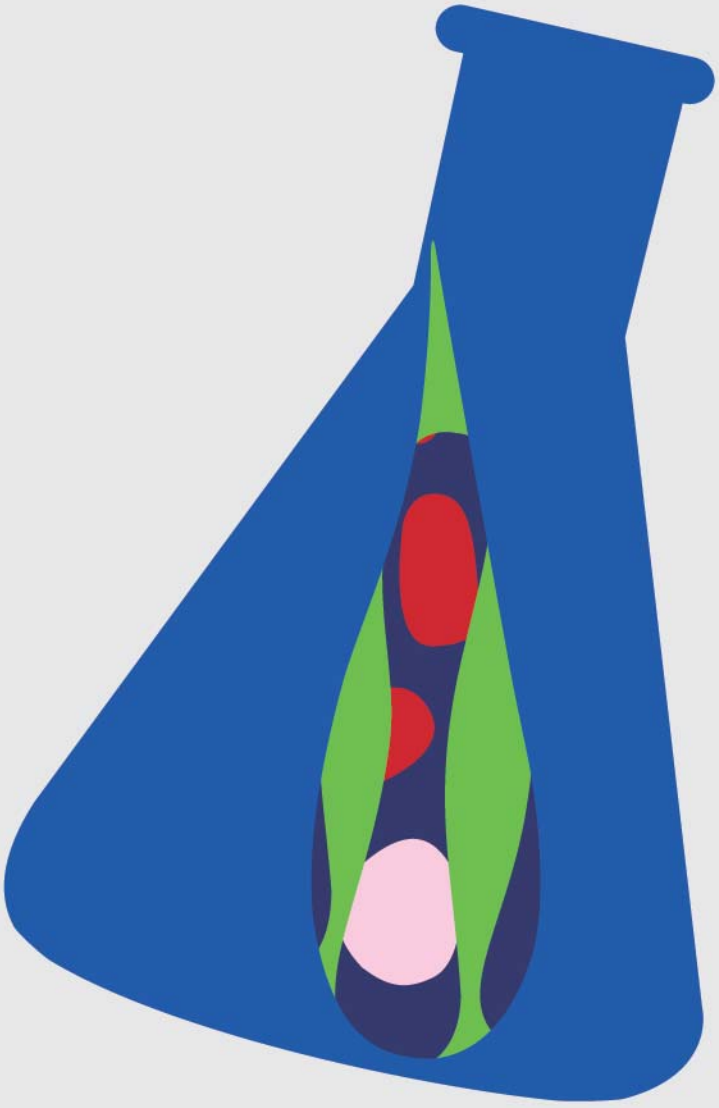
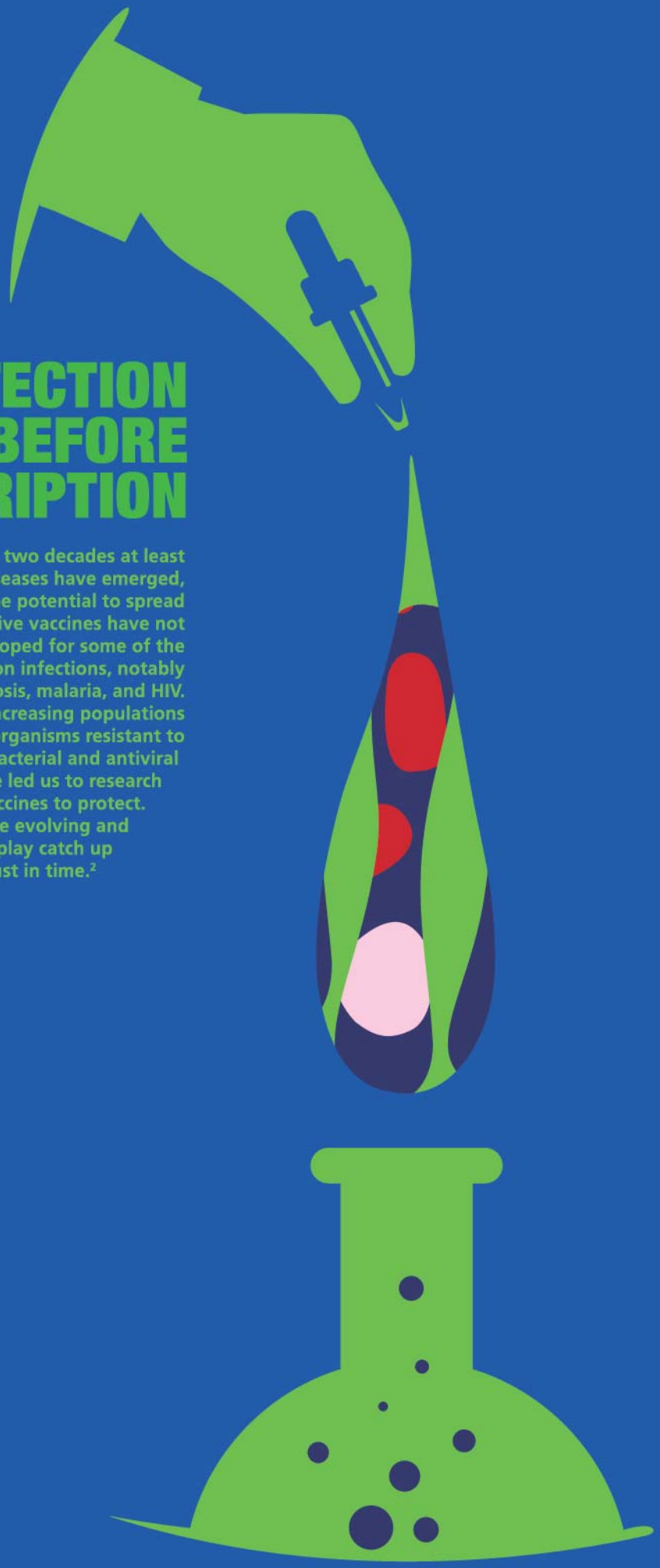
OPPI



IN SCIENCE WE TRUST

PROTECTION BEFORE PRESCRIPTION

Over the past two decades at least 30 new diseases have emerged, many with the potential to spread rapidly.[1] Effective vaccines have not yet been developed for some of the most common infections, notably tuberculosis, malaria, and HIV. Rapidly increasing populations of organisms resistant to antibacterial and antiviral agents, have led us to research for newer vaccines to protect. Infections are evolving and we need to play catch up soon and just in time.[2]



SEEK AND DISCOVER

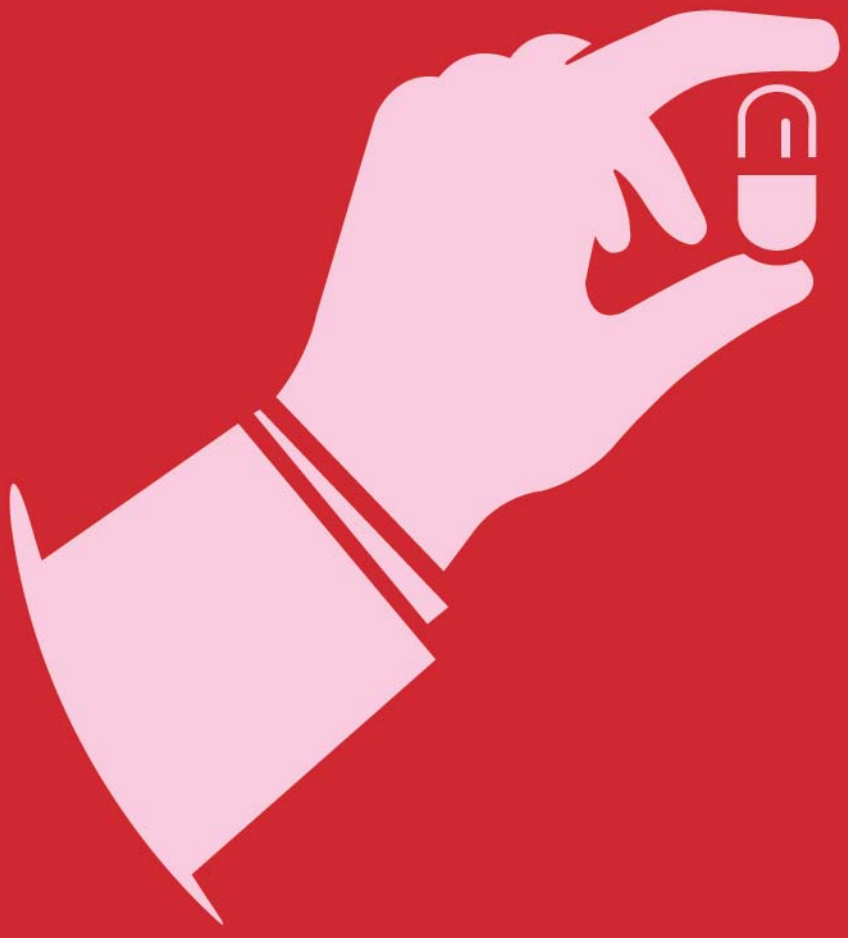
Drug discovery is a journey of time, money and passion to innovate. For example, even though the pharmaceutical industry spends around $33 Billion, only 35 new compounds were registered with the Food and Drug Administration in 2003.[3] Despite considerable progress made with the new molecular targeted therapies, the therapeutic options are still limited and the process of bringing a new drug to patients is still frustratingly slow with high failure rates- a problem often referred to as the "Valley of Death" - the chism between basic research and new drug approval.[4]

TRUTH LIES IN TRIALS

Clinical trials are integral in advancing research and in providing patients with new treatment options and reducing the disease burden, globally. The benefits of clinical trials stretch far beyond each patient, providing knowledge and insights that can lead to the next breakthrough.[5]

PATIENTS DESERVE GOOD QUALITY

Good manufacturing practices, good distribution practices, good storage practices and good quality control practices make for a "good" pill. Hence, millions of people all over the world are alive and in good health today because they have trusted the pill to do its job.[6]



TODAY'S INNOVATION IS TOMORROW'S MEDICINE

Cures don't appear on a schedule. In search of the unknowable, in search of curing the incurable, there is no one map, no singular template, no predictable milestones. Finding lifesaving medicines is the life's work of thousands of researchers who never say never. It's also the work of millions of patients who fight side by side with researchers in the battle for life. The lifeblood of health is research and discovery (R&D).[7]

REFERENCES

1. Cash RA, Narasimhan V. Impediments to global surveillance of infectious diseases: consequences of open reporting in a global economy. Bulletin of the World Health Organization. 2000;78:1358-67.
2. Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, Jha P, Mills A, Musgrove P, editors. Disease control priorities in developing countries. The World Bank; 2006 Apr; 2.
3. Spedding M. New directions for drug discovery. Dialogues in clinical neuroscience. 2006 Sep; 8(3):295.
4. Hoelder S, Clarke PA, Workman P. Discovery of small molecule cancer drugs: successes, challenges and opportunities. Molecular oncology. 2012 Apr; 1;6(2):155-76.
5. http://innovation.org/about-us/commitment/clinical-trials/florida-clinical-trials
6. https://www.indiaoppi.com/sites/default/files/PDF%20files/OPPI%20Quality%20Summit%20Web.pdf
7. http://innovation.org/index.php/about-us/commitment/research-discovery/our-co

INDEX

FOREWORD

"…Science by itself cannot advocate courses of human action, but it can certainly illuminate the possible consequences of alternative courses of action."

The Demon-Haunted World: Science as a Candle in the Dark by Carl Sagan

The 20th century witnessed unprecedented achievements in science and technology that radically reshaped society; the taming of the atom, the unraveling of the genome, and the digital interconnection of the world have shaped the New World Order. Interactions between nations and humans have increased manifold. All this has much to do with the scientific and technological advances that have fueled healthier ways of living and smarter ways of doing business.

The true power of science lies not in feeding into the simplistic solutions and established beliefs that prevail, but in the search for answers and methodical verifications that challenge these beliefs. We live in an age in which the power of science becomes evident every day. Economic benefits of scientific research are progressive and outlives the discovery driven by curiosity. The need to build a scientific temper across the globe has now gained wide recognition. There is no doubt that science is an enabler for social change and serves as a framework for civilizational advancement.

Science today has so many potential applications to public health and medicine. The advancements in medicine and public health have doubtlessly contributed to an increase in the life expectancy and better quality of life. Research in medicine does not end with one discovery; it is a series of continuous efforts to better outcomes for patients and simplify treatment regimens. While no one can predict with any certainty what the most successful inventions and technologies of the future will be, artificial pancreas to help patients with diabetes, pacemaker for sleep apnea, gene therapy for blindness, appear to be some that the future promises to deliver.

These remarkable scientific advancements are due, in part, to thoughtful public policies that promote innovation and discovery. These policies support the tireless efforts of real heroes wearing white lab coats and working tirelessly towards developing new therapies that can bring hope and, in some cases, cures to improve lives.

Addressing the world's health challenges requires international collaboration. Governments who recognize the dependence of the development of successful novel technologies on broadly supported basic research are more likely to be healthier and economically prosperous in the future.

A.VAIDHEESH
President- OPPI
Vice President- South Asia &
Managing Director, India
Glaxo SmithKline Pharmaceuticals Ltd

KANCHANA TK
Director General- OPPI

Collaborative partnerships between Government, research institutions, the industry, and Academia will continue to drive the scientific temperament that is so required for mankind.

India's participation in the new international economical conjuncture depends on both impetus given to technological and scientific innovation and an enabling policy environment that encourages competitiveness. The challenge for the construction of a new India lies thus in recognising the importance of science and research in its new competitive context.

"Everything that is not forbidden by the laws of nature is achievable, given the right knowledge"- David Deutsch

Knowledge consists in the search for truth… **In Science we Trust.**

IMPROVING HEALTH OUTCOMES IN INDIA: HOW CAN TECHNOLOGY CONTRIBUTE?

Dr. Y. K. Gupta, AIIMS

What is the importance of having robust data to alleviate disease burden in India?

For accurate health planning and strategising in India, data plays a crucial role. Unfortunately, in a country like ours, we still lack the data on several diseases; the extent of the disease burden in the country and more importantly data on drug-related adverse reactions.

In the absence of a national Pharmacovigilance Program of India (PvPI), and under-reporting by majority of the doctors and the paramedics, our decision to ban or to change the indication or precautions advised on drugs, is based largely on the adverse event profile of the drugs that occur outside India.

Here, the role of a robust system of pharmacovigilance, thorough reporting by stakeholders, data collation and analysis is imperative as the decision for Indian population will then be based on data relevant to our country. For this, we need to focus on three aspects:

Understand the need: All the stakeholders including public, paramedics, doctors, regulators and pharmaceutical companies should understand the need and importance of reporting Adverse Drug Reactions (ADRs).

Create awareness: There is need to create awareness that reporting ADRs does not amount to negligence, rather this is academic advancement, academic credit or professional ethics of the practitioner.

Use of technology for reporting: Technology plays a huge role here and could be used to design and customise apps for patients, doctors or any other concerned stakeholder to immediately report the ADRs. This can be compiled at national registry system.

Currently there is no national registry for cancer, diabetes or hypertension. There is a lack of data on non-communicable diseases. This makes it difficult for early stage diagnostics and prevention. With credible data, we could develop algorithms and predictive technology can help with a degree of certainty on the risk factors and therefore the precautions to be taken at the early stages to prevent a full-blown disease condition.

There is a need to create a robust data base for disease conditions which may not have high prevalence rates at present. Developing early diagnostic technology in this area is equally vital. Here I would like to highlight pregnancy related or drug related complications in child birth-teratogenicity. This is such an important area and can be easily done. There are many children born with deformity or mental disability partly because of drug intake during pregnancy. Data in this area will help to create an important predictive support for mother and child healthcare system and help India address its millennium development goals by reducing mortality rates in both mother and child.

What do you see as areas that can help alleviate the growing disease burden in India?

Role of Technology:
Nano Technology is the new area of Drug Development/Drug delivery System. This will be useful for diagnostics, and for the treatment of diseases like cancer and TB. Because penetrability of these drugs, regulation and predictive toxicology of nano pharma and capacity building are areas that need to be scrutinized. Government has been investing in this technology as it comes with several benefits for alleviating diseases in India.

Health Technology in health science will play a major role in next 20 years. For example, the need of the hour is to harness technology and use it to detect diseases at early stages: Imagine a kit or a system or a device which can detect cervical cancer at early stage in villages, or that can detect the early incidence of eye diseases within rural population, at their doorstep or that which can detect MDR-tuberculosis or that which can detect, malaria; dengue; chikungunya at a point of care at an affordable cost.
I am proud to say that India is now a breeding ground for many health tech and start-ups. The government is encouraging such start-ups and they have been graciously funded by

institutions such as BIRAC to help bring these technologies alive to achieve the healthcare needs of the country.

Role of Innovation: From Generic producers to New Drug contributors

Vaccines

I would like to state the importance of early introduction of vaccines for vaccine preventable diseases. Today India is ranked among the top manufacturers of vaccines. We also export vaccines to a large number of countries.

However, there is a pressing need to innovate and develop a vaccine to combat diseases such as dengue, malaria, chikungunya, TB and if possible, to several other viral and bacterial diseases.

Another challenge is that, once the vaccines are ready in the lab, the clinical trial of vaccines, particularly for the infectious diseases that require a population or a group of patients to administer the minimal infection or the controlled human infection trial. The clinical trials in India have been quite challenging. If one wants to introduce malaria or chikungunya, as part of the trail, in a healthy subject, to study the preventive aspects, there are several ethical issues around this. Consents need to be taken in a proper manner so that subjects understand that they are not being exploited and they need to be adequately compensated. Most critical is that patient safety is safeguarded. These are the current issues that are being debated and policies being discussed with ICMR and regulators on the way clinical trials could be promoted in the country.

Additionally, it is also important to develop a pharmacoeconomic and social impact of vaccines on the disease burden. Especially when we look at introducing a Human Papilloma Virus vaccine against influenza or dengue or malaria it is also important that we do study the pharmacoeconomic impact on the cost-benefit analysis in terms of disease prevented aids, manpower saved and most importantly life saved. Studies on the return on investment in terms of human resources or the health of society will help in strategising the costs and accessibility of the vaccines to the public at large.

I am of the opinion that Indian patients should also receive the benefit of new drug development. So far, India has been described as the hub of or the capital of generic drugs.

In the next 20 years we would like to be described as a nation contributing to the development of new drugs. For this, the government has to provide an eco -system that encourages drug research with grants and better incentives in terms of scientific recognition and robust laws that protect and reward innovation.

Government, through the Department of Science and Technology and Department of Biotechnology and CSIR, has provided opportunities for incubating the idea, developing it through liberal funding and bring it to commercialisation. The objective is to bring the new drug in the fastest and most cost-effective manner to the Indian population. For this, human trials or clinical trial is mandatory.

Clinical Trials

Clinical trial in India needs to be simplified yet being stringent so as not to allow any so called 'undue risk to the Indian population' or 'exploitation of the Indian population'. This calls for a balanced approach of ease of doing clinical research with complete ethical guidelines in place. We need to create a regulatory system that can have a fast track mechanism to introduce a drug in India, which is considered safe and is available in other well-regulated countries. There is a need for having a fast track mechanism for the new drugs which are specific to India, for example, for TB, malaria, dengue or diarrhea, or even cancer. It is imperative that the drug which has been developed will benefit a large number of Indian patients. **Today, in the Medical Technology for clinical trial or Research Technology for clinical trials, there is a specified number of subjects required in a clinical trial based on the expected variation and expected effect of the drug. This requirement can be drastically reduced, and the results of the clinical trials can be more consistent if the population on which it is tested upon is more uniform. Therefore, one of the approaches is to create organ on chips and create kidney, liver or hematological system on chip and do early stage of artificial clinical trial on these chips, integrate that and have a predictive algorithm so that this requirement is reduced.**

The other important thing is when we do genetic mapping of patients before they enter a clinical trial, the population can be more uniform and therefore the predictability of the effectiveness of the drug can be tested faster and with more accuracy.

Also in reference to clinical trials it is important to have in India the capacity building in clinical trials and the capacity can be built in two-three steps: One is the capacity building for human resources - training of potential investigators, means the doctors, paramedics and monitors (in clinical trials there are monitors of 600+ medical colleges and corporate hospitals). This is a huge task at the moment as there is an isolated minimal attempt by THSTI, CDSA, DBT, ICMR and ISCR. There is a need to have a consortium approach that every person who enters into clinical trial is conversant and competent to the trial so that nothing goes wrong. Clinical trials demand zero tolerance otherwise patient safety is compromised. Second, the education system needs to be more relevant and dynamic, not only in the AIIMS but consistently across colleges offering medical education throughout the country.

Rare Diseases

Coming to rare diseases, while the definition is a disease that affects less than one in 10000, we still need to incentivise drug development for such rare diseases. Take Gaucher's disease, an enzyme-deficiency disease, the treatment for this rare disease is not only expensive, the treatment needs to be administered throughout the patient's life. We need to look at drug development for such diseases so that treatments are made affordable. There is also a need to create a registry, though there are registries of Thalassemia & Gaucher's disease but there are more than 1800 rare diseases.

Role of Quality

Another important aspect is making drug available with quality assurance. India has often been facing challenge of poor quality or sub-standard drugs because these are produced at unscrupulous places. Though this is only a 0.1% or 0.3%, it cannot be ignored.

It is important to build an innovative approach in identifying and tracking the quality of drugs and also identifying and tracking the drugs which are spurious or sub-standard. Government plans to invest in capacity building and create at least 1000 laboratories in the country for quality checks.

While India ranks one among the top counties producing generic drugs, ironically, public confidence in generic drugs is low. We need robust mechanisms in place to ensure regular quality checks are undertaken effectively and smoothly.

A suggestion is to set up quality laboratories in all states- a Central and State Government partnership. We also require multiple labs that can serve as appellate labs.

What is your advice to the young scientists of the country?

Every young scientist in academic institutions and scientific laboratories, in my opinion should ask themselves two questions before they initiate their project or before the project is funded:

Ask the question 'so what'?:The impact of the study on the current therapeutic armamentarium juxtaposed with the specific medical need of the country. If that question does not receive a satisfactory reply, then the scientist should go back to his/her drawing board.

Second question, 'what next'?: This should focus on the way this innovation research will be taken up for translational research and most importantly the manner in which the research will either change the public policy or change the status-quo for patients at large.

I would like to urge scientists to have an objective approach to their research. Most of them are married to their idea and they pursue it endlessly without realising whether there is need to continue or even stop it or take a re-look at it. While it is painful, they should learn to even divorce the idea if it not productive or transformational. This critical no-go decision should be taken in the early stages after careful thought, to ensure that limited resources are fully- optimised, and the researcher's time and efforts are utilised in the right direction.

Any other comments?

I would like to end with an appreciation to OPPI. As an industry body, OPPI and its members have given paramount importance to Innovation and Science in enhancing and strengthening the healthcare capability of India to ensure that these innovations reach the millions of Indian patients who are in need of it; thereby delivering hope and better patient outcomes.

INSPIRATION

SYSTEMATIC PATIENT DISTRIBUTION ACROSS CLINICAL TRIALS CAN BE ACCOMPLISHED THROUGH CREATING ARTIFICIAL ORGANS LIKE KIDNEY, LIVER OR HEMATOLOGICAL SYSTEMS ON MICROCHIPS TO DO EARLY STAGE ARTIFICIAL CLINICAL TRIALS ON THESE CHIPS, AND DEVISING PREDICTIVE ALGORITHMS THAT CAN SOLVE SUBSTANTIAL PROBLEMS IN CLINICAL RESEARCH.

PASSION

"Imagine a kit or a system or a device that can detect cervical cancer at an early stage in villages, or detect early incidence of eye diseases within rural population, at their doorstep or which can detect MDR - tuberculosis, malaria, dengue, chikungunya at an affordable cost – this is where we can harness health technology in the next 20 years."

Dr. Y. K. Gupta
AIIMS

ASPIRATION

In the next 20 years we would like to be described as a nation contributing to the development of new drugs. For this, government has to provide an eco-system that encourages drug research with grants and better incentives in terms of scientific recognition and robust laws that protect and reward innovation.

ICMR: A HISTORY AND FUTURE VISION

Dr. Balram Bhargava, DG-ICMR

The Indian Council of Medical Research (ICMR) is the apex and premier medical research organization in the country which spearheads planning, formulation, coordination, implementation and promotion of biomedical research. It is one of the oldest medical research bodies in the world.

In 1911, the Government of India made a historic decision to establish Indian Research Fund Association (IRFA) with the specific objectives of sponsoring and coordinating medical research in the country. After independence, in 1949, the IRFA was re-designated as the Indian Council of Medical Research (ICMR) with considerable expansion in its functions and activities.

ICMR's vision is to translate Research into Action for improving the health of the population with a mission to generate, manage and disseminate new knowledge.

Today ICMR has pan-India presence with 26 research institutes mandated to work on national health research needs with the ICMR Headquarter as the nodal point of all ICMR funded extramural and intramural research. There are 14 divisions at ICMR Headquarters that deal with different areas of medical research.

The department of Health Research has several schemes such as Multidisciplinary Research Units, Model Rural Health Research Units Virology laboratory network.

