OPPI
Organisation of Pharmaceutical Producers of India

भारत के लिए

Vision 2047
INNOVATE INDIA
औषधि विज्ञान और अनुसंधान,
बढ़ते भारत की शान।

# Innovate India Vision 2047

*Aushadhi Vigyaan aur Anusandhaan,*
*Badhte Bharat ki Shaan*

**Organisation of Pharmaceutical Producers of India (OPPI)**

**29th–30th September 2023,**
**The Ashok Hotel, New Delhi**

**Knowledge Partner**
BAIN & COMPANY

Fireside chats, scientific roundtables, panel discussions, award felicitations, and more

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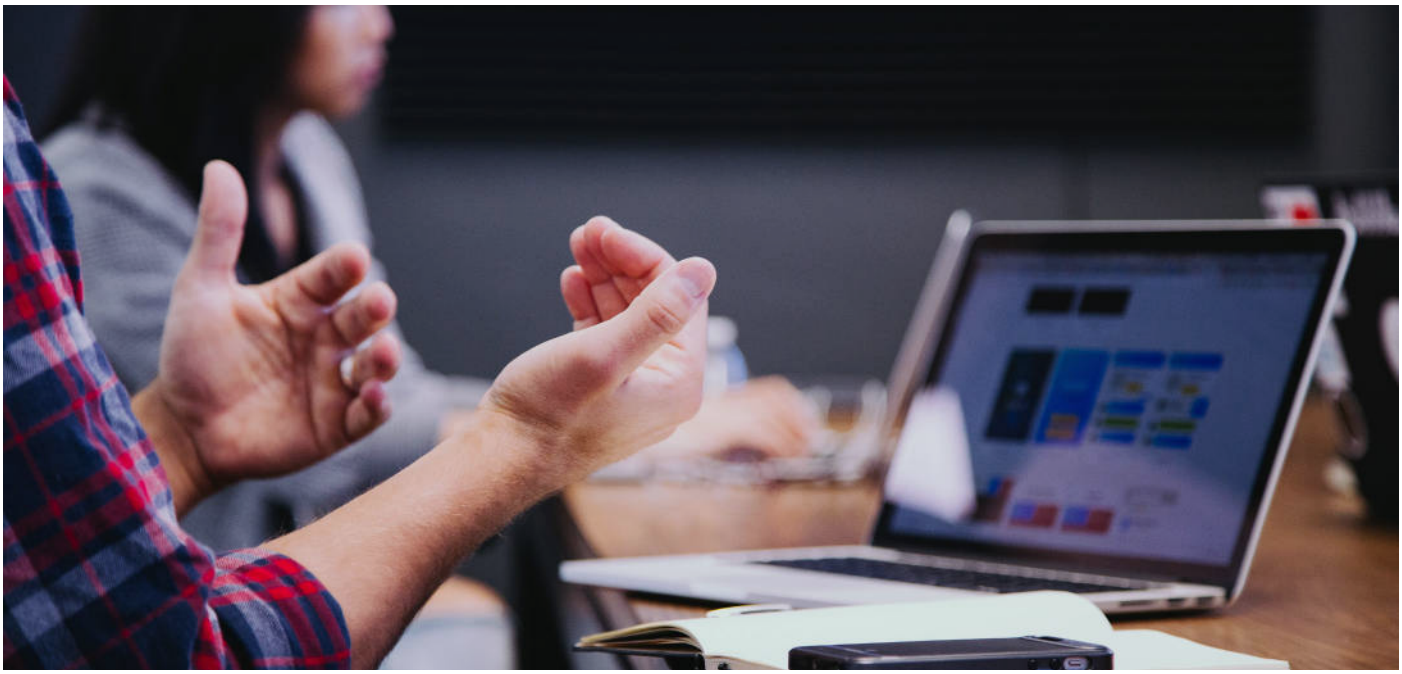
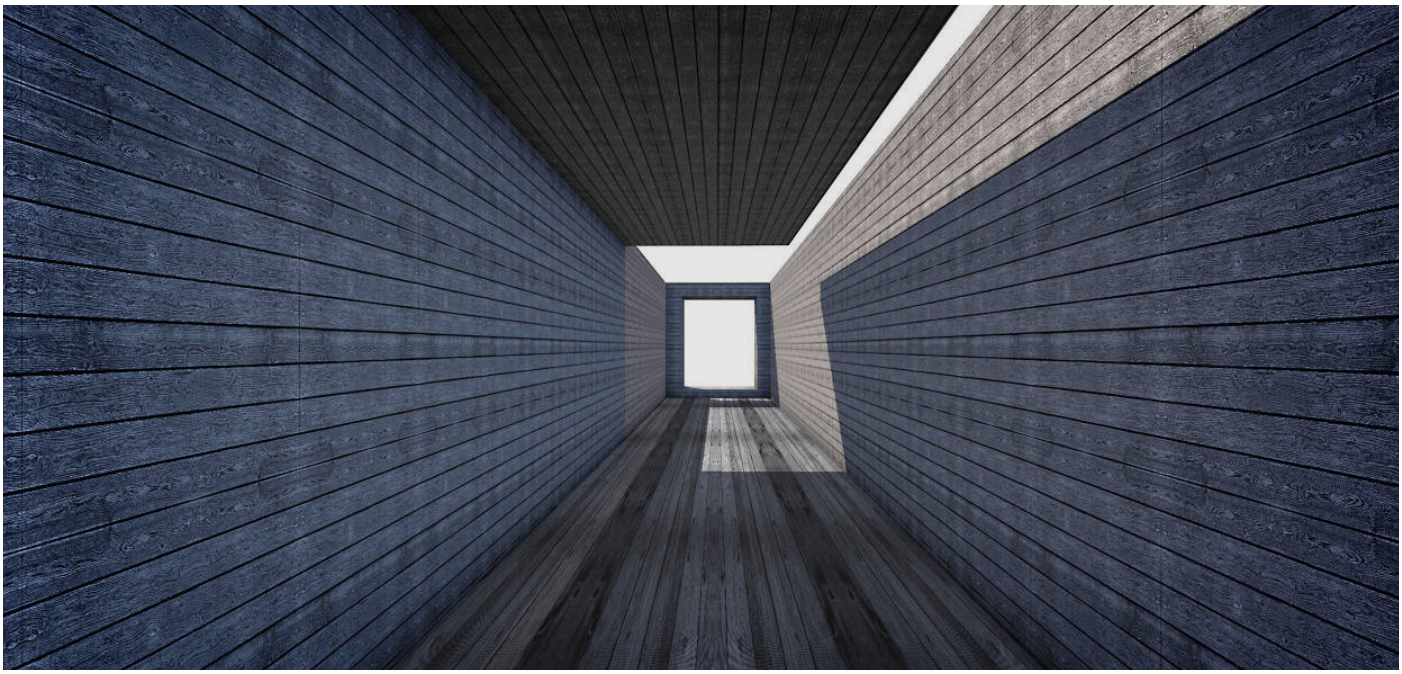


# Vision



The last four decades, beginning in 1990, have seen India transform from a drug-importing country to a drug-exporting one, earning the title of the "Pharmacy of the World".

Moving forward, there is a strong need and desire within the industry to focus on the research and development of innovative products to move up the value chain and achieve global leadership in the sector. Several government initiatives, including the Union Budget for the year 2022-23, the National Policy on Research & Development and Innovation in the Pharma MedTech Sector, and the Scheme for Promotion of Research, and Innovation in Pharma MedTech Sector (PRIP), aim to spur innovation within the industry.

Aligning with the government's move towards scientific innovation, the conference **'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan*'** served as an inclusive platform for professionals to collectively explore the forefront of innovative advancements in the field of healthcare.

By facilitating value-adding discussions and knowledge sharing amongst experts, policymakers, researchers, and industry leaders, the conference drove impactful change and paved the way for a thriving and innovative healthcare landscape in India.

Importantly, the conference is also an ode to the exceptional work by Department of Pharmaceuticals (DoP) and the Ministry of Health and Family Welfare (MoHFW) in gearing the pharmaceutical industry for its next leap into the world of innovation. Furthermore, this conference proceedings document provides 'Key Action Items' for relevant stakeholders, pushing the envelope to achieve the country's aspiration in innovation in the healthcare domain.

Going forwards, we believe the conference will play a pivotal role in providing a platform to identify and capitalise on opportunities for growth, attract significant investments, and solidify India's position as a globally trusted destination for cutting-edge research and innovation.

# Message

## Suresh Pattathil

President, OPPI and MD & GM, AbbVie India

It was heartening to see the Conference bringing together, an esteemed gathering of professionals and thought leaders from various sectors to discuss and deliberate over the latest cutting-edge innovative advancements and rising opportunities in the field of healthcare.

