# OPPI ANNUAL SUMMIT

CHANGING FRONTIERS OF HEALTHCARE RESEARCH
IN A DYNAMIC AND DIGITIZED WORLD

## ANNUAL SUMMIT REPORT

23rd & 24th March 2022

#ResearchRedefined

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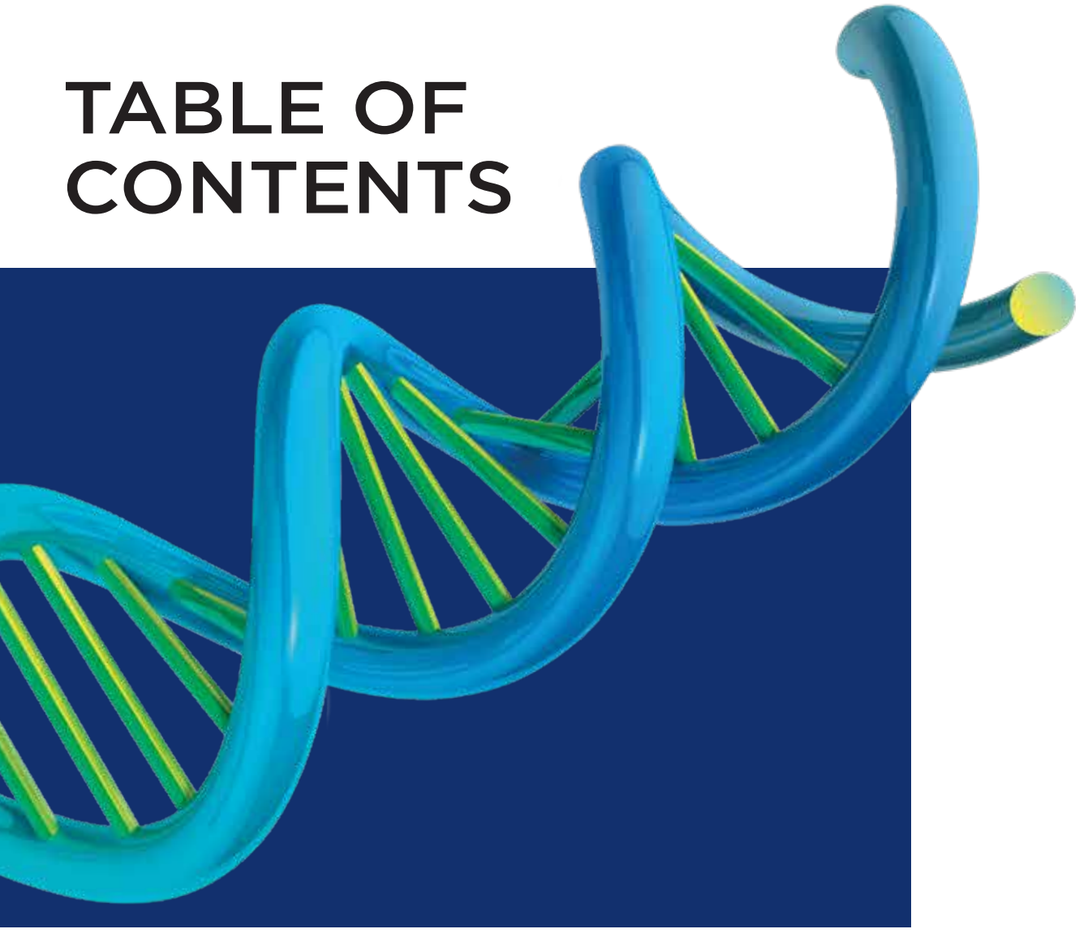


# ACKNOWLEDGMENTS

The Organisation of Pharmaceutical Producers of India (OPPI) would like to thank all our partners and stakeholders for their participation and insightful contribution to the deliberations of our Annual Summit, organized this year under the theme, 'Changing Frontiers of Healthcare Research in a Dynamic and Digitized World."

Our sincere gratitude to the high-ranking ministers and government officials, who took time out of their busy schedules to be with us, and to present informed perspectives that will contribute significantly to further strengthening the pharmaceutical sector of the country and ensure that it is fit for the future and the new reality that we live in.

We express our generous thanks to Shri. Bhagawanth Khuba, Hon'ble Union Minister of State for Chemicals and Fertilizers and New & Renewable Energy, for gracing the Annual Summit with his esteemed presence.

We thank Ms. S. Aparna: Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers; Prof. K. VijayRaghavan, Principal Scientific Advisor, Government of India; Dr. Ram Sewak Sharma, Chief Executive Officer, National Health Authority, Ministry of Health and Family Welfare; Dr. Renu Swarup, Former Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India, Dr Rubina Bose, Deputy Drugs Controller, at Central Drugs Standard Control Organisation (CDSCO) and Rama Vedashree, Chief Executive Officer, Data Security Council of India (DSCI), for their invaluable contribution to the discussion.

We also thank the senior officials of NITI Aayog, the Department of Scientific and Industrial Research, All India Institute of Medical Sciences, the Department of Biotechnology at the Ministry of Science & Technology.

We express our gratitude to Dr. Nilima. A. Kshirsagar, former National Chair of Clinical Pharmacology ICMR, and Dr. V. G. Somani, The Drugs Controller General (India), Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of India for introducing the Multi-Regional Clinical Trials (MRCT) Report. Alongside, we also extend our heartfelt thanks to Milind Thatte Managing Director, Procter & Gamble Health Limited, Susan Josi, Managing Director, Havas Health and You, SEA & ME region, and Judy Stenmark, Director General, Global Self-Care Federation for launching the Value of OTC in India Report on the second day of the summit.

We would also like to take this opportunity and extend our thanks and gratitude to the Department of Pharmaceuticals (DoP), Invest India and QCI for the sustained support and partnership in making the OPPI's Annual Summit a success.

The support of multilateral organizations, international government entities, academia, private sector leaders, and civil society has been invaluable. We thank the officials of Roche, Hilleman Laboratories, Boehringer-Ingelheim, EMD Serono, Inc., Takeda, IQVIA South Asia, Bayer Pharmaceuticals Pvt. Ltd.

Novo Nordisk India Pvt. Ltd., AstraZeneca Pharma India Limited, Pfizer Ltd., Christian Medical College, Vellore, Procter & Gamble Health Limited, Havas Health and You, Global Self-Care Federation, Accenture Life Sciences, US FDA India Office, Pharmaceuticals and Medical Devices Agency (PMDA), Japan, Johnson & Johnson, Niramai Health Analytix, IIT Madras, Invest India and the Indian Institute of Science (IISc), Bengaluru, among others for their support.



# EXECUTIVE SUMMARY

The OPPI Annual Summit, under the theme, "Changing Frontiers of Healthcare Research in a Dynamic and Digitized World", organized on March 23 and 24, 2022, was one of the key events that helped redefine the strategic direction of growth for the nation's pharmaceutical sector, especially following the challenges of the COVID-19 pandemic.

With digitization and fast-paced transformation reshaping every aspect of life, gaining fresh insight and perspectives on the opportunities and challenges for the pharma sector is of strategic importance in shaping the industry to unlock its true potential. 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, accelerating research and new developments in the biopharma and overall providing a holistic and conducive environment for innovations to nurture, that would cement India's position as the "Pharmacy of the World."

