

Proteomics Special Issue

BIOTECH EXPRESS

Editorial: From protein to proteomics – A quick 230 year snapshot

Press Release:
What's important for Biotech STARUPS in BioAsia 2019

Editorial: Proteomics companies in India

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WHO employs directors for Western Pacific and Southeast Asia regions

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Micromotors to deliver oral vaccines

Interview Republished:

Why Only 10 Indians on list of world's 4,000 top scientists: Explained by Dr. Ashok Pandey, who secured a place in the list



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



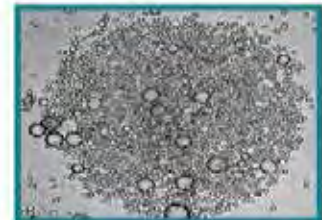
Transchymal-DP is Human deciduous teeth derived primary pluripotent stem cell aggregate model that can predict test chemical's safety and efficacy invitro



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
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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



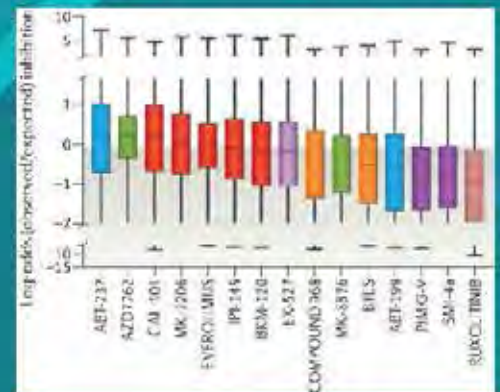
Turbidity Measurements



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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February 2019

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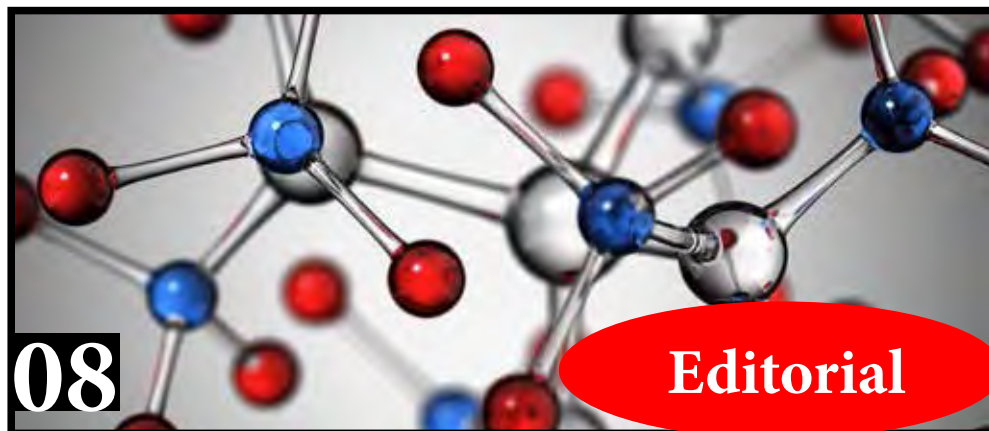
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From protein to proteomics – A quick 230 year snapshot

by Dr Seema Pavgi Upadhye

It was the first time in 1789 when Antoine Fourcroy distinguished several types of proteins (then called “albumins” or “Eiweisskörper”) such as albumin, fibrin, gelatin, and gluten. Today in 2019 we have evolved to Proteomics when we can study total proteins of a cell or an individual. The transition occurs due to knowledge and efforts of great many scientists which is further helping us to combat major issues like medical, food, environment and many others.

Although, there are many research papers and books where one can find details of discoveries, the major discoveries in proteomics can be summarized as Leucine was the first amino acid discovered in 1819 and threonine was last amino discovered in 1936. In 1902, Emil Fischer and Franz Hofmeister (independently) discovered the peptide bond. In 1934, J. D. Bernal and Dorothy Crowfoot Hodgkin obtain the first sharp X-ray diffraction pattern for a crystalline protein (pepsin), confirming its compact globular shape. In 1937, A. Tiselius (Nobel Prize in Chemistry, 1948) devises preparative electrophoretic methods to separate serum proteins

into four major groups. In 1941, A. J. P. Martin and R. L. M. Synge (Nobel Prize in Chemistry, 1952) adapt M. S. Tswett's method of chromatography (1906) to separate amino acids from protein hydrolysates.

Presence of peptide bond led scientists to think about chain of amino acids and finally first in 1955 English biochemist Frederick Sanger sequenced the amino acids of insulin, the first of any protein for which he was awarded Nobel prize in Chemistry in 1958. Har Gobind Khorana shared the 1968 Nobel Prize for Physiology or Medicine with Marshall W. Nirenberg and Robert W. Holley for research that showed the order of nucleotides in nucleic acids, which carry the genetic code of the cell and control the cell's synthesis of proteins.

Understanding of DNA and protein sequence soon led to the generation of many sequences of proteins. The next task was to determine structure of proteins, the first protein structures to be solved were hemoglobin and myoglobin, by Max Perutz and John Cowdery Kendrew, respectively, in 1958. Simultaneously, work of G N Ramachandran from India led to his creation of the Ramachandran plot for understanding peptide structure. He was the first to propose a triple-helical model for the structure of collagen.

After the sequencing the next task was to determine structure of proteins in great detail. It was in 1964 when Aaron Klug, working in Cambridge, showed X-ray diffraction can

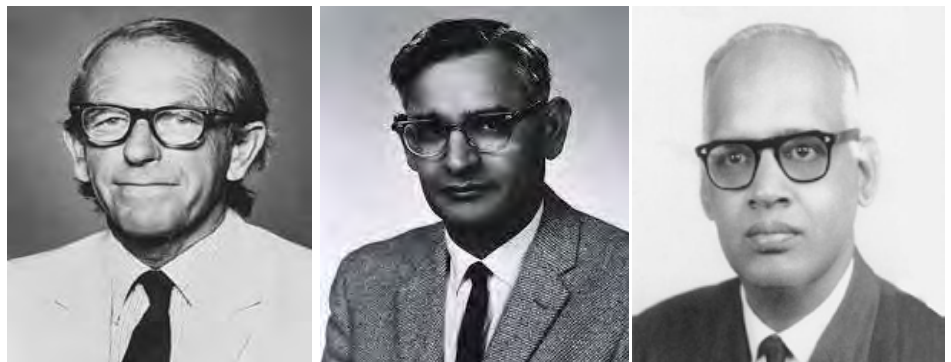


Photo: (L-R) Frederick Sanger, Har Gobind Khorana, G N Ramachandran

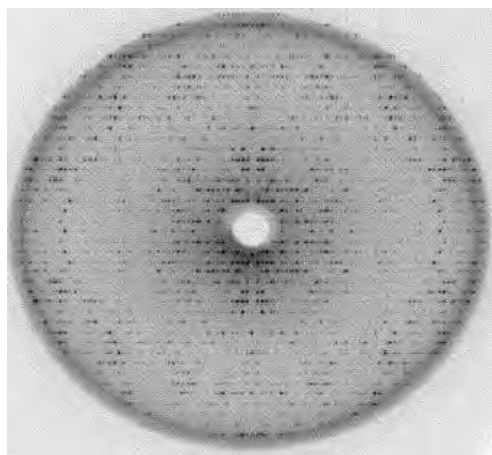


Photo: X-Ray Diffraction Pattern

be used to develop crystallographic electron microscopy, which helped scientists to study structures of intact viruses. Klug received the 1982 Nobel Prize in chemistry for the development of this

technique and his structural studies. Pioneering work in 1968 by David Davies, Brian Matthews, and others began to reveal the 3-D structures of antibodies (also called immunoglobins). Nobel Prize winner Dorothy Hodgkin deciphered the molecular structure of insulin in 1969 using X-ray crystallography.

Until 1972 scientists were studying what is available around them, but in 1973 one more breakthrough came which changed the way scientists think. In 1973, Herbert Boyer and Stanley N. Cohen developed recombinant DNA technology, showing that genetically engineered DNA molecules may be cloned in foreign cells.

Protein research was once again revolutionized after the discovery of fluorescent component in the bioluminescent organs of *Aequorea victoria* jellyfish, noted by Davenport and Nicol in 1955 (Davenport and Nicol 1955), but it was Osamu Shimomura of Princeton University who was the first to realize that this fluorophore was actually a protein. The complete primary sequence of this 238 amino acids of *Aequorea* green fluorescent protein was not revealed until the cloning and sequencing of its cDNA by Prasher in 1992 (Prasher et al. 1992).

The Sequences and structure of many proteins soon raised the need of classifying proteins based on different criteria. So, the first protein database was established and named Protein Data Bank (PDB) in the 1970's. The Protein Data Bank was announced in October 1971 as a joint venture between Cambridge Crystallographic Data Centre, UK and Brookhaven National Laboratory, USA. The PDB, now headquartered at Rutgers University and houses more than 50,000 structures. Today, in 2019, the number of Protein databases are enormous, they have emerged according to the need and specializations of researchers. For example, Swiss-Prot provides manually annotated and reviewed

data whereas TrEMBL has automatically annotated protein data. UniProt UniRef UniParc, NCBI, ProDom, Pfam, iProClass, SCOP, O-GlycBase, eSLDB, ReLiBase, ProTherm, iProLINK, SRS etc.

From 1980s protein Science has seen advancements with the invention or applications of various techniques. To generate more information and knowledge for the welfare of human, the Human Proteome Project (HPP) was conceptualized in 2010, which aims to characterize all 20,300 genes of the known genome, thereby to become a resource to help elucidate biological and molecular function and advance diagnosis and treatment of diseases.

Slowly the discovery of RDT led to more proteins and industrialization of Protein biology or what we say Biotechnology, because now people were able to synthesize proteins of human origin into other organisms like bacteria and yeast. For example, in 1982, human insulin was the first recombinant protein that was FDA approved for use in humans as a biopharmaceutical product.

HGP and HPP has provide enormous valuable information about genome and proteomic architecture of human and this has helped BioPharma manufacturers to make more robust and affordable drugs. Today there are hundreds of products which have been approved by FDA as BioPharmaceuticals and/or Biobetter, and hundreds are in discovery pipeline or waiting for the approval.

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Editorial

Proteomics Research in India

by Kamal Pratap Singh

In 2005, eminent Indian scientist and late President A P J Abdul Kalam noted that India has the “potential to tap research opportunities in proteomics and biochips to help understand the biological processes and treat diseases. This is possible even though the country has missed the opportunity to partner in the human genome project

India has no dearth of protein Scientists and some like Har Gobind Khorana and G N Ramachandran have received global recognition for their outstanding discovery of Ribosome structure which has revolutionized the way drug makers think.

The proteomics in India was mainly started with cancer biomarkers discovery. This was followed by application of proteomics in Agri sciences. India took the initiative in 2001–2002 when the Council of Scientific and Industrial Research (CSIR) initiated and supported a multi-institutional project on “New targets and biomarkers for cancer using Genomics and Proteomics” involving the CCMB, Hyderabad, Tata Memorial Centre-ACTREC, Navi Mumbai, IISc, Bengaluru, and Sri Sathya Sai Institute of Higher Medical Sciences, Bengaluru.

Proteomics in India was started with convention 2D gel electrophoresis, however tissue microarray and immunohistochemistry based protein profiling in various cancers was first done by Dr Sanjay Navani.

He and Lab Surg Path was acknowledged for the major contribution regarding annotation of immunohistochemically stained normal and cancer tissues, according to Human Proteome Atlas initiative.

Along with global research initiative Pandey and Kuster labs have independently drafted the ‘Human Proteome Maps’ using high-resolution mass spectrometry.

India has various higher authorities which provide grants for proteomics research. The collegium include Department of Biotechnology (DBT), Department of Science and Technology (DST), CSIR, ICMR and Board of Research in Nuclear Sciences (BRNS).

According to a Nature report India had 76 academic or research institutes and 145 labs working in the field of proteomics in year 2014. India also has great many institutions where Protein Biology is a routine thing. Also Indian scientists were part of “Human Proteome Project” which was completed in 2015.

There are around 76-80 Institutes in India where Scientists are exclusively working on Proteomics, though it cannot be said with surety but almost every institute which has biology in its curriculum is doing protein science to some or great extent. So this can make around a number 450 Institutes, in addition there are private players also which were not mentioned in any of the previous papers on Indian Proteomics. (see article proteomics companies in India of this issue)

Indian Proteomics databases: Some of the best protein databases which emerge from India are FISHPROT, Human Protein Reference Database (HPRD), Human Proteinpedia, Plasma Proteome Database, NetPath (a database of human signalling pathways), Pancreatic Cancer Database (PCD), Resource for Asian Primary Immunodeficiency Diseases (RAPID) etc.

The Indian Institute of Technology-Bombay (IITB) was the first institution which designed Virtual courses like the “Virtual Proteomics Laboratory (VPL)” and “Clinical Proteomics Remote Triggering Virtual Laboratory (CPRTVL)”. The VPL project consists of three modules; gel-based proteomics, MALDI-TOF/MS and Bioinformatics comprising experiments, simulations and animations. These programs were designed too give available knowledge to protein scientists who are expanding towards proteomics research.

India also has dedicated Society for proteomics. Established in 2009, the Proteomics Society, India (PSI) emerged out as a platform to foster interactions within the Indian proteomics community and to encourage exchange of ideas, enhance collaborations and boost innovations at the national and international level. Prof Utpal Tatu from IISc is the current President of the society.