Indian Pharmaceutical Industry has been at the service of the nation for the past 120 years and it has been striving to make a significant difference in the lives of people across the world. Rightly called as the 'Pharmacy of the World' India contributes 20% share of the global drug supplies by volume and over 60% demand of the vaccines. Employing over 3 Mn people, the industry stands at $50 Bn today and ranks 3rd in terms of volume and 13th in terms of value.

During the pandemic, when mankind witnessed one of the toughest challenges for survival, Indian pharmaceutical industry rose to the challenge. Guided by our Honorable Prime Minister the industry jumped to save the world by effectively supplying diagnostics, therapeutics, vaccines to over 150 countries across the world. Going forwards, the industry remains all set to play an even bigger role in world drug security and become the most favored pharmaceutical market in the world.

Taking this further, Department of Pharmaceuticals' efforts at finalising R&D policy is an excellent step in this direction aimed to catalyze R&D and innovation in pharma and med-tech sectors. The Union Budget for the year 2022-23 further announced supportive policies, light-touch regulations, facilitative actions to build domestic capacities, and promotion of research & development. The efforts will go a long way in enabling the Industry to tackle several challenges such as India's dependence on China for APIs, lack of skilled manpower, spurious & fake drugs, compliance with global regulations.

In this regard, Organisation of Pharmaceutical Producers of India or OPPI, an integral part of the healthcare journey of the country since 1965, remains committed in supporting the nation's healthcare objectives and collaborating with all stakeholders to find sustainable solutions to realise the collective vision of 'Health for All'. Aligning with Government's move towards scientific innovation, the organisation remains focused towards bringing more and more innovation to the doorsteps of the country.

The Summit **'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan*'** focused upon fostering innovation and R&D in the pharmaceutical industry in India, by sustaining collaborations and partnerships with other players of the ecosystem, embracing the digital disruption, tapping into new avenues for financing, taking advantage of the recent legislations & regulations, and overall providing a holistic and conducive environment for innovations to nurture.

# Foreword

**Nitika Garg**

Lead-Innovation Conference and
Director, Research, OPPI

**It was an honor to be the OPPI lead for the Innovate - India Vision 2047 Conference. The Conference 'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan*'** (Conference), organised in collaboration with Department of Pharmaceuticals (DoP) under Union Ministry of Chemicals and Fertilisers, was an endeavor to support our Honorable Prime Minister's vision in moving from 'MAKE IN INDIA' to 'INNOVATE IN INDIA' for the world and his clarion call for 'Jai Vigyaan Jai Anusandhan'.

Taking our Honorable Prime Minister's vision ahead from **MAKE IN INDIA** to **INNOVATE IN INDIA** for the world and his clarion call '**जय विज्ञान जय अनुसंधान**', we at OPPI endeavour to bring together experts from industry, academia, and social impact ventures (venture capitalists, supranational organisations) to accelerate our efforts in innovating for the world at large. OPPI member companies have been serving the country's healthcare ecosystem since pre-independence and remain committed to patient safety, quality care and healthcare innovation.

Today, while the Indian pharmaceuticals industry (Industry) provides a unique combination of low-cost production backed by skilled manpower and a well-established manufacturing base, it also boasts of a brimming ecosystem led by strong intellectual capital, robust start-up culture, largest youth population equipped with a strong aspiration for growth. OPPI endeavors to harmonise these strengths while collaborating with all the stakeholders to realise our collective vision of moving towards scientific innovation.

The two-day Conference was an endeavor in this direction bringing together an esteemed gathering of experts, policymakers, Indian industry research institutes, global R&D leaders and other healthcare innovation leaders besides country ambassadors and special representatives from select countries creating an environment for knowledge exchange, deliberation, and collaboration.

The conference provided valuable insights into a wide array of topics including assessment of India's new drug aspirations, unraveled insights and global perspectives on pharma and healthcare, advancements in innovation pioneering nations besides critical components required to foster an enabling R&D ecosystem in the country. The delegates also learnt from experts on what is needed in terms of operationalising of Research & Development in the country, how regulatory framework can norms enable more innovation for the country and how this innovation can reach the masses through innovative financing and investment strategies.

Basis valuable insights from esteemed panelists and speakers during the Conference, a comprehensive whitepaper shall be published by OPPI, intended for utilisation by the DoP as an instrumental component in the enhancement of their R&D Policy.

# Setting the Context

**Sriram Shrinivasan**

Partner, Bain & Company, India

It is with great honor and enthusiasm that we have launched the conference proceedings booklet to you for the Conference **'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan'*,** organised by OPPI in collaboration with DOP. As the Partner and representative of Bain and Company and the key knowledge partner for this distinguished event, it is my privilege to extend my warmest greetings to all those who have contributed to the success of this remarkable conference. In the annals of human progress, the pharmaceutical industry holds a unique position, touching lives, improving health, and advancing our understanding of science and medicine. With Innovate India Vision 2047, OPPI has undertaken the commendable task of fostering innovation and propelling India towards a future of healthcare excellence. This Conference is not just a milestone; it is a testament to our commitment to innovation in the pharmaceutical sector, a commitment that is pivotal for the well-being of Mns across our great nation.

In a world driven by constant change, staying at the forefront of innovation is not a choice, but a necessity. As we stand at the threshold of 2047, the year that marks the centenary of our nation's independence, we must reflect on our past achievements and look forward to the boundless opportunities that lie ahead. It is our collective responsibility to leverage our strengths, harness our creativity, and channel our determination into transforming the landscape of pharmaceutical innovation. Innovate India Vision 2047 brought together the finest minds and visionaries from the pharmaceutical industry, academia, and government agencies. Through addresses, talks, fireside chats, and panel discussions, this platform has facilitated a profound exchange of knowledge, ideas, and insights. The rich tapestry of perspectives shared during this event underscores our shared commitment to driving innovation within the pharmaceutical sector, equipping us to confront the complex challenges of our time. I believe that the ideas exchanged during this conference will serve as the seeds of transformation in our pharmaceutical landscape. From drug discovery to manufacturing, supply chain optimisation to regulatory policies, the conversations held here will catalyze innovation and inspire the development of solutions that will elevate the industry's global standing.

As we peruse these conference proceedings, let us not view them as a mere compilation of thoughts and conversations. Rather, let us see them as a roadmap for the journey that lies ahead. The future of pharmaceutical innovation in India is bright and optimistic, and the momentum generated by this conference will be the wind in our sails. I extend my deepest gratitude to all those who made this conference a resounding success — the participants, the organisers, the speakers, and, most importantly, the thought leaders who are pioneering innovation in India's pharmaceutical sector. Together, we are embarking on a journey that will redefine the boundaries of healthcare, setting a course towards a brighter and healthier India in the year 2047. I invite you to explore the insights, wisdom, and vision presented in these proceedings. Let the 'Key takeaways' section inspire you to think and take part in the transformative journey ahead. The future is indeed promising, and together, we shall embrace it with unwavering determination and boundless optimism.

# Acknowledgements

OPPI expresses gratitude to our partners and stakeholders for their valuable contributions to our annual conference, held under the theme **'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan*'.** We extend our sincere thanks to the government officials who participated and shared their invaluable insights, contributing to the growth of the pharmaceutical sector and its adaptation to the evolving reality.

We appreciate the presence of Ms. S. Aparna, Secretary, DoP, Ministry of Chemicals and Fertilizers, and her continued support to OPPI. We also thank Dr. Rajeev Raghuvanshi, DCGI, CDSCO; Dr Chandrashekar Ranga, Deputy Drugs Controller, India, CDSCO; Dr. Kamlesh Kumar Pant, Chairman, NPPA; Dr. Jitendra Kumar, MD, BIRAC; Dr. YK Gupta, Principal Advisor India Strategy Development – Global Antibiotics Research and Development Partnership (GARDP), President, AIIMS – Vijayanagar, Jammu; Prof. Ramesh K Goyal, Vice Chancellor, Delhi Pharmaceuticals Sciences and Research University, Govt. of NCT Delhi; Prof. Shubhini A Saraf, Director-NIPER, Raebareli; Dr. Aparna Mukherjee, Scientist E, In-Charge – Clinical Studies & Trial Unit, ICMR; Dr. Narender Kumar Ahooja, ex-State Drug Controller, Government of Haryana, and esteemed German and Danish Ambassadors to India, H.E. Dr. Philipp Ackermann and H.E. Freddy Svane respectively.

