“Clinical research is becoming more disintegrated with influx of data from different sources” — 37
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For patients with severe diabetes requiring a daily dose of insulin carrying the injection and insulin bottle everywhere, particularly while in travel and taking the dose regularly is quite cumbersome, but strictly unavoidable process. It not only takes time, but interrupts daily schedules making the life harrowing for those who need it. With no other choice, patients try to get adjusted to it and it becomes an unpleasant part of their life. But Massachusetts Institute of Technology, Women’s hospital and Novo Nordisk have come out with a pleasant solution to this problem in the form of an insulin pill.

The pill may take some time to hit the market as it is in a very early stage of development. The tests on rats and pigs have been proved successful as the blood sugar levels among these animals were lowered to that of observed in insulin injections. The results have been reported in Science magazine. But, testing it on humans and then bringing it to the market is still little a long process.

This is not the first attempt to develop such an insulin pill. US based Oramed pharmaceuticals has launched the clinical trial six months back to test its insulin pill. But it is to use in the treatment of non-alcoholic steatohepatitis (NASH). In another development a team of specialists from the Harvard John A. Paulson School of Engineering and Applied Sciences in Cambridge, MA, have also come up with an insulin pill. They say one problem in giving insulin orally is that it deteriorates while coming in contact with gastric acid or digestive enzymes. They claim to have developed a coating over the pill to safely carry insulin beyond the obstacles of digestive system and enter into the bloodstream. Thus, a race is on as many organisations are after such a type of product.

Developing oral insulin pill is not a new thinking for scientists. When a diabetic patient was given insulin for the first time in 1921, it was given orally. But it failed to show the desired result. Since then researchers have been struggling for nearly a century now to develop oral insulin, with some ups and downs in the process. Ups were that such pills were developed but the downs were that the absorption rate was too low. Despite developing a molecule, Novo Nordisk had stopped the project in 2016 as a viable improved delivery mechanism for the oral insulin could not be developed.

But that problem has been solved in the recent pill developed by MIT and Novo Nordisk. Strangely, a tortoise helped them in solving the problem of how to ensure that the injector in the pill would not misfire. The scientists found out that leopard tortoise has body structure that enables it to flip over when it falls onto its back. Scientists designed the pill with same shape to solve the problem. It is important that the pill reorients itself to be in the right position always because the pill has a microneedle to inject it in the gastric wall.

Another cumbersome process in comparison to insulin injection comes in the form of chemotherapy. Chemotherapy pills were approved by USFDA in 2003 and are available now. But in a major breakthrough of a step ahead of that – a more advanced pill even transmitting information from the body has now been developed. Described as ‘digital oral oncology medicine technology’ has been launched by a startup Proteus Digital Health is the US in association with Fairview Health Services and University of Minnesota health systems. This chemotherapy pill is packed with ingestible sensor that sends message to a patch worn by the patient which transmits information on the time of dose, type of oral chemotherapy taken and responses to the medicine to a mobile friendly platform.

Such technologies are simplifying the processes of undergoing cumbersome treatments, providing much needed relief to the patients. Hence they need to be made available for common people who are waiting eagerly, but of course after taking all necessary precautions.
Acknowledgement
Thank you BioSpectrum Asia for your continued support. It is always a pleasure working with you. The coverage on Lucence Diagnostics has come out well.
- Elena Tan, Singapore

Tech Hub
China is at the forefront of several knowledge- and tech-intensive industries and is expected to maintain its leading position as it undergoes industrial optimization. Many disruptive business models are appearing in China.
- Dr Davis, Singapore

Preventive measure
Osteoporosis, often referred to as the silent disease, is a leading cause of bone fragility and towards susceptibility to fractures. But building strong bones since the start is the best way to defend the body against osteoporosis.
- Alia P, India

Amazing Amazon
An interesting article on Amazon’s foray into healthcare. It is surely making a big splash.
- Dr Davis, Singapore

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Beyond meeting the needs of global pharma in simply providing access to patient pools and lower operational costs, the Asia-Pacific (APAC) region is also poised to realize the potential of a thriving biotechnology sector that is driving innovation on its own. APAC is gaining the experience and infrastructure needed to support the global biotech industry by performing work and fostering innovation through public private partnership (3Ps) that is moving up the pharmaceutical value chain.

**3Ps AUGMENTING DRUG DISCOVERY IN APAC**

Beyond meeting the needs of global pharma in simply providing access to patient pools and lower operational costs, the Asia-Pacific (APAC) region is also poised to realize the potential of a thriving biotechnology sector that is driving innovation on its own. APAC is gaining the experience and infrastructure needed to support the global biotech industry by performing work and fostering innovation through public private partnership (3Ps) that is moving up the pharmaceutical value chain.
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Head- Southeast Asia, Accreditation Council for Medical Affairs (ACMA), Mumbai

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“Clinical research is becoming more disintegrated with the influx of data from different sources”

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Japan approves immunoglobulins to treat CIDP

Global biotherapeutics leader CSL Behring has announced that Japan’s Ministry of Health, Labour and Welfare has approved two of its immunoglobulin therapies for the treatment of patients with chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). Hizentra, previously approved to treat primary immunodeficiency, is now the first and only subcutaneous immunoglobulin (SCIG) approved for maintenance therapy to treat CIDP in Japan. Privigen, an intravenous immunoglobulin (IVIG), is now approved for both acute and maintenance therapy of CIDP in Japan. The approval for Hizentra is based on the results of PATH (Polyneuropathy And Treatment with Hizentra) and its extension study, which comprise the longest CIDP research period to date and included a cohort of Japanese patients. The approval for Privigen is based on results from two Phase III clinical studies that focused on the use of immunoglobulin therapy for treating CIDP: the PATH study and the PRIMA (Privigen Impact on Mobility and Autonomy) study.

China to amend healthcare laws

China plans to amend laws on doctors to better regulate the country’s expanding medical personnel and adapt to changes in its healthcare sector. The laws on medical doctors, approved by the top legislature in June 1998, lay out entry requirements, practice rules, and appraisal and training systems for Chinese medical practitioners. After being in place for more than two decades however, the law is in urgent need of revision as China’s healthcare sector and medical product industry have improved, presenting new issues to be addressed. Medical professionals in China are typically concentrated in large hospitals in urban areas, while community clinics and medical institutions in rural regions draw from a much smaller personnel. According to Ma Xiaowei, Head of the National Health Commission, it is imperative to develop the management and working systems for medical practitioners in China. The commission intends to cooperate with the top legislature to amend clauses that are incompatible with current demands or contradict other regulations, and incorporate new items that have proved to be effective measures. Core issues to be studied will include medical education, qualification and training of medical personnel, fostering rural doctors, and protecting the rights of doctors and patients.

Israel collaborates with Finland for enhancing digital health innovation

The Israel Innovation Authority has launched together with the Israel-Europe R&D Directorate (ISERD) a collaboration programme between Israel and Finland in the field of digital health. As part of the programme, Finnish and Israeli companies will be invited to submit applications for projects focused on developing innovative products and applications or pilot technologies in digital health including analytics, telemedicine, wearables and sensors, medical devices, among others. The programme will be led by the Israel Innovation Authority and the Helsinki Business Hub, and will provide funding and matching services for Greater Helsinki-based and Israeli companies seeking to partner. Finland ranks among the strongest markets in healthcare technology in the world, with digital health its largest high-tech export, increasing more than five-fold over the last two decades.
Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Government of India recently signed a Memorandum of Understanding (MoU) with the African Union (AU) represented by Scientific Technical and Research Commission (AU-STRC) in New Delhi, India. The MoU will strengthen South-South collaboration in advancing health sciences research; enhance local capacity and ownership. Recognizing the common health challenges faced by limited public health resources the current initiative aspires to intensify cooperation and collaboration to develop cutting-edge, innovative and sustainable solutions catering to the health needs of respective regions of the globe. The programme would focus on training and strengthening capacity of health professionals, researchers, regulators and industry staff, support research collaborations for developing preventive tools and improved diagnostics for diseases which are regional priorities in India and Africa strengthening product development and manufacturing capacities for drugs and diagnostics.

Australia pumps $6.3M into Health Data Portal development

The Australian Government has invested a further $6.3 million towards developing the Health Data Portal, used to report on indigenous health data. The portal, used by Aboriginal and Torres Strait Islander health services and funded under the Indigenous Australians’ Health Programme (IAHP), allows healthcare providers to publish reports for public consumption or exchange data and other files with authenticated individuals, businesses and other government agencies. It aims to provide a simplified and streamlined process for organisations to deliver health services in communities. The portal is also used by Aboriginal and Torres Strait Islander health services to submit National Key Performance Indicators (nKPIs) and from July 1, will include the Online Services Report (OSR) and the Health Care Provider (HCP) number report.

Singapore backs biomedical research for better health outcomes

The Singapore Ministry of Health (MOH)’s National Medical Research Council (NMRC) has awarded about $82 million to four research projects under the Open Fund-Large Collaborative Grant (OF-LCG) programme. Since 2000, Singapore’s Health and Biomedical Sciences (HBMS) initiative has built a strong foundation of research capabilities and expanded beyond basic to translational and clinical research. The total grant amount of about $82 million is the highest since the launch of the OF-LCG. The Singapore LYMPHoma translatiONal study (SYMPHONY) seeks to focus on next-generation biomarkers which can be exploited for better diagnosis and prognostication as well as improved clinical response to immunotherapy. Singapore Parkinson’s disease Translational Clinical Programme (SPARK) Phase II will work towards identifying new drugs to improve health outcomes in Parkinson’s disease and identifying risk and protective factors so as to slow down disease progression. The Singapore Gastric Cancer Consortium seeks to further its goal of transforming gastric cancer management by tackling the key clinical and scientific challenges in gastric cancer, through specific themes in precision prevention, precision therapy and identifying novel targets through innovative technologies, data science and experimental models. Advancing Precision Medicine for Cardiovascular Disease and Diabetes in Asian Populations project seeks to translate the insights and discoveries made to clinical benefit, through improved identification and communication of risk, as well as development of evidence-based, scalable and personalised interventions.

India, African Union ink MoU for health science management

Indian Council of Medical Research (ICMR), Ministry of Health and Family Welfare, Government of India recently signed a Memorandum of Understanding (MoU) with the African Union (AU) represented by Scientific Technical and Research Commission (AU-STRC) in New Delhi, India. The MoU will strengthen South-South collaboration in advancing health sciences research; enhance local capacity and ownership. Recognizing the common health
Roche launches Hemophilia drug in India

Roche has declared that Emicizumab (Hemlibra) has been approved in India for Hemophilia A with factor VIII inhibitors. It is indicated as a prophylactic (preventive) treatment to prevent or reduce the frequency of bleeding episodes. Hemlibra is the first weekly subcutaneous (under the skin) prophylaxis injection shown to prevent or reduce the frequency of bleeding episodes and improve the quality of life. It is designed to bring together factor IXa and factor X proteins required to activate the natural coagulation cascade and restore the blood clotting process for people with Hemophilia A. All current prophylactic treatment options for people with Hemophilia A with factor VIII inhibitors require intravenous infusions several times a week. Even then, some people may experience joint bleeds that can lead to long-term damage. The approval of Emicizumab is an important advancement for the entire Hemophilia A community. It is a first-in-class of treatments for people with severe Hemophilia A, with inhibitors in nearly 20 years.
Cytovant Sciences to develop cellular therapies in Asia

Sinovant Sciences and Roivant Sciences have announced the launch of Cytovant Sciences, a biopharmaceutical company focused on developing and commercializing innovative cellular therapeutics in Asia. Cytovant will focus on development programmes that have the potential to transform the treatment of diseases that are prevalent in Asian patients. Concurrent with the company’s launch, Cytovant has entered into a multi-programme license and collaboration agreement with Medigene AG, a clinical stage biotechnology company focusing on the development of T-cell immunotherapies. Medigene has granted Cytovant exclusive licenses to develop, manufacture, and commercialize Medigene’s research-stage T-cell immunotherapy targeting NY-ESO-1 as well as a DC vaccine targeting WT-1 and PRAME, in Greater China, South Korea, and Japan. In addition, Cytovant and Medigene have entered into a strategic collaboration and discovery agreement for T-cell receptor (TCR) immunotherapies for two additional targets.

West Pharma expands APAC biz with new Korean office

West Pharmaceutical Services, a global leader in innovative solutions for injectable drug administration, has expanded its presence in the Asia Pacific region with a new sales office in Korea—West Pharmaceutical Services Korea Ltd. This new office is the result of West’s purchase of the distribution business of GIS Korea Ltd., a privately-owned medical device and healthcare products distributor serving the Korean market, who previously served as West’s distributor in the region. GIS has been partnering with West as a distributor since 2003 and has built an extensive network of customers across all segments. West has been operating for more than 95 years, delivering integrated containment and delivery solutions to customers, tailored to the specific needs of its pharmaceutical, biologic, generics, and medical device customer groups across the globe. With offices in Singapore, China, India, and Australia, and alongside its partner Daikyo Seiko, Ltd.’s presence in Japan, West is well-positioned to continue to address the increasing customer demand in this region.

Sectra inks 13 year contract with NSW Health

Medical imaging IT and cybersecurity company Sectra has signed a 13-year contract with NSW Health in Australia for an enterprise radiology imaging solution across Australia’s largest public health system. It will provide 11 NSW Health organizations with a common platform and the ability to seamlessly share images and information across departments and locations, resulting in better patient outcomes. The platform will closely integrate with other core clinical systems, including the electronic medical record, patient administration systems and enterprise imaging repository. The ultimate aim is to provide secure, easy and immediate access to medical imaging information across Australia’s most populous state, allowing clinicians to make timely decisions about patient care. The platform will be implemented and used across nine local health districts, the Sydney Children’s Hospital Network and NSW Health Pathology’s Forensic and Analytical Science Service. Together, they manage a joint volume of more than 1.8 million imaging exams per year. Approximately one billion historical image links are being migrated to the new system for quick and easy access to prior images, supporting improved patient care.
CMD receives A$1 M grant from FightMND

Collaborative Medicinal Development LLC (CMD), an Australian biopharmaceutical company developing innovative therapies for neurodegenerative diseases, has been awarded a A$1 million grant from FightMND to support a Phase 2 study of CuATSM for treatment ALS (amyotrophic lateral sclerosis), also known as Lou Gehrig’s disease, or Motor Neuron Disease (MND).

In 2016, FightMND helped to support the phase 1 clinical trial of CuATSM where it was given to MND patients as a therapeutic for the first time. The primary objective, as per any phase 1 trial, was to assess safety and tolerability of the drug and, if possible, identify a dose that could be taken to the next round of testing. By assessing the drug at a number of different doses the trial successfully identified a recommended dose for phase 2 testing. Although a Phase 1 study is not designed to prove efficacy, signals of disease modification were demonstrated. Accrual to the Phase 1 study is now completed.

