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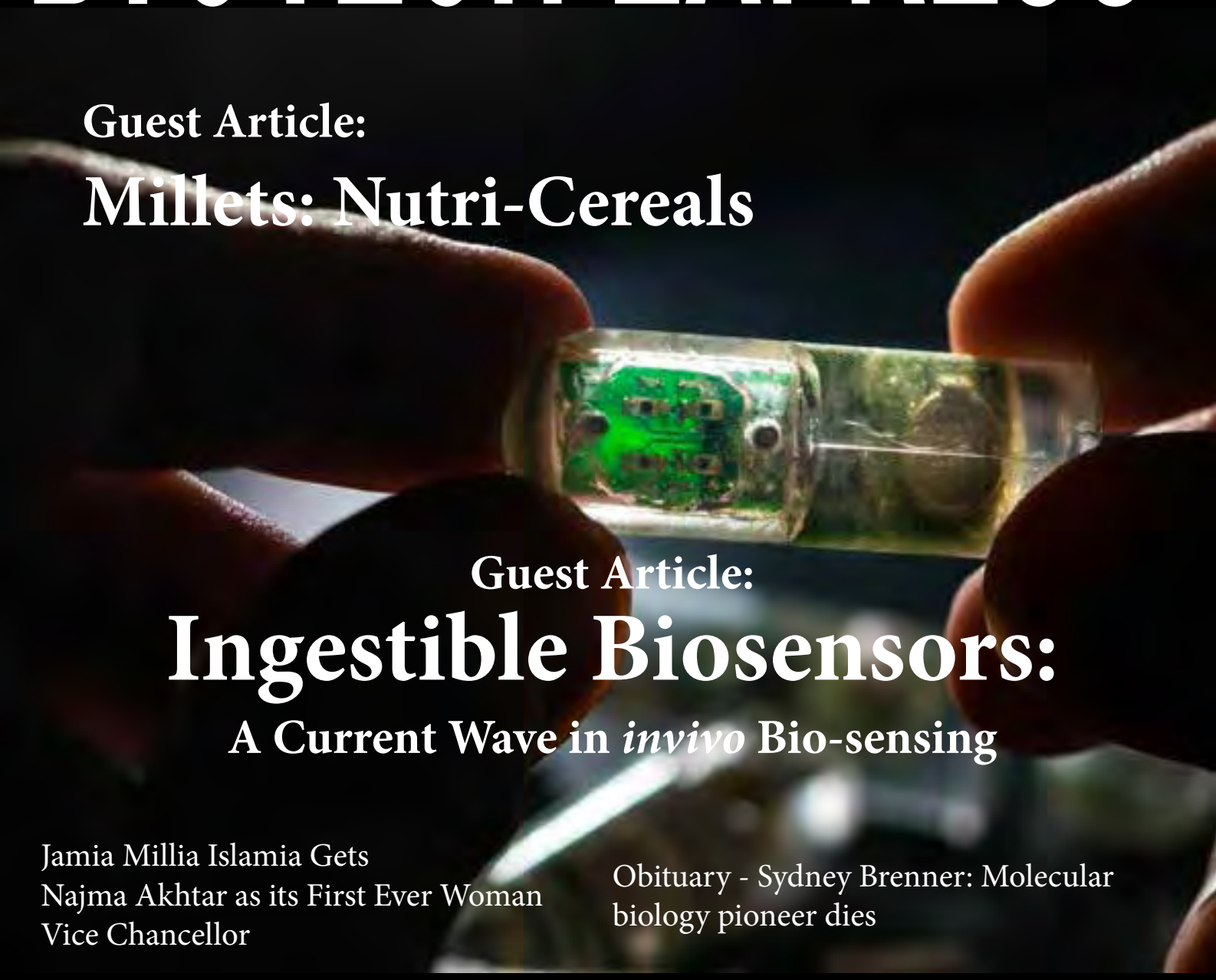

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TRANSCELL Oncologics

Transchymal

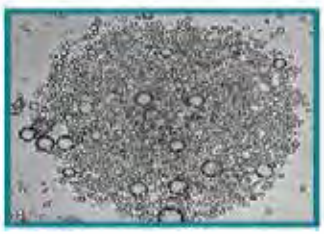
PRIMARY DONOR DERIVED CELLULAR PREDICTIVE PLATFORMS

Transchymal-UC is Human Umbilical cord derived primary pluripotent stem cell aggregate model that can predict test chemical's safety and efficacy invitro

Transchymal-DP is Human deciduous teeth derived primary pluripotent stem cell aggregate model that can predict test chemical's safety and efficacy invitro

Transchymal-AD is Human fat derived primary pluripotent stem cell aggregate model that can predict test chemical's safety and efficacy invitro

Trans-HSC is Human Umbilical cord derived primary hematopoietic stem cell aggregate model that can predict test chemical's safety and efficacy invitro



Real Time Safety & Efficacy of Chemical Entity

►Stem cell aggregates are either stromal or hematopoietic in nature
► Test readouts are 100% relevant to humans
► Tests performed can be robust, specific, sensitive, and reproducible
► Suitable for both low throughput and high throughput screening
► Suitable for cell based modelling
► Primary in nature; Not transformed; Not genetically modified Customized units
► Ready to use; Can be maintained at -800C till use

Real Time Test End Points in Oncology Features:

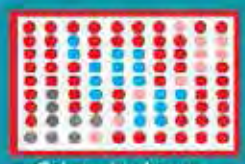
► Cancer & Type specific primary tissue architecture
► Tumor tissue derived primary cancer cells exhibiting native characteristics
► Suitable to develop Patient Derived Xenografts
► Tissue and Cancer cell based ex-vivo models for conducting assays
► Can be cryopreserved and re-used
► Suitable to develop Organoid models for regulatory or R&D testings
► Devoid of any bioburden

✶ Our products are human derived adult stem/cell based primary platforms that can be predictive real time human/patient relevant tools in your discovery, development, test compound's toxicity related testings, test compound's efficacy

Transchymal™ Primary cell solutions
Certificate of Analysis

Name:	
Source	Human Cord Tissue Matrix
Trade Name:	Transchymal™
ID:	Transchymal-CTMSC-134/R
Cells Harvested Date	
Passage No:	
Biosafety Level	1
Organism	Homo sapiens (Human)
Growth properties:	Adherent
Age:	Lot Specific
Morphology	Spindle-Shaped, fibroblast-like
Gender	Lot Specific
Volume/Vial:	5ml (2.3 million cells / 1ml)
No: of Vials	As required
Viability	≥92%
Population Doubling Capacity:	≥ 10 in complete growth medium and support differentiation
Shipped	Frozen
Storage	Liquid nitrogen or for short term storage at -80°C
Quality Assurance:	
Testing	Tested for CD73, CD90, CD105, CD34, and CD45. Primary cells display normal karyotype as assessed by G-banding of 20 metaphase cells.
Sterility Tests	Bacteria & Yeast : Negative Mycoplasma: Negative Endotoxin: Negative

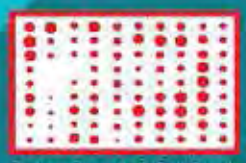
Transchymal + Test compound



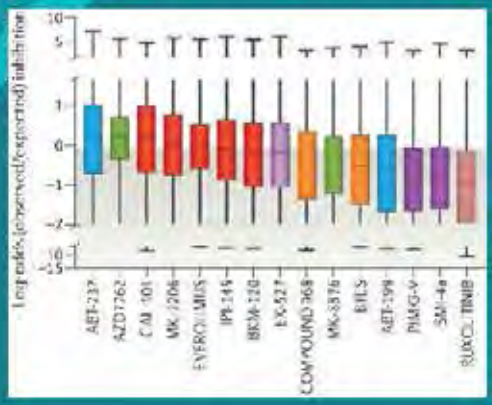
Colorimetric Assays

Turbidity Measurements

Cell Marker Expression



Colony Growth & Cell Death



Transchymal Use Case

- Acute Toxicity
- Chronic Toxicity
- Repeat Dose Toxicity
- Ic50
- Carcinogenicity
- Mutagenicity
- Draize Test
- Developmental Toxicity

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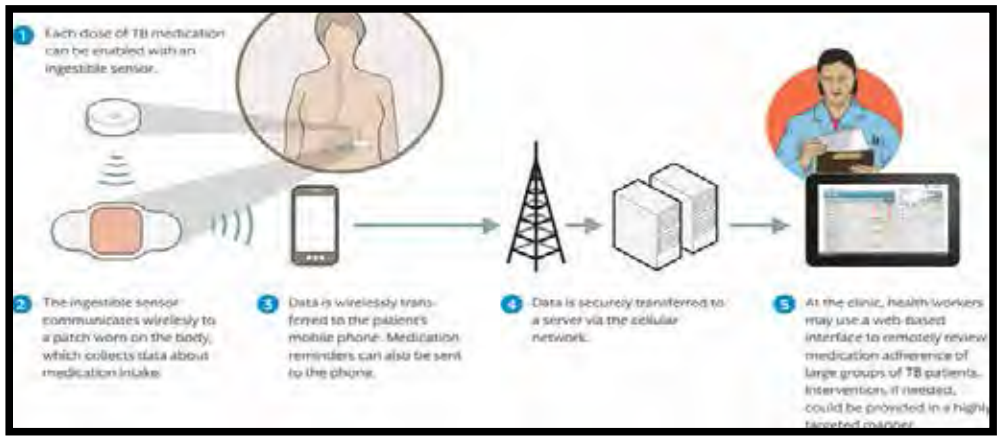

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Guest Article

Ingestible Biosensors: A Current Wave in *invivo* Bio-sensing

Anjali Sharma and Barkha Singhal*
School of Biotechnology, Gauatm Buddha University, Greater Noida (U.P.) Gautam Buddh Nagar 201310, U.P., India

*Corresponding author: BarkhaSinghal
E-mail: barkha@gbu.ac.in, gupta.barkha@gmail.com

Abstract:

The outburst of wearable and embeddable technology has facilitated a substantial upsurge in their prolific utilization in biomedical applications. The area of point-of-care diagnostics and online monitoring with wirelessmobile networking leads to the paradigmatic shift in health revolution. The continuous development of smart pill technology more technically known as "ingestible biosensors" has been envisaged to hold promising potential in the diagnosis, imaging and targeted drug delivery especially in GIT related disorders. However, their applications are not limited to GIT and still underway for the other organs and diseases. It is envisaged that a novel paradigm of doctor-patient care will be developed by implementation of such devices at commercial level. Therefore, this article intends to describe about the various aspects and embodiments related to ingestible biosensors with simultaneous emphasis on technological bottlenecks and future research priorities in the development of commercialized "ingestible devices".

Keywords: Smart pills; Ingestible devices; Wearable electronics; Bio-galvanic cells; Gastrointestinal tract (GIT).

Introduction

The rising stride to maintain health and well-being have been continuously seen and posits a significant challenge in today's world. The growing continuum of easy-to-use monitoring tools, point-of-care diagnostics and medical adherence tools as well as fast and sensitive technologies for the qualitative and quantitative detection of biological and chemical pathological hallmarks leads to the paradigmatic shift in health-care sector. The outburst of digital electronics in terms of "smart technology" has been seen prolific growth in the integration of living cells with electronic machines that can transform the retrieval of health information in-terms of disease diagnosis, preventive health care, fast and efficient drug delivery and so on. Though the body implants (pace maker, neuropatches, wearable electronics[1-3] in the form of electronic medical devices has successfully applied for the diagnosis and treatment of various diseases but still impeded due to inherent limitations of invasiveness, operability in fluctuating microenvironments, susceptibility towards microbial infection and inflammation. Therefore, the significant advancements have been seen through the promising amalgamation of advanced material science with electronics in-terms of "ingestible electronics" or "ingestible biosensors" defined broadly as an "electronic material that can be taken inside the body through the mouth and passed through gastrointestinal tract for physical as well as chemical sensing".

It has been envisaged that this budding science of electronics has been quite compatible with the most complicated and dynamic organ of the human body is gastrointestinal tract (GIT). As GIT confers an interacting platform between interior milieus to exterior environment, therefore this organ provides remarkable opportunities for responding against various environmental cues and suitable platform for the detection of physiological and pathophysiological signals from the entire human body. Therefore, these smart devices can be utilized for obtaining significant physiological information with close proximity to the other organs through GI tract. Ingestible electronics represented themselves as an emerging and interesting area of scientific innovation that opens an avenue of modern era of electronically assisted health care services.

Historical Background of Ingestible Biosensors

In 1957, Jacobson and Mackay have initialized the concept of ingestible electronic capsule for the assessment of body internal temperature and pressure using radiofrequency (RF) transmission[4]. The size of the capsule was kept at 33 mm in length by which it can passively navigate the GI tract through peristaltic contractions for the assessment of physical parameters. Then there was no progress has been seen until the era of 1990s when the miniaturization of electronic circuits becomes prevalent because of technological advancements. Later on, the ingestible capsule technology has been developed for alleviating the invasive, painful, less efficient endoscopic procedures of GI tract for understanding the various disease mechanisms[5]. Given Imaging Incorporation from Israel has introduces first wireless capsule endoscopy (WCE) comprised of small camera, batteries, LEDs for lighting, transmitter and microcontrollers based on the patents of Gavriel Iddan, DS.Can Israeli electro-optical engineer, who has initiated the concept of small charged coupled device (CCD) based ingestible capsule for the imaging of GI tract[6]. Since then, significant progress has been envisaged for the clinical utilization of this fascinating and innovative technology for investigation of various GIT diseases and sensing various physical and chemical factors of the entire human body.

Components of Ingestible Biosensors

The human body is one of the most complex and dynamic living system in which the sensing of the internal physiological parameters is embraced with countless technical challenges. Therefore, the designing of the ingestible sensors or monitoring capsular architecture requires rigorous considerable factors like physical dimensions, density, aerodynamics, battery life time, fidelity, mode of transmission, their dependency on active or passive locomotion and biocompatibility[7]. Inspite of the above mentioned considerations, the basic components are described below:

Sensors

The major technical component of the ingestible device is the sensors. The function of the incorporating sensors has to assess and retrieve the data on various physical (gases, temperature, and pressure) as well as chemical parameters (metabolites, enzymes, hormones and acids) inside the human body. The variety of sensors can be designed and incorporated in ingestible sensing devices based on their transducing interface.