Some of the major institutions where proteomics is routine exercise are:

1. Institute of Bioinformatics (IOB), Bangalore

It has been a pioneer of Omics technologies and research in India since 2002. Established in 2008 by Dr. Akhilesh Pandey, the Proteomics Facility at IOB has been providing expertise, services, education and training to enhance biomedical research through mass spectrometry-based proteomics. In its endeavor to assist the scientific community in India, the Proteomics Facility at IOB has provided its expertise to researchers from a number of leading academic institutes. The Proteomics Facility at IOB is equipped to provide services related to qualitative and quantitative analyses of proteomes (e.g. TMT, SILAC and label-free based quantitation). The facility also assists with computational analysis and in the development of customized applications for isolation, detection, characterization and quantitative analysis of post-translational mod-

ifications such as phosphorylation, acetylation and ubiquitylation.

Instruments IOB having are QExactive Plus mass spectrometer, Orbitrap Velos mass spectrometer, Thermo Scientific Easy n-LC 1000, Agilent 1200-infinity series HPLC systems, expedeon Gelfree 8100 Protein Fractionation System, Agilent 3100 OFFGEL Fractionator, Barocycler, Multiskan GO UV/Vis, Spectrophotometer, Lyophilizer, Vacuum Concentrator.

2. RGCB, Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram

RGCB Proteomics Core Facility houses the following instrumentation: Synapt G2-HDMS from Waters, NanoAcquity UPLCs from Waters, Hydrogen Deuterium Exchanger (HDX) from Waters, UltrafleXtreme MALDI-TOF/TOF from Bruker Daltonik, EASY-nLC II from Bruker, MALDI Tissue Imaging Setup from Bruker, Off-Gel Liquid Phase IEF system from Agilent, ProteOn™ XPR36 Surface Plasmon Resonance (SPR) System (Bio-Rad), Experion Microfluidic base-on-Chip, Electrophoresis System (Biorad), AB SCIEX 3200 QTRAP® LC/MS/MS System

3. MBU, IISc, BANGALORE

Facilities: UltrafleXtreme MALDI TOF/TOF (Bruker Daltonics), HCT Ultra PTM Discovery System (ETD II- Bruker Daltonics) with 1100 series HPLC (Agilent), Bruker Daltonics ESI Q TOF-(Maxis Impact) with Nano LC (Proxeon easy nLC).

4. CSIR-CCMB

CCMB is equipped with state-of-the-art chromatography systems and mass spectrometers for LC-MS and LC-MS/MS, with a wide range of bioinformatic tools for data interpretation and evaluation. The facility provides a range of services, including:

- Intact molecular weight measurement of proteins
- Protein identification from gel bands
- Protein identification from complex mixtures

- Identification of post-translational modifications
- SILAC, iTRAQ, and label-free quantification of peptides and proteins

Instrument platforms in CSIR CCMB include Q-Exactive-HF, Q-Exactive, Orbitrap Velos, and MDS SCIEX 4800 MALDI TOF/TOF mass spectrometers, ultra-high performance EASY-nLC 1200 Systems.

5. ICGEB, New Delhi

The Proteomics Facility uses state of the art techniques in mass spectrometry for protein identification, protein quantification, and the mapping of post translational modifications. The facility is equipped with modern electrophoresis and HPLC equipment for sample preparation and separation. The facility is currently equipped with two mass spectrometers: a Thermo Finnigan LCQdeca ion trap mass spectrometer, and an Applied Biosystems 4800 MALDI TOF/TOF.

6. Proteomics Laboratory at the Indian Institute of Technology Bombay India (IITB)

Dr. Sanjeeva Srivastava is the Group Leader of the Proteomics Laboratory at the Indian Institute of Technology Bombay India (IITB). He obtained his Ph.D. from the University of Alberta and further did post-doc from the Harvard Medical School in the area of proteomics, stress physiology and has specialized expertise in the applications of data-enabled sciences in global health, developing countries and resource-limited settings.

Current research in his group centers on biomarker and drug target discovery and deciphering the protein interaction networks in complex human diseases (e.g., gliomas) as well as infectious diseases (e.g., malaria) with the use of high throughput proteomics, nanoproteomics, protein microarrays, DIGE and mass spectrometry. Additionally, multi-dimensional Omics data are employed for in silico studies and models.

The group has developed E-learning resources such as Virtual Proteomics Laboratory and Open Source

Courseware Animations Repository as a community resource and is collaborating actively both across India and internationally to advance this knowledge frontier for the benefit of global health.

Dr. Srivastava has taught proteomics courses at the Cold Spring Harbor Laboratory and is the recipient of several awards including the National Young Scientist Award (Canada), Young Scientist Awards (Department of Atomic Energy and Board of Research in Nuclear Sciences India and the Department of Science and Technology India) and the Apple Research Technology Support Award (UK). His name is included in Who's Who in Medicine and Healthcare in Nov 2011 edition of Marquis Who's Who, USA.

Keeping pace with the growing proteomics research efforts, India is actively participating in global proteomics organisational activities and initiatives including the Human Proteome Organization (HUPO), Chromosome centric Human Proteome Project (C-HPP), Asia Oceania Human Proteome Organization (AOHUPO), International Plant Proteomics Organization (INPPO) and Asia Oceania Agricultural Proteomics Organization (AOAPO)

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Editorial

Protein Biosimilar drugs in India: Current status

By Kamal Pratap Singh

Corresponding e-mail: biotechexpressindia@gmail.com

Protein Biologics are class of Biopharmaceuticals that are composed of protein molecules. Biologics, in general, can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living cells or tissues. Other Biologics include vaccines, blood, blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein, and living cells used in cell therapy (including stem cells).

Biosimilars are biologics that are highly similar to the reference biological product with no clinically meaningful differences in terms of safety profile, purity, and potency. Protein Biologics and Biosimilars include Modified human proteins, Monoclonal antibodies, Vaccines, Growth factors and cytokines, Hormones, and other protein Blood products.

Global biopharmaceuticals market was valued at USD 237250.8 million in 2018, and is estimated to be valued at USD 388997.3 million in 2024, witnessing a CAGR of 8.59%. according to a market research company Mordor Intelligence. According to the report it is also evident that almost Proteins in one way or

another has acquired every drug manufacturer's attention, Majorly they are Antibodies, Vaccines and recombinant proteins

Also, since approved Gene therapy products are rare anywhere in the world, the majority of market is dominated by Protein drugs.

Overall, the total number of patents granted for biopharmaceuticals has risen significantly since the 1970s. In 1978 the total patents granted was 30. This had climbed to 15,600 in 1995, and by 2001 there were 34,527 patent applications.

Protein Biosimilars are gaining much attention nowadays because of their effectiveness and many other factors that make them drug of choice. The first protein biosimilar approved for therapeutic use was biosynthetic "human" insulin made through recombinant DNA technology. Marketed under the trade name Humulin, it was developed by Genentech, but licensed to Eli Lilly and Company, who manufactured and marketed it from 1982.

How are Biologics/Biosimilars drugs approved in India?

In India, CDSCO is the national regulatory authority in India that evaluates safety, efficacy and quality of

Future Patent Expirations of Major Biologics



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drugs in the country. CDSCO, headed by the Drug Controller General of India (DCGI) is the apex regulatory body under Ministry of Health & Family Welfare (MoHFW), Government of India which is responsible for the approval of clinical trials as well as new drugs.

DBT through Review Committee on Genetic Manipulation (RCGM) is responsible for overseeing the development and preclinical evaluation of recombinant Biologics. The Similar Biologics are regulated as per the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 (as amended from time to time) and Rules for the manufacture, use, import, export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989 (Rules, 1989) notified under the Environment (Protection)

Act, 1986.

According to "Guidelines on Similar Biologic: Regulatory Requirements for Marketing Authorization in India" the approvals from following Indian authorities are required in the approval process of Biologics/Biosimilars:

1. Institutional BioSafety Committee (IBSC)

IBSC is required to be constituted by any person including research institutions handling hazardous microorganisms and/ or genetically engineered organisms. IBSC is responsible for ensuring biosafety on-site, along with initial review of applications to be recommended to RCGM. IBSC is also assigned with the responsibility to review and authorize firm for exchange of aforesaid organisms for the

purpose of research.

2. Review Committee on Genetic Manipulation (RCGM)

RCGM is functioning from the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India. In the context of Similar Biologics, RCGM is responsible for authorizing the conduct of research and development, exchange of genetically engineered cell banks for the purpose of research and development and review of data up to preclinical evaluation.

3. Genetic Engineering Appraisal Committee (GEAC)

GEAC functions under the Ministry of Environment and Forests (MoEF) as statutory body for review of applications and approval of activities where final drug product contains genetically modified organisms/ living modified organisms.

4. Central Drugs Standard Control Organization (CDSCO)

CDSCO, headed by the Drug Controller General of India (DCGI) is the apex regulatory body under Ministry of Health & Family Welfare (MoHFW), Government of India which is responsible for the approval of clinical trials as well as new drugs. In the context of Similar Biologics, CDSCO is responsible for clinical trial approval (also grants permission for import of drugs for clinical trial and export of clinical samples for biochemical and immunological analysis) and permission for marketing and manufacturing.

How are Biologics/Biosimilars drugs approved in U.S.

In the United States, biologics are licensed through the biologics license application (BLA), then submitted to and regulated by the FDA's Center for Biologics Evaluation and Research (CBER) whereas drugs are regulated by the Center for Drug Evaluation and Research. Approval may require several years of clinical trials, including trials with human volunteers. Even after the drug is released, it will still be moni-

tored for performance and safety risks. The manufacture process must satisfy the FDA's "Good Manufacturing Practices", which are typically manufactured in a clean room environment with strict limits on the amount of airborne particles and other microbial contaminants that may alter the efficacy of the drug. USFDA approved first biosimilar in 2015.

How are Biologics/Biosimilars drugs approved in the European Union

In the European Union (EU), a legal framework for approving biosimilars was established in 2003. This framework means that biosimilars can only be approved centrally via the European Medicines Agency (EMA) and not nationally. Omnitrope (somatropin) was the first product approved in the EU as a biosimilar in 2006, To date, EMA has approved 58 biosimilars. EMA's scientific committees evaluate the majority of marketing authorisation applications for biosimilar medicines before they can be approved and marketed in the EU. EMA evaluates biosimilars according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines approved in the EU.

Current most selling Biosimilar in the market

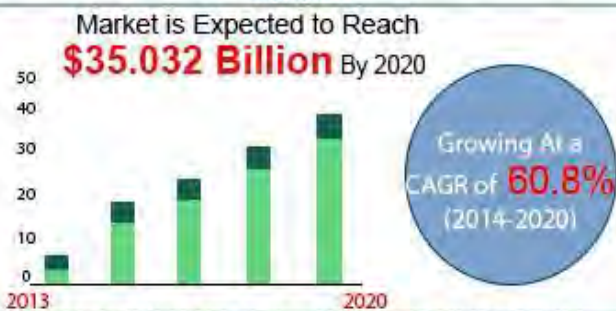
Today there are around hundred Biosimilars which are available in the market, but here we are discussing the biologics that achieved bumper revenue for their developers and manufacturers. List of Biologics and Biosimilar which are sold worldwide, in alphabetical order are as follows:

1. Abatacept - Abatacept is recombinant protein that is used for treating rheumatoid arthritis. It is an immunosuppressant, a drug that suppresses the immune system. It is sold under brand name Orencia.

BioSimilar: None

2. Adalimumab - Adalimumab was the first fully hu-

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET



GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET BY TECHNOLOGY

- Monoclonal Antibodies (MAb) Technology
- Nuclear magnetic resonance (NMR) technology
- Electrophoresis
- Western Blotting
- Recombinant DNA Technology (rDNA technology)
- Chromatography
- Mass Spectrometry
- Bioassay

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET BY APPLICATIONS

- Blood disorders
- Oncology diseases
- Chronic and autoimmune diseases
- Growth hormone deficiencies

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET BY PRODUCT TYPE

- Recombinant Non-Glycosylated Protein
- Recombinant Glycosylated Protein
- Peptides

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET BY SERVICES

- Contract Research and Manufacturing Services (CRMS)
- Clinical trials

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET BY GEOGRAPHY



North America, Europe, LAMEA
Asia-Pacific **\$1.110 Billion**
 Highest Revenue Generating Geography By 2020

GLOBAL BIOSIMILARS/FOLLOW-ON-BIOLOGICS MARKET DYNAMICS

Drivers

- Growing pressure to reduce healthcare expenditure
- Various blockbusters going off patent
- High prevalence of chronic diseases among aging population
- Favorable intervention from the developing economies

Restraints

- High initial investment in research and development
- Stringent regulations in developed economies to restrict investment
- Medical Efficacy and Patient Safety

man monoclonal antibody approved by the U.S. Food and Drug Administration. It is sold under brand name Humira. It was the third TNF inhibitor, after infliximab and etanercept, to be approved in the United States. It was constructed from a fully human monoclonal antibody, while infliximab is a mouse-human chimeric antibody and etanercept is a TNF receptor-IgG fusion protein.

BioSimilar: Amjevita, Cyltezo, Hyrimoz, TBD

4. Erythropoietin Erythropoietin (EPO) is a growth factor produced in the kidneys that stimulates the production of red blood cells. Epoetin alfa (Epo) was developed by Amgen Inc. in 1983 as the first rhEPO commercialized in the United States, followed by other alfa and beta formulations. It is used for the treatment of patients with anemia associated with various

clinical conditions, such as chronic renal failure, antiviral drug therapy, chemotherapy, or a high risk for perioperative blood loss from surgical procedures

BioSimilar: Retacrit, Binocrit, Biopoin, Epoetin, Epogen etc.