We also thank DoP, BIRAC, Ministry of Health and Family Welfare, IPA, FICCI, National Innovation Fund (NIF), Delhi Pharmaceutical Sciences and Research University (DPSRU), and Invest India in making the OPPI's Annual Summit a success.

Our sincere gratitude goes out to the member companies of OPPI whose active participation and engagement significantly contributed to the richness of discussions and the overall success of the conference. The OPPI working team deserves special recognition for their tireless efforts in planning, coordinating, and executing various aspects of the conference. We extend our deepest appreciation to Suresh Pattathil, President, OPPI and MD & GM, AbbVie India, whose leadership was instrumental in shaping the conference's success. We also thank our esteemed leaders Manoj Saxena, President Elect, OPPI and Country Division Head – South Asia, Bayer Pharmaceuticals Pvt. Ltd; Vikrant Shrotriya, MD, and Corporate VP, Novo Nordisk India; Amitabh Dube, MD, Novartis India Ltd; Rodolfo Hrosz, MD, Sanofi India Ltd; for their exceptional contribution to OPPI. We also earnestly thank OPPI Executive Committee team for all the guidance on the conference.

Our gratitude extends to multilateral organisations, international government bodies, academia, private sector leaders, and civil society. We appreciate dedicated support from Knowledge Partners, i.e., Bain & Company, IQVIA, Access Health International, Nishith Desai Associates along with Bill & Melinda Gates Foundation. We thank our Partners and sponsors Novo Nordisk, GoApptiv, Novartis, Pfizer, Sanofi, Eli Lilly, Servier, Allergan and Boehringer Ingelheim.

# Executive Summary

The OPPI Annual Summit, under the theme, **'Innovate India – Vision 2047 - *Aushadhi Vigyaan aur Anusandhaan, Badhte Bharat ki Shaan'*,** organised on September 29 & 30, 2023, sets forth the strategic vision and the key priorities required from the industry, government, and academia to cement India's position as the innovation leader in pharmaceutical sector.

India is a leading pharma manufacturing hub ranking 3rd globally in terms of volume. However, our participation is only 5-10% in the global market in terms of value. While the intrinsic cost-advantage in manufacturing is key in driving the Indian Pharma Market (IPM) for the past decades, these advantages would be short-lived in the future. Indian Pharma Market (IPM) is at this inflection point, making it imperative to focus on domestic R&D and innovation. Given this, the focus of the Summit was on fostering innovation and R&D in the pharmaceutical industry in India, by sustaining collaborations and partnerships with other players of the ecosystem, embracing the digital disruption, tapping into new avenues for financing, leveraging the recent legislations & regulations, and providing a holistic and conducive environment for nurturing innovation.

During the Conference, our esteemed speakers and panelists from the industry highlighted the incredible journey of IPM over the years in areas of R&D and innovation. The thriving Global Capability Centres (GCC) market in India with a huge talent pool in data science and Artificial Intelligence (AI), is a testament to the fact that India can perform complex value-added-tasks for the globe. There is also a growing startup ecosystem offering support services to global pharma players as CROs, CDMOs, IT solutions etc. India is also a natural candidate to conduct faster & cost-effective clinical trials with a large patient base. To accelerate these innovation capabilities, and to explore newer capabilities including drug discovery, med-tech, digital therapeutics etc., the industry requires robust regulatory support, investments for innovation and collaborations between stakeholders.

We were fortunate to have the presence of esteemed Officials from the Ministries, Government of India and Regulatory Agencies who elucidated on the schemes around R&D and innovation including the recently launched Scheme for Promotion of Research and Innovation in Pharma MedTech (PRIP) Sector also the impending new legislations such as the Drugs and Medical Devices Bill 2023 (DMDC). These are aligned with the nation's vision of "Jai Vigyaan, Jai Anusandhan" as presented by Honorable Prime Minister Shri Narendra Modi. Discussions were held on how industry can leverage government support & what other reforms can help bolster innovation.

The Conference also had several professors & directors of academic institutions sharing their thoughts on achieving Vision 2047 and how collaborations between academia, industry and government can be improved. All of them opined that while the focus on fundamental research should continue, there should also be an increased focus on research that addresses the near term needs of the industry. Further, the industry-academia collaborations can also be institutionalised by government via setting up a dedicated taskforce and, awarding grants and schemes to fund industry-relevant research.

By defining new frontiers, every stakeholder can transform their organisational growth pathways to gain strategic growth. In doing so, they can contribute even more to the health sector overall. Once all the elements and stakeholders join forces to initiate new advancements in the field of health research and augment pathways to drive innovation in India, the Industry will be greatly strengthened in the country.

# Agenda for the Conference


## Day 1

**Opening** of the conference and welcoming participants

**Welcome Address:** 'Significance of Innovation in Healthcare' by Suresh Pattathil, President, OPPI and MD & GM, AbbVie India

**Setting the Context** by Dr. Martin Holst Lange, EVP, Global Head of Development at Novo Nordisk

**Presentation:** 'India's healthcare innovation journey – Contribution of Global Pharma R&D companies' by Amit Mookim, MD, IQVIA South Asia

**Keynote address** by Ms. S. Aparna, Secretary, Department of Pharmaceuticals, Government of India

**Award ceremony** for Clinical research awards – Felicitation of winners

**Vote of Thanks** by Suresh Pattathil, President, OPPI and MD & GM, AbbVie India

**Fireside Chat:** 'Global perspective - Innovations Unveiled: A Global Perspective on Pharma and Healthcare Advancements in Innovation pioneering nations' with the Danish and German ambassadors to India led by Vikrant Shrotriya, Corporate VP and MD, Novo Nordisk India

**Vote of Thanks** by Manoj Saxena, President-Elect, OPPI and MD, Bayer Pharma

**Scientific Roundtable:** Enabling R&D Ecosystem in the country

**Panel Discussion 01:** India's NCE/NBE aspirations – Strategies for Achievement & the required Framework

**Panel Discussion 02:** Operationalising R&D and Drug Development: ushering in a robust Clinical Research Ecosystem

## Day 2

**Welcome & Preface** for the day by Rodolfo Hrosz, MD, Sanofi India Ltd.

**Address** by Dr. Rajeev Singh Raghuvanshi, DCGI, CDSCO, Government of India

**Panel Discussion 03:** Assessing regulatory framework norms as an Enabler for innovation in India

**Panel Discussion 04:** Access to Innovation

**Panel Discussion 05:** Breaking Barriers – Innovative Financing and Investment Strategies for R&D and Innovation

**Panel Discussion 06:** Industry-Academia Engagement - Enabling Faster Innovation

**Concluding Remarks and Vote of Thanks** by Nitika Garg, Lead-Innovation Conference and Director, Research, OPPI

# Day 1

Day 2

## Opening of the conference and welcoming participants

Nitika Garg,

Lead-Innovation Conference and Director, Research, OPPI

OPPI established in 1965 represents the research based global pharmaceutical companies in India which has been an integral part of the healthcare journey of the country. OPPI has been instrumental in achieving the nation's healthcare objectives and collaborating with all stakeholders to find innovative solutions to realise the collective vision of 'Health for All'. The two-day conference was based on the theme given by Honorable Prime Minister Shri Narendra Modi "Jai Vigyaan, Jai Anusandhan" which saw the coming together of experts from industry, academia, social and impact welfare, venture capitalists, public organisations to accelerate the innovation in the pharma space of India.


# Welcome Address

## Significance of Innovation in Healthcare

Suresh Pattathil,

President, OPPI and MD & GM, AbbVie India

Suresh Pattathil began by thanking the Hon'ble secretary Ms. S. Aparna for her continuous encouragement and support towards OPPI. He reinforced the message given by Dr. Mansukh Mandaviya, Honorable Union Minister of Health and Family Welfare of India, to focus on value and not just volume in the pharmaceutical industry going forward. He recalled on India's Honorable Prime Minister Shri Narendra Modi's vision of "Jai Vigyaan, Jai Anusandhan" and how Indian pharmaceutical industry has risen to the challenge and is poised to become the world's most favored pharmaceutical market.

## India as 'Pharmacy of the World'

- India is ranked **3rd in volumes globally** however we only participate in **5-10% of value** in generics. It is high time we begin to tap the remaining 90% of the value.
- With over **60% vaccine demand and 20% of the global drug supply**, India played a pivotal role in providing diagnostic and therapeutic vaccines to more than 150 countries during pandemic
- We have retained our **40th ranking in Innovation Index** - India has demonstrated capabilities in formulation development through innovations like extended release and other patient-friendly dosage mechanisms
- Digitalisation is another area of growth. Telehealth is on the verge of a major transformation in the country, with the market projected to grow at 31% and reach $5.4 Bn by 2025, making high-quality healthcare available even in the remotest parts of the country.

