

PH.A.S.E.S

A Student Run Magazine on Clinical Research

INTERVIEW with a
Pharmaceutical Industry
Expert

Clinical Research:
The Story of
Research
and Ethics

Aroma healing
—a daily peace
ritual

Bacteriophages
for Treating Lung
Infections

Anti-Inflammatory
Drugs May Prolong
Back Pain

May, 2022
Issue 1



SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(Category - I Deemed to be University) Porur, Chennai

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By Students of B.Sc. and M.Sc. Clinical Research

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FOREWORD

I am extremely happy to know that the students of BSc and MSc Clinical Research, SRIHER, are bringing out an e-magazine to mark the “Clinical Trials” day.

With the ever-increasing demand for better healthcare, development of newer drugs/vaccines has become much more challenging. The rate of success and failure of drugs in specific population, critical regulatory requirements and widespread reports of adverse reactions highlights the importance of proper conduct of clinical trials. The students who are pursuing undergraduate and postgraduate studies in the field of clinical research would be very well equipped if they follow each and every aspect of the clinical trials that are conducted and the challenges faced. In this student’s magazine, students have sourced information on clinical trials, their outcome, updates in regulations, and opinions from clinical trial industry experts and put them together in an exciting way for fellow students and research scholars to understand about this constantly expanding field.

This initiative to publish an e-magazine completely run by the students is a welcoming one. This will motivate students to read and review current research, and stay abreast of the updates in the field. The magazine also has sections to feed the curiosity of young students and freshers by way of familiarizing clinical research concepts through puzzles, crosswords and quiz and related activities. The students’ corner challenges the individual skills of students and keep them engaged. This is a good exercise to empower them with team work, organization and leadership skills that will help in their future career. It will also stand as an impressive document of our student’s profile for the future employers.

I wish the students great success and effective learning with this student-run e-magazine, a unique initiative that will add a feather to the cap of SRIHER.

Dr. P. Ramachandran
Head – Faculty of Clinical Research
SRIHER



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Background & Departmental activities

HOW P.H.A.S.E.S CAME INTO BEING...

Warm greetings from the students of clinical research program at SRIHER!!

It's usual practice for Universities, Colleges, Departments and Faculties to release newsletters describing the various happenings, achievements, activities and so on. Our SRIHER newsletter 'Bridges' captures every single event that happens at SRIHER and highlights the achievements and new ventures by students and faculty members.

You may wonder then, why do we need a magazine for clinical research. Let's get into the story of how it all started.

Clinical Research is a relatively a new field for many of us. When we opted to pursue Clinical Research as our U.G. or P.G. program, we had many thoughts and misgivings. While some of our postgraduate students were dentists (B.D.S), pharmacists (B.Pharm.), engineers (B.Tech. Biotechnology/Bioengineering) and science graduates of various origins (Microbiology, Molecular Biology, Chemistry, etc.) embarking on a new journey on a new path, undergraduate students were at a greater fix as they were choosing a degree program their relatives and friends have never heard of. Slowly as we moved across semesters, we realised the nature and importance of the field of clinical research and the abundant opportunities this field could provide for us. A plethora of clinical trials are being conducted currently and some of the key trials happen in India. We are learning the advantages of regulatory requirements, genetic diversity of the population and other factors in India that drive international pharma companies to conduct their clinical trials here. It is really beneficial to know different facets of health research that's happening around us at the same time getting trained as clinical trial professionals to take part in those research activities in future.

It was a struggle for us initially as there are not many standard books and texts in clinical research, as the curriculum of this new field is framed on the various aspects of clinical trial operations and regulations. The concepts discussed by the faculties in class combined with self-exploration of clinical trial documentation, has aided us in our learning. Following up clinical research across different fields through clinical trial registries and databases, keeping abreast of the guidelines by regulatory bodies like DCGI and FDA, hands-on training in various aspects of clinical trials have all contributed to our learning curve.

Background & Departmental activities

Many of us have interests in various topics and areas of clinical research. Reviewing information from exciting research work by individual students/ groups will lead to strong scientific interaction and combined learning. This magazine is a result of such combined learning effort across various semesters of students under clinical research program. Students will read, research, review and write interesting articles to share knowledge across various domains of clinical research. New and interesting facts on clinical trials, crosswords and puzzles that provide unique learning experience are also part of this magazine. As an additional benefit, we want to use this opportunity to showcase talents from our students and achievements for motivation.

This magazine is entirely prepared, proofread, edited and designed by student teams. This will be released as an e-magazine for every quarter of the year hereafter. And we are proud to announce the first issue of this magazine on the 'International Clinical Trial Day'

Looking forward to a greater learning experience,
B.Sc. and M.Sc. Clinical Research Students

Glimpse of the activities over past 3 years

One Day Workshop on “Good Clinical Practice (GCP)” 19th August 2019

Jointly organized by Faculty of Clinical Research & Institutional Ethics Committee (IEC)



Speaker:
Dr. Arati Borkar
Director - Quality
DiagonoSearch Life Sciences Pvt. Ltd.

Lectures on various aspects of clinical research were delivered:

- Ethical principles in clinical research
- Evolution of good clinical practice
- Project lifecycle
- Roles and responsibilities of Institutional Ethics Committee, investigating physician and other members of the clinical study
- Patient recruitment and informed consent
- Study drug or Investigational Product (IP) management
- Data handling, documentation
- Safety reporting and Pharmacovigilance

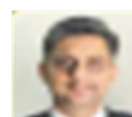
Sessions were interactive and each session had a quiz to assess understanding of the participants



Live Webinar on ““The Changing Face of Clinical Trials”” 9th August 2019



Ms. Yasmin Shenoy
Senior Director
Regulatory Affairs
Sanofi India Limited



Dr. Chirag Trivedi
Director and Head- Clinical Study Unit
India & South East Asia Cluster
Sanofi India Limited
President - Indian Society for Clinical Research (ISCR)

Sanofi India Ltd. organized the webinar to appraise the clinical research community on the New Drug & Clinical Trial Rules notified in March 2019.

The interactive session focused on defining academic trials, roles and responsibilities of investigator and ethics committee. The process of obtaining regulatory approval to conduct clinical trials were also discussed along with other exciting updates on the regulatory perspective of clinical research.

Members of Institutional Ethics Committee, Clinical Research Team from SRIHER, staff members and students from Faculty of Clinical Research & Faculty of Pharmacy attended the webinar.



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Semilunar LED illuminated mouth mirror

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Dental chair with handheld UV sterilization wand

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Flexible intra-oral cotton roll holder

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SARS COV-2 OMICRON VARIANT (B.1.1.529)- A REVIEW


Dr. Sushmitha. M, Dr. Karpagam. S, Dr. Merrylda Claribel. S, Dr. Mohammed Haroon. A.L, Dhinakar. R

M.Sc., Clinical Research, Sri Ramachandra Institute of Higher Education and Research,

ABSTRACT

Coronavirus disease (COVID-19) is a highly contagious disease that has caused a global health crisis with the death of more than 3 million people worldwide. It is caused by the SARS CoV-2 virus. Ever since the outbreak of the disease, the virus has been mutating constantly giving many variants. The delta variant that originated in Maharashtra, India has caused severe health issues and death. Other variants are alpha, beta, gamma, lambda, and mu. In November 2021, a variant of SARS CoV-2 was discovered in South Africa. The variant is named Omicron and WHO announced it as the Variant of Concern (VOC). This review article highlights the phylogenetics and features of the omicron variant.

Keywords: Omicron, SARS, COV-2, Covid-19



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Original Research Paper

Dentistry

AMELOGLYPHICS-AN UPDATED REVIEW


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Dr Mutum Sangeeta Devi	Dental Oncologist, Tata Medical Center, Kolkata, India.

ABSTRACT

In this modern era equipped with technologies, the crime rates are increasing exponentially. This requires newer methodologies to identify a person who is a victim as well as the perpetrator. Automated biometric systems helps in identifying the individuals by the stored information in the database which are unique for each individual. Some of the important methods are fingerprint biometrics and iris scanning. As these methods involves soft tissues they cant be relied upon during mass disasters like burn accidents and gas leakage accidents. Hence, a biometric system using the hard tissue is required for better identification of the individuals. Thus, Amelogyphics is introduced to aid in identification of individuals died during mass disasters and it plays a vital role in forensic odontology. This review highlights this technology in detail.