The company’s lead drug, CuATSM, was licensed from the University of Melbourne and entered clinical trials in ALS and Parkinson’s disease in 2017. The CMD team includes Craig Rosenfeld, MD (CEO), Kay Noel, PhD (COO), and Jim Babcock (Chairman, founder of Cthulhu Ventures LLC, CMD’s founding investor). The next step in development is to perform a randomized, double blind, placebo controlled study.

Cipla Medpro acquires stake in Brandmed

In recognition of the importance of the critical shift to a more patient-centric, integrated and predictive healthcare environment, Cipla Medpro, wholly-owned subsidiary of Cipla Limited and South Africa’s third largest pharmaceutical company in the private sector, will acquire a 30 per cent stake upon closure in the connected healthcare company, Brandmed (Pty) Limited.

In February, Cipla had announced a similar partnership in India with Wellthy Therapeutics to offer a clinically-validated digital disease management platform to patients in cardiometabolic health. Following the Definitive Agreement, Cip Tec will make an upfront payment of $22 million to Pulmatrix in exchange for assignment of all rights for Pulmazole in relation to pulmonary indications to Cip Tec. Thereafter, both parties will equally share costs related to the future development and commercialization of Pulmazole, and equally share worldwide free cash flow from future sales of Pulmazole. Pulmatrix will remain primarily responsible for the execution of the clinical development of Pulmazole, and Cip Tec will be responsible for the commercialization of the product. The partnership will be overseen by a Joint Steering Committee with equal representation from both companies.

Synaffix announces license agreement with Miracogen

Synaffix BV, a Dutch biotechnology company exclusively focused on continued advancement of its clinical-stage antibody-drug conjugate (ADC) technology for the development of best-in-class ADCs, has entered into a license agreement with Shanghai Miracogen Inc., a Chinese biotechnology company with a clinical-stage pipeline of ADCs. Under the terms of the agreement, Miracogen has been granted non-exclusive rights to Synaffix’s proprietary GlycoConnect and HydraSpace ADC technologies for use in its next clinical candidate. Synaffix is eligible to receive upfront and potential milestone payments that total $125 million, plus royalties. Miracogen will be responsible for the research, development, manufacturing and commercialization of the ADC product while Synaffix will be responsible for the manufacturing of components that are specifically related to its proprietary GlycoConnect and HydraSpace technologies.
Pacific insurance injects $74M in Chinese startup

Chinese online health management platform More Health has raised $74.42 million in a Series C round from Chinese insurance company Pacific Insurance. The investment has been routed through Pacific Medical and Healthcare Management Co, which are both wholly-owned subsidiaries of Pacific Insurance. Xiran Capital, a Chinese investment firm, also invested in the current round.

More Health, operated by Beijing Miaoyijia Information Technology Co, offers access to physicians to patients who suffer from potentially life-changing ailments such as cancer and heart disease. China Pacific Insurance, together with its subsidiaries, provides property and casualty, and life insurance; asset management; and pension and annuity products in China.

Aidoc receives another round of funding

Aidoc, an Israel-based provider of AI solutions for radiologists, announced that it has raised $27 million, bringing its total funding to $40 million. The Series B round, led by Square Peg Capital, will be used to grow Aidoc’s technology and go-to-market team to support the high market demand for its products. The funding comes as Aidoc announced that it has analysed its millionth patient’s CT scan in real-time – the largest number of images analysed by an AI tool and a landmark in the radiology AI ecosystem. In addition, Aidoc will be releasing its oncology line of products as well as the extension of its current suite for time-sensitive conditions to X-ray. Aidoc’s FDA-cleared and CE-marked solutions support and enhance the impact of radiologist diagnostic power, helping them expedite patient treatment and improve quality of care. Radiologists benefit from deep learning technology that is “Always-on”, running behind the scenes and freeing them to focus on the diagnosis. Aidoc’s solution flags the most critical, urgent cases where a faster diagnosis and treatment can be a matter of life and death.

Singapore firm invests $5M in Vietnamese startup

JiO Health, a healthtech startup based in Vietnam, has clinched $5 million in Series A funding led by Singapore venture firm Monk’s Hill Ventures. Founded in 2014, JiO operates an ecosystem of technology-driven healthcare services, including telemedicine, digital medical records and home doctor visits in Vietnam. It provides on-demand access to healthcare services such as primary care, chronic disease management, pediatrics and ancillary care services. It also has a vertically-integrated polyclinic, lab and pharmacy, which it claims enable it to deliver scalable and quality care services. JiO completed several thousand home visits and check-ups last year. It now plans to expand its care provider team and clinical operations across Vietnam.
EdiGENE raises $15M in Series B funding

EdiGENE, a Japan based emerging biotechnology startup developing new CRISPR based therapies for the treatment of genetic disorders has announced that it has raised $15 million as the first tranche of Series B round. Participants in the Series B included new investors, UTokyo Innovation Platform along with continued support of existing investors, including SBI Investment, Fast Track Initiative, SMBC Venture Capital, Mizuho Capital, CareNet Group. EdiGENE’s unique technology platform, CRISPR-GNDM (Guide Nucleotide Directed Modulation), is capable of normalizing levels of gene expression without cutting the DNA or RNA. By altering epigenetics to control levels of gene, and consequently protein expression, EdiGENE’s novel approach to gene modulation has the potential to prevent, modify and cure a wide range of genetic diseases to improve patients’ lives. EdiGENE plans to use the proceeds of the financing to advance the groundbreaking science forward, extend its leadership position in gene modulation technology, and progress pipeline programmes towards the clinic where they will impact patients suffering from serious genetic diseases.

NIRAMAI to develop AI based software for detecting River Blindness

Artificial intelligence (AI)-based Indian health-tech startup Niramai has announced that it will develop an AI-based computer-aided software for controlling spread of River Blindness. Niramai will leverage its innovative Thermalytix technology to detect the presence of live adult worms of Onchocerciasis which causes river blindness and significant disability. Thermalytix is currently being applied to early stage breast cancer detection. This innovative non-invasive detection method is expected to help assess the efficacy of new drugs being developed to control the disease by killing the adult worms, potentially accelerating the elimination of river blindness, which has today infects ~17 million people in Africa. This project has been made possible through support from Bill & Melinda Gates Foundation. Niramai has developed a novel technique called Thermalytix, an automated diagnostic tool, which combines thermal imaging with artificial intelligence which is being used to detect early stage breast cancer in many hospitals today.

Standigm secures $11.5M in Series B Round

Standigm, a Korean startup using artificial intelligence (AI) technology for drug discovery and development, announced it has raised $11.5 million in a Series B funding round led by Mirae Asset Venture Investment and Mirae Asset Capital. Standigm will use the funds to scale the AI technology platforms and advance its drug discovery pipelines toward license-out. The new round brings Standigm’s total financing to $15 million. The round included participation from Kakao Ventures, Atinum Investment, DSC Investment, LB Investment, Wonik Investment Partners, as well as Mirae Asset Venture Investment and Mirae Asset Capital. Kakao Ventures, one of the leading early-stage VCs in Asia, continued to invest Standigm since its seed round.
WHO marks five years polio-free certification

In March 2014, WHO South-East Asia Region was certified polio-free, proving wrong many public health experts who believed that the Region, which accounts for one-fourth of the global population, would be the last bastion for polio eradication. Five years on, the Region not only continues to maintain its polio-free status but is demonstrating how the polio legacy can effectively strengthen overall immunization and other programmes. The last case of wild poliovirus in the Region was reported from West Bengal, India, where a two-year old girl suffered polio paralysis on January 13, 2011. An intense response by Government of India supported by WHO, UNICEF, Rotary International and other partners ensured it remained the last case in WHO South-East Asia Region. Post certification, these efforts continue. Every year, more than 32 million children across the Region are being reached with oral polio vaccines under routine immunization and through mass polio vaccination campaigns to maintain high population immunity against polio. In India, an additional 460 million doses of oral polio vaccines were given to children through four mass polio vaccination campaigns conducted in 2018.

WHO releases first guideline on digital health interventions

The World Health Organisation (WHO) has released new recommendations on 10 ways that countries can use digital health technology, accessible via mobile phones, tablets and computers, to improve people’s health and essential services. Over the past two years, WHO systematically reviewed evidence on digital technologies and consulted with experts from around the world to produce recommendations on some key ways such tools may be used for maximum impact on health systems and people’s health. One digital intervention already having positive effects in some areas is sending reminders to pregnant women to attend antenatal care appointments and having children return for vaccinations. Other digital approaches reviewed include decision-support tools to guide health workers as they provide care; and enabling individuals and health workers to communicate and consult on health issues from across different locations.

Inaugural WHO Partners Forum launches new push

To meet the world’s most pressing health challenges, WHO, governments and global health leaders called for improved partnerships and resourcing to support WHO’s mission to deliver care, services and protection for billions of people by 2023. The inaugural two-day WHO Partners Forum opened in Stockholm on April 9 and was co-hosted with the Government of Sweden. The meeting resulted in a shared understanding of how to strengthen partnerships and improve effective financing of WHO, with an emphasis on predictability and flexibility. Global leaders in health and development, representing the public sector, health partnerships and non-State actors, came together to launch a new era of collaboration and innovation around WHO’s resource needs. Under the Organization’s Thirteenth General Programme of Work (GPW13), WHO needs $14.1 billion between 2019 and 2023. Other participants in the Inaugural WHO Partners Forum include leadership of the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Bill & Melinda Gates Foundation, International Federation of Red Cross and Red Crescent Societies and Gavi, the Vaccine Alliance.
Ghana opens Health Promotion Division

The Ministry of Health (MoH), government of Ghana in partnership with the Ghana Health Service (GHS), has opened a Health Promotion Division in Accra to sensitise the public on the maintenance of good health and prevention of deadly diseases. The Division, established at the Korle-Bu Teaching Hospital, would among other functions promote early preventive strategies, healthy behaviours and wellbeing, through the creation of environments where individuals, families and communities would be informed and empowered to live healthy and happier lives. It is also expected to promote innovations with digital platforms for healthy lifestyles. The facility has varied departments including the Advocacy and Social Mobilisation, Health Communication and Education, and Research and Health Policy Departments.

Rwanda launches Ebola vaccination for healthcare workers

The Ministry of Health in Rwanda has launched an Ebola campaign that will see health and frontline health workers immunised against the virus. The move is aimed at protecting healthcare workers from contracting the virus in case they have to deal with patients who have it. The announcement comes after a cabinet meeting approved the use of recombinant vesicular stomatitis virus vaccination, an experimental drug for the protection against the virus. According to Dr Diane Gashumba, the Minister for Health, although Rwanda is Ebola free, the vaccination is informed by the fact that the epidemic has persisted in neighbouring DR Congo. The vaccine was donated to Rwanda by Merck, the company that developed it. The support has been channelled through the World Health Organisation. It is estimated to be worth about $1 billion.

Liberia introduces code of conduct for health professionals

The Liberia Medical & Dental Council (LMDC) and partners have launched the country’s first code of conduct for health practitioners. The document is intended to guide all health professionals as well as those intending in venturing into the profession in the country. According to LMDC’s Chairperson, Dr. Linda Birch, the document will set the standard expected of healthcare providers. The Code of Conduct describes the behavior and attitude that are to be projected by all health practitioners. LMDC will carry out a thorough assessment of health institutions in making sure they abide by the codes. The Council will start taking drastic actions against unlicensed health operators.
Eli Lilly and Company and Avidity Biosciences, Inc. have announced a global licensing and research collaboration focused on the discovery, development and commercialization of potential new medicines in immunology and other select indications. The companies will utilize Avidity’s technology platform to progress new therapeutic approaches toward clinical development and commercialization. Avidity’s platform seeks to combine the tissue selectivity of monoclonal antibodies and the precision of oligonucleotide-based therapeutics to potentially overcome barriers to the delivery of oligonucleotides and target genetic drivers of disease. Under the terms of the agreement, Avidity will receive an upfront payment of $20 million, as well as an investment of $15 million. Avidity is also eligible to receive up to approximately $405 million per target for development, regulatory and commercialization milestones, as well as tiered royalties ranging from the mid-single to low-double digits on product sales.

Non-profit drug developer, TB Alliance, and pharmaceutical company, Mylan N.V. have announced a global collaboration to make the experimental drug pretomanid accessible for use in two investigational drug regimens for pulmonary tuberculosis (TB). Pretomanid is a new chemical entity and a member of a class of compounds known as nitroimidazooxazines. TB Alliance began preclinical development of pretomanid in 2002, and it has since studied pretomanid in 20 clinical trials alone or in combination with other anti-TB drugs. Pretomanid has been administered in a clinical trial setting to more than 1,200 people in 14 countries. The two pretomanid-based regimens under development include: (i) For XDR-TB and MDR-TB that is treatment-intolerant or non-responsive: All oral, six- to nine-month treatment regimen consisting of bedaquiline, pretomanid and linezolid (BPaL regimen); (ii) For DS-TB and MDR-TB: All oral, four- and six-month treatments, respectively, consisting of bedaquiline, pretomanid, moxifloxacin and pyrazinamide (BPaMZ regimen). As part of the BPaL regimen, TB Alliance has granted a license to Mylan to manufacture and commercialize pretomanid, pending regulatory approval, for XDR-TB and treatment-intolerant or non-responsive MDR-TB.
Humans have been battling chronic diseases for a long time. With rapid advancement of life science and biotechnologies such as gene editing and next-generation sequencing, recent times have seen more and more untreatable illnesses on the verge of being conquered. This has been possible with new drug discoveries and development taking place globally. North America, followed by Europe, has the largest market for innovative drugs due to high number of approved drugs and technological advancement in this region. However, in the recent times APAC has become one of the fastest growing markets for innovative drugs and is gradually establishing a position in the global market. There are quite a few domestic pharmaceutical companies in the APAC region that are going strong in the drug discovery space. But the major innovation is coming through the government and academic institutes. Public private partnerships (PPPs or 3Ps) between public organizations and pharmaceutical companies is contributing hugely to the development of the life sciences industry in the APAC region.

Countries like Korea and China are fostering increased innovation in novel drug development with the help of their respective government organisations.

Beyond meeting the needs of global pharma in simply providing access to patient pools and lower operational costs, the Asia-Pacific (APAC) region is also poised to realize the potential of a thriving biotechnology sector that is driving innovation on its own. APAC is gaining the experience and infrastructure needed to support the global biotech industry by performing work and fostering innovation through public private partnership (3Ps) that is moving up the pharmaceutical value chain.
In a bid to place Korea on the biotech global map, the Korean government has announced plans to inject $448 million into the pharmaceutical sector over the next 10 years. On the other hand, China has made faster development of research-based pharmaceuticals a national priority, by identifying the segment as one of seven pillar industries to be promoted in its 2011, 5 year plan. Similarly, this past decade, Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) has seen success in reducing almost by half, the time to review and approve drugs. In comparison, the impact of 3Ps is at its best in Singapore currently where the government’s main focus is on filling the innovation gap that straddles academia research and late stage research in pharmaceutical companies. Gradually catching up, the Indian pharmaceutical companies are also receiving the much required support from its government in order to make a mark in the drug discovery area.