Tele-communicators

The ingestible sensors has been comprised of complex electronic systems that allow electromagnetic waves to pass through the body tissues[8] and retrieve the information in the form of images, signals, chemical identification of molecules and transmission of these data to the user through smart devices. These systems include commercial transmitter chips and various antennae to enhance their processing and transmission efficiency[9].

Microcontrollers and Processors

These systems have to control the signals and commands to and from the sensors and transmitters through various CPUs integrated in a single chip. They are also used for maintenance of the privacy of data of patients as well as compress the information for the efficient utilization and storage.

Power Switches

These are the electromechanical devices that are used to check the flow of electricity between two points of the circuit and usually employ for the turning on the ingestible device for attaining its functionality.

Cladding

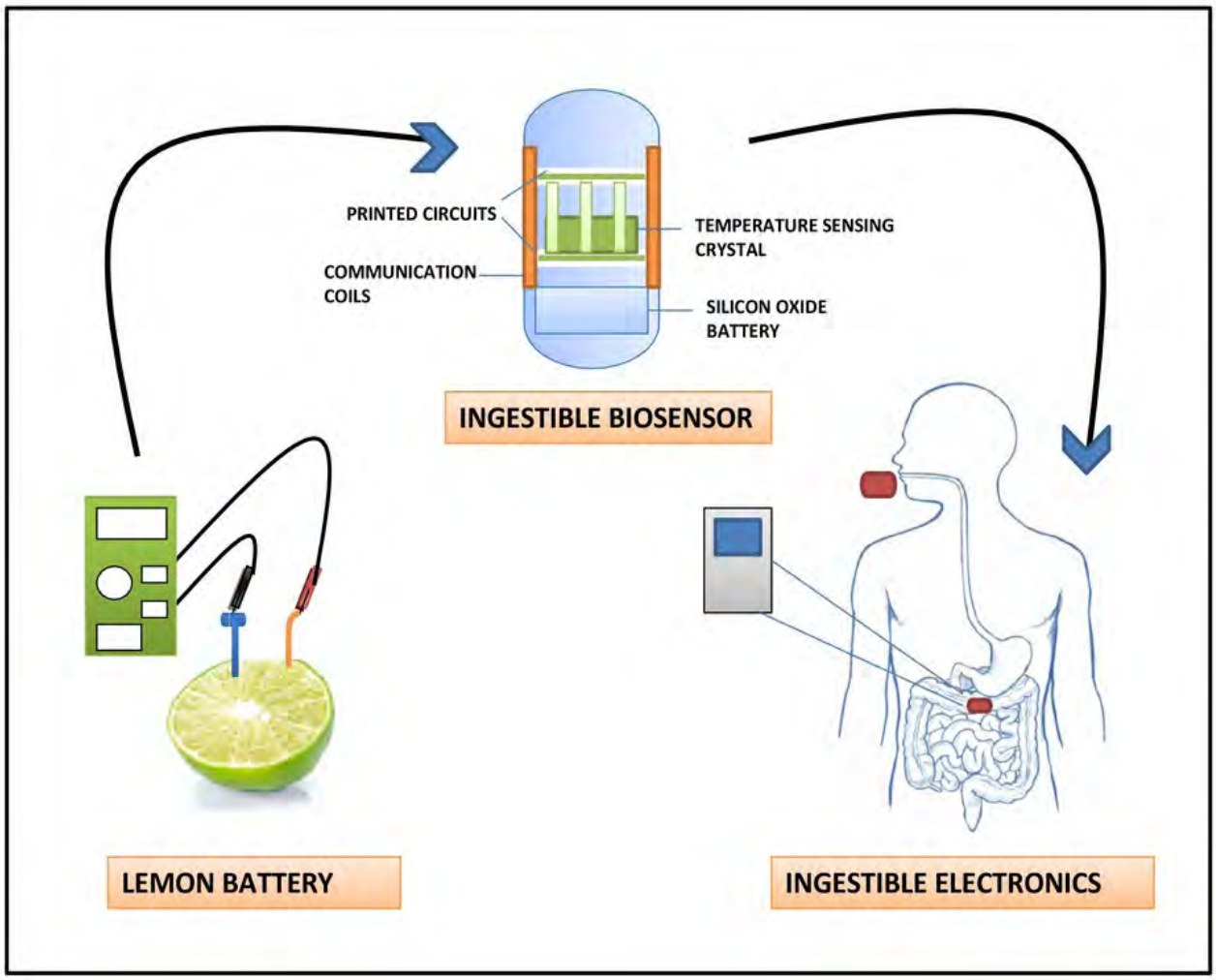
Cladding is the process of layering that is made up of biocompatible materials in ingestible devices[10]. The purpose of cladding has been done for making the device functional and tolerant in the presence of varied pH and peristaltic movements in the GI tract. The cladding is also necessary for permeation of target chemical species in the sensing membrane and gut lining by keeping the equilibrium between the gut environment and the sensing devices.

Power Supplies

The power supplies are the major bottleneck for the efficient working of ingestible devices. The prime requirement for the functionality of these devices is to keep their power consumption low because of simultaneously gathers and transmit the data at various locations and angles. However, the incorporation of batteries remains a tedious task among the research scientists. Initially, the silver-oxide and lithium coin-cell batteries have been implemented in ingestible devices but suffered from the inherent limitations of non-biocompatibility and toxicity in gastric environments. Therefore, scientists have currently developed the biocompatible galvanic cell that has low power consumption up to nano- watt ranges. This bio-galvanic cell was able to produce electric current through redox reactions occurring in living cell and able to receive continuous power supply in pig's GI tract for six days.

Working Mechanism of Ingestible Biosensor

An ingestible biosensor has been fabricated in the form of capsule or pill. An ingestible capsule composed of biocompatible polymer has been constructed in which all components of sensing devices like sensors, processors, controllers, radio-frequency transmitter have been embedded in the form of integrated circuit powered by bio-galvanic cells[11]. The concept of bio-galvanic cell has been taken from the trivial experiments conducted in lemon battery in which two different metals (galvanized nail and copper) inserted in lemon and citric acid present in lemon was able to carry electric current between two electrodes. The same principle has been replicated for the power supply in ingestible devices in which the dissolvable anode and inert cathode has been kept in pig's stomach and target parameters have been analyzed[12]. The diagrammatic representation of the working of ingestible biosensors has been depicted in **Fig. 1**. The functionality of ingestible devices is dependent on progression in the gut either passively or actively. Passive progression involves



the locomotion of ingestible device according to the body's movement leading to unreliable diagnoses of GI disease. Therefore, active locomotion can be accomplished by inserting internal magnet in capsule that can be used for guiding, collection of data and rotation of capsule at 360° for the imaging under the influence of external magnetic field.

Applications of biosensors

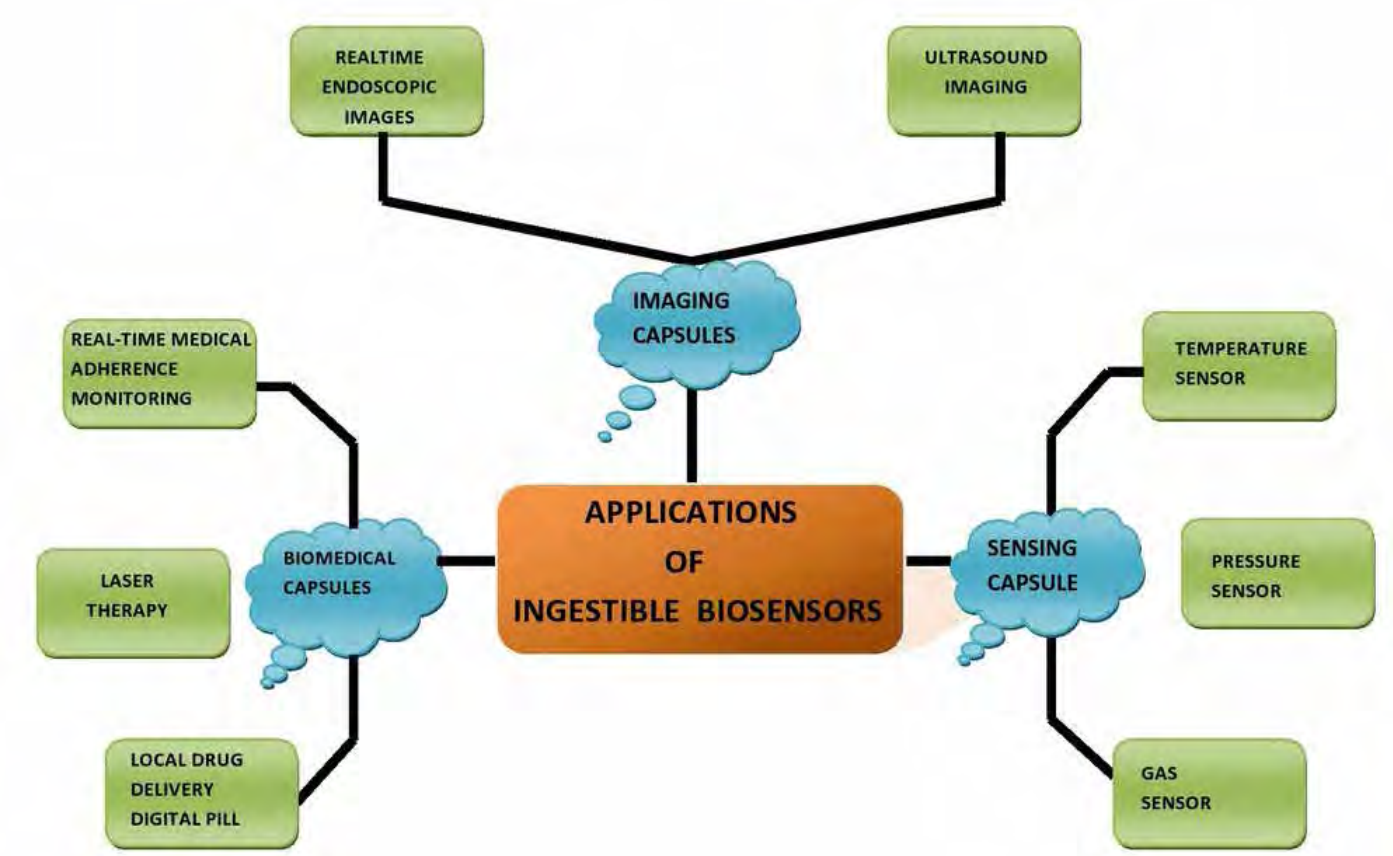
The exuberant field of ingestible bio-sensing has accelerated the real time monitoring of various physico-chemical entities present in GIT. Till date the immersive applications has been envisaged in the field of GI sensing, but their charisma can be exorbitantly utilized for sensing various clinical manifestations and pathological hall-marks in the other parts of the body. An overview of the various applications of ingestible biosensors has been depicted in **Fig. 2**. The broad range of applications is summarized below:

Oral Ingestible Sensors

The primary route for the passage of ingestible sensors occurs through mouth[13]. The mouth guard platform has been used for the fabrication of oral sensors and other electronic components like controllers, batteries and transceivers. Therefore pH[14], various electrolytes, enzymes, salivary uric acid present in saliva is the main target for oral sensing. The sensor has also been able to detect microbial flora and properties of their biofilms in food as well as tooth enamel [15].

Ingestible sensors as medication trackers

The ingestible sensors in the form of pill have been used for alarming/reminding the medicine needs for the patients as well as also tracks the amounts ingested by the body. Up on receiving the acidic stimuli inside the gut environment, the sensing device



gets activate and transmit a signal to battery-operated body patch followed by receiving the data in smart phone via blue tooth technology. This device has also been used to measure and improvise the adherence of drugs for chronic disorders. Recently, My/Treatment/ Medication (MyTMed), an ingestible biosensor has been developed to monitor real time adherence of drugs for antiretroviral therapy (ART) in stimulant induced HIV-infected individuals[16]. Therefore, the patient's routine activity has been monitored in context of adherence and non-adherence of the given treatment and intervened for taking the appropriate dose at right interval.

Ingestible devices for Temperature Sensing

In 1980s, NASA developed an ingestible temperature sensor to measure the temperature of astronauts. Later on this device has been used to monitor the temperature of the players during their competitive games and transmit the temperature fluctuation to the trainers. Currently, the temperature sensors have been advanced by technological interventions and used for monitoring the temperature of soldiers in the battle field, industrial employees, and heat stress in patients [17].

Ingestible sensors for pH Monitoring

The stability of ingestible sensors is highly dependent on their maintenance for their integrity in varied pH environment of GI tract. Currently, pH determination has been considered as gold standard methods for assessing the gastric reflux action and providing a good diagnostic platform for gastro-esophageal reflux disorders (GERD). Besides that, pH based ingestible sensors has also been used for the diagnosis of colonic malignancies, bowel dysfunctions and functional non-ulcer dyspepsia[18].

Ingestible devices for Pressure Sensing

The comprehensive understanding of the peristaltic movements in GI tract has been strongly influenced by the pressure inside the GI tract. Therefore, ingestible devices are able to monitor and measure different pressure patterns inside the gut and give valuable information regarding gut motility. However, the intensive investigations are still going on identifying the standard pressure range in GI tract.

Ingestible devices for Gas Sensing

The gases plays crucial role for maintaining the functionality of gut. The ingestible gas sensors are the better alternative of breath test which is considered as the gold standard method for the diagnosis of IBS, abnormal carbohydrate metabolism and indicator of overgrowth of bacterial population in small intestine and other GI disorders. The method suffers from serious limitation of measuring low concentration of gases leads to the inaccurate diagnosis. The use of ingestible devices offers significant reliability in the diagnosis of various disorders by measuring high concentration of gases. The capsule has been installed with various gas sensors like hydrogen, oxygen, carbon dioxide and methane and capable of working in both aerobic and anaerobic environments. The efficiency of ingestible gas sensing device has been maintained through the incorporation of high integrity gas permeable membranes.