5. Bevacizumab - Bevacizumab is a recombinant humanized monoclonal antibody and in 2004 it became the first clinically used angiogenesis inhibitor. IgG1 antibody binds to and inhibits the biologic activity of human vascular endothelial growth factor (VEGF). It is sold under the trade name Avastin. It is a medication used to treat a number of types of cancers and a specific eye disease.

BioSimilar: Mvasi

6. Darbepoetin alfa is a re-engineered form of erythropoietin containing 5 amino acid changes. It stimulates erythropoiesis (increases red blood cell levels). Darbepoetin alfa binds to the erythropoietin receptor on erythroid progenitor cells, stimulating RBC production and differentiation. Darbepoetin is marketed by Amgen under the trade name Aranesp.

BioSimilar: Epogen, Cresp, Procrit

7. Denileukin diftitox is a recombinant fusion protein of human interleukin-2 (IL-2) attached to diphtheria toxin fragments A and B that is used as an anti-neoplastic agent to treat cutaneous T cell lymphomas that express IL-2 receptors. It is sold under the brand name Ontak.

8. Etanercept is a fusion protein produced by recombinant DNA made from the combination of two naturally occurring soluble human 75-kilodalton TNF receptors linked to an Fc portion of an IgG1. It treats autoimmune diseases by acting as a TNF inhibitor. It has U.S. F.D.A. approval to treat rheumatoid arthritis, juvenile idiopathic arthritis and psoriatic arthritis, plaque psoriasis and ankylosing spondylitis. It is sold under brand name Enbrel.

BioSimilar: Etacept, Benepali, Erelzi

9. Filgrastim - Filgrastim is a human granulocyte colony stimulating factor. It is used to treat neutropenia, stimulating the bone marrow to increase production of neutrophils. It is sold under brand name Neupogen.

BioSimilar: Filca, Imuma, Grafee, Neukine, Emgrast, Religras, Nufi, Zarzio.

10. Golimumab is a human IgG1 monoclonal antibody derived from immunizing genetically engineered mice with human TNF α . It inhibits tumor necrosis factor alpha. It is sold under the brand name Simponi.

11. Infliximab - Infliximab is a chimeric monoclonal antibody biologic drug that works against tumor necrosis factor alpha (TNF- α) and is used to treat autoimmune diseases. It is sold under brand name Remicade.

BioSimilar: Inflectra, Remsima, Renflexis, Flixabi, Ixifi

12. Insulin human is a 51 residue peptide hormone, composed of two amino acid chains covalently linked by disulfide bonds. The structure is identical to native human insulin. Recombinant insulin is synthesized by recombinant DNA technology. Inserting the human insulin gene into the *Escherichia coli* bacteria or *Saccharomyces cerevisiae* produces insulin for human use. It is sold under brand name Actraphane among many many others. We wrote many two times because it is the protein drug which is manufactured by most of the biosimilar drug manufacturers.

BioSimilar: Huminsulin, Insuman, Lupisulin etc.

12.a Insulin Glargine: Insulin glargine is a long-acting form of insulin used for the treatment of hyperglycemia caused by Type 1 and Type 2 Diabetes. Insulin glargine differs from endogenous human insulin by the replacement of an asparagine residue at position A21 of the A-chain with glycine and addition of two arginines to the C-terminus (positions B31 and 32) of the B-chain. The resulting protein is soluble at pH 4 and forms microprecipitates at physiological pH 7.4 allowing for the slow release of small amounts of insulin glargine, giving the drug a long duration of action and no pronounced peak concentration. It is sold under brand name Lantus.

BioSimilar: Lusduna, Basaglar

13. Pegfilgrastim - Pegfilgrastim is a modified form of filgrastim which has been PEGylated at the N-terminus. It is sold under brand name Neulasta. It is a form of human G-CSF (Granulocyte colony stimulating factor) consisting of 175 residues and is produced from *E. coli* via bacterial fermentation. It is used in the treatment of chemotherapy-induced neutropenia by enhancing the production of neutrophils. Pegfilgrastim acts on hematopoietic cells by binding to specific cell surface receptors thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.

BioSimilar: Fulphila, Udenyca, Neupopeg, Nivestym, Truxima

14. Rituximab - Rituximab is a chimeric monoclonal antibody against the protein CD20, which is primarily found on the surface of immune system B cells. When

it binds to this protein it triggers cell death. Rituximab was approved for medical use in 1997. It is sold under the brand name Rituxan among others. Rituximab is used to treat certain types of cancer (such as non-Hodgkin's lymphoma, chronic lymphocytic leukemia). Rituximab is also used to treat rheumatoid arthritis and can decrease joint pain and swelling. It is also used to treat certain types of blood vessel disease (such as Wegener's granulomatosis, microscopic polyangiitis) and can decrease the swelling of the blood vessels. Rituximab is also used to treat a certain skin condition (pemphigus vulgaris). It helps to reduce the number of skin lesions.

BioSimilar: Rixathon, Ocrelizumab, Ofatumumab, Obinutuzumab

15. Somatropin – somatotropin also known as human growth hormone (hGH or HGH) in its human form, is a peptide hormone that stimulates growth, cell reproduction, and cell regeneration in humans and other animals. A recombinant form of hGH called somatropin (INN) is used as a prescription drug to treat children's growth disorders and adult growth hormone deficiency. Genotropin

BioSimilar: Bio-tropin, Humatrope, Nutropin, Omnitrope, Omnitrope, Serostim

16. Trastuzumab - Trastuzumab is a humanized IgG1 kappa monoclonal antibody that selectively binds with high affinity to the extracellular domain of the human epidermal growth factor receptor 2 protein, HER2. sold under the brand name Herceptin among others. Specifically it is used for breast cancer that is HER2 receptor positive. The drug was first discovered by scientists including Dr. Axel Ullrich and Dr. H. Michael Shepard at Genentech, Inc. in South San Francisco, CA.

BioSimilar: Ontruzant

17. Ustekinumab is a human monoclonal antibody used to treat psoriasis. It is a laboratory-manufactured, monoclonal antibody directed against interleukins IL-12 and IL-23. It is sold under the brand name Stelara.

Remarks: The Protein Biosimilar market has achieved enormous growth in past decade because of many factors like acceptability by patients and doctors, decrease in price and several other factors. Hundreds of Products are in pipeline and soon will be ready to hit the worldwide market. Although the information given in this article is true to writers's knowledge, the readers are advised to fact check the points before concluding anything.

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Editorial

Proteomics companies in India

By Kamal Pratap Singh

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Founded by Dr. K.I. Varaprasad Reddy in 1993, Shantha Biotechnics was one of the first Indian biotechs to create a recombinant product, obtaining World Health Organization (WHO) prequalification for its Hepatitis B vaccine in 2002. Then, the firm grown to 750 employees and brought 11 novel products to market. In 2009, Shantha sold over 120 million doses of Hepatitis B vaccine to dozens of developing countries around the world and had revenues exceeding USD\$90 million [1]. Later, in 2019, Shantha Biotechnics was acquired by the multinational giant Sanofi-Aventis (France) at a valuation of USD\$784 million.

The example given above shows how profitable is to produce biosimilars in India when its environment provides easy regulations and production. In India, the first “similar biologic” was approved and marketed much before the U.S. approved its first biosimilar in 2015.

About 100 protein biosimilars are currently available in the market and according to an analysis by Decision Resources Group in 2017, more than 40 biosimilars were in clinical development in India, equal those in development in the European Economic Area (EEA), and far more than in development in the United States. Feeling the market robustness many of the Pharma players have jumped already into Biopharmaceutical space, Reliance Life Science being the leader with as many as 14 Biosimilar products in their portfolio.

Lack of health coverage by all and need of patients to pay out from their pocket has led Indian companies to produce as much as 50% cheaper biopharma in some cases which led to the increase of sales around the globe.

The protein market of India is no less than any other developed economy because of extensive research and production going on in the country. India has many establishments and budding start-ups that are working in Protein Market domain.

Majority of Indian proteomics companies are involved in BioSimilar manufacturing. Few other companies are providing proteomics services to these big companies and to research institutions, however we have already

discussed Govt and NGOs which provide proteomics services in article “ ”

Altogether it makes a number around 110-120 companies which are involved in Protein Biology. Here is the list of major Indian Protein BioPharma companies with their products:

Top Indian Protein Biosimilar manufacturers/Suppliers

Here is the list of Indian companies which either produce or sell Biosimilars of other companies in India. This is a comprehensive list designed manually through comprehensive research of different websites like of Market research companies and online drugs suppliers. The BioPharma in India is fastly evolving and changes in sector takes fractions of second to occur. Though the list has been created with utmost care, readers are advised to go for cross check before making any decision out of this list.

Biologic	BioSimilar and Manufacturing/Marketing Company
Abatacept	Orencia (Bristol Myers Squibb)
Abciximab	AbcixiRel (Reliance Life Sciences)
Adalimumab	Adfrar (Torrent Pharmaceuticals), Exemptia (Zydus Cadila)
Bevacizumab	Bevacirel (Reliance Life Sciences), Bevacirel (Lupin), Cizumab (Hetero), Krabeva (Biocon)
Darbepoetin alfa	Actorise (Cipla/Hetero), Cresp (Dr Reddys Laboratories Ltd), Darbatitor (Torrent Pharmaceuticals)
Denileukin diftitox	ONTAK, (Eisai Pharmaceuticals)
Etanercept	Etacept (Cipla), Intacept (Intas Pharmaceuticals)
Erythropoietin	Zyrop (Cadila Healthcare), Ceriton (Ranbaxy Sun Pharma), Epofer (Emcure), Epopit/Erykine (Intas Pharmaceuticals), Eporec (Bioviz Technologies), Epotin (Claris Lifesciences), Erypro (Biocon), Relipoietin (Reliance Life Sciences), Repoitin (Serum Institute of India), Shanpoi- etin (Shantha Biotechnics/Merieux Alliance), Wepox (Wockhardt), Zyrop (Cadila Healthcare) etc.
Filgrastim	Emgrast (Gennova Biopharmaceuticals-Emcure), Fegrast (Claris Lifesciences), Filgrastim (Cadila Pharmaceutical), Filgrastim (Lupin), Filgrastim (USV), Grafeel (Dr. Reddy's Laboratories), Neukine (Intas Pharmaceuticals), Religrast (Reliance Life Sciences), Nufil (Biocon) etc.
Follitropin alfa	Folisurge (Intas Pharmaceuticals), FostiRel (Reliance Life Sciences)
Golimumab	Simponi Janssen Pharmaceuticals
Hepatitis B vaccines	Revac-B (Bharat Biotech), GeneVac-B (Serum Institute Of India Ltd.), Enivac HB (Panacea Biotec Ltd), Engerix-B (GSK Ltd), Biovac-B (Wockhardt) etc.
Human insulin	Insugen (Biocon), Wosulin (Wockhardt), Huminsulin (Eli Lilly and Company), Insuman (Sanofi India Ltd), Lupisulin (Lupin Ltd), Human Actrapid (Novo Nordisk India Pvt Ltd.) etc.
Insulin	Insulin (Gland Pharma) Sanofi and many others
Interferon alfa-2b	Intalfa (Intas Pharmaceuticals), Reliferon (Reliance Life Sciences), Shanferon (Shantha Biotechnics/Merieux Alliance), Zavonex (Cadila Healthcare)
Interferon beta-1a	Relibeta (Reliance Life Sciences)
Infliximab	Infimab (Epirus Biopharmaceuticals)
Insulin Glargine	Basalog (Biocon), Glaritus (Wockhardt)
Molgramostim	Molgramostim (Zenotech Laboratories)

Pegfilgrastim	Neupeg (Intas Pharmaceuticals), Pegex (Gennova Biopharmaceuticals-Emcure), Peg-filgrastim (Lupin), Peg-grafeel (Dr Reddy's Laboratories), Peg-interferon alfa 2b (Intas Pharmaceuticals) etc.
Rasburicase	Rasburicase (Virchow Biotech)
Ranibizumab	Razumab (Intas Pharmaceuticals)
Rituximab	Acellbia (Biocad), Maball (Hetero Group), MabTas (Intas Pharmaceuticals), Reditux (Dr. Reddy's Laboratories), RituxiRel (Reliance Life Sciences), Rituximab (Zenotech Laboratories), Toritz RA (Torrent Pharmaceutical) etc.
Retepase	MIrel (Reliance Life Sciences)
Somatropin	Saizen (Serum Institute of India Ltd.), Genotropin (Pfizer Ltd), Humatrope (Eli Lilly And Company (India) Pvt. Ltd). Norditropin Nordilet (Novo Nordisk Pharma India Ltd.) Genotropin (Pharmacia India (P) Ltd.) Zomacton (Ferring Pharmaceuticals) Eutropin (Lg Lifesciences) etc.
Streptokinase	Shankinase (Shantha Biotechnics/Merieux Alliance), Myokinase (Biocon)
Teriparatide	Terifrac (Intas Pharmaceuticals), Teriparatide (Cadila Healthcare), Teriparatide (USV)
Trastuzumab	CanMab(Biocon), Herclon (Roche), Herceptin (Roche), Biceltis (Emcure), Vivitra Zydu Cadila , Hersima Alkem Laboratories Ltd, Hermab RPG Life Sciences etc.