## Investments and collaborations for innovation

- **PRIP scheme** launched recently by the government will propel India to become a prominent global player in the pharmaceutical industry, meeting the goals of quality, accessibility, and affordability
- Global pharmaceutical companies in India have been actively investing in the country. Several OPPI members have built **Global Capability Centres** in cities such as Hyderabad, Pune, Bangalore, and others to perform complex value-added jobs for the globe.
- Companies have also been fostering collaborations with academia, startups, and research institutions. Such collaborative efforts have borne fruit in the form of innovative treatments and therapies. OPPI looks forward to furthering these engagements, identifying, and capitalising on growth opportunities, and strengthening India's position as a hub for pioneering research and innovation on a global scale.

> OPPI's renewed mission & vision, **"Bharat ke Liye"** underscores OPPI's unwavering dedication to India's well-being, focusing on pharmaceutical R&D, upholding industry quality standards, manufacturing, supply chain, patient care, and more, all aimed at fostering a healthier India through innovation"

# Setting the Context

## Dr. Martin Holst Lange,

EVP Global Head of Development at Novo Nordisk

Dr. Martin Lange joined virtually from Copenhagen, Denmark to give the perspective of Novo Nordisk of perceiving and accelerating innovation of drugs in a global context.

> Access to highly educated professionals in the fields of medicine, biology and data science is the driving force behind the innovation story in the Novo Nordisk in India"

## Novo Nordisk Innovation story

- Novo Nordisk is a global healthcare company founded in 1923 with the clear purpose of driving change to defeat chronic diseases through scientific innovation. The company's philosophy is centered around trying to meet the **unmet needs of patients suffering from serious chronic diseases**.
- The company has **~60k employees** and affiliates in **80+ countries** serving **45M patients** globally in disease areas like diabetes, cardiovascular diseases, and other chronic diseases
- It conducts clinical research in **55+ countries** which gives unique access to data, talent and capabilities. It has research and innovation hubs globally, and one such is present in Bangalore, India.
- In India, access to **highly educated professionals in the fields of medicine, biology and data science** is the driving force behind the innovation story in the company
- Novo Nordisk is currently working with **94 unique sites engaging in 126 unique investigators** across India. Novo Nordisk also wants to secure access to innovation for the patients through collaborations with different partners in India.

## Key ingredients for innovation

- Innovations need to stem from a clear **definition of purpose,** answering the question of what unmet need of patients we are solving
- Innovation also requires strategy, priorities, identifying current capabilities and identifying areas for next-gen capabilities by collaboration with academic institutions or by self. Execution of strategy is equally crucial for any endeavor as said by Thomas Edison, "Strategy without execution is just hallucination".
- One of the key enablers for innovation is **people. Bringing together bright minds and fostering diversity of thought is vital.** Investing in **inter-organisational collaborations** between governments, academia and industry is also key to innovation, Covid-19 being case in point.
- Access to **data, generating insights, and access to novel tech** are important for India to arrive at innovative solutions
- Accelerating innovation also requires a **willingness to take risks and long-term thinking**
- **Focus on fundamental research** is key. A recent article highlighted how 80% of today's drugs are based on the fundamental research conducted 40 years prior to commercialisation. Few examples include the research on insulin and research on RNA technology for vaccines.

> "For innovation to succeed, Execution of strategy is as crucial as strategy itself. Strategy without execution is just an hallucination"

Dr. Lange concluded his address by reiterating the philosophy behind innovation, which is- focusing on the unmet need, delivering purpose, defining strategy, and executing it with the right capabilities, data, tech, and collaborations.


# Presentation

## India's healthcare innovation journey – Contribution of global pharma R&D companies

Amit Mookim,
MD , IQVIA South Asia

> "From being a small medicines market in 1970s, with the support of groundbreaking regulations & support from local & global players, India is now the fastest growing healthcare market in the world estimated ₹185k Cr"

### Growth roadmap of Indian Pharma Market

- In the 70s, the size of the IPM was ₹10-15 Cr and was dominated by global pharmaceutical companies, with very few Indian players
- The **Indian Patents Act and Drug Price Control Order** came about in 1970 which led to the generation of pharma entrepreneurs. Until the 1990s, domestic companies spearheaded the operations and the IPM size grew up to ₹445 Cr.
- By 2010s, IPM size ballooned to ₹75k Cr due to R&D impetus and by servicing

## Growth roadmap...

global markets. Infrastructure that was USFDA and CGMP approved was setup.

- Currently, the IPM is the fastest growing pharma market in the world and is at the size of ₹185k Cr
- India has **~2000 Global Capability Centers (GCCs)** employing 5 Mn people with a market size of $35.9 Bn which is set to grow at a CAGR of 14% up to $110 Bn by 2030. Each year, around 115 new GCCs will be established, increasing the total number from 1580+ to 2400+ by 2030.

> Global pharma players have setup 15 GCCs in India. This is on the backbone of massive patient pool in India as ~20% of world diabetes patients are in India. Leveraging this GCC talent for local market & developing drugs locally will help in transitioning India from a cost-center to a profit-center"

## Investments in R&D and patient support programs

- Around **30 global pharma companies** have presence in India today, up from under 10 in the 1960s and have **1300+ global pharma** brands in IPM across therapy areas including specialty & patented products
- Around **400+ clinical trials** have been registered in India in the past five years. Investments in clinical trials and regulatory aspects have continued to scale over the last several years to reach **$2 Bn in 2022**.
- Global pharma companies have expanded the number of partnerships with Indian counterparts to **improve access**. India has seen **50+ programs** of discounted pricing for drugs e.g., Cipla X Roche for oncology and Sanofi X LSDSS, ORDI for rare diseases. **Ayushman Bharat** scheme put in place by the government also has boosted access from patient's side.
- India has become a priority market for new launches with several new products expected to be launched in the next five years

> India should no longer be just positioned as a manufacturing site for global pharma. We need to innovate beyond the pill – in areas of data science, AI, digital therapeutics etc. We need to build a strong pipeline of new drug launches – both global & Indian launches – from India"

## Innovation "beyond the pill"

- Globally we see new avenues like **software-as-a-medical device, dosage management as IP** etc. – India can contribute in these areas provided we solve the **access problem**
- India also has seen increased investments in local sourcing and manufacturing. Investments continue to be at a size of ₹5,700 Cr in 2019
- Beyond manufacturing, India is becoming a hub for **data science, AI, and digital therapeutics** for the global market

## Key priorities to stage India as the Innovation leader

Amit Mookim concluded his address by outlining the future strategic priorities of pharma companies operating in India:

- Help shape **healthcare ecosystem**: Partner with different stakeholders to drive access
- Extend **downstream growth**: Leverage talent from GCCs in India to other sectors
- **Improve access** for increasing patient pool: Continue to enhance accessibility and deliver innovative treatments to wide patient pools
- Grow **global operations hub**: Become the knowledge hub for global operations, through shared services as well as talent exports


# Keynote address

## Ms. S. Aparna, Secretary,

Department of Pharmaceuticals, Government of India

> "It is great to see the OPPI conference organised with a lot of interest & care. The topics & themes of the discussions in the conference are fully aligned with the priorities that are set for the nation towards public health & pharmaceutical industry"

Madam Secretary highlighted key nuances of the Indian Pharmaceutical market in her keynote address and outlined the pillars on which a successful pharma industry can be built.

### Unique tropes of Indian Pharma Market (IPM)

- We have a high dependence on generics, and we need to now focus on innovative and specialty products
- Current market is very heterogenous, populated by global pharma companies, MSMEs, and start-ups
- It has become clear that there is an increasing need to focus on R&D and growth investments. This offers triple benefits to the Indian population - public health benefit, economic benefit, and strategic benefit to launch India as a centerstage for global pharma industry.

## Pillars for success for IPM

- **Streamlining bureaucratic processes** and making a single window user-friendly system for R&D approvals
- **Promoting investment into innovation** by addressing the inherent risks of the scientific process
- **Creating collaborative partnerships** and an enabling ecosystem which leverages strengths from all members of the community

## What OPPI can offer to India?

- The ministry appreciates the extensive research & technological expertise that OPPI members have in their global HQs. This expertise can be available to the Indian market.
- Ministry is also looking forward to broad-basing technological innovations and platform capabilities of the members that can benefit all OPPI members & research institutions
- The long presence of some of the OPPI members with robust understanding of Indian public health needs will be useful in building the research portfolio in India
- OPPI can bring through its members a framework for structured collaboration between industry, academia & public institutions. OPPI members are invited to set up Centers of Excellence that can help build research capabilities in the public sphere.