Ingestible biosensors as Imaging Devices

The ingestible devices has been tremendously utilized in the field of imaging the GI tract and considered as an advanced method of endoscopy however, these devices confer immense benefits over conventional endoscopic methods. Therefore, first ingestible camera capsule for imaging of small intestine has been introduced by Given Imaging Incorporation in 2000. Later on more technological development has incurred in terms of better imaging and efficient battery systems for taking images at the specified locations of GI tract for the accurate diagnosis[19]. Currently, the advent of advanced computing systems including various algorithms for the detection of various diseases paved the way for the development of video capsule endoscopy. The fast signal processing enhances the diagnostic possibilities, reduce the review time of clinicians and assesse the internal functionality of GI tract.

Current Bottlenecks

The dynamic field of ingestible sensors is still in its early stage. The exorbitant cost of utilizing and administering these devices inside the body is prime challenge for the massive scale utilization. There is still rudimentary literature available regarding the regulations and guidelines for utilizing *invivo* devices. The reliability of these devices has not yet realized at global context. The lack of awareness about these devices and their quantitative output curtails the wide-spread commercialization.

Future Perspectives

The phenomenal development of ingestible biosensors leads to the paradigmatic shift in the field of clinical diagnosis, monitoring for the preventive and treatment modalities. In future, it will be expected that the technological advancements in the field of microelectronics, miniaturization and wireless sensing leads to the development of an efficient system-on-chip (SoC) devices for the *invivo* real time monitoring of the vital signatures of the body for maintaining the well-being of humans.

Conclusion

The prolific development in the field of an ingestible device has been envisaged now-a-days. They possess tremendous potential to overcome many challenges associated with painful invasive and costly surgical procedures, body implants, and risk of inflammation and infection by various microbial communities. It is worth to mention that the real time monitoring of vital signs from the internal system of the body along with motion and behavioral information opens up the avenue of patient monitoring in various chronic and intensive care conditions. Though, the development is still in infancy but certainly the potentiality of these devices will be wooed at global level in coming years for their gross utilization.

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Obituary

Sydney Brenner: Molecular biology pioneer dies

Prof Sydney Brenner
Born: 13 January 1927, South Africa
Died: 5 April 2019 (aged 92), Singapore

The South African of Lithuanian descent made many pioneering discoveries in the field of molecular and developmental biology, winning a Nobel Prize in 2002. The Nobel recognised his work with the tiny roundworm Caenorhabditis elegans, which is now widely used by researchers as a model to test the fundamentals of how all living organisms work.

But Brenner also made big contributions to the understanding of DNA. He worked routinely with the other greats in this area, such as Francis Crick, François Jacob, Linus Pauling and James Watson. Brenner helped establish the role played by the molecule RNA in carrying the "code of life" held in the DNA sequence to the ribosome protein factories in cells. He also realised the significance of codons - the sets of three bases, or "letters" - in the DNA sequence that signify the correct string of amino acids the ribosomes should use to assemble the proteins.

Born in 1927, Sydney Brenner had an impoverished start to life as an immigrant in South Africa, and famously taught himself to read from the newspapers that were used as tablecloths at dinner time. But his precocious talent saw him win a scholarship to medical school at the age of just 15. He later went on to study for a PhD at Oxford University in the UK, before moving across to Cambridge where he joined the hothouse environment of the Laboratory of Molecular Biology. The LMB produced a stream of Nobel Prize winners, and he was its second director from 1979 to 1986.

In his later years, he put much effort into building scientific capacity in Singapore. And it was the Agency for Science, Technology and Research (A*STAR), Singapore's lead public sector research agency, that announced Sydney Brenner's death on Friday morning.

Brenner received numerous awards and honours, including Fellow of King's College, Cambridge since 1959, Elected an EMBO Member in 1964, Elected a Fellow of the Royal Society (FRS) of London in 1965, Albert Lasker Medical Research Award in 1971, Royal Medal from the Royal Society in 1974, Gairdner Foundation International Award in 1978 and again in 1991, Kyoto Prize in 1990 and many others.

Guest Article

Millets: Nutri-Cereals

MuzaffarHasan[1], ChiragMaheshwari[2], Nitin Kumar Garg[3] and Mahesh Kumar[4]

[1, 2] Scientists, APPD Division, ICAR-CIAE, Bhopal

[3] Assistant professor, Rajasthan Agricultural Research Institute, Jaipur

[4] Scientist, ICAR- CAZRI, Jodhpur.

Introduction

Millets are small-seeded crops with different species such as pearlmillet (*Pennisetumglaucum*), finger millet (*Eleusinecoracana*),kodo millet (*Paspalumsetaceum*), proso millet (*Penicummiliaceum*),foxtail millet (*Setaria italic*), little millet (*Panicumsumatrense*), andbarnyard millet (*Echinochloautilis*). They are known as coarse cereals beside maize (*Zea mays*), sorghum (*Sorghum bicolor*), oats (*Avenasativa*), and barley (*Hordeumvulgare*) (Bouis 2000; Kauret. al., 2012). Millets are grown in semiarid tropics of Asia and Africa. Millets are utilizes as foods and fuel. Among various millets species pearl millet is the most commonly grown in India and Africa. According to FAO in 2018, India is the leading producing country in the world followed by Niger and China. In India, Rajasthan is the leading millets producing state followed by Maharashtra and Gujarat (Adekunle et al., 2018). Millets are often the only cereal crop that can grow in dried and warm climate condition and require very less amount of water (350-400 mm annual rainfall). Some pearl millets varieties can survive up to 64°C temperature.

Nutritional status and Health benefits of millets-

In general millets contain 7-12 % protein, 2-5% fat, 65-75% carbohydrates and 15-20% dietary fiber.Proso millets and Foxtail millets have the higher percentage of protein 12.5% and 12.3% respectively than the wheat (11.8%) and rice (6.8%). Calcium contains are much higher in finger millets (344mg/100gm) than the wheat (41mg/100gm) and rice (10mg/100gm), even three times higher than the milk. Mothers from Mali, Indonesia to Mumbai, India used Finger millets as baby porridge because of its richness in calcium. Pearl millets also have the enormous amount of iron and zinc. Millets like Proso, Foxtail and Little millets shows the significant amount of sulfur containing amino acid (Methionine and Cysteine). Micronutrients are also significantly higher than the wheat and rice. Monounsaturated fatty acids (MUFAs) and polyunsaturated fatty acids (PUFAs) are significantly higher in millets than the wheat and rice. Table 1 show the nutrient composition of millets.

Food grain	Protein (g)	Fat (g)	Crude fiber (g)	Minerals		Sulfur containing amino acids		Unsaturated fatty acids		
				Ca(mg)	Fe(mg)	Methionine	Cysteine	Oleic	Linoleic	Linolenic
Finger millet	7.3	1.3	3.6	344	3.9	210	140	-	-	-
Kodo millet	8.3	1.4	9.0	27	0.5	-	-	-	-	-
Proso millet	12.6	1.1	2.2	14	0.8	160	-	53.80	34.90	-
Foxtail millet	12.3	4.3	8.0	31	2.8	180	100	13.0	66.50	-
Little millet	7.7	4.7	7.6	17	9.3	180	90	-	-	-
Barnyard millet	6.2	2.2	9.8	20	5.0	180	110	-	-	-
Sorghum	10.4	1.9	1.6	25	4.1	100	90	31.0	49.0	2.70
Bajra	11.6	5.0	1.2	42	8.0	150	110	25.40	46.0	4.10
Wheat (whole)	11.8	1.5	1.2	41	5.3	90	140	11.50	56.30	3.70
Rice (raw milled)	6.8	0.5	0.2	10	0.7	150	90	42.50	39.10	1.10

Table 1: Nutrient compositions of millets compared to wheat and rice (per 100g).
(Source: *Nutritive value of Indian foods, NIN 2007*)

Hypoglycemic property of millets-

GI (Glycemic index) of millets is less than the other cereal crops. The glycemic index is a scale that assigns a number to every food. It is used to indicate how fast and how high a particular food can raise our blood glucose (blood sugar) level. If the GI value comes between 0 to 55 then the food place in low GI category, 56 -69 is for moderate and more than 70 mean high GI.

Factors which contribute to make the millets low GI food are the effects of Starch, proteins, lipids, polyphenols and fibers on millets starch hydrolysis. The millet starch architecture (polygonal and spherical) has also been mentioned as one of the reasons for their hypoglycemic property. Foxtail, Proso and Pearl millets starch have pores in the structure which facilitate the starch hydrolyzing enzymes into the starch granules. Finger millets don't have pores in the starch granules.

Starch hydrolysis index of these millets are Finger<Pearl<Foxtail<Proso millets. Lowering the GI in the diets beneficial to reduce the blood glucose level, reduce cholesterol level, reduce the risk of type 2 diabetes mellitus and reduce the risk of cardiovascular disease. The absence of gluten protein in millets prevents coeliac disease and related complications.

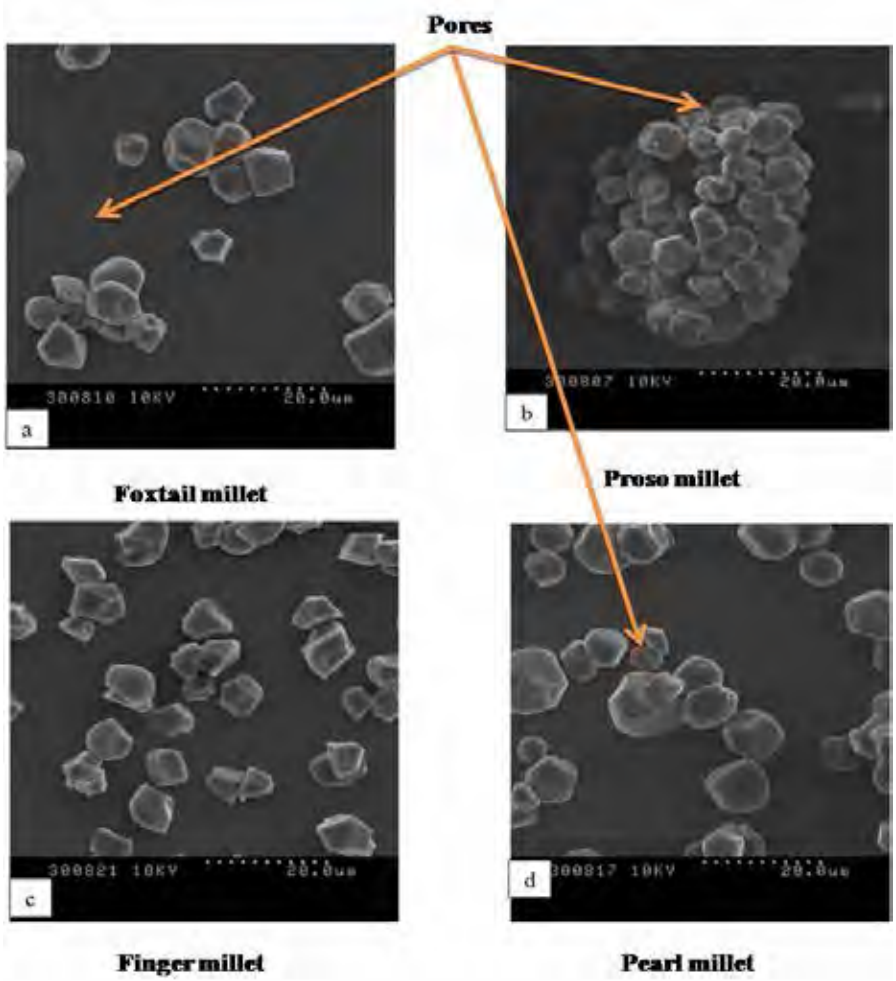

Fig.1: Scanning Electron Micrographs of Millet Starches. (*Annor et.al., 2017*)

Anti-nutrients in millets

Anti-nutrients are also founds in millets like phytic acid, polyphenol, Cyanogenic glucoside, tannins, oxalates, amylase inhibitor. These anti-nutrients reduce the bioavailability of nutrients in the body. The proportions of these anti-nutrients can be reduced in the meals by adopting some household food processing techniques like fermentation, malting, germination, decortication etc, which improve the bioavailability of nutrients.

S. No.	Processing techniques	Function
	Soaking	• Reduce the amount of phytic acid and polyphenolic compound • Improve the protein digestability
	Germination	• Decrease the level of tannins (1.6% to 0.83%) • Increase bio-accessibility of minerals such as calcium, iron and zinc
	Fermentation	• provides many varieties of food products with different flavors and texture • decreases the levels of anti- nutrients and improves the protein availability, digestibility in vitro and appreciable change in chemical composition of food material
	Popping or puffing	• HTST (high-temperature short time) method used for starch gelatinization and the endosperm bursts open giving highly desirable flavor and aroma, helpful to promote ready to eat millets based products.

Table 2. Processing techniques to overcome the effect of anti-nutrients in millets based meals. (*Sarita and Singh, 2016*)

Conclusion:

Millets are the major coarse cereals which have high human health benefits. They are rich in protein and carbohydrate, having high anti-nutritional activity and low in glycemic index. So consumption of millets with high nutritional value, have high impact on human health.

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NEWS IN FOCUS

Canada Gairdner International Awards 2019

2019 CANADA GAIRDNER AWARDS RECOGNIZE WORLD-RENOWNED SCIENTISTS FOR TRANSFORMATIVE CONTRIBUTIONS TO RESEARCH THAT IMPACT HUMAN HEALTH
April 2 2019

On the 60th anniversary of the Canada Gairdner Awards, the Gairdner Foundation announceed the 2019 Canada Gairdner Award laureates, recognizing some of the world's most significant biomedical research and discoveries. Laureates receive a $100,000 cash honorarium and are formally presented with their awards on October 24, 2019 at the annual Canada Gairdner Awards Gala in Toronto.