List of BioPharma Manufacturers/Suppliers companies in India

- | | |
|--------------------------------------|---|
| 1. Alembic Pharmaceuticals | 19. LG Lifesciences |
| 2. Alkem Laboratories | 20. Novo Nordisk India |
| 3. Aristo Pharmaceuticals | 21. Pfizer |
| 4. Biocon | 22. Ranbaxy |
| 5. Bharat Serums & Vaccines | 23. Reliance Life Sciences |
| 6. Biological E Ltd | 24. RPG Life Sciences |
| 7. Biochem Pharmaceutical Industries | 25. Sanofi India |
| 8. Claris | 26. Shantha Biotech |
| 9. Dabur India | 27. Samarth Life Sciences |
| 10. Dr. Reddy's Laboratories | 28. Serum Institute Of India |
| 11. Emcure | 29. Sun Pharmaceutical Industries |
| 12. Eli Lilly and Company | 30. Torrent Pharmaceuticals |
| 13. Ferring Pharmaceuticals | 31. USV Private |
| 14. Health Biotech | 32. Vhb Life Sciences |
| 15. Hetero Drugs | 33. Wockhardt |
| 16. Intas Biopharmaceuticals. | 34. Zydus Cadila |
| 17. Life Medicare & Biotech | 35. HLL Lifecare Limited (Govt. of India Enterprises) |
| 18. Lupin | |

Companies which provide proteomics and purification services:

The Global Proteomics Market is Segmented on the lines of Equipment Analysis, Application Analysis, Service Analysis and Regional Analysis. By Equipment Analysis this market is segmented on the basis of Chromatography, Protein Microarray, Mass Spectroscopy, Protein fractionation, X-ray Crystallography and Others. By Application Analysis this market is segmented on the basis of Drug discovery, Clinical Diagnosis and Others.

1. Shantani Proteome Analytics Pvt. Ltd.
2. Sandor Proteomics Pvt. Ltd.
3. Yashraj Biotechnology Ltd
4. SciGenom

5. Bhat Bio-Tech India (P) Ltd
6. Premas Biotech

Startups, MNCs and other Proteomics Service Providers in India

- | | |
|------------------------------------|-------------------------------|
| 1. Danone India | 11. Chromous Biotech |
| 2. Proteomics International- India | 12. DENOVO BIOLABS |
| 3. Ideal Protein | 13. Richcore |
| 4. SGS House | 14. Biotech India |
| 5. ABGENEX | 15. Nirav BioSolutions |
| 6. VProteomics | 16. Agri Life SOM Phytopharma |
| 7. Aumgene Biosciences | 17. Krishna Enzytech |
| 8. Bioklone Biotech Pvt | 18. Biotrance |
| 9. BioResouce Biotechnology | |
| 10. Biotrance Exim | |

Some key players in this market who are providing tools to researchers and manufactureres are Thermo Fisher Scientific, Inc., Agilent Technologies, Inc., Bio-Rad Laboratories, Inc., Merck KGaA, Danaher Corporation, Luminex Corporation, Perkinelmer, Inc., Waters Corporation, GE Healthcare etc.

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Advertorial

PROTEIN COMPANIES IN INDIA

YASHRAJ BIOTECHNOLOGY LIMITED (YBL)

20 YEARS OF EXCELLENCE IN TRANSFORMING WASTE TO WELL-BEING

By Dr. Gauri Awasthi, Senior Executive (Bioinformatics & Techno-Commercial)

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Introduction

Progress is not about how we grow, it is about how we make a difference in lives of others! This is the guiding principle at Yashraj Biotechnology Limited (YBL), a pioneering biotechnology company located in Navi Mumbai, India. The founder members of the company Mr. Arvind Bhanushali, Mr. Bharat Dagha and Dr. Paresh Bhanushali started the company in 1999 and this year the company is celebrating its 20 years of existence.

The company was established with a vision to be the best in the diagnostic field and make diagnostics affordable and easily available to the common man. Today, YBL is a leading name in the *in vitro* diagnostic market, supplying high purity Antigens, Antibodies, proteins and enzymes to some of the world's top 20 diagnostic companies.



The founders of YBL



Mr. Arvind K. Bhanushali is the Founder Director and the Chairman of the company. He is an experienced financial adviser to many reputed business groups in India and Abroad for more than 30 years.



Mr. Bharat T. Dagher is the Founder Director of the Company and is responsible for the Business Development & Marketing. Under his aegis the company has grown exponentially and successfully establish international branches in Germany, USA and South Korea.



Dr. Paresh B. Bhanushali is the Founder and Technical Director (Research & Development). He oversees activities in both R&D and Production departments. He holds a PhD Degree in Medical Biotechnology and has an extensive knowledge and experience in protein chemistry.

From Bio-Medical Waste to Diagnostic Application Products: An Innovative Approach

YBL capitalizes on usefulness of the human biomedical waste generated by the hospitals for diagnostic purposes by manufacturing Native Antigens (Table 1) which are purified from the effusions of patients suffering from cancer, renal, and cardiac failures. In addition to diagnostic use, the manufacturing processes at YBL indirectly helps in reducing the environmental pollution due to disposal of human biomedical waste which is a major concern to the hospitals, the regulatory authorities and the citizens.

The Biomedical waste management teams at YBL have created a Pan India network to access Bio-medical fluids for extraction and purification of high quality Native and Recombinant Antigens in a time-effective manner.

State-of-the-Art Research & Development

YBL has a well-equipped Research & Development (R&D) unit in which a wide range of high-quality Antigens (Native and Recombinant), Proteins, Enzymes are manufactured using advanced chromatography systems like AKTA prime plus and AKTA Pure for protein purification.

The Recombinant R&D facility manufactures highly purified proteins and enzymes both with and without tags and by using different expression systems like Bacterial (*E. coli*), Mammalian (CHO, HeLa, HEK293, MCF7), Baculovirus (*Spodoptera frugiperda*) Sf9/Sf21 insect cells and Yeast (*Saccharomyces cerevisiae*).

Highly specific and high affinity monoclonal and polyclonal Antibodies are developed and characterized by Surface Plasma Resonance (SPR) using Biacore T200 system. These Antibodies are validated by external agencies and certified for use in development of immunoassays like Enzyme-linked Immuno Sorbent Assay (ELISA), Flow Cytometry, Chemiluminescence Assays (CLIA) and Immunohistochemistry (IHC).

YBL products basket contains more than 25 Native and 22 Recombinant Antigens with a purity percentage ranging from 90-99% (To download YBL products booklet please write to marketing@yashrajbio.com).



Photo: Siemens Advia Centaur XP Analyzer

Efficient Production and Rigorous Quality Checks

A seamless transition occurs between the R&D and the production unit for scaling up and mass production of protein. Standard operating procedures are followed to maintain batch to batch consistencies irrespective of capacity (from small to bulk production). The emphasis lies on the maintenance of long-term stability, specificity and purity of the products which is ensured by Quality Control. Rigorous testings are performed on multiple platforms like Roche Cobas e411 & c311 and Siemens Advia Centaur CP & XP analyzers.

Protein quantification and validation is done using ELISA, ECLIA, Immunonephelometry, Immunoturbidimetry and Latex Agglutination, SDS-PAGE, Western Blotting, HPLC, Crossed immunoelectrophoresis (CIE) and Mass-Spectrometry. Real and accelerated stability tests are performed for batch consistency and viral contamination is identified by performing PCR and USFDA approved CLIA techniques. Once the protein quality is confirmed and certified, they are properly labeled and packaged for a timely delivery to the customers worldwide.



Photo: Roche Cobas e411 & c311 analyzers

Stem Cell & Antibody Phage Display: **New Ventures**

In the last 2 years, YBL is diversifying its R&D activities to develop iPSCs Stem Cell technology for drug discovery and screening. It has successfully developed methodologies to bio-bank peripheral blood mononuclear cells and erythroblast cell populations from cancer patients and healthy individuals (controls).

In 2018, YBL ventured into production of Recombinant Monoclonal Antibodies using Phage Display for Diagnostic & Research purpose. Currently, both the facilities are in initial stages of development and the products are expected to be available in the market by July 2020.



Photo: YBL Scientist working on Merilyzer EIAQuant

CSR at YBL: **Grants and Awards Sponsorship**

Every year YBL donates a percentage of the profit for Corporate Social Responsibility (CSR) initiatives like Healthcare and Education for the welfare of economically weaker section of the society. The amount depends

Purification Source	Product purified
Ascitic Fluid / Pleural fluid	C-Reactive Protein (CRP)
Cancer Fluid	Cancer markers (CA 15-3, CA 19-9, CA 125, CA 72-4), CEA, HE4
Human Cord Blood	AFP
Placental Fluid	Ferritin, PAPP-A
Plasma / Serum	Soluble Transferrin Receptor (STFR), D-Dimer, Transferrin.
Renal Failure Urine	B2M, A1M, A2M, Cystatin C, RBP, Kappa FLC, Lambda FLC
Neutrophils	Myeloperoxidase (MPO), Proteinase 3, NGAL, Azurocidin, Calprotectin
HBsAg Positive Plasma	HBsAg-Ad & HBsAg-Ay
Human Seminal Plasma	PSA
Human Seminal Plasma and Blood	PSA- ACT Complex

Table 1: **Purified proteins from the Bio-medical waste of patients.** Table showing production of various purified proteins from the Bio-medical waste of patients collected from various hospitals Pan India. For a complete list of products see the link www.yashraj.com.

on the profit generated and is decided by the Board. For more details please see <http://yashraj.com/csr/>

Moreover, YBL in collaboration with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) sponsors the **IFCC-Yashraj Biotechnology Limited Distinguished Clinical Chemist Award & IFCC-Yashraj Biotechnology Limited Distinguished Award for Contributions to Affordable *In vitro* Diagnostics** to recognize researchers who have made significant contributions in this discipline.

Come and join us at Yashraj Biotechnology Limited in our quest to make diagnostics more affordable and accessible!

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The YBL company's major activities involve:

Isolation, purification and production of Native and Recombinant proteins;

Development of polyclonal and monoclonal Antibodies against Immunogens;

Production of cell-derived Native Antigens using appropriate cell lines.



What's important for Biotech STARTUPS in BioAsia Hyderabad



In the upcoming event BioAsia 2019 from 25-27 February 2019, a lot of fruitful discussions are expected to happen regarding the business of Life Science, Biotech and Pharma companies in India. In this India's biggest and finest Biotech industry meet, industry leaders gather under one roof and discuss the latest ongoing projects. The event is gaining much wider attention from the last few years. In the year 2017, interesting ideas were shared by Dr Vas Narsimha, Dr Paul Stoffels, Dr Saumya Swaminathan, Prof. Michael Hall, Lasker Awardee 2017, Dr. Udit Batra, Member of the Executive Board, CEO Life Science, Merck, Mr. Satish Reddy, Chairman, Dr. Reddy's Laboratories, Mr. Jawed Zia, Country President, Novartis India Ltd and many more dignitaries who were there in 2018.

Similarly in this year many leaders of Life Sciences have registered themselves to meet the largest and finest crowd of Life Science Industry. In the current event a startup session has also been carved out by Tech Mahindra to support excellent Life Science start-ups that can make the big changes in the society. Tech Mahindra has also funded 50 Lakhs Rupees in BioNest Hyderabad recently, which shows its commitment toward the Life Science Sector.

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Interview Republished

Why Only 10 Indians on list of world's 4,000 top scientists: Explained by Dr. Ashok Pandey, who secured a place in the list

February 7, 2019

Mahendra Singh, PhD

Source: <https://mahendratalkshow.com/>

Scientist Dr. Ashok Pandey, is in the list of World's most influential scientist in the world along with nine other Indian scientists. The report is prepared by Clarivate Analytics. Dr. Pandey is the only scientist from CSIR and working in CSIR-IITR Lucknow. I have contacted Dr. Pandey to understand about the various aspects of reports.

First of all congratulations to you for this great recognition. Definitely you deserve it, as I have seen your CV and it is having huge lists of your work either in form of research article, books or other relat-

ed activities.

Q- Highly Cited Researchers (HCRs), what it means to non scientific people or laymen?

Scientist Dr. Pandey: This in a way shows that the research and technological developmental work done by the person has been highly read by the community which found it of great relevance for them; then they followed it for their won works and referred it in their papers.

Q- Is HCRs report is free from limitations or this too has similar to ongoing debate of judging the working on the basis of impact factor or number of article v/s quality of article?

Scientist Dr. Pandey: For sure there can be endless debate and arguments and various issues can be raised (even just for the sake of raising the issues!) but it is well proven and accepted that the methodolo-



gy adopted for this is perhaps the best. In fact, globally it has widest recognition.

Q- What you think about this report, it will be helpful for scientific community around the globe?

Scientist Dr. Pandey: Yes, it is of not just only of great relevance for individuals (great recognition), it helps overall the community to network and collaborate (based on the common interests and to com-

pliment the expertise).

Q- You are the only scientist from CSIR, world's largest scientific organizations having more than 5000 scientists, in the list of Highly Cited Researchers? It seems that somewhere is problem or limitations either in CSIR or in the methodologies followed by Clarivate Analytics while preparing the HCRs lists?

Scientist Dr. Pandey: As I have mentioned above, the methodology adopted by the Clarivate Analytics is the best one- at least now (tomorrow there may be possibilities of some other better methods); this is un-disputed method globally. In fact, if you look at various other kinds of scales, which are used to rank, for example, universities, institutes, etc globally, similar reflection we find for us (for Indian universities and institutes); we should resist to blame others and try to do truthful analysis/introspection and take remedial actions.

It's not easy to summarize in one sentence the reasons for the poor performance of Indian scientist in the list (of for that matter that of CSIR scientists) but let me try to tell you in my individual/personal capacity (which of course is based on my professional experience as an individual and also as global traveler for professional works/collaboration).