## What can India offer?

- Huge pool of talent that the academic and research institutions of the country have to offer. Cross-sector utilisations of talent pool and accessing newer tech like AI, ML can lead to produce new drugs in shorter periods of time.
- There is a thriving CRO industry and community of clinical practitioners. There is growing number of clinical trials milking the present cost advantage in India which is bound to dissipate over time.
- When all countries are looking to secure their supply chain, India offers a unique opportunity for back-end integration for bulk-drug manufacturing
- There is a growing explicit commitment given by regulators to facilitate innovation at back-end
- India also has growing local demand with growing aspirations with govt. schemes like Ayushman Bharat, PMJAY etc. enabling this growth
- India had a success story in launch of COVID vaccines and quick licensing of vaccines and repurposing of drugs served a larger network of countries

The Secretary closed her address by highlighting the inherent cohesive nature of the Indian Pharmaceutical industry & how seamless collaboration is present within various bodies.

> “In the spirit of Vasudhaiva kutumbakam, access & affordability should not be sacrificed at the altar of innovation”

# Clinical Research Awards

Introduced this year, the clinical research awards were presented by Ms. S. Aparna, Secretary, Department of Pharmaceuticals, Government of India and Suresh Pattathil, President, OPPI and MD & GM, AbbVie India.

**Winner:**
Sanofi

**First runner up:**
Novartis India Ltd.

**Second runner up:**
Roche Products India Pvt. Ltd.

Distinguished jury panel included Dr. Shoibul Mukherjee, Consultant Clinical Pharmacology and Drug Development, Dr. Manish Diwan, head of Strategic Partnership & Entrepreneurship Development, and Mission In-charge at BIRAC, and Dr. Sanish Davis, President of ISCR.
Additionally, Vikrant Shrotriya, Corporate VP, and MD of Novo Nordisk India, served as an observer during the judging process.


# Fireside Chat

## A Global Perspective on Pharma and Healthcare Advancements in Innovation Pioneering Nations

### Moderator

Vikrant Shrotriya, Corporate VP and MD,
Novo Nordisk India

## Panelists

H.E. Dr. Philipp Ackermann -
German Ambassador to India

H.E. Freddy Svane -
Denmark Ambassador to India

## Key takeaways

- Innovation in pharma is extremely costly, and India is poised to become a global hub for pharma innovation due to its cost advantage and big population. This calls for an open dialogue between all the stakeholders which needs to be facilitated by the government.
- There is still a large unmet gap for collaboration, and we need to marry engineering and digitisation efforts between India and Germany
- Denmark emphasizes preventive health awareness right from the primary school days. This is missing in India. Novo Nordisk foundation has taken steps to promote health awareness in an inclusive way. India brings scale and scalability and since health is a global issue, India needs to be a part of the conversation.
- Clinical and field trials in India could lead to innovative insights as elucidated by the Danish ambassador to India
- European countries envision a future in India, not just because of cheap labor but also due to its potential as a knowledge-based hub


# Scientific roundtable

## Enabling R&D ecosystem in the country

### Moderator

Utkarsh Palnitkar, Independent advisor, Healthcare Industry

## Panelists

Dr. Jitendra Kumar,
MD, BIRAC


Dr. Sadhna Joglekar, Senior VP and Head,
Global Drug Development,
Hyderabad, Novartis

Dr. Sanjay Singh, CEO, Gennova Biopharmaceuticals Ltd (virtual)

Sudarshan Jain, Secretary General,
Indian Pharmaceutical Alliance

Achin Gupta, CEO, One India Business,
Cipla (virtual)

The panelists emphasized the crucial role of a robust research and development ecosystem in a nation's progress. The panel discussed the importance of sustained government support, funding, and favorable policies to create a conducive environment for research and development. They also highlighted the need for greater clarity on government norms and guidelines and explored ways to streamline bureaucratic processes and incentivise investments in R&D.

## Key takeaways

**Collaborative R&D Ecosystem Development:**

- Fostering R&D across all healthcare constituents, including Indian Pharma companies, MNCs in India, startups, public institutes, and academia
- Encouraging collaboration with global institutes and companies to enhance domestic R&D efforts and translate research into practical solutions
- Implementing national policies to incentivise startups for research activities and establish incubation centers in universities and research institutions for generating intellectual property and Centers of Excellence
- Promoting transparency and creating a unified dashboard of available research facilities to facilitate collaboration and resource sharing

**Financial and Investment Incentives:**

- Developing incentives for private equity and venture capitalists (PE/VCs) to invest in research-based startups, potentially through tax breaks
- Recognising the need to address the capital crunch faced by smaller companies and startups engaged in pure R&D

**Innovative Collaborative Models:**

- Advocating for innovative public-private partnership (PPP) models, such as those seen in Singapore's collaboration between universities and pharmaceutical companies to address talent quality concerns
- Drawing inspiration from international initiatives like the CATAPULT project in the UK, which accelerates innovation and improvement across various sectors through impartial innovation-as-a-service offerings


Overall, the primary focus is on fostering a collaborative and incentivised R&D ecosystem in India, which involves partnerships, resource sharing, investment, and creative models of collaboration to address the unique challenges and opportunities in the healthcare and pharmaceutical industry.


# Panel Discussion

## India's New Chemical Entity (NCE)/New Biological Entity (NBE) aspirations - Strategies for achievement and the required Framework

### Moderator

Parijat Ghosh, Managing Partner,
Bain & Company India

## Panelists


Manoj Saxena, MD,
Bayer Pharma

Amitabh Dube, Country President,
Novartis India

Vikrant Shrotriya, Corporate VP and MD,
Novo Nordisk India

Meenakshi Nevatia, Country President,
Pfizer India

Dr. Rajesh Jain, Chairman and MD,
Panacea Biotec (virtual)

The panel unanimously emphasized upon the importance of trust amongst all the stakeholders in order to achieve the NCE/NBE aspirations of the country. Trust should be present between the patient and pharma company, within pharma companies, and between pharma company and public regulatory bodies. Simplification of the regulatory processes and mechanism is essential to provide an impetus to NCE/ NBE development in India. Active involvement by government departments will help. Also, the Government of India's mantra should not just be 'Make in India' but also 'Discover in India'.

## Key takeaways

**Regulatory and Funding Challenges:**

- Regulatory hurdles pose significant obstacles to Indian players engaged in R&D, causing delays and resource expenditure
- Predictability in the regulatory system is vital, necessitating dedicated project managers to offer timely responses and guidance
- Startups face capital shortages due to a lack of incentives for private equity and venture capitalists to invest in pure R&D

**Industry and Government Collaboration:**

- Large pharmaceutical companies like Pfizer recognise India's potential and engage in extensive supply chain and sourcing activities in the country. They adjust product pricing to improve healthcare access.
- Collaboration between industry leaders, such as Novartis and Novo Nordisk, focuses on addressing tropical and infectious diseases and expanding access to essential medicines
- India's need for a more robust pharmaceutical talent pool is emphasized, alongside stronger IP and patent protection laws to encourage innovation and value-driven research

**Role of Regulatory Bodies and Intellectual Property Framework:**

- Regulatory bodies are critical in facilitating the development of New Biological Entities (NBE) and New Chemical Entities (NCE) in India, as demonstrated during the pandemic when expedited steps were taken for vaccine development
- The IP and patent framework in India must be reinforced to enhance the protection and enforcement of intellectual property rights. This is especially crucial for smaller players engaged in NCE/NBE development.

In summary, the discussion underscores the importance of regulatory streamlining, industry-government collaboration, and an improved intellectual property framework to stimulate R&D and innovation in the pharmaceutical sector in India


# Panel Discussion

## Operationalising R&D and Drug Development: Ushering in a Robust Clinical Research Ecosystem

### Moderator


Shoibal Mukherjee, Consultant Clinical Pharmacology and Drug Development

## Panelists

Dr. Sanish Davis,
President, ISCR

Suneela Thatte, Head R&D India,
Merck KGaA

Dr. Anil Kukreja, VP Medical Affairs and Regulatory, AstraZeneca

Dr. Narender Kumar Ahooja, ex-State Drug Controller, Government of Haryana

India's clinical trial landscape presents several issues and opportunities. Despite its vast population, only 4% of global clinical trials occur in India (2010-22), making it vital to expand the research ecosystem by involving more patients and sites, including Tier 2 and 3 cities. Regulatory clarity is essential, as existing regulations often leave room for interpretation, hindering seamless implementation. As India scales up clinical trials, regulatory capacity must also expand, necessitating the inclusion of more experts and medical professionals in governing bodies to ensure ethical trials. The emphasis should always be on patient advocacy in clinical trials, and healthcare professionals need to refer patients, embedding trust in the process. Skill development and better collaboration between the private sector and the government are critical, as is the need for transparency in the approval process. India already has regulatory guidelines in place, such as GMP, GCP, and GDP, but there is room for improvement. Finally, the curriculum for clinical research must evolve to meet the dynamic nature of the industry, broadening the base of institutions involved in national importance. These measures can bolster India's role in clinical research, benefiting both the healthcare system and global medical advancements.