“Asia’s rapid growth in biotechnology is driving an increase in capacity building and a transfer of technology. There is also a steady increase in innovative local drug development like antibody-drug conjugates (ADC) and biospecific drugs, as well as next generation medicine like gene and cell therapeutics. The drug discovery space is generating a lot of excitement and we see an increase in research and development activities across APAC”, shares Benoit Opsomer, Head of BioProcessing, Life Science, APAC, Merck.

Besides getting the due support from the government, a key strategy being employed by a number of pharmaceutical companies in the APAC region is collaboration. In order to maintain a flow of innovative drugs there is a growing realisation that companies cannot allow the status quo to remain as it is and the need to identify sources of appropriate knowledge and expertise outside of their own organisations is paramount. As a result, companies
### Steps involved in new drug development

- Discovering and validating the target
- Pre-Clinical Testing
- Investigational New Drug application filing
- Phase 1 clinical studies
- Phase 2 clinical studies
- Phase 3 clinical studies
- New Drug Application filing
- Prescription Drug User Fee Act decision
- Phase 4 clinical studies

### Drivers for Drug Discovery market

- Increase in R&D activities in drug discovery
- Technological advancements
- Need to improve existing drugs
- Requirement of novel drugs
- Increase in incidence rates of several diseases
- Rise in healthcare concerns

are coming together to bring out better and effective solutions collectively.

**Megha Joshi, Healthcare Consultant**, points out “Collaborations to enable drug discovery brings in a lot of advantages, such as technology sharing, designing solutions specific to select patient groups, access to representative patient segment for clinical trials and a window for smooth transition from lab to the market. Drug discovery collaborations also offer a window to understand stakeholder requirement and unmet needs in the market”.

At present, many pharma and biopharma companies are collaborating with each other at domestic as well as international levels in a number of therapeutic areas such as cardiovascular, diabetes, endocrinology, nephrology, immuno-oncology, infectious diseases, inflammation, neuroscience, Non-Alcoholic Steatohepatitis (NASH), oncology, Orphan Drug Development for Rare Diseases, Paediatrics, to name a few.

“APAC is expected to be the most profitable region for pharma and biopharma drug development. In case of Biopharmaceutical industry, cell therapy is set to witness a strong growth over 25 per cent in the next 5-7 years owing to the robust drug pipelines. Stem Cell therapy research is more pronounced in APAC region with several Chinese, Japanese and Korean companies developing innovative drugs across therapy areas including musculoskeletal, Neurology and dermatology alongside oncology”, points out **Aarti Chitale, Senior Research Analyst, Transformational Health, Frost & Sullivan**.

Although collaboration promotes both external and internal sources of innovation, it thrives in an environment where ideas are spun in and out of the companies in a very dynamic way. The stakes of a successful partnership in the drug discovery space are slightly higher due to the many challenges associated with drug research and development.

“Given the risks associated with discovery research, very few enterprises can venture along the entire value chain alone. Partnerships are at the core of success. Partnerships are built on trust and with a very long term perspective. In Asia, such partnerships haven’t been as many as seen in the West. But in recent times there has been a significant growth in the number
of companies, especially young enterprises in the drug discovery sector across Asia. This could be attributed to the dividends being reaped of the sustained support programmes of Government, be it in China, Singapore or India”, mentions Utkarsh Palnitkar, Founder & Managing Partner, Aarna Corporate Advisors.

KOREA
For the Korean pharmaceutical industry, the past 30 years have been marvellous with advancements in new drug research and development with full support from the government. With over 900 new medicines under development, Korean companies now boast ownership of a full 4 per cent of global drug development pipelines. As of 2017, Korea has developed 29 new drugs since the countries first locally developed medicine in 1999, the Sunpla Injection for the treatment of cancer. Of the 29 new medicines, a total of 8 new drugs have been approved by the US FDA and 9 new drugs have also been approved by EMA as of March, 2018. Besides making efforts at the domestic level, Korean pharmaceutical companies are also gaining recognition overseas for their new drug development capabilities by partnering with a growing number of internationally renowned pharmaceutical giants to export their newly developed drugs with more success. The latest in line is the collaboration between SK Biopharmaceuticals and US based twoXAR, Inc. for the development of first-in-class therapeutics for non-small cell lung cancer (NSCLC).

JAPAN
On the pharmaceutical front, Takeda is the leading player in Japan. Although it is the largest pharmaceutical company in Asia, it ranks only 17th in the world, trailing far behind the Western rivals such as Pfizer and Novartis. These global giants spend more than twice what Takeda does on drug development. But Takeda does not seem to mind that. As a unique strategy, Takeda has relocated 15 of its scientists to the U.S. from Japan to work with researchers at Memorial Sloan Kettering Cancer Center, Rockefeller University, and Weill Cornell Medical College, forming a new partnership known as the Tri-Institutional Therapeutics Discovery Institute (TDI). This partnership is allowing Takeda to witness cutting-edge science first-hand, and pass along valuable information about drug discovery and design. To further establish a drug discovery ecosystem in Japan, Takeda has taken another step by creating a joint investment fund called the Drug Discovery Gateway Investment Limited Partnership, by teaming up with Japan-based Alternative Asset Management Firm, Whiz Partners, Inc. On the other hand, the second lead player in the Japanese pharma sector, Daiichi Sankyo, is making best efforts in establishing international collaborations for enhancing drug development. In March 2019, Daiichi announced a global drug development association with AstraZeneca, in the area of oncology.

CHINA
As the most populous country in the world, China has the largest population of a broad spectrum of diseases, offering a unique environment for research and development in biomedicine and disease therapies. Although most pharmaceutical companies in China have been focused on making generic drugs in the past, some efforts in developing first-in-class drugs are paying off, especially in the small-molecule drugs. HitGen is one
such player in China that has established a platform for small molecule drug discovery research centred on the design, synthesis and screening of DNA encoded chemical libraries (DELs). HitGen is collaborating with pharmaceutical, biotech, and chemical companies, foundations and research institutes in North America, Europe, Asia and Africa to discover and develop approaches for novel medicines and other solutions. Last year, American multinational pharmaceutical corporation, Pfizer entered into a drug discovery collaboration with the Chinese biotech company DL Medicine, utilising screening resources from HitGen.

**INDIA**

Over the past few years, India has become a world leader in bringing generic drugs to the market in a cost-effective way. Indian pharma companies have also demonstrated the capability to develop biosimilars for global healthcare markets. Although these activities are highly valuable, providing essential and established medicines at more affordable prices to people around the world, the future of India lies beyond generics and biosimilars. As a result, this growing trend of pharma collaborations for drug discovery has taken a turn in India as well. Pharma companies in India are actively conducting research and development for new drugs by joining hands with international players. India’s leading drug maker Cipla has entered into an agreement with US based Pulmatrix for developing a drug against asthma. Joining the league is Syngene International that has collaborated with GSK for accelerating the discovery of new drug candidates using Syngene’s discovery services platforms.

**SINGAPORE**

Singapore has been attracting global companies for a long time and has thus evolved as a hub for drug innovation. More than 30 of the top global biomedical sciences firms including Novartis, Eli Lilly, and GSK have a R&D presence in Singapore. Novartis is one of Singapore’s top three biomedical investors, with almost $1 billion invested in pharmaceutical and healthcare products. Companies are attracted by a favourable regulatory environment combined with the Singaporean government’s commitment to growing its biomedical industry. Many pharma companies have brought their early-phase drug development programmes into Singapore, especially in oncology and infectious disease areas. Singapore has been able to conduct such studies with rapid turnaround, fast patient accrual, and experienced investigators to provide key opinion on the direction of development. R&D in Singapore is keenly focused on high net value research and development into discovery, preclinical, and clinical development of drugs to proof of concept. On the domestic front, there are a few pharmaceutical companies running successfully in Singapore but the major innovation is coming through the government and academic institutes.

**Drug Discovery is challenging**

Although a growing number of new molecules are being discovered that are leading to the development of pioneering therapeutics for treating an extensive range of diseases, the fact remains that drug discovery has never been an easy path to walk on. With the resource-draining R&D process requiring 10-12 years and millions of funds to complete and deliver a new treatment to patients, the road to drug discovery comes with its own set of challenges.

Megha Joshi, Healthcare Consultant elaborates, “Drug discovery is associated with high costs and inability to convert cost-intensive R&D programmes to blockbuster drugs may deter investment in the APAC region. This can be overcome by understanding patient unmet needs and investing in high-value drug candidates, rather than me-too drugs that do not offer significant clinical advantage over already marketed options.”

In 2017, across the global pharmaceutical industry, there were nearly 15,000 pipeline products being investigated across all clinical trial development phases and disease areas. However, the challenging environment permits only few to successfully pass all stages of development required to become a medicine available to patients.

“While APAC emerges as the high growth region
for drug discovery and development, several impeding issues pertaining to lack of sufficient funding, improper regulatory and reimbursement processes as well as inadequate drug development facilities are pertinent. The region mainly faces challenges in terms of lacking a centralized regulatory authority such as FDA or EMA. Every country has its individual regulatory authority with their own set of policies for drug discovery, development and manufacturing which adds to the existing barriers”, adds Aarti Chitale, Senior Research Analyst, Transformational Health, Frost & Sullivan.

In order to counter some of these challenges, leading biopharmaceutical companies believe a solution is at hand. Pfizer is using IBM Watson, a system that uses machine learning (ML), to power its search for immuno-oncology drugs. Sanofi, on the other hand, has signed a deal to use UK start-up Exscientia’s artificial-intelligence (AI) platform to hunt for metabolic-disease therapies, and Roche subsidiary Genentech is using an AI system from GNS Healthcare in Cambridge, Massachusetts, to help drive the multinational company’s search for cancer treatments.

Likewise, China has emerged as another major contender that is exploring AI in a large number of fields. As a matter of fact, global pharma companies are reaching out to China in order to foster their drug discovery plans through the AI facilities available in China. Insilico Medicine, named one of the world’s top 20 artificial intelligence (AI) drug-development companies by Forbes Magazine, has moved its headquarters from the United States to Hong Kong in April 2019. Insilico has also collaborated with Chinese biopharma company WuXi App Tec to apply next-generation AI to discover the ideal pre-clinical candidates for novel and challenging biological targets, including orphan targets with no known crystal structure and no known ligands.

Following the pattern, DeNA and DeNA Life Science in Japan are currently engaged in collaborative research with pharmaceutical companies to validate the potential of AI technology in drug discovery. Tokyo based Summit Pharmaceuticals is supporting activities aiming to establish this AI-driven drug discovery programme as well as exploring opportunities for

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### Leading companies involved in novel drug discovery

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- Sinovant Sciences
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- BeiGene
- HaiHe Biopharma
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- Innovent Biologics

- Sun Pharma
- Lupin
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- Syngene International

- Zumutor Biologics
- Jubilant Life Sciences
- Dr Reddy’s
- Glenmark
- Cipla
- Curadev Pharma
- Connexios Life Sciences

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future global business deployment. Also in tow is Fujitsu Labs that is implementing machine learning (ML) to accelerate the process of drug discovery and development.

It seems likely that in the coming years, the pharma sector will explore the utilisation of these new age technologies to address the challenges related to the drug discovery process. But every new thing takes its own time to settle in. “There is so much being spoken about the implementation of AI and ML in the pharma sector. The technological and paradigm shift to these technologies in the pharmaceutical industry is enabling researchers to use novel computational algorithms to support the drug discovery process. As biomedical data are highly complex, using algorithms in designing new drugs has become more possible than it has ever been. However, there will be challenges in the long term implementations of these technologies that will require further conditioning”, points out Mike Agostini, Senior Manager, Application Engineering, MathWorks.

Role of 3Ps

Drug development faces the double challenge of increasing costs and increasing pressure on pricing. These challenges require the mobilization of significant resources from a wide variety of stakeholders. With time, public-private partnerships (3Ps) have been identified as a promising solution for addressing challenges in pharmaceutical innovation. 3Ps represent attractive means to leverage resources dispersed across industry, academia, and organizations in order to address multiple challenges of drug development in an era of constrained resources and increased regulatory pressure.

The Novartis Institute for Tropical Diseases (NITD) is one of the earliest 3Ps in Singapore dedicated to the development of new drugs against neglected diseases. NITD was established with the combined financial, manpower and IP resources of Novartis and public organizations in Singapore, including the Economic Development Board (EDB) and the Agency for Science, Technology and Research (A*STAR), a statutory board under the Ministry of Trade and Industry of Singapore. Apart from that, an A*STAR research institute Experimental Therapeutic Centre (ETC) and its sister organization, D3, are front runners that are actively engaging the pharmaceutical industry to develop innovative drugs. “Public research organizations host many critical drug discovery and development capabilities and resources. Through 3Ps, these capabilities are constantly being sharpened and their associated resources are put into effective use, resulting in benefits for the industry, for the nation’s healthcare, and ultimately for the patient”, shares Professor Alex Matter, CEO of the Experimental Therapeutics Centre, A*STAR, Singapore.

The concept of 3Ps has been adopted by Japan as well in order to advance the research and development of new medicines. The Global Health Innovative Technology Fund (GHIT Fund), the first public-private partnership of its kind in Japan, has been initiated by the Government of Japan, a consortium of Japanese pharmaceutical companies such as Astellas Pharma, Daiichi Sankyo, Eisai Co., Shionogi & Co., and Takeda Pharmaceutical, and the Bill & Melinda Gates Foundation. GHIT Fund has a total of 17 billion yen invested in over 80 global product development partnerships. In addition, Japan government is also promoting industry-academia collaboration at an international level for discovering new drugs. In 2016, multinational pharmaceutical company Boehringer Ingelheim GmbH joined hands with Kyoto University which came around as a rather unusual move since institution rarely works with non-Japanese pharmaceutical companies at the early stages of drug development. Going strong in this direction, Kyoto has recently ties up with
global enterprise Bayer to discover new treatment approaches against lung diseases.

**Rathnam Chaguturu, Managing Partner, iDD Partners, US** says, “The rate of discovery of new therapeutic mechanisms, enabling technologies, and novel translational models are increasing year over year. Pharmaceutical research siloed within a company, the norm of yesteryears, is no longer the case anymore. Likewise, drug discovery in an academic setting has also evolved significantly in recent years, and the value of partnering with private industry has increased. The value is not solely monetary. These diverse partnerships bring together the best ideas and approaches for identifying novel therapeutic targets, address translational chemical biology deficits, and develop new technologies and chemistry to advance the utility of these public-funded discoveries. Transformation of academic discoveries for common good can only be achieved through the involvement of industry”.