KEYWORDS : Amelogyphics, tooth prints, forensic dentistry


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Review Article

Vitamin D nemesi of COVID-19

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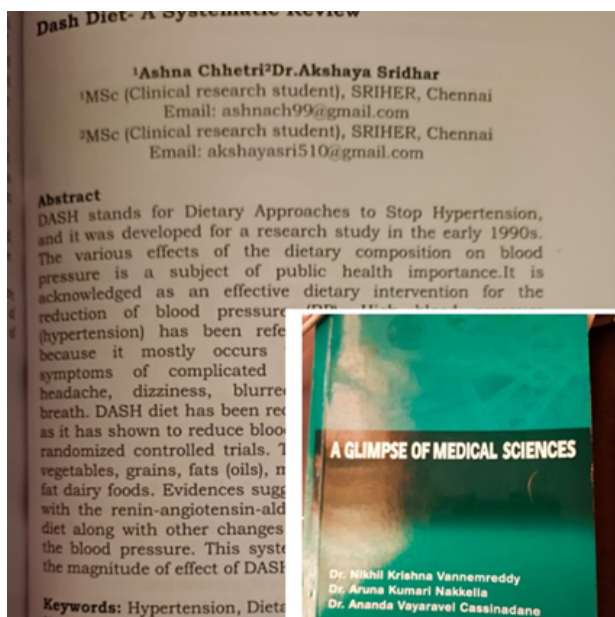
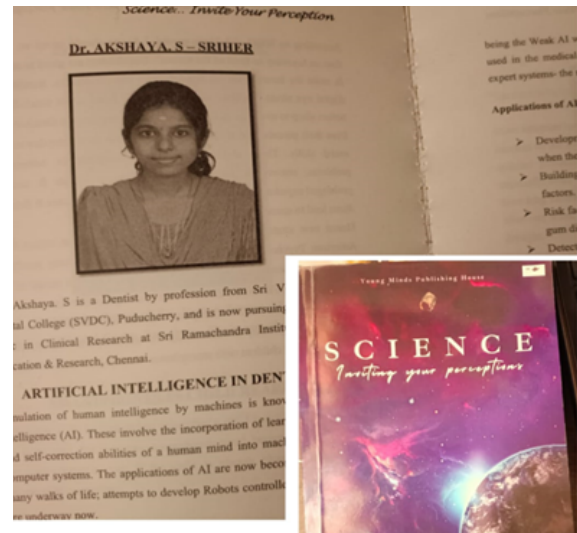
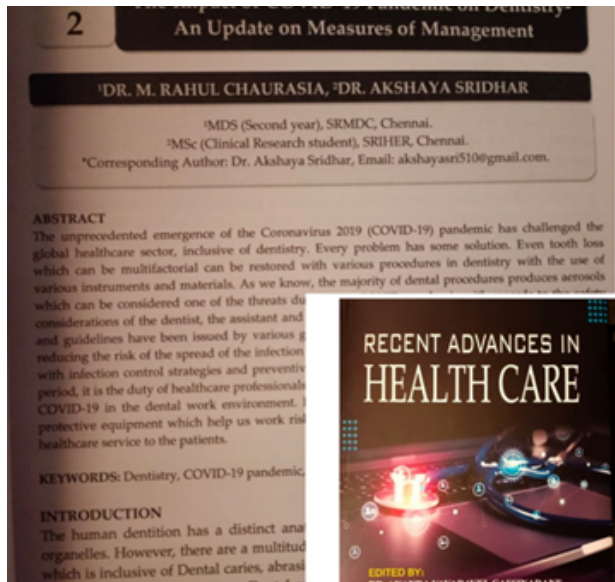
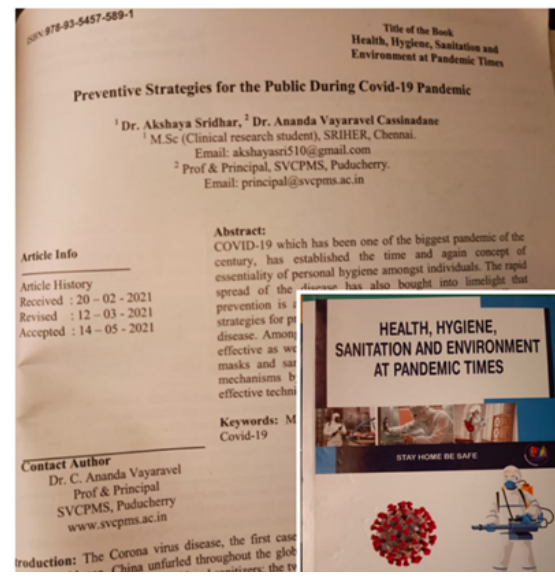
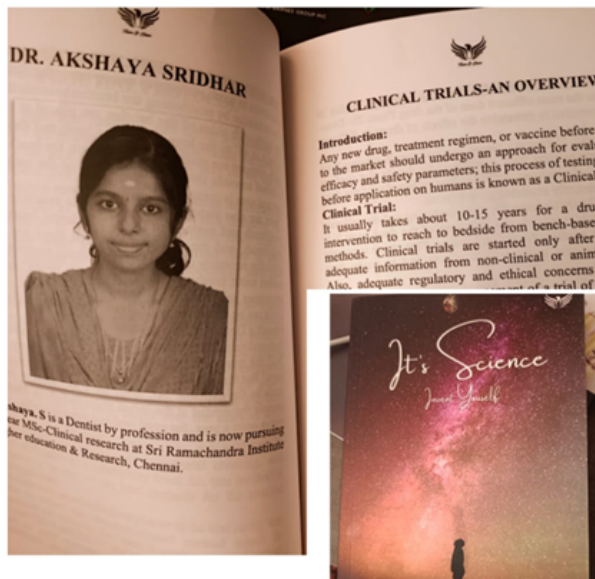
Covid- 19

Cytokine storm

ABSTRACT

The surge in the spread of the corona virus disease (COVID-19) pandemic alerted us to opt for the preventive medicine, as prevention is always better than cure. Apart from wearing mask, frequent hand washing and social distancing, strengthening our immune response plays a pivotal role in preventing infections. Vitamin D not only aids in calcium and phosphate homeostasis but also acts as an immunomodulator; the deficiency of which is linked with various respiratory and systemic infections. Hence we took up this review to study the effect of vitamin D in corona illness. Vitamin D exerts the expression of pro-inflammatory cytokines, hinders zinc metabolism, lowers Interleukin 6 levels and thereby inhibits cytokine storm in covid patients. Studies have proved that the covid patients have vitamin D deficiency and its supplementation improves the disease severity as well as the length of hospital stay. To

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Ms. Dhanalakshmi M



Dept. of Microbiology
CSIR – CLRI
Chennai

Ms. Krishnapriya RB
Ms. Jaahnavi
Ms. Hemalatha

Aaranya
BioSciences

INDUSTRY VISITS BY B.SC. CLINICAL RESEARCH STUDENTS

Scitus Pharma Services Pvt. Ltd.

Contract research organisation (CRO) located in Chennai, India.

- Conducts Bioavailability and Bioequivalence studies on healthy volunteers and patients
- Phase II to Phase IV clinical trials
- Assists pharma companies to develop generic drug products from active pharmaceutical ingredients to formulation development, analytical development, stability, clinical development and regulatory support for ANDA submission



Innospecs Bioresearch Pvt. Ltd.

Contract research organisation (CRO) located in Chennai, India

- Conducts Phase I to Phase IV clinical studies
- Clinical studies for Nutraceutical, Herbal, Cosmetic products to establish safety and efficacy.
- Vast& highly equipped Bioanalytical facility catering to:
 - o Clinical end point determination
 - o Patient based PK studies
 - o Establishing proof of concept

STUDENT INTERACTIONS WITH INDUSTRY EXPERTS



“All human interactions
are opportunities
either to learn or
to teach.”

-
M. Scott Peck

Mr. AbishekKunwar
National Professional Officer- Cardiovascular Disease
World Health Organization-India



Mr. Rohit Shivram Joshi
Manager – Clinical Operations
Stempeutics Research Pvt. Ltd.

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**Clinical Research Division,
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Dr. Mohammed Haroon

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Mr. Vasanth T
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Mr. Balaji. K
Mr. Kollamsetti Anantha Balaji

INTERNATIONAL CLINICAL TRIALS DAY

— 20TH MAY 2022

“His trial was the foundation over which modern clinical trials were built on”



James Lind (1716-1794)

When we trace back the history of clinical trials, the first ever report of a clinical trial can be found in one of the oldest books in the world, The Bible. Yet, the first ever controlled clinical trial was conducted in the year 1747 by Dr. James Lind on Scurvy.

May'1747

James Lind was a surgeon aboard the British Royal Navy fleet, HMS Salisbury that patrols the English Channel. Huge numbers of seamen were affected by Scurvy and lost their lives during that time. The loss of life from Scurvy was much higher than that from the clashes with French and Spanish troops.

James Lind had a theory that Scurvy was caused by putrefaction of the body and he thought introduction of acids could be a cure for Scurvy.

He allotted 12 men into six groups (2 each) containing different treatments. The treatment options included 1.1 litres of cider, twenty-five millilitres of elixir vitriol (dilute sulphuric acid), 18 millilitres of vinegar three times throughout the day before meals, half a pint of sea water, two oranges and one lemon, a medicinal paste made up of garlic, mustard seed, dried radish root and gum myrrh. He continued this treatment for 6 days.

He found that those allocated with citrus fruits experienced “the most sudden and good visible effects”.

His study was not recorded to have been conducted after any approvals and not have documented informed consent form and other modern requirements of clinical trial. Yet, his trial was the foundation over which modern clinical trials were built on. James Lind was credited with having rightly ‘compared like with like’, and the design of his trial have inspired and informed future clinical trial design. To commemorate his clinical trial, 20th May is celebrated as International Clinical Trials Day, to create awareness about clinical trials and for taking measures to improve the quality of clinical trials.

DR. RAMANATHAN L, DGM APEX LABORATORIES PVT. LTD.

Insight With An Industry Expert



"Attitude, ability to learn new things, involvement in the team work and knowledge are the qualities that makes an applicant recruitable"

Some of us clinical research students had the wonderful opportunity of conducting an online interaction session with Dr. L. Ramanathan and his team Mrs. Shruthi from Apex Laboratories over Zoom video conference. We talked about the expanding grounds of clinical research, the regulatory affairs and the increasingly diverse job opportunities in those areas.