Let us see about CSIR alone. At times, we encourage to publish; then suddenly someone decides 'we don't want publication'; "we just want technologies". There are peo-

ple –at top management who even used (impolite) statements like 'we don't want PAPER SCIENTIST'. What is most pity that such statements and changes in stance have often been related with the policies of government (central government), which perhaps is never true. For any government obviously the most important agenda would be welfare of the people. For the development, govt would want to take the help from the scientists of the country for ways to improve the health, hygiene, good, infra-structure development, etc. That means scientific knowledge developed by the scientists should have avenues for its utilization as technologies, etc. No govt said that you don't do good science! It is the people who mis-conducted themselves in leadership roles and mis-governed the scientific community.

For any scientist, the bottom line is to do good science; good science needs to be known to the people (for which avenue is paper publication). Note that its highly competitive world for quality publications as well. Thus, at no point of time, it should be point blank discouraged. Then, the second aspect, which is important for the scientist is to carefully evaluate the findings – individually and/or through institutional team to identify if any of the results could be of technological relevance. Such results should be protected (patenting) and then look for industrial avenues for these. Note that every work cannot be high quality science or patentable results; also, note that some scientists would always like to do works directly related with the society, such as environmen-

tal programs, or modern farming, etc, which too are of extremely relevance. These should not be neglected.

I am very happy that at least now, the new DG of CSIR, Dr Mande has put the policy framework and working goals for CSIR scientists very clearly. In his message to CSIR community on 1st January 2019, he mentioned about the three aspects, which included science for society, doing good quality science (and to publish) and explore/exploit the work for technological developments. The message is very clear.

Having said all above, I would also want to briefly touch upon one another issue. In fact, honestly telling this could be even controversial but I am putting straight forward fact to you. One very critical issue, which is in some way responsible for not high quality publications or technological developments coming out is directly related with the manpower quality we have. We see that large number of highly meritorious scholars do not get job, while much less meritorious get! Then, how should you expect the 'high quality science' from them?

Q- Scientist CNR Rao told Time of India that 15 years back China and India were at same level but now China (15-16%) is contributing far more in World science than India (3-4%). Mean time, Indian academics became leader in publishing the fake research. What went wrong with both the cases India and China?

Scientist Dr. Pandey: I would not like to comment on who said what

but would elaborate more here what I just said in last above. I do not believe so-called 'blame-game'; I never did it any time in my professional career (note that I am just one; you would find a number of such people who would want to work, rather not getting involved in gossip-groups, which are very popular in CSIR institutes).

In a sting operation a few years ago, two professors from Wisconsin University created a large number of fake research manuscripts based on 7th and 8th standard science books and sent them for publication in some 250 open access journals (mostly having very modern and fancy names); to sum-up the story majority of these journals accepted large majority of these 'papers' within seven days. Whatever above, now the fact is this that many-many Indian researchers, including from those whom we call as 'premier institutes' are too happy to publish in those journals. Who is responsible scientist/professor? Or, the student? To me, the onus lies on former ones.

Now I will comment specifically on the question with China. In China (and many other coun-

tries, including South Korea), there is internal recognition system. If a professor/scientist publishes one paper in a Q1 journal (based on impact factor and h index, journals are classified, in which Q1 is highest), he/she is given cash intensive for this (which he can share with all co-authors). The amount for various countries varies and it could be as high as US\$ 1200-1500 per paper. I am not asking to simply follow what others are doing but at least we can stop discouraging the scientists.

Q- When I talked about Ease of Doing Science in India, similar to Ease of Doing Business, few scientists recommended liberalizing the lateral entry for Indian researcher working abroad setup lab in India and removing the age limit in recruitment of scientists.

1- What do you think about these recommendations and

2- What types of measures you would recommend to improve the Ease of Doing Science with quality in India?

Scientist Dr. Pandey: I would not be shy to tell

that firstly we need to learn to respect the merit. Absolute efforts should be made to recruit meritorious scholars (note that I do not mean that this is not happening; for sure this is happening but only a small portion). I do not (fully) agree that there is no environment for doing Ease of Science in India; there are hurdles but still it is happening. As far age limit, there are different levels of scientist, for example in CSIR (same for any other organization), where age limit is different for different level).

Recruit meritorious people with open grading system based on credentials and institutional requirement,

Allowing to establish individuals to do science of their choice with a set portion of time and rest time for the institution project with team building. The former one to see/allow for a given period (not open ended).

Emphasis on team work with defined and quantifiable goals.

Objective based evaluation (no subjectivity at all) for career growth.

Incentives based on performance.

Q- As you are recipient of Shanti Swaroop Bhatnagar Prize and veteran scientist, Please make a comment on below query. I have also contacted with other concerned authority dealing with Shanti Swaroop Bhatnagar Prize.

what is the logic or reason behind putting the 45 age limit for considering a candidate for India's highest multidisciplinary science awards for Science and Technology. The other different awards either of a particular field such as sports or films or padma awards etc (as far as I know) they do not have the age limit criteria for conferring award to any eligible candidate.

Scientist Dr. Pandey: Sorry; I am not recipient of SSB prize.

Thank your once again sir, for sparing time for answering the queries. I am hopeful that this will help the scientific community in one way or other way.

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NEWS: Govt & Industry

Budget 2019 for Higher Education:

February 1, 2019

Piyush Goyal, the Union Minister for Finance and Corporate Affairs presented the interim budget for 2019-20 and earmarked Rs 93,847.64 crore for the education sector. The allocation this year has seen an increase of 10 percent from last year. The center during the Budget 2018 presentation had allocated Rs 85,010 crore for the sector. Out of the total allocation for 2019-20, Rs 37,461.01 crore has been assigned for higher education, while the rest of the amount, Rs 56,386.63 crore has been allocated for school education.

The center has given a major boost to the Indian Institutes of Technology (IITs) and National Institutes of



Technology (NITs) as they have proposed the setting up of 'Schools of Planning and Architecture' (SPA). While talking about the same, FM Piyush Goyal proposed the setting up of two new full-fledged SPAs that will be selected on challenge mode. Along with this, he also said an additional 18 SPAs will be established in the IITs and NITs as autonomous schools.

While there is a boost for IITs and NITs in terms of the establish-

ment of SPAs, there has been a decline in the budget outlays for IITs, IIMs, IISER, UGC and AICTE. While the Human Resource Development Ministry has called in for the implementation of 10 pct reservation for the economically weaker sections from the upcoming session onwards along with the increase in seats at varsities for the poor, the Higher Education sector this year has faced a massive loss.

As per the interim budget 2019,

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the budget outlay for the Indian Institutes of Management (IIMs) as seen a decline of 59.9 per cent from last fiscal's allocation from Rs 1,036 crore to Rs 415.41 crore. The IITs have also seen a decline in their budget from Rs 6,326 crore in 2018-19 to Rs 6,223.02 crore this year. However, this is not the first time when there has been a cut in the budget outlay for the IITs. The top technical institution saw a cut in the last fiscal from Rs 8,337.21 crore in 2017-18 to Rs 6,326 crore in 2018-19.

Along with these two top higher education institutions, the budget outlay for the Indian Institute of Science, Education and Research (IISERs) has also seen a drop from Rs 689 crore in 2018-19 to Rs 660 crore in 2019-20. Apart from these educational Institutions, the statutory and regulatory bodies such as UGC and AICTE have also witnessed a decline. There has been a decrease from Rs 4,722.75 crore in 2018-19 to Rs 4,600.66 in the budget outlay for the University Grants Commission (UGC). On the other hand, the outlay of All India Council for Technical Education (AICTE) has come down to Rs 466 crore this year as compared to Rs 485 in 2018-19.

Nigeria Approves First GM Food Crop for Open Cultivation



Nigeria is on the path to becoming the first country ever to cultivate biotech cowpea after the country's biosafety agency granted approval for the crop's cultivation by farmers. This development adds a new crop to the global biotech basket from Africa. The National Biosafety Management Agency (NBMA) permitted the Institute for Agricultural Research (IAR) to commercially release Pod Borer-Resistant Cowpea (PBR Cowpea)-event AA-T709A, genetically improved to resist lepidopteran insect pest *Maruca vitrata*. The permit is valid until the end of 2022.

In a Decision Document dated January 22, 2019, the Agency said the issuance of the permit was made after taking into consideration the advice of National Biosafety Committee, National Biosafety Technical sub-committee and the risk assessment and risk management report provided by IAR, the applicant.

“After a thorough analysis of the application dossier, Risk Assessment and Risk Management Plan prepared in connection with assessment of the application, it is unlikely that the proposed release

will have adverse impact on the environment and human health,” read part of the document.

The approval is a culmination of more than nine years of intensive trials into genetically modified (GM) cowpea that can resist *Maruca vitrata* pod borer, an insect that can cause up to 80 percent yield loss. The release is a relief to millions of Nigerian farmers who depend on cowpea for food and income. Results from the research, led by Nigeria's Institute for Agricultural Research in partnership with the African Agricultural Technology Foundation (AATF), have shown that Btcowpea will reduce the use of pesticides from eight to about two sprays per season and increase yield up to 20 percent. This means that Nigeria will record a revenue increase of more than N48 billion (\$132 million) annually from cowpea.

This is the second GM crop to be released in Nigeria after Bt cotton which was approved for open field cultivation last year.

Comprehensive Review of the Environmental Safety of Bt Crops Now Published

A comprehensive review authored by scientists from Switzerland and

the United States summarized the existing literature on Bt crops from laboratory and field-based studies. The authors, Jörg Romeis, Steven E. Naranjo, Michael Meissle, and Anthony M. Shelton highlight the contribution of Bt crops to conservation biological control.

The paper published in the journal *Biological Control* reports that Bt crops have been grown on more than 1 billion acres over the last 20+ years, and on 100 million hectares in 2017 alone. A major concern related to this technology is that the proteins could harm non-target organisms, specifically those that provide important ecosystem services such as biological control. However, studies have proven that proteins from Bt crops did not harm natural enemies. Furthermore, Bt crops support the conservation of natural enemies and contribute to more effective biological control of both target and secondary pests and lead to a reduction in insecticide use.

The paper concludes that the efficacy of Bt crops in controlling important target pests has been very high. The large-scale adoption of Bt crops in some parts of the world has led to area-wide suppressions of target pest populations that benefited both the farmers that adopted the technology and those that did not.

The Union Cabinet granted approval to an expenditure of

over Rs 3,600 crore for setting up of 13 new central universities

The new central universities were established under the Central Universities Act, 2009 in Bihar, Gujarat, Haryana, Himachal Pradesh, Jammu and Kashmir, Jharkhand, Karnataka, Kerala, Orissa, Punjab, Rajasthan and Tamil Nadu. While one university each is to be set up in 11 of these states, Jammu and Kashmir will get two new central universities.

“The Cabinet has given its approval for incurring an expenditure of Rs 3,639.32 crore for the 13 central universities for recurring cost and creation of necessary infrastructure for completion of the campuses. The work will be completed within 36 months,” Union Minister Piyush Goyal said at a press conference. “The Cabinet has also given ex-post facto approval for Rs 1,474.65 crore being the amount spent over and above the earlier cabinet approval of Rs 3,000 crore for these central universities,” he added.

The minister said the move will increase access to higher education and set exemplary standards for other universities to emulate and will help in minimising the regional imbalances in educational facilities.

UGC to Educational Institutions: Implement 10% Reservation for Poor

The Centre has directed all educational institutes and universities to implement 10 per cent reservation for economically weak in general category in the upcoming educational year.

Addressing a press conference here on Sunday, Union HRD Minister Prakash Javadekar said an office memorandum has been issued to implement the stipulated quota. Government has issued an office memorandum to implement 10 per cent reservation. We have issued orders yesterday to all institutes and universities to implement it in the upcoming educational year.

We have also asked states to implement it he said. The Parliament recently passed the Constitution (124th Amendment) Bill, 2019 to grant 10 reservation in education and government jobs to economically weaker individuals belonging to the general category, across religions.

The reservation is meant for individuals whose annual earning is below Rs. 8 lakh and who possess less than 5 acres of agriculture land.

WHO employs directors for Western Pacific and Southeast Asia regions

The WHO has appointed Dr Takeshi Kasai as Regional Director for WHO's Western Pacific Region, and re-appointed Dr Poonam Khetrapal Singh for a second term as Regional Director for WHO's Southeast Asia Region.

Dr Kasai said he plans to build on the decade of leadership and legacy of the outgoing Regional Director. He is a Japanese national, has worked for WHO for more than 15 years. As Director of Programme Management for the last 4 years, he served as deputy to the Regional Director.

Prior to this, Dr. Kasai was instrumental in developing and implementing the Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies, which guides

the Member States to improve readiness and response in public health emergencies. Dr Kasai also served as the WHO Representative in Viet Nam from 2012 to 2014.

A physician by training, his career in public health began nearly 30 years ago, when he was assigned to a post on the remote northeast coast of Japan, where he saw firsthand the value of building strong health systems from the ground up.

“It is a privilege to once again be appointed as Regional Director for WHO South-East Asia Region. The confidence you have reposed in me is humbling,” said Dr Khetrapal Singh, whose first term as Regional Director was marked by numerous initiatives and public health achievements.

Dr Khetrapal Singh, an Indian national, is the first woman Regional Director of WHO South-East Asia, and assumed office on 1 February 2014. On 5 September 2018, she was unanimously nominated by for a second 5-year term.

Kiran Mazumdar Shaw elected as Foreign Members to US's National Academy of Engineering



Kiran Mazumdar Shaw have been chosen as Foreign Members to the National Academy of Engineering (NAE). NAE is a US-based private, independent, and non-profit institution, which is a part of the National Academies of Sciences, Engineering, and Medicine, and provides engineering leadership in service to the nation.