As the pharma sector of the country records robust growth, underpinned by governmental support, including policy reforms, it is important that all the stakeholders - the government, private sector, academia, R&D, and civil society – are brought together to share their views on the dynamics of the industry.

By defining the new frontiers, every stakeholder can transform their organizational growth pathways to gain strategic growth, and in doing so, contribute even more to the health sector overall. Once all the elements and stakeholders join forces in initiating new advancements in the field of health research and augment pathways to drive innovation in India, the pharmaceutical industry will be strengthened multi-fold in the country.

Dr. Nilima. A. Kshirsagar, former National Chair of Clinical Pharmacology ICMR, and Dr. V. G. Somani, The Drugs Controller General (India), Central Drugs Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of India, revealed the Multi-Regional Clinical Trial Report on the first day of the Summit, which set the stage for in-depth discussions centred on how its findings can be leveraged for the greater good.

**The Summit delivered on its key objectives which included:**

1. Putting the spotlight on the new trends, opportunities, and challenges facing the pharma sector of India
2. Bringing together multiple stakeholders to activate impactful and action-driven discussions for strengthening the industry, with a key focus on R&D
3. Recognizing and honouring excellence in the pharma sector

# CHIEF GUEST ADDRESS


**Shri. Bhagwanth Khuba**
Hon'ble Union Minister of State
for Chemicals and Fertilizers and
New & Renewable Energy,
Government of India

**Highlights**

India is the 3rd largest pharmaceutical industry in the world and the sector grew 9-11% in the last 2 years. The government will focus on certain specific medical areas such as Bulk drugs valued at INR 3,000 crores: PLI Schemes of value INR 15,000 crores and medical devices at INR 34,000 crores. It is important to update the pharma curriculum to make sure that new pharmacists are upgraded. Our goal is to establish the Indian pharma industry as a US$130 billion industry by 2030. In driving this, HCPs, policymakers, academicians, and scientists are involved in an integrated manner. Strong regulatory approval is involved in the drug development and research phase. To foster the growth of our talent and research, we must improve industry-academia collaborations and build incubation hubs. Digitization in the pharma sector AI, Big data, and IoT is key to accelerating 'Make in India'. Companies need to understand how to work together with the patients in the digitization journey. The COVID-19 pandemic has taught us how to collaborate and innovate by joining forces.



# MAIN TAKEAWAYS

**R&D: The Engine of Growth for the Indian Pharma Industry**
One of the key takeaways from the Summit was the remarkable potential for growth in India's pharma sector. Today, there are multiple concerted efforts to strengthen capacities in driving regulatory amends and approvals.

The various reforms undertaken by the government are aimed at ensuring patient safety as the top priority. The government is also incentivizing investments in R&D, forging a collaborative network, and ensuring that public funding is available to accelerate research and innovation.

The Summit underpinned the need for stronger public-private partnerships and academia-industry linkages, with OPPI focused on leveraging the large talent pool in the country and strengthening the domestic research and innovation base.  The Summit discussed next-generation technologies and the role of manufacturing, with continuous manufacturing technologies, especially vaccines and biologics, having a major impact on development, commercialization, timelines, and a positive impact on the supply chain. Learning from the pandemic, the country needs to strengthen public health awareness, and upgrade manpower and medical infrastructure, especially in smaller cities, in addition to promoting teleconsulting to improve preventive health.

Continuous R&D is imperative for the nation, the speakers said, as it provides a flow of knowledge; this involves cutting-edge technology for developments that make solutions and treatments more affordable and accessible. The three key pillars or 3 Cs to be focused on are capacity building of human resources and infrastructure, focus on cutting-edge technologies, and collaboration.

Addressing the audience, Shri. Bhagwanth Khuba, Hon'ble Union Minister of State for Chemicals and Fertilizers and New & Renewable Energy, Government of India, said the country is the third-largest pharmaceutical industry in the world, and the sector grew 9-11% in the last two years.

He called on the need to update the pharma curriculum to make sure that new pharmacists are upgraded, adding that the national goal is to establish the Indian pharma industry as a US$130 billion industry by 2030.

## Ms. S. Aparna

Secretary, Department of Pharmaceuticals, Government of India


**The keynote address delivered by**

**Ms. S. Aparna**

Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India had some key insights for the nation's pharmaceutical industry.

She spoke on the following pointers:

**Potential for transformative growth**

India has ensured an uninterrupted supply of medicines to all countries and will continue to pursue to achieve Universal Healthcare (UHC) by providing good quality medicines at affordable prices. However, there is a great potential for transformative growth, which the Department of Pharmaceuticals is committed to unlocking, through its partnership with other organizations. A detailed paper has been drafted to provide more impetus to research and innovation in the pharma sector. There are also concerted efforts to strengthen capacities as well as in driving regulatory oversight and swift approvals. Advanced research to drive innovation, as well as homegrown entrepreneurship, will help in developing new pathways to ensure good quality of well-being is provided to all in India.

**Support of the government**

The various reforms undertaken by the government are aimed at ensuring patient safety as the top priority. The government is also incentivizing investments in R&D, forging a collaborative network, and ensuring that public funding is available to accelerate research and innovation, which is the backbone of the pharma sector. The government has announced funding for the sector, including blended finance products, and more flow of funds to research companies that are members of OPPI. India will focus on research in neglected diseases and the country is an attractive destination for a generic drug & IP development, supported by a strong manufacturing base

**Promoting public-private & academia-industry linkages**

A priority area to accelerate R&D is to promote public-private collaborative research as well as academia-industry linkages, in addition to encouraging innovation hubs. The country has strong potential to develop research capabilities in biopharma, rare disease research, and gene and cell therapy – all of which will establish the country as a strong pharma player globally. Digitization in clinical research and drug development, as well as cross-sectoral partnerships, will strengthen the nation's pharma sector without compromising the safety of patients. OPPI must also leverage the large talent pool in the country and strong research base to provide equal and easy access to quality medicines for all.



## Mr. S. Sridhar

President, OPPI and Managing Director, Pfizer Ltd.

Mr. S. Sridhar highlighted how scientific and medical research is indispensable for resolving public health challenges – whether it be tackling diseases of poverty, responding to the rise of chronic diseases, or pre-empting the future challenges/pandemics. Investment of resources and manpower in research has led to significant discoveries, the development of new therapies, and a remarkable improvement in health care and patient health.

Today, the Indian pharmaceutical sector stands at the cusp of greatness. He stated that we are poised to reach USD 130 Billion by 2030 because of targeted interventions and policies aimed to boost self-reliance, research, and access to innovative medical solutions for a healthier population. The pandemic has transformed the general perception of the pharma sector, with the quick turnaround on vaccines and uninterrupted supply of medicines. This was only possible through concerted efforts by the government in addition to the industry stakeholders under whose leadership the sector was able to not just thrive but scale newer heights.

According to him, being future-ready involves recurrent dialogue to explore and enhance partnerships and encourage newer collaborations to advance R&D within a conducive policy landscape. He also lauded the government and its efforts in generating partnerships among foreign multinational -players and Indian pharma companies to enable quick accessibility of medicines and therapies during the COVID19 pandemic. Furthermore, the power of digitization has been in full play in recent months given the pandemic, when the pharma sector seized the digital opportunity, bringing in unprecedented levels of ease of access, safety levels, and convenience.

This value is further underpinned by the Ayushman Bharat Digital Mission which provides universal health coverage by integrating digital systems within the healthcare infrastructure. Mr. Sridhar mentioned that the pharmaceutical sector in India has, in addition to safeguarding the health and wellbeing of people across the world, significantly contributed to the Indian economy, employment, and innovation metrics as well which has helped consolidate our position in the global value chain. Through such forums, OPPI aims to increase the frequency of dialogue amongst stakeholders while also understanding and deliberating cross-sectoral partnerships and the gains they may present.

**Mr. K.G. Ananthakrishnan**
Director General, OPPI

Mr. KG Ananthakrishnan, DG OPPI in his address at the OPPI Annual Summit, focused on Dynamism and Digitization, as the guiding principles of the industry over the past two years – with the pharma sector in close collaboration with the Government accelerating growth across both domestic and global markets. He spoke of the pertinent role of the Government in managing the pandemic while offering pathways to embark on a journey towards $130 billion, with a focus on spurring innovation and encouraging cross-sectoral partnerships and how that was key to arresting the spread of the virus and simultaneously accelerating sectoral growth, which we have witnessed over the past two years.

He further emphasized how the pandemic has shown us that we need a future-ready model of disease surveillance and response for our people. This road is paved with research and development (R&D) - from understanding the ailment to responding to and eliminating it. This was further illustrated by the sector's response to COVID – from sequencing the virus to developing multiple vaccines and therapies, R&D through collaborations across industry, academia, and government stakeholders was key.

However, being future-ready includes driving forth the vision of a research-based biopharmaceutical ecosystem rooted in innovation. This is only possible through frequent dialogue to understand and enhance partnerships and encourage newer collaborations to advance R&D within a conducive policy landscape.

Mr. Ananthakrishnan mentioned that under the Government's Make in India initiative, the pharmaceutical industry in India has established a leading position in generics/ manufacturing. Now, as we continue accelerating our momentum to improve public health outcomes in India and across the world, it is important to sustain the spirit of innovation and collaboration we have witnessed over the past two years and move from Make in India to Discover in India.

What is significantly encouraging for the future of research in this country is the Government's unwavering perseverance towards building an even more predictable, transparent, and consistent policy environment through closer collaboration amongst the stakeholders. He then requested Mr. S Sridhar, President, OPPI to share his views on the Summit and how OPPI is Reinforcing Healthcare Research.



# REPORTS RELEASED DURING SUMMIT

# VALUE OF OTC IN INDIA

## PARTICIPANTS

**Milind Thatte**
Managing Director,
Procter & Gamble
Health Limited

**Susan Josi**
Managing Director,
Havas Health and You,
SEA & ME region

**Nitika Garg**
Director Research,
OPPI India

**Judy Stenmark**
Director General,
Global Self-Care
Federation

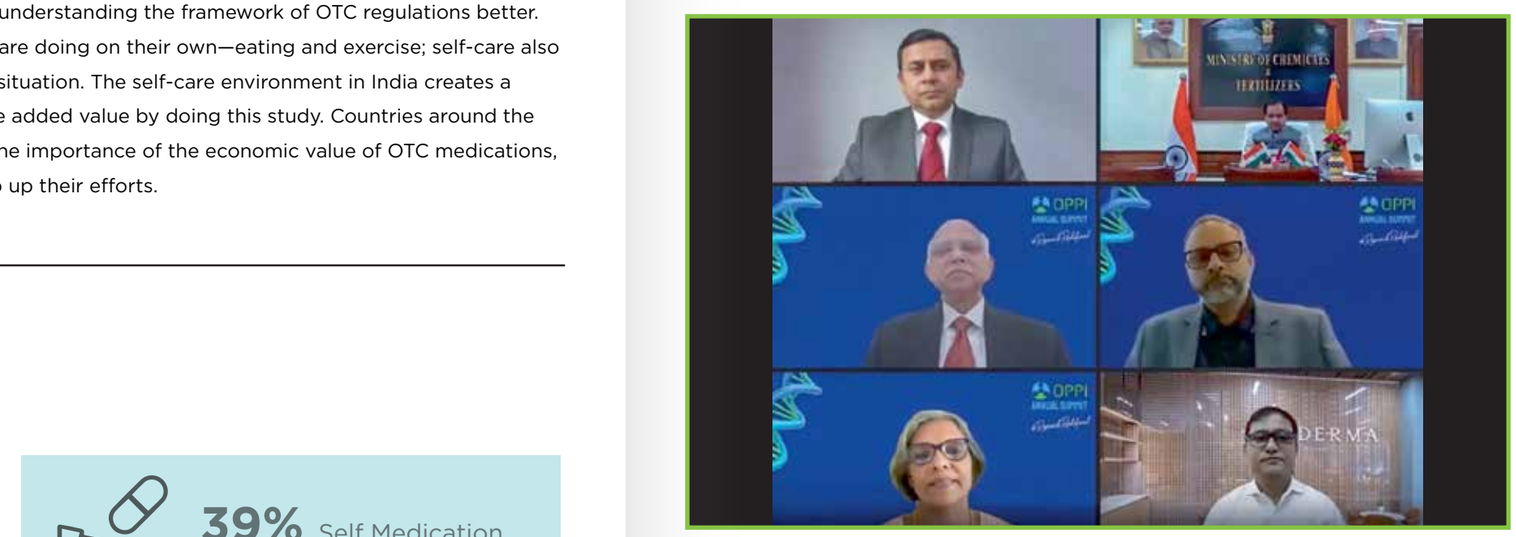
## UNDERSTANDING OTC REGULATIONS

Minor ailments can be addressed better, by reducing OOP and reducing the burden on the HCPs by understanding the framework of OTC regulations better. At a micro-level people are doing on their own—eating and exercise; self-care also comes in the comorbid situation. The self-care environment in India creates a platform, where we have added value by doing this study. Countries around the world have underlined the importance of the economic value of OTC medications, and India needs to ramp up their efforts.

## DETAILS OF THE STUDY

The study looked at 27 common ailments that witnessed common medication behaviours. The study covered 25 cities and metros to understand the rationale and behaviour of people, interviewing 10,000 respondents, including housewives, children, and homeowners. There are typically three layers: people who go to docs, people who self-medicate, and people who go to pharmacists; today 39% of people do self-medication.

Only 13% seek pharmacists' advice and 58% depend on HCPs. In all, INR 35,820 crores is spent on ailments, of which 86% is spent through HCPs. However, these are only minor ailments and need to empower our consumers. As the ratio of doctor to patient is very low—we need to build a more resilient India. 43% can be saved with self-medication; so, it is important to empower pharmacists, which will help save up to 37%.




**Empowering every Indian**

Formulating OTC regulations will strengthen the policy environment and framework in the country. Every Indian must be empowered to responsibly self-medicate; this will lead to enhanced outcomes, but we must also prevent the misuse of medicines. OTC regulations will also increase engagement with pharmacists. OTC drugs should be the new regulatory law and it needs to be recognized as the new type of medication in India. In terms of best practices, even countries like Brazil and Mexico have implemented the study using an advanced model and system.

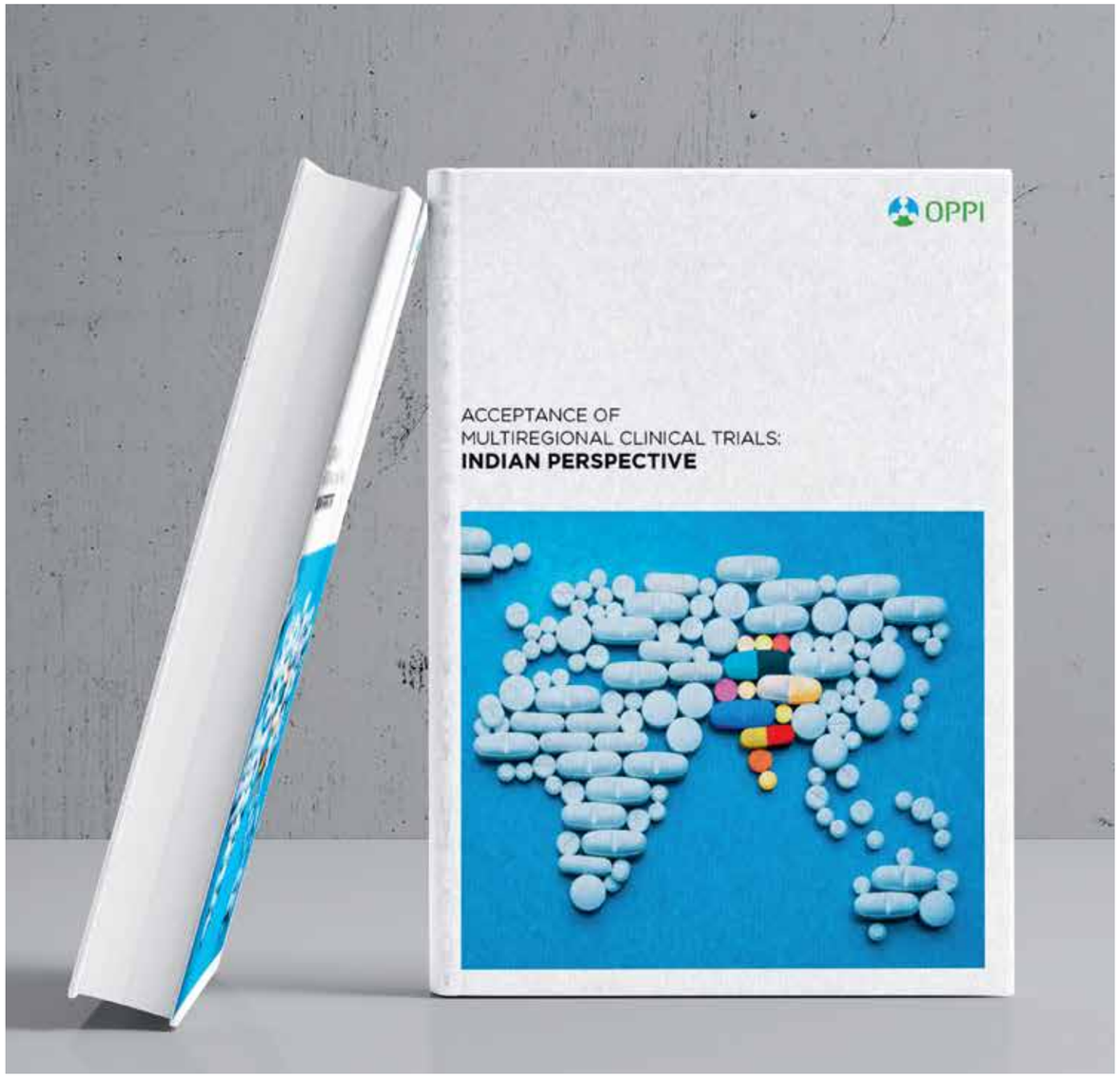
**For a nation like India, while we do have adequate policies in place, we need to culminate our knowledge and leverage our best practices in ensuring the practical implementation of these policies for the greater good.**




**On screen**

1. Milind Thatte, Managing Director, Procter & Gamble Health Limited
2. Shri. Bhagwanth Khuba, Hon'ble Union Minister of State for Chemicals and Fertilizers and New & Renewable Energy, Government of India
3. Mr. KG Ananthakrishnan, Director General, OPPI
4. Mr. S. Sridhar, President, OPPI and Managing Director, Pfizer Ltd.
5. Susan Josi, Managing Director, Havas Health and You, SEA & ME region
6. G. Satyanarayanan, Managing Director, South Asia Galderma India Pvt. Ltd.

# MULTI-REGION CLINICAL TRIALS REPORT (MRCT)







**On screen**

1. Mr. S. Sridhar, President, OPPI and Managing Director, Pfizer Ltd
2. Mr. KG Ananthakrishnan, Director General, OPPI
3. Dr. V. G. Somani, The Drugs Controller General (India), CDSCO, Ministry of Health & Family Welfare, Government of India
4. Dr. Nilima A. Kshirsagar, Former National Chair Clinical Pharmacology ICMR

## OVERVIEW OF THE MRCT REPORT

In recent years, we have seen regulatory reforms, and the pandemic has accelerated the process. During the pandemic, Indian regulatory agencies were responsive, which resulted in preventive and proactive actions that protected patients. Streamlining the regulatory framework by exploring opportunities for harmonization with other advanced and emerging geographies can address amplified approval timelines for drugs and clinical trials, allowing for a greater commitment to innovation and the rapid delivery of newer therapies to patients. This momentum must be retained to improve patient access to cutting-edge treatments.

## PARTICIPANTS

**Dr. Raju Titus Chacko**
Professor of Medical Oncology, Christian Medical College, Vellore

**Dr. Rubina Bose**
Deputy Drugs Controller, Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Directorate General of Health Services, Government of India

## OVERVIEW OF THE MRCT REPORT

In recent years, we have seen regulatory reforms, and the pandemic has accelerated the process. During the pandemic, Indian regulatory agencies were responsive, which resulted in preventive and proactive actions that protected patients. Streamlining the regulatory framework by exploring opportunities for harmonization with other advanced and emerging geographies can address amplified approval timelines for drugs and clinical trials, allowing for a greater commitment to innovation and the rapid delivery of newer therapies to patients. This momentum must be retained to improve patient access to cutting-edge treatments. The goal of such harmonization is to make better use of human, animal, and material resources, and to eliminate unnecessary delays in the global development and availability of new medicines while maintaining quality safeguards. This report is the result of a productive scientific dialogue between Indian regulatory authorities, academia, subject matter experts, and the industry to facilitate the adoption of multiregional clinical research and drug development approaches and potentially align current practices with internationally accepted principles.

## ADVANTAGES OF INDIA

India has 20% of the global disease burden—hence we would have an advantage of getting early access to drugs. But to ensure that, there must be buy-in from people for drugs, regulatory hurdles and cost hurdles must be cleared and doctors need to be trained enough to use those drugs. Designer drugs need to be used carefully and companion drugs must be studied. With rapidly evolving scientific knowledge, we need to have a good regulatory framework, so that India can sustainably use the knowledge and make it available to the patients.

## LEVERAGING MRCT

India needs to harp on the MRCT that is taking place, such as utilizing targeted therapies. We need to have a mechanism in place by which we can figure out unusual toxicities. Post-marketing surveillance mechanisms could be better, and digitization could be helpful with the government's digital approach contributing immensely to this regard. We need to get our physicians, scientists, and researchers to understand this better so that our patients utilize these MRCTs better to the optimum levels.

## BUILDING COMMON UNDERSTANDING

A common understanding of how we harmonize the regulatory approvals when we have such a diverse population is important. The commonalities in treatment processes, assessment processes, and also reporting processes must be identified. Pharmacovigilance is included very clearly in the NDCT rules, and the tools are being used for different types of approvals. Structured post-marketing surveillance with the support of different stakeholders is needed.



# KEYNOTE ADDRESS

## Preparedness to address the current and emerging healthcare challenges in India

**Dr. Randeep Guleria,**
Director, All India Institute of Medical Sciences, New Delhi

**Learning from the pandemic**

It is important to develop strategies to address future outbreaks and improve our healthcare system based on the lessons from the pandemic, which has demonstrated the vulnerabilities present in the healthcare systems across the world. There is no going back to the pre-pandemic healthcare system. In India, the public healthcare system has focused on primary healthcare delivery, community-level programs, and decentralized programs for a wide reach. Most in-patient care has come from the private healthcare system which predominantly focused on Tier 1 & 2 cities as the system isn't too developed in smaller cities. The challenges we have identified are lack of awareness of public health, lack of access due to geographical inequalities, and affordability along with the limited human resource. Private hospitals & labs also observed a decline due to delays; surgeries were postponed, and revenues declined. Basic healthcare was disrupted such as routine childhood immunization, non-COVID/nonessential emergencies, and limited funds along with minimal infrastructure

**Overhauling the healthcare system to 'One Health'**

Based on these learnings, we must have an action plan in place and do an overhaul of our healthcare system. With more urbanization, connectivity & travel, we have seen quite a few outbreaks and a rise in infections in the past. Viruses are now jumping species and are now compatible with human-to-human spread; to curb this and develop appropriate strategies, we need a holistic plan to achieve 'One Health' that includes the health of human beings, animals as well as our environment. The action points are to increase public health awareness, upgrade manpower and medical infrastructure, especially in smaller cities, in addition to promoting telemedicine to improve preventive health, develop strategies for pandemic preparedness, and have provisions for the early development of drugs and vaccines.

**Health policies beyond COVID-19**

In terms of support, the Indian government is ensuring an increase in hospital beds per 1000 population. More government medical colleges are being started in unserved areas, and more hospital chains are being encouraged to open centers in tier 2 & 3 areas. A robust health insurance scheme and awareness is also a priority for the entire population to reduce OOP expenses. Along with Ayushman Bharat Scheme (PMJAY scheme), we must look at more inclusive schemes that cover a wider population. During the pandemic, the major focus was given to the usage of technology through CO-WIN and Aarogya Setu. However, technology is still underutilized and requires a massive push. As we move ahead, some additional challenges to be addressed are surveillance systems, laboratories with biosafety facilities, training of public health officials, and existing public health framework and research capacity to quickly develop medicines and vaccines. Applied research must be strengthened for broad-spectrum therapeutics against zoonotic pathogens. Collaboration between academic institutions, industry, and govt must move swiftly during an outbreak phase. We must continue to brainstorm on health policies beyond COVID-19 and a significant change is required to deliver effective and affordable healthcare to all.

## R&D (Innovation) the key determinant to address current and emerging healthcare challenges

**Dr. Renu Swarup**
Former Secretary, Department of Biotechnology, Ministry of Science & Technology, Government of India

**Focus on the 3Cs**

COVID-19 bought a global focus on SNT and its role in bringing out solutions that tackled the pandemic. Continuous R&D is imperative and provides a flow of knowledge; this involves cutting-edge technology for developments that make solutions and treatments more affordable and accessible. The three key pillars or 3 C's to be focused on are capacity building of human resources and infrastructure, focus on cutting-edge technologies, and collaboration

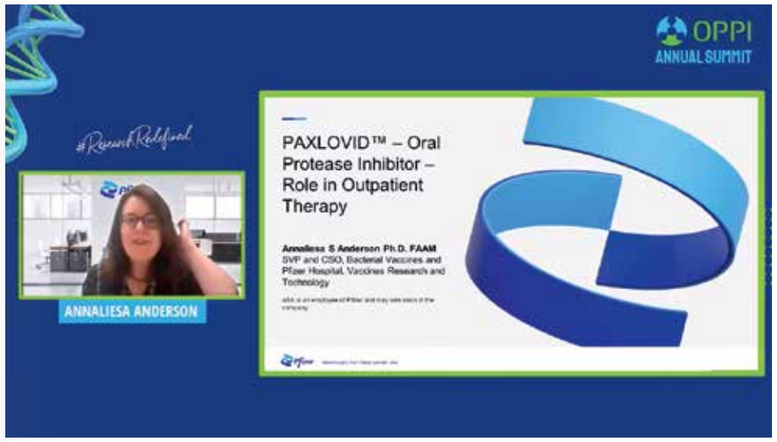
**Accelerate collaboration**

Collaboration is most crucial, covering academia, industry, start-ups, investors, regulators, and policymakers for better healthcare delivery. International collaboration is equally important as the key emphasis is on sharing knowledge and data and bringing together best practices to address the global healthcare challenges. India must keep the momentum going and the capacity is sustained and is moved ahead for other health priorities. We should not lose sight of manufacturing and must look at innovative ways to promote it. Our ecosystem is future-ready, we should find innovative models to scale it up and sustain it to meet the needs and requirements.



## Project Lightspeed: COVID-19 and beyond

**Rod Mackenzie**
EVP and Chief Development Officer, Pfizer




**Dr. Annaliesa S. Anderson**
Ph.D., FAAM,
Senior Vice President & Chief Scientific Officer, Bacterial Vaccines & Hospital, Pfizer Inc.

**Accelerating investments**

Through Project LightSpeed, Pfizer has been able to secure EUA for its Covid vaccines. In a similarly accelerated timeline, Pfizer designed and secured approvals in 17 months. This has enabled Pfizer to understand COVID is a catalyst for change and such innovations ought to be extended to non-COVID ailments such as cancer and rare diseases. It is important to accelerate breakthrough investments for all patients by building a digitally resilient clinical trial system and ensuring robust and transparent dialogue.

**A thriving ecosystem for R&D**

India's thriving R&D ecosystem will play a crucial role in shaping the future of the industry. Pfizer's global Innovation Centre in Chennai houses more than 650 researchers and clinicians in breakthrough innovations for global product development. By applying the lessons through the pandemic, the nation can emerge stronger, be more innovative, and be patient-centric to support the scientific breakthroughs of tomorrow.

# Accelerating bio-pharma R&D journey in India

**Prof. K. VijayRaghavan**
Principal Scientific Advisor,
Government of India

**Key takeaways from the pandemic**

Our learnings from the pandemic are important in driving the healthcare system and pharmaceutical industry forward globally and in India. The current situation showcases those efforts need to be scaled up.  More accessibility is important for people across all countries. The pandemic has shown us how to relook at different issues in the biopharma industry. While the pharma sector is growing and we applaud India's efforts in containing the pandemic, we also need to be vigilant of the fact that several viruses, unknown to mankind are around us, and pose a severe threat to our healthcare systems. Public health is of importance right now and we need to move into a collaborative model with developing and developed societies to work hand in hand. Financial and research investments are needed right now which will enable us to solve the impending health crisis in the pharma sector. With the right kind of sciences, finances, collaborations, and strategy, businesses will come together and address all future health problems efficiently.

**Understanding the components of the pandemic**

3 essential components stood out during the pandemic and going forward we should imbibe our learnings from these components to devise strategies that will enable us to manage future pandemics better.

1. **Public Health Sector & Capacity Building:** We need to shift our focus on important matters like understanding the needs of the public and looking to analyze health issues of the public. All societies have large investments in public health, what we need to understand is, are these structures resilient to the sudden surge of diseases? What is the surge capacity for us to deal with future pandemics? Lateral movement of resources from other sectors to the public health sector is imperative for us to improve our surge capacities and respond well to a particular situation.
2. **Vaccine research & development:** Non-pharmaceutical interventions need to be scaled up to protect people and healthcare workers from all kinds of occupational hazards that are present. Deployment of pharmaceutical and non-pharmacological resources should be a routine task for us going forward. Better structural planning and management of diseases are needed to build capacity, speedy responses, and resilience across the world. We need to enquire that is it worthwhile for companies to prepare vaccines for diseases and epidemics that haven't been discovered yet. Strategic global partnerships are required to understand how we can work together for making vaccines, past phase 1, and go into the clinical developments.
3. **Drug & Biologics Development:** Our regulatory processes need to be examined, after the pandemic wanes, we should have a steady and concise overarching pandemic understanding that equitable access to drugs and vaccines is present for all across nations. Understanding the mechanisms of viruses is important to developing drugs, and hence broadening financial investments is crucial for us across the pharma sector so that drug discovery is enhanced by a regulated approach by pharma companies. Speedy diagnosis and testing needed to be scaled up—so that we can develop personalized medicine at the earliest



# PANEL DISCUSSIONS

## New Frontiers in Vaccines and Drug Discovery

**PARTICIPANTS**

**Dr. Johanna Bendell**
Global Head of Pharma Research and Early Development, Oncology, Roche

**Dr. Darryl B. McConnell**
Senior Vice President, Research Site Head, Boehringer-Ingelheim Regional Centre Vienna, Austria

**Dr. Raman Rao**
Chief Executive Officer, Hilleman Laboratories

**Klaus Urbahns**
Global Head of Discovery and Development Technologies, EMD Serono, Inc.

**Inge Lefevre**
VP, Head Development, Vaccine Business Unit, Takeda

**Dr. Shoibal Mukherjee**
MD, DM, Sr. Consultant, Clinical Pharmacology & Drug Development

**ROLE OF MANUFACTURING TECHNOLOGIES**

Continuous manufacturing technologies, especially in the case of vaccines and biologics, can have a huge role in having an impact on development, commercialization, timelines, and a positive impact on the supply chain. To get new vaccines to patients it is important to modulate the risk and approach and accelerate investment by multiple stakeholders. Time is of the essence in achieving the new frontiers, and government, public health authorities, and academia must work together to identify the right solutions. Building a strong healthcare infrastructure, supported by investments and policy reforms, will promote cross-sector collaboration.

**UNDERSTANDING THE NEW FRONTIERS**

Following the COVID-19 pandemic, there are new opportunities to accelerate the pharma and drug sector.  The 'small molecule area' is gaining importance as formerly non-druggable target receptors are being drugged using more inventive and innovative methods. When PROTACs first came out, they could be applied to everything, except for CNS diseases. Now with innovation and research, they are also used to treat CNS diseases. New forms of vaccine therapies – such as mRNA vaccine – must be stimulated; there is also ongoing research to identify antibodies for targeted chemotherapies. Bio-specific technology has a lot of potential and could address cancer-targeted T-cells in hematologic malignancies.

# Economic and Health footprint of the Global Pharmaceutical Industry in India

## PARTICIPANTS

**Amit Mookim**
Global Managing Director – IQVIA South Asia

**Manoj Saxena**
Managing Director, Bayer Zydus Pharma and Country Division Head, South Asia – Pharmaceuticals

**V. Simpson Emmanuel**
Managing Director & CEO, Roche Products (India) Pvt. Ltd.

**Vikrant Shrotriya**
Managing Director and Corporate Vice President, Novo Nordisk India Pvt. Ltd.

**Sai Sethuraman**
Head R&D – Parenteral Products Development, Pfizer Ltd.

**Gagan Singh**
Country President, and Managing Director, AstraZeneca Pharma India Limited

## GROWTH OF PHARMA IN INDIA

It is important to understand the evolution of the life sciences industry and individual contributions. Today, pharma is one of the fastest-growing sectors with a current value of over INR 185,000 crores with MNCs playing a key role in driving innovative therapies and R&D. India is one of the fastest-growing markets in the world, recording consistent double-digit growth and underpinned by a retail-driven market that signifies that there is potential to spur institutional growth.

The therapies driving the growth are anti-diabetic, cardiac, and respiratory. The industry landscape today comprises 600 companies (45 MNCS), more than 50k brands and 80k SKUs with 4800 new products launched every year. We are at the cusp of growth and require innovation to ensure accelerated growth.

## ADDRESSING AFFORDABILITY

One of the biggest issues India faces is affordability, and partnerships between India and MNCs are crucial in addressing it. Today one-third of global launches are happening in India; the time frame has decreased to less than a year. Companies are spending extensively on R&D with over 400 global clinical trials with Indian patients, registered in the past 5 years. More MNCs are accelerating launches in India so Indian patients get immediate access to crucial medicines. India majorly contributes participants to clinical trials in addition to being fertile ground for the ecosystem-building activities which are ongoing. Many MNCs are strengthening their level of engagement with start-ups in India, helping address affordability and accessibility.



## THE IMPACT OF INNOVATION

India continues to play a critical role in terms of innovation, especially in custom synthesis. Talent acquisition has also diversified to be on par with global standards, backed by talent nurturing. India will continue to remain a fertile ground for immense growth – while there are some aspects, needed, such as incentivizing innovation which will enable the shift from the pharma hub to the innovation hub. It is also important to partner with academia as well as government organizations to spur innovation. Manufacturing has made a big splash in the past, but the future lies in R&D and innovation. Leveraging machine learning, artificial intelligence, and digital capabilities will lend a paradigm shift to the pharma industry. There is a lot of room for improvement in strengthening the ecosystem infrastructure, which will require PPPs to drive the scope and increase access.

# Leveraging Data as the future of R&D

## PARTICIPANTS

**Sanjay Jaiswal**
Managing Director
at Accenture

**Dr. Geetha Manjunath**
Founder, CEO, and CTO,
Niramai Health Analytix

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Global Head – Clinical Data Sciences and Analytics, Bayer

**Prof. Balaraman Ravindran**
Heads the Robert Bosch Centre for Data Science & Artificial Intelligence (RBCDSAI), IIT Madras

**Ms. Srividhya**
Assistant Vice President, Sector Head-Pharmaceuticals and Biotechnology, Invest India

**Dr. Vijay Chandru**
Commissioner at Lancet Citizen's Commission, Founder and Chairman, Strand Life Sciences, Professor Indian Institute of Science (IISc), Bengaluru

**Nicole Van Poppel**
Accenture's Global Life Sciences R&D Data-led Transformation Lead | Managing Director, Accenture Strategy - Life Sciences

## CHALLENGES RELATED TO DATA IN THE PHARMA INDUSTRY

Getting access to data is of significant importance for us right now, we are facing some challenges in the pharmaceutical industry, which are related to findable, accessible, interoperable, and reliable data for all of us here in this industry. Medical devices are also facing some huge challenges regarding accessing reliable data which is imperative for our growth as an industry. Medical devices crunch data, only for the ones that are available, we need structures in place for novel data analysis to make sure that innovative solutions are coming in place for unique data available. Screening devices, depend on having a large cohort of the population, and here is where machine learning comes in. Scaling up regulatory reforms and other compliance rules is required so that a uniform approach is put in force for the usage of medical devices across all countries. Optimizing data across different silos of the pharma industry is important now so that we have a unified approach since everything is interwoven and interconnected in this industry. Data-driven approaches for uniting data across sectors are important.



**Current Data-Driven Strategies in Healthcare**

Data is going to drive the new wave of innovations in India. Policy related to data is also important for us, the government is also focusing on these approaches. Two draft policies have been released by the government, which will help us scale up developing innovative products that will be conducive to optimizing processes related to data and move into a more tech-supported interface that will interact with the data available and other regulations in place. Data analysis and data management is an interdisciplinary field that has people from multiple fields come together and collaborate and partner with one another generating great results in the healthcare and pharma industry.

**Critical Success Factors for Using Data in R&D**

There is an inherent need for upskilling and training people, researchers, and scientists on data analysis and data interpretation. Training people and employees to analyze data and use it operatively in their day-to-day work processes will help us in creating error-free sets of results which is necessary for us as an industry. Lots of advancements are also underway in the policy perspective for collaborating with policymakers, data analysts, and researchers to ensure that the final data-related matter we have as a sector is fool-proof and compiled using a data-driven approach.

# Disruptions & Digitization Trends in Clinical Research

**KEYNOTE ADDRESS**

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Global Head of Clinical Development and Operations, Bayer

**PARTICIPANTS**

**Kailash Swarna**
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**Dr. Ogata Akiko**
Division Director, Division of Training Center Management, Division of Asia I, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

**Dr. Vijay Prabhakar**
Head, Therapeutic Area, Clinical Development & Operations, Boehringer Ingelheim

**Prof. Y. K. Gupta**
President AIIMS Bhopal & AIIMS Jammu, Former Dean and Head of Pharmacology, AIIMS, New Delhi

**Dr. Rominder Singh**
Head of Asia Region Global Regulatory Affairs, Pfizer Inc.

**Dr. Sanish Davis**
R&D Director, GCO India, Johnson & Johnson; President, Indian Society for Clinical Research (ISCR)

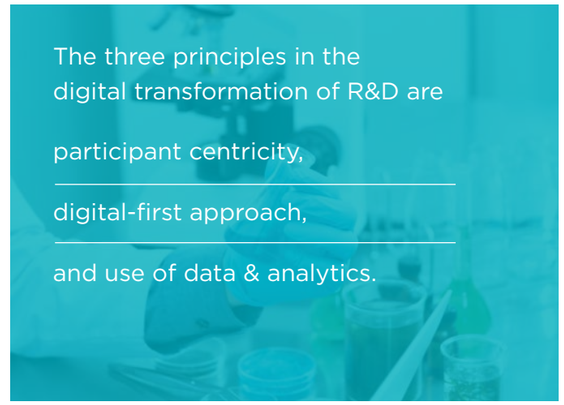


**INNOVATION TO REACH ALL**

We are working in a way that our innovation reaches all, and we achieve the highest level of quality. We must ensure that we create a landscape that enables us to use different technologies together and utilize the newest technology at our disposal. To use advanced analytics and insights, we must ensure that we have the right platforms in place that can process and store the casting quantity of data to ingest and analyse. Decentralized clinical trials will make it easier for patients to participate; the idea of DCT is to successfully collect data and modernize the conduct of trials. However, there is still scepticism about the process and the data collected via it. Metadata-driven automation increases the efficiency of running DCT. The importance of real-world evidence will increase to generate data and will be relied upon for making regulatory and safety decisions.

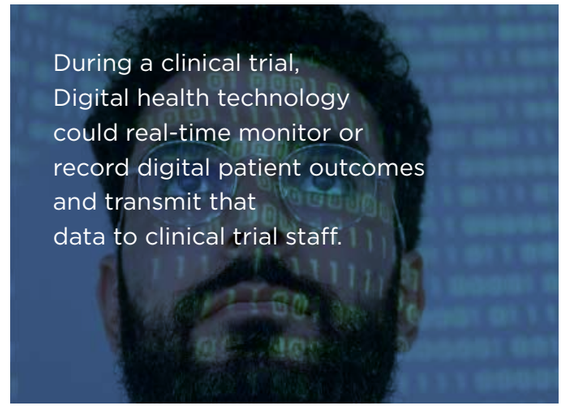
**The need to transform R&D**

We can transform R&D to deliver three factors: lower cost, faster pace, and accessibility. Participation in clinical trials is lower comparatively due to lower recruitment, poor engagement and retention, and high costs. COVID-19 has underlined the need to reach out to patients for clinical trial programs and technology played a key role in it. The three principles in the digital transformation of R&D are participant centricity, digital-first approach, and use of data & analytics. There is a wide scope in AI and the use of radionics is still untapped.




**Challenges in accessing data**

During a clinical trial, digital health technology could real-time monitor or record digital patient outcomes and transmit that data to clinical trial staff. But it is important to assess if the technology being used is fit for the purpose or if it is reliable and if it will provide valid data. There is also a risk of cybersecurity. Today, access to great-quality data is a challenge in India, and it must be addressed. Collaboration ensures that patients get what they want by participating in clinical trials and makes them feel valued – this builds the clinical research ecosystem stronger and in a better way.



# FIRESIDE CHAT

## Data driven Healthcare in India

**Dr. Ram Sewak Sharma**
Chief Executive Officer, National Health Authority, Ministry of Health & Family Welfare, Government of India

**Rama Vedashree**
Chief Executive Officer,
Data Security Council of India (DSCI)

**Challenges in curating data**

Data on its own is a latent potential power source. It must be curated & cleaned up to drive the right insights. The data is not just from historical clinical trials but also from other sources in the industry. As we break down the silos & create public-private partnerships and bring intellectual forces together, we get to the final frontier, making the discovery process faster. One of the biggest challenges that we face when talking about data insights is first accessing data in a format where we can ingest, understand, and process the data to derive insight.

**Curate data for context**

Curated datasets provide greater value as they can be contextualized. When building predictive models for retinopathy of prematurity, different factors affect the models when using Indian data as compared to global data. One of the key pillars is process optimization. When we talk about putting data together with regulatory boards, there need to be common pathways to share information.

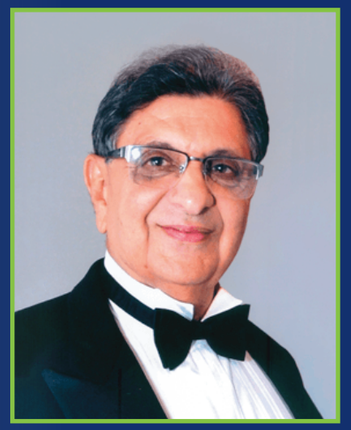
**Building a robust data pipeline**

We have begun creating a huge, interoperable system, based on architectures such as the federated data structure. What we aim to build is a robust pipeline. We aim to create a unified health interface that will help systems that currently remain in silos to connect and communicate with each other through well-defined APIs.



# AWARDS & RECOGNITIONS FOR 2021

## OPPI Lifetime Achievement Award



**DR. CYRUS S POONAWALLA**

The OPPI Summit also made headlines through the awards and recognitions announced during the event.
**Dr. Cyrus S Poonawalla, Chairman and Managing Director of Serum Institute of India Pvt. Ltd.** was conferred the OPPI Lifetime Achievement Award 2021 for his relentless efforts and contributions to India and across the world supplying vaccines made in India during the COVID19 pandemic.

# OPPI Special Recognition Awards

### DR. RANDEEP GULERIA

The OPPI Special Recognition Award was presented to Dr. Randeep Guleria, Director, All India Institute of Medical Sciences, New Delhi, for his outstanding contributions.

### INDIA MEDICAL ASSOCIATION


OPPI's Special Recognition Award was conferred on the India Medical Association for their research and achievements in the field of medical and scientific breakthroughs that shine a light on India's developing medical sector.

# OPPI Scientist Awards


### Woman Scientist of the Year

**Dr. Parul Ganju**
Co-founder and CEO,
Ahammune Biosciences Pvt. Ltd.

**On screen**
1. Prof. K. VijayRaghavan, Principal Scientific Advisor, Government of India
2. S. Sridhar, President, OPPI and Managing Director, Pfizer Ltd.
3. Anandram Narasimhan, Managing Director, Merck Specialities Pvt. Ltd.
4. Dr. Parul Ganju, Co-founder and CEO, Ahammune Biosciences Pvt. Ltd.



**Dr. Bushra Ateeq**
Associate Professor,
Department of Biological Sciences and Bioengineering,
Indian Institute of Technology, Kanpur

**On screen**
1. Prof. K. VijayRaghavan, Principal Scientific Advisor, Government of India
2. S. Sridhar, President, OPPI and Managing Director, Pfizer Ltd.
3. Dr. Bushra Ateeq, Associate Professor, Department of Biological Sciences and Bioengineering, Indian Institute of Technology Kanpur

### Young Scientist of the Year

**Dr. Chandra M. R. Volla**
Associate Professor,
Department of Chemistry,
Indian Institute of Technology Bombay

**On screen**
1. Prof. K. VijayRaghavan, Principal Scientific Advisor, Government of India
2. S. Sridhar, President, OPPI and Managing Director, Pfizer Ltd.
3. Ms Kalpana Umakanth, Group director finance, Apeejay stya , Svran group
4. Dr. Chandra M. R. Volla, Associate Professor, Department of Chemistry, Indian Institute of Technology Bombay

# OPPI Excellence in Innovation Award

**Briota Technologies Pvt. Ltd.**

The pandemic brought out the true mettle of healthcare provision in India as lockdowns across the nation meant low to zero access to healthcare products, services, and medicines. Organizations have been challenged to come up with durable solutions to deliver healthcare to a diverse country like India. And it is commendable to see the increasing entrepreneurial spirit displayed by these start-ups to have risen to the occasion in such a compelling environment.

Furthering its commitment to pushing the country's agenda on equitable access to healthcare, OPPI wishes to applaud the efforts of entrepreneurs with its **Excellence in Innovation Health care Start-up of the Year award**.

This award will recognize the innovative mindset and digital, social focus to increase the healthcare outreach OPPI aprograms and amplify the access to healthcare products, services, and life-saving medicines.
nnounced the winner of the Excellence in Innovation Healthcare Start-up of the Year 2021 Award at the Summit. This year, Briota Technologies Pvt Ltd, a digital health and wellness company, innovating for remote care, diagnostics, and management of chronic respiratory conditions has been conferred the award for developing a novel chewable gel for autistic children.


**On screen**
1. Manoj Saxena, Managing Director, Bayer Zydus Pharma and Country Division Head, South Asia – Pharmaceuticals
2. Shardul Joshi, Cofounder, Briota Technologies Private Limited
3. Aditi Pais, CEO, Briota Technologies Private Limited
4. Gajanan Sakhare, Founder, Briota Technologies Private Limited



# OPPI-QCI Quality Award For Excellent Facility

The Award is instituted jointly by OPPI and the Quality Council of India (QCI) to recognize pharmaceutical facilities excelling in quality manufacturing processes. OPPI and QCI announced the launch of a national award to celebrate excellence in manufacturing processes in the pharmaceutical sector in the country.

The award is launched to help meet the country's agenda of increased manufacturing of pharmaceutical products with high quality at Indian facilities, meeting global manufacturing standards. This award highlights the importance of setting and adopting best-in-class global quality standards in the pharmaceutical industry, keeping patient safety at the core. There has been growing awareness of improving and scaling up quality standards for manufacturing facilities in the country.


**On screen**
1. Suresh Pattathil, General Manager & Managing Director, Allergan India Private Ltd. (an AbbVie Company)
2. Champak Kumar Biswas, CEO, NBQP
3. Mohan H Bhandari, Chairman & Managing Director, Bilcare Limited
4. Dr. Firdosh S Gardin, Head – External Supply Operations APMA Novartis
5. Adil Zainulbhai, Chairman, Quality Council of India (QCI)

## Large Pharma Companies

**Medreich Limited (a Meiji Group Company), Unit 7 facility located in Bangalore**

**On screen**

1. Suresh Pattathil, General Manager & Managing Director, Allergan India Private Ltd. (an AbbVie Company)
2. Champak Kumar Biswas, CEO, NBQP
3. Mohan H Bhandari, Chairman & Managing Director, Bilcare Limited
4. Dr. Firdosh S Gardin, Head – External Supply Operations APMA Novartis
5. Adil Zainulbhai, Chairman, Quality Council of India (QCI)
6. Mr. Y.A. Chowdary, Chief Operating Officer, Medreich Limited (a Meiji Group Company)
7. Mr. Pankaj Garg, Managing Director, Medreich Limited (a Meiji Group Company)
8. Mr. G.Subramaniam, Executive Vice President, Medreich Limited (a Meiji Group Company)

## Micro, Small and Medium Enterprises (MSME)

**Winner: Galentic Pharma, Manufacturing unit 2 located at Gandhi Dham, Gujarat**

**On screen**

1. Suresh Pattathil, General Manager & Managing Director, Allergan India Private Ltd. (an AbbVie Company)
2. Adil Zainulbhai, Chairman, Quality Council of India (QCI)
3. Bhupendra Sangani, Managing Director, Galentic Pharma
4. Hemang Vohra, Director, Galentic Pharma
5. Jay Mehta, Director, Galentic Pharma



# SUMMARY

The 2-day OPPI Virtual Annual Summit 2022 shed light on the changing frontiers of healthcare research in a dynamic and digitized world and how they have been the guiding principles of the industry over the past two years. The summit shared insights on the research, development, and innovation spurring across the pharmaceutical industry in the country. The panelists, participants, and speakers shared their thoughts on how India can accelerate the ongoing momentum toward building a pharmaceutical research hub. Having said that it is the need of the hour to take the learnings and insights from the Summit and utilize it with on-ground practical implementation to ensure that India is future-ready to deal with any other pandemics.

Research being an indispensable element for resolving public health challenges, the industry, in close collaboration with the Government, can not only make but also discover and innovate in India. OPPI will continue its advocacy in this direction and cement its partnership with the government to ensure that India is one of the key pharmaceutical players in the world.

***- Asawari Sathaye, Director Communications and Patient Advocacy, OPPI***

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**Organisation of Pharmaceutical Producers of India**

Peninsula Chambers, Ground Floor, Peninsula Corporate Park, Ganpatrao Kadam Marg,

Lower Parel, Mumbai 400 013.