The five 2019 Canada Gairdner International Award laureates are recognized for seminal discoveries or contributions to biomedical science are:

Dr. Susan Band Horwitz, Ph.D.
Distinguished Professor, Rose C. Falkenstein Chair in Cancer Research, Department of Molecular Pharmacology, Albert Einstein College of Medicine, New York
Awarded "For defining novel mechanisms of action and resistance of drugs of natural product origin, most significantly Taxol®, and promoting their use for treatment of cancer"

Dr. Timothy A. Springer, Ph.D.
Latham Family Professor of Biological Chemistry and Molecular Pharmacology, Professor of Medicine, Harvard Medical School and Boston Children's Hospital; Chairman, Institute for Protein Innovation
Awarded "For discovery of the first immune system adhesion molecules, elucidation of their roles in antigen recognition and leukocyte homing, and translation of these discoveries into therapeutics for autoimmune diseases"

Dr. Bruce Stillman, Ph.D., FRS
President, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York

Dr. John F.X. Diffley, Ph.D., FRS FMedSci
Associate Research Director, The Francis Crick Institute, London, U.K, Awarded "For their pioneering research on the eukaryotic DNA replication cycles including initiation, regulation and responses to DNA damage"

2019 John Dirks Canada Gairdner Global Health Award
The 2019 John Dirks Canada Gairdner Global Health Award laureate is recognized for outstanding achievements in global health research:

Dr. Vikram Patel, Ph.D., FMedSci
The Pershing Square Professor of Global Health and Wellcome Trust Principal Research Fellow, Department of Global Health and Social Medicine, Harvard Medical School; Professor, Harvard
TH Chan School of Public Health; Honorary Professor of Global Mental Health, Centre for Global Mental Health, London School of Hygiene & Tropical Medicine; Adjunct Professor, Centre for Chronic Conditions and Injuries, Public Health Foundation of India, New Delhi; Co-founder, Sangath, India.
Awarded "For his world-leading research in global mental health, generating knowledge on the burden and determinants of mental health problems in low- and middle-income countries and pioneering approaches for the prevention and treatment of mental health in low-resource settings"

2019 Canada Gairdner Wightman Award
The 2019 Canada Gairdner Wightman Award laureate is a Canadian scientist recognized for outstanding leadership in medicine and medical science throughout their career:

Dr. Connie Jean Eaves, Ph.D.
Distinguished Scientist, Terry Fox Laboratory, BC Cancer; Professor, Department of Medical Genetics, University of British Columbia, Vancouver, BC
Awarded "For her pioneering work and leadership in the study of hematopoietic, mammary and cancer stem cells and her dedicated advocacy for early- career investigators and women in science"

Hyderabad-based OMICS fined $50 million for 'unfair, deceptive business practices'

A US federal court has ordered Hyderabad-based OMICS International – which claims to publish over 700 peer-reviewed journals – to pay a fine of over $50 million to the Federal Trade Commission (FTC) for engaging "in unfair and deceptive practices". The case was heard in Nevada because OMICS is legally incorporated there.

According to the March 29 court order, the US-based body arrived at the amount by calculating OMICS Group's gross revenue during the period August 25, 2011-July 31, 2017 and deducting the $609,289.13 paid as refunds made by the company. The fine is apart from the permanent injunctions against most of the organisation's activities that are highly objectionable, R. Prasad wrote in The Hindu.

The ruling it first of its kind against one of the largest publishers of so-called predatory journals, Jeffrey Brainard noted in Science magazine. 'Predatory' journals are the ones that will publish anything in exchange for an often substantial fee.

Apart from publishing journals, OMICS has claimed on its website that it organises over 3,000 conferences globally on topics ranging from medicine, pharma and engineering to science, technology and business.

The Wire previously reported that the OMICS Group – a notorious name in scientific publishing – was sued by the FTC in September 2016 for "bilking researchers out of potentially millions of dollars". It had alleged that the group had made misleading claims about

manuscripts being peer-reviewed and had without consent used named of prominent researchers as editors of journals.

FTC had further alleged the OMICS had not been transparent about the publication fees charged per manuscript until after it had accepted an article for publication. The group was also alleged to often deny researchers from withdrawing articles after submission.

Calling the summary judgment without calling for a trial "unjustifiable," Kishore Vattikoti, the lawyer for OMICS said in an email to The Hindu that the company plans to appeal.

He said: "The founders of the defendant companies were not permanent residents in the United States nor there had been any physical presence or operations commenced from United States," adding that "My client had already [sought] $3.1 billion damages from FTC during [its] motion for Summary Judgement. FTC might have expected that if the trail was scheduled and happened in my client's presence, the defendant would have [sought] for $3.1 billion damages because of FTC's alleged unfair activity. This might be the reason [the] final order has been announced without a trail."

IIT Delhi researchers design AI-based low-power electronic hardware system to detect four diseases in few milliseconds

Artificial Intelligence and deep learning research have enabled techniques leading to development of innovative solutions for a wide variety of applications.
In a similar landmark/crucial development, a team of IIT Delhi researchers designed and demonstrated AI-based low-power electronic hardware system that can help with detection of Malaria, Tuberculosis, Intestinal Parasite, and Cervical Cancer in few milliseconds.

IITD researchers' work is focused on building an intelligent Neuromorphic system which can be used for healthcare access in resource-constrained areas with limited access to human specialists.

The IITD researchers have demonstrated a proof-of-concept (PoC) low-power rapid AI hardware implementation based microscopy diagnostic support system for four different diseases: Malaria, Tuberculosis, Cervical Cancer and Intestinal Parasite Infection.
Prof. Manan Suri, Department of Electrical Engineering, IIT Delhi, said:

"While several software AI models exist for healthcare and diagnostic related applications, 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 approach demonstrated by the researchers is portable, low-power and can classify with high accuracy in detection of the diseases.

The long-term impact and goal of this work will be to enable potential future deployment of the platform in rural and resource-constrained areas and improve the access to diagnostic health-care.

The research team led by Prof Manan Suri, Dept of Electrical Engineering, IITD, had presented this work at two flagship healthcare conferences i.e., IEEE BioCAS-2018 in Cleveland, USA and IEEE BioCAS-2017 in Torino, Italy.

The work was showcased at Rashtrapati Bhawan and also received the prestigious Gandhian Young Technology Innovation Award (GYTI) in 2018.

Jamia Millia Islamia Gets Najma Akhtar as its First Ever Woman Vice Chancellor

Image: Prof Najma Akhtar

After five months of Talat Ahmad quitting as vice chancellor (VC) of Jamia Millia Islamia (JMI), Najma Akhtar, on April 11, was appointed the new VC. Akhtar is a member of the NIEPA (National Institute of Educational Planning and Administration).

Akhtar was chosen by the Human Resource Department Ministry out of the three people shortlisted by a committee it had set up for the task.

The other two were S.M. Ishtiaque of IIT-Delhi and Furqan Qamar, the secretary general of Association of Universities. The VC was finalised by the President, Ramnath Kovind, who gave his approval on April 11 to the HRD ministry to appoint Najma Akhtar for the post of VC.

Akhtar heads the department of educational administration at NIEPA and has a specialisation in minority education and the decentralisation of education.

New Enzyme discovered to Arrest Bacterial Growth by Scientists of CCMB, India

Center for Cellular & Molecular Biology (CCMB) Scientists has found a new enzyme which helps in breaking cell walls of bacteria and consequently, offers a potential for a new drug delivery route to arrest the anti-bacterial resistance through existing antibiotic drugs.

In a press conference held on Tuesday, CCMB Director Rakesh Mishra and Seniors scientist Manjula Reddy explained – that for research it is vital to understand how the cells grow in bacteria to comprehend the resistance to antibiotics that were currently available.

Image: CCMB director Rakesh Mishra, left, Manjula Reddy and research scholar Ch. Pavan Kumar
Source: The Hindu

Dr. Reddy along with her research scholar Ch. Pavan Kumar has been working on how the cell governs the machinery to construct the cell wall in the first place, identified the players on the other side of the process and discovered that the mechanism or enzyme through which the cell regulates the growth of its wall.

Other bacteria, also, have the enzyme since the cell wall is fundamental for bacterial growth and division. By blocking this 'scissors' enzyme' from working – effective ways to target microbes can be figured out leading to the development of novel antibiotics.

In contrast, existing antibiotic drugs functions by targeting the last stages in cell development to block cell growth like penicillin that hits on the machinery that creates the cell wall – a mesh-like structure of sugars and peptides.

Dr. Mishra and Dr. Reddy Concluded that – The Research done till now is very innovative. Now further they have to find out the molecule of the enzyme endo-pepcidine and it needs to undergo drug trials to unravel a new mix of drugs to replace existing antibiotics though it's tough to forecast a timeframe.

The above research by CCMB was published in the latest issue of Proceedings of National Academy of Sciences, USA.

JNCASR's molecule improves recovery after spinal cord injury

JNCASR researchers used a small molecule conjugated to carbon nanospheres to activate an enzyme (Cbp) that promotes axon regeneration and recovery after spinal cord injury. Regeneration and growth of axons led to recovery of sensory and motor functions in the animals with spinal cord injury. Mice could walk normally on the floor without limping and quickly sense and remove the adhesive stuck to the hindpaws indicating recovery.

Spinal cord injury can now be repaired using a small molecule (TTK21) synthesised by a team led by Prof. Tapas Kumar Kundu from the Molecular Biology and Genetics Unit at Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), Bangalore, a study has found. The small molecule tested both on mice and rat models promoted regeneration and growth of new sensory and motor axons leading to recovery of sensory and motor functions in the animals with spinal cord injury.

This finding in animal models prompted the researchers to investigate the underlying molecular mechanism to identify a therapeutic target to achieve recovery after spinal injury. They found that post spinal cord injury, animals that were earlier exposed to different stimuli expressed changes in the Cbp enzyme–mediated acetylation. This change brought about by the enzyme caused an increase in the expression of a set of genes associated with regeneration and growth of axons.

"Mimicking the regenerative effect of environmental stimuli, we wanted to test if our small molecule could activate the Cbp enzyme and promote axon regeneration and recovery," says Akash K. Singh, a PhD student at JNCASR and co-author of a paper published in the journal Science Translational Medicine.

In trials carried out in mice and rats, the small molecule injected four hours after the injury and once a week for five weeks resulted in regeneration and growth of axons at the site of injury. "The extent of regeneration and functional recovery of axons was nearly the same in both mice and rats. This proved our small molecule has a therapeutic effect," says Dr. Sarmistha H. Sinha, post-doctoral fellow from JNCASR and co-author of the paper.

"Along with the Imperial College London, we are exploring the possibility of conducting pre-clinical trials and jointly develop the molecule for therapeutic use in humans," Prof. Kundu says.

Accomplishment of India in last month

NEWS: Govt & Industry

NCI's Norman Sharpless has been appointed as Acting Commissioner of FDA

March 13, 2019

Sharpless, who was on a short-list of candidates to replace the popular Gottlieb at the regulatory agency, will take over at the FDA later this month. Sharpless has been head of the National Cancer Institute, a part of the National Institutes of Health, since 2017. Health and Human Services Secretary Alex Azar announced Sharpless' name as acting commissioner during a House Energy & Commerce Health Subcommittee Hearing on Tuesday. Azar appeared before the subcommittee to talk about the White House's proposed 2020 budget, as well as lower drug prices and the opioid crisis.

In a brief statement, Azar said Sharpless' "deep scientific background and expertise will make him a strong leader for the FDA." Azar noted that despite the loss of Gottlieb, there will be no let-up in the FDA's focus on multiple issues, including addressing the opioid crisis and discouraging the use of e-cigarettes among youth.

Sharpless, who co-founded G1 Therapeutics, is well known for his deep understanding of oncology and big data. Sharpless previously ran the University of North Carolina's Lineberger Comprehensive Cancer Center, where he was a physician-scientist, running a lab and treating patients.

On Twitter, Gottlieb said he was delighted about the appointment of Sharpless to the role of acting commissioner.

"Ned is a friend to FDA, a great public health champion, a dedicated physician, and will be warmly welcomed into his new role. FDA will benefit greatly from his leadership," Gottlieb said.

The administration has not announced a timeline for when it might name a permanent replacement for Gottlieb. Sharpless would certainly be a contender for the position. Other potential candidates to permanently take over at the FDA include Amy Abernathy. In December Abernathy, the chief medical officer of Roche-owned Flatiron Health, was named the Principal Deputy Commissioner of Food and Drugs at the FDA. Another name brought up as a potential contender for the role is Brett Giroir, who is currently the assistant secretary for health at HHS. Giroir was the founder and CEO of consulting firm Health Science and Biosecurity Partners.

Genentech's Tecentriq Wins Approval for ES-SCLC

March 19, 2019

Genentech's Tecentriq has picked up its second regulatory approval this month from the U.S. Food and Drug Administration (FDA). Late Monday the regulatory agency approved Tecentriq in combination with chemotherapy (carboplatin and etoposide) for the initial treatment of adults with extensive-stage small cell lung cancer.

Genentech
A Member of the Roche Group

This approval marks the first new initial treatment option for this difficult-to-treat type of lung cancer in more than 20 years. The latest approval for Tecentriq, an anti-PDL1 inhibitor, was based on results from the Phase III IMpower133 study, which showed that Tecentriq in combination with chemotherapy helped people with this disease live significantly longer compared to chemotherapy alone. That was the first Phase III study to show an immunotherapy-based combination significantly improved overall survival as an initial treatment for people with ES-SCLC, 12.3 months versus 10.3 months. In addition to improving overall survival, Genentech said the combination also improved progression-free survival in the same patients.

Tecentriq is also approved in combination with Avastin, paclitaxel and carboplatin, as a first-line treatment of adults with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations. Additionally, Tecentriq is approved by the FDA to treat adults with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy.

Biogen Loses $18B in Value as It Kills Aducanumab Alzheimer's Program

Biogen Inc and partner Eisai Co Ltd are ending two late-stage trials of their experimental Alzheimer's disease drug aducanumab, a major setback in the quest to find a treatment for the mind-wasting disease and a blow to Biogen, which lost more than $18 billion of its value on Thursday.

Experts had seen aducanumab as one of the last tests of the hypothesis that removing sticky deposits of amyloid from the brain of patients in earlier stages of the lethal disease could stave off its ravages, which include loss of memory and the ability to care for oneself.

Biogen shares fell nearly 30 percent to $225.70, its largest drop since February 2005, when they fell nearly 43 percent to close at $38.65 on Nasdaq.

The decision was based on a so-called futility analysis of aducanumab data by an independent monitoring committee that determined the trials had little hope of succeeding.