Reacting to the announcement, Dr Mazumdar-Shaw noted that she is humbled to receive this recognition. She tweeted “Just learnt of my induction to the National Academy of Engineering NAE - a huge honour - I am humbled to be elected to this prestigious body.”



This year, the National Academy of Engineering has elected 86 new members and 18 foreign members, taking the count to 2297 U.S. members and 272 foreign members. The new members would be formally inducted in a ceremony at the Academy's annual meeting in Washington D.C., on the 6th October 2019.

Cabinet approves MoU between India and Finland in the field of Biotechnology

The Union Cabinet chaired by Prime Minister Narendra Modi has approved the MoU between India and Finland for collaborating based on mutual interest in the field of Biotechnology, for funding and implementing ambitious industry-led innovative and transnational projects within the broad scope of research development and innovation.

Benefits:

The Mou will support creation of long-term Research, Development & Innovation collaboration mechanism and to establish and strengthen cooperative network between Indian and Finnish organizations. By funding need-oriented, ambitious joint projects of high international standards, the two countries aim to help reach world-

class innovations beneficial to both countries. It will also facilitate knowledge sharing and knowledge generation among scientists, researchers and industry in the two countries.

First Ayurvedic drug for cancer 'Kudos CM 9' launched



According to researchers at CSIR-IICB, the drug is beneficial in both benign and malignant tumour treatment.

Developed by Government of India's, Ministry of Science & Technology, (Council of Scientific & Industrial Research-Indian Institute of Chemical Biology) CSIR-IICB, the drug was launched on World Cancer Day.

“Kudos CM9 is the result of 30 years of extensive research by Govt. of India's Ministry of Science & Technology, CSIR-IICB to find the first ever ayurvedic cancer cure drug which has no side effects and has been proven to be the most effective and the safest medicine for the dreadful disease cancer,” said Prof Chitra Mandal, Senior Scientist, Cancer Biology & Inflammatory Disorder Division, CSIR- IICB. Kudos CM 9 is beneficial in both benign and malignant tumour treatment. It is very highly useful in curing early stage / early diagnosed cancer patients and in controlling further spread of cancer growth in patients undergoing

chemotherapy, radiotherapy and hormone therapy also prevents relapse of cancer.

“Kudos CM9 helps to fight cancer by blocking certain cancer promoting enzymes and hormones. Kudos CM9 helps to prevent cancer in high risk individuals. The drug also possesses antimutagenic, chemoprotective and radioprotective properties,” explained Dr Priyanka, CEO, Kudos Ayurveda .

Tecan's NGS DreamPrep Offers Automated Approach to Library Preparation

Tecan, Maennedorf, Switzerland, has announced the launch of its NGS DreamPrep, a fully automated approach to next-generation sequencing (NGS) library preparation for research use. The new approach offers quality-controlled, sequencing-ready NGS libraries within hours, with minimal manual interaction and no sample loss. NGS DreamPrep combines the Tecan Fluent liquid handler and Infinite plate reader together with Celero DNA-Seq and Universal Plus mRNA-Seq library preparation kits to improve speed, flexibility, accuracy, and precision. Quantification, normalization, and pooling of samples can all be achieved in significantly shorter timelines compared to other methods that use qPCR or capillary electrophoresis. Importantly, this is the first library preparation method to incorporate a QC step, which takes just 5 minutes, ensuring the generation of highly reproducible libraries that are ready to sequence.

“Next-generation sequencing continues to revolutionize genomic research,” says Klaus Lun, PhD, executive vice president and head

of Tecan's life sciences business division. “Previously, the technique relied on libraries being quantified and normalized using methods that were time-consuming and subject to variability. NGS DreamPrep enables users to easily transform samples into high quality, ready-to-use libraries.”

The Celero DNA-Seq and Universal Plus mRNA-Seq kits are the first of the company's NGS kits to be available for the NGS DreamPrep.

Sanofi and Regeneron Cut Price of Praluent by About 60%

Sanofi and Regeneron, following Amgen dropping the price of Repatha in October 2018, have dropped Praluent to \$5,850 a year. This is about a 60-percent reduction from the original price for both the 75 mg and 150 mg doses. stated Michelle Carnahan, North American Head of Primary Care Business Unit at Sanofi. “With announcement, we are looking to help bridge that gap, and have now made Praluent available at a price that is approximately 60 percent lower. We hope that payers will do their part to help ensure savings are directly passed on to more patients, through lower out-of-pocket costs.”

Sanofi and Regeneron indicate that with the newer pricing, most Medicare Part D patients will pay

between \$25 to \$150 per month, a possible savings of up to \$345, varying from insurance plan to insurance plan. The PCSK9 inhibitors, both of which were approved in 2015, are largely focused on patients who don't respond to diet, exercise and the far more affordable statin drugs. Statins, such as Pfizer's Lipitor, typically are priced at about \$50 per month.

Clinigen Group To Acquire U.S. Rights to Proleukin From Novartis

London-based Clinigen Group pc will have full rights to Proleukin (aldesleukin, human recombinant interleukin-2). This morning, the U.K.-based pharmaceutical and services company struck a deal with Novartis to acquire the U.S. rights to the metastatic renal cell carcinoma treatment.

Clinigen signed an agreement with the Swiss pharma giant to acquire the U.S. rights for up to \$210 million in cash. The payment consisted of a \$120 million upfront payment, a deferred payment of \$60 million and future sales-related milestones that could total \$30 million. Clinigen already owns the rights to Proleukin outside the US, which it acquired in July 2018.

Shaun Chilton, group chief executive officer at Clinigen, said the

U.S. rights to Proleukin will be significant for the whole of the company, not just its Commercial Medicines division. Chilton noted that the acquisition will allow the Clinigen Group to expand its footprint in the U.S. market.

In its announcement, Clinigen said Proleukin further diversifies its Commercial Medicines portfolio of niche hospital-only and critical care products. That division also has the U.S. rights to other assets, including Foscavir, Ethyol and Tactect. Commercial rights for those three drugs have been licensed to Pfizer (Foscavir) and Cumberland Pharmaceuticals (Ethyol and Tactect), Clinigen said.

Proleukin generated \$60 million in revenue in the United States for the year leading up to June 30, 2018, Clinigen said, citing data from IQVIA. The company said gross profit margin is expected to be similar to other specialty medicines within its Commercial Medicines division.

Brexit Likely to Cause Talent Shortage for Biopharma in the UK

As Britain's plans to leave the European Union—Brexit—stagger toward the March 29 deadline, the UK biopharma industry is taking stock of the likely impact. One big move was simply that

the European Medicines Agency (EMA), the equivalent to the U.S. Food and Drug Administration (FDA), moved its headquarters from London to Amsterdam. During the transition, the EMA was scaling back some of its operations, particularly as it dealt with an expected loss of about 30 percent of its staff.

Major UK drug makers, as well as European drugmakers, such as AstraZeneca, GlaxoSmithKline, Sanofi, Novartis and Roche, all made plans to stockpile extra drugs in preparation for the likelihood of supply chain disruption. More than 2,600 drugs, according to Reuters, have some stage of manufacture in Britain, and 45 million patient packs are supplied from the UK to other European countries, with another 37 million going from Europe to the UK.

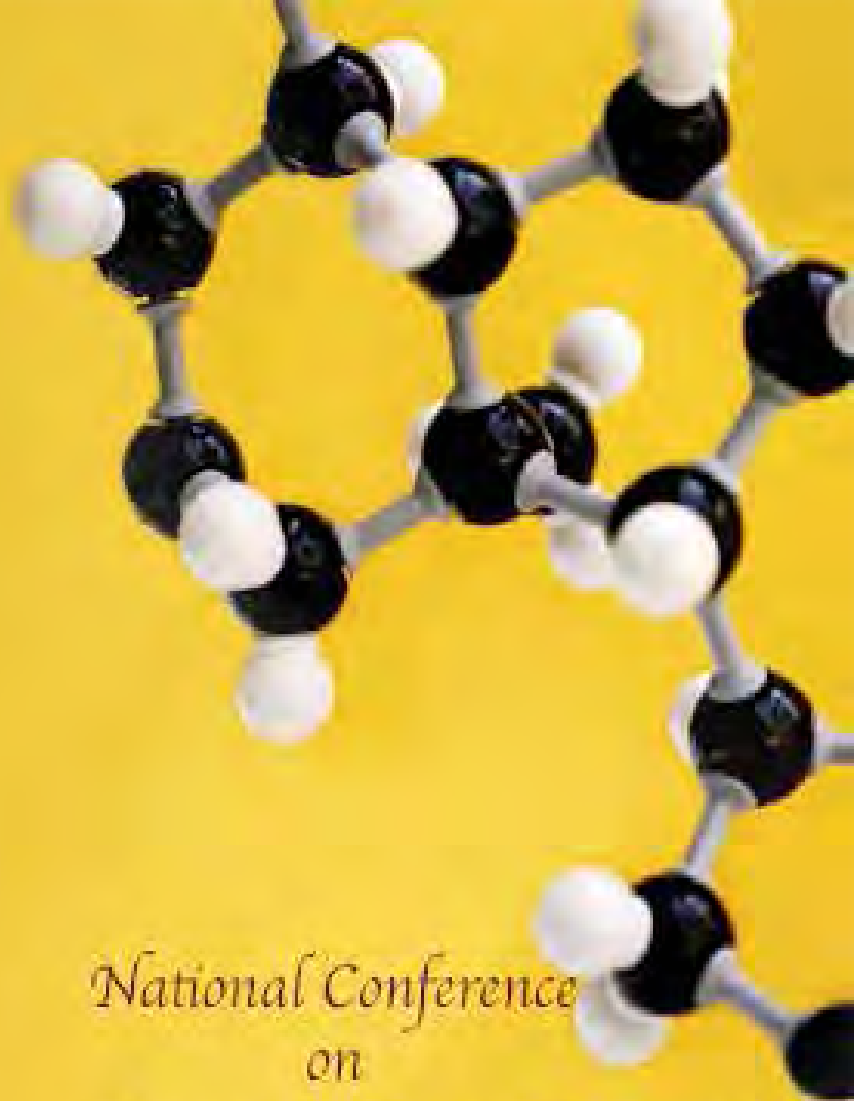
In fact, that import number appears to be quite low. Novartis recently indicated that its contingency plans were continuing and the company was making “all preparations possible to ensure continuity of supply to UK patients of the over 120 million packs of medicines we import to the UK from Europe each year.”

An analyst with GlobalData wrote that in the past decade the UK has seen a 16 percent increase in students studying STEM topics. However, the number of EU students studying STEM topics in the UK rose more than 52 percent over the same period, with the number of non-EU students raising more than 63 percent.

In a recent discussion titled “Brexit Impact on Biotech” published by Kineticos Life Sciences Consulting between several industry experts, Derek Hennecke, former president of Capsugel Tampa and former chief executive officer and president of Xcelience before it merged with Capsugel, said, “The money part is definitely important, it's going to be bad for all of Europe, but specific to the UK, the UK has had a very strong pharma history and I think they're still going to hold leadership in terms of GMP and regulatory guidance. But the MHRA (UK's Medicines and Healthcare products Regulatory Agency) is talking about infrastructure, and knowledge, and leadership, which are all facets. As Mark (Osterman, senior vice president of Kineticos' Biopharmaceutical Practice) said, money is important, but so are people and knowledge and skills.”



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Drug Discovery and Translational Medicine

(DDTM-2019)

14-16 March 2019



Department of Biochemistry and Biotechnology
Annamalai University

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Topics Covered

The Conference will be an interdisciplinary event for stimulating discussions and knowledge sharing on the following topics:

- Drug design & Development
- Therapeutic Targets
- Biochemical Pharmacology
- Drug Delivery Strategies
- Natural Products
- Chemical Biology
- Pharmacogenomics
- Translational Medicine &
- Precision Medicine

Best Oral/Poster Presentation Award

Based on subject content and presentation 3 best oral/poster presentations will be awarded to young researchers.

Registration Fee

Student/Research Scholar : INR 800
Staff/Scientist/Faculty : INR 1500
DD should be drawn in favour of the "The Registrar, Annamalai University"

Contact Person

Dr. N. Rajendra Prasad
Convener, DDTM-2019
Dept. of Biochem. & Biotech.
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Speakers

Dr. Michale Gromiha
IIT-Madras, Chennai

Dr. Sathees C Raghavan
IISc Bangalore

Dr. CK. Panda
Chittaranjan National Cancer Institute, Kolkata

Dr. Ritushree Kukreti
CSIR-IGIB, New Delhi

Dr. S. Kabilan
Annamalai University
Annamalainagar

Dr. S. Sudhakar
MS University, Thirunelveli

Dr. Medha Rajappa
JIPMER, Puducherry

Dr. V. Thirunavukkarasu
Bharathiar University
Coimbatore

Dr. Mohane Coumar
Pondicherry University
Puducherry

&

Many Others

Last date for abstract Submission:
15th January 2019.
Abstracts should be mailed to
ddtm2019@gmail.com

For Brochure, Registration Form
please visit
www.annamalaiuniversity.ac.in



NATIONAL CONFERENCE ON ADVANCES IN MICROSCOPY AND FOLDSCOPE

(UNDER THE DBT FOLDSCOPE INITIATIVE)

15-16 March, 2019

www.microscopy2019.org



Broad Areas/Themes

- Health, Environment and Industrial Biotechnology
- Innovation and Translational Research
- Foldscope Related Research

About

The Conference is to provide up-gradation of knowledge and skills in the area of Microscopy and Foldscope. Faculty/Scientist/Principal Investigators and Research Students/Ph.D. students/JRFs who are interested for Microscopy and Foldscope related research are welcome to join the same. The conference shall also provide a platform for collaboration, twinning, and idea exchange among different scientists working in the similar or interdisciplinary areas.