Holding a promise in India as well, an example of 3Ps can be reflected through the recent collaboration between the Translational Health Science and Technology Institute (THSTI) funded by the Department of Biotechnology, Government of India and Revelations Biotech Pvt. Ltd. (RBPL) to develop a drug against diabetes. The researchers at THSTI have also developed a genetic tool to speed up drug discovery research that is being used successfully by scientists working across USA, Germany, UK and Japan.

Although many academic organisations are doing great work, researchers in China have observed that the commercialization of R&D output to real innovative drugs is still falling behind. As a result, the Chinese government is working harder to ensure more output in the drug discovery zone. The collaboration between government funded Tsinghua University and the Bill & Melinda Gates Foundation to jointly establish the Global Health Drug Discovery Institute in China has been a major development.

“In the pharmaceutical sector, in order to create an innovation-oriented environment, the China government has increased the drug innovation funding by launching appropriate projects over time. For instance, the ‘Key Drug Innovation project’ launched in 2007 was a notable example. During the entire 12th Five- Year Plan, the project ‘Key Drug Innovation’ was supported with about $16 billion from the central government and more than $49 million from local governments”, highlights **Yuanjia HU, Associate Professor, University of Macau, China**.

Working equally hard, the Korean government has been supporting the pharma industry through its funding over a long time. Recently, the Ministry of Health & Welfare of Korea has designated 46 R&D based Korean pharmaceutical companies as innovative pharmaceutical companies. More than anything else this means that the government is readily guiding and urging the industry to be innovative and to become the leading industry in the global market. In this bid to place Korea on the biotech global map, the Korean government has announced plans to inject $448 million into the pharmaceutical sector over the next 10 years, with the goal of producing around 100 new drugs by 2026. To top it further, the government has also initiated a collaboration through its Korean Drug Development Fund with Germany based Lead Discovery Centre for maturing innovative drug discovery projects in the country.

So far, the experience gained by 3Ps provides evidence that collaboration between pharmaceutical industries, government agencies, academic institutes can result in significant advances for the development of innovative drugs. Although the scenario between US, Europe and APAC are quite different, the implementation of 3Ps is key towards augmenting new drug discovery and development. [5]  

**Dr Manbeena Chawla**  
manbeena.chawla@mmaactiv.com
The Asia Pacific (APAC) is the fastest aging region globally with more than 200 million people expected to move into the ranks of the elderly (aged 65 years and above) between now and 2030. It already has some of the oldest “ultra-aged” societies e.g., Japan. Many more are poised to join Japan’s ranks including Australia, Hong Kong, China, Taiwan, South Korea, Thailand, Malaysia and Singapore with improved life expectancies and falling birth rates. The speed at which APAC societies are aging poses an unprecedented challenge. Singapore’s elderly demographic segment will rise from 11 – 20 per cent in the next 15 years. It took France 49 years to do the same. The United Nations has projected that Thailand’s working-age population (aged between 15 and 64) as having peaked last year. Its data showed that 8.9 per cent of the population was aged 65 and more in 2010. This is projected to increase to 19 per cent in 2030. By 2040, 25 per cent of Thailand’s population could be over the age of 65.

Singapore’s silver market is expected to hit $11.7 billion by 2030. Just healthcare costs alone have been estimated to exceed $20 trillion on a cumulative basis from 2015 to 2030 for the APAC region. Eldercare is expected to surpass real estate as China’s largest industry within 13-15 years, and is estimated to be worth $263 billion by 2020 and $1.1 trillion by 2050.

With the growing presence of data and adoption of artificial intelligence, technology invariably plays a part in converging technical systems and solutions to enable the elderly and/or their caregivers continue to undertake daily fundamental functions. Gerontechnology (a mix of “gerontology” and “technology”) enable the elderly community to maintain their autonomy or to compensate for any functional impairments.

According to figures released by Singapore’s Ministry of Health, there will be a cumulative 40,000 nursing homes, home care and community care places by 2020. The numbers may prove insufficient given that there will be more than 60,000 people aged over 65 by then. In China, the number of beds as a percentage of elderly in China was 4.7 per cent by the end of 2015 compared to 5.0 per cent in Japan and 5.9 per cent in the US. This is a gap that needs to be breached even though China is like Japan 30 years ago. Statistics show that an additional 3.4 million nursing homes will needed up to 2021 to keep pace with growing demand.

Other APAC economies look set to emulate one of Singapore’s policies to provide some relief for future financial planning purposes. CareShield Life is a national long-term care insurance that will be launched in 2020. The insurance provides financial aid to those afflicted with severe disabilities and will provide for cases with pre-existing conditions.

BioSpectrum’s Priyanka Bajpai spoke to Jude Uzonwanne, Principal Consulting Services, Asia Pacific IQVIA, Singapore; S.R. Dinesh, Vice President, Healthcare, Asia Pacific, Frost & Sullivan, Malaysia; Alexis En, Regional Marketing Director, Omron Healthcare Asia Pacific, Singapore and Chris Hardesty, Director, KPMG Singapore Life Sciences on elderly healthcare market in the region, how the market is emerging? and how technology is helping this space? Edited excerpts;
What is the present scenario and the growth prospects of the Asia-Pacific elderly healthcare?

Chris Hardesty: KPMG led a global study of elder private care opportunities, including across the Asia-Pacific region. The numbers are mind-boggling – over the next 15 years, the number of people aged 65 and older will grow from 11 to 17 per cent of total population, adding an additional 600 million individuals into the category. By 2050 the size of the group will double to represent 25 per cent of humanity. And these trajectories are particularly acute in the Asia-Pacific, where some of the oldest populations are based. Taking care homes as an example, assuming an industry-standard 12 per cent of the elderly category will require assisted living support, this creates a potential customer group that would be the fifth largest country in the world. The average annual bed charge for assisted living facilities is $24.5K which, extrapolated across the size of the future customer group, is a figure in the multiple trillions of dollars and equal to the current energy sector market. What’s more, with an average retirement age of 64 and life expectancy of 79, eldercare is a recurring need. There are also qualitative factors impacting the category in the Asia-Pacific such as smaller family units and non-traditional lifestyles.

Indeed, the M&A in this category has now reached about $25 billion per year so there’s lots of movement.

S.R.Dinesh: Asia Pacific will be the fastest growing region in the world in terms of elderly (>65 years old) numbers. Elderly are more likely to suffer from chronic conditions (diabetes, hypertension, cardiac diseases) than other population. Elderly also suffer from ageing condition such as osteoarthritis and osteoporosis. Disease such as age-relate macular degeneration, Alzheimer’s, dementia are also common. Because of all these and many more ailments, elderly may need assistance of care givers or nurses or both depending on severity of the condition. They could be cared for at home with the help of nurses and caregivers, but many have to go to nursing homes.

There are 3 types of senior living facilities seen in Asia.

(1) Independent living, where elderly can take care of themselves. (2) Assisted living, where they need some help from caregivers to do a few to most activities. (3) Nursing care, where elderly have a medical condition and hence need nurses to help them manage their condition, for a few hours to most of the time. Asia Pacific market is quite fragmented. Japan and Australia lead the way with sophisticated senior living facilities some of which pilot or employ robots to carry the elderly and to help nursing staff with their tasks. At the other end of the spectrum are the emerging countries.

Alexis En: Asia Pacific is home to rapidly ageing societies like Singapore, China, Hong Kong, Japan, Thailand and South Korea. This trend is not expected to be reversed anytime soon as Asia is expected to have the oldest population in the world in the next few decades. The elderly healthcare industry is set to continue growing in this region. In addition to ageing societies, another major factor that will fuel the growth of the APAC elderly healthcare market is government initiatives. Many governments in Asia have introduced initiatives to provide more affordable medical treatment as they continue to adjust policies in view of an ageing population.

Jude Uzonwanne: We anticipate that by 2030, Asia Pacific will have about 60 per cent of the world’s elderly. The volumes will vary by country e.g 25 per cent of Singapore’s population will be over 60 years by 2030.
How are the markets in emerging economies? How far is the APAC senior care market from achieving a true financial?

**S.R. Dinesh:** Typically in the emerging countries in Asia, children take care of the elderly, however with globalization that is not possible—there are substantial growth in the number of single nested families (elderly living with their spouses or alone at home). So elderly have started to realize that they would be better off in a place which has likeminded elderly people as friends where they can do their activities that they have common interest in, at the same time know that they will be taken care of if there is a need for caregivers or nurses. Their children are also happy to know they are being taken care of. The market is still nascent but growing, especially the high-moderate segment. There are challenges such as inadequate availability of funds, poor insurance coverage, etc. So it is not growing as much as it should or could; but it is a matter of time before technology enabled, efficient senior living facilities will become available at affordable prices at various price points.

**Chris Hardesty:** There are two major healthcare topics at the top of emerging country governments’ agendas: achieving “health for all” by 2030 (UN Universal Health Coverage (UHC) goal) and better integration of efforts across health + social care. Clearly eldercare sits right in the middle of the discussion given the large proportion of disease management spend as well as the required social support. In the KPMG study, it is estimated that government spend on aged care will quadruple by 2050 to $2.7 trillion. But spread across the number of people in the category, this only comes out to about $6.2K each. So clearly there is a major gap between demand and government capacity, which is where a variety of stakeholders from the private and middle sectors need to get involved.

**Jude Uzonwanne:** The markets are in transition. The financial attractiveness of aging in Asia is still new for many investors. Many companies are still determining how best to serve the elderly market. Obvious segments include food supplements, vitamins and specialized medications e.g. related to bone health. Less obvious options include access to housing and care givers. The housing market play is in flux due to cultural preferences around keeping families together, so the elder housing market that is a US or European staple is unlikely to take off in Asia; an amended form will likely emerge with a host of services delivering into existing homes rather than the customer moving to a new home entirely.

The “medicalised” model is shifting to become more social and rehabilitative globally. How are the field and needs of preventive healthcare evolving?

**Jude Uzonwanne:** Preventive care is growing quickly driven by greater patient awareness of their own health options and a desire by regulators and governments to encourage it. Thus, consumers are being encouraged to consume more vitamins, supplements and other additives that in principles help overall wellness. In addition, healthy behaviours such as increasing exercise and eating better is being pushed by a range of government bodies. The net objective is to reduce the probability of the population developing a chronic condition, and in the event that they do, the cost of care associated with it.

**S.R. Dinesh:** Digital technology has create a culture of health which the consumers want to manage more proactively. The emergence of patient portals, social media, clinical wearables to monitor the vital parameters and share it with their physicians and friends and families is becoming more prevalent today. Payors are also aligning with this trend and there are incentive programs provided to consumers to manage their health and are rewarded at the end of the program. This eventually will cover the population and will lead to better population health management and outcomes. Going forward the needs of the market would be use and integration of consumer generated data with other sources of data and analytics for consumers to make better decisions, physicians to be able to predict and manage health for their customers and for the public health organisations to cut down on healthcare costs and provide access to all.

**Alexis En:** The classic adage – prevention is better than cure – cannot be more appropriate to emphasise how important preventive healthcare is today. Especially with an ageing population, we cannot seek
treatment only when we fall sick or when symptoms of a condition surface. We must be proactive when it comes to monitoring our health and securing our quality of living.

It is encouraging to see governments across the region recognising the importance of preventive healthcare. For example, subsidised health screenings are offered to selected Singaporeans over 40-years-old to test for health conditions such as high blood pressure and diabetes, two examples of prevalent health issues in Singapore.

We must also be more proactive in monitoring our health. Currently, we are blessed with the convenience of technology. Portable blood pressure monitors today can be purchased from stores and kept at home for easy monitoring. The readings of your daily measurements can be synchronised to health apps and can be shared with doctors in an instance.

Today, the health of senior citizens can be monitored in the comforts of their home through health devices such as blood pressure and blood glucose monitors.

Chris Hardesty: Care at home is certainly a major point of interest, though this becomes trickier in the eldercare space where multiple morbidities are common and modern family structures require outside support for assisted living. Community-oriented care is one answer, and technology is also helping though as mentioned in the KPMG report, we expect the growth of the aged care facilities to continue to be a boom. And these facilities aren’t what we might picture from before, many of them now are high quality, community-oriented, and even situated in semi-vacation locations.

Preventative care follows a similar trajectory in terms of hot topic but mass changes coming a bit slowly. There are many efforts underway with employer programs, wearable tools/reminders, insurance premium incentives, general education about healthier lifestyles. But it remains true that for the first time in human history, more people are dying from diabetes-related conditions than malnutrition. Hopefully we start to shift the tide for the next generation which will then have future implications for eldercare. I have also seen some practical innovations for the elderly such as interactive games to keep the mind fresh (i.e. slowing dementia onset) and exercise programs designed specifically for the elderly (simultaneously addressing the loneliness issue).

What is the prevalence of AI being deployed in elder care robots currently? How is it being applied?

Jude Uzonwanne: Overall, the use of AI is relatively limited outside of Japan and Korea. The care model in Southeast Asia and South Asia emphasizes more family care hence the penetration of AI and robots will be limited. That said, in markets such as Japan and Korea, we anticipate that within the next decade (by 2028 – 2030), AI enabled robots will be in at least 30 per cent of homes providing support related to medication, telemedicine, and disease prevention.

S.R. Dinesh: There is always some element of AI in any robot including ones used in the healthcare industry as well. The prevalence depends on the functionality of the robots – overall the adoption is still low.

Robots can be used for physical support or cognitive support. The robots in elderly care are mostly deployed for basic functions to provide communication, give alerts to take medicine-using chatbots, enable physical activities. However AI is used in robots to help learn the preferences, behaviour and personality of the individual and can suggest specific physical activities, games, diet etc. The prevalence of AI in such functional robots is high but the deployment of robots itself is low.

Alexis En: Elder care robots are starting to be deployed especially in more developed markets to provide relief for the human resource crunch in elderly nursing homes and facilities. Through artificial intelligence, these robots are not limited to performing menial and laborious task like transportation.

In countries like China, elderly care robots are taking on more value-added jobs and are assisting doctors and nurses in serving and treating patients in elderly nursing homes and facilities. These robots can track blood pressure and monitor other health indicators. More robots are now equipped with data analysis and self-learning capabilities. These robots can study and memorise patient preferences and use the findings for future interactions. Robots equipped with AI can also remind the elderly when their next doctor’s appointment is and to take their medications.
Where is this technology headed in the future in terms of new applications and what progress has been made in this regard?

**Jude Uzonwanne:** Technology is evolving rapidly and increasingly designed to improve patient experience, the care environment, and health outcomes. The majority of technology is designed to either transform the hospital environment today, or the at home care environment. Thus, we expect that AI related technologies will continue to evolve with 3 objectives in mind: reduce cost; improve work flow; and transform the experience for patients and healthcare professionals. For example, applications that combine a patient’s genetic data with a disease diagnosis and treatment options library will cut the time to treatment by potential 50 per cent or more, and ensure that stays in hospital settings is materially reduced. It also frees up the physician to focus on broader questions about the patient’s wellness rather than trying to decipher what the patient’s disease is.