ICMR has made outstanding contribution as a knowledge generating agency and contributed in understanding various diseases of national importance such as malaria, Japanese encephalitis, tuberculosis, AIDS, Kala-azar, Filariasis, Leprosy and Poliomyelitis. Additionally, ICMR has made extensive contributions in the areas of nutrition, reproduction and maternal and child health, occupational and environmental health and research complimenting health systems.

Achievements Contribution:

Historical:
Historically ICMR's contributions include Research on Indigenous Drugs under Col R.N. Chopra, initiated in 1918. His books are treasure house of insightful information.

Nutritive value of Indian foods and planning of satisfactory diets was prepared way back in 1937, with several subsequent editions and updates, latest being-

Indian Food Composition Tables- 2017, comprising of data of 526 varieties of Indian foods and their nutritive values.

National Urban Nutrition Data report has been prepared by - National Institute of Nutrition (NIN) after a study of 171,928 individuals across 16 states.

The NIN has established recommended daily allowances for Indians, formulated dietary guidelines for Indians, highlighted the calorie gap as a major bottle neck in protein energy malnutrition.

In 1958, collaboration of NIRRH and KEM Hospital led to birth of first scientifically documented test tube baby in India.

Communicable diseases:
Treatment of **tuberculosis** has been revolutionised by introduction of antitubercular drugs and **clinical trials** done by **ICMR NIRT** Chennai. Shortening the duration of treatment, rationalizing the treatment based on bacterial resistance and patient acceptability have been some of the contributions. NIRT is collaborating with industry for development of diagnostics, drugs and vaccines.

Malaria research centre and the ICMR centre of excellence in Mumbai have monitored antimalarial drugs, **identified resistance** problem in geographical areas, malarial parasites and for different drugs which has helped in policies for National Malaria Control and now elimination. NIMR has also investigated the vector susceptibility to insecticides.

Non-Communicable Diseases:
ICMR-INDIAB, an epidemiological study on diabetes is a landmark study providing authentic epidemiological data on diabetes, prediabetes, hypertension, dyslipidemia and obesity from the various States of India. The study has been completed in 14 states and one UT and the data obtained has been shared with the State health departments.

Roll out of India Hypertension Management Initiative has been done for better control of hypertensive patients in the Public health system. Hypertension is the second most important risk factor for NCDs after Tobacco.

Climate Change & Health:

To address the impact of climate change on human health and promote use of space technology tools, ICMR has developed an early warning system for Japanese Encephalitis (JE) for Upper Assam, initiated studies on mapping of malaria and mosquito-genic conditions and developed models for predicting filariasis.

A Memorandum of Understanding (MoU) has been signed on 2nd January, 2018 between ICMR-NIMR (National Institute of Malaria Research), Delhi and ISRO-IIRS (Indian Institute of Remote Sensing), Dehradun for development of geospatial solution for disease surveillance particularly vector-borne diseases and work in the area of Health and GIS for disease modelling.

Clinical trials:
Clinical research/trials are important for evaluating new medicines for safety and efficacy in humans. Studies must be done ethically and scientifically. ICMR has developed National guidelines for biomedical health and research 2017 for ethical conduct of clinical research and has set up a clinical trial registry which is one of the 16 Primary Registries of the WHO Registry Network.

With CDSCO, ICMR contributes to regulating safety and efficacy of medicines marketed in the country, and reviewers, contributing to pharmacovigilance program of India, evaluating fixed dose combinations.

Stem cells:
In recent years application of stem cells for prevention and treatment of diseases has caught public imagination and there is lot of hype and hope. ICMR has developed guidelines for stem cell research so that unproven modalities are not used to treat patients putting them at risk of developing long term harm and unprecedented cost.

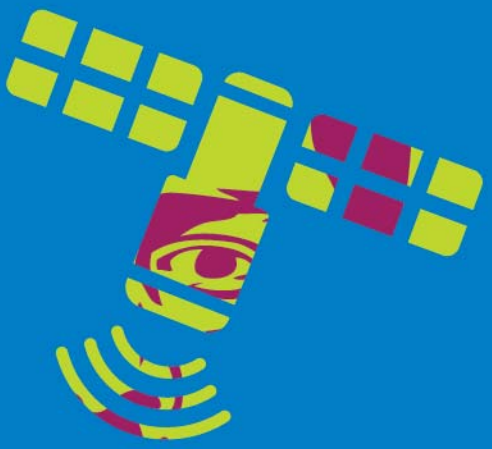
Traditional Medicine:
National Institute of Traditional Medicine Belagavi, ICMR Centres Of Advanced Research at CDRI Lucknow, BYL Nair Hospital Mumbai, Kusturba health Society & hospital, Mumbai as well as ICMR experts on committees of AYUSH Ministry, CSIR, phytopharmaceuticals, have led to scientific approach for understanding, evaluating and bringing to public health these products, some of the products being evaluated are for malaria, dengue, cancer, arthritis, diabetes, etc.

Training Capacity building:
Training and capacity building of young investigators, medical and allied health professionals and providing funding support for research projects to investigators all over the country are other very unique and significant contributions of ICMR.

ICMR continues to provide extramural funding to strengthen research capabilities within the institutes of the council as well as other research institutes, medical colleges and non-governmental organizations for various research projects. It promotes extramural research through different schemes such as Centres for Advanced Research in chosen research areas, task Force studies with goal-oriented approach and clearly defined targets; and grants-in-aid to stand-alone research applications received from various parts of the country.

INSPIRATION

TO ADDRESS THE IMPACT OF CLIMATE CHANGE ON HUMAN HEALTH AND PROMOTE USE OF SPACE TECHNOLOGY TOOLS, ICMR HAS DEVELOPED AN EARLY WARNING SYSTEM FOR JE FOR UPPER ASSAM, INITIATED STUDIES ON MAPPING OF MALARIA AND MOSQUITO-GENIC CONDITIONS AND DEVELOPED MODELS FOR PREDICTING FILARIASIS.



PASSION

"Recently, a Memorandum of Understanding (MoU) has been signed between ICMR-NIMR (National Institute of Malaria Research), Delhi and ISRO-IIRS (Indian Institute of Remote Sensing), Dehradun for development of geospatial solution for disease surveillance, particularly vector-borne diseases and work in the area of Health and GISs (Geographic Information Systems) for disease modelling."

Dr. Balram Bhargava
Director General-ICMR

ASPIRATION

ICMR's vision is to translate Research into Action for improving the health of the population with a mission to generate, manage, and disseminate new knowledge.

HEALTHCARE RESEARCH AND BIOTECHNOLOGY IN INDIA: THE PAST AND FUTURE

Dr. Renu Swarup, Secretary, Department of Biotechnology

What role does science play in alleviating the disease burden of the world? Name three areas of significant contribution.

The role of science & technology is enormous in human, societal and economic development of the world. If we see in past, the practice of immunisation dates back to hundreds of years, however, 19th and 20th centuries saw the systemic development of several important vaccines viz. Anthrax, BCG, Plague, inactivated Polio Vaccine etc. Vaccination has made an enormous contribution to global health. Through vaccination, smallpox was eradicated worldwide by 1980, and polio cases declined by 99 percent.

The beginning of the 20th century, the average human life expectancy even in the industrialised country was 45-47 years whereas in India in the year 1950 the same was 31 years and less than half that in the US (68 years). With the antibiotics revolution in the late 1940's and further, development of novel antibiotics during 1950 to 1970 revolutionised the treatment of infectious diseases. Now, the life expectancy at birth in India has increased to 69 years and Science and Technology development in India have contributed immensely to improve healthcare. From improved devices, diagnostics and implants, the country has witnessed a large transformation through development and delivery of improved innovative affordable and accessible healthcare products and technologies.

India is a hub for vaccine manufacturing. 1 out of every 3 doses of vaccines administered globally is manufactured in India. **Our recent success in academia driven indigenous vaccine production – Rotavirus has given us an added confidence that India is not only a vaccine manufacturer but has capacities for indigenous new vaccine development.**

A major technology which has made a significant contribution to alleviating the disease burden and has revolutionised the dynamics of healthcare is the recombinant DNA technology. Today, 8 out of 10 blockbuster drugs are developed and produced using biotechnology-based tools and techniques including recombinant DNA technology. In India, there has been a major focus on biotherapeutics. The National Biopharma Mission - a recent initiative of Department of Biotechnology aims to promote an innovation ecosystem for development of new innovative biopharma products and strengthening industry - academia partnerships, also allowing start-ups and entrepreneurs to take forward their research.

Science has been working steadfastly to usher improvements in the health of humanity. Name three big areas of the future that can positively impact the health of people across the globe?

The three potential big areas of the future in healthcare are Gene editing technology including Personalized medicine or precision medicine, Artificial intelligence, and Big data and technologies to address Anti-microbial resistance.

One such growing area of interest is the gene editing technology. How do you think it can impact human lives?

Gene editing is boon for monogenic disorders which are the result of a single defective gene on the autosomes. 5,000–8,000 monogenic diseases, defined as inherited conditions arise from mutations on a single gene.

Further, this technology has **wider application in stem cell therapy, gene therapy and personalised medicine.** It would be interesting to see how the **advancement of it in the field of gene editing technology motivates adoption of this technology and addresses societal and ethical concerns associated with its application in the laboratory and in the clinic.**

What is the role of academia in encouraging science-based medical research?

Academia plays an important role in taking forward science- based medical research. The science- based medical research benefits from the insights academia brings on fundamentals of medical science along with an understanding on interdisciplinary sciences. The challenge, of course, is a translation of these research outcomes. For this Industry-Academia partnership needs to be strengthened. It is also important to build Academia-Industry science clusters which allow seamless interaction between researchers, clinicians, hospitals and industry. Research has to be need-based and for its effective translation deep engagement with all concerned key player is crucial, only then we can see the fruitful results. The Department of Biotechnology and its Public Sector Biotechnology Industry Research Assistance Council have played a major role in creating this ecosystem in the country. Having built strong Human resource and infrastructure capacities in academic research institutions across the country, there has been a major effort to promote Industry-Academia partnership. The Translational Health Science and Technology Institute was the first cluster set up by Department of Biotechnology on Translational health research. The Clusters at Kalyani and Bangalore also focus on connecting the Academia and Industry for Translational Research. Effort is now being made to have the start-ups become an integral part of this and link research innovation to translation to clinical validation to scale up and finally manufacturing.

Academia has a great responsibility to produce skilled and research-minded workforce and also has the capacity to innovate for development of new products and medicines to cater to the healthcare need. It is necessary that we should inculcate a culture of quality clinical research among physicians and promote innovative research & development activities in medical colleges.

Innovation is closely linked with a robust policy environment that supports it. What in your opinion are the three points that India needs to focus on to become a nation that respects, protects and rewards innovation?

In India, the S &T innovation ecosystem is being supported by forward-looking initiatives of Government of India such as: Startup India, Make in India, Digital India initiative etc. India has moved up 3 places from 2017 and ranked as the 57th most innovative country in the world. The last few years have seen India being recognized as a nation which is fostering and nurturing innovation. The key areas that we need to focus on are – rewarding high-risk innovation research, strengthening industry-academia partnership and making available opportunities for investors to bring in investment for high-risk innovations especially to cover the valley of death.

What is your advice to the young scientists of the country?

The Science and innovation ecosystem in the country today is at the most exciting period. Young scientists of the country are doing wonderfully well and it is evident from the growing numbers of startups based on science & technology and further, by increasing number of technologies commercialisation by the research institutions. They have a passion for science and my advice to them is to complement this passion with dynamics of societal need, intellectual property, translation science, and commercialisation acumen; not as an individual but as a team. This can build a great connect with the society and make S &T based innovations as a major contributor to growing economy.

INSPIRATION

GENE EDITING IS A BOON FOR MONOGENIC DISORDERS, HAS WIDER APPLICATIONS IN STEM CELL THERAPY, GENE THERAPY AND PERSONALISED MEDICINE. IT WOULD BE INTERESTING TO SEE HOW ITS ADVANCEMENT IN GENE EDITING TECHNOLOGY CAN HELP ADDRESS SOCIETAL AND ETHICAL CONCERNS ASSOCIATED WITH ITS APPLICATION IN THE LABORATORY AND IN THE CLINIC.

PASSION

"Our recent success in academia driven indigenous vaccine production – Rotavirus – has given us an added confidence that India is not only a vaccine manufacturer but has the capacity for indigenous development of new vaccines."

Dr. Renu Swarup
Secretary, Department of Biotechnology

ASPIRATION

Today, 8 out of 10 blockbuster drugs are developed and produced using biotechnology based-tools and techniques, including recombinant DNA technology. Our institute aims to promote an ecosystem for innovation by developing innovative biopharma products and strengthening industry-academia partnerships along with allowing start-ups and entrepreneurs to take forward their research.

NANOTECHNOLOGY IN MEDICAL SCIENCE

Dr. Taslimarif Saiyed, CEO & Director, Centre for Cellular and Molecular Platforms

What would be the likely applications of nanotechnology in medical science?

Nanotechnology field is opening many new avenues in terms of its applications in healthcare. It could have significant applications in medical sciences in the coming few years. These will include:

a) Novel nanotechnology-based drugs
e.g. Nanotechnology to modulate host immune system,
b) Nanotechnology-based drug delivery mechanism
e.g. i) Nanotechnology for targeted drug delivery,
ii) Nanotechnology for high uptake and high efficacy of drugs and
iii) Nanotechnology for controlled drug release mechanism,
c) Novel nanotechnology-based mechanisms of point-of-care diagnostics devices for more affordable and accessible diagnostics, and
d) Nanotechnology-based disease prevention technologies
e.g. Nanotechnology-based pesticide toxicity to farmers, prevention of ICU-related hospital-acquired infections etc.

Can we expect to see new ways of administering drugs in the next 10-20 years? For example, Oral Thin Films (OTF) technology or any other forms of drug dosage forms.

The field is already moving in towards new ways of administering drugs. In the next 10-20 years, it is very much likely that we may see new ways of administering drugs, which would add to the current ways of administering drugs.

Among these possible approaches,

I feel the most exciting one would be biomarker-based approaches for drug release through

a) topical drug administrations and
b) implant-based approaches for the treatment.

Would we see synthetic versions of drugs currently manufactured through fermentation, as we had once seen in the synthetic penicillin analogs?

There are two significant reasons for synthetic version manufacturing not being utilized largely:

a) The cost of synthesis of bio-based drugs being prohibitively expensive compared to fermentation based due to technological limitation and
b) Structure of biologics, crucial to their function and efficacy, are complex enough to be able to synthesise them with the precision otherwise.

Till the time, these two aspects are addressed by new technologies, it would be difficult for industry to industry to implement synthetic manufacturing of biological drugs. etc.

Would tissue culture and transplants reduce the demand for substances like insulin and other hormones?

Indeed, there is a strong possibility. Stem cells research has made significant advancements in last few years including induced pluripotent stem cells (iPSCs) technology, which doesn't require embryonic stem cells and allows differentiation of somatic cells to specific types of cells like neurons, muscle cells etc. With possibilities of building patient specific organoids using stem cells and tissue culture, stem cell-based implants have the potential to provide "original-like" organ function needed in case of insulin or some hormones.

What are the three points that India needs to focus on to become a nation that drives research?

For India to foster scientific research and become one of the world leaders, India needs to:

a) Invest significantly more in scientific research as an percentage of GDP (at least 3x or more compared to as of now) to build a critical mass of scientific research groups working across India. This needs to coincide with long-term planning towards science and technology led the economy of the country.
b) Building translation capabilities should be one of the key focus areas for government to achieve envisaged applications of scientific research. Towards this, there should be an effort to set up dedicated scientific centers to take science outcomes in translation mode i.e. post discovery mode, towards applications, which would have a transformative global impact.
c) Build national-level mission-mode blue sky research programmes with a focus on national needs, with strategic collaborations across top-institutions within India and outside, with clear deliverables and assessments.

What is your advice to the young researcher of the country?

Young researchers are future science leaders. These are exciting times, opportunities are plenty but, only for those who jump high and grab these opportunities.

INSPIRATION

WITH SIGNIFICANT ADVANCEMENTS IN STEM CELL RESEARCH, THERE ARE POSSIBILITIES OF BUILDING SPECIFIC ORGANOIDS, THAT WILL HAVE POTENTIAL TO PROVIDE "ORIGINAL ORGAN -LIKE" FUNCTIONING.

PASSION

"As a student of biology, I was always interested in knowing how biology as a system works in a holistic manner, how things are controlled, optimised, and evolved. Also the exposure you get in your field of interest matters a lot regardless of what sector you are a part of."

Dr. Taslimarif Saiyed
CEO & Director, Centre for Cellular and Molecular Platforms

ASPIRATION

My current interest and passion is about the translation of academic research for real world impact. There is a lot that goes on in science in our country and most countries invest a lot in building scientific knowledge; but very little of that scientific knowledge actually gets to an application, more with a societal impact. Hence I have decided to move my scientific interest into niche areas of translation so that I continue to push some of the gems of academic science towards making them applicable for a societal impact.

DR. BARBARA E. BIERER

MD, Professor of Medicine,
Harvard Medical School Faculty Director,
Multi-Regional Clinical Trials Center of BWH
and Harvard

MARK BARNES

Partner, Ropes & Gray LLP
Faculty Co-Chair, Multi-Regional
Clinical Trials Center of BWH and
Harvard Lecturer, Yale Law School and
Yale School of Medicine

THE CRITICALITY OF THE CLINICAL TRIAL ENTERPRISE IN INDIA

India is home to over 1.3 billion people, an estimated 17% of the global population, and responsible for 20% of the global disease burden. Over the past two decades, the nature of those diseases has included communicable (infectious) diseases—more recently with an increase in emerging pathogens—and a variety of non-communicable diseases (NCDs) such as cardiovascular disease, diabetes mellitus, chronic obstructive pulmonary disease, and cancer. Currently, the majority of morbidity and mortality in India is attributable to NCDs.[1] Treatment of such a vast population requires investment in public health, including health services and disease prevention, infrastructure, workforce development, and innovation. Innovation is key to explore transformative approaches to treat, prevent, and lessen the burden of NCDs and emerging diseases at scale.

Since 2013, the Indian regulatory authorities have worked with institutions, investigators, national and multinational pharmaceutical companies, contract research organizations, non-profit organizations and the public to strengthen and revitalize the conduct and oversight of clinical trials in India. Significant improvements in regulatory processes have been made: the regulatory framework for medical devices has been clarified with the publication of the Medical Device Rules, 2017,[2] tiers of regulatory review and approval have been simplified and clarified, and a new online submission process serves to structure the information requested and increase efficiency. These and other changes have led to a shortened and more predictable timeline for decision-making. Similarly, arbitrary regulations in the conduct of clinical research, such as restricting the number of trials allowable for an investigator, requiring all clinical trials to be conducted in a pre-selected hospital with at least 50 beds, and audiovisual recording of all informed consent procedure, have

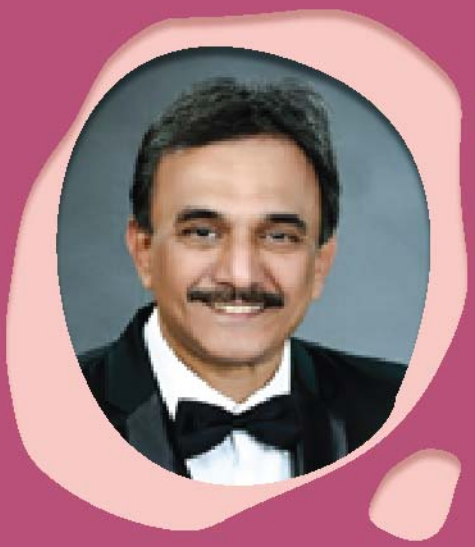
been modified or eliminated. Perhaps most importantly, significant improvements in the protection of human research participants have been made. Registration of research ethics committees, empowered to protect the rights and welfare of participants, and training and education of the members, is required. Soon accreditation of research ethics committees will be required.[3] Audiovisual recording of the informed consent process is required only for the most vulnerable of the population, and even there, trials for certain diseases are exempted from the requirement. Immediate medical management of potential adverse events is required and should be provided until relatedness and causality is established. Compensation for lack of therapeutic effect of an investigational product is only required if standard of care, if available, is denied. Financial compensation of clinical trial- related injury or death is now formulaic, increasing predictability of and easing the process for payment. Indeed, India is the first country to develop a comprehensive compensation scheme for research-related injury and death, regardless of culpability, applicable to all trials including those sponsored by academic, industry, and government entities.

Collectively, these changes present an opportunity to reinvigorate and stimulate the clinical trial enterprise in India. The changes, coupled with a well-educated professional workforce, a diverse potential participant population that is afflicted with both acute and chronic diseases and often therapy-naïve, technical strengths in genetic sequencing and other methodologies, and informatics capabilities that streamline communication and oversight render India well-positioned for investment in and conduction of clinical trials. India also represents an emerging yet very stable economy where the cost basis for performance of clinical trials remains comparatively affordable for industry and academia. Progress, however, cannot stall or revert as confidence in the Indian market is recovering and increasing, any regression will have injurious and long- lasting consequences. A positive clinical trial environment will stimulate executing clinical trials in India, with consequent investment in infrastructure, training, and health systems strengthening.

In 2018, the government of Prime Minister Narendra Modi announced a plan to provide health insurance to more than 500 million Indians at 500,000 rupees per family annually, the largest public health insurance program in the world. The National Health Protection Scheme (NHPS) is a bold and necessary plan that is estimated to provide health care access to approximately 40% of the most vulnerable of the population. Ideally, this investment should leverage technology– a core strength in India— and be coupled with advances in efficiencies in treatment and prevention. These advances are dependent upon basic, technical, and clinical research and can only be accomplished by innovation. Innovation must then be subject to rigorous analysis of benefit, risk, and economic viability, not only as a means of maintaining an affordable cost structure for the NHPS but also for improving the health and welfare of its population. India is poised to marshal its progress, unify these strengths, and execute on these commitments in caring not only for its own population but also in providing a model for the world to emulate. Innovation, with efforts in both pre-clinical and clinical research, and with regulatory structures that facilitate this research, is key to this crucial national endeavor.

REFERENCES

1. Upadhyay RP. An overview of the burden of non-communicable diseases in India. Iranian journal of public health. 2012;41(3):1.
2. See: Ministry of Health and Family Welfare Notification, dated 31st January, 2017, at: http://www.cdsco.nic.in /writereaddata/Medical%20 Device%20Rule%20gsr78E(1).pdf. Accessed 1 September 2018.
3. See: National Accreditation Board for Hospitals and Healthcare Providers. Accreditation of Clinical Trial (Ethics Committees: Introduction.) at http://www.nabh.co/ClinicalTrial.aspx. Accessed 1 September 2018.



DR. SANTOSH SOANS
President 2018, Indian Academy of Pediatrics

DR. DIGANT SHASTRI
President 2019, Indian Academy of Pediatrics

SCIENTIFIC MEDICINE AND CHILD HEALTH IN INDIA

Medicine and science have greatly enhanced our ability to treat health conditions in children. For example, over 90% of cases of cancer in children today are curable; respiratory support using surfactants has proved to be life saving for many babies. Treatment of cancer and respiratory support are just two of many powerful examples.

However, while therapies are available and medical advancement is happening at a fast rate, many children in India do not benefit due to lack of access to accurate diagnosis and advice. Many superstitious beliefs and myths also act as barriers to effective use of medical technology.

The widespread prevalence of child health issues.
There are many common treatable conditions prevalent amongst children in India. Disease burden, general health and nutrition status of Indian children is quite poor when compared to most countries of the world.

The nutrition status of children and treatment of cancer are two examples that indicate the extent of child health challenges and the factors that drive them. Almost 40 percent of children under the age of five are stunted. Incorrect maternal and child care advice, along with superstition have a major role to play in poor nutritional status of mothers and children. Despite the majority of cancer cases in children being curable, over 50 children die of cancer in India every day, because majority of the cases remain undiagnosed.

Close to a million children die of preventable causes in India every year. Pneumococcal disease alone causes approximately two hundred thousand child deaths.

What is the solution?
These conditions can be prevented or treated in a large number of children if:

1. Accurate advice is available at the right time
2. Therapies and medicines are available and accessible
3. Families are educated about myths, so that superstition does not interfere with adoption of the advice or the therapy

The poor health and nutrition status of mothers, as well as deeply entrenched socio-cultural gender issues also have a direct impact on the health and well-being of children.

Accurate and timely advice
India has a shortage of doctors. In India, there is less than one doctor per thousand people. This number becomes even more skewed when we talk about child specialists (pediatricians).

To add to this problem, most qualified doctors prefer to practice in the cities and towns. There are very few doctors and poor medical facilities in rural and small town India which has over 70 percent of the population. When we go up to specialists (pediatricians), over 70 percent of IAP members are in Tier 1 and Tier 2 cities. This leads to widespread low quality access to pediatric care. The following statement from a study by the NCBI tells us the whole story:

"Overall low levels of medical training among health care providers; in rural Madhya Pradesh, for example, 67 percent of health care providers who were sampled, reported no medical qualifications at all. There are only small differences between trained and untrained doctors in areas like adherence to clinical checklists. Correct diagnoses were rare, incorrect treatments were widely prescribed, and adherence to clinical checklists was higher in private than in public clinics."

Caregivers (pediatricians, doctors, paramedics, frontline health workers, nurses, midwives etc.) need access to professional education resources and training in best practices for pediatric care. In addition, they need access to specialists, so that a doctor can reach out to a pediatrician for a second opinion or for advice.