Eligibility

Faculty/Scientist/Principal Investigators of Foldscope Project/Research Students/Ph.D. Students/others, who are working in the area of Microscopy or want to come across with Microscopy and Foldscope research.

Deadline(s)

Abstract Submission: 15 February 2019
 Acceptance: 18 February 2019
 Early bird registration: 22 February 2019
 Last date of registration: 05 March 2019
 Conference Dates: 15-16 March 2019

Registration Fees

	Early Birds (Till 22 Feb. 2019)	Late Registration
Faculty/Scientist/PI	Rs. 6000	Rs. 6500
Student/JRF/Ph.D.	Rs. 4500	Rs. 5000
Accompanying Person	Rs. 2000	Rs. 2000

Awards/Grants

- Young scientist award
- Best paper presentation award
- Best microscopy picture award
- Best Foldscope Microscopy award
- Limited number of discounted Registrations, Accommodations and Travel Grants are available. The candidate should apply with proper justification and endorsement from their Head of the Institution.

Contact

Dr. Vishnu Agarwal,
 Convener & Organizing Secretary
 Department of Biotechnology
 Motilal Nehru National Institute of Technology
 Allahabad, Prayagraj-211004 (India)
 Mobile:+919235682651, +916392651837
 (Email: vishnua@mnnit.ac.in)
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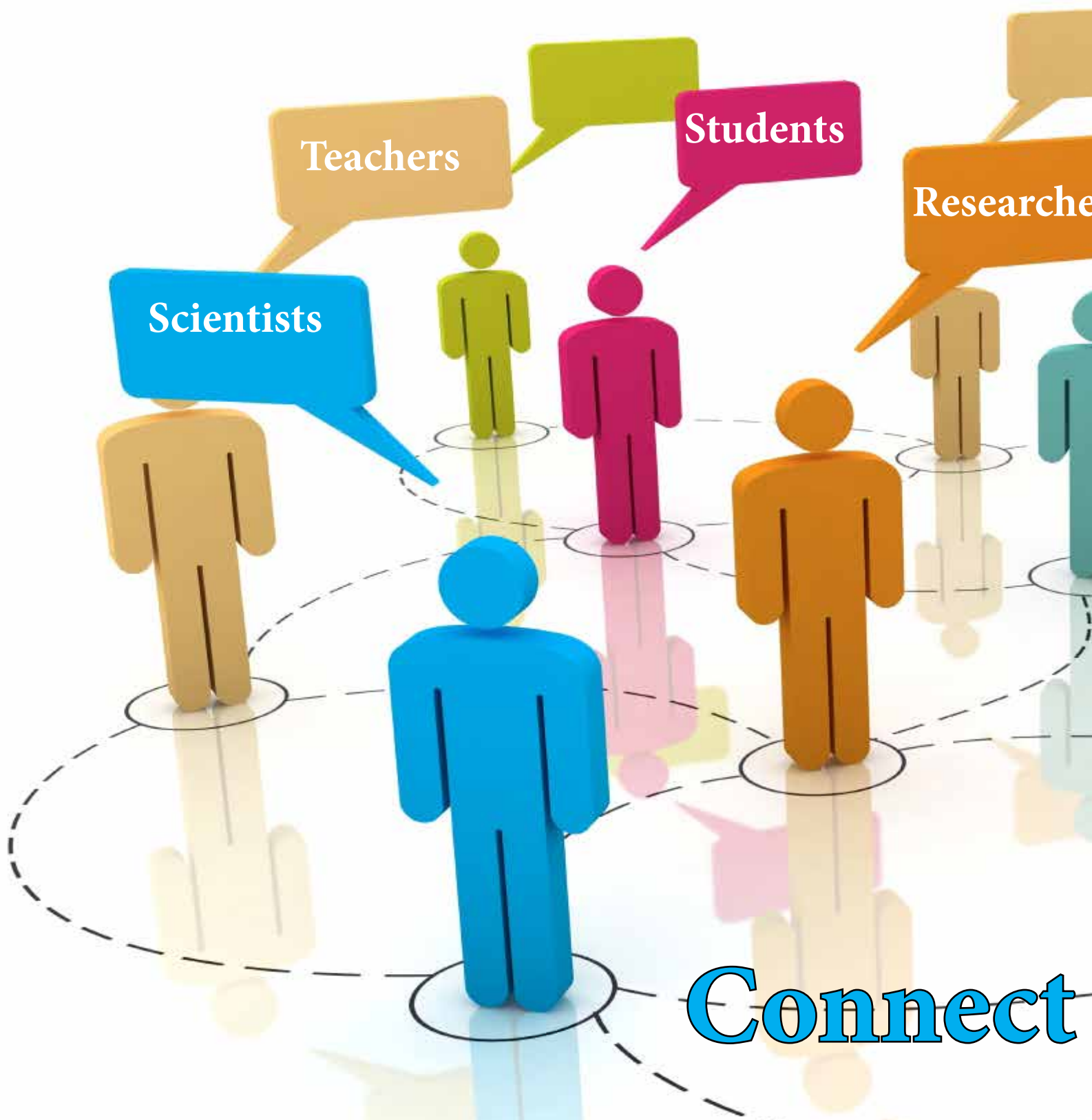


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RESEARCH NEWS

From other High Impact Journals

The first spontaneous animal model of human hypophosphatasia uncovered

A research group led by Professor Hannes Lohi at the University of Helsinki and Folkhälsan Research Center has uncovered a new skeletal disease in dogs. The disease was recognized in the Karelian Bear Dog breed and associated with an autosomal recessive defect in the alkaline phosphatase gene, ALPL. In humans, ALPL defects cause hypophosphatasia, which is a rare metabolic bone disease of varying severity. Until now, hypophosphatasia has not been reported as a spontaneously occurring disease in animals.

In humans, close to 400 hypophosphatasia-causing mutations have been reported in the ALPL gene. The hallmarks of the human disease are reduced serum alkaline phosphatase activity and defective

mineralization of bone and teeth. However, disease severity can vary from death in utero to a mild dental disease in adulthood.

The canine gene defect was identified by whole exome sequencing of a single affected dog. Altogether seven affected Karelian Bear Dog puppies were included in the study, all of which had inherited the ALPL gene defect from both of their parents.

"Clinical and pathological examinations of the affected dogs revealed a generalised disorder of bone mineralisation and growth. Furthermore, similar to human patients, some of the affected puppies developed seizures. Due to the severity of the clinical signs and a poor prognosis, the affected dogs were euthanised," says Kaisa Kyöstitä, PhD.

The study has resulted in a gene test for the breed, which helps in identifying carriers of the ALPL gene defect, thus preventing the birth of affected puppies.

Journal Reference:

Kaisa Kyöstitä, Pernilla Syrjä, Anu K. Lappalainen, Meharji Arumil-

li, Sruthi Hundi, Veera Karkamo, Ranno Viitmaa, Marjo K. Hytönen, Hannes Lohi. A homozygous missense variant in the alkaline phosphatase gene ALPL is associated with a severe form of canine hypophosphatasia. *Scientific Reports*, 2019; 9 (1) DOI: 10.1038/s41598-018-37801-2

Scientists develop tool to measure success of HIV cure strategies



Scientists funded by the National Institutes of Health have developed a new assay to accurately and easily count the cells that comprise the HIV reservoir, the stubborn obstacle to an HIV cure. This advance will enable researchers who are

trying to eliminate the HIV reservoir to clearly understand whether their strategies are working.

A team led by Robert F. Siliciano, M.D., at Johns Hopkins University School of Medicine analyzed DNA sequences from more than 400 HIV proviruses taken from 28 people with HIV. Among these proviruses, the scientists mapped two types of flaws: deletions and lethal mutations. The researchers then developed strategically placed genetic probes that could distinguish the deleted or highly mutated HIV proviruses from the intact ones. Finally, the scientists developed a nanotechnology-based method to analyze one provirus at a time with these probes to determine how many proviruses in a sample are intact.

The researchers demonstrated that their method can readily and accurately measure the number of rare, intact proviruses that make up the HIV reservoir. The hope is that this new method will speed HIV research by allowing scientists to easily quantify the number of proviruses in an individual that must be eliminated to achieve a cure.

Journal Reference:

Katherine M. Bruner, Zheng Wang, Francesco R. Simonetti, Alexandra M. Bender, Kyungyoon J. Kwon, Srona Sengupta, Emily J. Fray, Subul A. Beg, Annukka A. R. Antar, Katharine M. Jenike, Lynn N. Bertagnolli, Adam A. Capoferri, Joshua T. Kufera, Andrew Timmons, Christopher Nobles, John Gregg, Nikolas Wada, Ya-Chi Ho, Hao Zhang, Joseph B. Margolick, Joel N. Blankson, Steven G. Deeks,

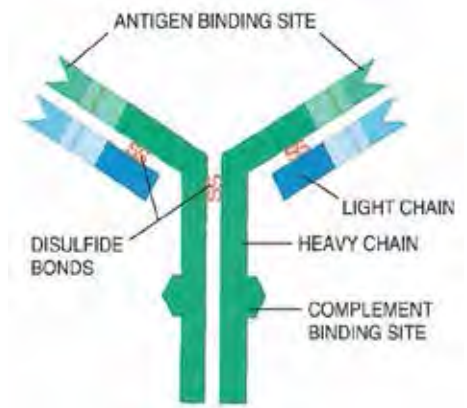
Frederic D. Bushman, Janet D. Siliciano, Gregory M. Laird, Robert F. Siliciano. A quantitative approach for measuring the reservoir of latent HIV-1 proviruses. *Nature*, 2019; DOI: 10.1038/s41586-019-0898-8

An unexpected mode of action discovered for an antibody

Studies of human monoclonal antibodies isolated from survivors of coronavirus-induced severe acute respiratory syndrome (SARS) or Middle-East respiratory syndrome (MERS) are unveiling surprising immune defense tactics against fatal viruses. Currently, no vaccines or specific treatments are available for any of the six coronaviruses that can infect humans. Some of these coronaviruses cause only common-cold like symptoms, but others provoke lethal pneumonias.

An international team headed by UW Medicine scientists is among those attempting to understand how SARS and MERS coronaviruses infect humans, and how their presence elicits a response from the immune system. The research group is particularly interested in how neutralizing antibodies target the coronavirus' cell-invasion machinery.

Previous studies in the Veessler lab at UW Medicine looked at the structural states that occur in the



coronavirus spike before and after the membrane fusion reaction. The researchers saw large conformational changes in the spike glycoprotein. Details about activation of the membrane fusion cascade, however, remained unclear.

Using cryo-electron microscopy and other powerful technologies, the researchers gained insight into how the neutralizing monoclonal antibodies from the SARS and MERS survivors inhibit the viruses at the molecular level. Their findings also helped elucidate the unusual nature of coronavirus membrane fusion activation.

The researchers found that both the SARS and the MERS coronavirus antibodies blocked the virus spikes from interacting with the receptors on the host cell membrane.

The SARS coronavirus antibody also did something unexpected: it functionally mimicked receptor-attachment and induced the spike to undergo conformational changes leading to membrane fusion. This trigger seems to be driven by a molecular ratcheting mechanism.

Journal Reference:

Alexandra C. Walls, Xiaoli Xiong, Young-Jun Park, M. Alejandra Tortorici, Joost Snijder, Joel Quispe, Elisabetta Cameroni, Robin Gopal, Mian Dai, Antonio Lanzavecchia, Maria Zamboni, Félix A. Rey, Davide Corti, David Veasler. Unexpected Receptor Functional Mimicry Elucidates Activation of Coronavirus Fusion. *Cell*, Jan. 31, 2019; DOI: 10.1016/j.cell.2018.12.028

Microbes hitched to insects provide a rich source of new antibiotics

In an exhaustive search of microbes from more than 1,400 insects collected from diverse environments across North and South America, a research team found that insect-borne microbes often outperformed soil bacteria in stopping some of the most common and dangerous antibiotic-resistant pathogens.

Cameron Currie, a University of Wisconsin-Madison professor of bacteriology, has shown that some of these insect-associated microbes provide their hosts with protection against infections, suggesting that insects and their microbiomes may be a rich new source of antibiotics for use in human medicine.

So with a team of collaborators, Currie set out to test that idea,

thousands of times over. In an exhaustive search of microbes from more than 1,400 insects collected from diverse environments across North and South America, Currie's team found that insect-borne microbes often outperformed soil bacteria in stopping some of the most common and dangerous antibiotic-resistant pathogens.

In their work, the scientists discovered a new antibiotic from a Brazilian fungus-farming ant, naming it cyphomycin. Cyphomycin was effective in lab tests against fungi resistant to most other antibiotics and combatted fungal infections without causing toxic side effects in a mouse model. The researchers have submitted a patent based on cyphomycin because of its effectiveness in these early tests, setting up the team to begin to do the significant additional work required before cyphomycin could be developed into a new drug used in the clinic.

The study is the largest and most thorough to assess insect-associated microbes for antibiotic activity to date. In all, the insects provided more than 10,000 microbes to test. The team isolated another 7,000 strains from soil or plant sources.