**S.R. Dinesh:** The current AI technology used is more cognitive computing that is used to aid decision-making. The AI technology in robotics in the future will move towards providing better health outcomes. The future of AI in robotics will be machine learning and deep learning. E.g Hybrid assisted limbs developed by Cyberdyne will react to electrical impulses in the skin without the need for actual movement. This can give elderly their movement and flexibility.

**Alexis En:** As far as preventive healthcare is concerned, healthcare devices will continue to play a vital role in elderly care. These devices will continue to grow in user-friendliness, providing convenient access for elders to monitor their health and prevent conditions such hypertension, diabetes and other conditions that prelude to serious health problems. They will progress from reporting the health status of users to advanced alerts and predictive capabilities. This will go a long way to ensure early detection and delivery of care where necessary.

The importance of robots in elderly care will also be magnified as Asia Pacific will be home to the oldest population in the next few decades. The progress of robotics technology will continue to benefit the elderly care market which is perpetually hamstrung by human resource shortages. With the adoption of advanced technologies such as machine learning, cognitive computing and cloud robotics, the role of robotics in the elderly care market is limitless.

**According to you, how is the role of social and health services evolving in the care of an increasingly ageing world population?**

**Jude Uzonwanne:** The notion of a separate social and health services will evolve and eventually disappear. What matters more is the ecosystem of care within which the patient will operate. The ecosystem will include more technology enabled solutions over time working alongside human specialists and care givers. A role shift will occur with the care givers and social workers focused more on the broader context of care, as well as long range outcomes for the patient, leaving the data collection, analysis and recommendation to the AI enabled systems. In such a world, while we will not need to add as many new care givers as we would have 20 years ago, it also means that the skill level expected of care givers will actually rise e.g. providing more emotional support than previously was the case.

**Chris Hardesty:** Governments are waking up to the facts that fragmentation of health and social services is not only an inefficient use of funds but more importantly causes tremendous stress for the common citizen (whether it be the elders themselves or the caregivers). We are moving from a means-tested system into one that recognizes the social determinants as a major impact on health. And this becomes especially important in the Asia-Pacific context with the oncoming implementation of UHC. The “social” element could also be the missing link in making the value-based contracting function across the public and private health spheres. Even if the stakeholders (including drug and device companies) are able to agree on the measurements of success from a health outcomes perspective, the individual behaviour of humans is the wild card that needs more incentives and guidance. And this is also where technology, caregivers, education, transport, among many others must work together to take a whole system approach for support.
BridgeTech Program 2019 boosts Australia bio SME sector

To support the financial requirements of the emerging medical devices/biotechnology sectors and young entrepreneurs and professional, the Australian government has announced BridgeTech Program in 2018. With the success of the first such initiative the government has now launched BridgeTech Program 2019 in March which will help industry to move up the growth ladder.

Following the success of the inaugural BridgeTech Program in 2018, the Federal Government in Australia has announced the opening of 2019 BridgeTech Program at QUT’s Institute of Health and Biomedical Innovation in Brisbane on March 15.

Administered by QUT, the $22.3 million BridgeTech Program is jointly funded by the Medical Technologies and Pharmaceuticals Growth Centre (MTPConnect) and a consortium of medtech companies and the Medical Device Partnering Program, universities and industry associations. The BridgeTech Program represents a unique initiative designed to support and enhance the commercialisation of Australian medical technology and medical devices via the professional development and training of medtech researchers and entrepreneurs.

Participants of The BridgeTech Program are selected from a competitive pool of applicants and receive exclusive commercialisation training and advice through a dynamic and complex 12-month program including online training modules, a rotating series of seminars and a three-day intensive training symposium. In addition, participants are introduced to a growing network of program alumni and have invaluable access to advice and expertise from the industry consortium whose representatives include Stryker, Siemens Healthcare and Cochlear.

The 2018 BridgeTech Program saw the selection and participation of 77 inaugural members and in the short time since the completion of the commercialisation training and professional development program, participants have already reported successful commercialisation behaviours such as initiating industry and academic partnerships and collaborations, pitching technology to international investors and securing funding and R&D contracts.

Following the success of the BridgeTech Program and its sister program – The Bridge Program – both programs received multi-year funding commitments through MTPConnect and the Federal Government’s Medical Research Future Fund via the announcement of the Biomedical Translational Bridge Program.

Under the Biomedical Translation Bridge (BTB) program, projects for new therapies, technologies and medical devices will be eligible for up to $1 million over a period of up to three years to support translation of Australian medical research through to the proof of concept stage. The BTB program has a strong commercial imperative, driving development

**Brief on BridgeTech Program**

The BridgeTech Program is specifically set up as a national, sector-wide program that will benefit a large number of participants and their organisations, particularly those from the SME sector. The program will not only benefit trainees, it will also improve the planning and execution of research & development in their organisations, and the networking opportunities available to them. This will ultimately deliver more advanced and commercially viable leads, better deal opportunities, and higher returns from Australian research.

- Industry - Biotechnology
- Company size - 2-10 employees
- Headquarters - Kelvin Grove, Queensland
- Type - Educational Institution

- Founded - 2018
- Specialties - medical devices, Entrepreneurship, professional development program, research, medical research, biotechnology, biomedical, professional, university sector, networking, development, and innovation
- Website - https://research.qut.edu.au/bridgetech/
of research initiatives to improve the health of Australians that also generate commercial returns to help create the high paying jobs of the future.

The BTB program, will see the creation of a partnership between BioCurate (University of Melbourne and Monash University), UniQuest (University of Queensland through its drug discovery initiative QEDDI) and the Medical Device Partnering Program (MDPP, led by Flinders University), all pre-eminent organisations engaged in the translation and commercialisation of health and medical research.

Welcoming the government’s announcement, MTPConnect, CEO, Dr Dan Grant says “As the national growth centre for the Medical Technologies and Pharmaceuticals sector, MTPConnect is uniquely positioned to partner with industry and deliver the Biomedical Translation Bridge program. MTPConnect is already responsible for two schemes for the Federal Government which provide funding to 48 projects across the country, so to be awarded this new and exciting health program is welcome recognition of our achievements.”

Talking about its role in the program, BioCurate CEO, Dr Glenn Begley, says “BioCurate’s focus is working closely with researchers to address the barriers that limit the translation and commercialisation of their early stage research. The BioCurate team brings extensive ‘hands on’ international industry experience and we look forward to sharing our scientific and commercial expertise as part of the program.”

Hailing the opening of the program, Dr Begley says “This announcement was an acknowledgement of the leadership and vision demonstrated by Monash University and the University of Melbourne, and the long-term support by the Victorian state government. Their shared goal was to build research-translation and early commercialisation capability. It also recognises our deep industry-experience in drug development.”

“This announcement recognises UniQuest’s unsurpassed track record in the translation of Australian biomedical research and the world leading biomedical research of The University of Queensland, which includes the cervical cancer vaccine Gardasil and Spinifex Pharmaceuticals – the subject of one of Australia’s largest ever biotech acquisitions,” says Dr Dean Moss, CEO, UniQuest.

MDPP Director, Professor Karen Reynolds, says “MDPP has a 10-year track record of successfully facilitating early-stage ideation and research for new medical devices. Through the BTB program we will leverage our diverse connections and expertise to optimise the success of Australia’s medtech ventures.”

The Biomedical Translation Bridge grant opportunity will support one or more organisations to fund and nurture early stage health and medical research ventures to reach proof-of-concept stage with potential to attract further capital and support. It will provide $22.3 million over four years from 2018-19 to 2021-22 as follows: $10.4 million in 2018-19, $5.3 million in 2019-20, $5.3 million in 2020-21 and $1.3 million in 2021-22. With this much needed support from the Federal Government the medical devices/biotechnology industry will go a long way with participation of other stakeholders like researchers and academia.
“Growth opportunities are enormous as livestock health is largely underserved”

Started in 1988, Hyderabad based Brilliant Bio Pharma Private Limited (BBPL), engaged in manufacture of veterinary biologicals and medicines has completed 30 years. BBPL is one of the largest veterinary vaccines manufacturers in Asia with strong presence in domestic and international markets. The company has state-of-the-art BSL-3 facilities to produce several other animal vaccines, chiefly Foot and Mouth Disease Vaccine (FMD), Animal rabies and Bacterial vaccines for cattle. The company is ISO 9001-2015 certified and is accredited with GMP, WHO-GMP, GLP certifications and our vaccines are approved by AU-PANVAC. The company has received HMTV’s “The Best Pharma Company Award 2019”. The R&D wing is certified by the Department of Scientific & Industrial Research (DSIR), Government of India.

BBPL clearly understands the needs of animal health and productivity. The company is continuously striving for the best of it by swiftly adapting to the current trends in vaccine production technologies. In this endeavour, the company has technology tie ups with various premier institutions engaged in veterinary vaccines research. The products are registered and exported to various countries in Asia Pacific region, Gulf, Middle East, Far East, CIS, Africa, Latin America. BBPL is one of the registered suppliers of Veterinary Vaccines and Medicines to Food & Agriculture Organization (FAO), Rome, Italy and has exported to DPRK (North Korea), Bangladesh, Chad and Yemen as per FAO orders.

Mourya Boda, daughter of T G Venkatesh, Ex-Minister, present Member of Parliament and Chairman of TGV Group is spearheading the company since 2005 when she was 23. Mourya Boda holds a Bachelor Degree in Law and Masters in Business Management. She has been conferred with International Women Entrepreneurial Challenge (IWEC) 2015 Award at Istanbul and Pharma Leaders Innovative Woman Biotech Leader Award of the year 2018. BioSpectrum spoke to her about her journey and her plans for the company in the coming years. Edited excerpts;

How do you see the journey of the company till now?
I think that we have done fairly well considering that we are in the difficult business of making a difficult vaccine like Foot and Mouth Disease (FMD) vaccine, among others, and supplying it to the National FMD Control programme. We remained focused on animal health and on vaccines. As a result, we are the second largest FMD Vaccine producer in the world. We have built up sales revenues of Rs 150 crore and are among the fastest growing animal health companies in India today.

What were the challenges then and now the company is facing?
The challenges when you take reins of company struggling to find its feet are different from when it has found its feet and aspires to grow. Our early focus was on getting a bandwidth in terms of products, technology and market space in our chosen segment i.e cattle in livestock. Now it is really on how we can grow the business by entering new segments and new geographies, while at the same time consolidating the existing business. Also, we have challenges in building new capabilities in the organization to make it dynamic and market oriented with competent human capital.

India being agrarian country with huge livestock population, how do you see the opportunity for your business?
The growth opportunities are enormous considering that livestock health is largely underserved, whether it
THE INDIAN ANIMAL HEALTH MARKET, according to our estimate is about Rs 4800 crore in size by sales revenues, with an annual growth rate of 12% p.a. Biologicals account for about Rs 800 crore. In terms of growth, the action is really in the animal feed supplements and the companion animal segments. The animal feed supplement business is about Rs 1500 crore by sales revenues and the canine segment about Rs 300 crore. Both segments are witnessing growth of +15% p.a.

is health, nutrition or breeding. As you are aware, it is not just the per capita consumption of animal derived product which are abysmally low in India, but the consumption products and services catering to animal health is also very low. In addition, we have to now support the One Health initiative which converges human and animal health systems to make common ground in providing safe food from livestock free of non-zoonotic and zoonotic diseases. This does provide new opportunities for our business.

What target you will be looking at for the company by 2025?
We are among the Top 15 animal health companies today. We want to be among the Top 5 animal health companies by 2025 with a portfolio of products across all major segments in livestock and companion animal business.

How do you see competition in the market as market for diary business is opening up very fast in last couple of years?
I can only say the competition is getting intense with more domestic companies in the fray. Besides, stand-alone animal health companies are also viable now, unlike in the past when they were divisions of human health companies and dependent on human health product spinoffs to serve animal health. As regards the dairy business, it is still the branded generic play with more innovative product offerings which is giving advantages to companies from differentiation.

According to you what is size of Veterinary Biologicals & Medicines market in India? What are the current trends in these markets? What is percentage of growth these businesses are growing now?
The Indian animal health market, according to our estimate is about Rs 4800 crore in size by sales revenues, with an annual growth rate of 12% p.a. Biologicals account for about Rs 800 crore. In terms of growth, the action is really in the animal feed supplements and the companion animal segments. The animal feed supplement business is about Rs 1500 crore by sales revenues and the canine segment about Rs 300 crore. Both segments are witnessing growth of +15% p.a.

Having presence in 30 odd countries now, are you looking at entering other regions as well?
We would rather consolidate our presence in the markets that we presently serve and strengthen our relationships here before we embark on the other geographies in a more concerted manner.

In which part of the world, outside India the company is doing very well and you wish to concentrate more there?
We are doing well in the MENA (Middle East and North African region), an area where there is considerable livestock population, especially small animals.

Are you looking at inorganic growth to take the company to next level in the coming months?
Yes, we could if a suitable opportunity arises, if it is affordable and if it provides a good fit to our current business.

What are the new initiatives of the company?
We are currently engaged in increasing its production capacity of Foot & Mouth disease vaccine in order to meet the expected increase in demand of this vaccine in the FMD Control Programme in India. Alongside this, we are now poised to enlarge our presence in the animal vaccines market with launch of new vaccines for the small livestock – sheep and goats. The vaccines that are in the list are Sheep Pox, Goat Pox, PPR (Pestes Petits de Ruminants), Blue Tongue and combination vaccines. We also have plans to develop other cattle vaccines such as for Brucellosis and Theileriosis and a full range of canine vaccines. These vaccines should be ready for launch in the next two years. We are also building a new facility to manufacture a range of animal nutrition and feed supplement products which meet strict national and international regulatory requirements.

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“We intend to bring uniformity and highest standards of excellence in education and training”

Accreditation Council for Medical Affairs (ACMA), an internationally recognized, self-governing entity which offers the only accredited training and certification for pharmaceutical industry professionals in medical affairs and sales. The ACMA works collaboratively with academia and the pharmaceutical industry to ensure that there are adequate educational and professional development opportunities for professionals involved in medical affairs as well as providing the first ever career pathway for physicians, scientists and pharmacists pursuing careers in the pharmaceutical and life sciences industry. The ACMA reinvests back into the community, which ensures its ability to create valuable educational programs, resources and events that support the Medical Affairs community. It offers the Board Certified Medical Affairs Specialist Program (BCMAS), a self-paced, online certification program now available in over 30 countries including India.

Dr Sakharam Garale, a physician with over 17 years’ experience in global medical affairs and clinical research and development in the pharmaceutical industry, is heading ACMA Southeast Asia office in Mumbai since January 2018. BioSpectrum spoke to Dr Sakharam Garale about ACMA and its partnerships with India and his plans for the upcoming years.