It is not possible to greatly increase the number of doctors in a short timeframe. India's best bet to rapidly upgrade the quality of care at all points of care is to use technology. Technology eliminates distance barriers, communication costs and increases treatment capacities.

Technology such as online clinics and telemedicine can be used to ensure that doctors who are not specialists or highly qualified, have easy access to specialist advice. Technology can be used for widespread availability of professional education, patient education and diagnostic tools at the point of care.

The Indian Academy of Pediatrics (IAP) is at the forefront of the adoption of technology for pediatrics. IAP has developed and owns its own electronic medical records and practice management system "IPAN", which will be given free of cost to all pediatricians. IAP is investing in its own digital pediatric professional education platform "IAP Courses", which will become the principal pediatric education resource in the country, to educate doctors and caregivers and connect them to specialist advice.

IAP has the largest vaccination reminder program "IAP-ImmunizeIndia". This opt-in service is available free of cost to parents anywhere in India and has about 2 million children enrolled.

Availability and accessibility of medicines and therapies
Access to affordable medicines and therapies for children is necessary for many Indian families. There is a pressing need for the pharma industry, government and development organisations to work together and create solutions that make medicines affordable for patients who are not well to do. IAP will be happy to contribute to this effort.

Education to dispel myth and superstition
A significant barrier that inhibits efficient use of medical technology is superstition and myths related to child and maternal health. Large scale public education and awareness is required to change the mindset of a majority of the population.

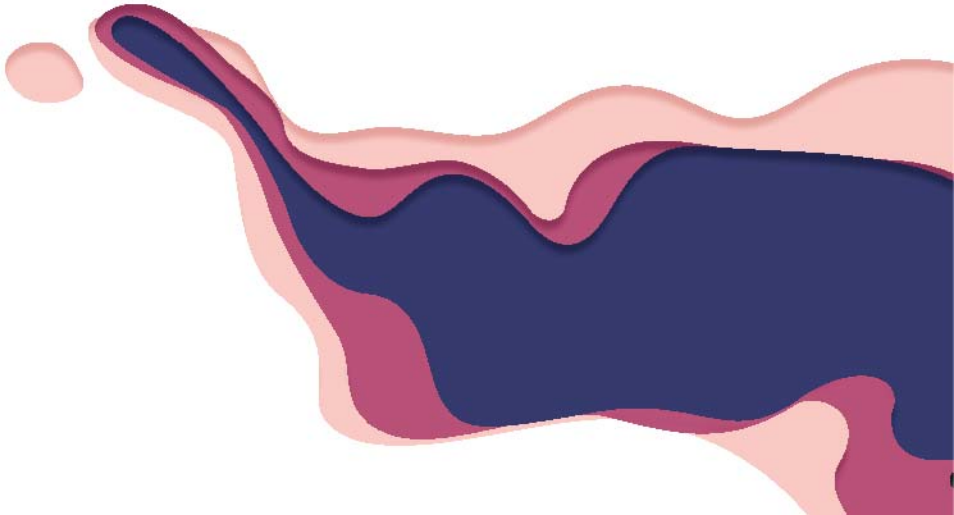
It is important to empower doctors and caregivers with effective and easy to share maternal education information in local language.

IAP is developing its own maternal and child health consumer education platform "IAP Vaani", which will create and distribute hundreds of videos in 12 languages. Each video will address specific maternal and child health issues. Mothers, families, caregivers, health workers, state governments, hospitals, NGOs and doctors will all be able to use the content free of cost.

IAP's consumer education efforts include IAP TV, a closed television educational network at pediatric clinics which delivers entertaining yet medically accurate education content to the mother. IAP TV is installed in 1200 clinics, reaching 4 million mothers annually. IAP is working to expand this network to 20,000 clinics, to reach 80 million mothers.

In conclusion
The Indian Academy of Pediatrics is committed to the improvement of the health and well being of all children.

In our view, a three pronged approach is required for modern medicine to reach its potential and greatly enhance the health of mothers and children in India. First, deliver access by using technology to collapse capacity and distance barriers. Second, all stakeholders to work together and create solutions for affordable treatment. Third, create and distribute effective, specific and locally relevant maternal and child education to improve behaviours and to dispel myths and superstition.



DR. JAYASREE K. IYER
Executive Director, Access to Medicines Foundation

VACCINES IN THE PUSH TO LIMIT ANTIMICROBIAL RESISTANCE

It is more than 30 years since researchers first discovered that bacteria producing extended-spectrum beta-lactamase (ESBL) enzymes were resistant to many penicillin and cephalosporin antibiotics, and to other types of antibiotics. Today, antimicrobial resistance (AMR) is recognised as a growing threat, emerging at a global level. It poses complex challenges to the treatment of infectious diseases, particularly in low- and middle-income countries and in infections acquired in hospital settings.[1]

Vaccines have the potential to play a significant role in helping to alleviate the problem of drug resistance. This role has been promoted by several organisations, such as Chatham House and the Sabin Vaccine Institute.[2,3,4] The potential has also been acknowledged in the final report of the UK-based Review on Antimicrobial Resistance[5], the 2016 UN declaration on antimicrobial resistance[6], the UN IACG Framework for Action[7] and the Davos Declaration.[8] While it is vital to develop new antibiotics to treat people who have a bacterial infection, it is equally vital to develop vaccines to prevent the incidence of infection. Vaccines can guard against major diseases such as tuberculosis and malaria and can prevent viral infections (for which antibiotics are often wrongly prescribed).

Vaccines do not just avert morbidity and mortality; they also reduce the need to use antibiotics. By limiting the use of antimicrobial medicines, they can, in turn, slow down or curtail the emergence of resistance.

To combat AMR, vaccines constitute a clear and key line of defence. Yet, there is still much work to be done to explore and assess the range of health and economic benefits they can offer in this area. In this article, the Benchmark reports how companies are marketing and developing vaccines against pathogens with a critical level of resistance. This overview shows the pathogens and diseases for which the focus should be on improving immunisation coverage, on sustaining R&D efforts and/or on embarking on R&D in the very first place.

PREVENTING INFECTION AND AVOIDING ANTIMICROBIAL MEDICINE MISUSE AND EXPOSURE

There is overwhelming evidence that immunisation programmes can have a profound impact on public health in general, and AMR more specifically. A recent notable example is the USA's introduction of the 13-valent pneumococcal vaccine in 2010, which has led to a significant reduction in disease in both vaccinated (direct protection) and unvaccinated (herd protection) children.[9] Between 1998 and 2008, use of pneumococcal vaccines in the USA has been shown to reduce antibiotic-resistant infections in children by 64%, and in elderly patients by 45%.[10] Further, in geographic regions where vaccines for *S. pneumoniae* (pneumococcus) and *N. meningitidis* (meningococcus) have been introduced and widely deployed, resistant strains have been eliminated.[11] Similarly, use of the H. influenzae type b (Hib) conjugate vaccine, used to prevent Hib from causing meningitis and non-central nervous system infections has, in certain areas, almost eliminated ampicillin-resistant Hib.[11] Introduction of rotavirus vaccination in the USA in 2007 has led to more than an 80% decline in community-acquired rotavirus hospital admissions and more than a 60% decrease in hospital-acquired infections.[12] After introduction of a 7-valent pneumococcal vaccine in South Africa in 2009, rates of invasive pneumococcal disease dropped more than 50% in children younger than two years of age and more than 30% in adults 25 to 44 years of age, between 2005 and 2012.[13]

Nevertheless, vaccines continue to have a huge untapped potential for improving public health. Millions of children around the world die from vaccine-preventable diseases before they reach the age of five. Overall, some two million of these deaths each year may be prevented if children receive the right vaccine. While immunisation coverage is increasing globally, in 2015 nearly one in five children did not receive the basic life-saving vaccines recommended by WHO for routine immunisation. The number of those not immunised with newer vaccines, such as those to prevent pneumococcal disease and rotavirus infection, is even higher.[14,15,16] WHO estimates that among children under five years old, there are 14.5 million episodes of serious pneumococcal infections each year worldwide, with more than 800,000 deaths[17] arising from pneumonia, meningitis, ear and sinus infections, and bloodstream infections.

Although pneumococcal vaccines are marketed and available, the worldwide immunisation rate of infants in 2016 was just 42%. In general, the factors that deter or prevent vaccination include weaknesses in health systems and supply chains, insufficiencies in the

supply of vaccines, challenges in financing and difficulties within communities in accepting vaccination.

For newer vaccines, affordability and production capacity are among the key issues. The situation remains complex, but the impact of missed opportunities for immunisation is profound.

Providing greater access to vaccines

The spread of disease in a community can be halted when enough people receive a vaccine, leaving too few susceptible individuals to infect. While it is often desirable to administer vaccines across large proportions of populations, these vaccines must first be purchased in considerable volumes. As immunisation programmes often aim to reach whole demographic groups, even small decreases in unit price can make large differences in the cost of each round of immunisation.

Affordability – particularly of newer vaccines–remains an issue. Affordability issues can become acute when a country's level of national income rises, and it moves from low-income up to lower-middle income status (as defined by the World Bank). Typically, it then loses access to pooled-procurement systems, putting pressure on the country's resources, especially for procuring more expensive vaccines (e.g., for human papillomavirus (HPV), rotavirus and pneumococcal infections).[18]

UNICEF* and the Pan American Health Organization (PAHO)** run pooled- procurement systems, as does Gavi, the Vaccine Alliance***, a public - private global health partnership aiming to increase access to immunisation. These systems, which enable low-and middle- income countries to club together to buy vaccines in bulk, have been successful in helping countries to negotiate lower prices for vaccines. Companies that make and market vaccines need to develop and embed a systematic approach to equitable pricing, particularly for countries that receive no Gavi support and cannot participate in pooled-procurement systems. They need to form clear strategies on pricing for all low and middle-income countries and share this global pricing information. This will help to facilitate negotiations and, by promoting a more competitive environment, help to ensure prices are fair. More broadly, in some countries, companies can improve the way they prioritise registration of vaccines according to public health needs.

In low and middle-income countries, governments and other vaccine procurers need to invest further in regulatory systems and immunisation programmes. This investment is especially important for vaccines used to prevent infections caused by priority pathogens. Access to and wider use of these vaccines has the potential to curtail antibiotic resistance, and to avert 2.6 million deaths per year from infectious diseases, most of them (2.4 million) from tuberculosis and pneumonia worldwide.†

Global vaccine coverage against pneumococcal disease was estimated to potentially avert up to 11.4 million days of antibiotics for pneumonia caused by *S. pneumoniae* per year in children younger than five years of age.[19]

Supply, availability and affordability are closely interlinked. Multiple factors affect whether a population is able to obtain sufficient vaccine coverage, but an essential first step is to make high-quality, effective vaccines available and affordable, allowing procurers to purchase the quantities of vaccines necessary to immunise adequately the populations they target. As they work to create and guarantee a stable and affordable supply, all parties involved must recognise and reward effort, and pool resources wherever possible.

Unaddressed priority gaps

Of the 19 priority pathogens overall, seven remain multidrug-resistant Acinetobacter spp. (including *A. baumannii*), drug-resistant Campylobacter spp., vancomycin-resistant Enterococcus (VRE), multidrug-resistant *P. aeruginosa*, erythromycin-resistant group A Streptococcus, clarithromycin-resistant *H. pylori* and fluconazole-resistant Candida spp.

Attrition rates for R&D projects are high, and other organisations may be developing vaccines against these priority pathogens. Even so, it is important to incentivise large players which have the resources to develop and roll out vaccines effectively – to engage in developing vaccines that can prevent infection from these drug-resistant pathogens.

Surveillance of vaccines

It is important to monitor the impact of vaccines on the emergence of resistance, so that efforts to curb AMR can be evaluated. To this end, pharmaceutical companies can support national and international efforts to run AMR surveillance programmes, which collect, analyse and share data on infection rates and associated mortality rates.

THE WAY FORWARD: ENSURE VACCINES ARE ACCESSIBLE

The use and effectiveness of vaccines to address AMR remains understated and under-reported. Among options proposed to tackle the problem of AMR, vaccines comprise an important tool. By creating immunity and reducing infection, vaccines can eliminate the need for antimicrobial medicines. This helps to prevent the use of these medicines, averting the need for further interventions to conserve their utility. Several organisations – including the Bill & Melinda Gates Foundation[25], Gavi, the Vaccine Alliance[26] and the Wellcome Trust[27] – are now advocating for vaccine development and higher rates of vaccination globally, not only to prevent disease but also as an essential intervention in tackling AMR.

Companies play an integral part in this intervention, as they have the means and responsibilities to make this a reality by: (1) Responding to R&D gaps as identified by WHO and CDC to develop new vaccines; and (2) Ensuring the accessibility, affordability and supply of these vaccines that make it to the market. The incentives put forward by major funders and other stakeholders involved must be aligned with these two responsibilities. Major funders can support companies' efforts in vaccine R&D and assist in the pooled procurement of vaccines to improve accessibility and affordability.

This is an excerpt from a 'cross-cutting story' that was published in the Antimicrobial Resistance Benchmark 2018.

REFERENCES:

1. ReAct - Action on Antibiotic Resistance. (October 2017). Antibiotic resistance strikes hardest at the poor. Retrieved 26 October 2017 from https://www.reactgroup.org/news-and-views/news-and-opinions/year-2017/antibiotic-resistance-strikes-hardest-at-the-poor
2. Heyman, D. & Omaar A. (September 2016). Chatham House: New vaccines are essential to fighting antimicrobial resistance. Retrieved 1 November 2017 from https://www.chathamhouse.org/expert/ comment/new-vaccines-are-essential-fighting-antimicrobial-resistance
3. Clift, C. & Salisbury D.M. (2017). Enhancing the role of vaccines in com- batting antimicrobial resistance. Vaccine, 4(35):6591-93.
4. Gellin, B. (August 2017). Vaccines are part of the solution to the emerging crisis of antibiotic resistance. STAT.Retrieved 1 November 2017 from https:// www.statnews.com/2017/08/01/ antibiotic-resistance-vaccines/
5. O'Neill, J. (May 2016). Tackling drug-resistant infections globally: final report and recommendations. The Review on Antimicrobial Resistance.
6. United Nations. (September 2016). Draft political declaration of the high- level meeting of the General Assembly on antimicrobial resistance. Retrieved 26 October 2017 from https://www. un.org/pga/71/wp-content/uploads/ sites/40/2016/09/DGACM_GAEAD_ ESCAB-AMR-Draft-Political-Declaration- 1616108E.pdf
7. IACG on Antimicrobial Resistance. (August 2017). AMR Framework for Action Supported by the IACG. Retrieved 1 November 2017 from http://www.who.int/ antimicrobial-resistance/interagency-co- ordination-group/20170818_AMR_FfA_ v01.pdf
8. Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combatting Antimicrobial Resistance. (January 2016). Retrieved 3 January 2018 from https://www.amrindustryalliance. org/wp-content/uploads/2017/12/AMR- Industry-Declaration.pdf
9. Tomczyk, S., et al. (2016). Prevention of Antibiotic-Non-susceptible Invasive Pneumococcal Disease with the 13-Valent Pneumococcal Conjugate Vaccine. Clinical Infectious Diseases, 62(9), 1119-25.
10. Hampton, L., et al. (2012). Prevention of antibiotic-non- susceptible Streptococcus pneumoniae with con- jugate vaccines. Journal of Infectious Diseases, 205(3), 401–11.
11. Lipsitch, M., et al. (2016, June). How Can Vaccines Contribute to Solving the Antimicrobial Resistance Problem? MBio, 7(3), e00428-16. doi: 10.1128/ mBio.00428-16.
12. Anderson, E., et al. (2011) Impact of Rotavirus Vaccination on Hospital- Acquired Rotavirus Gastroenteritis in Children. Pediatrics, 127(2), e264–e270. doi:10.1542/peds.2010- 1830
13. Von Gottberg, A., et al. (2014). Effects of Vaccination on Invasive Pneumococcal Disease in South Africa. New England Journal of Medicine, 371, 1889-1899.
14. UNICEF. (2016). Immunization: Introduction. Retrieved 25 October 2017 from https://www.unicef.org/immuniza-tion/index_2819.html
15. WHO. (July 2017). Immunization coverage. Retrieved 24 October 2017 from http://www.who.int/mediacentre/ factsheets/fs378/en/
16. WHO. (October 2017). Children: reducing mortality. Retrieved 25 November 2017 from http://www.who.int/mediacentre/factsheets/fs178/en/
17. O'Brien, K., et al. (2009). Burden of disease caused by Streptococcus pneumoniae in children younger than 5 years: global estimates. Lancet, 374, 893–902.
18. UNICEF. Vaccine Price Data. Retrieved 18 December 2017 from https://www.unicef.org/supply/ index_57476.html
19. Laxminarayan, R., et al. (2016). Access to effective antimicrobials: a worldwide challenge. Lancet, 387, 168–75.

* UNICEF is the world's largest supplier of vaccines to children and works with many stakeholders to increase demand for vaccines, including through pooled procurement.

** PAHO is a UN public-sector procurement agency that has established a fund that enables member states to access lower vaccine prices.

*** Gavi brings together many key organizations in a single decision-making body regarding access to vaccines and works to accelerate the introduction of new and underused vaccines in over 70 of the poorest countries.

† Data from Global Health Data Exchange, based on 2016 calculations for H. influenzae type b (48,000 deaths), pneumonia (1.2 million), tuberculosis (1.2 million) and typhoid fever (128,000).

DR. ANIL WALI

Managing Director
Foundation For Innovation And Technology Transfer
Indian Institute of Technology, Delhi

DRIVING TECHNOLOGY BASED MEDICAL RESEARCH

WHAT DO YOU THINK WILL BE THE THREE BIG AREAS IN HEALTHCARE AND PHARMA THAT WILL EXPERIENCE THE BENEFIT OF TECHNOLOGICALLY DRIVEN INTERVENTIONS?

I believe the following areas besides others may continue to attract attention:

- Synthetic Biology
- Personalised Medicine
- Digital Therapeutics

HOW COULD 3D SIMULATION WORK FOR PATIENT BENEFIT? COULD IT HELP IN IMPARTING ADVANCED MEDICAL SKILLS TO THE PRACTITIONER OR DEVELOPING PROGNOSTIC MODELS CUSTOMIZED FOR PATIENTS?

3D simulation can be an effective training tool that can address various limitations in capability building in the medical field. Along with AR/VR and other advanced techniques, the scope of 3D platforms for the trainers/practitioners is huge given the limitations in existing methodologies towards quality impact.

WHAT ARE THE THREE POINTS THAT INDIA NEEDS TO FOCUS ON TO BECOME A NATION THAT DRIVES RESEARCH?

a) Incentivising top quality (with credible and measurable output) R&D programs.

b) Technology-oriented organisations/industry should focus on hiring PhDs of caliber.

c) Quality Research programs should draw more funds and research careers should be promoted/regarded as aspirational career avenues.

INNOVATION IS CLOSELY LINKED WITH A ROBUST POLICY ENVIRONMENT THAT SUPPORTS IT. WHAT IN YOUR OPINION ARE THE THREE POINTS THAT INDIA NEEDS TO FOCUS ON TO BECOME A NATION THAT RESPECTS, PROTECTS AND REWARDS INNOVATION?

- Prioritise adoption of indigenously designed and developed technology solutions in government programs
- Techno-entrepreneurship has to be vigorously promoted in academia and research organisations
- IPR regime should be diligently enforced

HOW ACCORDING TO YOU, CAN INDIAN COMPANIES SUPPORT IIT TO ENCOURAGE INNOVATION-BASED MEDICAL RESEARCH?

Active engagement through sponsored R&D programs including supporting Ph.D. careers. Another way is through CSR interventions; the Pfizer-IIT Delhi Innovation and IP Program is a unique unencumbered support model towards encouraging innovations and IP creation in the broad healthcare domain.

WHAT IS YOUR ADVICE TO THE YOUNG SCIENTISTS OF THE COUNTRY?

The young scientists carry a lot of expectations. Towards addressing the various challenges that we face, they should do what needs to be done and not simply stay in their comfort zone to do what they can/like. Besides, they should pursue R&D excellence in terms of completeness, quality and outcomes.

CERELIA NUTRITECH

With a vision to augment the global efforts for Sustainable Development Goals 2.1, 3.1 & 3.2; Cerelia Nutritech Private Limited was co-founded by N V V Kiran Vuppala, Ruchi Singh, Dipti Mohanty in 2016 with the mission of Cerelia is to develop a frugally innovative product for alleviating iron & vitamin deficiency anaemia. Cerelia is leveraging the seminal shifts in technology, changing consumer behavior to develop a unique product by transforming a moisturizer into a multi-micronutrient transdermal delivery system by integrating Nutritional supplement and Cosmetic markets.

Under the Pfizer IIT Delhi Innovation and IP Program, Cerelia is developing an Affordable, Accessible, Available nutrition intervention for prophylactic treatment of vitamin and iron deficiency anaemia offering unique benefits like increased micronutrient absorption, reduced dose wastages, malabsorption, increased bioavailability and compliance over the conventional delivery modes like oral pills and syrups etc. engaging the 3 'A's of Indian healthcare - ASHA, ANM, AWN, the team aims to ensure last mile delivery of this innovative healthcare solution that will eventually improve the nutrition status thereby improving the productivity and economic status of our Nation. Currently, we are at Pre-commercialisation stage i.e., TRL 6 – Prototype is being tested in a simulated operational environment or in a high-fidelity laboratory environment.

ENDO NASAL AIR PURIFICATION SYSTEM (ENAPS)

Air pollution is one of the major health hazards claiming one life every 23 seconds in India and causing huge amount of morbidity. While attention is being paid to policy-level changes, the need to protect health of people is unquestionable. However, existing solutions such as masks are unable to meet user expectations due to major drawbacks, including associated social stigma, difficulty to breathe, lack of comfort and inconvenience.

Our approach to solve this problem is based on the fact that approximately 95% of air that we breathe is through the nose. ENAPS is an innovative solution which comfortably hides in nostril and purifies air with high efficiency (comparable to gold standard) without offering significant resistance to breathe. It is based on a novel air purification technology comprising unique pollutant capturing substances. Air interacts with these substances coated over specially designed air pathways and pollutants are captured. The design ensures maximal interaction of air with such material, with minimal air-flow resistance.

ENAPS includes several unique features that are briefly discussed below:

1. Highly efficient in real scenario: Masks do not seal effectively, hence offering a false sense of protection. ENAPS **conform to different types of nostrils and seal it by implementing multilayered compliant/shape retaining material to exert gentle outward force on the inner surfaces of the nostril.** This provides a well-sealed and highly efficient system to purify air before it enters the respiratory tract.

2. Minimum resistance to breathe: Another unique and very important feature of ENAPS is a seamless breathing experience for users without causing any discomfort. It is based on a **novel technique for air purification that does not suffer from high air-flow resistance as opposed to the current state-of-art techniques.** Our approach is unique as we are focusing on trapping pollutants from the air rather than filtering them through membranes.

3. Barely visible: ENAPS camouflage inside the nostrils (nasal vestibule) making it barely visible. This unique feature not only makes it aesthetically appealing but would also solve the problem of social stigma associated with wearing face masks.

4. User friendly: ENAPS is user friendly and does not cause any pain and discomfort to users as opposed to face masks. Users could conveniently talk, eat, and perform their daily activities without any restriction.

EARLY STAGE, COST-EFFECTIVE DIAGNOSIS AND ANTIBIOTIC SUSCEPTIBILITY TEST OF TYPHOID IN 7 HOURS

VALETUDE PRIMUS HEALTHCARE PRIVATE LIMITED

21 million case of infection and 6 lakh deaths per year worldwide make typhoid a huge global healthcare challenge. Despite the availability of cheap curative medication, high number of mortality and morbidity typhoid cases happen due to unavailability of timely and accurate diagnosis. Existing typhoid diagnosis methods are blood culture and immune response based assays. Blood culture based assay is sensitive to detect infection in early stage but the long processing time of 2-3 days make it unsuitable to initiate specific treatment. Widal®, tubex® and typhidot® assays are rapid test methods but can diagnose

the disease only after 4-8 days of disease manifestation. After disease confirmation, the antibiotic susceptibility information is also important for proper treatment. There are several strategies and ways has been developed for antibiotic susceptibility test that include microbiology lab based disk diffusion test, antimicrobial gradient methods, broth dilution method and advanced automated AST systems (Vitek, Sensititre ARIS 2X, walkaway instruments etc.). All these systems have limited usage as they are time consuming, require trained expertise and expensive.

We have developed a portable device iMC2-iAST which can detect typhoid within 5-6 hrs followed by antibiotic susceptibility information of *S. typhi* strain. This process involves culture followed by immuno-magnetic enrichment and fluorescent labelling of the target cells using iMC2 device, all in easy to handle iMC2 capture cassette. The enriched and fluorescently labelled target cells used for confirmation of *S. typhi* presence using an inbuilt fluorescent signal detector. The iMC2 confirmed typhoid sample loaded to iAST cartridge and placed in automated iAST device. iAST cartridge has 24 wells preloaded with different antibiotics at different concentrations and other iAST reagents. Fluorescent signal reading records automatically at t = 0, 30, 60, 90 and 120 minutes. These values calculated on the background for generation of antibiotic susceptibility pattern along with minimum inhibitory concentration (MIC) value.