"This disappointing news confirms the complexity of treating Alzheimer's disease and the need to further advance knowledge in neuroscience," Biogen Chief Executive Officer Michel Vounatsos said.

Eisai and Biogen said they would continue to work on other Alzheimer's treatments, including BAN2401.

Guggenheim analyst Yatin Suneja said Biogen instead should be looking to build its pipeline through acquisitions.

"They need to stop wasting or stop investing money in Alzheimer's now," Suneja said.

Suneja said Biogen has about $42 billion in financing capacity and identified potential acquisition targets such as Sage Therapeutics Inc , GW Pharmaceuticals and Zogenix Inc that are "very interesting companies that should be considered now, more seriously."

AstraZeneca and Daiichi Sankyo enter collaboration for novel HER2-targeting antibody-drug conjugate

28 March 2019

AstraZeneca has entered into a global development and commercialisation collaboration agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo) for trastuzumab deruxtecan (DS-8201), a proprietary antibody-drug conjugate (ADC) and potential new targeted medicine for cancer treatment.

The collaboration is aligned with AstraZeneca's science-led strategy in Oncology, which is based on four key scientific platforms: tumour drivers & resistance, DNA damage response, Immuno-Oncology and ADCs.

Trastuzumab deruxtecan is currently in development for the treatment of multiple HER2-expressing cancers, including breast and gastric cancer, and in patients with HER2-low expression. In 2017, trastuzumab deruxtecan was granted Breakthrough Therapy Designation by the US FDA for the treatment of patients with HER2-positive, locally-advanced or metastatic breast cancer who have been treated with trastuzumab and pertuzumab and have disease progression after trastuzumab emtansine.

The companies will jointly develop and commercialise trastuzumab deruxtecan worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply.

Under the terms of the agreement, AstraZeneca will pay Daiichi Sankyo an upfront payment of $1.35bn, half of which is due upon execution, with the remainder payable 12 months later.

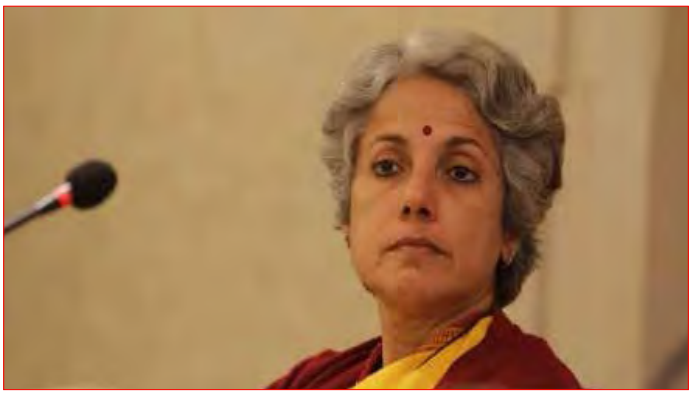
Contingent payments of up to $5.55bn include $3.8bn for potential successful achievement of future regulatory and other milestones, as well as $1.75bn for sales-related milestones.

Overall, the transaction will be accounted for as an intangible asset acquisition, recognised initially at the present value of non-contingent consideration, with future milestones capitalised into the intangible asset as they are recognised. AstraZeneca and Daiichi Sankyo will share equally development and commercialisation costs as well as profits from trastuzumab deruxtecan worldwide, except for Japan.

WHO paves way for stronger international human gene-editing regulations

March 21, 2019

The World Health Organisation committee on gene editing has called on all scientists conducting human genome research to open discussions with the committee so as to ensure that their work meets current scientific and ethical best practices.



This call was made by the advisory committee set up by the health agency to develop a global standard for governance and oversight of human genome editing.

The committee was set up after the birth of the first gene-edited babies – the results of an experiment by a Chinese scientist, He Jiankui.

Mr Jiankui had genetically altered human embryos and planted them in a woman who gave birth to twins last year. Mr Jiankui's action had caused alarm among researchers, ethicist, and policymakers because there is little known information about the safety and health effect of gene editing of a human embryo.

Some of the concern raised is that the technology can be misused to create genetically altered human beings and heighten their physical features, intelligence among others.

Among those who voiced concerns were Bill Gates, the co-founder of Microsoft and a philanthropist.

In his 2018 wrap-up notes, Mr Gates warned that nobody is paying attention to gene editing, a new technology that could make inequity worse, especially if it is available only for wealthy people.

Based on the concerns, the WHO committee on gene editing, after a two-day meeting in Geneva, agreed to work towards a strong international governance framework in the area.

Soumya Swamanathan, WHO Chief Scientist, said the committee will develop essential tools and guidance for all those working on this new technology to ensure maximum benefit and minimal risk to human health.

WHO said over the next two years, through a series of in-person meetings and online consultations, the committee will consult with a wide range of stakeholders and provide recommendations for a comprehensive governance framework that is scalable, sustainable and appropriate for use at the international, regional, national and local levels.

Russia Opens the Door for Stem Cell Clinical Trials

Mar 25, 2019

The widespread global outreach potential of stem cell therapies is becoming apparent, especially given the recent news of a second person going into long-term remission (some saying "cured") of HIV after undergoing a stem cell transplant. Regenerative medicine is becoming a powerful instrument for providing cures to previously incurable diseases. According to a recent statement, the US FDA expects to receive over 200 investigational new drug (IND) applications per year by 2020, many of which include cell and gene therapies. In fact, the FDA estimates that 10 to 20 new cell and gene therapy products per year will be approved by 2025. The number of stem cell trials carried out globally has also been growing exponentially, having over 7000 trials registered on ClinicalTrials.gov with 16 FDA-approved cellular and gene therapies.

The Russian Federation government has recently issued specific decrees which outline the stem cell technologies development strategy for 2018-2020. This program undertakes the development of knowledge sharing centers, both from the product development and production points of view, as well as medical center accreditations for them to be eligible for such studies," Vadim Merkulov, Deputy Director of the Russian Ministry of Health Scientific Centre for Expert Evaluation of Medicinal Products, elaborated.

The Russian pharmaceutical and healthcare markets have a lot of potential for stem cell studies and clinical trials in general. Key strengths of the region include fast patient enrollment, large clinical trial participation and favorable currency exchange rates. Fast patient enrollment is especially essential for early-stage trials to allow for faster project initiation. Some US and European corporations might be cautious to enter the market because of language barriers or logistic issues. However, these concerns can be avoided by choosing a reputable CRO with experience.

Syngene, BIRAC set up centre for advanced protein studies in Bengaluru

Biocon arm Syngene International Friday said it has set up a centre for advanced protein studies in collaboration with Biotechnology Industry Research Assistance Council (BIRAC), at the former's campus in Bengaluru.

The centre will host a state-of-the-art good laboratory practices (GLP) accredited analytical laboratory, the company said in a filing to the BSE.

The centre for advanced protein studies (CAPS) facil-

ity will provide the right ecosystem for this talent to pursue their research objectives, she added. The centre will run under the 'Innovate in India' programme of the National Biopharma Mission, it added.

he centre will address the challenge of availability of GLP compliant analytical facility that the startups, small and medium sized enterprises (SMEs) and middle market enterprises (MMEs) and the academia in India have to face and will be a boost in advancing biopharma research and product development in the country, it added.

"It is indeed an honour for Syngene to collaborate with BIRAC in setting up the CAPS facility," Syngene International CEO Jonathan Hunt said.

Wockhardt receives USFDA approval for cancer drug Decitabine Injection

April 11, 2019

Wockhardt has received approval from the United States Food & Drug Administration (US FDA) for an ANDA for 50mg injection of Decitabine, which is used to treat certain forms of cancer. Wockhardt's Decitabine Injection is a generic version of Dacogen, marketed in USA and other countries by Otsuka.

Decitabine is used to treat Myelodysplastic syndromes (MDS), a group of cancers in which immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells.

According to IQVIA February 2019 data, the product has sales of $120 million in the US.

The product is being manufactured at a contract manufacturing facility, based near Hyderabad, India.

Merck's Keytruda Wins Approval for Yet Another Lung Cancer Indication

Apr 12, 2019

The U.S. Food and Drug Administration (FDA) approved the anti-PD-1 checkpoint inhibitor for yet another indication, this time as a monotherapy for the first-line treatment of stage III non-small cell lung cancer (NSCLC) in patients who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and patients whose tumors express PD-L1 as identified on an FDA-approved companion diagnostic, with no EGFR or ALK genomic tumor aberrations.

The approval for this expanded label is based on the Phase III KEYNOTE-042 clinical trial. In that trial, Keytruda alone showed a significant improvement in overall survival compared with chemotherapy in this patient population. There was originally an earlier date, but Merck submitted additional data late in

2018, and on December 20, the company indicated the agency found it made up a major amendment and extended the target action date three months to April 11, 2019.

"This expanded first-line indication now makes Keytruda monotherapy an option for more patients with non-small cell lung cancer, including those for whom combination therapy may not be appropriate," stated Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories.

Keytruda was the first anti-PD-1 checkpoint inhibitor therapy to be approved in metastatic NSCLC as a first-line choice either alone or in combination.

Merck indicates that Keytruda is currently in more than 900 clinical trials in a broad range of cancers and treatment settings.

Merck has had a lot of recent approvals for Keytruda. On March 14, 2019, the company announced that the European Commission had approved Keytruda in combination with carboplatin and either paclitaxel or nab-paclitaxel, for first-line treatment of adults with metastatic squamous non-small cell lung cancer (NSCLC). On April 1, Merck announced that Keytruda had been approved by China's National Medical Products Administration (NMPA) in combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor mutations.

At the recent American Association for Cancer Research (AACR) meeting, Merck presented results from a post-hoc analysis of patients with liver or brain cancers from the Phase III KEYNOTE-189 trial. The point of the post-hoc analysis was to evaluate outcomes of Keytruda in combination with chemotherapy in liver and brain cancers.

The company also presented pooled data from KEYNOTE-158 and Phase Ib KEYNOTE-028 evaluating Keytruda in patients with previously treated advanced small cell lung cancer (SCLC). Data from these trials supported the company's first application in SCLC for Keytruda. The sBLA was accepted by the FDA for priority review and has a target action date of June 17, 2019.

FDA approves Evenity of AMGEN for new treatment of osteoporosis in postmenopausal women at high risk of fracture

Apr 10, 2019

The U.S. Food and Drug Administration today ap-

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proved Evenity (romosozumab-aqqg) to treat osteoporosis in postmenopausal women at high risk of breaking a bone (fracture). These are women with a history of osteoporotic fracture or multiple risk factors for fracture, or those who have failed or are intolerant to other osteoporosis therapies.

Evenity is a monoclonal antibody that blocks the effects of the protein sclerostin and works mainly by increasing new bone formation. One dose of Evenity consists of two injections, one immediately following the other, given once a month by a health care professional. The bone forming effect of Evenity wanes after 12 doses so more than 12 doses should not be used. If osteoporosis therapy is needed after the 12 doses, patients should begin an osteoporosis treatment that reduces bone breakdown.

The safety and efficacy of Evenity were demonstrated in two clinical trials involving a total of more than 11,000 women with postmenopausal osteoporosis. In the first trial, one year of treatment with Evenity lowered the risk of a new fracture in the spine (vertebral fracture) by 73% compared to placebo. This benefit was maintained over the second year of the trial when Evenity was followed by one year of denosumab (another osteoporosis therapy) compared to placebo followed by denosumab. In the second trial, one year of treatment with Evenity followed by one year of alendronate (another osteoporosis therapy) reduced the risk of a new vertebral fracture by 50% compared to two years of alendronate alone. Evenity followed by alendronate also reduced the risk of fractures in other bones (nonvertebral fractures) compared to alendronate alone.

Evenity increased the risk of cardiovascular death, heart attack and stroke in the alendronate trial, but not in the placebo trial. Therefore, Evenity contains a boxed warning on its labeling stating that it may increase the risk of heart attack, stroke and cardiovascular death and should not be used in patients who have had a heart attack or stroke within the previous year. Health care professionals should also consider whether the benefits of Evenity outweigh its risks in those with other risk factors for heart disease and should discontinue Evenity in any patient who experiences a heart attack or stroke during treatment. Common side effects of Evenity included joint pain and headache. Injection site reactions were also observed.

Sanofi to cut U.S. insulin costs for some patients to $99 per month

APRIL 11, 2019

Sanofi SA is expanding its Insulin Valyou Savings Program and will allow uninsured patients in the United States to purchase up to 10 boxes of insulin pens or vials with a valid prescription for $99 per month, beginning in June.

The price of other manufacturers' leading insulin products is $178 to $300 per vial and $235 to $563 per pack of pens, according to Sanofi.

The move is an expansion of Sanofi's "Insulin Valyou Savings Program" launched last year and represents a significant savings for patients already enrolled who had been paying $99 for each vial of insulin and $149 for each pack of insulin pens.

Sanofi is not the first company to cut insulin prices in response to intensifying criticism from patients and politicians. Last month, Eli Lilly announced plans to sell a half price, authorized generic version of its popular Humalog insulin injection. The list price for Lilly's authorized generic, to be sold only in the United States, will be $137.35 per vial.

In terms of profitability, Sanofi said it believes the pricing program is sustainable for the long term. The company's diabetes business brought in about 2.2 billion euros ($2.5 billion) in U.S. sales last year.

Since Sanofi launched its "Insulins Valyou Savings Program" last April around 12,000 patients have utilized the program, saving about $10 million, the company said.

Alcon Debuts as Independent, Publicly Traded Company

APRIL 9, 2019

Alcon, the global leader in eye care dedicated to helping people see brilliantly, announced its debut as an independent, publicly traded company and the completion of its separation from Novartis.

Alcon is the largest eye care device company in the world, with complementary businesses in Surgical and Vision Care. The company has a global presence in 74 countries and serves patients in more than 140, with fast-growing businesses in emerging markets. Alcon has the widest array of eye care offerings in the industry with products that can treat eye disorders at each stage of life.

"For more than 70 years, Alcon has been dedicated to helping people see brilliantly and now, as an independent company, we are pursuing even more opportunities to further that mission," said David Endicott, Chief Executive Officer of Alcon.