Edited excerpts:

Tell us about ACMA and its partnerships in India. The Mission of the ACMA is to establish standards of excellence for credentialing of qualified pharmaceutical industry professionals. In India, ACMA has collaborated with Indian Pharmaceutical Association (IPA) for delivering training and certification to Pharmacy graduates and the industry professionals.

What is the current scenario in the sector of medical affairs in the industry? With continuous pressure from regulatory agencies, more and more activities are pushed into medical affairs organizations. Today, these organizations commonly involve medical activities such as Medical field teams that include medical science liaisons and others who lead relationship management and communication of product information with healthcare providers, planning and execution of interventional and observational studies post-launch of clinical trials, medical information services including the medical staff who distribute medical information in response to drug information inquiries, medical communications that includes the writing and support for peer-reviewed publications and other medical and scientific communications, Medical strategic activities, including development and leadership of the medical—brand strategy for each product by medical directors and collaboration with development, commercial and others to shake the products cross functional life cycle strategy and planning and Health economics and outcomes research (HEOR) activities, including research and communications related to product value. For example product value dossiers.
What role does ACMA want to play in India? Why is it planning to enter the Indian market?
Currently, India does not have any industry standardization norms for students and professionals in this sector. ACMA would be an accrediting organization for pharma industry professional and student willing to enter this industry. It wants to ensure that entry level academic norms are standardized in India for pharmaceutical industry and wants to provide global platform for ACMA community to discuss, interact and learn from each other.

There has been a dramatic growth of medical affairs specialists in the pharmaceutical industry. Can you elaborate on that?
Pharmaceutical industry is shifting from innovators to generic / branded-generic products. Medical device industry is rapidly growing along with cosmeceuticals and nutraceuticals. We anticipate a paradigm shift in availability of tools in product lifecycle management. We are heading towards digital healthcare. Medical affairs is now not just limited to the management of routine regulatory reporting requirements but it also encompasses strategy, safety, communications, post-launch trials, field teams and much more. These are definitely pharma centered operations.

What role can a medical affairs specialist play in the pharma industry?
In the changing scenario, need and importance of MA function is high and undisputed. However, the dimensions of role have been evolving. A MA resource must be digitally literate and expert to make use of available tools in the best interest of patient wellbeing and safety with quality products. Perform a role of a SAFETY GUARDIAN in compliance with local regulations without a commercial bias. A medical affairs specialist complimented by scientific training can be an asset to the pharma industry. The role includes but is not limited to: providing medical insight into the disease area, knowledge of treatment patterns and unmet clinical needs, knowledge of healthcare system, critical appraisal of clinical trial data and ensuring that activities of the company are in the interest of patients. A MA specialist now also has to give actionable and valuable medical insights, drive scientific exchange communications, do early patient screening, have awareness of treatments, track the emergence of new KOLs and other influencers with data science solutions and statistical techniques, advance medical evidence insights based on standard of care and market access and when speaking of multi-national companies collaborate between medical-clinical-commercial-market access and global/regional affiliates.

What are the major challenges in this sector?
Challenges in this sector are many such as to demonstrate product value with real-world patient outcomes data, correctly identify stakeholders, create and deliver tailored real-time content, establish credibility using transparent, relevant and unbiased medical information, generate and translate high quality data and insights in specialty therapy areas, rigorous regulatory environment and increased public scrutiny.

What are the plans of ACMA for the upcoming years?
The mission of ACMA is to establish a high level of global, independent standards of excellence in the pharmaceutical, biotechnology, diagnostic and medical devices industries. We are a self-governing entity which works collaboratively with academic & industry organizations to ensure that there are adequate educational and professional development opportunities for the life sciences. Our training programs are used by pharmaceutical, biotechnology, medical device and diagnostic companies as a go-to resource and reference. We intend to bring uniformity and highest standards of excellence in education and training for Medical Affairs and Sales departments in life science companies in India and Asia.

Where do ACMA see itself five years from now?
We see ourselves as a well-known accreditation organization in India for Pharmaceutical Industry Professionals and aspiring graduates and also have a strong network of ACMA community within India and globally for knowledge and best practice sharing in the pharmaceutical industry. We see us as a pioneer in sharing genuine research, innovations within industry with non-profit objectives.

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Asia Pacific is expected to become the destination of choice for clinical trials due to its fast-growing pharmaceutical market, dynamic healthcare landscape and access to patient pools. To capitalize the business opportunities from this growing market, keep up with healthcare needs and market demand, healthcare providers are turning to technology and digital platforms to bring drugs to patients faster and to generate much needed insights to address evolving healthcare challenges. Medidata solutions is one such prominent participant in the clinical trials IT solutions market that is making headway by applying artificial intelligence and advanced analytics to deliver meaningful insights to the industry. Medidata was recently honored with the Asia Pacific Clinical Trial IT Solutions Provider of the Year Award at the annual Frost & Sullivan Asia-Pacific Best Practices Awards held at Singapore. Edwin Ng, Vice President, Field Operations, APeJ, Medidata spoke to BioSpectrum about how disruptive technologies are setting the future for clinical trials.

**Edited Excerpts:**

**What are the basic services being provided by Medidata Solutions to the healthcare industry?**

At Medidata we transform clinical research with cloud-based technology and pioneering analytics via a unified platform. We work closely with pharmaceutical, biotech, medical device companies and academic institutions to provide solutions from enhancing clinical trials design and planning with scientific insights, bringing greater efficiencies, quality and cost savings to clinical trial data capture and management, to minimizing risk and optimizing outcomes of clinical trials to bring new drugs to the market faster. By utilizing our unified platform, pioneering analytics, and our expertise in big data and artificial intelligence, we drive end-to-end value from study start to finish. Our offerings span from applications to analytics and benchmarks that make current trial processes more efficient, productive and streamlined. We also work with clinical trial sponsors and contract research organizations (CROs) to deliver patient-centric clinical trials, leveraging mobile health technology and patient cloud solutions.

Medidata has the capability to support researchers with unmatched flexibility to conduct clinical trials virtually, on-site, or as a hybrid with eConsent and eCOA. By equipping patients with mobile health solutions such as sensors and wearables, it reduces patient burden and creates better insights from data.

**Asia Pacific is expected to become the destination of choice for clinical trials. What are your views on this, and what are the challenges you foresee in this regard?**

I agree that Asia Pacific (APAC) is set to become the destination of choice for clinical trials with its fast-growing pharmaceutical market, access to patient pools, skilled talent, strong intellectual property (IP) and legal infrastructure, and regulatory reforms. For example, with nearly two-thirds of the world’s population based in Asia Pacific, the region provides researchers with a large pool of patients to tap on patient recruitment. Additionally, governments are also realizing the region’s potential and needs, and have been investing into their local industries for growth. Take Korea for example. In 2018 the Ministry of Health and Welfare proposed a 64.24 trillion won ($56.8 billion) budget that includes the spending of 11.5 billion won to build a big data platform for healthcare, 3.6 billion won to create a bio-health technology business ecosystem and 4.6 billion won to strengthen the competitiveness of medical device industry. This investment is up 11.4 per cent from 2017, accounting for 15 per cent of the total government expenditure of 429 trillion won.

On the regulatory reform front, China has and continues to introduce new guidelines to encourage
more innovation in the life sciences industry. One example is that by deregulating some of the requirements for conducting clinical trials in-market, China is making room for domestic trials to take place, and thus increasing market potential.

While the region as a whole is becoming attractive for clinical trials, a key challenge is that clinical research is becoming more disintegrated with the influx of data from different sources. CROs and sponsors also face high level of operational complexities due to cross-country differences in terms of varying factors from culture and language, to policies and regulations. There is a disparity in financial, commercial and environmental conditions that companies must adapt to. For regulations specifically, while there is an increasing convergence in standards globally, there remains considerable difference around what is permissible in different territories. Compliance with national laws and pharmaceutical industry marketing codes is of utmost importance.

Patient recruitment for clinical trial is also a common challenge for sponsors and CROs particularly in markets with limited patient pool such as Singapore.

**How is Medidata Solutions addressing the current challenges floating in the clinical trials landscape globally?**

To address the challenge of operational complexity, and capture, manage, and analyze this data correctly, clinical trials must move away from the traditional paper-based practice, and fully capitalize the technology-powered solutions such as electronic data capture (EDC), clinical trial management system (CTMS) and electronic trial master file (eTMF). These are all available – and seamlessly connected – as part of the suite of solutions on Medidata Rave.

The second challenge is patient retention. It is estimated that patient drop-outs in studies can be as high as 30 per cent, potentially disrupting the research. To help with this, Medidata has a few solutions that engage and empower patients along their clinical trial journeys.

Firstly, Medidata’s eConsent solution is a patient-friendly electronic informed consent and patient enrollment system that eliminates the risk of paper consent. Not only does it give patients, sites, CROs, and sponsors a unified enrollment system, but it also ensures participants are informed and understand the risks and benefits of the study, through an intuitive and engaging mobile application. This informed consent process is a critical element of running both ethical and effective trials which is particularly important in APAC, as traditionally many patients have gone on trials without consent.

To further support and enhance participant experiences, Medidata’s RAVE suite offers Electronic Clinical Outcome Assessments (eCOA) / Electronic Patient Reported Outcomes (ePRO), which allow patients to track and submit their data daily via phones and tablets anywhere, anytime. This empowers and saves time for patients by eliminating the need to physically visit a site. Because it is part of the Rave architecture, it’s beneficial to sites, CROs and sponsors too as the patient data seamlessly integrates right into an eClinical system, reducing cost and accelerating study time, while remaining totally compliant.

**How can machine learning and AI improve clinical trial data quality, integrity, and efficiency?**

Technology is an essential driver in improving outcomes, efficiency, and decreasing cost and risks across all phases of clinical trials. In fact, using artificial intelligence (AI), drugs and therapies can actually be brought to market quicker by preventing delays in approvals. Today, the industry’s current practices used to evaluate protocol adherence and data entry may be inadequate, as it can potentially lead to missed adverse events and data anomalies, resulting in delays to the approval process.

By switching to technology that has automated statistical analysis, sponsors and CROs can identify potential errors early, which under normal practice may slip through. Medidata’s Rave Trial Assurance is one such example, providing extra analysis to identify data anomalies by contextually comparing lab and clinical data patterns, often revealing data quality issues the customer may be unaware of. Ultimately, this increases the inspection-readiness for submission to regulatory agencies. Medidata’s machine learning capabilities is also improving outcomes for clinical trials globally. For example, using Medidata’s Rave Omics, a machine learning-based solution, the Castleman Disease Collaborative Network (CDCN) discovered new patient subgroups for Idiopathic Multicentric Castleman Disease (iMCD), a rare, difficult to diagnose, life-threatening disorder. These discoveries provide novel insights into treatment response and potential new drug targets, highlighting the value of precision medicine.

**Dr Manbeena Chawla**

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The Healthcare Quandary India Faces

India needs both arms of healthcare ie public and private sectors to move in harmony to achieve its stated goals and improve access and quality of healthcare in the country. Private health care providers on their part could well do with being more transparent on pricing and look to increase efficiency through better use of technology and process improvements at competitive costs. They could also invest more in community initiatives to build trust in the local population. Self-regulation on quality and transparency in clinical outcomes will further enhance their credibility and trust. Besides, public sector is also making its efforts to support the private players to make healthcare affordable.

Over the past year, India celebrated as its economy overtook France to become the sixth largest economic power in the world. What was missed however, was the Healthcare and Quality Index (HAQ) survey, where India continues to languish at 145th place out of 195 countries surveyed. The index is calculated on 32 causes of death which can be prevented by effective medical care - vaccine preventable disease, maternal and child health, non-communicable diseases and so on. The challenge is now to improve this ranking.

The government of India budgetary allocation, although higher than previous years, was an increase of barely 5 per cent from the Revised Estimate of the previous year at Rs 52,800 crore and effectively 1.1 per cent of the GDP. We still have a long way to go before we can be considered a developed nation. The per capita spend of $16 pales in comparison to developed nations like the US ($4800) or the UK ($3500).

In a growing economy with a large work force, such a low spend also reduces the workforce productivity and increases absenteeism and therefore adds indirect costs to the economy.

The Government of India has ambitious plans as part of its Rural and Urban Health Missions to develop 1,50,000 Health and Wellness Centres, in lieu of the existing Primary Health Centres with focus on preventive health; with the District and State/Central Government funded hospitals providing Secondary and Tertiary level care. The plans, however well intentioned, have some way to go before they fructify considering the allocations actually made in the budget. Certain hospitals apart (the Sardar Patel Hospital which was recently opened in Gujarat is one example which hopefully will set new benchmarks) most government hospitals continue to be underfunded with long waiting times, low levels of nursing care, deficiency of medical staff and poor state of infrastructure.

Growth of Private Healthcare Service Providers

The gap in health care delivery is what led to the growth of private healthcare in India. Initially, dominated by standalone hospitals or nursing homes and clinics, the past two decades have seen consolidation and growth with 6-8 major groups having a pan India or near pan India presence. Simultaneously, a number of smaller hospital chains exist at the regional level besides numerous standalone state of the art hospitals both in metros, non-metros and a few in Tier 2 and 3 cities. Nursing homes and clinics have had little choice but to follow suit ultimately benefiting the patient. The nudge of central authorities like accreditation to NABH/NABL, greater compliance to regulation, passing of the Clinical Establishment Acts in many states and inflow of international patients have further
contributed to raise the quality of healthcare in private hospitals in India.

The outcome has been that quality of healthcare provided by private healthcare enterprises in India rivals the best in the world at a fraction of the cost. Private players today provide approximately 80 percent of the total out patient service and at least 50 percent of in-patient services in the country. This is in spite of the fact that of the total bed capacity of approx. 13 lakh beds available nationally, 5.5 lakh are in government hospitals (Health and Family Welfare Statistical Yearbook). Of the balance, 80 per cent (approx. 6.3 lakh beds) are in private nursing homes with less than 30 beds and about 13000-15000 beds are in private hospitals above 200 bed capacity (Note. Some of these figures are extrapolated as even government data does not have a clear fix on the exact number of beds for private hospitals). Clearly, private nursing homes are the bulwark on which Indian healthcare is surviving.

High end tertiary care is being met by a mix of some good work happening in government hospitals like All India Institutes of Medical Sciences (AIIMS) and larger private corporate hospitals. Undoubtedly, there is a large pent up demand which is waiting to be filled with capacity expansion and green field growth as Purchasing Power grows.

It is no surprise therefore, that, out of a total healthcare expenditure of approx. 3.9 per cent of the GDP, only 36 per cent is attributed to Public Sector (and whose cost is met by the government ); the balance is met by the citizen either through insurance of some form or as an out of pocket expenditure. Notably, 52 per cent of pocket expenditure is made towards procurement of medicines off the shelf, 22 per cent towards bills to private hospitals and about 10 per cent to medical and diagnostic labs. The nursing homes though fragmented and varying in quality and clinical skill therefore also account for the bulk of hospital expenditure in the country. Secondary and Tertiary care private hospitals follow.