PHYSICAL SIMULATOR FOR ENDOSCOPIC THIRD VENTRICULOSTOMY (ETV) AND VENTRICULAR SHUNT PLACEMENT

(Funded to: Virmat Pvt. Ltd.)

(Funded by: Pfizer IIT Delhi Innovation and IP Program)

The use of high definition stereoscopic operating microscopes and neuro-endoscopes for minimally invasive techniques has resulted in significant improvement in surgical outcome. However, these technological advancements pose several challenges to the neurosurgeons due to constrained operative field. Specialized training is required for developing surgical skills for these procedures. In the current apprenticeship model, the neurosurgeons learn by observing and assisting an expert inside operating room. But, the modern sophisticated neurosurgical equipment demands hands-on training to develop the required skills. The traditional approach of training is becoming more and more prohibitive due to lack of efficient training. To cope with these inherent problems of apprenticeship model and to provide effective training, the use of surgical simulators is an effective alternative.

Hydrocephalus is a medical condition resulting from the abnormal accumulation of cerebrospinal fluid (CSF) in the brain. It is treated either by performing endoscopic third ventriculostomy (ETV) or by placing a ventricular shunt. In ETV, an endoscope is inserted into the ventricular system by making a burr hole in the skull and an opening is created on the floor of the third ventricle. This allows the CSF to flow directly to the basal cisterns and hence short-cutting the obstruction. The other method for treatment of hydrocephalus involves placement of a ventricular shunt to bypass the excessive CSF into the abdomen.

Our project is related to development of a synthetic physical simulator to mimic surgical treatment of hydrocephalus. The simulator is being designed with the CT and MRI data of patients. It provides real surgical constraints as well as CSF circulation. The different synthetic materials being used for fabrication of skin, skull and brain are having relative bio-mechanical properties. The simulator is also designed to provide sensor-based surgical skills evaluation. Validation of the simulator will be done by expert and novice neurosurgeons.

DR. VIKRAM SAHANE
MBBS, MPH Research Scholar (SCTIMST)
Consultant, Tata Trusts

TRANSFORMING HEALTH THROUGH SCIENCE: THE TATA TRUSTS EXPERIENCE

The American theoretical physicist Brian Greene has explained science as a process that takes us from confusion to understanding in a manner that's precise, predictive and reliable - a transformation, for those lucky enough to experience it, that is empowering and emotional. In today's complex world, it is science that shows an objective route to navigate and find solutions to health challenges with their myriad aspects. It is science that allows us to touch lives that are confronting disease and find answers that transform the daily existence of those affected by disease and ill health.

It is a matter of pride that our Constitution includes the development of scientific temper, humanism and the spirit of inquiry and reform as one of the fundamental duties of every citizen of India. Faced with a problem or an issue, the attitude to problem-solving should involve reason, logic and rational thinking. Sustainable solutions can only be reached by observing, questioning, analysing, testing, hypothesising and communicating. It is a scientific temper that requires one to be free of any dogma or superstition. Communication is an important aspect of this as people need to be informed and educated about the significance of a scientific approach.

The Tata Trusts have been working in the health sector for many years through partnerships with governments, local panchayat bodies and partner organisations, and direct implementation to create a sustainable, socially relevant and state-of-the-art infrastructure and ecosystem to cater to varied healthcare problems. Using evidence-led methodology and available knowledge base to ensure targeted health outcomes, the various initiatives of the Trusts also focus on the creation of knowledge and keeping the knowledge base up to date to build capacities in delivering affordable and quality healthcare solutions as well as positively influencing healthcare policy.

Take the case of malaria, a disease that finds mention in many ancient texts along with its relation to bites of insects and mosquitoes. Ancient Indian literature describes many fevers akin to malaria. Dhanvantari (800 BC) claimed that fever with shivering can be caused by the bites of mosquitos. The Susruta Samhita (100 BC) also attributed malaria-like fevers to the bites of certain insects. Through the centuries, it has been a scientific approach that led to knowledge about

malaria increasing along with methods of treatment and control. This scientific approach has helped the Trusts approach the issue of endemic malaria in Odisha, a state that records the maximum disease burden despite being home to only 4% of India's population.

Malaria control in Odisha faces multiple challenges including patients presenting late for detection and awareness, increased drug and insecticide resistance, inaccessible areas and health infrastructure. As per the National Vector Borne Disease Control Programme in India, 1.13 million malaria cases were reported in 2015 with Odisha suffering 38 percent of India's malaria affliction. Inadequate surveillance and under-reporting of cases has led to a huge gap in the actual and reported incidence of malaria. The signing of an MoU with the Ministry of Health and Family Welfare, Government of Odisha led to the programme being implemented through an associate organisation, Livolink Foundation and five partner organisations covering five blocks in three districts of Kalahandi, Kandhamal and Rayagada, covering a population of 1,20,000.

The approach to the issue included a focus on protection, early detection and treatment and ensuring adherence to the treatment course. Steps undertaken included the development of a package of resource materials for launching a malaria campaign throughout the state as part of a communication campaign. Training was conducted on issues relating to malaria and malnutrition to enhance the capacities of a team that consisted of 9 core team members, 68 cluster coordinators and 411 village health volunteers. The prevalence of afebrile malaria which was responsible for over 50% of cases not being diagnosed was challenge. With support from the state government, RDK (rapid diagnostic kits) and anti-malarial drugs were supplied and the program was operationalised.

The RDK is a simple test that ASHA and Community Volunteers can use in remote areas where immediate laboratory facilities are not available.

The National Institute for Research on Tribal Health was roped in to conduct a baseline study in143 sample villages. Over 11,000 people were screened for malaria at seasonal mass screening camps held across 62 villages in Rayagada districts with logistics support from the state government. Those found positive were treated and counselled for treatment compliance. Supply of quality indoor residual sprays in inaccessible villages was also facilitated.

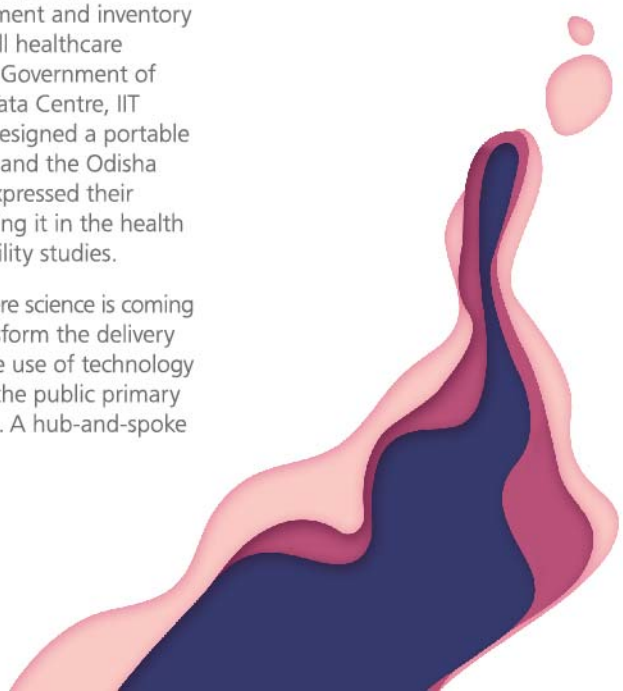
This initiative was also marked by the use of technological innovations which helped overcome the challenges of cultural and language barriers in remote, inaccessible tribal areas in collection of data to give a more complete picture of malaria prevalence. Furthermore, frontline health workers will be provided with handheld devices that are user friendly. This will enable them to accurately collect data and information related to health at the village level including data on fever, birth and death.

Going forward, the indirect outreach of the programme is expected to touch 8 million individuals across eight districts using effective communication strategies. The focus will be on piloting and integration of technology related solutions for surveillance, early detection and reports. Initiatives on these lines include working towards providing technical assistance to the Government of Madhya Pradesh, developing EHR/EMR (electronic health records and electronic medical records) with the Government of Telangana, and establishing a healthcare delivery system to automate procurement and inventory management for all healthcare providers with the Government of Maharashtra. The Tata Centre, IIT Bombay has also designed a portable digital microscope and the Odisha government has expressed their interest in integrating it in the health system after feasibility studies.

The other area where science is coming to the fore to transform the delivery of healthcare is the use of technology in supplementing the public primary health care system. A hub-and-spoke Telemedicine Network in Andhra Pradesh covers a population of over 10 lakh people over 256 Gram Panchayats.

The model includes a hub with doctors, located in Vijayawada, and 20 health centres spread across rural Vijayawada parliamentary constituency. These are supported by two mobile medical care units for outreach health services. The latest ICT tools connect the hub and the health centres. This enables qualified doctors at the hub to consult and guide the 20 health clinics and mobile medical units. These are empowered to offer consultation for primary and major medical conditions, basic lab services, treatment, screening (Cancer, ophthalmic conditions, diabetes and hypertension), and health education.

Throughout our history, it may be noted, a scientific approach has brought about transformation and has allowed us to address problems. A scientific approach ensures that the operational models are as per internationally accepted frameworks and guidelines with rigorous documentation for future learnings. It is essential that any methodology takes into account ethnographic factors and is culturally sensitive and aware if it is to truly transform lives in a sustainable manner. For a sustained improvement in health and quality of life, it is a structured and organised scientific approach that will allow us to make better decisions and surmount health challenges that we are facing through innovations in approach and technology.



DR. RATNA DEVI

Board Member, IAPO
(International Alliance of Patient Organisations)
Founding member IAPG
(Indian Alliance of Patient Groups)

EMPOWERING PATIENTS WITH TECHNOLOGY IN HEALTHCARE

AS A MEDICAL DOCTOR AND A BOARD MEMBER OF THE IAPO, HOW DO YOU VIEW THE CONVERGENCE OF TECHNOLOGY AND SCIENCE, IN THE INTEREST OF THE PATIENT?

Technology has many dimensions to it in the context of medical science. It could be research for new and innovative drugs, advanced diagnostic systems, patient monitors and life support devices, collection and use of data for better management of conditions, increasing communication, risk alerts and advance warning systems, wearables etc. Technology is everywhere. It aids and assists both providers as well as patient to manage the conditions well. It is therefore very important to converge technology with medical science for the betterment and protecting the interests of the patient.

WITH THE GROWING TECHNOLOGICAL INTERVENTION, HOW HAS THE PATIENT BECOME MORE EMPOWERED?

Today's patients are becoming more empowered than ever by taking an active role in their own healthcare experience. By assuming a greater role in the care they receive, patients can become informed and engaged medical consumers. And because there is more data than ever — as well as more paths to connect to it — the relationship between providers, patients and the way care is provided is changing. Data is being provided and accessed literally with the touch of a button, giving healthcare providers more insight into their patients' health and patients a direct line to healthcare wherever they are. By taking advantage of patient portals, data analytics, the cloud and other empowering IT solutions, healthcare providers can lay a solid path for improving patient outcomes and strengthening their patient engagement efforts. Patients are also searching for and connecting on the web for sharing experiences, have better access to information and are able to reach across continents to collectivise and advocate for their causes.

With the continued growth in the adoption of health apps and wearables, information on web, PHRs etc, providers are challenged by today's savvy patients, who are demanding more access and better data integration. As with any initiative in healthcare, addressing the needs of an empowered patient isn't satisfied by one solution. There are many moving parts and the technology needed to empower patients will be effective only if it is properly integrated and utilised.

PATIENT EMPOWERMENT COMES WITH ITS OWN RESPONSIBILITY AND ACCOUNTABILITY. WHAT IS THE ROLE OF THE PATIENT GROUP SUCH AS IAPO IN THIS CONTEXT?

As a representative of the patient voice IAPO has a very important role to play on five fronts

a. Provide authentic, validated scientific information to its members.

b. React and interact responsibly with stakeholders and their statements, stands and other public announcements.

c. Encourage patients and their groups/ representatives to work ethically, be apolitical and to work jointly and singly for raising the patient voice at all forums for the betterment of health systems.

d. Encourage patients to be honest with their care providers, take charge of their health condition and be responsible for the care pathway suggested to them.

e. Not be discouraged or afraid to raise issues that may be uncomfortable but are important and will help protect patient interests in the long run.

HOW DO YOU THINK THE GOVERNMENT, INDUSTRY AND PATIENT GROUPS CAN WORK TOGETHER TO PROMOTE INNOVATION- DRIVEN RESEARCH TO PROMOTE BETTER PATIENT OUTCOMES?

The first and foremost front is to recognise that patient groups are an important stakeholder and invite them to participate in important meetings, technical groups, advisory groups etc.

Support them financially and with other means so that they can thrive and work for the cause and not be bogged down with issues of survival as a group.

Build capacities to become advocates, use of social media and governance as well as management.

Support design of educational material, patient information booklets, etc.

Support research through empowered patients creating a demand for better healthcare.

IN WHAT WAY AND TO WHAT EXTENT WOULD THE EMERGING SCIENCE OF EPIGENETICS CHANGE THE WAY A FUTURE CLINICIAN APPROACHES THE PATIENT?

It is still very nascent in the context of India. However, it has a large scope in integrated medicine as lifestyle, mental and physical status affect gene expression profoundly. Environmentally influenced epigenetic changes have also been associated to many diseases such as cancer and neurodegenerative disorders, with patients that do not respond, or only poorly respond, to conventional therapy. Disorders based on an individual's personal genomic/ epigenomic profile can rarely be successfully treated with standard therapies due to genetic heterogeneity and epigenetic alterations and a personalised medicine approach is far more appropriate to manage these patients. The understanding of genetic and epigenetic is becoming increasingly important for the prevention, diagnosis, and treatment of several diseases and much attention has been given to molecular medicine. The development of molecular medicine, the fast progress of the new epigenetic approaches, and the reversible nature of the epigenome offer great advances in the fields of drug targeting and personalised medicine. India's healthcare systems and the patients' ability to pay for such therapies will need a lot of strengthening before such therapies become popular in India.

DR. JOERG MOELLER

Head of Research and Development,
Bayer Pharmaceuticals Division

MOVING FORWARD IN MEDICINE WITH INNOVATIONS

The burden of non-communicable diseases (NCDs) – conditions such as cardiovascular disease and cancer is set to increase with the aging population in Asia and across the world. India, with its proportion of elderly people (60 years or more) rising at an unprecedented rate to reach of 18% of its population in 2050, is facing a similar challenge.

Bayer is committed to addressing these unmet needs of patients globally through research and development (R&D) of innovative medicines. In 2017, Bayer increased its global R&D investments to nearly € 4.5 billion – 64.1 percent of the R&D investment is in pharmaceuticals. Bayer's pharmaceuticals pipeline is well-stocked with about 50 development projects in Phase I to III of clinical development to serve such medical needs. Among the drug candidates in clinical development are six new molecular entities (in the mid to late stage pipeline) which will have potential to treat various types of cancers, diabetic kidney disease, chronic heart failure and uterine fibroids which are also prevalent in India and in Asia-Pacific.

Moving forward, our objective is to get the right treatment to the right patient at the right time. By advancing the paradigm of "precision medicine", we want to tailor treatment approaches to the underlying molecular cause of an individual patient's disease and identify responders. This enables us to target those patients who would benefit most while allowing the healthcare system to reduce the number of unnecessary interventions. For example, we have been analysing the DNA of patients and monitoring the progression of their disease over the course of several years to predict patient outcomes based on patient genomics/biomarkers.

The IMI-funded Big Data for Better Outcome projects in hematological malignancies (called HARMONY), prostate cancer (called PIONEER) and heart failure (called Big Data@Hearts) are some examples. Our collaboration with LOXO Oncology is another example for a precision medicine approach where we are developing Larotrectinib, the first tumor-agnostic biomarker-guided precision medicine for Bayer Oncology which has been submitted to FDA for regulatory approval early 2018.

In combining deep expertise in biochemistry, engineering and data sciences, we now also have the chance to become more efficient and faster in bringing new medicines to the patients. We leverage big data and advanced analytics to accelerate drug discovery and improve drug development productivity. Examples include the move from *in vitro* to in silico work through cooperation with startup companies to better predict research outcome as well as the improvement of clinical trials e.g. by bringing the trials to patients rather than the patients to the trials. Another example is our recently established joint Precision Cardiology Laboratory at Broad Institute in Cambridge, MA, USA which will help us to stratify patients through genotype-phenotype correlation in cardiovascular indications.

Collaboration and partnership are integral to our company's innovation strategy. Collaborative research complements our R&D efforts in developing innovative medicines for patients worldwide. Bayer also believes that the industry, academia, governments and other partners in society must work together to make innovative medicines accessible to patients and are committed to this partnership to bring novel therapies to patients.

DR. THOMAS BREUER

Senior Vice President,
GSK Vaccines

ARE VACCINES SAFE?

Is this safe? This is the nagging question asked by the little voice in our head; the whisper that questions the choices we make. This little voice gets louder when we are boarding a plane, causing some of us to nervously close our eyes or grip the armrests during take-off and landing. It is the worried voice that joins us in a dark parking lot at the end of a long day, making us walk just a little faster when we hear footsteps in the distance. And, it is this same voice that talks to us when we, or someone we love, is waiting to get vaccinated. A little voice asking, is this safe?

While the nagging little voice is influenced by our subconscious and prone to irrational thoughts, as demonstrated in a previous post, my goal today is to tackle this question as rationally as I can. And, what better place to start than by answering the question:

WHAT DOES IT MEAN TO BE SAFE?

According to the Merriam-Webster dictionary, there are several definitions for the word safe. The first is "**free from harm or risk**". In applying this definition to vaccines, we need to acknowledge that vaccines, like all medications, can have side effects. In case of vaccines, these often occur at the injection site and can include redness, swelling, and/or some short-lasting pain. Other side-effects include malaise and fever, and normally, these pass quite quickly. More severe side-effects are very rare and closely monitored.

A second definition of safe is "**secure from threat of danger, harm, or loss**". This is a much better fit with vaccines as they are designed to help secure us from the threat of a real danger: Vaccine-preventable diseases.

It all comes down to what is known as a benefit-risk assessment. A vaccine is only approved for use if clinical trials show that the **benefits** of vaccination outweigh the **risks** associated with its use. And, we at GSK work with the world's leading medicine regulatory agencies on an on-going basis to monitor and evaluate the safety of our medicines and vaccines once they have been introduced. It is important to note that as vaccines are given to millions of healthy people (including small children) annually, this bar is set very high; the benefit of vaccines must **greatly outweigh the risk**, especially when it comes to public acceptance.

Weighing benefits and risks
For a moment, let's return to that nagging little voice at the start of this post, the one that questions the safety of the choices we make. With the summer holiday season wrapping up here in Europe, I see that I was not alone in rating the benefit of time spent on the beach as outweighing a fear of flying. I was also not alone when I recently chose to receive the non-live, adjuvanted Shingles vaccine (in use since 2017). It is estimated that more than 1.5 million people have received the vaccine since it was approved in several countries like the U.S., Canada, and my home country of Germany.

Background: Shingles is a painful rash that develops on one side of the face or body and is caused by the varicella virus — the same virus that causes chickenpox. The lifetime risk of getting Shingles is 1 in 3, increasing to 1 in 2 when you are over 80 years of age. The fact is that as we age, our immune system loses the ability to mount an effective response to shingles infection. And, the chance to suffer from Postherpetic neuralgia (PHN), a burning pain that lasts long after the rash and blisters of shingles disappear, is 30%. 1 million cases of shingles are estimated each year in the US.

The benefit of receiving the vaccine: Great decrease in the chance of developing shingles or its complications. The overall efficacy of the vaccine for people my age (50-59) is 96.6%, the efficacy against the severe pain syndrome (PHN) for the same age group is 91.2%. In fact, the vaccine demonstrated efficacy against shingles for more than 90% population across all age groups studied, including those over 80 years of age.

The risk of receiving the vaccine: Local side effects with this vaccine are common, short lived and expected since they are signs of the local activation of the immune system. Subjects greater than 50 years of age have reported local pain, redness, and swelling. My advice is that if you have any questions or concerns, talk to your health care professionals about whether vaccination is appropriate for you and, if so, what to expect in terms of side effects from vaccination and how best to manage them.

SO, WHAT DO YOU THINK? ARE VACCINES SAFE?
As Chief Medical Officer of GSK Vaccines, I want to assure the public that when it comes to vaccines overall, the benefit outweigh the risks; by far. As shown above, I have recently exposed myself to one vaccine in particular, weighing the risk of short-lived side effects with the far higher reward of almost certainly avoiding a painful, vaccine-preventable disease.

So, to close, although I know that is impossible to stop those little voices from questioning our safety, my advice to you is to not let that little voice determine the choices you make or the life you live. Instead, take that flight to your dream holiday destination, take the right precautions to minimize risk - walk with friends late at night and talk to your doctor about the vaccines that may be appropriate for you - and enjoy your life.

DR. MARK BACH

VICE PRESIDENT & HEAD -
Asia Pacific Medical Sciences
and China Innovation Leader
Janssen, Pharmaceutical Companies
of Johnson & Johnson

PHARMACEUTICAL INNOVATIONS TO COMBAT INFECTIOUS AND LIFESTYLE DISEASES

WITH INCREASING THREATS OF INFECTIOUS DISEASES AND PANDEMICS AROUND THE WORLD, HOW CAN PHARMACEUTICAL INNOVATIONS BETTER CONTRIBUTE TO COMBAT THESE DISEASES?

Developing and ensuring access to new medicines to address unmet medical needs is the core of what we do. This is where pharmaceutical innovation can play a very big role.

Major strides have been made over the decades to counter the escalating threats of infectious diseases such as HIV. Today, HIV is a very different disease than it was when it emerged over 30 years ago. We have characterised the disease and understood what its mechanisms are, how it is transmitted, and what to do and not to do for treatment. We have gone from treating HIV patients with up to two dozen pills a day to being able to treat them with one pill a day. People are living long healthy lives, thanks to the development of more than 20 drugs and combination therapies. But there are still more than 19.5 million people living with HIV on antiretroviral treatment; a recent study showed that more than 10 percent of patients in 6 of the 11 countries surveyed had strains of the disease that were resistant to the most widely used medicines.

Tuberculosis is another example. For the first time in over 40 years, a new TB drug with a novel mechanism of action, bedaquiline, has been made available for patients with multi-drug resistant tuberculosis. Our goal is to now get this innovation to patients who need it the most. That's where multi-sectorial collaborations step in. All sectors—public, private, and civil society—must put their minds together and look at innovative ways to accelerate access for patients.

WHAT IS YOUR VIEW ON "OPEN INNOVATION"?

Today's medical challenges are far more complex than ever before. That's why we cannot limit the search for new science and new medicines to our own four walls and need to embrace open innovation.

At Johnson & Johnson, we seek innovative ideas wherever they occur. Through our Johnson & Johnson Innovation Centers in London, Boston, California and Shanghai; our internal venture arm Johnson & Johnson Development Corporation; and the JLABs incubators. We are combining our internal Research & Development (R&D) with external innovation to solve unmet patient needs around the world.

In India, Johnson & Johnson has announced a new tuberculosis research partnership with the Council for Scientific and Industrial Research (CSIR-IMTECH) for the discovery and development of next generation anti-TB drugs. Through this partnership, IMTECH and Johnson & Johnson will collaborate in R&D activities to accelerate the end of TB by creating shorter, simpler and safer treatment regimens for MDR-TB.

CAN ARTIFICIAL INTELLIGENCE CHANGE HOW WE DISCOVER NEW MEDICINES?

Yes, our scientists at Janssen, the pharmaceutical division of Johnson & Johnson, have found a way to speed up the drug discovery process with artificial intelligence (AI).

Traditionally, the process of discovering new medicines would take years, due to the vast amount of data scientists must comb through to first identify the chemical compounds that are most likely to help treat a targeted disease—before they can even begin testing their effectiveness.

But a recent paper published in the journal Cell Chemical Biology presented an exciting development when it comes to drug discovery. Janssen scientists have found a new way to leverage AI - using computer systems to perform certain tasks that normally require human intelligence, also known as "machine learning"—to help speed up the process.

AS YOU LOOK TO THE FUTURE OF INNOVATION, WHAT ARE THE BIG TRENDS YOU EXPECT WILL SIGNIFICANTLY IMPACT HEALTHCARE IN THE NEXT FIVE YEARS?

We see three big trends in innovation: use of health technology, early detection and early intervention. In the past few years, we have witnessed good progress in these fronts. From what started with the evolution of Fitbits is now transforming into sophisticated, health technology-driven approaches to data acquisition and monitoring and AI-based analytics that can identify potential health risks early and deploy better solutions to keep people healthy. Technologies such as low dose CT scans are aiding affordable and early detection of cancer thereby contributing to early medical intervention and better recovery.