Through this conversation, we gained insight to the works of Apex Laboratories and their contributions to the field of clinical research.

Started in 1978, apex is a pharmaceutical manufacturing and marketing company headquartered in Chennai, India. They currently have 4 manufacturing plants, R&D division(with 18 full time Scientists), and IPR section (with 118 patterns).

THE INDUSTRY EXPERTS:

Dr. Ramanathan, DGM, Regulatory Affairs, Apex laboratories

Dr. Ramanathan started as a Lead scientist and has worked his way up to the Deputy General Manager of Regulatory affairs & BD at Apex Laboratories Pvt. Ltd.

He completed his PhD in Nanoscience (Targeted Drug Delivery System) from Israel Institute of Technology.

Dr. Ramanathan takes care of the Regulatory Affairs, Clinical Trials and Business Analytics

Mrs. Shruthi Krishnan- Assistant Manager in Pharmaceutical Regulatory Affairs, Apex Laboratories Pvt. Ltd.

THE INTERVIEW EXCERPT:**Q: What is the future of clinical research, R&D and Pharmaceutical research and Regulatory Affairs in India?**

Dr. Ramanathan: There is a bright future, because lately all the drugs that come under BCS Level II & IV drug will need to be tested for bioequivalence and like in the US, we have also brought in subsequent NDA which definitely require phase 1 and 2 studies. That is, if you have a product and if its strength or indication has been changed, then it is mandatory to conduct a clinical trial in that case.

Throughout the years, the need for clinical trials have drastically increased. If you go through the clinical trial websites, you will come across a lot of registered trials. And especially after the pandemic, a lot of drugs are repurposed.

Q: Sir, We all are from Clinical Research background, we study different aspects of CR in a more focused way than people from Biotechnology or Pharmacology. So, what are the main skills that you look for while you hire graduates?

Dr. Ramanathan: I am more focused on translational research, so my team consists of people from different backgrounds like Clinical Trial, BDS, Pharm D, Chemistry, Biotechnology and so on. It doesn't matter which background you are from, the requirements for each of them will be different.

If you have some hands-on experience from the pharmacology part of the trial (like primary & secondary endpoint, inclusion & exclusion criteria) that would be very helpful apart from the skills required for monitoring, site visits etc. And you should also be familiar with designing protocol for the whole study. Attitude, ability to learn new things, involvement in the team work and knowledge are the qualities that can be taken into consideration. He added, your CV must be specific to the job title that you have chosen and must be unique from others in some aspects.

Q: Can you give us a basic run-through of Regulatory application filing for your company.

Dr. Ramanathan: Most of the application is for similar products that already exist, there we just compare the efficacy of generic drugs to the patented ones. There is some variation limit allowed in each country, if the values fall within the limit, then it's fine.

On the other hand NDA is a bit tricky, we need to see if we have a reference product or not, look at drug-drug combinations, drug-device combinations and we also need to do a number of in vivo and in vitro to determine the different aspects before applying for the NDA. Then we need to attend a lot of pre-NDA and scientific meetings to get feedback.

The DCGI has an subject expert committee. Once a NDA is applied, it is reviewed for its regulatory part, clinical part by the subject expert committee. So the committee mandates a trial unless it has been tested in India. If the trial is conducted elsewhere, then the committee demands a bridging study.

Mrs. Shruti: Currently we are working on a US based new drug, so for the IND we follow the 21 CFR 312 regulations and for the preclinical studies we need to follow the 21 CFR 58. Later when we get the IND approval from the US FDA, we can initiate the clinical trials.

Q: As you have worked on applications for both Indian and US based regulatory bodies, which one do you think is the most hectic to apply for?

Dr. Ramanathan: It's the Indian ones. In the US based regulatory bodies there are a lot of departments to whom you can send your queries or approach them for an open discussion. But in India it's an upcoming system, so the clarity is a bit less and everything depends on the Subject Expert Committee (they decide upon the protocol and other parameters)

Q: During COVID there was a need for rushed approvals, so are there any protocols dedicated just for a worldwide emergency?

Dr. Ramanathan: For any known or repurposed drug that was classified as an antiviral, the DCGI gave out the notification for it to be on a fast track mode (around March 2020). For example, if a drug was tested for its antiviral property in some other country, you can directly go in for a phase 3 trial here without the need for pre-clinical testing.

They also developed an information center for the COVID drugs. So if you call them, they will secure a pathway for drug approval.

Q. What are the guidelines that are to be followed while running a clinical trial on drugs?

Dr. Ramanathan: CDSCO, AYUSH and the guidelines listed by the Ministry of Health and Family Welfare. If the drug is plant based, then the approval must be acquired from AYUSH. He further added that the drug named “Clevira” is a plant based drug for which approval from AYUSH has been obtained for conducting clinical trials which has been used for the treatment of mild to severe covid-19 infection.

Q. What is the most important feature for a drug to be approved by the regulatory body?

Dr. Ramanathan: Label claim is the most important feature for a drug to be approved by the regulatory body.

Q. What are the online certifications that you recommend the freshers to be done with?

Dr. Ramanathan: If your educational background is from clinical research, there is no need for any certification as your curriculum includes all the necessities for a job. If you have keen interest in exploring new things related to clinical trials, then you can definitely enroll yourself and have the certification. As far as a job is concerned, you must have prior working experience as an intern for about 6 months to one year at any company.

Q. What do you find most enjoyable about your job?

Dr. Ramanathan: The most enjoyable part is facing new challenges like holding discussion meetings to convince the clients for approval of clinical trials, drugs which makes me feel thrilled and confident.

Q. What are the difficulties in conducting clinical trials in India?

Dr. Ramanathan:

- Identifying a right clinical trial site for conducting trials is the most challenging task.
- Location of the ethics committee for a multi-centric study involving a large population.
- Withdrawal from the trial by the rural people at the mid of the trial after signing the informed consent form. So, statistics will be affected which is the other challenge for reporting the data.
- Development of apps for Case Report Forms and the monitoring of scales.

Q. What kind of exposure would a fresher who wants to pursue a career in Regulatory affairs be aware of?

Dr. Ramanathan: You must be aware of the Drugs and Cosmetics Act, ICMR Guidelines, ICH-GCP, CIOMS Guidelines, CDSCO and FSSAI regulations and the current affairs on CDSCO and FSSAI websites. Also a basic knowledge of Indian Pharmacopoeia (IP) and British Pharmacopoeia is enough.

Q. In preclinical toxicology, rather than testing on animals, in-vitro research is more preferred. So, is there any such advancement in clinical toxicology?

Dr. Ramanathan: Usage and treatment of animals so far has changed. For testing toxicity in invitro condition, there are not many absolute methods established. To get CPCSEA approval one should have all necessary data like irritancy, toxicity and also if any previous records. There is no absolute replacement for animal models currently but regulations are changing to decrease the number of animals used keeping animal ethics in mind and new methods are implemented to eliminate animal experimentation possibilities.

Q. Future of AYUSH products outside India

Dr. Ramanathan: AYUSH products are currently very limited to countries like the Netherlands and Germany. It has a lot of scope but more studies are required. Every country has their own set of regulations. They want their studies to be conducted on their native population rather than already existing data from countries like India and China.

Q. In the regulatory aspect, which one is more challenging: pre-clinical or clinical studies?

Mrs. Sruthi: The challenges are different in clinical and preclinical studies, the objective of preclinical studies should be convincing for the regulatory agencies that it will be fruitful and beneficial for human use. But incase of clinical studies, we need to prove that our product is safe and efficient for human use. To conduct toxicology studies or proof of concept studies in animals you need to approach the GLP accredited labs as per the different guidelines that are provided by the regulatory bodies. So, the application part is more important once you choose the pre-clinical center. We cannot compare the clinical and preclinical studies because of the different aspects and importance of each but the clinical part is more challenging considering safety and efficacy in humans.

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CLINICAL RESEARCH: THE STORY OF RESEARCH AND ETHICS

Clinical research is a term which refers to all research carried out on humans. It helps to find more information on diseases which aids in the development of diagnostic methods and treatment methods or medical devices conclusively results in the betterment of patient care. Clinical research has 2 main types,

- Observational studies
- Interventional studies or Clinical trials

“The charm of history and its enigmatic lesson consist in the fact that, from age to age, nothing changes and yet everything is completely different.”

- Aldous Huxley

The long path of Clinical research is an enticing one, the World's first clinical trial was mentioned in “Book of Daniel” Bible, which was done by King Nebuchadnezzar during his rule in Babylon. He ordered his people to eat only meat and drink only wine which he believed to be the best diet to maintain sound physical condition, but some of the royal people who loved vegetables objected so he allowed them to take only legumes and water for only 10 days. After the experiment end, the people who ate vegetables were well nourished than others so he allowed his people to continue the diet.

The First Physician who done the Controlled Clinical trial of Modern Era was “James Lind” in 1747. He worked as the Surgeon on ship, was disturbed by the deaths due to “Scurvy” among sailors and planned the trial. He selected 12 members and divided into 6 different groups, each with different treatment option and followed up for 6 days. From which he found that people who

“Ethics is not definable, is not implementable because it is not conscious; it involves not only our thinking but also our feeling”

-Valdemar.W.Setzer

ate Oranges and Lemon showed speedy recovery than other treatments.

Followed by, the word Placebo was appeared in medical literature in 1800. The first double blind study was done in 1943 by Patulin Clinical Trials Committee on Common cold. The first Randomized control trial was designed by Sir Bradford Hill involving statistics in Research which is considered to be the groundbreaking point for clinical research.

Along the evolution of Clinical research, there were lot of tragedies which shouted to the world about the importance of “Ethics” in clinical research.

Some of the Unethical clinical research experimentations and tragedies on History are

- Nazi war experiment
- Willow brook Hepatitis study
- Jewish Chronic disease study
- Tuskegee syphilis study
- Thalidomide tragedy

Due to the above mentioned experiments and tragedies the importance of ethics in human experimentation considered, following various acts and committees were formed along the history which is represented in the Fig.1

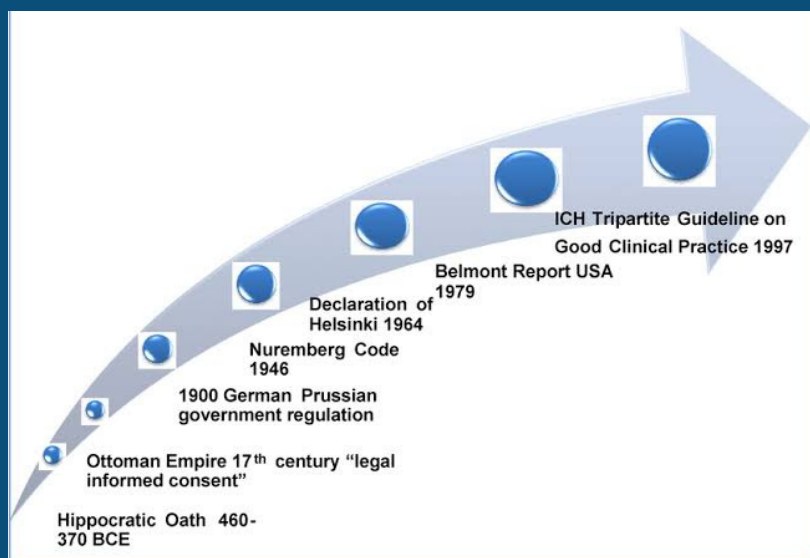


Fig.1: The image represents the evolution ethics in clinical research

Present scenario of Clinical research in India:

The India accounts for nearly 16.0% of the population worldwide and nearly 20% of the disease burden across the globe, yet less than around 1.4% of total global clinical trials are conducted in the country. While there is no database maintained in publicly accessible locations that tracks the industry, based on market estimate and forecast, the Indian clinical trial market size was estimated at USD 1,897.43 million in 2019 and is expected to reach USD 2,064.30 million in 2020. India accounted for an 8.3% share of the global clinical trials activity in 2020. The Indian clinical trials market is expected to grow at a compounded annual growth rate of 8.7% from the period 2017 to

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2025 to reach USD 3,125.16 million by 2025. While it is difficult to validate these numbers, it can be safely stated that there is definitely an uptick in the number of clinical trials done by the pharmaceutical industry. Infectious Disease was the leading therapy area for industry-sponsored clinical trials in India in 2020 with approximately 30% share.

It is well known that there were several clinical trials for COVID-19 therapeutics and vaccines being done in 2020 and continuing well into 2021. Oncology studies also showed a steady increase in numbers from 2020 and several sponsors and CROs are bringing their oncology portfolio of work to India.



Fig.2: represent the present and future Clinical trial market in India

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List of New Drugs Approved in Year 2022 in India

Name of drug	Indication
Triamcinolone Hexacetonide injectable suspension 20mg/ml	For intraarticular, intra-synovial or periarticular use in adults and adolescents for the symptomatic treatment of subacute and chronic inflammatory joint diseases including rheumatoid arthritis and Juvenile Idiopathic Arthritis (JIA), Osteoarthritis and post-traumatic arthritis, Synovitis, tendinitis, bursitis and epicondylitis.
Gimeracil bulk & Oteracil potassium bulk and Tegafur 15mg/20mg, Gimeracil 4.35mg/5.8mg and Oteracil 11.8mg/15.8mg capsules	Indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin.
Nitric oxide nasal spray	For treatment of adult high risk patients with mild Covid-19 having risk of progression of the disease.
Vericiguat tablets 2.5mg/ 5mg/ 10mg	Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%
Inosine pranobex bulk and Inosine pranobex 500mg tablet	As add on therapy for treatment of mild Covid-19 patients with co-morbidities and moderate Covid-19 patients, in light of Covid 19 outbreak for restricted emergency use in the country
Desidustat bulk and Desidustat tablets 25mg and 50mg	For treatment of Anemia in adult patients with chronic kidney disease (CKD) not on Dialysis and on Dialysis
Lumacaftor bulk, Ivacaftor bulk & Lumacaftor and Ivacaftor tablets 100mg/125mg and 200mg/125mg	Indicated for the treatment of cystic fibrosis (CF) in patient age 2 years and older who are homozygous for the F508del mutation in the CFTR gene.
Liothyronine sodium bulk and Liothyronine sodium tablets 5mcg & 20 mcg	To treat some of the more severe conditions in which the thyroid does not produce enough thyroxine and balance the effect of medicines used to treat an overactive thyroid.
Polyhexamethylene guanidine hydrochloride 1.000lit	For surface disinfection

Finerenone 10mg/20mg film coated tablets	Indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 Diabetes (T2D)
Sugammadex sodium bulk and Sugammadex injection 100mg/ml (single dose vial for bolus injection, IV)	Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery
Nirmatrelvir bulk and Combipack of Nirmatrelvir 300mg tablets (2x150mg tablets) and Ritonavir tablets 100mg	For treatment of adult patients with COVID-19, with SpO ₂ >93% and who have high risk of progression of the disease including hospitalization or death, in light of Covid 19 outbreak for restricted emergency use in the country
Aviptadil bulk and Aviptadil injection (Each ml vial contains Aviptadil 15 mcg)	For treatment of patients with severe COVID-19 with Acute Respiratory Distress Syndrome (ARDS), in light of Covid 19 outbreak for restricted emergency use in the country



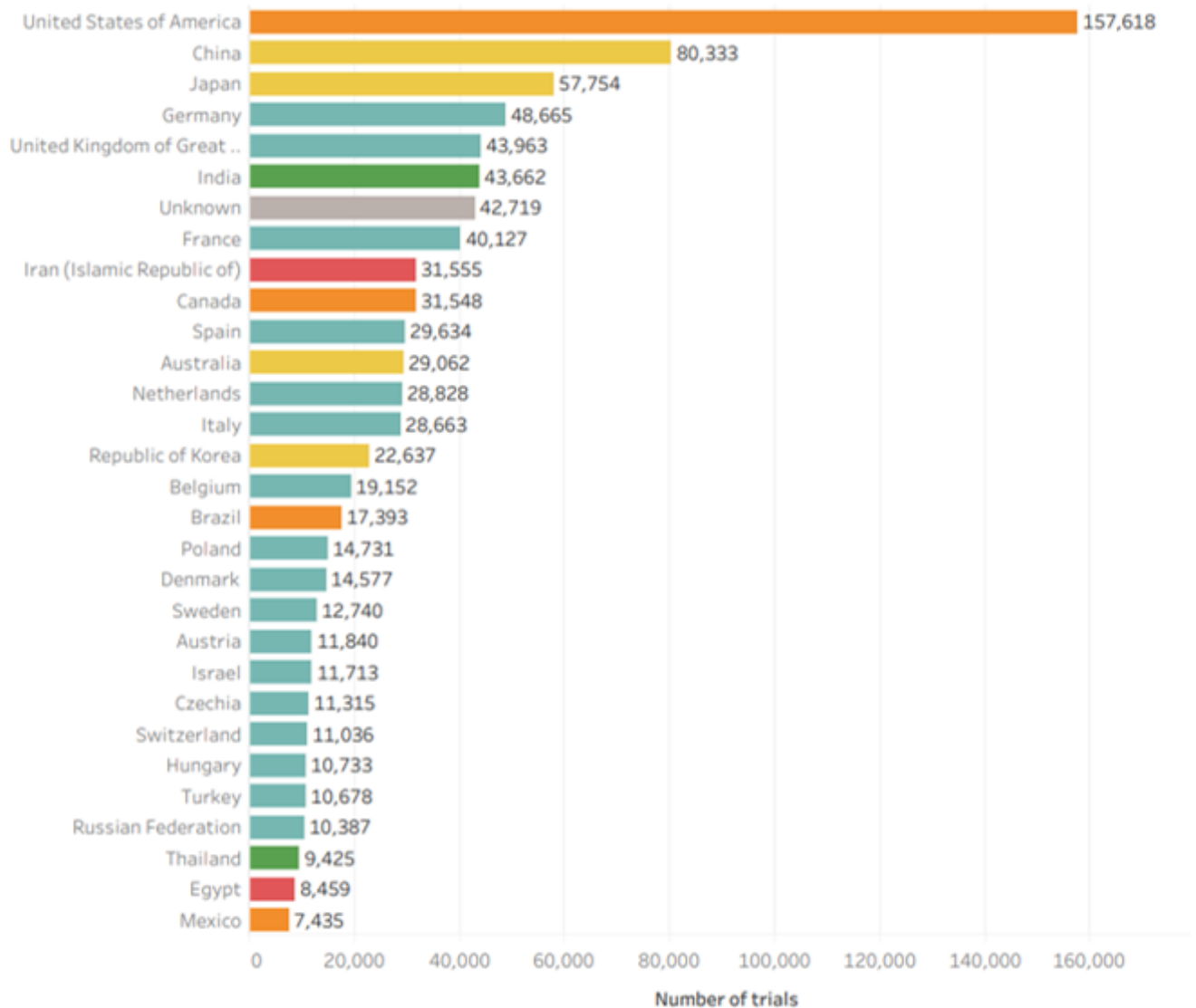
This table was procured from the official website of CDSCO (Central Drug Standard Control Organization) which comes under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. The Drug Controller General of India (DCGI) heads the CDSCO and acts as the National Regulatory Authority (NRA) of India.

The main objective of CDSCO is to approve Drugs, conduct of Clinical Trials, Standards for Drugs and Quality of Imported Drugs in India. It is also responsible for the co-ordination of the activities of State Drug Control Organizations by expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

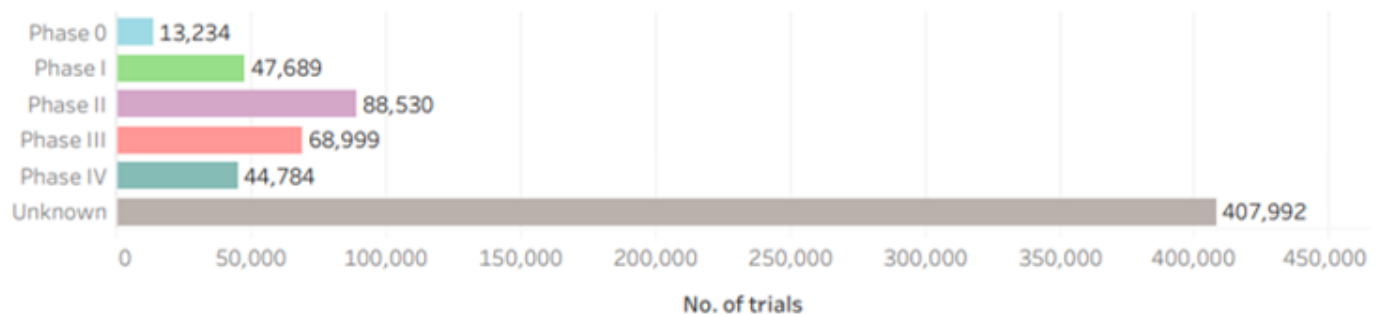
Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

CLINICAL TRIAL BEING CONDUCTED ACROSS THE WORLD

Trials by Country or Area

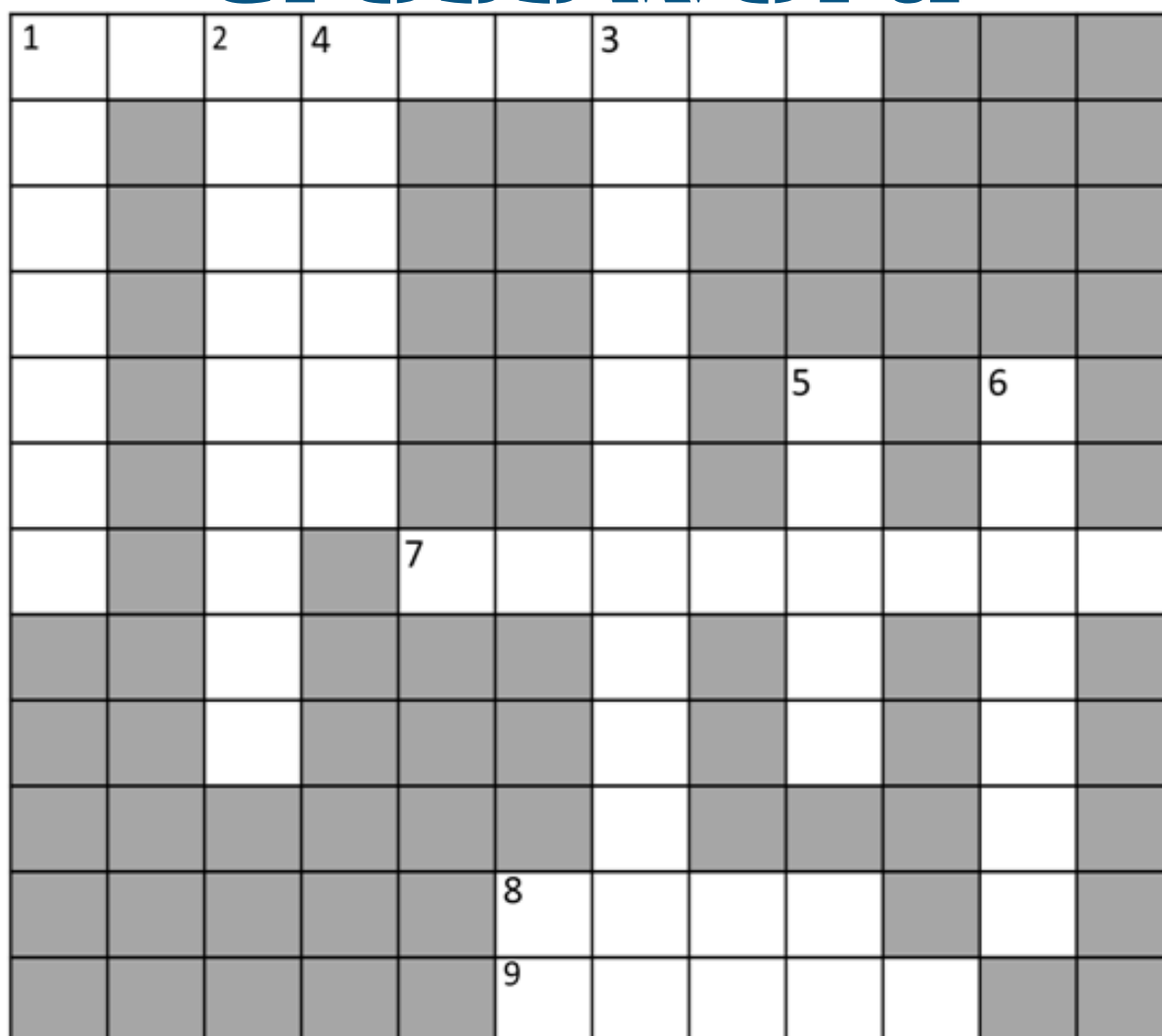


Trials by phase of development



Ref: WHO International Clinical Trials Registry Platform (ICTRP) Report, Feb'2022

Crossword



DOWN

1. An individual or a company that takes the responsibility for the initiation, management and financing of a clinical trial.
2. The process of assigning patients by chance to groups that receive different treatments.
3. The person in charge of overall process of clinical trial at the site
4. The moral principles that govern a person's behaviour
5. Systematic and independent examination of trial related activities
6. Form given to the potential participants before involving in a trial.

ACROSS

1. Activity performed after obtaining informed consent to ensure participants are qualified for the study.
7. This type of trial is conducted to avoid bias
8. Quantity of drug taken at a particular time
9. Research study aimed to evaluate a medical intervention in humans

Check your answers in the last page



Deepeeka R
MSc. Clinical Research
Semester II

Amazing discovery: Does genetic mutations benefit humans?



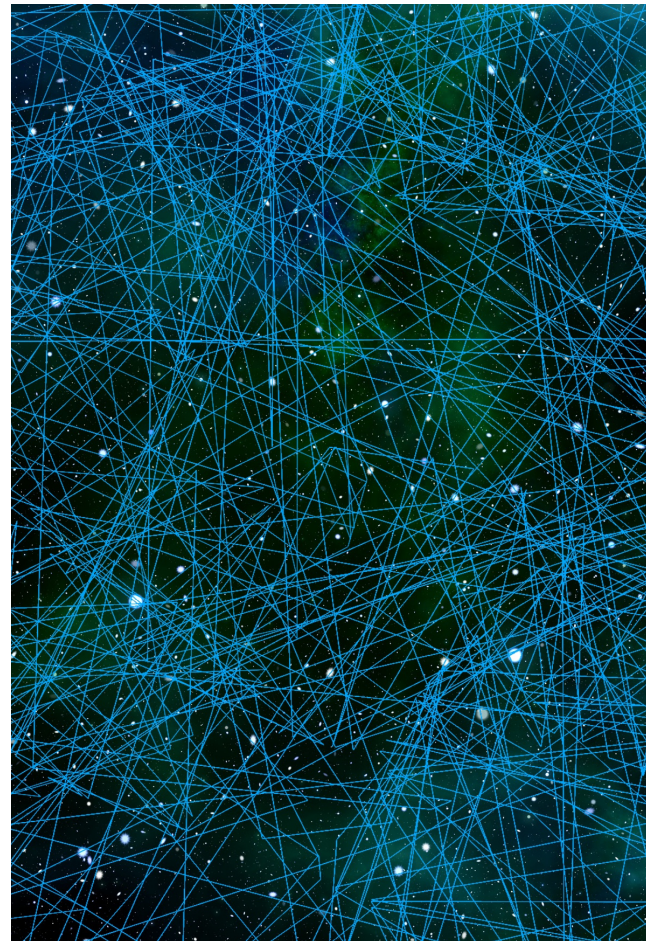
The most researched genetic mutations are those associated to human disease, but what about mutations that bring some benefit? Researchers have discovered mutations that can accomplish both. Cone-rod dystrophy is a series of illnesses that affect the retina and can result in blindness. Patients with this disorder are of above average intelligence. Mutations in a few distinct genes, including Rab3-interacting molecule 1, RIM1, can cause this illness.

Scientists modelled the mutation in the fruit fly, an insect with many genes in common with humans, in new research published in *Brain*.

The researchers discovered that the mutation improved the function of synapses, that are the places where neurons connect and communicate with one another.

Normally, mutations that alter synaptic proteins are expected to impede brain function, but not in this case.

"It's quite rare for a mutation to result in betterment rather than loss of function," stated Leipzig University Professor Tobias Langenhan.



The researchers demonstrated that the normal fly version of RIM1 acts similarly to the human counterpart. The researchers then added human mutations into the fly protein to investigate the impact.

They measured synaptic activity in flies with RIM1 mutations using electrophysiological techniques.

Langenhan stated that "They actually noticed that the animals with the mutation had much greater data transfer at the synapses."

"This extraordinary action on fruit fly synapses is undoubtedly found in the same or comparable way in human patients, and could explain both their higher cognitive capacity and their blindness,"

Further investigation found that the mutation brings the molecular components involved in synaptic transmissions closer together.

At mutant synapses, more neurotransmitters were released, demonstrating how the mutation can speed up neuronal impulses.

According to Langenhan, super-resolution microscopy allowed the researchers to investigate individual molecules, even counting them to confirm that they are more closely grouped than typical.

About 75% of the genes associated with human disease are also carried by fruit flies, according to Langenhan, who plans to continue modelling disease-associated mutations in the fruit fly alongside colleagues.

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Image Courtesy: Understanding genetic mutations: Why do some cause disease, while others don't? | Carla Garnett | National Institutes of Health

What Happens at The Synapse? |Dana.org| |Kayt Sukel
neurosciencenews.com



By

Kavitha .M

MSc Clinical Research Semester II

QUIZ

1. Which country is the most attractive location to perform clinical trials outside the United States?

2. Disease of unknown cause

3. Which document created in 1964 forms the basis of ethical considerations in clinical research?

4. The minimum blood alcohol level at or above which one can get punished for drunken driving under Indian Motor Vehicles Act is

5. Who is responsible for conducting clinical trials on site?

6. Term that defines Hansen's disease.

7. What is Phlebitis?

8. Dilation of Lymph vessel is known as

9. Document mandatory to enroll subject in a clinical research study?

10. Expand DSMB.



Check your answers in the last page

Mumpi Giri MSc Clinical Research Semester II
Gokul J. BSc Clinical Research Semester IV
Kapisha.K BSc Clinical Research Semester IV

AROMA HEALING

*Healing begins with an aromatic
bath and daily massage
- Hippocrates*

From stone age to digital age, the world has evolved through diverse phases. But still, nature has always been a part of humanity. Aromatherapy is just one of the several natural therapies which establishes an intimate relationship with man since ages. The essential oils used in aroma therapy, are most effective in their purest form. The first known distillation of essential oils was done by the Persians. But even before that ancient India, Egypt and China has been following aroma healing in the form of oils, resins and balms. The first publication about essential oils was made in Germany in the 16th century. French were reported to be using aromatherapy during 19th century.

This inexpensive essential oil healing is would carry your mind, body and spirit through a tranquil state. The molecules directly act on the hypothalamus and stimulate the happy hormone synthesis, serotonin. The oils not only lullabies you to sleep but also ease your stress, depression and anxiety. The effect of aromatherapy derives their origin from the essence of plant leaves, flowers, bark, roots, and peels. The various commonly used essential oils in India includes lemon oil, basil oil, chamomile oil, camphor oil, cedarwood oil and more.

Essential oils can be used as bathing salts, diffusers, creams, lotions, hot and cold compressions. The essential oils can be applied on skin as well as inhaled. By massaging or adding to bathing water, the essential oils will relax your mind and body in a holistic way.

Although the essential oils have a widespread popularity, their medical effects are still scientifically unproven. The essential oils are not regulated by the FDA (Food and Drug Administration), hence it is essential to ensure that the quality of the purchase based on the producer. Recently the effects of aromatherapy is gaining more attention with the evolving research studies on aroma healing effects. In a research conducted in 2016 at the University of Montana, US essential oils has proved to reduce stress, and anxiety in college students. It also improved the sleep quality of the students. Another meta-analysis of 30 studies shows that aromatherapy has improved the stress, sleep quality, depression, anxiety, and fatigue to statistically significant levels.

By

Dr Roja SK and Harthi
MSc Clinical Research Semester II

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GUESS THE NAME

1



2



3



4



5



Check your answers in the last page

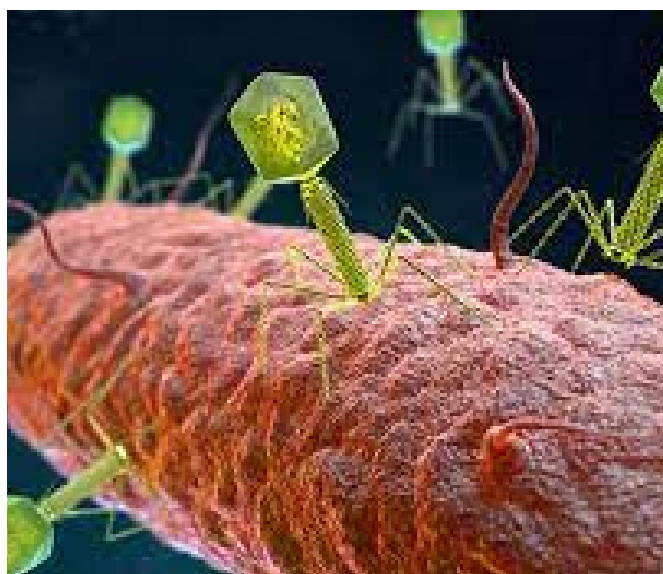
Gokul.U & Hemapriya.s
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3rd Year and 2nd Year

Cystic Fibrosis is an inherited disease that causes a buildup of thick mucus in the lungs, leading to repeated bacterial infections that damage the lungs and can cause respiratory failure. The new treatment have greatly improved the prognosis for people with cystic fibrosis, life expectation still remains significantly reduced.

TREATING ANTIBIOTIC RESISTANT MYCOBACTERIUM INFECTION WITH EXPERIMENTAL BACTERIOPHAGE THERAPY

Johnson is a 26-year-old with cystic fibrosis. He has suffered from repeated lung infections throughout his life and has been hospitalized several times right from his childhood. Over past six years, there has been a rapid decline in his lung function following persistent Mycobacterial infection. In 2020, his lung function fell below 30% and doctors felt he cannot survive without a lung transplant. His mycobacterial infection and the challenges associated with administering immunosuppressive medications post-transplantation led to refusal by transplant centers. That's when Dr. Nick and his team at National Jewish Health suggested Phage therapy for Johnson.

How Phages are used as therapy? Bacteriophages, for short are viruses that attack bacteria. With increasing resistance to antibiotics, treating bacterial infections are challenging and Phages are sought after as potential means of targeting bacterial infections. Dr. Graham Hatfull from University of Pittsburg is the key person behind this new therapeutic option. When Dr. Nick and colleagues sent Mycobacterium samples taken from Johnson's lungs, looking for a suitable phage, Dr. Hatfull and his team screened and identified two effective genetically engineered bacteriophages that killed the Mycobacterium isolated from Johnson's lungs. They provided the phage that was used to treat Johnson.



Doctors at National Jewish health received authorization from the U.S. Food and Drug Administration for compassionate use of experimental treatment.

Johnson received his first infusion of phages in Sep'2020, followed by 500 days of twice daily infusions. Within two months, a variety of genomic, cell culture and clinical markers indicated that the treatment was succeeding. Just over a year after the phage treatment began, Johnson's infection appeared to have cleared. Once the infection was found to be controlled (*M. abscessus*), he was enlisted for lung transplant. One year after the initiation of phage therapy he had a successful lung transplant on day 379. A range of makers has indicated no evidence of the infection following the transplant.

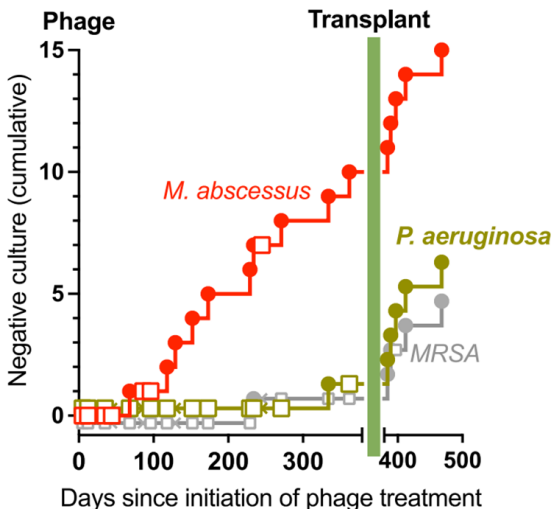
Johnson has now discontinued all the treatment for mycobacterial infection and is living a normal life.

The success of therapy on this patient has opened up the way for positive regulatory approvals and has given new hope for countries like India, with higher TB burden.

Reference:

Nick et al., Host and pathogen response to bacteriophage engineered against Mycobacterium abscesses lung infection, Cell (2022)

Mycobacterium are a common and wide rubric of bacteria that can cause tuberculosis, leprosy and nontuberculous mycobacterial (NTM)infections. Mycobacterium is a particularly aggressive and challenging NTM infection. Combinations of multiple antibiotics and treatment extending a period or longer are frequently unprofitable. National Jewish health has the largest adult Cystic Fibrosis Program in the country and is a leading centre for treatment of NTM infections.



By,
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BSc Clinical Research Semester II

FACTS ON OUR TRADITION

Namaste - Science says that joining the tip of the fingers activate the pressure points of eyes, ears and mind which eventually help us to remember the person for a long time.

The sindoor powder used on forehead is made of mercury and turmeric both of which helps in easing stress and also stimulates sexual hormone regulation thereby maintaining blood pressure.

Women wear bangles not only accentuate their beauty but also stimulates the centre of the wrist area which increases the blood flow.

Inflammation has often been cast as a villain in drug — and has long been tied to the sensation of pain and to painful conditions like arthritis. Still, a new study of patients with low back(reverse) pain surprisingly shows that the body may need inflammation to help acute pain not turning into habitual (chronic) pain.

● Acute pain - pain that resolved in less than three months

● Habitual pain - pain lasting longer than three months.

.

with whose pain persisted at the end of the study. By examining blood samples, experimenters discovered that people whose low back pain was resolved had high inflammation driven by neutrophils, a type of white blood cell that helps the body fight infection.

The researchers found that blocking neutrophils and administration of NSAIDs prolongs pain.

The analysis found that those patients with low back pain taking these drugs(NSAIDs) were more likely to have pain 2 to 10 years latterly (chronic stage).

The study also showed that individuals with acute back pain and using NSAIDs were at 1.76-fold greater risk of developing chronic back pain than those who were not taking NSAIDs.

ANTI-INFLAMMATORY DRUGS MAY PROLONG BACK PAIN



Low reverse pain is the most constantly reported form of habitual pain, clinicians generally treat downward back pain with NSAIDs, which target inflammatory responses produced by the immune system. However, these medicines relieve symptoms temporarily and do not always bring endless relief.

A study involved 98 patients with low reverse pain and an analysis of data from a case database in the U.K. The cases with low reverse pain were administered nonsteroidal anti-inflammatory drugs (NSAIDs). The experimenters compared these data between patients whose acute pain resolved after the three months and

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- <https://www.webmd.com/back-pain/news/20220512/using-anti-inflammatory-drugs-may-prolong-back-pain#:~:text=The%20analysis%20found%20that%20those,people%20with%20low%20back%20pain>

By

Dhanalakshmi M and Krishna Priya RB
BSc Clinical Research Semester II

மருத்துவ ஆராய்ச்சி

அறிவியல் ஒரு அற்புதம் - அதில்
 மருத்துவம் ஒரு கற்பகம்
 ஆதி முதல் அந்தம் வரை
 ஜோதியாய் ஒளிர்வது மருந்து
 இன்று தளிர்விடும் நோய்களை
 கொன்று குவித்திடும்
 ஈட்டியாம் தடுப்பூசி - முறையாய்
 போட்டுக்கொள்வது அவசியம்
 உருவங்கள் பல மாறினாலும்
 பருவங்களைக் கடந்த மருந்து என்றும்
 ஊன்றுகோலாய் திகழும் விருந்து
 சான்றுகள் பல கூறினாலும்
 எதிர்காலத்தில் வரும் நோய்கள்
 புதிர் போடவைக்கும் - அக்னி
 ஏவுகணை போல செயல்பட்டு
 சாவுகளைத் தடுக்கும் முயற்சியே
 ஐயங்களைத் தீர்க்கும் ஆராய்ச்சி
 கையுறைகளை அணிந்திடும் பயிற்சி
 ஒருவரின் வாழ் நாளில்
 இருளாய் வரப் போகும்
 நோய்களுக்கு எதிரான புரட்சி
 ஓய்வின்றி உழைத்து
 ஓளடதத்தின் தன்மையை அறிவாய்
 நீ!



திருநாவுக்கரசு
முது நிலை முதலாம் ஆண்டு மருத்துவ ஆராய்ச்சி

THE PSYCHOPATH INSIDE

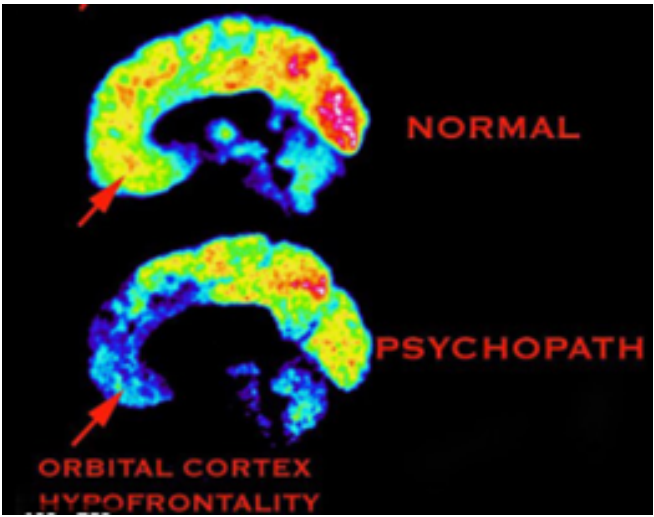


Psychos have been described as the conjunction of interpersonal dominance, low anxiety, callous-unemotional traits and externalizing behavioral tendencies. This is normally noticeable by a lack of remorse for their actions, a lack of empathy for others, often criminal tendencies, narcissism, impulsivity, etc.

Neuroscientists from Nanyang Technological University, Singapore (NTU Singapore), University of Pennsylvania and California State University have established the existence of biological difference between psychopaths and non-psychopaths. Using a magnetic resonance imaging (MRI) scan, they found that the region of the forebrain known as the striatum prevailed an average of ten percentage larger in psychopathic traits individuals compared to a control group of individuals that had low or no psychopathic traits. The striatum is a subcortical region of the brain that comprises the entire cerebrum and coordinates numerous elements of cognition, including motor and action planning, decision-making, motivation, reinforcement, and reward perception.

The striatum is a portion of the basal ganglia, a network of neurons deep in the brain's center. The cerebral cortex sends impulses to the basal ganglia, which governs cognition, social behaviour, and determining which sensory information has to be paid attention to.

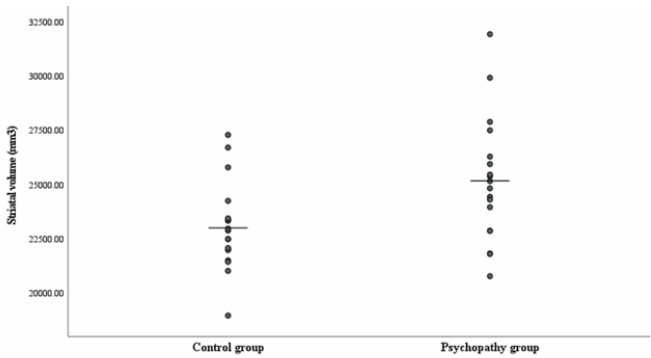
Previous, studies have linked that an overly active striatum is responsible to psychopathic behaviour but did not conclusively establish the relationship between the striatum's size and a person's behaviour. The new study reveals that there is a significant biological difference between people who have psychopathic traits and those who do not. It shows a clear evidence that psychopath is linked to more violent behavior but not every psychopaths break the law and not all criminals come under psychopathic criteria. The understandings of the role of biology in antisocial and criminal way of behaving may help in improving the existing theories of behavior, as well as in illuminating strategy and treatment choices.



Researchers correlated that having a larger striatum increases an urge for the stimulation, through thrills and excitement, and a higher likelihood of impulse behaviors. According on the researchers' criteria, 42 men and five women out of a total of 120 participants were identified as psychopaths.

One reason for the high psychopathic rates in the study when compared with the general population was the participants were recruited from temporary employment agencies, who may differ slightly from individuals in the general community.

Asst. Prof. Choy said: “The neuroscientists say that In human development, the striatum typically becomes smaller as a child matures, suggesting that psychopath could be related to differences in how the brain develops” and added that: "A better understanding of the striatum’s development is still needed.”



In the conduct of their research, the neuroscientists scanned the brains of 120 participants in the United States and interviewed them using the Psychopathic Checklist - Revised, a psychological test that can be used to see if someone has psychopathic tendencies. Associate Professor Andrea Glenn of The University of Alabama's Department of Psychology, who was not involved in the research, emphasized the importance of the work done by the joint research team: "This study strengthens our belief that psychopathy is linked to structural differences in the striatum, a brain region that is involved in a variety of cognitive and social processes. The reasons that may lead to these structural disparities will require more research.” The findings from the meta-analysis were just published in the peer-reviewed academic Journal of Psychiatric Research. It was found that the difference in size of the striatum was correlated to the level of appetite for stimulation i.e, bigger the striatum, larger the appetite for stimulation.

Prof. Raine added: "We have always known that psychopaths go to extreme lengths to seek out rewards, including criminal activities that involve property, sex, and drugs. We are now finding out a neurobiological underpinning of this impulsive and stimulating behaviour in the form of enlargement to the striatum, a key brain area involved in rewards".

The scientists hope to carry out further research to find out the causes of the enlargement of the striatum in individuals with psychopathic traits.

Currently many approaches based on compassion focused therapy that are being explored to reduce psychopathic traits.

One such recent study is addressing the efficacy of a 20-session individualized Compassion Focused Therapy-based intervention called the PSYCHOPATHY.COMP among detained youth (Ref: ClinicalTrials.gov Identifier: NCT03971682)

Further probing the causes of enlargement of striatum among psychopaths, early life exposure that can be linked to this phenomenon, etc., could help in developing effective means of managing psychopathic traits as well as improving the psychophysiological and behavioural features.

Reference:

- <https://www.straitstimes.com>
- <https://www.ehtrend.com>

Story source:

Materials provided by Nanyang technological university.

Journal reference:

Olivia Choy, Adrian Raine, Robert Schug. Larger striatal volume is associated with increased adult psychopathy. Journal of Psychiatric Research, 2022; 149: 185 DOI:10.1016/j.jpsychires.2022.03.006.

Image Source: Dr. James Fallon, Neuroscientist, UC Irvine School of Medicine



STUDENT CORNER



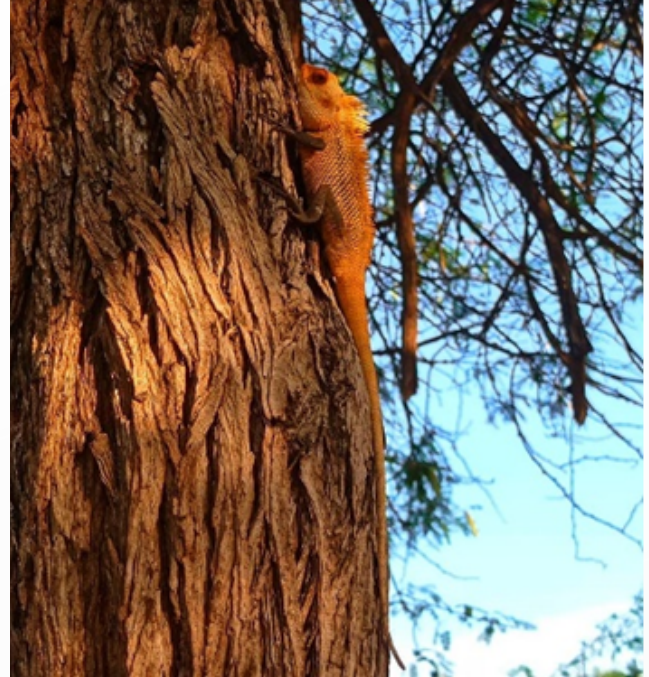
Logeshwaran, a passionate student, Environmentalist, Social Activist who have interest in documentary photography took photos documenting Lifestyle of North Chennai along with other 5 young photographers for a period of 6 Months in a workshop conducted by Chennai Climate Action Group, Coastal Resource Centre and Zenith Learning Centre mentored by Palani Kumar (cinematographer - Kakkus Documentary film) and showcased his work in REFRAMED - North Chennai Photo Exhibition under 5 different themes Work, Play, Culture, Loss, Evection. Some of the photos were taken during the November - 2021 Floods which showcase the loss of people.



Logeshwaran
M.Sc. Clinical Research
Semester IV

 @_mr_antidote_

STUDENT PHOTOGRAPHY



Beauty can be seen in all things. Seeing and composing the beauty is what separates the snapshot from the photograph.

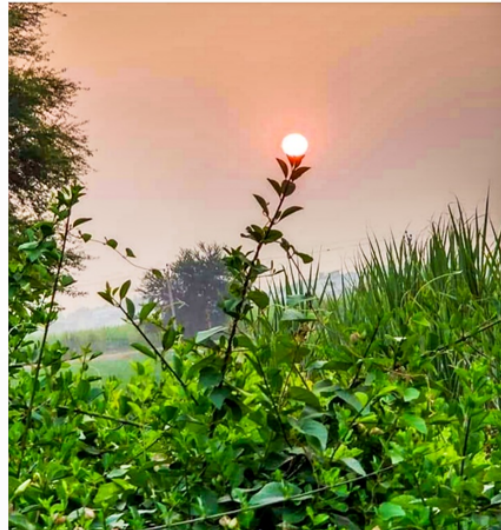


Hemapriya S
B.Sc. Clinical Research
Semester IV



Sneha. S
B.Sc. Clinical Research
Semester II

STUDENT PHOTOGRAPHY



Everything has beauty, but not everyone sees it.



Gokul U
B.Sc. Clinical Research
Semester VI



If there is an appetite for adventure in you then there is plenty of room in Kerala for you



Sayan Kundu
M.Sc. Clinical Research
Semester II



Jaahnavi. K,
BSc Clinical Research
Semester VI

STUDENT ARTS & CRAFTS



Rajashwari
BSc Clinical Research
1st Year



You can never meet your potential until you truly learn to love yourself!!!



Dr Priyadharshini M
MSc. Clinical Research
Semester II

Maa Durga in Mandala art, Mandala is an art form which helps people to feel more relaxed and also helps in concentration. Using pen on paper, detailed abstract designs are striking for both their playfulness and their neatness and precision of line.



Dr Mythili R
MSc Clinical Research
Semester II



"Dance is an art; paint your dream and follow it."

Steven Thompson



Poornima O
MSc Clinical Research
Semester II



I 'm keen on using strokes for sketching. Colours make me feel joyful. So embrace the colours by experimenting them!



Reshmi S
BSc Clinical Research
Semester IV



Art adds therapeutic value to one's life. It can heal one's personality. It helps a person to see the world from a different perspective. When a person has his or her passion for art, they will find peace and purpose in life.



Dr. Sushmitha makes fine quality art work (pencil sketches, soap carving, glass and water colour painting, yarn knitting, wire art, embroidery for her customers through her Instagram page



Dr. Sushmitha . M
BDS
MSc Clinical Research
Semester IV

STUDENT ACHIEVEMENTS AND ACTIVITIES

M.Sc. Clinical Research students were selected for pre-incubation by BIRAC BIONEST @Sri Ramachandra incubation and Innovation Center (SRIIC)



Dr. Merrylda Claribel, Dr. Karpagam and Dr. Sushmitha receiving the pre-incubation agreement from the Dean (Research), SRIHER.

Ms. Krishna Priya from B.Sc. Clinical Research received Founder Chancellor Shri NPV Ramasamy Udayar Cash Award for the year 2019



Krishna Priya
B.Sc. Clinical Research
Semester VI

Ms. Hema Priya B.Sc. Clinical Research participated in Hockey India Junior Women Academy National Championship in Mar'2021



Hema Priya
B.Sc. Clinical Research
Semester VI

Mr. Surya B.Sc. Clinical Research Participated in South Zone Inter – University Kabaddi (Men) Tournament organised by the Association of Indian Universities and coordinated by Bharathidasan University in Dec' 2021

South Zone Inter University Kabaddi Tournament For Men, 2021-22
Organised by
Bharathidasan University, Tiruchirappalli
23-12-2021 to 27-12-2021

POOL - B

23	Dr.NTR University of Health Sciences, Vijayawada	25		
24	Bharathidasan University, Tiruchirappalli			
25	KLEF University, Vaddeswaram	57		
26	Sri Ramachandra Institute of Higher Education and Research, Chennai	41		
27	Rani Channamma University, Belagavi	6		
28	Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore	7		
29	Dr.MGR Educational and Research Institute, Chennai	42		
30	B.S.Abdur Rahman Crescent Institute of Science and Technology, Chennai	8		
31	Sri Venkateswara University, Tirupati	58		
32	Mahatma Gandhi University, Nalkonda			
33	Sree Sankaracharya University of Sanskrit, Ernakulam	26		
34	Pondicherry University, Puducherry			
35	SASTRA, Thanjavur	27		
36	SCSVMV University, Kanchipuram	59		
37	Yenepoya (Deemed to be University), Mangalore	43		
38	Tamil University, Thanjavur	9		
39	The Tamil Nadu Dr.Ambedkar Law University, Chennai			
40	JSS Academy of Higher Education & Research, Mysuru	10		
41	Kalasalingam Academy of Research & Education, Krishnankoil	44		
42	Chettinad Academy of Research & Education, Kelambakkam	60		
43	Periyar Maniammai Institute of Science and Technology, Vallam	28		
44	Manonmaniam Sundaranar University, Tirunelveli (III-Place)			



Surya
B.Sc. Clinical Research
Semester VI

ANSWERS FOR SMART SECTION



QUIZ

- 1.China
- 2.Idiopathic
- 3.Declaration of Helsinki
- 4.30mg%
- 5.Clinical research coordinator
- 6.Leprosy
- 7.Inflammation of a vein
- 8.Lymphangiectasis
- 9.Informed Consent
- 10.Data Safety Monitoring Board

CROSSWORD

ANSWER KEY

DOWN:

- 1.Sponsor
- 2.Randomize
- 3.Investigator
- 4.Ethics
- 5.Audit
- 6.Consent

ACROSS:

1. Screening
7. Blinding
8. Dose
9. Trial

GUESS THE WORD

1. Protocol
2. Cancer
3. blinding
4. Patent
5. Placebo



SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Deemed to be University)



P.H.A.S.E.S

A Student Run Magazine on Clinical Research

nlclinical@gmail.com

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