India (the Associate Professor level is ideal)

Strengthen the regulatory capacity building with more in-house expertise;

The good news is that there is optimism about innovations over the next two years

IMPLICATIONS AND NEXT STEPS