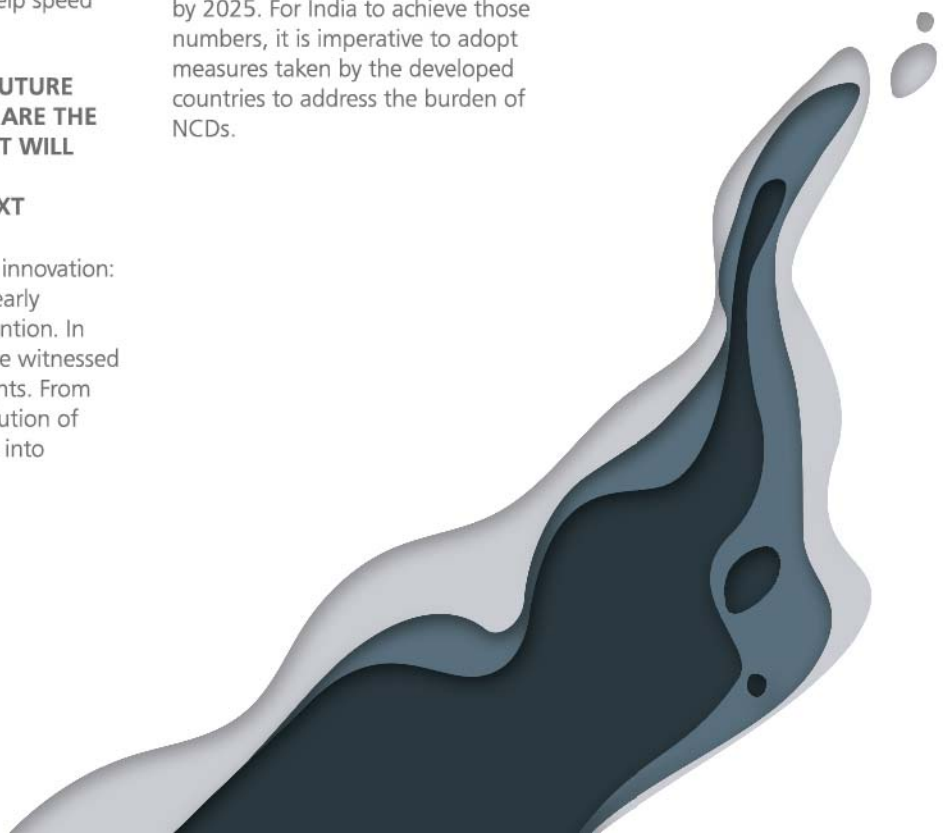
On the therapy side, new modalities such as gene editing and CAR-T are beginning to mature, giving rise to medicines we couldn't have even predicted five years ago. At the same time, new drug-development tools such as organs-on-a-chip are enabling biological research on a whole new level, which will lead to new ways to treat disease.

WITH NCDs BECOMING A GLOBAL PUBLIC HEALTH HAZARD, WHAT ARE SOME OF THE STEPS TAKEN BY THE MORE ADVANCED NATIONS TO COMBAT NCDs?

Every year, roughly 5.8 million Indians die from heart and lung diseases, stroke, cancer and diabetes. In other words, 1 in 4 Indians have a risk of dying from an NCD before they reach the age of 7. As per the WHO's Global action plan for the prevention and control of NCDs 2013-2020, India is the first country to develop specific national targets and indicators aimed at reducing the number of global premature deaths from NCDs by 25% by 2025. For India to achieve those numbers, it is imperative to adopt measures taken by the developed countries to address the burden of NCDs.

The need of the hour is an integrated policy environment, which is framed on disease trends, risk assessment intelligence and cause-specific mortality analytics. The penetration ratio of both public and private health insurance is very low for India at 3.4 per cent in 2015, as against world average of 6.2 per cent, according to ASSOCHAM. Therefore, it is important for both the public and private sectors to come up with innovative health financing schemes that use basic principle of risk pooling, cross-subsidization and comprehensive services package to cover NCDs and reduce out-of-pocket expenses.

It is time to adapt uniform, web-enabled and tiered surveillance systems throughout the country to understand the disease profile better. These evidence-based policies will lead to the strengthening of the current healthcare system in treating NCDs, making it robust, accessible for all, affordable, and effective. It will guide a shift from curative to preventive care with a focus on creating awareness, early diagnosis and counselling, and the development of a highly skilled workforce adequate to meet the health requirements of our people.



DR. ROY BAYNES

Senior Vice President and
Head of Global Clinical Development,
Chief Medical Officer,
MSD Research Laboratories

EXPLORING POSSIBILITIES WITH IMMUNOTHERAPY IN CANCER TREATMENT

Cancer remains the dreaded Big C for most of us. Today, immuno-oncology therapy is deemed to be the future of cancer treatment.

WHAT ARE THE DIAGNOSTIC TOOLS THAT WILL AUGMENT THIS THERAPY? WHAT IS THE ROLE OF GENETIC MARKERS IN CANCER, BOTH IN TERMS OF DIAGNOSIS AND PROGNOSIS?

Research has enabled us to reach where we are today. As a practicing oncologist for more than 30 years, I believe we are at an inflection point for some cancers, but much more progress is needed as the burden of cancer continues to grow. Further research is critical to maximize the application of monotherapies and realize the clinical potential from the evaluation of cancer combination regimens.

Building on our work demonstrating the application of the PD-L1 and MSI-H/dMMR biomarkers in immunotherapy, MSD is conducting research with a wide range of pan-tumor predictive biomarker and diagnostic development programs.

In addition to biomarker research, a key area of focus for MSD is improving understanding of the relationships between tumor inflammation, tumor mutational load, and response to immunotherapy in order to better understand why some patients respond and others do not.

HOW CAN THIS TREATMENT OUTCOME BE BALANCED WITH REACH AND AFFORDABILITY? WHAT ARE SOME OF THE GLOBAL PRACTICES FOLLOWED IN THIS REGARD?

Cancer is one of the greatest health challenges of our time. Today, we have unprecedented momentum in treating a wide range of cancers, including advanced lung cancer, for which previously there was little hope. Many regulators and payers around the world have moved rapidly to ensure that patients can access immunotherapies as quickly as possible. For example, accelerated pathways have been used to evaluate these medicines, often using early trial results. Some payers have used innovative funding and reimbursement approaches to accelerate access to immunotherapy while improving the predictability of funding these medicines.

Evidence-based reimbursement for immunotherapy will encourage further research to find the best approaches to cancer treatment in the widest possible population of patients.

MSD is working with regulators and payers to develop innovative approval and funding processes that will address the complexities of immunotherapy, including the use of combination treatment and biomarkers for improving survival. MSD is committed to work with patients, clinicians, payers, and governments to help ensure sustainable access to cancer immunotherapy. The promise of immunotherapy can only be fully realized if we all work together to make these treatments accessible to patients who need them.

HOW SPECIFIC ARE LIQUID BIOPSY TECHNIQUES LIKELY TO BECOME IN THE NEAR FUTURE?

Liquid biopsy techniques offer a compelling opportunity to provide a non-invasive means to identify, evaluate and monitor treatment options and outcomes for patients with cancer. Further work is required to refine the current technologies and fully characterise their utility in cancer diagnosis, informing choice of therapy and monitoring therapeutic responses.

Notably, in 2017 MSD invested in Grail, one of the leading developers of liquid biopsy technologies.

In case of developing orphan drugs, discovery of drugs for river blindness changed the way Africa saw the world.

WHAT ARE THE CONDUCIVE FACTORS REQUIRED FOR THE DEVELOPMENT OF ORPHAN DRUGS FOR DISEASES AFFECTING COUNTRIES OF LOWER ECONOMIC STATUS IN THE WORLD?

MSD initiated research on ivermectin for use in humans for the neglected tropical disease onchocerciasis (river blindness) in 1978, leading to the creation of the now 30-year old MECTIZAN Donation Program. We are enormously proud of the impact that ivermectin has had and that the Program continues to be a model for others to emulate. Through a range of in-house programs and external partnerships, we continue to conduct research to address the burden of neglected tropical diseases (NTDs), for example: We are an original signatory to the London Declaration, a collaborative effort launched in 2012 to accelerate progress toward eliminating or controlling 10 NTDs by the end of the decade.

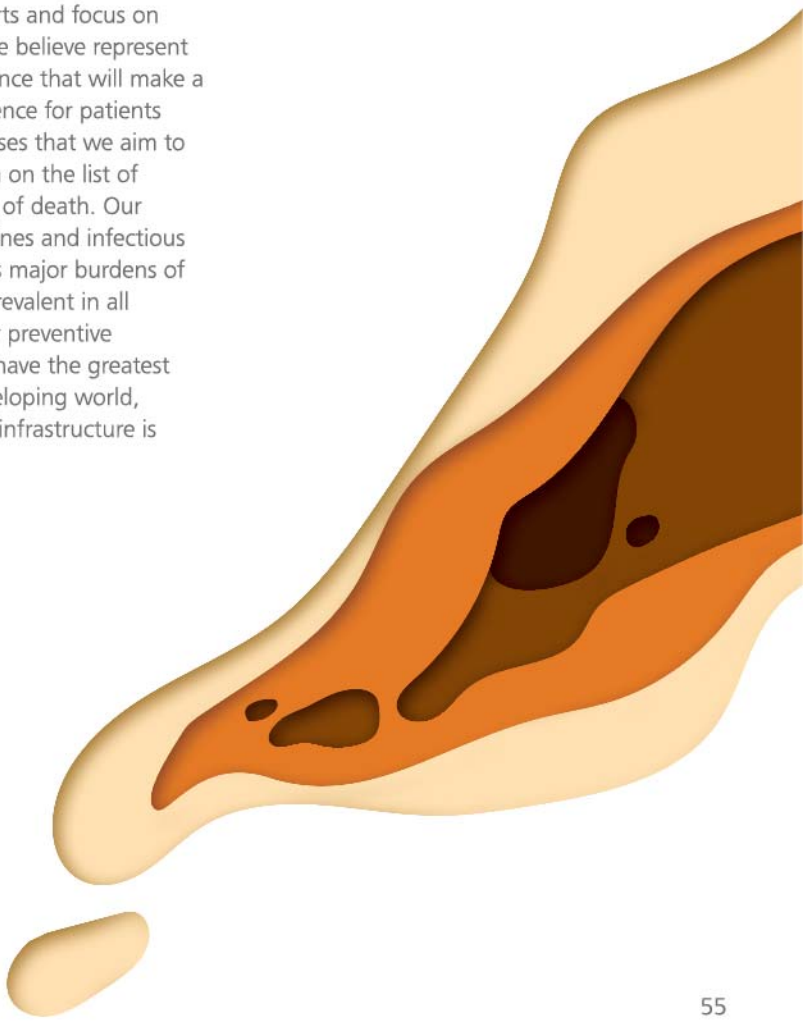
MSD is one of the founding members of WIPO Research, a consortium of public and private organizations that facilitates research on NTDs, malaria and tuberculosis.

Starting with the Ebola virus outbreak in West Africa in 2014, along with international agencies and governments, MSD has played a leadership role in efforts to contain the spread of the virus and put necessary steps in place to address emerging threats in the future through evaluation of an investigational vaccine to the virus.

We prioritize our research and development efforts and focus on candidates that we believe represent breakthrough science that will make a meaningful difference for patients globally. The diseases that we aim to address, rank high on the list of worldwide causes of death. Our research into vaccines and infectious diseases addresses major burdens of disease that are prevalent in all countries, and our preventive treatments could have the greatest impact in the developing world, where healthcare infrastructure is weak or nonexistent. Orphan diseases by their very definition affect fewer individuals and are not a key area of focus for MSD.

WOULD THERE SOON BE TECHNOLOGICAL WAYS TO MANUFACTURE OLDER DRUGS AT A LOWER COST AND SHORTEN THE PRODUCTION TIME?

We are always seeking new ways to improve the efficiency of our manufacturing processes and procedures while ensuring the quality of our products, within our own facilities and with our supply chain partners around the world. We support industry and regulatory efforts to develop and optimise quality and manufacturing standards worldwide, including alignment with those of the International Conference on Harmonization.



DR. RAMESH PANCHAGNULA
MD, Nektar Therapuetics

BRINGING HEALTHCARE INNOVATIONS IN INDIA: A DREAM NOT FAR ENOUGH

AS YOU TRANSITIONED FROM SCIENTIST, PROFESSOR AND NOW TO A BUSINESS LEADER, WHAT IS YOUR THOUGHT OF 'DREAM BIG' AND RESULTANT OUTCOME?

German scientist Robert Koch is the reason we understand TB. It is the poorest and socially excluded groups that mainly carry this disease and India is on top of the list (in disease burden). Many innovations and therapies have been made to fight against TB which is commendable, but we are not yet close to accomplishing global elimination.

I have been working for about 30% of my time on anti-TB drugs for the past decade. The fieldwork experience gained in India/US/Europe as well as International Organizations (with WHO, UNDP, World Bank, GATB, IUATLD, MSF, IAPSO, Stop TB initiate and Global Drug Facility, NGOs and Indian Pharmaceutical Industry) through collaborative research and exchanges in connection with quality assurance and assessment, bioavailability aspects of anti-tubercular drugs, TB drug discovery, development and delivery has contributed immensely in fighting tuberculosis through Fixes Dose Combinations (FDCs).

The comprehensive and systematic studies that characterised the pharmaceutics of anti-TB drugs for the first time have resulted in the availability of high quality FDCs.

Therefore in this back drop, it is my dream that when my great grandchild goes to Medical School, professors of that generation should be teaching "For centuries there was one disease that use to affect people of developing and underdeveloped countries which was known as tuberculosis and that this dreadful disease is now confined to textbooks and completely eradicated from the face of the earth."

WHY THE COST OF INNOVATION TO BRING NEW MEDICINES TO TREAT PATIENTS IS HIGH?

The current generation pharma/biopharma companies are continuously re-investing in future R&D. About 2+ billion dollars are invested to develop a new medicine with very low success rates which takes about 12 years. The innovation in medicines is driven by the complexity of biology or pathology. Further, it is driven by the need for new and better medicines that can go beyond just managing the diseases, in some cases to be able to prevent the disease. While development is proving new medicines are not only safe/efficacious (preclinical and clinical development) but produced in GMP environment with quality repeatedly being as per regulatory requirement (pharmaceutical development and manufacturing).

Drug discovery is a costly, highly risky and time consuming process. As per current estimates it costs around 2 billion US dollars and around 8–10 years to bring a new medicine to the market. The innovations in medicine are driven by the complexity of biology/pathology, the need to ensure the drugs are safe and efficacious (preclinical and clinical development) produced using robust process and are of highest quality (pharmaceutical development and

manufacturing). The pharmaceutical industry is one of the most regulated industry and rightly so because we are dealing with human life here. All this adds to the cost of discovering and developing medicines.

But I would also like to add that for decades, the pharmaceutical industry has been working actively to drive down the cost of drug failure in terms of time and money. There is a huge effort from the industry both at the scientific and strategic levels to try and improve the efficiency of R&D processes. On their part, the regulators have also taken initiatives to bring down the time for approval of new drugs e.g., the time between approval of first and second medicines in a therapeutic class has declined dramatically from 10 years in 1970 to 2 years during 2005–2011. All these developments are science driven to help patients.

WHERE DO YOU SEE NANOTECHNOLOGY IN HEALTHCARE AND MEDICINES?

Nanotechnology is expected to play an integral part in human healthcare and medicines. There are several examples that highlight the role of nanotechnology in life cycle management of small molecules. It could be used to improve the performance in existing indications, used in treating new indications as well as applied to biopharmaceuticals. In particular, the dependency on this technology is increasing in areas such as manipulating the genetic material to correct the diseases that happens inside the cell which is about 10 microns in size; while some efforts describe the use of genetic material to create a nanostructure to transport a molecular payload to manipulate the cell behavior. At the same time nanotechnology is also being used to make drugs on demand at the site of action.

While the potential is huge, concerns surrounding nanotechnology are delaying the progress. To address such issues it is important to involve all the stakeholders in the policy making that includes academic, industry, regulator, clinician and the patient advocacy groups. It is also important to secure public confidence to maximize the benefits of nanotechnology, which is the future of healthcare and medicines.

WE HEAR ABOUT DISRUPTIVE INNOVATION IN MANY OTHER INDUSTRIES CAUSED BY ENABLING TECHNOLOGIES. WHAT IN YOUR OPINION ARE THE TECHNOLOGICAL ENABLERS THAT WOULD DRIVE INNOVATIONS IN THE FIELD OF HEALTHCARE/ PHARMACEUTICAL SECTOR?

As in other fields, technology has the potential to cause disruptive innovations in the field of healthcare in general and that is expected to have a cascading effect on pharmaceuticals and the way drugs are discovered and developed.

As we all are aware the landscape of technology is changing exponentially and there are three technologies, which in my opinion could have far reaching implications on diagnostics, treatments and delivery of healthcare in the future. These are:

1. Artificial Intelligence (AI):
AI systems have the potential to provide physicians and researchers with clinically relevant, real-time and quality information. This can revolutionize the way clinical trials would be conducted in the future. It also has potential to transform quality management systems.

2. Data analytics:
This area can open immense possibilities such as predictive analysis so that practitioners can predict the likelihood of patient being diagnosed with a disease. Such capabilities will shift the paradigm of healthcare from treatment of symptoms to prevention measures and complete cure. Further, data analytics could lead to consumerisation of health through increased access to data by patients via technological enablers like wearable devices, apps, gamification and digital medicine, enabling patients to better understand and get more involved in managing their conditions.

3. 3D printed biological materials:
As access to 3D modelling and design softwares becomes readily available, its application in medicine could encompass printing of biological materials such as embryonic stem cells, printing skin, blood vessels and heart tissues, replacing cartilage and bones as well as replacing organs.

WHICH INNOVATIONS IN SCIENCE HAVE BIGGEST POTENTIAL TO IMPACT THERAPY/HEALTHCARE?

The innovations in medicine are steering away from small molecule drugs to biologics that have the ability to target specific group of patient based on genetic makeup, using body's own immune system to fight the disease, and some of the examples include:

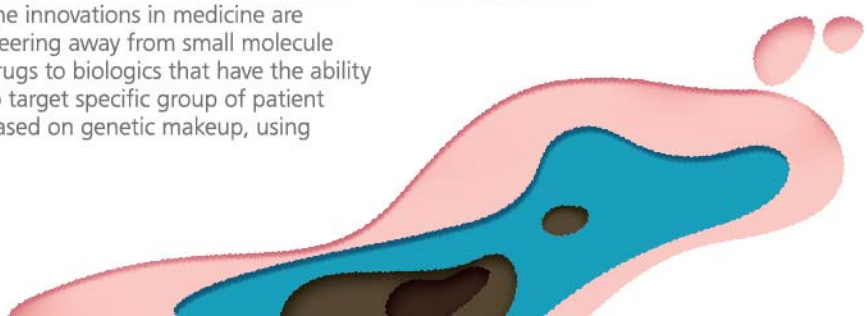
- Latest CRISPR/Cas9, a gene editing technique, which can be used to make targeted modifications to DNA accurately, cost effectively and reliably. Gene therapy could be used to treat diseases in neurosciences, ophthalmology, hematology, enzyme replacement, oncology, etc.

- Research on microbiomes and their role in human health is expected to tell us more around the connection between the mind and the GUT and between heart disease and the GUT.

- I know the industry is focused currently on degenerative diseases of the brain such as Alzheimer's, use of BP medication for a long time. The cause of Alzheimer disease is another area which is receiving significant attention around the world. New understanding of disease biology/pathology is providing opportunity to refine/identify new avenues about how mind works or degenerates, thereby providing clues for newer medicines.

- Another very exciting area of emerging science is that of cell-based gene therapy where you take the cells out of the body and reprogram the cells and inject them back in the patient's body to illicit a desired response. Example is Kymriah, the pioneering cell-based gene therapy for cancer treatment from Novartis that was approved very recently by US FDA. Once this science is established successfully it could be expanded for treating genetic disorders too. These therapies have the potential to transform medicine such that we could start dreaming of treating and even curing some of the illnesses that are currently considered intractable.

- Finally, the recent approval by FDA of the first therapy based in RNA interface (RNAi) is a landmark approval for a technology that was awarded the Nobel prize in 2006. RNAi could be used to target virtually any gene of the human genome that is causing disease to stop its expression, thus unlocking molecular targets that were inaccessible.



DR. SUBODH DESHMUKH
Head of Global Development,
Novartis India

NOVARTIS BRINGS NEW AND BETTER THERAPIES FASTER TO PATIENTS IN NEED

Just as the invention of the wheel changed the way of transport forever, so will the giant strides being taken in data and digital, change the way human healthcare is managed, especially how new therapies are discovered and developed. To put this in perspective– disruption in healthcare is happening 3000 times faster than the industrial revolution. While technological change is not new, what is different is the number of technological disruptions happening at the same time and the speed at which this is happening.

Technology disruptions are moving from hardware to software – and from there to data. The enormous progress in the use of technology in science starting with the sequencing of the human genome and the plethora of data that is generated and analysed has begun having far reaching impact on the way medicines are discovered and developed. Think about it. There are more than 300,000 healthcare applications today as compared to just a few years ago.

We see this as a tremendous opportunity to not only quicken the pace of drug development but also improve our ability to bring newer and better therapies to patients in need. Technology has the potential to help address several issues that scientists face with using traditional means as they seek to find better solutions with far improved health outcomes.

CHANGING FOCUS FROM TREATING SYMPTOMS TO HEALTH OUTCOMES

A healthcare system that is focused on health outcomes would look very different from a healthcare system that is focused on treating symptoms. It would include clear performance measurement and management. It would have well-trained healthcare providers who would be rewarded for their ability to keep patients out of the hospital or reduce the overall burden of disease. This would lead to optimal use of limited resources, minimal wastage of public funds and much better health outcomes.

As scientists and researchers it is important to understand that the world is interconnected like never before and with it, expectations of people everywhere are rising. Today, a person in India has similar expectations of healthy longevity as a person living in the United States, for example, both demand a better quality of life and a more equitable access to health services.

As demands for healthcare rise, governments and societies will need to look at how best they can deliver efficient healthcare and this will mean gearing up to deliver better health outcomes. Data will play a key role here as the value of everything that will drive those health outcomes will need to be captured including diagnostics, preventive care, use of medication, services provided by the healthcare practitioner and hospitals and so on.

GOING BIG ON DATA AND DIGITAL

Going big on data and digital is a strategic priority for Novartis and we are looking at new ways to harness the power of digital technology in all aspects of our business – from early stage discovery to drug development; from manufacturing and sales to digital therapeutics. Globally we have collaborations with leaders in digital technology – Microsoft, Qualcomm, Apple and Google to name some. We follow a similar approach in India where we are partnering with technology startups and leading universities.

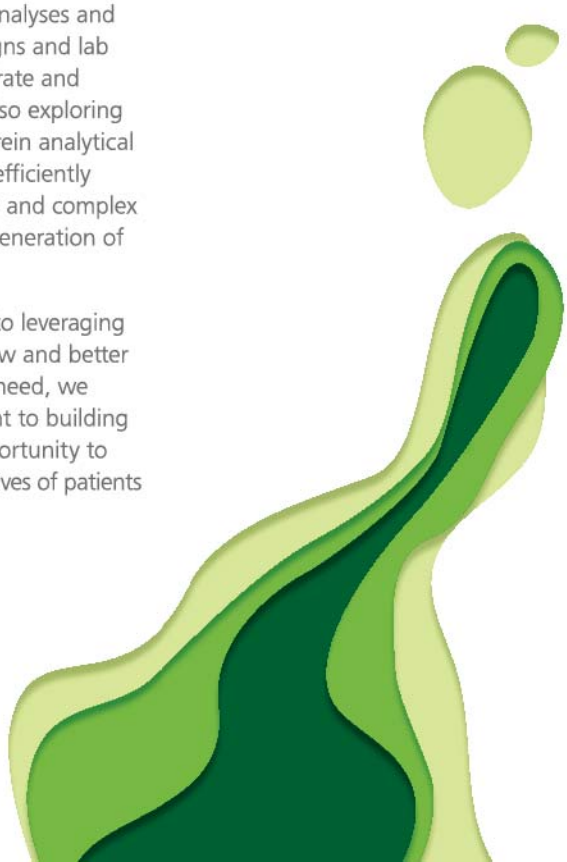
Given the technological advances in computing and data processing, the current models of collecting and curating data are going through some systemic changes. As the use of Artificial Intelligence (AI) and machine learning become more widespread, it will sharpen our ability to rapidly analyze huge amounts of data sets and deliver results in far more efficient ways, radically reducing the time taken to bring new drugs to the market.

At Novartis, technology is already being applied in several areas of drug development – clinical trials for example, that we do right here in India. Last year we had more than 60 clinical studies happening across the country covering a range of therapeutic areas; across oncology, cardio metabolics, immunology and dermatology, ophthalmology, respiratory and neurosciences. Each study involves the collection and analysis of large amounts of data that will help us to serve our patients better through the medicines we develop. The use of technology and data analytics helps us analyze and evaluate clinical data in real time very swiftly as opposed to weeks earlier. Unleashing the power of advanced analytics can help us define targeted patient populations, find new disease biomarkers and even create medicines in silico.

We are also looking at more effective ways to integrate predictive analytics into our everyday practices. Advanced analytics is helping us lead with real-time, data-driven decision-making in our clinical trials. All of these have helped us fundamentally change the way we initiate and facilitate clinical trials, improving efficiencies and allowing us to identify trends and determine efficacy early on in the drug development cycle.

Our teams are working closely with academic institutes and industry partners to develop technology solutions that will automate certain data management processes to make the analyses and interpretation of vital signs and lab data quicker, more accurate and insightful. The team is also exploring data lake solutions wherein analytical tools can be applied to efficiently access and analyse large and complex data sets to accelerate generation of medical insights.