## Key takeaways

**Enhancing Clinical Trial Ecosystem in India:**

- India's low share (4%) of global clinical trials, despite its vast population, calls for the upskilling and upscaling of the clinical trial research ecosystem
- Expanding clinical trials beyond metropolitan areas to Tier 2 and 3 cities to broaden the patient base and research sites

**Regulatory and Ethical Frameworks:**

- The need for balanced and seamless regulations to ensure that the good intent of regulations is translated into effective implementation, enhancing the value of clinical trials
- Emphasis on patient advocacy and the encouragement of advocacy plans within clinical studies to engage with the patient community

**Capacity Building and Collaboration:**

- Scaling regulatory capacity as India expands, with more experts and medical professionals involved in committees and governing bodies, leading to increased on-ground inspections and ethical trials
- Recognising the importance of experienced investigators and bio-statisticians in the competitive field of clinical trials

**Transparency and Industry - Government Collaboration:**

- The call for better collaboration between private entities and the government, with a focus on predictability in the regulatory process and the quality of research conducted by private companies
- The need for greater transparency in the clinical trial approval process and the importance of aligning Indian regulations with global standards, fostering ethical practices and promoting clinical trials in the country


Overall, these themes underline the imperative of enhancing India's clinical trial ecosystem, aligning regulations with international standards, building capacity, and fostering collaboration to make clinical research more transparent, competitive, and patient-centric.

Day 1

# Day 2

# Welcome and Preface for the Day

## Rodolfo Hrosz,

MD Sanofi India Ltd

Day 2 was kickstarted by a preface address by Rodolfo Hrosz, MD of Sanofi India Ltd. He thanked all the speakers, panelists and the partners for successful execution of Day 1 of the conference. He talked about the three layers of innovation – tech innovation, business embracing the innovation and scaling it, and effective regulation of activities – and how all three layers were represented in the OPPI – Innovate India conference. He provided a summary of the key takeaways from panel discussions on Day 1 and created a seamless segue to the events for Day 2. Rodolfo concluded his address by iterating the objective of the conference, which is to create a "tsunami of innovation" and find ways to accelerate India's progress as a protagonist of innovation

# Address by

## Dr. Rajeev Singh Raghuvanshi,

DCGI, CDSCO, Government of India

Dr. Raghuvanshi utilised the opportunity to engage in a collaborative and meaningful dialogue with all the participants in the audience. He emphasized the need to shift from volume to value, and from generics to specialty drugs. He elucidated the provisions in the New Drug Bill & gave a glimpse of the reforms taking place with CDSCO.

> “India is at the inflection point to enter the rapid growth phase bringing about real change in the whole industry and bringing us closer to our vision for 2047”

## New legislation to bolster vision 2047

- The Government of India has already launched the DMDC Bill 2023 (which seeks to replace the Drugs and Cosmetics Act, 1940 (DCA) as the law governing the manufacture, sale and distribution of drugs, medical devices, and cosmetics
- There are a few provisions in the DMDC Bill 2023 that can be called as paradigm-shifting from the existing DCA. Such provisions include promoting innovation, as outlined in the preamble itself. Additionally, the Bill aims to promote digital interventions and support the medical devices industry by establishing a separate vertical for medical devices.
- Previously, medical devices were regulated in the same way as drugs. However, going forward, professionals with specific education in med tech and medical devices field will sit on the regulatory boards for regulating medical devices.

> There is a major cultural shift within the regulatory bodies to create and use digital data for all key processes to maintain accountability & transparency"

## Paradigm shift towards digitisation & collaboration

- By daily utilisation of digital data for reviewing files and monitoring dependencies, accountability and transparency are being increased in the system
- An ambitious project has been started to digitise the entire regulatory process in the country and build a unified digital portal/ digital regulatory ecosystem
- Earlier, there were a lot of misalignments between central and state agencies regarding the interpretation of some regulations. To address this, the government has started monthly escalation meetings with state regulators.
- CDSCO is also open to collaborations with regulators from other markets to oversee global clinical trials taking place in India. If invited, DCGI is also willing to join ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

## How can industry support regulators?

- Collaboration in building the regulatory framework for genetic tech, gene therapy, cell therapy, and medical device startups is encouraged
- Investing in serialisation technologies (e.g., QR codes) to prevent sale of spurious medicines, improve labelling and packaging etc
- Supporting MSME players in CRO/CDMO space who exhibit good governance and regulatory compliance is emphasized


# Panel Discussion

## Assessing Regulatory Framework Norms as an Enabler for Innovation in India

The panel was aligned on the future priorities for the regulatory framework. Both the industry participants and the regulators agreed on increasing transparency and agility within the system. There was also a call for a more harmonious regulatory framework, where the agency can work closely with the developers and guide them on every step of ethically developing a new drug via a panel of experts, rather than just playing the role of a watchdog.

### Session Chair

Dr. Chandrashekar Ranga,
Deputy Drugs Controller, India, CDSCO

### Keynote Speaker

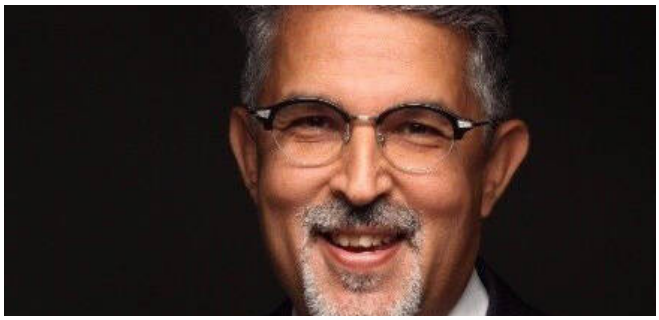
Dr. Matias Diez,
Head - International regulatory affairs, Sanofi

## Moderator

Sriram Shrinivasan,
Partner, Health and Lifesciences,
Bain & Company, India

## Panelists

Sanjiv Navangul,
MD & CEO, BSV



Rominder Singh,
Head-Regulatory Affairs,Asia, Pfizer (virtual)

Dr. Milind Antani, Lead, Pharma, Life Science and Healthcare Practice; Head, Social Sector Practice, Nishith Desai Associates

Dr. Villoo Morawala-Patel,
Founder, Chairman and MD, Avesthagen

# Key takeaways

## Adaptive and Self-Regulatory Frameworks

- Recognising the need for self-regulation within the pharmaceutical industry, as technological advancements often outpace the creation of governing laws
- Advocating for a system that periodically updates regulations to keep pace with the dynamic nature of the pharmaceutical sector, reducing the regulatory burden and customising regulations based on the type of product, whether it is chemical, biological, or genetic therapeutics
- Emphasising agility, transparency, and predictability within the regulatory framework to foster innovation and promote health while building trust in the system

## Biologicals & Innovation Focus

- Highlighting India's readiness to harness the potential of biologicals and innovation, with the presence of experts and a growing risk capital in the market
- Encouraging the development of regulatory corridors and collaboration with global regulatory agencies to enable the private sector to navigate regulatory complexities efficiently and launch innovative drugs in both the Indian and international markets

## Support for Independent Innovators and Intellectual Property (IP) Protection

- Shifting the regulatory focus from solely safety and efficacy to also consider value and innovation in legal vocabulary
- Placing the onus on regulators to strengthen the IP system to protect independent innovators and support them with capital and marketing assistance, thereby accelerating the journey from the lab to the market


# Panel Discussion

## Access to Innovation

### Session Chair

Dr. Kamlesh Kumar Pant, Chairman, NPPA (virtual)

### Moderator

Maulik Chokshi, Deputy Country Director-Technical, Director, Health System, ACCESS Health International

### Panelists

Gilbert Verkuijlen, Regional Value and Access Head, Novartis (virtual)

Pankaj Kakkar, Senior VP, Global Operations, Indegene

Rajasekhar Parcha, Co-Founder, CEO, GoApptiv

Dr. Monika Puri, Chief Country Access and Policy Officer, Roche

Sanchit Nanda, Sr. Director, Global Patient Solutions, Gilead Sciences

The panel discussed the challenges and opportunities related to accessing innovation across both private and public settings, with a focus on ensuring equitable and inclusive access for all. Working on the demand side and strengthening of the health system architecture are critical for the uptake of innovative products and services. Innovations in digital platforms can help improve access to information and innovations in last-mile delivery and pricing policies, ensuring that every person in need of the product or service receives it – which is the ultimate goal of innovation. After demonstrating proof of concept, innovative ideas enabling access need to be taken under the arm of local governments and incorporated into legislation to benefit the community.