An alarming fact is that around 85 per cent of the population does not have access to any kind of health insurance and of the balance 15 per cent, three fourths are covered by some kind of government scheme and the balance by private insurance schemes. It goes without saying that an increase in health insurance penetration through innovative tie ups and schemes, more so in Tier 2 and 3 cities and rural areas, would improve access and quality of care substantially.

The above statistics point to the fact that healthcare has to be driven by a synergy between private and government facilities – the government has neither the finances nor logistics to take this forward on its own, at least in the near future. The Ayushman Bharat scheme launched by Prime Minister of India in October last year is a bold and courageous step in this direction. The thought process behind the scheme is laudable and if implemented well can have far reaching consequences for access to quality care by the most marginalised in the country. The scheme provides free insurance for approx. 10 crore households in the country whose annual income is less than Rs 5 lakh. Private healthcare providers are free to join the scheme and be reimbursed by the government at the rates provided.

It should be therefore in the logic of things to create an environment where private health care providers can grow, attract the right kind of investment and valuation to complement healthcare services provided by the government. This unfortunately does not seem to happen on many occasions for a variety of reasons. Therein lies the paradox.

Challenges

Private healthcare providers (more so the large corporates) are perceived to be only profit oriented. Obviously, no private entity would invest without a plan to make a business sustainable and profitable. Moreover such hospitals would never survive in a competitive market if their patients were not happy or if their outcomes not good. Annual reviews of pubic listed health care companies indicate that most hospitals are squeezed for margins and competition and price caps will make sustainable growth challenging in the future. Certain actions by hospitals in the past have not helped to reduce this bias either.

The onus of correcting this bias lies with no one else but private healthcare providers and they need to get
their act together with concrete actions to be rid of this misrepresentative label.

Quality corporate hospitals provide an ambience of ‘Five Star’ culture from the outside, which coupled with high prices can create resentment in the local community, specially in semi-urban areas. In reality, the clean and sterile environment ensures international standards of infection control and hygiene thereby reducing complications, length of stay and cost to the patients. This is little understood. Hospitals may be seen to be catering only to an elite section of society or to international patients. It is important to change this image and the ability to do so is again in the hands of the hospitals themselves by outreach programmes, competitive and transparent pricing and doctor-patient connect which is transparent, ethical and healthy.

On average, private hospitals bills will be about 2–5 times those of government ones. While the country has emerged as a medical tourism hub due to its low cost and quality of care; even this cost is beyond the reach of large sections of India’s poor. Private hospitals are handicapped due to large capital needed for land and equipment to build a hospital. This is true even for Tier 2 cities. This high capital costs needs to be ploughed back and inability of hospitals to achieve break even in a limited time will deter investors and entrepreneurs. Likewise, operational costs are daunting, and since government hospitals are funded arbitrarily, no in-depth study has been done by any autonomous body to understand the reasons why healthcare is priced the way it is in the country. The government could well do by initiating such a study to understand the true cost of providing health care service in the country.

What is being attempted in the name of helping control health care costs is a cap on the price of various goods and services without a de novo, holistic understanding of the costs involved. The procedure pricing in the case of Ayushman Bharat is one example. Such artificial fixing of price, while needed for a section of society, could set unsustainable benchmarks which other players are bound to follow. This could set off a domino effect the sector could do well without considering the low operating margins hospitals currently operate. It will also deter innovation and force hospitals to avoid risks currently taken to invest in top quality infrastructure and equipment.

One needs to keep in mind that all government backed low price schemes survive due to the fixed costs of hospitals being met from other channel segments who are, so to say, cross subsidising such schemes. There is little scope of hospitals (both government and private) meeting even its operational costs based on such schemes alone. Smaller hospitals and nursing homes who have no choice but to get empaneled on such schemes, since this would impact a large segment of their patient base, could be in serious danger of shutting down altogether and larger hospitals would also feel the brunt over a period of time. It may also result in hospitals compromising on quality to be able to provide care within the given cost – certainly not the best idea for an industry which is setting global standards in healthcare.

Providing land/services at subsidised price and incentives by the government to private players could be one way of passing on subsidy to patients by private entities. Tax breaks specially for private investments in rural areas or the hinterland is another. A robust Public Private Partnership model (there are some successful examples of this) on a large scale is a workable option which could benefit all parties. Such models would need long term stability and continuity in government policy.

Private health care providers on their part could well do with being more transparent on pricing and look to increase efficiency through better use of technology and process improvements at competitive costs. They could also invest more in community initiatives to build trust in the local population. Self-regulation on quality and transparency in clinical outcomes will further enhance their credibility and trust.

India needs both arms of healthcare to move in harmony to achieve its stated goals and improve access and quality of healthcare in the country. Private organisations can be a force multiplier in the right environment giving greater impetus to achieving the objectives.
Scientists in Japan convert fungus into potential drug

By genetically modifying a fungus, researchers from the University of Tokyo in Japan can produce large quantities of ascocurcanone, a promising antibiotic for the treatment of African sleeping sickness. African trypanosomiasis, or African sleeping sickness, affects thousands of people in remote, rural areas of sub-Saharan Africa each year. People can develop the disease by being bitten by a fly which carries a parasite. In a recent study, researchers sought to produce an antibiotic against the parasite that causes African sleeping sickness. Rather than synthesize the antibiotic chemically, the researchers relied on the fungus Acremonium egyptiacum, which naturally produces two different types of antibiotic. One is toxic to humans, but the other, ascocurcanone, was identified as a potential treatment for African sleeping sickness in 1996. The research team identified that the fungus’s two antibiotics are both made from the same precursor molecule. After the precursor is created, two separate groups of enzymes produce the two different antibiotics. Researchers left the precursor molecule and worked on the genes responsible for the desired antibiotic by simply deleting the genes responsible for the other toxic antibiotic. The researchers have applied for a patent on the engineered strain of fungus.

NTU researchers link bronchiectasis with allergy

An international research team led by Nanyang Technological University, Singapore (NTU Singapore) has found that patients with the lung disease bronchiectasis also often display sensitivity to airborne allergens, and has highlighted the particular role that fungi appear to play. Their discovery suggests that doctors should examine bronchiectasis patients for a range of allergies, since the treatment for allergies already exists and controlling them could prevent the bronchiectasis from worsening. Led by Assistant Professor Sanjay Haresh Chotirmall from the Lee Kong Chian School of Medicine (LKC-Medicine) at NTU, the team included researchers from Tan Tock Seng Hospital, Singapore General Hospital, Changi General Hospital, National University of Singapore, Agency for Science, Technology and Research (A*STAR), National University of Malaysia, and the University of Dundee in Scotland. They assessed fungal infection in over 200 bronchiectasis patients from Singapore, Malaysia and Scotland. While previous bronchiectasis research focused on non-Asian populations, this new study matched patients in Asia (Singapore and Malaysia) to patients in Europe (Scotland) in terms of age, gender and the severity of bronchiectasis. The matching of patients allowed researchers to control the influence of these factors and hence show that the types and causes of allergies associated with bronchiectasis vary across regions.

PolyU team designs unique electrostatically charged nanofiber

The Department of Mechanical Engineering of The Hong Kong Polytechnic University (PolyU) has recently developed an electrostatically charged nanofiber filter with multiple separator layers, which can capture pollutant particles that are below 100 nm in diameter (covering the most common airborne nano-particles and viruses). The electret PVDF nanofiber filter can be used in Western Blot, an analytical technique widely used to detect or extract proteins. In the process, PVDF membrane is often used in transferring proteins separated from the original sample. The PolyU innovation can help greatly enhance the nanofiber mat’s electrostatic force in capturing protein, while maintaining the protein integrity without affecting its organization. The innovation can also be applied to effective release of protein-based drugs. Drugs made in powder form, for example asthma drug, can be captured electrostatically by the charged PVDF nanofiber mat for more effective release and inhalation by users. Other than drugs delivered by inhalation, the innovation can also be applied similarly to drugs for use topically over skin.
Australian researchers develop technique for eye surface cancer detection

A team of researchers from the Centre for Nanoscale BioPhotonics (CNBP) in Australia has developed a new automated non-invasive technique for diagnosing eye surface cancer (ocular surface squamous neoplasia or OSSN). The technique has the potential to reduce the need for biopsies, prevent therapy delays and make treatment far more effective for patients. Reported in a clinical journal 'The Ocular Surface', the innovative method comprises the custom-building of an advanced imaging microscope in association with state-of-the-art computing and artificial intelligence operation. The result is an automated system that is able to successfully identify between diseased and non-diseased eye tissue, in real-time, through a simple scanning process.

Indian scientists create AI hardware to detect diseases

Researchers at the Indian Institute of Technology (IIT), New Delhi have developed an artificial intelligence (AI)-based low-power electronic hardware system that can help in detecting diseases like malaria, tuberculosis, an intestinal parasite, and cervical cancer in a few milliseconds. The research focuses on building a neuromorphic system which can be used for healthcare access in resource-constrained areas with limited access to human specialists. According to the research team, several software AI models exist for healthcare and diagnostic related applications but need of the hour is to efficiently map these models on portable dedicated low-power, low-cost hardware to enable edge-AI systems accessible to all in low resource environment. The long-term impact and goal of this work is to enable potential future use of the platform in rural and resource-constrained areas and improve the access to diagnostic health-care.

Duke-NUS study reveals new treatment option for liver cancer

Researchers from Duke-NUS Medical School, Singapore General Hospital (SGH) and Lion TCR have demonstrated that they were able to engineer HBV-specific T-cells, a type of immune cells found in the body, to treat Hepatocellular carcinoma (HCC), a commonly occurring liver cancer. The treatment was also individualised, as T-cells that were engineered were specific to the patients. The approach was successfully performed on two liver transplanted patients who had HBV associated liver cancer recurrence with one patient seeing a reduction in size of the tumour lesions. Chronic hepatitis B virus (HBV) infection is predominant in Asia and is highly associated with the development of Hepatocellular carcinoma (HCC), the commonly occurring liver cancer. The currently effective treatments for small to moderate size HCC are restricted to surgery, liver transplantation and loco-regional treatment that kill cancer cells by interventional radiologic means, while treatment with drugs helps only in a modest increase in the overall survival in more extensive disease. In patients who have HCC recurrence after liver transplantation, the treatment options are even more limited.
Technology collaboration to enhance innovation ecosystem

Dimension Data and Nippon Telegraph and Telephone Corporation (NTT) have entered into a Memorandum of Understanding (MOU) with Deakin University and Western Sydney University (WSU) in Australia to collaborate on research projects with a focus on solving social challenges that are common between Australia and Japan. This joint-vision partnership is the first time NTT has entered into an agreement of this nature with research institutions outside of Japan. Under this agreement, all parties will start working together to develop and implement innovative solutions with the joint vision of improving the lives, health and wellbeing of citizens. Japanese societal transformation plan, ‘Society 5.0’, has inspired the MoU and explores how the development and access to disruptive technologies, such as connected healthcare can transform and improve society. This partnership provides a framework for Australia and Japan to drive the creation and commercialisation of technologies and solutions to address real-world issues such as the needs of the disabled and those of an ageing population.

HKBU teams up with Golden Meditech for cell therapy research

Golden Meditech, a leading integrated healthcare enterprise in China, has formed a collaboration with the Department of Biology of Hong Kong Baptist University (HKBU) to conduct in-depth research in the area of cell therapy, particularly treating neurodegenerative diseases with stem cells. The Department of Biology of HKBU has been committed to conducting research on cell therapy for treating neurodegenerative diseases. A series of the internationally influential research has been published and some of which has succeeded in commercialization. It is expected that the collaboration between Golden Meditech and HKBU in developing a new therapeutic approach for treating neurodegenerative diseases will certainly create research results and patents that can benefit patients not only in the Greater China Region but also the world.

Indian institutes collaborate for big data science

Six leading Indian Institutes of Higher Education are collaborating to establish up the first Joint Indian-German Research Training Group (RTG) on Bio Big Data Science to promote the use of big data methods in biological applications. The programme aims towards educating the next generation of first class young researchers in this vibrant field of science. The Institutes include IIT Guwahati, IIT Kanpur, IIT Madras, University of Allahabad, University of Delhi and Jawaharlal Nehru University. They are partnering with Heidelberg University, Germany, and Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India. The Research Training Group will set up as many as 50 PhD projects, which will be supervised by Research tandems consisting of leading Indian and German scientists. The first funding of the programme will be between 2019 and 2025 with an investment of € 3 million from each of the two organizing partners (Heidelberg University and DBT).
Beckman Coulter receives FDA clearance for sepsis assay

A major milestone on its strategic mission to lead in sepsis diagnostics, Beckman Coulter has announced that its Early Sepsis Indicator has received 510(k) clearance from the U.S. Food and Drug Administration. Sepsis is a global healthcare crisis that affects more than 30 million people worldwide. The Early Sepsis Indicator is a first-of-its-kind, hematology-based cellular biomarker that is designed to help emergency department physicians identify patients with sepsis or at increased risk of developing sepsis. As part of the pivotal clinical trial for the Early Sepsis Indicator, findings showed that Beckman Coulter’s unique monocyte distribution width (MDW) biomarker best discriminated sepsis from all other conditions when combined with the current standard of care. The Early Sepsis Indicator can be used in conjunction with Beckman Coulter’s patented Multidiscipline Reflex Rules in REMISOL Advance middleware. These reflex rules can create customized, automated reflex panels of Beckman Coulter’s industry-leading portfolio of in vitro diagnostic tests in the current sepsis identification and management care pathway across multiple disciplines, including hematology, clinical chemistry, immunoassay, microbiology and urinalysis. The Early Sepsis Indicator is also part of Beckman Coulter’s clinically impactful menu that matters which address the most prevalent and costly health conditions.

Bio-Rad introduces assay to diagnose Lyme disease

Bio-Rad Laboratories, Inc., a global leader of life science research and clinical diagnostic products, has announced that it has received U.S. Food and Drug Administration (FDA) clearance for its BioPlex 2200 Lyme Total Assay, an innovative multiplex test method to aid in the diagnosis of Lyme disease, the most common tick-borne illness in the United States. The BioPlex 2200 Lyme Total Assay can simultaneously detect multiple targets, providing laboratories valuable information in the early stages of Lyme disease so patients are able to receive treatment as quickly as possible. The release of the BioPlex 2200 Lyme Total assay is the latest offering in Bio-Rad’s infectious disease menu for the BioPlex 2200 System, an automated multiplex technology platform. The BioPlex 2200 System provides clinical laboratories the capability to rapidly process or multiplex multiple individual tests that are traditionally processed separately, conserving patient sample volume and simplifying workflow.