Eye care is an approximately $23 billion a year market, growing at roughly 4 percent annually. Last year, Alcon had sales of $7.1 billion, including $4.0 billion in Surgical – up 7 percent from the prior year – and $3.1 billion in Vision Care – up 3 percent.

s an independent company, Alcon will have more focus and flexibility in pursuing its own growth strategy driven by rapid iterative innovation. The company will have a distinct investment identity with a more efficient capital structure that will allow it to expand markets, enter promising adjacencies and introduce new business models. These benefits, combined with Alcon's industry-leading customer relationships, favorably position the company to achieve sustainable growth.

Alcon is headquartered in Geneva. The company has maintained a presence in Switzerland for more than 40 years and it is where the company was incorporated prior to the Novartis acquisition. Alcon's facilities in Fort Worth, Texas, will remain a major operational center and innovation hub with a large base of employees.

The company launched a new global website that can be found at www.alcon.com.

ViiV Healthcare's 2-Drug Combo for HIV Approved by FDA

Apr 09, 2019

The U.S. Food and Drug Administration (FDA) approved ViiV Healthcare's Dovato, a once-a-day, single-tablet combination of dolutegravir (DTG) and lamivudine (3TC) for HIV-1 in adults who had not received treatment before. ViiV Healthcare is a division of GlaxoSmithKline.

Dolutegravir is an integrase strand transfer inhibitor (INSTI), which prevents HIV replication by keeping the viral DNA from integrating into the genetic material of T-cells. Lamivudine is an NRTI that interferes with the conversion of viral RNA into DNA. This prevents the virus from multiplying.

It was just last week that ViiV announced 3-year data for another of its two-drug HIV combos, Juluca. They presented the data from the SWORD 1 and 2 clinical trials in HIV. The data was presented at the 25th Annual Conference of the British HIV Association (BHIVA) in Bournemouth, UK.

The studies found that 84% of patients who switched from a three- or four-drug antiretroviral regimen to the two-drug combo Juluca maintained viral suppression. Juluca is a two-drug combination of ViiV Healthcare's dolutegravir and Johnson & Johnson's Janssen Sciences Ireland's rilpivirine.

In June 2014, ViiV Healthcare and Janssen Sciences Ireland partnered to investigate the possible combination of dolutegravir and rilpivirine. Juluca has been approved in the U.S., the European Union (EU) and in other countries as a complete regimen for HIV-1 infection in adults who are virologically suppressed, which is defined as less than 50 copies of HIV-1 RNA per mL. Dolutegravir is an integrase inhibitor. Rilpivirine is a non-nucleoside reverse transcriptase inhibitor. The pill is taken once a day.

The SWORD Phase III program is studying the efficacy, safety and tolerability of switching to dolutegravir plus rilpivirine from current combination therapies. The primary endpoint is the proportion of patients with plasma HIV-1 RNA less than 50 copies per milliliter at week 48. Key secondary endpoints include evaluation of viral resistance development, safety and tolerability, and changes in renal, bone and cardiovascular markers. Health-related quality of life measures are assessed as well.

"The SWORD 1+2 studies are the first Phase III HIV studies to show long-term data for switching from three-drug combination to an oral 2-drug regimen," stated John C. Pottage, Jr., ViiV's chief scientific medical officer, "and the efficacy, tolerability and barrier to resistance out to three years demonstrated in the study provides further reassurance of the suitability of Juluca for many virologically suppressed adults living with HIV."

Of the Dovato approval, Jeff Berry, of the Test Positive Aware Network (TPAN), stated, "The approval of Dovato is a welcome paradigm shift, as it brings an innovative treatment approach to newly diagnosed adults with HIV-1. By exposing patients to fewer drugs at the start of treatment, the hope is to help address concerns arising from overall management of prolonged ARV therapy."

Vanta Biosciences arm signs Rs 29 crore deal with Emcure Pharma

Vanta Bioscience Limited has announced that its step-down subsidiary 'Vayam Research Solutions Limited' has entered into a non-exclusive CRO Service Agreement with Emcure Pharmaceuticals Limited, Pune, for providing services of bio-analytical and bio-equivalence services to the company for a period of three years from 2019 to 2022.

In a listing to the bourses, the company said the agreement provides for a minimum revenue assurance between ₹7 crore and ₹9 crore for the financial year 2019-20 and ₹20 crore for fiscal 2020-21.

Regeneron and Alnylam ink $1 Billion Eye and Central Nervous System R&D Deal

Regeneron Pharmaceuticals and Alnylam Pharmaceuticals announced a collaboration deal to discover, develop and commercialize treatments for the eye and central nervous system (CNS), as well as several targets expressed in the liver, utilizing RNA interference (RNAi).

Under the terms of the agreement, Regeneron is paying $400 million upfront to Alnylam and acquiring another $400 million in equity at a price per share of $90, or 4.44 million common shares. Alnylam will be eligible for up to another $200 million in milestone payments during early clinical development for the eye and CNS programs.

Alnylam plans to work exclusively with Regeneron to discover RNAi therapeutics for the two primary indications, eye and CNS diseases. Regeneron will lead development and marketing for programs that target the eye and Alnylam will be eligible for milestone payments and royalties. The two companies will work together to advance and alternate heading the CNS programs, with the lead group holding global development and commercial responsibility. For CNS programs, both companies will be able to participate equally in the other's programs at the point of candidate selection.

Regeneron and Alnylam indicate they plan to advance programs directed to 30 targets, with many of them being advanced into clinical development during the initial five-year discovery period. That also includes an option to extend the partnership.

Regeneron will pay Alnylam $2.5 million in funding at the initiation of a program and another $2.5 million in annual discovery funding. This amounts to approximately $30 million in potential annual discovery funding to Alnylam.

Bain, Piramal-led India Resurgence Fund invests $144m in Panacea Biotec

April 9, 2019

India Resurgence Fund (IndiaRF), backed by Piramal Enterprises and Bain Capital Credit, is investing about $144 million (Rs 992 crore) in New Delhi-based drug firm Panacea Biotec, per an announcement.

The investment proceeds will be used for a one-time settlement with existing lenders, general working capital and growth requirements of the company, IndiaRF and Panacea Biotec said in a joint statement. IndiaRF, which is an equal joint venture between Piramal Enterprises and Bain Capital Credit, has been active in the pharma business.

The announcement comes after a February 26 announcement by Panacea about reaching a one-time settlement with its lenders to pay off Rs 864 crore of debt. The investment has been structured by way of non-convertible debentures (NCDs) of up to Rs 864 crore and subscription amount of Rs 32 crore towards share warrants to be allotted on a preferential basis.

The subscription amount represents 25 per cent of the Rs 128 crore proposed to be raised upon issu-

ance of equity shares against warrants, the statement added. Subject to the exercise of warrants, IndiaRF along with its affiliates will collectively end up owning 10.4 per cent stake in the company on a fully diluted basis, it added.

"The purpose of this investment is to not only restructure the company's balance sheet, but more importantly, work closely with the promoters and management team, to drive rapid revenue growth and sustainable profitability improvement," IndiaRF MD Shantanu Nalavadi said.

Panacea Biotec is a biotechnology company focused on the manufacturing and marketing of pharmaceutical formulations, biopharmaceuticals and vaccines. Its portfolio includes products in therapeutic areas of oncology, organ transplantation, nephrology, diabetes, osteoporosis, cardiovascular diseases and pediatric vaccines.

The company said it is working on a pipeline of generic products using nanotechnology and platform drug delivery technologies like micro-particles, liposomes and gastro-retentive systems.

Veeda Clinical Research Achieves ISO 27001:2013 Certification Validating the Quality of its Information Security Management System

Veeda Clinical Research Pvt. Ltd., India's leading independent CRO, is pleased to announce that Bureau Veritas has awarded the ISO 27001:2013 Certification to Veeda Clinical Research thereby certifying the compliance of the company's Information Security Management System (ISMS) with the required international standards. The certified ISMS is enterprise wide covering Clinical, Bioanalytical, Biopharmaceutical, Medical Affair and Pharmacovigilance operations, Information and Communication Technology systems, processes and applications, Human Resources, Assets and Access management.

On this important milestone, Mr. Apurva Shah, Founder and Director of Veeda Clinical Research, remarked, "Veeda consistently strives for Excellence in Quality and endeavours to become the partner of choice for our Sponsors and our Stakeholders. We continuously review and strengthen our policies, systems, processes and culture to be best-in-class and set industry benchmarks. The ISO 27001:2013 certification is yet another external validation of our commitment to Quality and a reassurance to our clients of our trustworthiness."

"Veeda Clinical Research is committed to upholding the highest standards of information security to protect our sponsors' most sensitive information on which they run their business. By achieving the ISO 27001:2013 certification, Veeda has shown its commitment with all the necessary controls in place to ensure that data security and confidentiality is maintained," stated Dr. Venu Madhav - COO at Veeda Clinical Research.

Mr. Rajesh Limbachia, Head-ICT at Veeda Clinical Research, added, "We have invested in the ISO 27001:2013 certification to provide additional transparency to our customers as it demonstrates our clear commitment to information security management

and assures our sponsors that we have the requisite security controls in place to handle their data."

About Veeda CRO
Veeda is the leading independent CRO in India. Veeda offers a diverse range of clinical studies including bioequivalence as well as PK, PD and Clinical End point studies for Generics, NCE and Biopharmaceuticals. Veeda is a partner of choice for many global pharmaceutical companies and is reputed for its best-in-class scientific knowledge, quality and ethics.

Veeda has an exemplary regulatory track record of successfully completing 29 USFDA, 6 ANVISA, 5 WHO, 3 MHRA, 1 AGES, 1 ANSM, 1 MCC, 12 DCGI and 3 NPRA audits till date.

Bristol-Myers Squibb and Concerto HealthAI Announce Strategic Agreement

March 28, 2019

Bristol-Myers Squibb and Concerto HealthAI, a market leader in oncology-specific Real-World Data (RWD) and advanced Artificial Intelligence (AI)-enabled insight solutions for Real-World Evidence (RWE) generation, announced a multi-year strategic agreement that will cover a diverse range of cancers, integrate multiple data sources, and apply AI and machine learning to accelerate clinical trials, enable robust protocol design and generate insights for precision treatment and improved patient outcomes.

Bristol-Myers Squibb will use Concerto HealthAI's Real-World Data and novel AI insights platform, eurekaHealth™, to accelerate insights through novel health economic outcomes and clinical development synthetic control arm studies. With this agreement, the companies will advance the use of RWE for regulatory purposes, validate clinical application of AI solutions and execute clinical studies to advance patient care.

"With the increasing importance of Real-World Data and Real-World Evidence, healthcare providers and regulators need to have confidence in the credibility and accuracy of the data sources and methods of evidence generation," said Jeff Elton, Ph.D. and CEO of Concerto HealthAI. "Our agreement with Bristol-Myers Squibb is a recognition that we have reached a pivot-point for RWE – it is not just a tool for generating insights into the current standard of care, but a field in its own right that can lead to optimization of current treatments and new therapeutic innovations."

"At Bristol-Myers Squibb, we have seen the value of Real-World Data in our efforts to discover, develop and deliver medicines for patients," said Jeff Conklin, Senior Vice President and Head of Business Insights and Analytics at Bristol-Myers Squibb. "This strategic agreement with Concerto HealthAI – a leader in AI solutions for precision oncology – reinforces our commitment to pursue data science to accelerate disease insights, advance novel study concepts and achieve precision in treatment, with the goal of improving patient outcomes."

"Concerto HealthAI's singular mission," said Dr. Elton "is to partner with leading medical societies, healthcare providers and life science companies to bring together data, technology and talent to enable new RWE insights and improve the use and broaden the beneficial impact of cancer therapies for patients. The strategic agreement between Bristol-Myers Squibb and Concerto HealthAI reflects both how far the field has advanced and its high near-term potential."

Recently, the 21st Century Cures Act accelerated adoption of RWE-based approaches to clinical trials and post-approval studies. In December 2018, the U.S. Food and Drug Administration (FDA) reinforced its commitment to expanding use of RWD in studies, and to preference where RWE would be used for key decisions – by issuing a framework to assess RWE in regulatory decisions and approvals. Concerto HealthAI integrates data from sources including CancerLinQ®, a platform that collects and analyzes

real-world data from patients at practices nationwide and delivers knowledge back to physicians and researchers. CancerLinQ® is developed and operated by CancerLinQ LLC, a nonprofit subsidiary of the American Society of Clinical Oncology (ASCO). As an exclusive licensee, Concerto HealthAI works closely with CancerLinQ to broaden the use of RWE for pre- and post-approval studies.

Concerto HealthAI is a technology leader in definitive Real-World Data (RWD), Precision Evidence and AI solutions for oncology. Our mission is to accelerate improvements in clinical outcomes for cancer patients through our partnerships, unique real-world data assets, leading AI-based technologies, and the world's top outcomes research and data science talent. For more information, visit us at http://www.concertohealthai.com. Concerto HealthAI is a SymphonyAI company. eurekaHealth is a trademark of Concerto HealthAI.

BALVERSA™ (erdafitinib) Receives U.S. FDA Approval for the Treatment of Patients with Locally Advanced or Metastatic Urothelial Carcinoma with Certain FGFR Genetic Alterations

The Janssen Pharmaceutical Companies of Johnson & Johnson announced that BALVERSA™ (erdafitinib) received accelerated approval from the U.S. Food and Drug Administration (FDA) for the treatment of adults with locally advanced or metastatic urothelial carcinoma (mUC) which has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and who have progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.1 BALVERSA is the first FGFR kinase inhibitor approved by the FDA. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.1 Today's approval follows FDA Breakthrough Therapy Designation in March 2018 and Priority Review Designation of the New Drug Application submitted in September 2018.

Janssen is offering BALVERSA and associated patient services through a single source specialty pharmacy provider, US Bioservices. This model is part of Janssen's ongoing commitment to provide high-quality products, services, access, and support to healthcare professionals and patients.

Mathai Mammen, Global Head of R&D for the Janssen Pharmaceutical Companies of Johnson & Johnson shared on Linkedin, "I am very proud of the Janssen team that worked for many years and overcame many significant challenges to bring forward Balversa (erdafitinib) from our labs to patients with bladder cancer that possess a particular molecular signature. It is extraordinarily difficult to progress first-in-class therapies, as there will always be questions, risks, doubts. Success requires a team with passion, creativity and grit, and of course incredible talent and conviction born of data. This drug will save lives".