## Key takeaways

- India can successfully leverage the synergistic benefits of a robust IT ecosystem and the healthcare & pharma industry to set the benchmark in emerging markets for being an innovation hub and improving access to innovations via novel methods
- The gestation time from innovation to the launch of a drug can be very long, and coupled with the lower price points in the Indian context, it may hamper innovation. One way to reduce the the gestation time is by leveraging digital platforms to reach a wider base of patients. Tech like generative AI can also accelerate the creation of the submission documents required for regulatory purposes. By reducing the gestation time, access to the drug can be enhanced.
- Rural populations in India are discreet and heterogenous pockets with lower levels of awareness compared to urban counterparts. There is a lack of physician support for diagnosis, as well as fulfillment and distribution services in the rural setup. Building clusters where doctors can diagnose, deliver point-of-care investigations, and have access to medicines will improve access for rural communities. A digital ecosystem could be developed where players from different industries can collaborate and serve various clusters based on the

needs identified by medical and nursing professionals.

- Tech lies at the heart of improving access. Covid tailwinds have made health-related apps a second nature for everyone. Need to capitalise on this behavioral shift and institute digital platforms to enable access to quality products and services. It is imperative to prioritise data privacy while building these platforms.
- Co-development of the health architecture, in line with innovative molecules, ensures that innovation does not go to waste and can be utilised effectively. Scaling up the manufacturing of these innovative molecules and implementing appropriate pricing models will foster access to such innovations.
- Need to include 'value-based' benefits while evaluating a molecule. This should not just be in terms of $s for the company but in terms of better health outcomes for the affected patient population. Conversations between private research organisations and regulatory bodies should encompass this aspect, as it may help in expediting processes to improve access to innovative molecules.
- Develop partnerships across the value chain to expedite access to innovative molecules, through partnerships with best-in-class manufacturers, supply chain players, point of care players, amongst others. India's markets are very heterogenous with different market leaders in various geographies. It is imperative to identify the best player with the widest distribution network and partner to diffuse the innovative product/ service to the masses.
- Value-based healthcare models are being employed in Western nations, where the government continues to invest in healthcare reform in order to create value by improving outcomes and reducing costs. This includes establishing service guidelines, healthcare delivery models, integrated health information systems, and piloting different payment models that incentivise outcomes, such as pay for outcomes or diagnosis-based payment.
- The latest epidemic in India is that of non-communicable diseases (NCDs), which are contributing to the triple burden of diseases. Innovation in the preventive health space can help reduce the burden of NCDs.
- Widening the coverage of insurance products to include biologics, immunotherapy, and other newer modalities of treatment, coupled with awareness of the insurance products via counseling sessions, is a must in increasing access to innovative products and services


# Panel Discussion

## Breaking Barriers - Innovative Financing and Investment Strategies for R&D and Innovation

### Moderator

Harish Iyer, Deputy Director,
Digital and Health Innovation,
Bill & Melinda Gates Foundation

## Panelists

Murali Ramachandra, CEO,
Aurigene Oncology

Rajeev Ranjan, Ex Secretary,
Government of India

Shridhar Narayanan, CEO,
Foundation for Neglected Disease Research

Devdutt Marathe, Senior VP,
Brookfield Asset Management (virtual)

Dr. Dhananjay Bhakhle, Executive VP,
Medical Research, Lupin

The panel discussion on healthcare and pharmaceuticals revealed several key takeaways. Currently, India's healthcare spending remains far below the targeted 2.5% of GDP, with expenditures ranging from 1.1% to 1.5%. While newer channels for financing health startups have emerged, the pharmaceutical sector faces unique challenges. New drug development is characterised by lengthy gestation periods, high failure rates, and substantial costs. In terms of funding, India's expenditure on research and development in both domestic and multinational pharma companies is around $3 Bn, which is just a fraction of the $300 Bn spent in the USA. To stimulate innovation, some large pharmaceutical firms have adopted new organisational models, creating autonomous entities dedicated to research and development, which can even raise private funding. The discussion also underscored the need for stronger collaboration between private pharma companies, government entities, academic institutions, equity financiers, and recommended government incentives and licensing models to support organisations focused on rare and neglected diseases. Additionally, investment in nutrition and animal health was highlighted as a promising area for research and development, emphasizing the importance of government-formulated tax incentives for companies engaged in innovative products and clinical trials.

## Key takeaways

- Currently, the proportion of GDP used for health is still below the target of 2.5%, at about 1.1 – 1.5%. This includes all the expenses by the state and central governments.
- Newer channels have emerged to finance startups in the health space, such as social impact bonds and PPP models. But, the pharma space is unique as new drug development has a long gestation space, high failure rates and huge expenditures.
- Funding scenario in India is only a fraction of the current levels in the USA. Government entities like BIRAC support research projects, but the number is very limited. The total expenditure on R&D by domestic and multinational pharmaceutical companies in India is approximately $3 Bn, compared to $300 Bn in the USA, which is a key reason why no blockbuster drug has emerged from India.
- Many large pharma companies have come up with newer organisational models to encourage innovation, such as having a separate autonomous entity under their wing involved in innovative R&D. These entities can even raise private funding. Such models should be explored and adopted by other pharma companies as well.
- India has eminent academic institutions like NIPER and a large population of PhDs and MDs but the current scale of collaboration between private companies and academic institutions on research is very limited. Collaboration can easily and effectively happen in a few areas like cell and gene therapy.
- Need to develop a formal channel of collaboration between the private pharma companies, government entities, academic institutions, and equity financers
- Organisations focused on rare and neglected diseases are usually financed by grants, donations, and corporate social responsibility projects; imperative for the government to step in and establish incentives for other players. Licensing models also help in generating funds.
- Two areas which came up in discussion for investment strategies for R&D and innovation in the Indian pharmaceutical industry were nutrition and animal health. The benefits from successful products in these two areas are massive. Nutrition, like public sanitation, is a public good, and the rising number of crossovers of pathogens from animals to humans necessitates the need to deepen the research in animal health.
- Imperative for government to formulate tax incentives for companies focusing on innovative products and clinical trials


# Panel Discussion

## Industry-Academia "How to enable stronger engagement between industry and academia for quicker innovation?"

### Moderator


Dr. YK Gupta, Principal Advisor, India Strategy Development, Global Antibiotics Research Development and Partnership, President, AIIMS Vijayanagar, Jammu

## Panelists

Lene Hylling Axelsson, Senior VP, Global Solutions, Novo Nordisk

Prof. Ramesh K Goyal, Vice Chancellor, Delhi Pharmaceuticals Sciences and Research University, Govt. of NCT Delhi

Prof. Shubhini A Saraf, Director, NIPER, Raebareli

Sudheendra Kulkarni, MD & CEO/Board Member, India, South Asia & ASEAN region, Ferring

Hitesh Sanganee, Executive Director and Head of Emerging Innovations, AstraZeneca (virtual)

Pushpa Vijayaraghavan, Director, Healthcare & Lifesciences advisory, Sathguru Management Consultants

Prof. Anurag S. Rathore, Department of Chemical Engineering, IIT Delhi

The panel discussion addressed several critical points for the healthcare and pharmaceutical sectors. It highlighted the need for closer collaboration between academia and industry, proposing that industry veterans teach at professional colleges and professors undergo industry externships. The inclusion of academic institute names on medicine labels was suggested to recognise their contributions. The government was urged to promote collaboration with funding initiatives. Institutions were advised to become more industry-friendly by setting up IP divisions and funding short-term research projects. Collaboration through platforms like OPPI was encouraged. Healthcare spending remains below target, and India lags far behind the USA in pharmaceutical R&D expenditure. Innovative organisational models in large pharma companies were endorsed. The panel also emphasized government support for rare disease organisations, investment in nutrition, animal health research, and tax incentives for innovation.