While we look forward to leveraging technology to deliver new and better therapies to patients in need, we reaffirm our commitment to building on this tremendous opportunity to improve and extend the lives of patients everywhere.



SCIENCE INSPIRES

Allergan

FIVE COMPOUNDS IN LATE STAGE DEVELOPMENT

- First Oral CGRP Antagonists in Migraine- Atogepant (Migraine Prevention) & Ubrogepant (Acute Treatment of Migraine)
- Rapastinel, an NMDA Receptor Modulator, as a Rapid-Acting Antidepressant (MDD)
- Abicipar, an Anti-VEGF Treatment, utilizing DARPin® Technology for AMD & DME
- Relamorelin, a potential new prokinetic treatment for Diabetic Gastroparesis & Cenicriviroc, First-in-Class CCR2/CCR5 Inhibitor for Treatment of NASH

ALLERGAN IS ALSO WORKING ON GENE THERAPY AND GENE EDITING TECHNOLOGIES FOR EYE DISEASES.

AMGEN

Amgen has a robust and differentiated pipeline with a mix of innovative molecules, new indications and biosimilars. ~75% of its preclinical and clinical programs have genetic support. The U.S. FDA has granted Breakthrough Therapy Designation for **Tezepelumab** in patients with severe asthma without an eosinophilic phenotype.

European Commission Approves **BLINCYTO® (Blinatumomab)** For Use In Pediatric Patients With Philadelphia Chromosome-Negative Relapsed Or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia.

astellas

Astellas has in line the FLT3/AXL inhibitor **Gilteritinib** for the treatment of adult patients who have relapsed or refractory **Acute Myeloid Leukemia** (AML) with a FLT3 mutation which occurs in around 30% AML patients and associated with poor survival outcomes.

It is also working on getting approval for the JAK inhibitor **Peficitinib** for the treatment of **Rheumatoid Arthritis** in patients who have an inadequate response to conventional therapy.

AstraZeneca

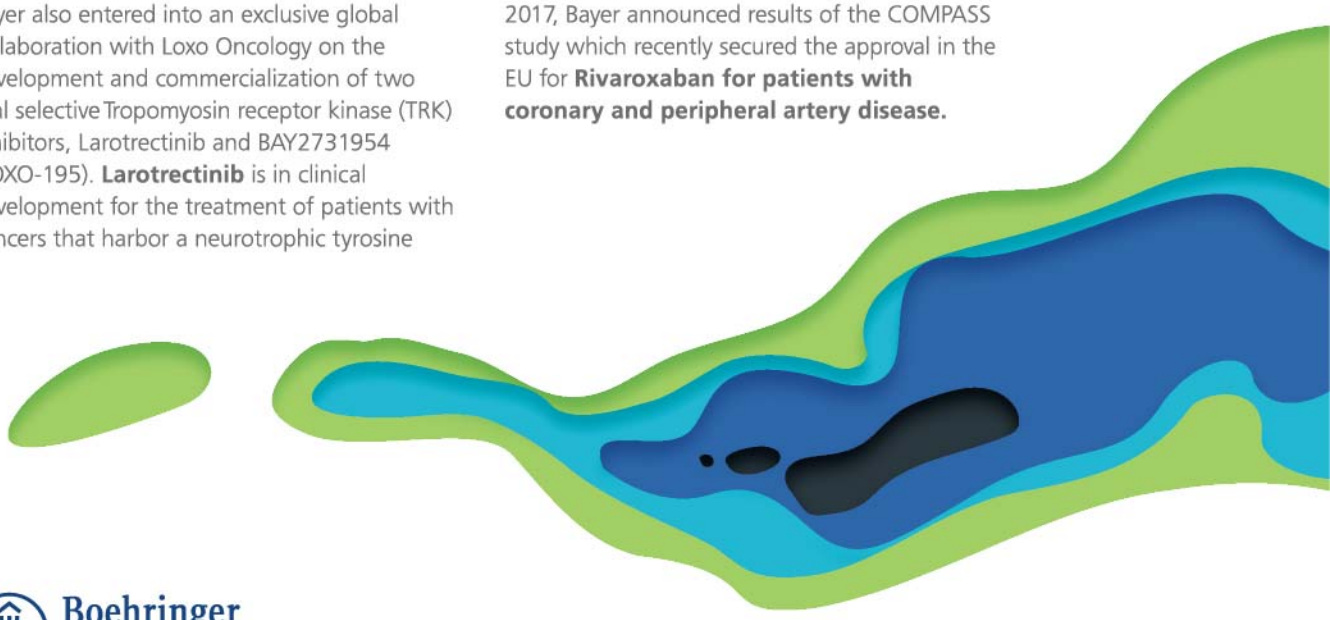
The company has an exciting and balanced pipeline underpinned by great science across its three areas of focus – Cardiovascular Renal Metabolics, Respiratory and Oncology. The company's global pipeline has the potential to deliver 10 new medicines by 2020.

US FDA recently approved Imfinzi, the only immunotherapy approved for patients with unresectable Stage III non-small cell lung cancer and Osimertinib, as monotherapy for the 1st line treatment of adult patients with locally-advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations. Breakthrough Therapy Designation has been granted by US FDA for Tezepelumab for patients with severe asthma and EMA has granted Selumetinib orphan designation in Europe for neurofibromatosis type1.

Bayer's pharmaceutical pipeline is well-stocked with about 50 development projects in Phase I to III of clinical development to serve the unmet medical needs of the world's aging population. Among these projects, six of them (in the mid to late stage pipeline) will have potential to treat various types of **cancers, diabetic kidney disease, chronic heart failure and uterine fibroids.**

Bayer also entered into an exclusive global collaboration with Loxo Oncology on the development and commercialization of two oral selective Tropomyosin receptor kinase (TRK) inhibitors, Larotrectinib and BAY2731954 (LOXO-195). **Larotrectinib** is in clinical development for the treatment of patients with cancers that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. NTRK gene fusions are genomic alterations resulting in uncontrolled production of Tropomyosin receptor kinase (TRK) fusion proteins, and lead to tumor growth.

In addition to new drug candidates, Bayer conducts studies with its launched products to further expand their spectrum of indications. In 2017, Bayer announced results of the COMPASS study which recently secured the approval in the EU for **Rivaroxaban for patients with coronary and peripheral artery disease.**



Boehringer Ingelheim

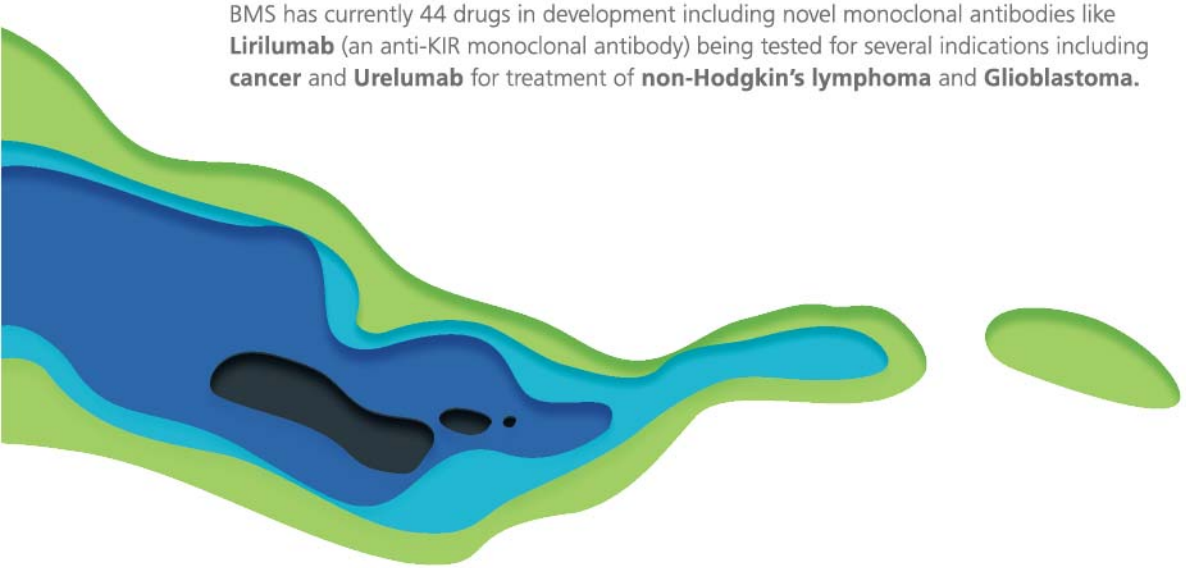
The Company's R&D strategy and current pipeline has the potential to deliver 15 new medicines for approval by 2025. With a high percentage of first-in-class and breakthrough potential drug candidates, Boehringer Ingelheim continues the successful implementation of its R&D strategy.

Boehringer Ingelheim is committing more than € 20 billion euros to Research & Development for human pharmceuticals by 2025.

- BI has encouraging drugs lying in its pipeline like Vargatef (Nintedanib) for the treatment of advanced non-small cell lung cancer which is currently undergoing phase 3 trial
- Further development of Jardiance (Empagliflozin SGLT2 inhibitor), is ongoing which aims to investigate the treatment of people with chronic heart failure with and without diabetes
- The SENSCIS™ trial is the the largest global prospective clinical trial in SSc-ILD to date which is evaluating the efficacy and safety of Nintedanib in patients with SSc-ILD

Bristol-Myers Squibb

BMS has currently 44 drugs in development including novel monoclonal antibodies like **Lirilumab** (an anti-KIR monoclonal antibody) being tested for several indications including **cancer** and **Urelumab** for treatment of **non-Hodgkin's lymphoma** and **Glioblastoma.**



Eisai

Eisai has one of the most promising pipeline of drugs with innovative line of approach to help millions of patients have better quality of life. Many of these drugs are in niche therapeutic area which underlines Eisai's approach of Human Health Care (HHC).

This pipeline prominently include BACE (beta-site amyloid precursor protein cleaving enzymes) inhibitor **Elenbecestat, BAN 2401 and Aducanumab** for early **Alzheimer's disease** and selective monoamine oxidase B (MAO-B) inhibitor **Safinamide** for **Parkinson's disease. Lemborexant,** an orexin antagonist, **for sleep disorder and Lorcaserin,** a serotonin receptor activator for weight loss are other drugs expected to be launched by Eisai in near future.

Lilly

For more than 140 years, Lilly has worked tirelessly to discover medicines that make life better. Their fundamental strategy is predicated on discovering new medicines. Lilly currently has one of the robust mid-to-late stage pipelines in its history.

- 7 molecules in phase 3 clinical development
- 10 molecules in phase 2 testing
- 22 molecules in phase 1 testing
- 1 molecule in regulatory review

To accelerate progress for patients, they are focused on three interlocking R&D initiatives: Next Generation Development, Next Generation Research and External Innovation.

GILEAD

Gilead's research and development program identifies and evaluates investigational compounds that show potential to advance the treatment of life-threatening diseases in areas of unmet medical needs. Gilead has multiple NCEs in therapy areas such as hematology, oncology, inflammation, respiratory, liver diseases and HIV across various stages of clinical development.

gsk do more feel better live longer

GSK (Glaxo Smithkline) has **Mepolizumab**, an anti-IL-5 monoclonal antibody which is approved as an add-on treatment for severe refractory eosinophilic asthma in adult and adolescent patients and has just received approval in Europe for use in children from six years old. It is also approved for **Eosinophilic granulomatosis with polyangiitis** in the US, Japan and Canada and is being investigated in COPD, severe hypereosinophilic syndrome (HES) and nasal polyposis.

Johnson & Johnson PRIVATE LIMITED

Johnson & Johnson has a 130-year legacy of impacting human health through innovation. The company is relentlessly pursuing the best breakthroughs in science and technology through its own labs and from its powerful network of scientists and entrepreneurs all over the world. With a portfolio focused on six core therapeutic areas – Immunology, Infectious Diseases & Vaccines, Neuroscience, Cardiovascular & Metabolism, Oncology, and Pulmonary Arterial Hypertension – the Janssen Pharmaceutical Companies of Johnson & Johnson are an industry leader in research productivity. Since 2011, the company has received U.S. Food & Drug Administration approval for 14 new molecular entities, and in India Janssen has launched eight new breakthrough medicines in the last five years. Looking ahead, the company anticipates introducing an additional 10 innovative products in India across diabetes, immunology, infectious diseases, and oncology.

Lundbeck

Focus on R&D is the most important pillar in Lundbeck's ambition to improve treatment for people living with psychiatric and neurological disorders.

Merck has a promising drug pipeline with anti-cancer drugs such as **Tepotinib** (c-Met kinase inhibitor) undergoing phase 2 clinical trials for **non-small cell lung cancer** and **hepatocellular cancer** and immunotherapy monoclonal antibody - **Avelumab** (Anti PD-L1) undergoing Phase 2 & 3 trials for a wide range of cancers like **non-small cell lung, gastric, ovarian, head and neck, urothelial, renal** etc.

Besides these, Merck's oncology and immuno-oncology programs include other very promising compounds such as:

- M7824 (also known as anti-PD-L1 TGFß trap) is a potential novel first-in-class bifunctional immunotherapy currently being evaluated in Phase I in patients with advanced solid tumors. The PD-L1 and TGFβ pathways are 2 key immune evasion pathways that have independent and complementary immunosuppressive function.
- M3814 – highly potent and selective inhibitor of DNA-PK – currently in Phase 1 trials in solid tumors. DNA-dependent protein kinase (DNA-PK), regulates one of the major pathways responsible for repair of DNA double-strand breaks.

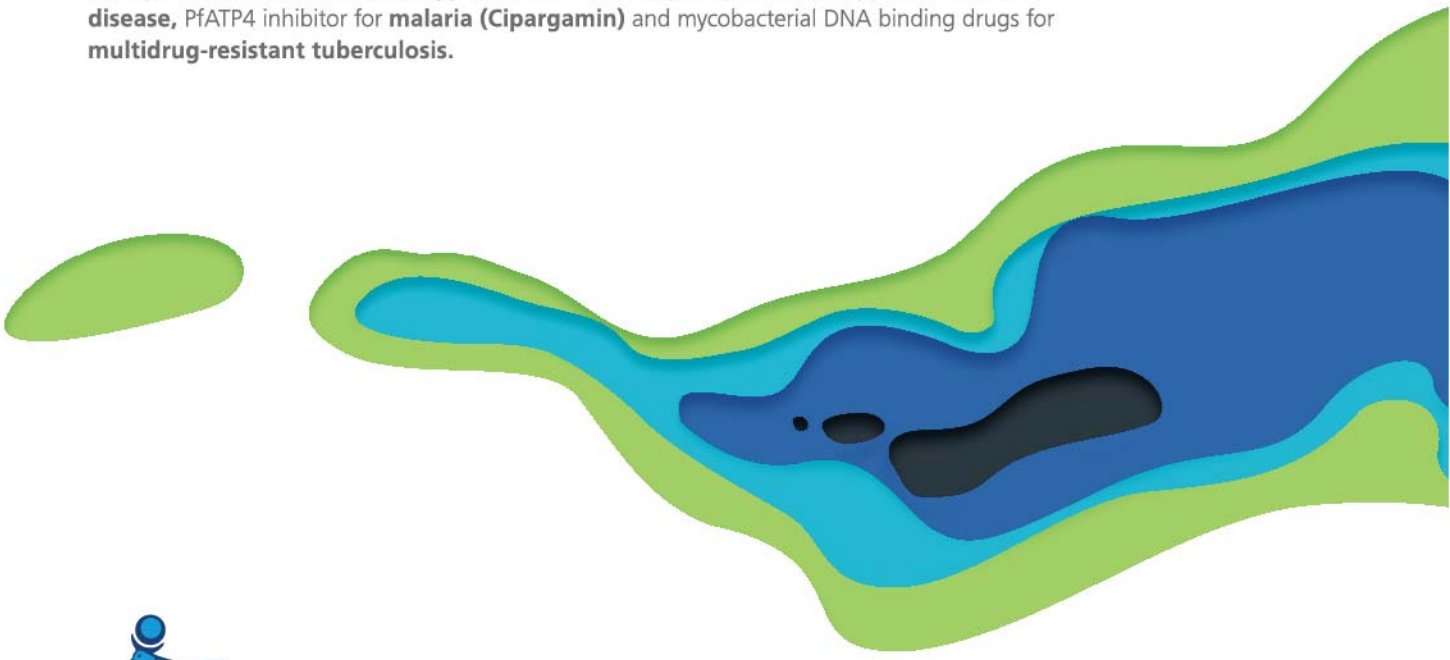
MSD has a robust pipeline, with a wide range of product candidates across each phase of development. Recently, the company's ZERBAXA® (ceftolozane and tazobactam) met primary endpoints of Non-Inferiority Compared to Meropenem in pivotal phase 3 study of adult patients with hospital-acquired bacterial pneumonia or ventilator-associated bacterial pneumonia. Also, FDA granted priority review to the company's application for KEYTRUDA® (pembrolizumab) monotherapy for first-line treatment of locally advanced or metastatic non-small cell lung cancer in patients whose tumors express PD-L1 (TPS ≥1%).

Nektar Therapeutics is a research-based development stage biopharmaceutical company with an R&D pipeline that includes treatments for **cancer, auto-immune disease** and **chronic pain.** Nektar leverages its proprietary and proven chemistry platform in the discovery and design of new therapeutic candidates including **NKTR-181,** the first analgesic opioid molecule to exhibit a low incidence of specific CNS-mediated side effects, such as euphoria, through the targeted alteration of brain-entry kinetics, **NKTR-214,** a CD122-biased agonist designed to stimulate the patient's own immune system to fight **cancer** and **NKTR-358,** for the treatment of autoimmune conditions including **systemic lupus erythematosus.**

Nestle Skin Health has a new drug in pipeline, Nemolizumab – a biotherapy treatment for moderate-to-severe atopic dermatitis. It is slated to become a first-in-class solution for atopic dermatitis.

NOVARTIS

Novartis is consistently rated as having one of the industry's most respected development pipelines with more than 200 projects in clinical development. Many of these projects are for potentially best-in-class or first-in-class medicines that could significantly advance treatment standards for patients worldwide. Some of the drug candidates in pipeline are **SEG101 (Crizanlizumab)** for **sickle cell disease,** the new drug **BYL719 (Alpelisib)** for **breast cancer**, neprilysin inhibitor for **resistant hypertension,** beta-amyloid-protein therapy for **Alzheimer's disease,** PfATP4 inhibitor for **malaria (Cipargamin)** and mycobacterial DNA binding drugs for **multidrug-resistant tuberculosis.**



novo nordisk®

Novo Nordisk has a strong product pipeline, especially in diabetes care, with **oral Semaglutide** and other **antidiabetic** drugs undergoing Phase II/III clinical trials. There is also **Somapacitan** for **growth disorders** and **Concizumab,** an anti-tissue factor pathway inhibitor antibody for **hemophilia.**

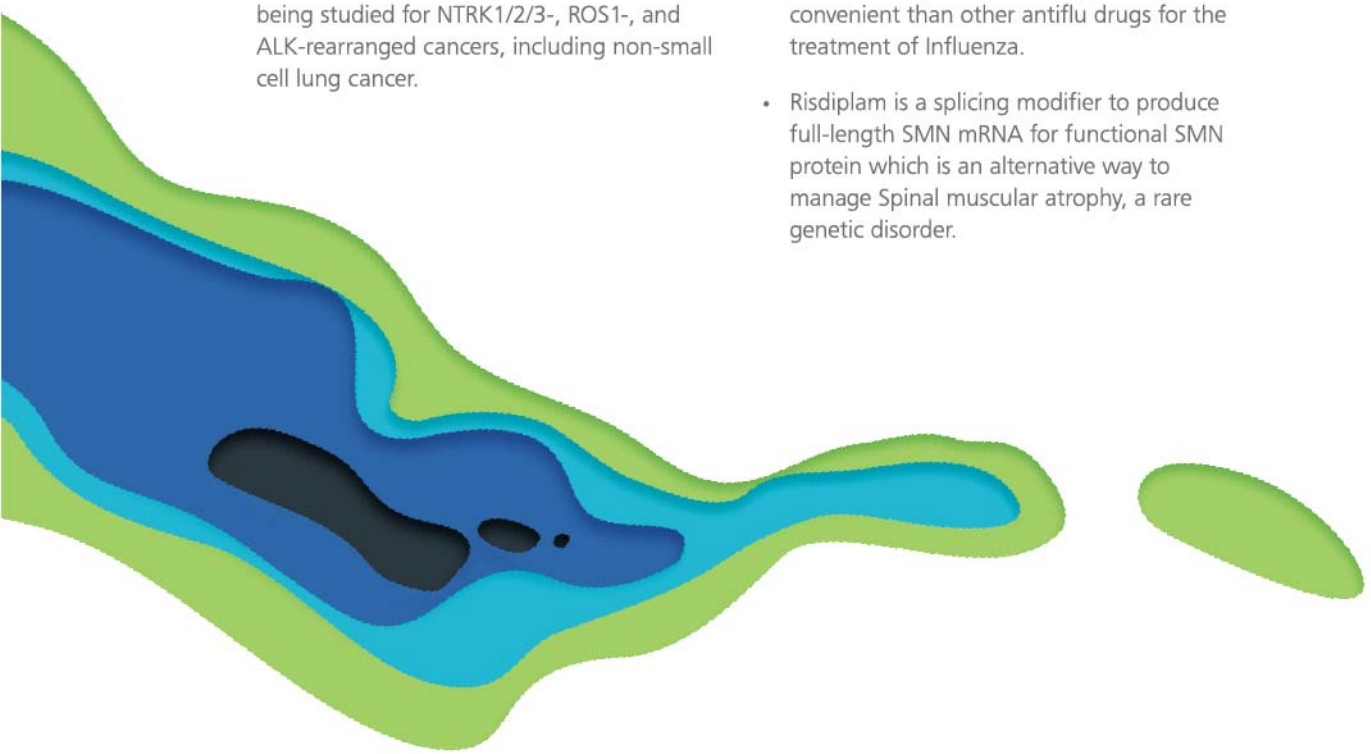
Pfizer

Pfizer's priority is researching and developing products and treatments that will benefit patients around the world. Pfizer has significant R&D drugs lined up across a range of therapeutic areas especially in oncology, rare disease, vaccine and biosimilars. More than 98 projects are in different phases of Clinical Development/Registration including Lorlatinib (ALK/ROS1) for NSCLC and next generation Pneumococcal Conjugate Prophylactic Vaccine for invasive and non-invasive pneumococcal infections.

Roche

Roche is pursuing efforts to advance Cancer immunotherapy-based combinations including personalised cancer vaccines. Roche has ~ 72 new molecular entities in its Pharmaceuticals R&D Portfolio with a number of medically differentiated products to address unmet needs, few of which are mentioned here:

- Entrectinib, a multi tyrosine kinase inhibitor is being studied for NTRK1/2/3-, ROS1-, and ALK-rearranged cancers, including non-small cell lung cancer.
- Polatuzumab, an anti-CD79b antibody drug conjugate undergoing trials for refractory B-cell lymphoma based on its potential to selectively bind to CD79b expressed on malignant B-cells.
- Baloxavir marboxil, developed in partnership, is a cap-dependent endonuclease inhibitor, one-time, single-dose therapy, more convenient than other antiflu drugs for the treatment of Influenza.
- Risdiplam is a splicing modifier to produce full-length SMN mRNA for functional SMN protein which is an alternative way to manage Spinal muscular atrophy, a rare genetic disorder.



SANOFI

Sanofi continually innovates and invests in research to solve tomorrow's healthcare problems. In 2017, Sanofi invested €5.5 bn in R&D. Their R&D model leverages new proprietary technology platforms, multi-targeting molecules and biologics. They have a robust pipeline that is expected to support long-term growth. At the end of July 2018, their R&D pipeline contained 87 projects including 40 new molecular entities in clinical development. 36 projects are in phase 3 or have been submitted to the regulatory authorities for approval in Immuno-inflammation, oncology, rare diseases, multiple sclerosis and neurology, diabetes, cardiovascular diseases and vaccines. 5 of the Phase III global clinical trials in diabetes and cardiovascular diseases are currently running in India.

Servier has 36 drug candidates in research and development, including 26 new molecular entities in 5 major R&D areas- cardiovascular, immune-inflammatory and neuropsychiatric diseases, cancer and diabetes. This includes an exenatide implant for diabetes, a GABA antagonist for post stroke and 7 drugs from different classes undergoing trials for cancer.

Shire is the global biotechnology leader serving patients with rare diseases and specialized conditions. It seeks to push boundaries through discovering and delivering new possibilities for patient communities who often have few or no other champions. Relentlessly on the edge of what's next, they are serial innovators with a diverse pipeline offering fresh thinking and new hope. Their diverse portfolio of therapeutic areas includes Immunology, Hematology, Genetic Diseases, Neuroscience, Internal Medicine, Ophthalmics, and Oncology. Shire has a strong portfolio of products in various stages of research and development. Currently, they have 35+ programs in clinical pipeline and ~65% of clinical programs focused on rare diseases.