RESEARCH NEWS

From other High Impact Journals

Biologists find a way to boost intestinal stem cell populations

March 28, 2019

MIT biologists found that intestinal stem cell populations declined in aged mice compared to younger mice.

The researchers also showed that they could reverse this effect in aged mice by treating them with a compound that helps boost the population of intestinal stem cells. The findings suggest that this compound, which appears to stimulate a pathway that involves longevity-linked proteins known as sirtuins, could help protect the gut from age-related damage, the researchers say.

"One of the issues with aging is organ dysfunction, accompanied by a decline in the activity of the stem cells that nurture and replenish that organ, so this is a potentially very useful intervention point to either slow or reverse aging," says Leonard Guarente, the Novartis Professor of Biology at MIT.

Guarente's lab has long studied the link between aging and sirtuins, a class of proteins found in nearly all animals. Sirtuins, which have been shown to protect against the effects of aging, can also be stimulated by calorie restriction.

In a paper published in 2016, Guarente and Igarashi found that in mice, low-calorie diets activate sirtuins in intestinal stem cells, helping the cells to proliferate. In their new study, they set out to investigate whether aging contributes to a decline in stem cell populations, and whether that decline could be reversed.

By comparing young (aged 3 to 5 months) and older (aged 2 years) mice, the researchers found that intestinal stem cell populations do decline with age. Furthermore, when these stem cells are removed from the mice and grown in a culture dish, they are less able to generate intestinal organoids, which mimic the structure of the intestinal lining, compared to stem cells from younger mice. The researchers also found reduced sirtuin levels in stem cells from the older mice.

Once the effects of aging were established, the researchers wanted to see if they could reverse the effects using a compound called nicotinamide riboside (NR). This compound is a precursor to NAD, a coenzyme that activates the sirtuin SIRT1. They found that after six weeks of drinking water spiked with NR, the older mice had normal levels of intestinal stem cells, and these cells were able to generate organoids as well as stem cells from younger mice could.

To determine if this stem cell boost actually has any health benefits, the researchers gave the older, NR-treated mice a compound that normally induces colitis. They found that NR protected the mice from the inflammation and tissue damage usually produced by this compound in older animals.

Guarente says he believes that NR is likely acting through a pathway that his lab previously identified,

in which boosting NAD turns on not only SIRT1 but another gene called mTORC1, which stimulates protein synthesis in cells and helps them to proliferate.

"What we would hypothesize is that the NAD replenishment in old mice is driving this pathway of growth that's working through SIRT1 and TOR to reverse the decline that has occurred with aging," he says.

The findings suggest that NAD might have a protective effect against diseases of the gut, such as colitis, in older people, he says. Guarente and his colleagues have previously found that NAD precursors can also stimulate the growth of blood vessels and muscles and boost endurance in aged mice, and a 2016 study from researchers in Switzerland found that boosting NAD can help replenish muscle stem cell populations in aged mice.

In 2014, Guarente started a company called Elysium Health, which sells a dietary supplement containing NR combined with another natural compound called pterostilbene, which is an activator of SIRT1.

Journal Reference:
Masaki Igarashi, Masaomi Miura, Eric Williams, Frank Jaksch, Takashi Kadowaki, Toshimasa Yamauchi, Leonard Guarente. NAD supplementation rejuvenates aged gut adult stem cells. Aging Cell, 2019; e12935 DOI: 10.1111/acel.12935

Cultured stem cells reconstruct sensory nerve and tissue structure in the nose

A team of researchers at Tufts University School of Medicine developed a method to grow and maintain olfactory stem cells in culture, which can then be used to restore tissue in the nose. The discovery raises hope that future therapies could be developed to restore the sense of smell in individuals where it has been damaged by injury or degeneration.

The stem cells, called horizontal basal cells (HBCs), can repopulate all olfactory epithelium (OE) cell types, including sensory neurons, when transplanted into injured tissue. Published today in the journal Stem Cell Reports, the development paves the way for further research into stem cell transplantation therapies, or pharmacological approaches that stimulate stem cells within the nose to regenerate tissue.

The nerves that confer the sense of smell are unique when compared to the rest of the nervous system, in that they can trigger a robust and nearly complete regenerative response after injury. OE tissue contains two types of stem cells -- globose basal cells (GBCs) and HBCs. The GBCs have been successfully cultured and appear to have a primary role in repopulating cells that have been lost to routine turnover. HBCs, however, remain dormant and are not activated until there is an injury. Unfortunately, studies on these cells have been limited by the fact that they could not be expanded and maintained in culture. In this study, the researchers determined the optimal conditions for expanding and maintaining healthy HBC stem cells in culture, borrowing methods and factors used to maintain respiratory stem cells.

"Once we determined that we could grow HBCs in the lab, and that they expressed the same identifying molecular markers found in vivo, we sought to confirm whether they would work as well as the in vivo HBCs -- can they regenerate tissue that has been injured -- and they did!" said James Schwob, M.D., Ph.D., professor of developmental molecular and chemical biology at Tufts University School of Medicine, and corresponding author for the study.

Despite a natural ability for regeneration, dysfunction in the sense of smell is still reported among 19.4 percent of the population (OLFACAT study, 2003), with 0.3 percent experiencing complete loss of smell. Causes range from aging, injury, smoking, and neurodegenerative diseases to certain medications.

Schwob and his team discovered that the lab-grown HBCs were able to fill in olfactory lesions, generating multiple cell types including Sus cells, basal cells and olfactory sensory neurons.

"The HBCs in culture remained quiescent, pretty much as they do in vivo, but we were able to trigger them into an active state to start the process of differentiation into various olfactory epithelial cells just before engrafting them into injured tissue," said Jesse Peterson, Ph.D., first author of the study and currently a post-doctoral fellow at the MRC Laboratory of Molecular Biology. Peterson conducted the study as part of his doctoral dissertation at the Sackler School of Graduate Biomedical Sciences at Tufts, advised by Schwob.

The trigger used was retinoic acid, which has the effect of lowering levels of the protein P63 in the cells, leading to stem cell activation. P63 functions as a "master control switch" and is known to decrease levels during injury, transitioning HBCs from dormancy to activation in vivo. A more thorough understanding of the role of P63 has been hampered by the slow pace of in vivo studies. With lab-grown HBCs, the mechanisms of activation can be examined more closely.

"Now that we can create a reserve of dormant stem cells, we see this as a useful tool for exploring ways to guide cell differentiation toward specific cell types, and develop new stem cell therapies for tissue and sensory regeneration -- using the patient's own stem cells for culturing and transplantation, or pharmacological interventions to activate the patient's own dormant stem cells within the nose," said Schwob.

Other authors contributing to this study are Brian Lin, Ph.D., Camila Barrios-Camacho, Daniel Herrick, M.D., Ph.D., and Julie Coleman, Ph.D., all graduates or students at Tufts, Woochan Jang, Ph.D., former research assistant professor at Tufts, and Eric Holbrook, M.D., of Massachusetts Eye and Ear, and Harvard Medical School.

Journal Reference:
Jesse Peterson, Brian Lin, Camila M. Barrios-Camacho, Daniel B. Herrick, Eric H. Holbrook, Woochan Jang, Julie H. Coleman, James E. Schwob. Activating a Reserve Neural Stem Cell Population In Vitro Enables Engraftment and Multipotency after Transplantation. Stem Cell Reports, March 28, 2019; DOI: 10.1016/j.stemcr.2019.02.014

Fluorescence discovered in tiny Brazilian frogs

An international team of researchers was studying the acoustic communications of certain miniature frogs. When they discovered that Brachycephalus ephippium could not hear its own mating calls, they searched for alternative visual signals the frogs could use to communicate instead. Unexpectedly, when they shone an ultra-violet (UV) lamp on the frogs, their backs and heads glowed intensely.

"The fluorescent patterns are only visible to the human eye under a UV lamp. In nature, if they were visible to other animals, they could be used as intra-specific communication signals or as reinforcement of their aposematic coloration, warning potential predators of their toxicity," says Sandra Goutte.

Pumpkin toadlets (also called Brachycephalus ephippium) are tiny, brightly-colored, and poisonous frogs that can be found in the Brazilian Atlantic forest. During the mating season, they can be seen by day walking around the forest and producing soft buzzing

calls in search of a mate.

An international team of researchers led by NYU Abu Dhabi Postdoctoral Associate Sandra Goutte was studying the acoustic communications of these miniature frogs. When they discovered that Brachycephalus ephippium could not hear its own mating calls, they searched for alternative visual signals the frogs could use to communicate instead. Unexpectedly, when they shone an ultra-violet (UV) lamp on the frogs, their backs and heads glowed intensely.

In a new paper published in the journal Scientific Reports, the researchers report that fluorescent patterns are created by bony plates lying directly beneath a very thin skin. In fact, the toadlet's entire skeleton is highly fluorescent, but the fluorescence is only externally visible where the layer of skin tissue over the bones is very thin (about seven micrometers thick). The lack of dark skin pigment cells (which block the passage of light) and the thinness of the skin allow the ultraviolet light to pass through and excite the fluorescence of the bony plates of the skull. The fluorescent light is then reflected back from the frog's bone, and can be seen as bluish-white markings by the observer if they have a UV lamp.

"The fluorescent patterns are only visible to the human eye under a UV lamp. In nature, if they were visible to other animals, they could be used as intra-specific communication signals or as reinforcement of their aposematic coloration, warning potential predators of their toxicity," said Goutte. "However, more research on the behavior of these frogs and their predators is needed to pinpoint the potential function of this unique luminescence."

The researchers compared the skeletons of the two species of pumpkin toadlets to closely related, non-fluorescent species. The pumpkin toadlets' bones proved to be much more fluorescent. Pumpkin toadlets are diurnal, and in their natural habitat, the UV or near-UV components of daylight might be able to create fluorescence at a level detectable by certain species.

Journal Reference:
Sandra Goutte, Matthew J. Mason, Marta M. Antoniazzi, Carlos Jared, Didier Merle, Lilian Cazes, Luís Felipe Toledo, Hanane el-Hafci, Stéphane Pallu, Hugues Portier, Stefan Schramm, Pierre Gueriau, Mathieu Thoury. Intense bone fluorescence reveals hidden patterns in pumpkin toadlets. Scientific Reports, 2019; 9 (1) DOI: 10.1038/s41598-019-41959-8

Mice reveal 38 new genes involved in hearing loss

To identify new molecules involved in hearing loss, the researchers took a genetic approach and created 1,211 new mouse mutants. They screened each of these mice using a sensitive electrophysiological test, the auditory brainstem response, to find out how good their hearing was.

This large-scale screen of targeted mouse mutants identified 38 genes involved in hearing loss in the mice, that had not been previously suspected to be involved in hearing.

The researchers also analysed human DNA data to ask if any of these 38 genes discovered in mice were associated with human adult-onset hearing loss. They found eleven of these 38 genes were significantly associated with hearing ability in the UK population. Furthermore one gene, SPNS2, was associated with childhood deafness.

Some of these genes revealed molecular pathways that may be useful targets for drug development.

Dr Chris Lelliott, an author from the Wellcome Sanger Institute, said: "This is the first time that a study of this scale has looked at levels of hearing and different types of hearing loss in mouse mutants and shows the power of large genetic screens. Only a handful of genes have previously been linked specifically to age-related hearing loss in adults, now our study adds many more potential new genes to follow up."

Further analysis of the genes identified, and the many different mechanisms within the ear that were revealed by the mutations, suggested that hearing loss is an extremely varied disorder and may involve as many as 1,000 genes.

Dr Selina Pearson, from the Wellcome Sanger Institute said: "This study is giving a huge insight into the complicated biology of hearing loss, and shows that because of all the different genes and pathways found, there won't be a single 'magic bullet' to stop all age-related deafness. This emphasises the value of mouse studies for identifying genes and mechanisms underlying complex processes such as hearing."

Prof Karen Steel, senior author on the paper from the Wellcome Sanger Institute and King's College London, said: "Several of these new mouse mutant lines showed normal development of hearing followed by later deterioration, suggesting the genes involved are good candidates for human age-related hearing loss. Our next step is to find out if we can influence the molecular pathways involved to slow down or stop the progression of hearing loss."

Journal Reference:
Neil J. Ingham, Selina A. Pearson, Valerie E. Vancollie, Victoria Rook, Morag A. Lewis, Jing Chen, Annalisa Buniello, Elisa Martelletti, Lorenzo Preite, Chi Chung Lam, Felix D. Weiss, Zöe Powis, Pim Suwannarat, Christopher J. Lelliott, Sally J. Dawson, Jacqueline K. White, Karen P. Steel. Mouse screen reveals multiple new genes underlying mouse and human hearing loss. PLOS Biology, 2019; 17 (4): e3000194 DOI: 10.1371/journal.pbio.3000194

Study shows dogs can accurately sniff out cancer in blood

Dogs have smell receptors 10,000 times more accurate than humans', making them highly sensitive to odors we can't perceive. A new study has shown that dogs can use their highly evolved sense of smell to pick out blood samples from people with cancer with almost 97 percent accuracy. The results could lead to new cancer-screening approaches that are inexpensive and accurate without being invasive.

"Although there is currently no cure for cancer, early detection offers the best hope of survival," said Heather Junqueira, who is lead researcher at BioScentDx and performed the study. "A highly sensitive test for detecting cancer could potentially save thousands of lives and change the way the disease is treated."

Junqueira will present this research at the American Society for Biochemistry and Molecular Biology annual meeting during the 2019 Experimental Biology meeting to be held April 6-9 in Orlando, Fla.

For the new study, Junqueira and her colleagues used a form of clicker training to teach four beagles to distinguish between normal blood serum and samples from patients with malignant lung cancer. Although one beagle -- aptly named Snuggles -- was unmotivated to perform, the other three dogs correctly identified lung cancer samples 96.7 percent of the time and normal samples 97.5 percent of the time.

"This work is very exciting because it paves the way for further research along two paths, both of which could lead to new cancer-detection tools," said Junqueira. "One is using canine scent detection as a screening method for cancers, and the other would be to determine the biologic compounds the dogs detect and then design cancer-screening tests based on those compounds."

BioScentDx plans to use canine scent detection to develop a non-invasive way of screening for cancer and other life-threatening diseases. As a next step, the company launched a breast cancer study in November in which participants donate samples of their breath for screening by trained cancer-sniffing dogs. The researchers also plan to separate the samples into their chemical components and present these to the dogs to isolate the substances causing the odor that the dogs detect.

Source: https://experimentalbiology.org/2019/home.aspx

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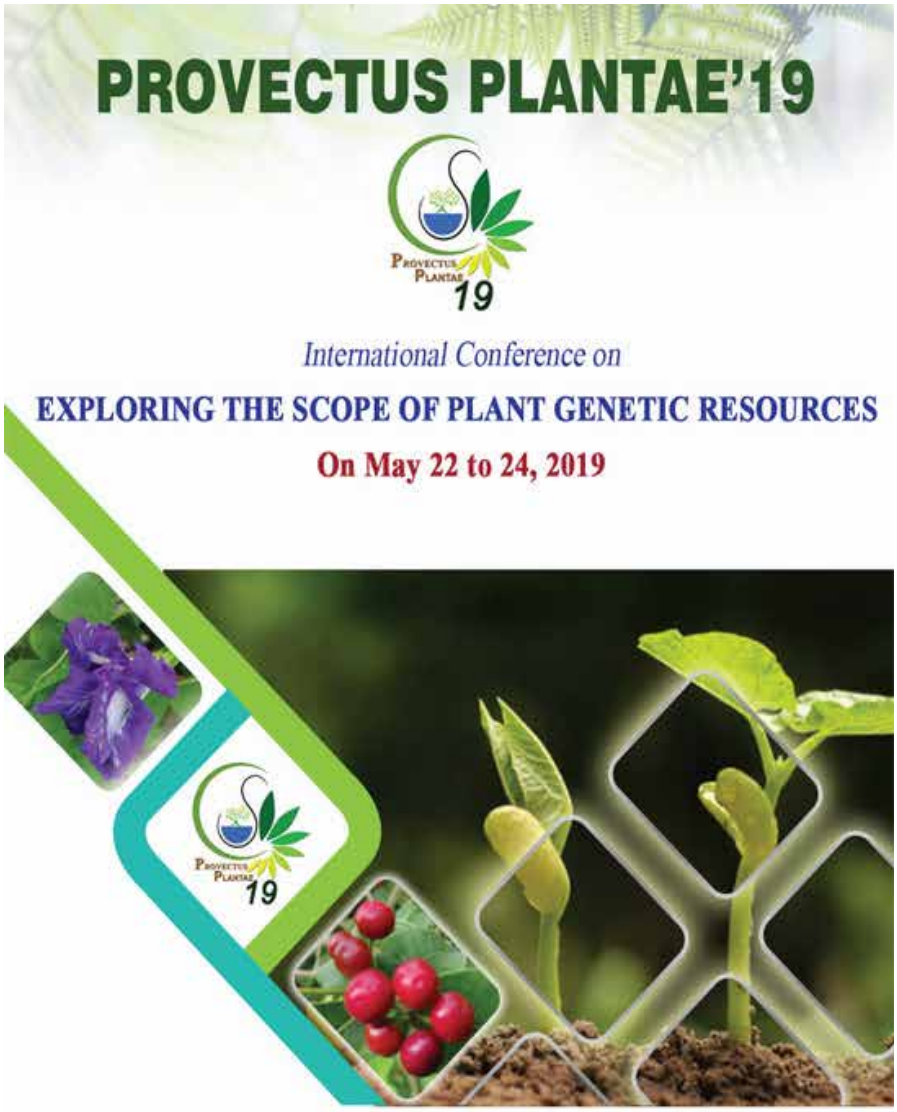
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NOTIFICATIONS

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The official notification for the PhD Science Admissions 2019 at AcSIR. Admissions AcSIR for Biological Sciences area 2019.

Eligibility Criteria for PhD (Sciences) and Sponsored PhD (Sciences)

PhD (Sciences):
Candidates with a Bachelor's degree in Engineering/ Technology, Medicine or Master's degree in Science with a keen sense of scientific enquiry for pursuing advanced research in frontier areas of Biological, Chemical, Physical and Mathematical & Information Sciences leading to a Ph.D. degree.
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Project Assistants, Senior Research Fellows and CSIR Scientists are also eligible to apply (as per AcSIR Ordinance No. 4(5)).

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Master's degree in Science with endorsement from Industry, Academic or Research Institutes for required academic leave and financial support during program.

Applicants qualifying their degree in percentage shall use the formula, CGPA=(Percentage + 5) /10. Applicants with percentage ≥ 95%, shall fill 10 CGPA.

Important Dates
23-05-2019 is Last date of submission of Online Application.
More Info: http://acsir.emli.in/ACSIRAdmissionPortal/online-admission/portal/acsir-online-adm-portal/index.php#

INDIAN COUNCIL OF MEDICAL RESEARCH
Division of Human Resource Planning & Development (HRD)

APPLICATIONS ARE INVITED FOR THE POST OF CONSULTANT (SCIENTIFIC)-NON-MEDICAL

No. 01/Head-HRD/Sci-B-02-2018 Dated: 08.04.2019

Applications are invited for one contractual post of Consultant (Scientific)- Non-Medical, for a period of six months (extendable as per requirement), in the Division of HRD, ICMR Hqrs., New Delhi. The interested candidates may send their application form duly filled and signed as per prescribed format given in **Annexure–I** (given below) along with self-attested documents *viz.* (Academic Degrees/Certificates, Professional degrees/Certificates, Caste certificate [if applicable] and detailed Curriculum Vitae). Only the shortlisted candidates will be called for Interview and will be informed through email accordingly.
The last date for submitting the applications is **22nd April 2019 (5:30 pm)** by post addressed to:

Senior Administrative Officer
R. No. 424,
Division of HRD,
V. Ramalingaswami Bhawan,
Ansari Nagar,
New Delhi-110029
Note: *Envelope should be super scribed with Post Name*

Following is the criteria for eligibility and other information:

1. **Duties/Responsibilities of the Consultant (Scientific):**

   i. Management of HRD programs, viz. Junior research Fellowship (JRF), Post Doctoral Fellowship (PDF), MD Thesis, International Travel Grant Support, etc.

   ii. Helping and assisting the Head of the Division as required.

   iii. Any other work assigned by Divisional Head from time to time

2. **Qualifications-**

   Essential: 1st class Master's degree in any field of Life Sciences/ Biological Sciences from a recognized university or 2nd class Master's degree with Ph.D. degree in Life Sciences/ Biological Sciences from a recognized university, with research & development experience and published papers.
   Desirable: Post-Doctoral research experience, Experience/skill in scientific writing, Handling of Databases, Knowledge of IT/computers.

Department of Biotechnology
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CALL FOR PRE-PROPOSALS

Artificial Intelligence Applications for Affordable and Accessible Healthcare -Big Data and Genomics

(Last date for submission – 15th May, 2019)

BACKGROUND

Artificial intelligence (AI) aims to mimic human cognitive functions. It is bringing a paradigm shift to healthcare, powered by increasing availability of healthcare data and rapid progress of analytics techniques. Often requiring to perform repetitive tasks and analyzing millions of data - structured and unstructured, AI comes as a perfect way to deal with these challenges. Integration of AI approaches such as machine learning, deep learning, and natural language processing to tackle the challenges of scalability and high dimensionality of data, better understanding of genomics and find patterns in the data that makes sense and to transform big data into clinically actionable knowledge is expanding. Department of Biotechnology (DBT) announces this Call under the new initiative "Artificial Intelligence Applications for Affordable and Accessible Healthcare - Big Data and Genomics".

MODE OF SUBMISSION

Pre-Proposals may be submitted in the prescribed Format, clearly stating 'Pre-Proposal on Artificial Intelligence Applications for Affordable and Accessible Healthcare - Big Data and Genomics' in the subject line of the email and send it to bioinformatics@dbt.nic.in. Your queries, if any, may be addressed to Dr. Suchita Ninawe, Adviser/Scientist 'G' at this same email ID. The closing date of the call is 15th May, 2019.

Subsequently, two hard copies should also be sent to: Bio-informatics Division, Department of Biotechnology, Block-2, Room No. 707, 7 th Floor, CGO Complex, Lodhi Road, New Delhi110003. Please mention 'Pre-Proposal on Artificial Intelligence Applications for Affordable and Accessible Healthcare - Big Data and Genomics' on the envelope. Hard copies should reach by 20th May, 2019.

Note: The proposal should be more scientific and technical and should contain all the details and quantitative information e.g. size of data, algorithms, tools, softwares to be used, etc., that may require by the Committee to evaluate it. However, repetitions and not-relevant information may be avoided. The Preproposal document should not be more than 12 pages (including CVs and enclosures, if any), A4 size, Times New Roman, 12 font size, normal margins.

INDIAN COUNCIL OF MEDICAL RESEARCH
Division of Epidemiology and Communicable Diseases

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Application are invited on plain paper for purely temporary contractual post of **Scientist 'B' (Non-Medical)** in Division of Epidemiology and Communicable Diseases in ICMR Project at ICMR Hqrs., New Delhi

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Essential Qualification

- 1st Class Master's degree in Life Sciences from a recognized university with 2 years experience in related field (Bioinformatics)

  OR

  2nd Class Master's Degree with Ph.D in relevant subject from a recognized University

  OR
- BDS/ B.V.Sc degree with one year experience.

Desirable Qualification

- Master's Degree in Life Science with Ph.D Degree. Post-Doctoral research experience, Experience of working in a scientific/public health related projects, proficient with computer programming and data analytics. Basic knowledge of life science public health and computer application, data entry and analysis on **DHIS2 platform**.

Job Requirements : Project Management and coordination, data entry and analysis.

The candidates are requested to submit their application on plain paper with complete details with a recent passport size photograph duly affixed on it, and self attested photocopies of all relevant certificates latest **by 22.04.2019 till 2:00 pm to the office of Dr. Nivedita Gupta, Scientist 'E' in room number 315. Phone/mobile number and e-mail address need to be provided in the application.** Eligible candidates would be shortlisted and informed about the date of interview.

Eligible candidates who will be called for- interview are required to bring five sets of photocopies of their Curriculum Vitae and all other certificates/testimonials as also the original certificates for verification.

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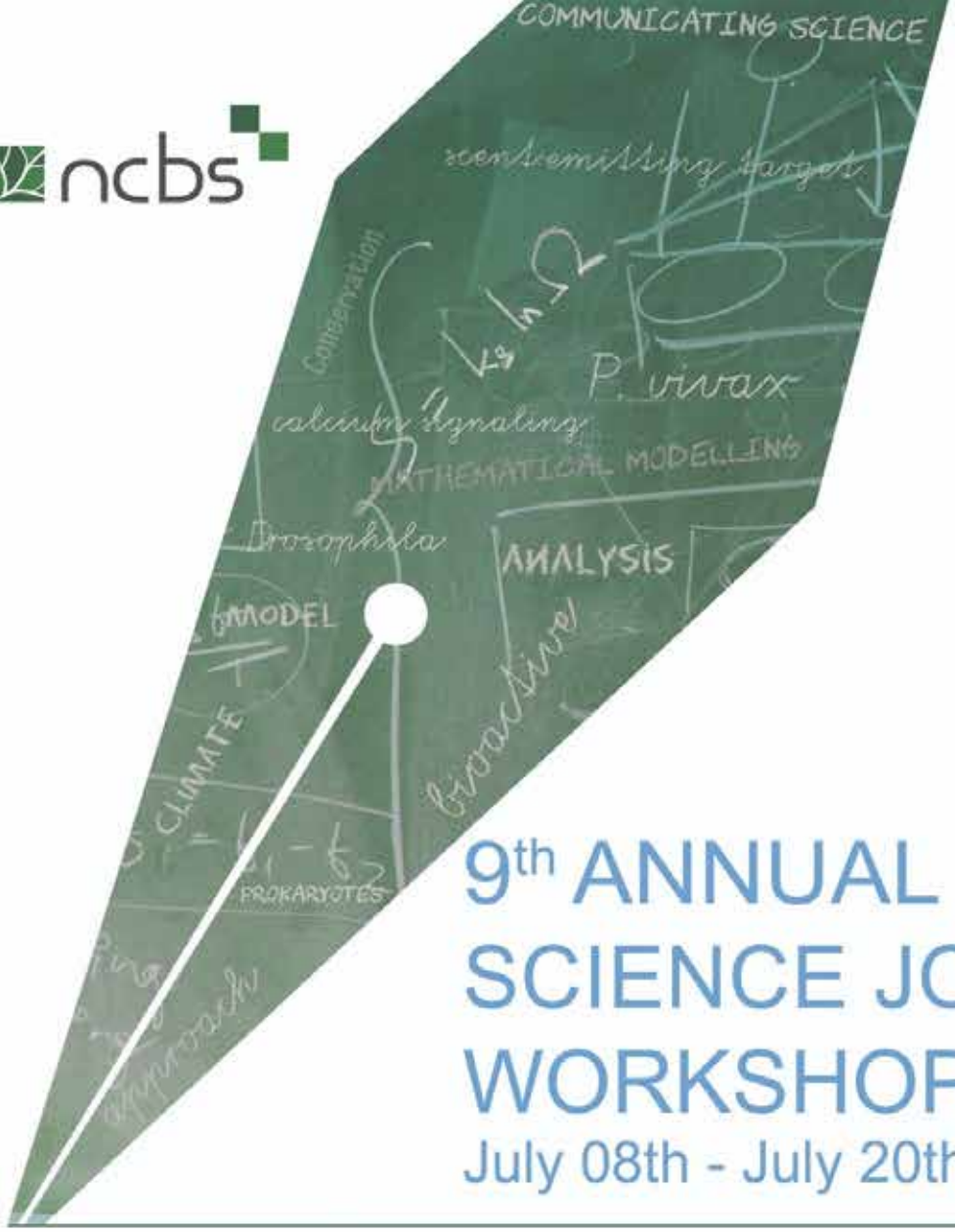

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