## Key takeaways

- Cross-pollination of ideas and expertise by having industry veterans teach in professional colleges and college professors undergo compulsory rotatory externships within the industry
- Increased participation from the academic body in pharmaceutical conferences
- Addition of the name of the academic or research institute as a contributor to the development of a particular medicine should be included in the label
- The government can promote collaboration through setting up schemes like Ucchatar Avishkar Yojana, where research would be funded, provided there is funding from industry
- Institutions should also focus on being industry-friendly by setting up IP divisions, making their labs Good Laboratory Practices (GLP) compliant, and funding shorter-term industry-related research projects
- Industries and platforms like OPPI can maintain formal dialogue with academia by setting up dashboards where they can share their day-to-day problems/proof of concepts with institutions

# Key Action Items

## For the industry

- **Industries and platforms like OPPI maintain formal dialogue with academia** by setting up dashboards where they can share their day-to-day problems/proof of concepts with institutions
- **Develop partnerships across the value chain** to expedite access to innovative molecules, through partnerships with best-in-class manufacturers, supply chain players, point of care players amongst others. Develop more GCCs in India to extend growth. India's markets are very heterogenous with different market leaders in various geographies. It is imperative to identify the best player with the widest distribution network and partner to diffuse the innovative product/ service to the masses.
- Only 4% of the clinical trials globally take place in India (2010-22). Given the size of the population, this is an extremely low proportion. Need to upskill and upscale the clinical trial research ecosystem by including a larger patient base and clinical trial sites. Clinical trials need to expand into Tier 2 and 3 cities, and not just focus on metros.
- **Doctors and HCPs should refer patients** to participate in clinical trials on a case-by-case basis. This embeds trust in the clinical research trials and makes it a mainstream conversation. Need to inculcate this behavior via medical conferences.
- **Need to grow global operations hub in India** that goes beyond just back-end processes but go to advance in the value chain of the drug discovery cycle and become the knowledge hub for global operations. This can be achieved through shared services and exporting talent.
- **To increase access to innovative products and services,** it is essential to expand insurance coverage to include biologics, immunotherapy, and other newer modalities of treatment. Additionally, raising awareness about these insurance products through counseling sessions is a necessity.
- **Larger MNCs to innovate newer financing and equity** models so as to mitigate the capital crunch faced by smaller companies and startups engaging in pure R&D
- **To have separate entities** focusing on innovation and drug discovery and to build a startup culture within them
- Need to include 'value-based' benefits while evaluating a molecule. This should not just be in terms of $s for the company but in terms of better health outcomes for the affected patient population. Conversations between private research organisations and regulatory bodies should encompass this aspect, as it may help in expediting processes to improve access to innovative molecules.

## For the public agencies

## For the regulators

- Current regulations focused on safety and efficacy rather than value and innovation. There is a need to define true innovation within in the legal vocabulary of the regulatory system.
- **Bringing about organisational changes** through active engagement with the industry is crucial for building a sustainable regulatory framework. Regular collaboration with the industry in building the regulatory framework for genetic tech, gene therapies, cell therapy, and medical device startups is encouraged, as the regulatory system needs to evolve with the pharma industry.
- **Need to reduce regulatory burden** for both the regulators and the sponsors by increasing capacity and by having dedicated project managers who can provide timely responses and guidance to the private industry. India's committees and governing bodies should also include more experts and medical professionals, which would result in more on-ground inspections and ethical trials.
- **Predictability** of the regulatory system to be improved by increasing the scope of unified digital portal by including all regulatory processes; Transparency to be increased by citing TATs and unnatural delays to the applicants.
- **Regulations need to be customised** based on the type of product, such as different regulatory frameworks for chemicals, biologicals, and genetic therapeutics
- Address misalignment between central and state agencies, enhancing transparency and accountability, and digitising the entire regulatory process with a unified digital portal
- It is crucial to enable dialogue between different regulatory agencies of the world and to embed the newer regulations with minimum delay to enable the private players
- Helpful to foster regulatory corridors between India regulatory agencies of other countries, wherein support is provided to small to mid-level private players who desire to innovate and launch drugs not only in India but also other global markets
- **Addition of the name** of the academic or research institute as a contributor to the development of that medicine should be included in the medicine label
- The onus is on the regulator to make the IP system in the country extremely robust to protect independent innovators. Support to be given to such innovators in terms of capital and marketing in order to shorten the process of lab to market.
- Aligning with the theme of the conference, 'Innovate India – Vision 2047', the stakeholders also emphasised the need to incentivise R&D through IP. This included education and awareness of IP in academia, strengthening IP & transfer of knowledge between companies & institutions etc. To tap into the 'value-based' benefits, the participants agreed on several steps including streamlining value chain, upskilling, expanding financing ecosystem. Collaborations between OPPI members, academia, and public agencies also emerged as a key priority to support the vision.

## For the public agencies

## For the ministries

- National policies to be rolled out which incentivise startups to take up innovative research, incentivise PE/VCs to invest in research-based startups through tax breaks
- **Innovative PPP models** should be developed to attract private sector researchers and scientists to conduct research in Indian universities and use their state-of-the-art tech (e.g., collaboration between Novartis and NTU & NUS of Singapore)
- **Multi-disciplinary entities** to be created that provide impartial innovation-as-a-service to public bodies, businesses, and infra providers to catalyv e improvements and serve as collaboration points (e.g., Catapult project in UK, Project Orbis in USA). They can focus on non-communicable diseases that contribute to the disease burden in India as well as on the current capabilities of Indian pharmaceutical industry like vaccines manufacturing and drug development.
- **Increasing the capacity, scale, and scope** of agencies like BIRAC that act as industry-academia interface through multiple impact initiatives like targeted funding, tech transfer, IP management, joint projects with industry and academia, etc.
- **Building CoEs and incubators exclusively for the sunrise industries** in India, such as medical devices, gene therapy, immunotherapies, and biologicals, to encourage innovation through funding, technology transfer, and mentorship

## For the academia

- **Increase participation** from the academic body in pharmaceutical conferences
- **Encourage cross-pollination of ideas** and expertise by having industry veterans teach in professional colleges and require college professors to undergo compulsory rotatory externships within the industry
- Institutions to focus on being industry friendly by setting up IP divisions, making their labs GLP compliant, funding shorter-term industry related research projects and to have incubation centers which generate IP and in turn create COEs for startups
- Clinical research is concentrated in institutions of national importance. It is imperative to broaden the base of clinical research by making it compulsory in the curriculum.
- **Evolve the curriculum** basis the dynamic nature of the industry
- Established institutes and research organisations should aim to more transparent in citing facilities that they have and being open to third parties conducting research. A one-stop dashboard needs to be created where all facilities like instruments, machines, and tech can be written down and made available for the startups and innovators.

# Event Partners

## Government Collaboration

## Association Partners

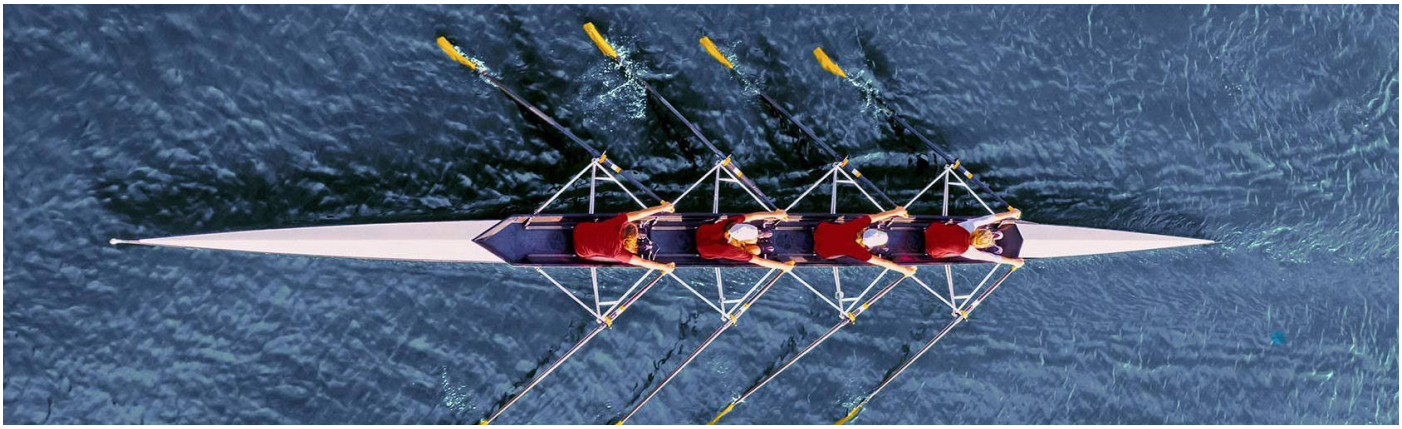
## Platinum partners

## Diamond partners

## Gold partners

## Innovation spotlight

## Knowledge Partners



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