UCB has a promising portfolio of R&D drugs targeting severe diseases including unnamed molecules undergoing trials for epilepsy and Parkinson's disease, and antibody based drugs like romosozumab and bimekizumab being tested for osteoporosis and rheumatoid arthritis respectively. A collaborative research effort between UCB, Imperial college London and Duke University/ University of Singapore, which began in 2012, has led to the development of a completely novel discovery platform for future antieplileptic (AED) drugs.

Takeda is a world-class & worldwide R&D organization with focused therapeutic areas. Takeda R&D continues its transformation driving patient-centric approach and commitment to deliver innovation. They innovate with a focus on three therapeutic areas - oncology, gastroenterology (GI), and Neuroscience. They also leverage their world-class capabilities to develop vaccines to address critical public health threats using novel development platforms and collaborate with leading partners.

BREAST CANCER

Medical history will record that breast cancer was one of the most significant health threats facing women in the 20th century.[1]

In the 1990s alone, more American women died of the disease than all the U.S. lives lost in war from the Civil War to Vietnam.[1]

From 1930 to 1990 there was no improvement in cure rates; however, over the last 3 decades, with resilience of scientists and clinical experts, a large number of clinical trials using a broad spectrum of drugs have undoubtedly demonstrated that survival could be increased in patients with breast cancer.

SOME OF THE TREATMENTS INCLUDE[3-5]

Protein-bound Paclitaxel
used in advanced stages of breast cancer, usually in combination with other drugs

Doxorubicin
used before or after surgery in advanced breast cancer, usually in combination with other chemotherapeutic drugs

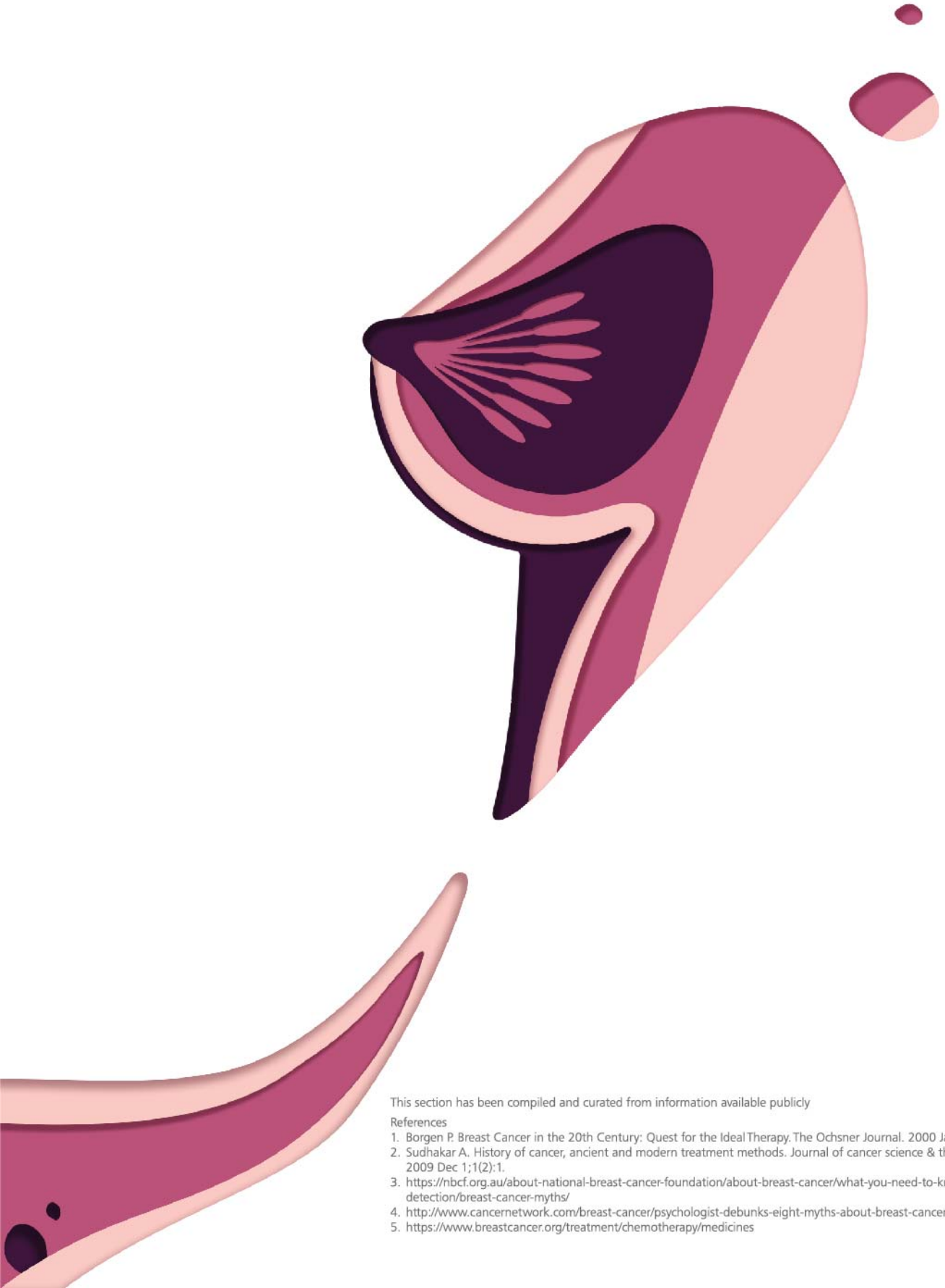
Carboplatin
the only approved platinum therapy for breast cancer

Daunorubicin
belongs to anthracycline class of drugs, like doxorubicin, used in some leukemias as well

Gemcitabine
used in advanced stage of breast cancer

Epirubicin
anthracycline class of drugs, used in lymph node positive patients

Cyclophosphamide
damages genetic material of breast cancer cells



This section has been compiled and curated from information available publicly

References
1. Borgen P. Breast Cancer in the 20th Century: Quest for the Ideal Therapy. The Ochsner Journal. 2000 Jan;2(1):5-9.
2. Sudhakar A. History of cancer, ancient and modern treatment methods. Journal of cancer science & therapy. 2009 Dec 1;1(2):1.
3. https://nbcf.org.au/about-national-breast-cancer-foundation/about-breast-cancer/what-you-need-to-know/detection/breast-cancer-myths/
4. http://www.cancernetwork.com/breast-cancer/psychologist-debunks-eight-myths-about-breast-cancer
5. https://www.breastcancer.org/treatment/chemotherapy/medicines

CERVICAL CANCER

Cervical cancer had been a nightmare for women a few centuries ago when it was blamed on excessive sexual activity.[1]

Until early 20th century cervical cancer screening was very rare and most of the times cervical cancer was discovered accidentally while performing other screening tests on women.[2]

In England, prior to 1988, at least two-thirds of patients with cervical cancer had never been screened and in those aged over 40 years (70% of cases), 90% had never been screened.[3]

It took nearly 150 years for scientists to figure out that 'cancer of the uterus' might be related to sexual lifestyle and for Human Papilloma Virus (HPV) to be established as the cause of cervical cancer in the 1980s.[4]

With huge success of the Pap smear technique for early screening and discovery of chemotherapeutic drugs , there was a dramatic decrease in mortality rate of women with cervical cancer - in England, Wales and Scotland, the mortality rate for women age 20-34 years halved between 1986 and 2000-2001.[3]

SOME OF THE TREATMENTS INCLUDE[5-10]

Cisplatin
known as the penicillin of cancer is also used in many cancers like breast, bladder, lung, etc.

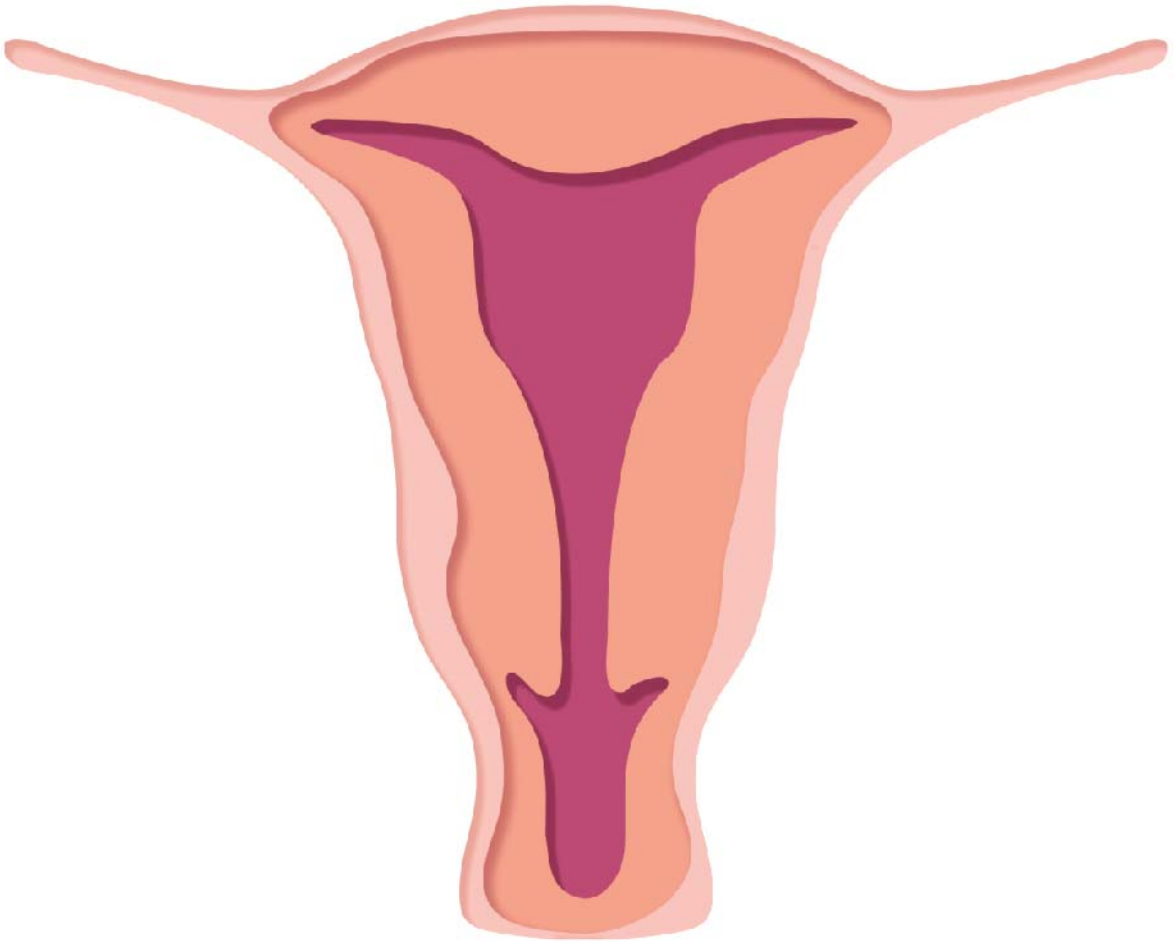
Paclitaxel
also used in cancer of ovaries, lung, breast, pancreas, etc.

Topotecan
used in relapse after radiotherapy

Gemcitabine
also used in advanced breast cancer

Bevacizumab
used in colon, lung and renal cancers

Irinotecan
also used in colon and lung cancer



This section has been compiled and curated from information available publicly

References

1. Moscucci O. Gender and cancer in Britain, 1860–1910: The emergence of cancer as a public health concern. American journal of public health. 2005 Aug;95(8):1312-21.
2. Cervical Cancer Screening: Yesterday and Today. PAHO factsheet. [Internet]. [Cited 2018 September 11]. Available at: https://www.paho.org/hq/index.php?option=com_content&view=article&id=9995:2014-cervical-cancer-screening-yesterday-and-today&Itemid=40275&lang=es
3. Comber H, Gavin A. Recent trends in cervical cancer mortality in Britain and Ireland: the case for population-based cervical cancer screening. British journal of cancer. 2004 Nov;91(11):1902.
4. Reynolds LA, Tansey EM. History of cervical cancer and the role of the Human Papillomavirus, 1960–2000. Wellcome Trust Centre for the History of Medicine at UCL; 2009.
5. https://www.mdanderson.org/publications/cancerwise/2017/05/5-cervical-cancer-myths.html
6. https://blogs.cdc.gov/cancer/2018/01/09/3-myths-about-cervical-cancer-screening/
7. http://www.nccc-online.org/hpvcervical-cancer/myths-and-facts/
8. http://www.jhf.org/admin/uploads/HPV-Vaccine-Myths-Myth-Busting.pdf
9. https://www.cancer.org/cancer/cervical-cancer/treating/chemotherapy.html
10. https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/cancer-drugs/drugs/topotecan

This section has been compiled and curated from information available publicly

References

1. Sharp PM, Hahn BH. Origins of HIV and the AIDS pandemic. Cold Spring Harbor perspectives in medicine. 2011 Sep 1; 1(1):a006841.
2. Broder S. The development of antiretroviral therapy and its impact on the HIV-1/AIDS pandemic. Antiviral research. 2010 Jan 1; 85(1):1-8.
3. https://www.avert.org/hiv-transmission-prevention/myths
4. https://www.webmd.com/hiv-aids/top-10-myths-misconceptions-about-hiv-aids#1
5. https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines/
6. http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/emtriva/emtriva_patient_pi.pdf
7. http://www.trogarzo.com/

HIV

The HIV-1 was discovered as the causative agent of one of the most devastating infectious disease of modern times, which is Acquired Immunodeficiency Syndrome (AIDS).[1]

Since its identification 3 decades ago, HIV-1 has infected at least 60 million people and caused more than 25 million deaths.[2]

However, in the last 25 years, HIV-1 has gone from being an "inherently untreatable" infectious agent to one eminently susceptible to a range of approved therapies.[2]

Scientists in the mid-1980s discovered and developed the first generation of antiretroviral agents which turned HIV infection from a terrifying and lethal disease to a treatable condition which ensured survival of patients.[1]

SOME OF THE TREATMENTS INCLUDE[3-7]

Nucleoside reverse transcriptase inhibitors
(Emtricitabine)

Non-Nucleoside reverse transcriptase inhibitors
(Nevirapine)

Protease Inhibitors
(Darunavir)

Fusion Inhibitors
(Enfuvirtide)

CCRS antagonists
(Maraviroc)

Integrase strand transfer inhibitors
(Dolutegravir)

Post-attachment inhibitors
(Ibalizumab-uiyk)

HEPATITIS

Hepatitis was known as the plague of mankind that killed civilians and impacted military personnel for centuries.[1]

It was the work of scientists such as Pasteur, Lister, and Koch in the 1800s that led to the isolation of pure cultures of bacteria and identification of viruses which demonstrated their causal role in infectious diseases.[2,3]

Their identification has been associated with milestones in virology with antiviral drugs like lamivudine, tenofovir, which revolutionised treatment for viral hepatitis.[1]

SOME OF THE TREATMENTS INCLUDE[4-12]

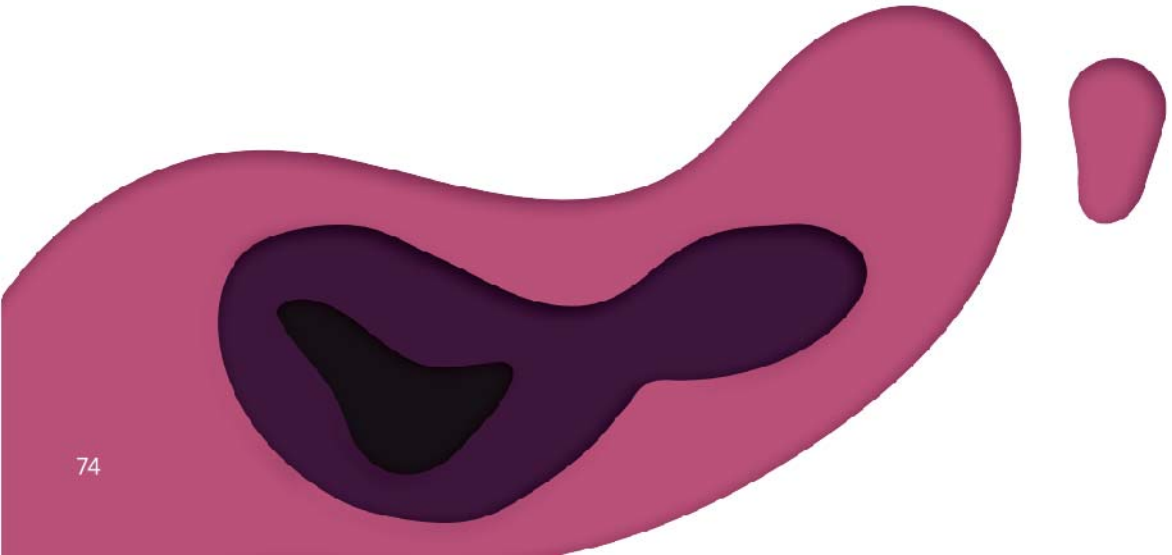
Glecaprevir (Pibrentasvir), Elbasvir and Grazoprevir

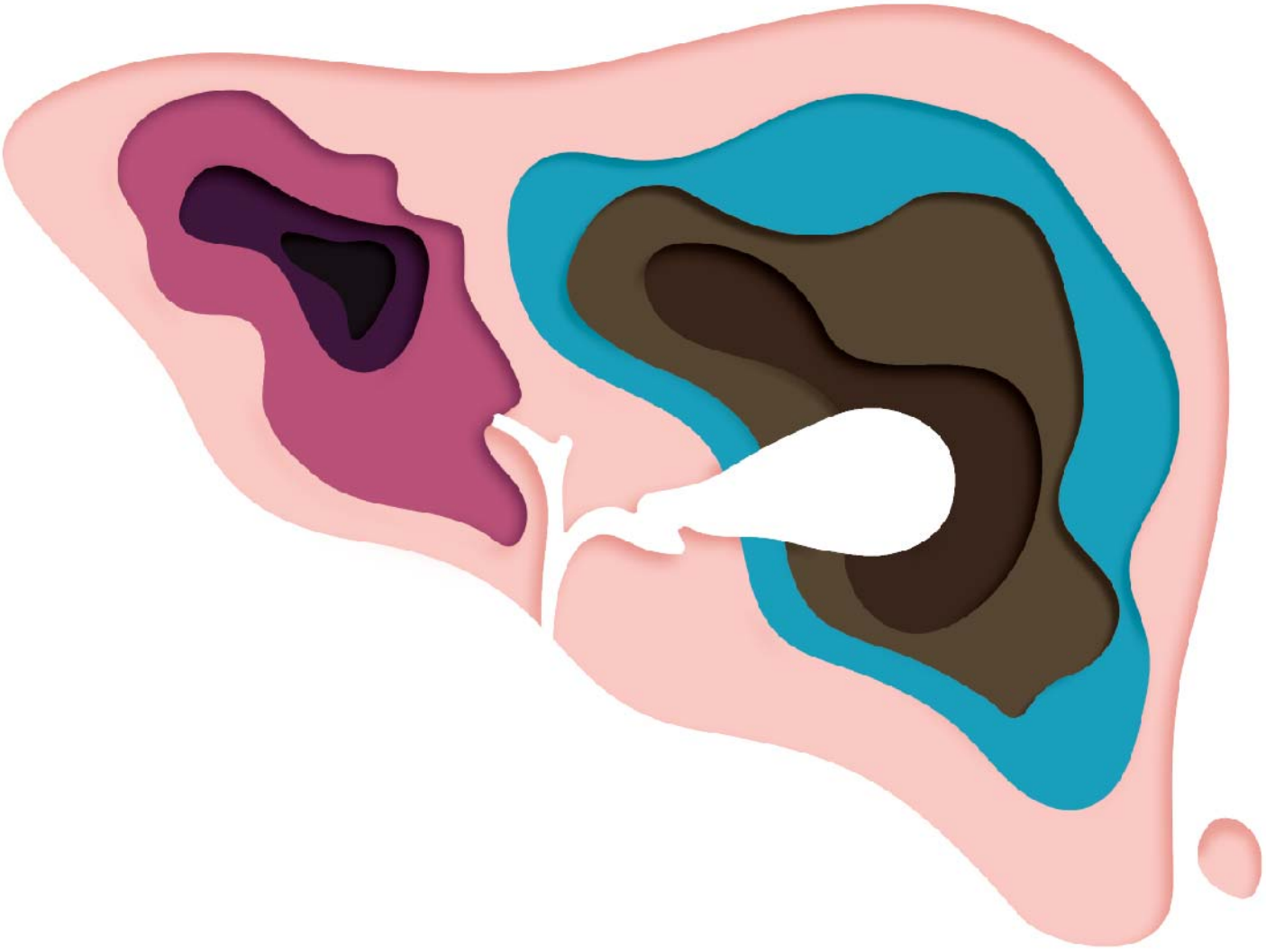
Sofosbuvir and Ledipasvir

Sofosbuvir, Velpatasvir and voxilaprevir

Sofosbuvir with peginterferon, Simeprevir with peg-interferon

Ribavirin with interferon





This section has been compiled and curated from information available publicly

References

1. Trepo C. A brief history of hepatitis milestones. Liver International. 2014 Feb; 34:29-37.
2. Wong DT, Jain D. Historical path of discovery of viral hepatitis and the role of human experimentation. Pathology. 2014 Jan 1; 46:S107.
3. Cuthbert JA. Hepatitis A: old and new. Clinical Microbiology Reviews. 2001 Jan 1; 14(1):38-58.
4. https://offeringhope.org/myths-of-hepatitis-c/
5. https://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf
6. https://www.roche.com/dam/jcr:2e330e70-320f-4072-8a70-af03f526d109/en/understanding_hepc.pdf
7. https://www.england.nhs.uk/wp-content/uploads/2014/11/Hepatitis-C-Factsheet.pdf
8. https://www.webmd.com/hepatitis/digestive-diseases-hepatitis-c#1
9. https://www.nhs.uk/conditions/hepatitis-c/treatment/
10. https://www.merck.com/product/usa/pi_circulars/z/zepatier/zepatier_pi.pdf
11. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm567467.htm
12. https://www.accessdata.fda.gov/drugsatfda_docs/label/2001/pegsche080701LB.htm

EPILEPSY

For centuries epileptic patients suffered the stigma of "being possessed" by demonic influence.[1]

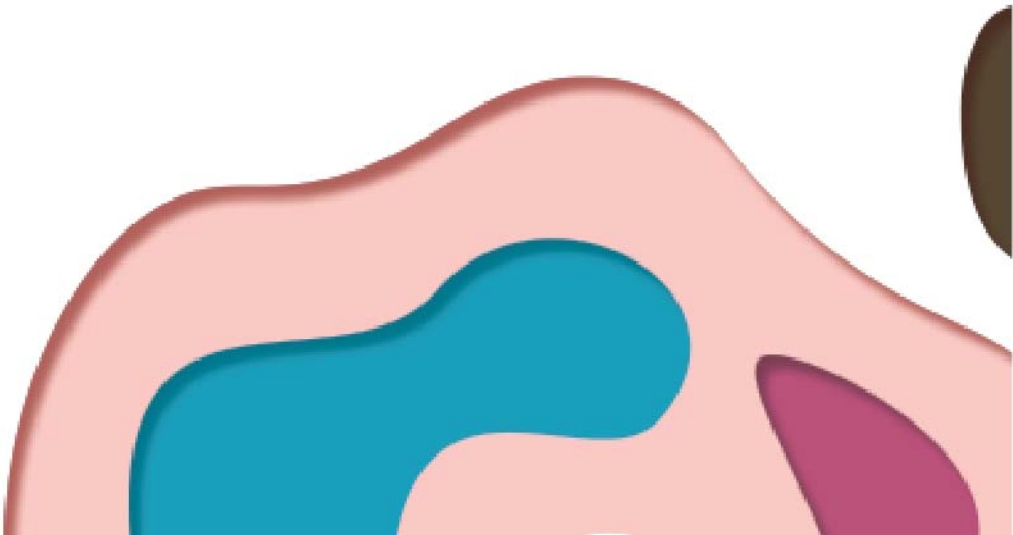
Major advances in the understanding of epilepsy later during the 18th and 19th century involved theories on epilepsy formulated on a solid scientific basis and early anti-epileptics like phenobarbitone, phenytoin, carbamazepine being used for the first time to treat epileptic patients as individuals with disease and not as lunatics or possessed.[2]

SOME OF THE TREATMENTS INCLUDE[3-7]

Anti-epileptic drugs (AEDs) classified into Narrow Spectrum and Broad Spectrum

Narrow spectrum AEDs include Phenytoin, Carbamazepine, Gabapentin, Pregabalin, Vigabatrin

Broad spectrum AED include Sodium valproate, Lamotrigine, Zonisamide, Clonazepam, Rufinamide



This section has been compiled and curated from information available publicly

References
1. The History and Stigma of Epilepsy. Epilepsia, 44(Suppl. 6):12–14, 2003.
2. Magiorkinis E, Diamantis A, Sidiropoulou K, Panteliadis C. Highights in the history of epilepsy: the last 200 years. Epilepsy research and treatment. 2014;2014.
3. https://www.epilepsysociety.org.uk/epilepsy-myths#.W0S2FNJKjIU
4. http://www.epilepsy-ohio.org/about-epilepsy/characteristics/myths-about-epilepsy/
5. https://www.epilepsy.com/article/2014/3/summary-antiepileptic-drugs
6. https://www.drugs.com/depakote.html
7. https://www.drugs.com/lamictal.html