PerkinElmer unveils genetic screening test

In collaboration with Helix, PerkinElmer, Inc., a global leader committed to innovating for a healthier world has launched GenePrism: Actionable Insights, a new genetic screening test, offering the most comprehensive clinical-grade DNA sequencing and interpretation on the market right now, for anyone who wants to learn about underlying disease risks. Users’ DNA is sequenced by Helix, then results are interpreted by board-certified medical geneticists at PerkinElmer Genomics using ODIN (Ordered Data Interpretation Network), PerkinElmer’s proprietary high-throughput software platform. While most commercially available tests only look at an extremely limited number of letters in a gene sequence, which represent a very small percentage of a person’s overall disease risk and can provide a false sense of reassurance or concern, GenePrism: Actionable Insights analyzes each of the 59 genes in its entirety, including BRCA1 and BRCA2. PerkinElmer Genomics also maintains one of the largest databases of known genetic variations from different ancestries around the world, so GenePrism: Actionable Insights customers receive a more in-depth assessment.
GE Healthcare teams up with Rockwell Automation

GE Healthcare and Rockwell Automation are combining their automation, IT and single-use solution expertise to build bioprocessing operations for the digital age. The two companies will help biopharmaceutical companies create flexible and scalable facilities of the future, focused on rapid response to market demands, streamlined production technologies and adaptable manufacturing environments. GE Healthcare has also joined the Rockwell Automation Partner Network Program as an OEM Partner to help drive a best-in-class distributed control system offering. GE Healthcare and Rockwell Automation can help companies gain greater efficiency with FlexFactory single-use equipment integrated with Figurate bioprocess automation that improves reproducibility, repeatability and compliance; to digitize batch files and processes to reduce review times by weeks and even achieve real-time reviews; and deliver instructions to workers with augmented reality to improve batch execution, operations, equipment setup and training.

Qiagen launches companion diagnostic

Qiagen has announced the U.S. launch of its novel therascreen FGFR RGQ RT-PCR Kit (therascreen FGFR Kit) as a companion diagnostic to help guide the use of the newly approved FGFR kinase inhibitor, BALVERSA (erdafitinib), developed by Janssen Biotech, Inc. (Janssen). The test will aid in identifying patients with urothelial cancer whose tumors have certain alterations in the fibroblast growth factor receptor 3 (FGFR3) gene. The U.S. Food and Drug Administration co-approved the new test with BALVERSA, as announced by Janssen. Urothelial cancer begins in tissues lining the bladder and other genitourinary organs and is the sixth most common type of cancer in the United States. An estimated 15,000 patients a year in the United States are diagnosed with advanced or metastatic urothelial cancer, but current treatment options are limited so the prognosis is poor. A percentage of urothelial carcinoma tumors have certain FGFR alterations which are thought to be key drivers of tumor growth. Detection of these alterations utilizing the companion diagnostic will help identify patients eligible for treatment with BALVERSA.

Thermo Fisher, NX Prenatal to develop pregnancy outcome assay

Thermo Fisher Scientific, the world leader in serving science, and NX Prenatal Inc., a recognized leader in the detection, monitoring and management of pregnancy-related complications using novel exosome-based methods, have entered into a collaboration to develop clinical mass spectrometry-based proteomics assays to monitor fetal health in utero and assess the risk of adverse outcomes, including preterm birth and preeclampsia. This new collaboration recognizes the challenges faced by medical professionals who have few tools available for noninvasive risk stratification for adverse pregnancy outcomes. By combining NX Prenatal’s NeXosome platform with Thermo Fisher’s leading liquid chromatography-mass spectrometry (LC-MS) instrumentation, the workflows can address the reliability, accuracy and precision of the analytical solutions currently available to clinical scientists. The unique NeXosome technology is used to enrich maternal blood samples for microparticles, such as exosomes, which play key roles in maintaining certain balances between the mother and fetus during pregnancy. Aberrations in these balances have been shown to correlate with the likelihood of adverse pregnancy outcomes.
Daiichi Sankyo announces CEO change

Daiichi Sankyo Company has announced the change of Chief Executive Officer (CEO), which was resolved at the Board of Directors meeting held in March 2019. Sunao Manabe, currently the company’s president and chief operating officer, will succeed George Nakayama as CEO, effective June 17, 2019. Nakayama has been Daiichi’s CEO since 2010 and took on the additional role of chairman in April 2017, when Manabe became president. Manabe has served several positions since 1978 when he joined Sankyo. He has graduated from Faculty of Agriculture at the University of Tokyo. In 2005, Manabe held the position of Vice President, Medicinal Safety Research Laboratories at Sankyo followed by the same position in Daiichi Sankyo in 2007. In 2009 he served as the Corporate Officer, Vice President of Global Project Management Department, R&D Division. Further he was in charge of Global Sale & Marketing in 2015. Manabe has also been responsible for handling medical affairs, general affairs and human resources at the company.

GHIT fund names Catherine Ohura as new CEO

Japan based Global Health Innovative Technology Fund (GHIT) has announced the appointment of Catherine Ohura as the organization’s new CEO and Executive Director. Ohura brings depth and breadth of expertise and invaluable experience working for R&D and Commercial functions. In the R&D function, Ohura worked in clinical operations, regulatory affairs, quality assurance, project management, finance/resource management, portfolio management, and governance creation/management. Prior to her appointment as CEO and Executive Director of GHIT, Ohura served as the Executive Officer and Unit Head of Japan Commercial Operations & Customer Experience at Bristol-Myers Squibb (BMS) K.K. (located in Japan). She also served as Executive Officer and Senior Director, Regional R&D Operations (responsible for Japan, China R&D Operations) at BMS K.K. At BMS (in the US), one of her roles was the Global Lead/General Manager for the BMS Network of Women (B-NOW). In this groundbreaking industry leadership role, she drove business performance at BMS globally by fostering a more powerfully diverse and broadly inclusive people and business strategy. Prior to her role at BMS, Ohura worked in Japanese pharmaceutical company for clinical development, regulatory affairs, quality assurance, pharmacovigilance, and project management.

Medidata Solutions brings Dr Rama Kondru as CIO

Medidata Solutions has appointed Dr Rama Kondru as its first-ever chief information officer (CIO). He is currently leading the company’s enterprise data strategy, architecture and future platform development for Medidata’s product portfolio. With his expertise, Medidata will accelerate the creation of leading-edge technologies, such as AI and IoT capabilities, for broad use in healthcare. Dr Kondru is now part of Medidata’s senior leadership team. As the former CIO of Janssen Americas, Dr Kondru is an innovative and strategically focused executive with over 20 years of experience in diverse roles in pharma, medical devices, data science, and academia. He brings a wealth of experience designing and developing technology products to deliver enhanced patient outcomes and experiences. Dr Kondru is well recognized in the industry having received multiple awards and developed 25 patents, along with authoring more than 30 peer-reviewed scientific publications.
IPA appoints Sudarshan Jain as Secretary General

The Indian Pharmaceutical Alliance (IPA) has announced appointment of industry veteran Sudarshan Jain as Secretary General of the group with effect from April 8, 2019. Jain has an experience of more than 40 years in the healthcare industry with leadership position in leading Indian and multinational companies. Formerly, he was a Managing Director at Abbott Healthcare Solutions. He is currently member of the board of a number of companies in the healthcare space and also associated with leading educational institutions. He is an alumnus of the Indian Institute of Management, Ahmedabad and St. Stepahan’s College, New Delhi.

Dr Vavvas joins OliX Pharma’s Scientific Advisory Board

OliX Pharmaceuticals, a Korea based leading developer of RNAi therapeutics has announced that Demetrios G. Vavvas, M.D., Ph.D., one of the world leaders in the field of Ophthalmology, has joined its Scientific Advisory Board (SAB). Dr Vavvas is a distinguished scientific expert in Ophthalmology and has pioneered research in diabetic retinopathy, ocular tumors, and the dry form of age-related macular degeneration (AMD). Dr Vavvas currently serves as Associate Professor of Ophthalmology Harvard Medical School and Monte J. Wallace Ophthalmology Chair in Retina at The Massachusetts Eye and Ear Infirmary (MEEI). Dr Vavvas was named one of the ophthalmologist’s power list 2019. He has received over 32 awards and honors and is the author of over 183 publications and cited by others 10,400.
Indo-Swiss HealthTech Conclave 2019
Showcases cutting-edge technologies and innovations in healthcare

World Health Day is celebrated on April 7 every year to commemorate the establishment of the World Health Organisation (WHO) headquartered in Switzerland. Swissnex India took this opportunity to put forward a platform to showcase cutting-edge technologies and innovations in healthcare from Switzerland and India. Indo-Swiss HealthTech Conclave 2019 on Digital Health was conducted in Bengaluru on April 8, 2019. The Digital Health Conclave (DHC) 2019 brought together selected representatives of the Swiss and Indian healthcare sector presenting their vision for enhancing the quality of patient-hospital interaction and healthcare delivery at the conclave.

“Switzerland is known to be an innovation hub, particularly in medical technologies and pharmaceutical research, while India’s health-tech sector is changing rapidly, creating many opportunities for both countries to collaborate in education, research and innovation”, said Sebastien Hug, CEO of swissnex India and Consul General of Switzerland in India.

Presenting the Swiss innovations in healthcare space, Prof. Dr med. Andreas Trojan, Founder, Consilium said “We have developed smartphone healthcare app referred to as Consilium which is currently under validation in Switzerland. We have plans to launch the service soon in Singapore and India.” Joining him in the same session, Randy Ramin-Wright, International Business Director, Clinerion spoke about his plans of introducing a Real World Data ecosystem in India very soon.

“Traditional trial countries in Europe and North America are in high demand and may be somewhat saturated, with clinical trials competing for the same patient population. However, regions like Asia offer attractive untapped potential. Moving East has become a highly effective way for pharmaceutical companies to streamline operations and concentrate on their core activities. However, the local infrastructure and cultural understanding of emerging regions can present formidable barriers”, Ramin-Wright pointed out.

Prof Zeilhofer, Innovation, University of Basel shared his insights on the growth of healthcare innovations in India in order to address the disease burden particularly diabetes and hypertension. In sync with these thoughts, Samuel Cobbi, Science Officer, Embassy of Switzerland in Singapore talked about the Swiss intentions to collaborate with India and China on various healthcare projects in the coming times.

Highlighting the implementation of technology in the area of diagnostics, Prof Hans-Peter Beck, Head of Molecular Parasitology-Epidemiology Unit, Swiss Tropical and Public Health Institute elaborated upon an artificial intelligence (AI) programme his team is working on for improving malaria detection. “For all our efforts to control malaria, diagnosing it in many parts of the world still requires counting malaria parasites under the microscope. Now an AI program can do it more conveniently. We are currently conducting studies in Odisha in India and few parts of Africa so that we can implement the AI technology for malaria detection in these parts”, Prof Beck mentioned.

Clemedi is another player in the field of digital health in Switzerland who has developed a TB diagnostic test based on machine learning. “We wish to tailor our test for the Indian market by collaborating with the right partners. We are planning to conduct multi-centre studies in countries such as India, South Africa and Eastern Europe where there is high prevalence of drug resistant strains of TB”, said Dr Prajwal, Founder & CSO, Clemedi.

The conclave also saw interesting presentations made by the healthcare experts in India. Dr Sailesh Mohan, Joint Director, Public Health Foundation of India (PHFI) talked about the various health technologies developed by PHFI keeping affordability in mind.

An interactive session between Dr Paul C Salins, Senior VP- NH Narayana Health; Medical Director-Mazumdar Shaw Medical Centre and Dr Shravan Subramanyam, MD, Roche Diagnostics India was quite engaging as the experts spoke about the various challenges facing the healthcare system in India. “India needs to scale up and skill up the healthcare system. The trend is now shifting from treatment to prevention. We are at a pivotal moment in healthcare history. An unprecedented convergence of medical knowledge, technology and data science is revolutionising patient care. In order to ensure timely screening, diagnosis, treatment and even prevention of diseases, we need to ensure the right treatment for the right patient at the right time”, said Dr Shravan.

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Global Cooperation and Training Framework workshop

“Taiwan is able to share its medical experience to enhance TB prevention capabilities”

The Ministry of Foreign Affairs, Ministry of Health and Welfare, Taiwan Centers for Disease Control, American Institute in Taiwan (AIT) and Japan-Taiwan Exchange Association, organised a four-day Global Cooperation and Training Framework workshop on drug-resistant tuberculosis in Taipei City, bringing together international experts and officials to discuss best practices and the latest ideas on managing the public health challenge.

The workshop was opened by Taiwan Vice President Chen Chien-jen on April 30 and attended by Dr Tom Price, former U.S. secretary of health and human services, as well as 15 TB prevention professionals from Cambodia, Indonesia, Japan, Mongolia, Pakistan, Papua New Guinea, Thailand and Vietnam.

Speaking at the workshop, Chen Chien-jen said “TB prevention and treatment is a top priority of the U.N. It was the focus of the first high-level meeting at the General Assembly last year and is a topic at the upcoming World Health Assembly. As a responsible member of the international community, Taiwan is ready, willing and able to share its medical experience and know-how in assisting Indo-Pacific countries enhance disease prevention capabilities while building a seamless global health care network.”

Echoing Chen’s remarks, AIT Director Brent Christensen said “This is our sixth workshop focused on public health under the Global Cooperation and Training Framework – a sign of the tremendous expertise Taiwan has in this area. And now Taiwan is partnering with the United States, Japan, and other countries to improve our collective understanding of multi-drug-resistant TB. Taiwan’s experience and success in lowering the TB incidence rate can serve as a valuable reference for health care authorities around the world.”

Taiwan has demonstrated the will to solve global problems by sharing its experience with others. And was able to participate in the World Health Assembly as an observer from 2009 to 2016. Unfortunately, that has not been possible since then.

As U.S. Secretary of Health and Human Services Alex Azar said, since health crises do not respect borders, it is difficult to reconcile the global community’s shared concern over cross-border infectious diseases while excluding representatives of the 23 million people of Taiwan. Taiwan, as a responsible global citizen, has much to contribute to efforts to address infectious disease and many other international health concerns. Recognizing this, the United States and other likeminded countries will continue to press the WHO to put global health above politics and allow Taiwan to once again participate in the World Health Assembly.

Alex Azar further said “It is our hope that the participants in the workshop will leave with a greater appreciation of how important it is for the global community to come together on health issues like multi-drug-resistant TB, and why Taiwan should be a very welcome partner in these efforts.

Quoting WHO data, Ministry of Health and Welfare, noted that the world recorded around 558,000 cases of first-line drug resistant TB in 2017, with 82 per cent deemed multidrug-resistant and only 55 per cent fully recovered after treatment.

The 72nd WHA—the governing body of the WHO—takes place May 20-28 in Geneva. A number of member states have publicly and privately urged the organization to uphold its constitution and invite Taiwan to participate in the nine-day event.
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