Journal Reference:

Marc G. Chevrette, Caitlin M. Carlson, Humberto E. Ortega, Chris Thomas, Gene E. Ananiev, Kenneth J. Barns, Adam J. Book, Julian Cagnazzo, Camila Carlos, Will Flanigan, Kirk J. Grubbs, Heidi A. Horn, F. Michael Hoffmann, Jonathan L. Klassen, Jennifer J. Knack, Gina R. Lewin, Bradon R. McDonald, Laura Muller, Weilan

G. P. Melo, Adrián A. Pinto-Tomás, Amber Schmitz, Evelyn Wendt-Pienkowski, Scott Wildman, Miao Zhao, Fan Zhang, Tim S. Bugni, David R. Andes, Monica T. Pupo, Cameron R. Currie. The antimicrobial potential of *Streptomyces* from insect microbiomes. *Nature Communications*, 2019; 10 (1) DOI: 10.1038/s41467-019-08438-0

Over 800 new genome regions possibly relevant to human evolution identified

A study by the research group Bioinformatics of Genome Diversity at the Universitat Autònoma de Barcelona (UAB), published in the journal *Nucleic Acids Research*, increases by 40% the total number of signals of natural selection detected in the human genome to date. Researchers were able to add a total of 873 new regions of the human genome as firm candidates to have been the target of natural selection at some point from the emergence of our species to the present. These are added to the 1,986 regions that had already been detected, providing a very valuable set of data to help answer the question: what makes us humans?

In 2018, the research group Bio-

informatics of Genome Diversity at the Universitat Autònoma de Barcelona (UAB), in collaboration with scientists from the Institute of Evolutionary Biology (IBE), published PopHuman, the greatest inventory of genetic diversity measures computed throughout the human genome using the data from the 1000 Genome Project. By using PopHuman, the UAB researchers scanned a set of 8 measures, which detect different selection footprints and cover distinct time scales along the genome. The detection of these regions in our species allows us to assess the general genomic impact as well as to determine the specific genomic variants responsible for the different human adaptations.

The study includes information from 22 human populations and a total of 2,859 candidate regions under selection. A total of 1986 of these regions had already been detected. The new study by the UAB researchers therefore contributes with 40% more genomic signals relevant to human adaptation, some of which are related to the hybridisation of our species with the Neanderthals and other hominid species. Among the results obtained are well-known examples of local adaptations, such as the recurrent adaptations produced in the region containing the LCT gene, which encodes the enzyme responsible for the degradation of lactose. Another classical example of local adaptation can be found in the region containing the EGLN1 gene, related to the route of the hypoxia inducible factor (HIF), which is related to the ability to live in high-altitudes, such as those living in Tibet.

Journal Reference:

Jesús Murga-Moreno, Marta Coronado-Zamora, Alejandra Bodelón, Antonio Barbadilla, Sònia Casillas. PopHumanScan: the online catalog of human genome adaptation. *Nucleic Acids Research*, 2019; 47 (D1): D1080 DOI: 10.1093/nar/gky959

Micromotors to deliver oral vaccines

Researchers reporting in the ACS journal *Nano Letters* have developed oral vaccines powered by micromotors that target the mucus layer of the intestine.

In addition to avoiding needles, oral vaccines can generate a broader immune response by stimulating immune cells within the mucus layer of the intestine to produce a special class of antibody called immunoglobulin A (IgA). Joseph Wang, Liangfang Zhang and colleagues wondered if they could use magnesium particles as tiny motors to deliver an oral vaccine against the bacterial pathogen *Staphylococcus aureus*. When coated over most of their surfaces with titanium dioxide, magnesium microparticles use water as fuel to generate hydrogen bubbles that power their propulsion.

To develop the oral vaccine, the researchers coated magnesium micromotors with red blood cell membranes that displayed the Staphylococcal β -toxin, along with a layer of chitosan to help them stick to the intestinal mucus. Then, they added an enteric coating that protects drugs from the acidic conditions of the stomach. When given orally to mice, the micromotors safely passed through the stomach, and then the enteric coating dissolved, activating the motors. Imaging of mice that had been given the vaccine showed that the micromotors accumulated in the intestinal wall much better than non-motorized particles. The micromotors also stimulated the production of about ten times more IgA antibodies against the Staphylococcal β -toxin than the static particles.

Journal Reference:

Xiaoli Wei, Mara Beltrán-Gastélum, Emil Karshalev, Berta Esteban-Fernández de Ávila, Jiarong Zhou, Danni Ran, Pavimol Angsantikul, Ronnie H. Fang, Joseph Wang, Liangfang Zhang. Biomimetic Micromotor Enables Active Delivery of Antigens for Oral Vaccination. *Nano Letters*, 2019; DOI: 10.1021/acs.nanolett.8b05051

Researchers develop human cell-based model to study small cell lung cancer

Researchers from Weill Cornell Medicine have used human embryonic stem cells to create a new model system that allows them to study the initiation and progression of small cell lung cancer (SCLC). The study, which will be published February 8 in the *Journal of Experimental Medicine*, reveals the distinct roles played by two critical tumor suppressor genes that are commonly mutated in these highly lethal cancers.

SCLC is thought to develop from a particular type of lung cell, called pulmonary neuroendocrine cells (PNECs), but until now, no one knew how to induce human embryonic stem cells to become PNECs in the lab. "We discovered a means to induce pulmonary neuroendocrine-like cells from cultured human embryonic stem cells after first differentiating them into lung progenitor cells," says Huanhuan Joyce Chen, a postdoctoral fellow at the Meyer Cancer Center, Weill Cornell Medicine, who was one of the lead authors on the study. "We did this by blocking an important cell signaling pathway known as the NOTCH pathway."

"Our system should enable further

studies of the progression of these early-stage tumors into invasive SCLCs that resemble the more aggressive cancers found in patients," says Harold Varmus, co-lead author of the study and Lewis Thomas University Professor at Weill Cornell Medicine. "If so, it should be possible to test cells at different stages of tumor development for susceptibility and resistance to therapeutic strategies."

Journal Reference:

Huanhuan Joyce Chen et al. Generation of pulmonary neuroendocrine cells and SCLC-like tumors from human embryonic stem cells. *JEM*, 2019 DOI: 10.1084/jem.20181155

Indian researchers find antimalarial drug that may be repurposed to treat zika

In their search for a possible treatment for Zika virus infection, a team of Indian researchers have identified a viral protein that can be targeted by an already available antimalarial drug, hydroxychloroquine (HCQ).

Researchers hit upon the protein when they conducted a high throughput virtual screening of a library of drugs approved by America's Food and Drugs Authority. Out of 1861 compounds

in the library, five including HCQ appeared to be possible candidates for the treatment of Zika virus. It has also been found that HCQ limits the Zika virus transmission from mother to foetus. The study was conducted by researchers at the Indian Institute of Technology, Mandi, Alagappa University in Karaikudi, Tamil Nadu and Washington University at St Louis.

"Hopefully we are close to finding a potential drug against Zika. We have successfully identified the target protein on which HCQ acts. Since it is an FDA approved drug our journey for validation may be less tedious and we can go for pre-clinical trials faster," said Dr Rajanish Giri, a researcher at IIT Mandi, while speaking with India Science Wire. "Repurposing approved drugs can be an efficient method to identify drug compounds, which may be capable of activating or inhibiting new targets. This approach has some advantageous features, including reduced development time and expense and improved safety" he added.

The team of researchers include Dr Rajanish Giri from IIT Mandi, Prof. Indira U. Mysorekar from Washington University and Prof. Sanjeev Kumar Singh from Alagappa University. A paper on the work has been recently been published in journal *ACS Omega*.

NOTIFICATIONS

**Ministry of Science & Technology
Department of Science & Technology
SwarnaJayanti Fellowships Scheme 2018-19**

Government of India had instituted a scheme titled “SwarnaJayanti Fellowships” to commemorate India’s fiftieth year of Independence. Under this scheme a selected number of young scientists, with excellent track record, are provided special assistance and support to enable them to pursue research in frontier areas of science and technology. The fellowship is scientist specific and not institution specific.

Scientists selected for the award will be allowed to pursue unfettered research with a freedom and flexibility in terms of expenditure as approved in the research plan. The project should contain innovative research idea and it should have a potential of making impact on R&D in the discipline.

The duration of the fellowship along with the project will be for a period not exceeding five years.

The fellowship is open to Indian Nationals having a regular position in a recognized Indian academic/research organization. The applicant should possess Ph.D in Science/ Engineering/ Medicine and should not be drawing Fellowship from any other Scheme of GOI.

The fellowship is open to scientists between 30 to 40 years of age as on December 31, 2018. Applications from candidates who have completed 40 year of age as on or before 31.12.2018 will not be considered.

Applications for the “SwarnaJayanti Fellowships Scheme 2018-19” are invited from eligible candidates. Candidates may log on onlinedst.gov.in from 15-02-2019 to access the home page of the “DST e-PMS Portal” for details & downloading the format from SwarnaJayanti Fellowships Scheme and submit the application in online mode only. There is no need to send a hard copy.

The last date for submission of applications is March 31, 2019 by 1159 pm.

Recent Biotech Notifications

DST SwarnaJayanti Fellowships Scheme 2018-19

(Last date: 10/03/2019)

DBT invites application for Scientist H Government Job

(Last date: 10/03/2019)

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Phone : 080-2852 8900/01/02; Mobile: 99160 22174; Email: biopolicypgd@gmail.com

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- Livestock health and improvement
- New and improved agricultural tools
- Reducing post-harvest losses
- Combating environmental pollution



Who can apply?

- Academic institute, University, NGO or Research Foundation having proper registration/accreditation from a government body is eligible to apply with one or more partners of which at least one is a company

- Companies/Start-ups/Limited Liability Partnerships - LLP (with minimum 51% Indian ownership) are eligible to apply either alone, or in collaboration with another Company/academic institution

How to apply?

Proposals are required to be submitted online only. For scheme details and submission of proposals, log on to BIRAC website (www.birac.nic.in)

For queries, please contact: Head-Investment (BIRAC): investment.birac@gov.in

Last date for submission of proposals

11th March, 2019

Recent Biotech Notifications

Walk-in-Interview for contractual positions of Scientist-D, Scientist-C, Consultant in DHR, Ministry of Health and Family Welfare.
(Walk in date: 22/02/2019)



DEPARTMENT OF BIOTECHNOLOGY

Ministry of Science & Technology

Government of India

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PRE iGEM 2019

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Details of Eligibility can be access from : <http://www.dbtindia.nic.in/wp-content/uploads/Eligibility-Criteria-2.pdf>

Registration Form can be access from : <http://www.dbtindia.nic.in/wp-content/uploads/Registration-Form-2.pdf>

Soft copy of the proposal can be send to the undersigned E-mail address followed up by the hard copy of the same to the undersigned office address.

IMPORTANT DATE

February 28th, 2019

Last Date for proposal submission

(*Grant of Release is subject to proof of registration and signing of MoA)

For and other issues, kindly contact concerned officer:

Dr. Sangita M. Kasture
Scientist

Room No. 717, Block -2 ,C.G.O. Complex
Department of Biotechnology
Ministry of Science & Technology
Government of India
Lodhi Road, New Delhi-110003, INDIA

Email: sangita.kasture@nic.in

9th Workshop on Bioinformatics and Molecular Modeling in Drug Design (BIF-MMDD-2019)



ACBR

MARCH 25 – 27, 2019

VENUE: SEMINAR HALL, ACBR, UNIVERSITY OF DELHI, DELHI

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Bioinformatics & its Application in Understanding Gene/Protein Function

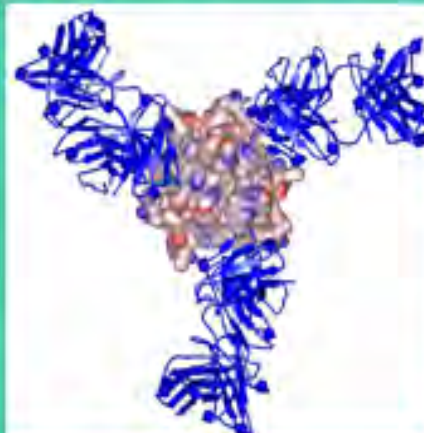
Protein Structure Prediction

Energy Minimization & Molecular Dynamics

Understanding Bio-molecular Interactions

Structure and Ligand Based Drug Design

Protein-Protein Interaction Network and Big Data Analysis



Selection Criteria

Selection will be based on one-page write-up describing how the workshop will benefit you in your area of research. Send your applications through email to Dr. Madhu Chopra. Preference will be given to active researchers, teachers and scientists working in this field. You will be informed by email. For details and registration form please visit our website www.acbrdu.edu.

Important Dates

Last date of application:

March 11, 2019

Intimation of selection:

March 15, 2019

Number of participants: 30

REGISTRATION

Without Accommodation

With Accommodation**

FEE*

Rs. 1200 /- (Faculty)

As per University Guest House rates

Rs. 800 /- (Students)

* Registration Fee will be accepted in the form of DD in favour of Director, ACBR, payable at Delhi and is to be paid only after selection

** An accommodation for 4-5 persons can be arranged on first cum-first serve basis

Invited Speakers

Prof. B. Jayaram, IIT, New Delhi
Dr. Debasisa Mohanty, NII, New Delhi
Dr. Dinesh Gupta, ICGEB, New Delhi
Dr. Anshu Bhardwaj, IMTECH, Chandigarh
Dr. Gitanjali Yadav, NIPGR, New Delhi
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Dr. Lipi Thukral, IGIB
Dr. Arnab Bhattacharjee, JNU
Dr. Madhu Chopra, ACBR

Chairperson

Prof. Daman Saluja
Director, ACBR

Scientific Advisory Committee

Prof. Vani Brahmachari
Prof. K. Natarajan
Dr. P. M. Luthra

Conference Secretariat for Correspondence

Dr. Madhu Chopra

Course Director & Coordinator,
Bioinformatics Infrastructure Facility (BIF-DBT Sponsored)
Dr. B. R. Ambedkar Center for Biomedical Research (ACBR)
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