LEPROSY

Leprosy has a history of being associated with extreme prejudice, fear, and revulsion.[1]

In addition to the physical deformities caused by the disease, millions of patients suffered severe social stigma and ostracism from their families, communities, and even health professionals to such an overwhelming extent that leprosy was known as the "death before death" since ancient times.[1]

The modern era of leprosy treatment started in the 1940s, when Dr. Guy Faget was able to show remarkable benefits of sulfone therapy in treating the disease. This discovery was heralded as "the miracle of Carville" and marked the onset of the first real hope that leprosy could be successfully treated and "cured".[1]

The onset of antibiotics like dapsone, phenazine, rifampicin, discovered by bacteriologists and clinicians led to a marked decline in incidence and prevalence of leprosy worldwide.[1]

In the last few decades, the advent of multidrug therapy (MDT) and the use of anti-inflammatory therapies has facilitated substantial improvements in long-term health outcomes for individuals diagnosed with leprosy.[2]

The reported global prevalence of active leprosy infection has dropped by almost 90 percent by the combined efforts of scientific experts, health professionals and non-governmental organisations (NGOs).[1]

SOME OF THE TREATMENTS INCLUDE[3-5]

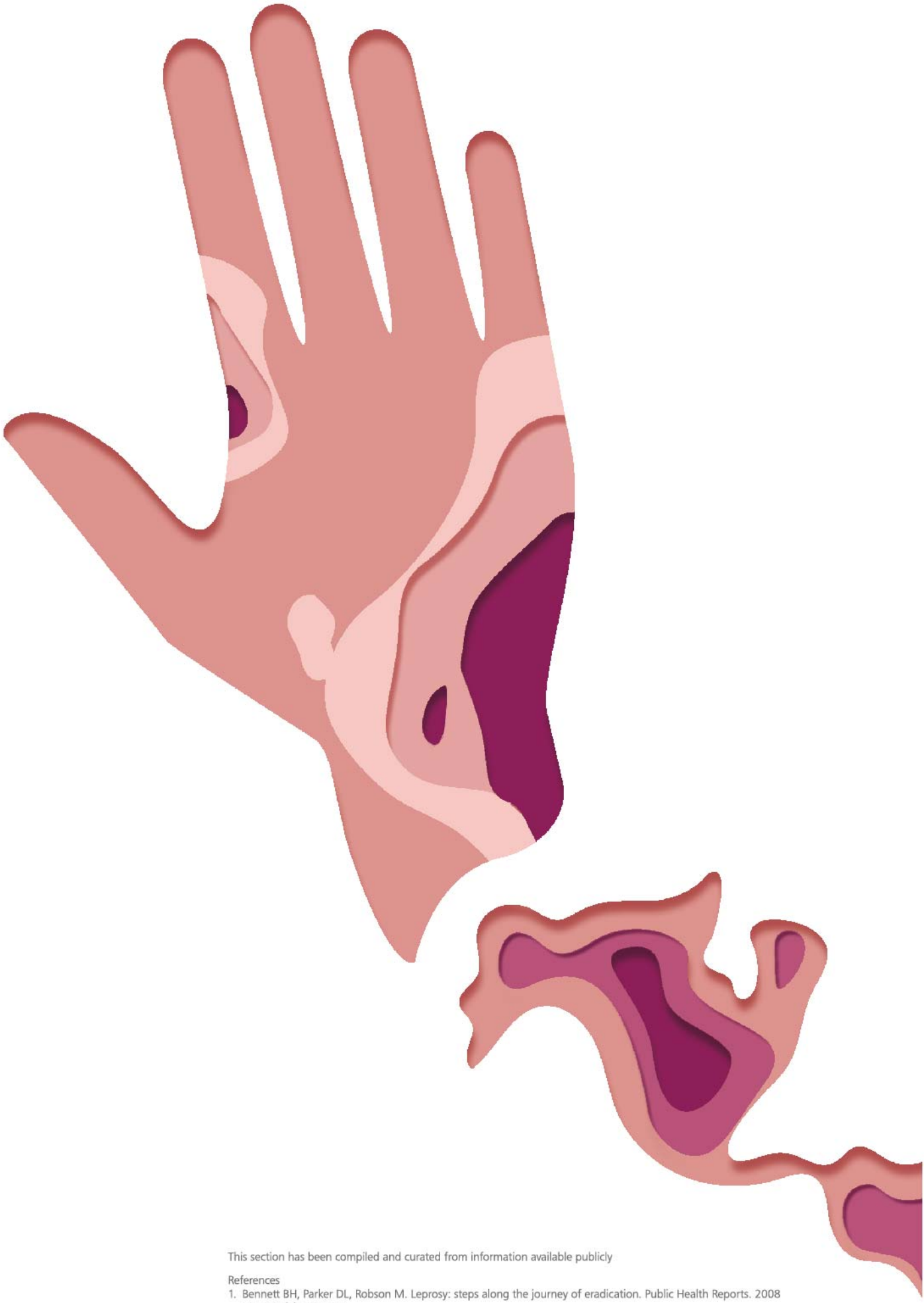
DDS

(Diamino-Diphenyl-Sulfone) also known as Dapsone is the traditional therapy for Leprosy (Hansen's Disease).

The six-month therapeutic regimen or Paucibacillary Leprosy (PB) comprises of Dapsone with Rifampicin, one of the drugs used for TB is also used in Leprosy.

The 12-month schedule used for Multi-bacillary (MB) consists of three drugs (given together): Dapsone, Rifampicin and Clofazimine

For Single Lesion Paucibacillary (SLPB) Leprosy, the recommended therapy is one-time dose of three drugs given together, – Rifampicin, Ofloxacin and Minocycline



This section has been compiled and curated from information available publicly

References
1. Bennett BH, Parker DL, Robson M. Leprosy: steps along the journey of eradication. Public Health Reports. 2008 Mar;123(2):198-205.
2. White C, Franco-Paredes C. Leprosy in the 21st century. Clinical microbiology reviews. 2015 Jan 1;28(1):80-94.
3. https://www.cdc.gov/features/world-leprosy-day/index.html
4. https://www.lepra.org.uk/News/six-leprosy-myths-busted
5. http://apps.who.int/medicinedocs/en/d/Jh2988e/

POLIOMYELITIS

Poliomyelitis before 1954 (i.e. the prevaccine era), was a disease annually crippling more than half a million people of all ages around the globe or often leading to death after a tortuous agony.[1]

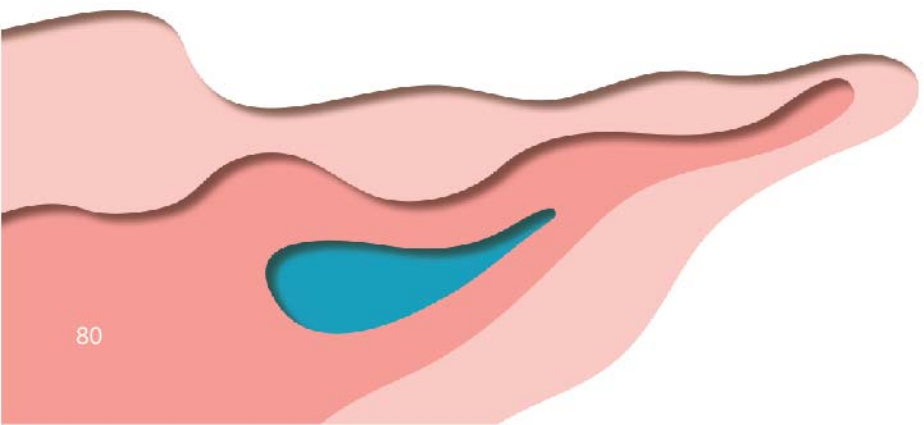
The efforts of virologists Dr. Jonas Salk and Dr. Sabin paved the way for vaccines against the polio virus which lead to a dramatic worldwide decrease in the number of cases of poliomyelitis cases with virtual eradication of wild polioviruses reported in some European, Asian, Western Pacific countries, and the Western Hemisphere.[1]

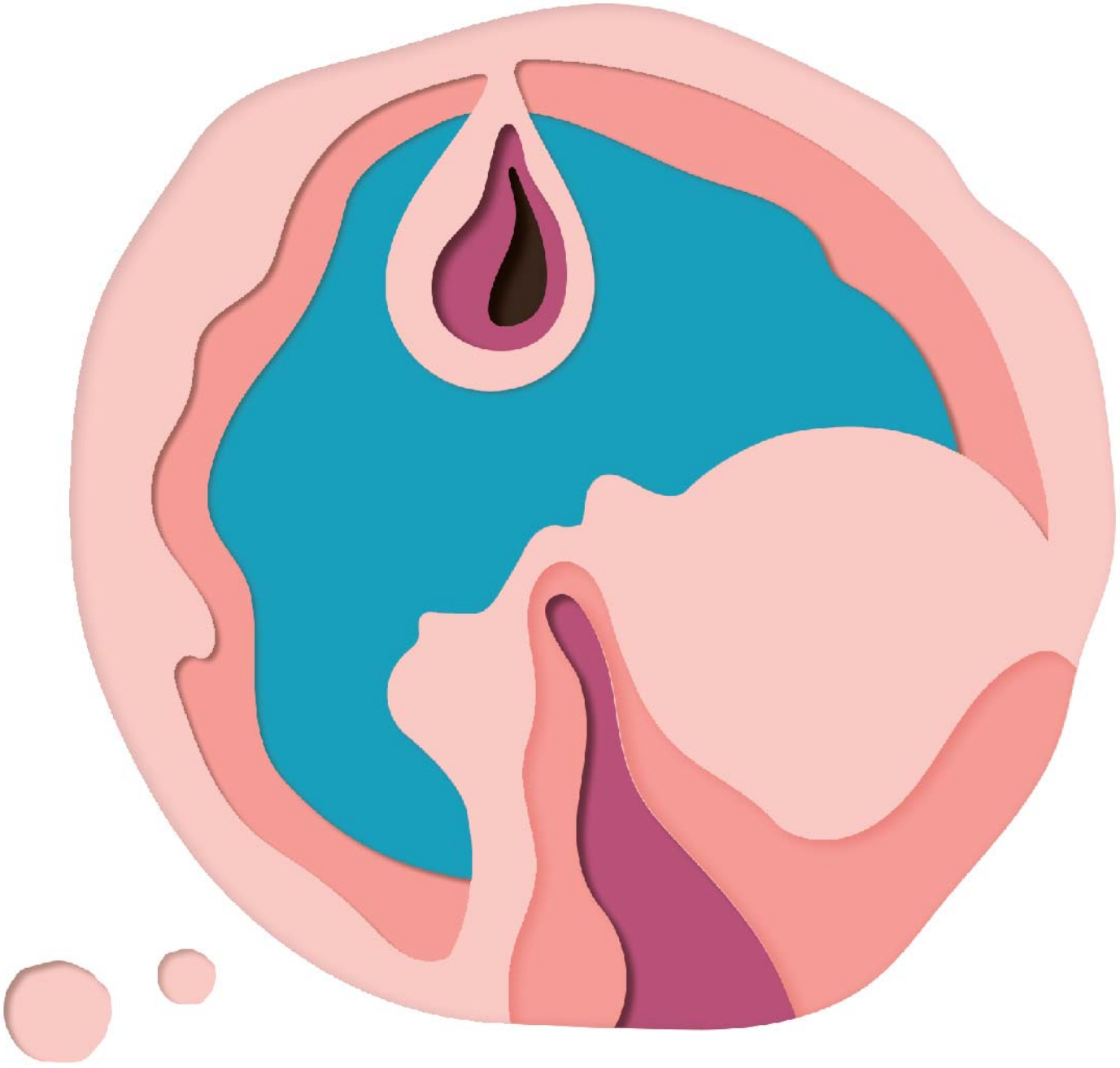
SOME OF THE TREATMENTS INCLUDE[2-4]

IPV
(Inactivated Polio Vaccine), contains the deactivated polio virus to be injected to elicit immune response

OPV
(Oral Polio Vaccine) drops to be administered orally

Surgical correction of polio-affected limbs has been used in many countries





This section has been compiled and curated from information available publicly

References
1. Eggers HJ. Milestones in early poliomyelitis research (1840 to 1949). Journal of virology. 1999 Jun 1;73(6):4533-5.
2. http://www.post-polio.org/edu/pphnews/pph18-2.html#pol
3. https://vaxopedia.org/2017/06/21/myths-about-polio-and-acute-flaccid-paralysis/
4. https://www.skepticalraptor.com/skepticalraptorblog.php/polio-vaccine-causes-cancer-myth/

RARE DISEASES

For many years, people with rare diseases walked alone with daunting medical and financial issues and no one to guide the way.

Very little was being done to study these diseases or develop treatments.[1]

It is estimated that over 350 million individuals worldwide are infected by one of over 7000-8000 rare diseases.

A number of countries introduced orphan drug legislations through which commercial incentives were provided to the pharmaceutical industry to make rare disease drug development financially viable.

Today, over 380 orphan designated drugs are commercially available on the global market and more than 800 are undergoing clinical development. To expedite the access of patients with unmet needs to novel therapies, regulatory initiatives exist which have the potential to accelerate market approval.[2]

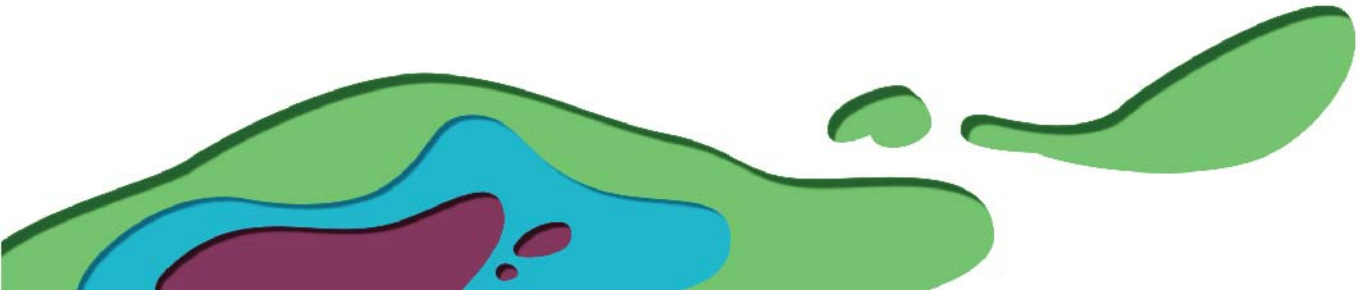
SOME OF THE TREATMENTS INCLUDE[3-11]

Erythropoietic Protoporphyria treated with Afamelanotide, Cholestyramine, Ursodiol

Retinitis Pigmentosa
which affects I/3500 people in US, has gene therapy products under trial with Orphan Drug status

Polycythemia Vera
medicine alpha-interferon, Ruxolitinib

Narcolepsy
which affects 1/2000 people in US, often not diagnosed through life is currently treated with Modafinil. Earlier treatment: Methylphenidate



This section has been compiled and curated from information available publicly

References

1. History of Leadership. National Organisation of Rare Disorders. [Internet]. [Cited 2018 September 11]. Available at: https://rarediseases.org/about/what-we-do/history-leadership/
2. Bax BE. Drug Development for Rare Diseases: Challenges and Regulatory Initiatives. Arch Sci 2017, 1:2
3. https://rarediseases.org/advocate/rareinsights/5-myths-orphan-drugs-orphan-drug-act/
4. https://www.eurordis.org/about-rare-diseases
5. http://www.fromhopetocures.org/fighting-rare-diseases
6. https://rarediseases.info.nih.gov/diseases/fda-orphan-drugs
7. https://globalgenes.org/toolkits/drug-development-overview/introduction/
8. https://www.orpha.net/consor/cgi-bin/index.php
9. http://ec.europa.eu/health/archive/ph_threats/non_com/docs/rdnumbers.pdf
10. https://rarediseases.info.nih.gov/diseases/5694/retinitis-pigmentosa
11. https://www.blindness.org/sites/default/files/pages/pdfs/Advances-RP-June-2015.pdf

TUBERCULOSIS

TB had become an epidemic in Western Europe during the 18th century, with a mortality rate as high as 900 deaths per 100,000 inhabitants per year. Since the deaths were more elevated among young people, TB was also called as "the robber of youth".[1]

With the untiring efforts of experts from scientific and technological fields, anti-tubercular antibiotics like isoniazid, streptomycin and para-amino salicylic (PAS) were developed which led to a steady decline in TB-related deaths from the early 1900s.[2]

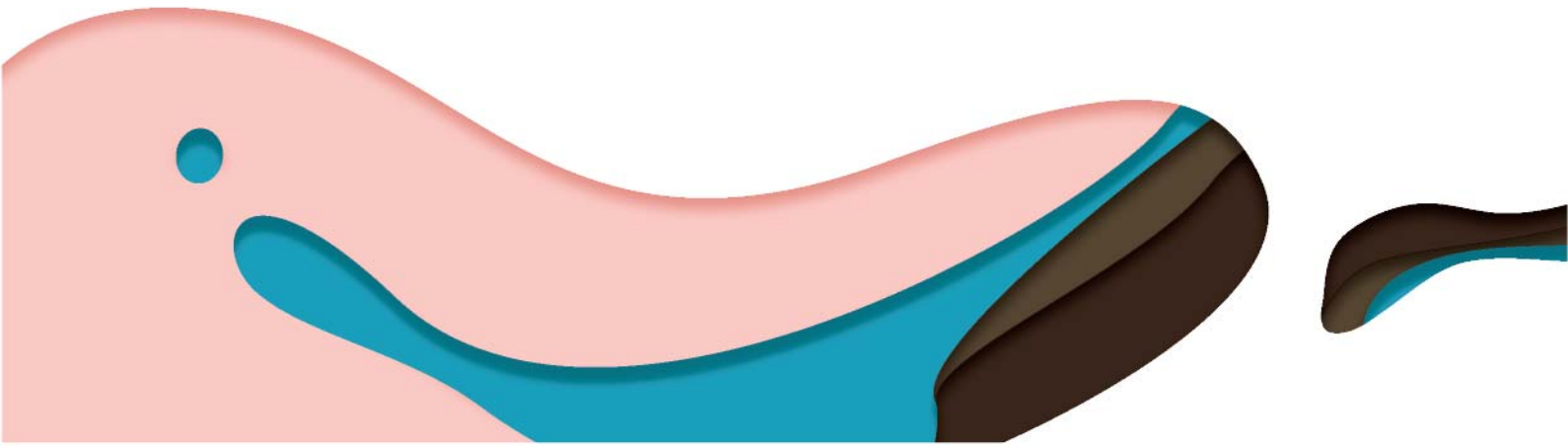
SOME OF THE FIRST LINE DRUGS USED EVEN TODAY ARE[3-10]

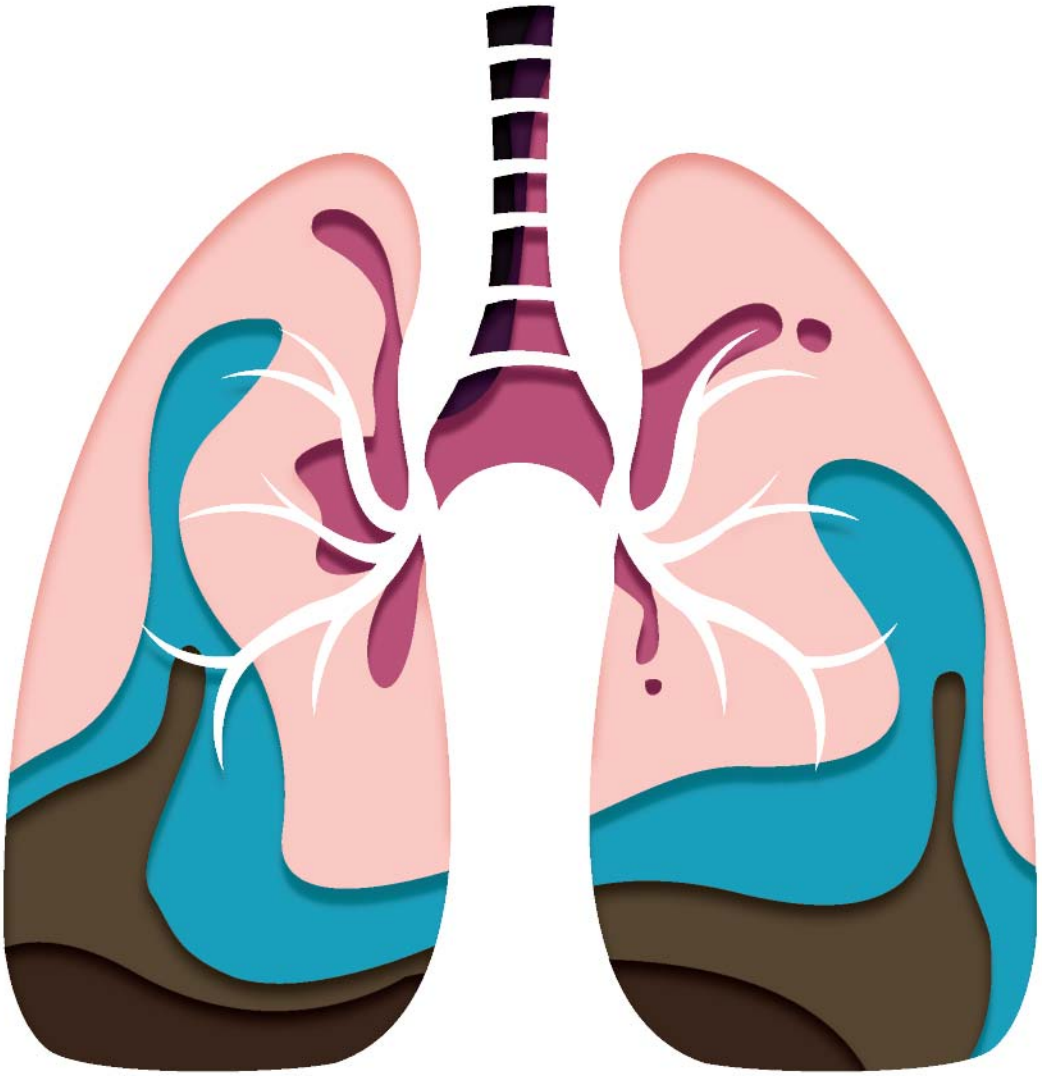
Streptomycin, PAS, Isoniazid and Ethambutol, Pyrazinamide and Rifampicin

Cycloserine and Capreomycin are both second line anti-TB drugs

Amikacin used for MDR-TB and Rifapentine used for two months in intensive phase of anti-TB therapy

Bedaquiline latest drug in anti-TB arsenal, got US FDA approval in 2012





This section has been compiled and curated from information available publicly

References

1. Barberis I, Bragazzi NL, Galluzzo L, Martini M. The history of tuberculosis: from the first historical records to the isolation of Koch's bacillus. Journal of preventive medicine and hygiene. 2017 Mar; 58(1):E9.
2. Tuberculosis Factsheet NIH. [Internet]. [Cited 2018 September 07]. Available at: https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=31
3. https://www.tbalert.org/about-tb/global-tb-challenges/stigma-myths/
4. https://www.healthxchange.sg/heart-lungs/lung-conditions/tuberculosis-treatment-myths-facts
5. https://www.cdc.gov/tb/topic/treatment/tbdisease.htm
6. https://www.cdc.gov/tb/publications/factsheets/treatment/treatmenthivnegative.htm
7. https://www.cdc.gov/tb/publications/factsheets/treatment/drugresistanttreatment.htm
8. https://www.cdc.gov/tb/publications/factsheets/treatment/bedaquiline.htm
9. https://emedicine.medscape.com/article/230802-medication#2
10. Ethambutol discovery: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2818403/

NOTE FROM CURATOR

BHAVNA SINGH
Director Communications- OPPI

All living things are in search of a better world. To quote Karl Popper from his book, In search of a better world:

"The search for truth...no doubt counts among the best and greatest things that life has created in the course of its long search for a better world."

The central theme of In Science we Trust, the OPPI 2018 publication, features Science as the protagonist. The scientific way of thinking is both imaginative and disciplined, constantly juxtaposing new ideas with established wisdom.

In this publication, we have curated pieces from global as well as Indian scientists, researchers, innovators, institutions, world-wide groups and Government representatives from India on the newer scientific thinking that is a clarion call of change. We thank all of them who have contributed to this publication and who have been collaborative throughout the making of this book.

This publication has not only fueled my quest to know more, it has enriched my knowledge on the value of science. The journey has become so much more interesting thanks to Kanchana TK, Director General, OPPI whose guidance and valuable input has ushered richness and freshness to this publication. Our gratitude to the President of OPPI who has provided support and encouragement to this initiative.

Be a part of a revolution that makes Science Cool.

Designed by:

Medulla Communications Pvt. Ltd.
Unit No.602, Opulence, 6th Road, TPS III, Santacruz(E), Mumbai–400 055
Tel: +91 22 67589426. info@medulla.in | www.medulla.in

Organisation of Pharmaceutical Producers of India
Peninsula Chambers, Ground Floor, Peninsula Corporate Park G.K. Marg, Lower Parel, Mumbai 400 013.
Tel: +91 22 2491 8123, 2491 2486, 66627007. www.indiaoppi.com

Follow us on: