SRI RAMACHANDRA
FACULTY OF CLINICAL RESEARCH

P.H.A.S.E.S

a student run magazine

CREDITS

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

The articles written by students in the magazine are based on peer reviewed articles and reports/ guidelines from regulatory bodies. The references are cited under each article.

Cover Page
Logos of regulatory bodies related to clinical trials worldwide

P.H.A.S.E.S
A student run e-magazine from Faculty of Clinical Research
nlclinicalresearch@gmail.com

Prepared with Canva

FOREWORD

Dear All

Warm Greetings!

I feel proud to share that our B.Sc. and M.Sc. Clinical Research students have come up with the second issue of their e-magazine.

It was heartening to see the students taking an initiative and a step towards self-learning. They have put up lot of effort to bring this second issue amidst their exams, semester targets and other assignments that occupy their academic calendar and have successfully completed.

Our students have brought out a variety of articles by learning literature and also added other exciting and informative elements in this issue.

I sincerely believe that this exercise will turn out to be critical to shape their skills and enhance their team-work, research capabilities, self-directed learning.

I wish to highlight the quote of Benjamin Franklin:

"Tell me and I forget,
Teach me and I may remember,
involve me and I learn."

I am sure this initiative will help the students to enhance their learning, achieve excellent opportunities and a good career in clinical research.

My best wishes to the students!!

Dr. Solomon F.D. Paul
Head – Faculty of Clinical Research

CONTENTS

Dr. MANOJ PATEL

VICE PRESIDENT, CLINICAL TRIAL OPERATIONS

Lambda Therapeutic Research Ltd

Insight With An Industry Expert

Mr. Manoj Patel is an expert in clinical trials with 20 plus years of experience. He started his career with clinical trial to establish Bioavailability and Bioequivalence in 2001 after his post-graduation in pharmacy. Till 2019, he has worked in various capacities in Quality Assurance of clinical research. Since 2019, he heads the clinical operations team for therapeutic and PK end point trials in various therapeutic areas.

Interview Panel of students

SAYAN KUNDU
M.Sc. Clinical Research
2021-2023

RESHMI S
B.Sc. Clinical Research
2020-2023

RAJESHWARI R
3rd year B.Sc. Clinical Research

JAYALAKSHMI
3rd year B.Sc. Clinical Research

Excerpts from the Interview:

1. Sir, can you give us an overview of clinical trial policies of Lambda, one of the big CROs in India?

At Lambda Therapeutic Research Ltd, our goal is to create benchmarks and shape the future of the clinical research industry. We are committed to ensuring quality, reliability, and providing value-added services to our clients. With over 22 years of experience and a team of 1500+ professionals, we strive to deliver excellence in every aspect of our operations.

At Lambda, we stay at the forefront of the industry by keeping pace with the latest techniques and procedures, ensuring the scientific validity of all research projects, and complying with global regulations. Our comprehensive end-to-end clinical research services cater to the global innovator, biotech, and generic pharmaceutical industries. By leveraging cutting-edge technology and innovative solutions, we offer a full spectrum of clinical trial solutions from preclinical research to post-marketing studies.

Our dedication to excellence has earned us numerous accolades, including the distinction of 'Best Indian CRO' by Frost & Sullivan (USA) and the coveted title of 'Great Indian Workplace' by UBS Transformance. With a strong focus on quality, reliability, and value-added services, we aim to make a lasting impact in the clinical research industry, contributing to the development of innovative therapies and shaping the future of healthcare.

2. Many CROs have come up. Can you please highlight the uniqueness of Lambda Therapeutic that helps it stay atop the competitors?

At Lambda customer focus is our top priority. We have dedicated teams specializing in various sectors of clinical research, ensuring expertise in every area. What sets us apart from other CROs is our unique networking system, which plays a crucial role in our success. It allows us to build valuable connections and collaborations within the industry, staying updated with the latest developments.

Our teams, comprising experienced professionals, are committed to understanding and fulfilling our customers' unique needs. Whether it's pharmaceutical research, medical device studies, or biotechnology trials, we provide tailored solutions and deliver exceptional results. With our robust networking system, we gain access to cutting-edge advancements and thought leaders, enabling us to remain agile and provide innovative solutions.

3..According to the India Bioeconomy report of 2022, by 2025 BioPharma sector is expected to grow nearly 1.4 times and that a major segment of that could be recombinant and biosimilar products. What is your take on that from your experience sir? Do we have more biosimilar studies being conducted?

Yeah, Currently, there is a growing demand for biosimilar studies as the need to discover and study biosimilar products increases. The emergence of new diseases has also heightened the demand for recombinant vaccines. Translational research in medicine is thriving, bringing significant benefits to humanity as it bridges the gap between scientific discoveries and clinical applications. These advancements have the potential to positively impact public health and improve the overall well-being of individuals worldwide.

4.The Pandemic has brought in new challenges and new adaptations to clinical trials. For example, let is consider decentralised trials. Will decentralised trials be suitable for Indian scenario? Please share your opinion and experience on this context.

We have not tried decentralized trials so far. But, yes, the concept of decentralised trials is good and could well suit Indian scenario. It is highly beneficial for patients as they need not often visit the trial site for screening and follow up visits. But, when we take clinical researchers into account there are challenges associated with quality, maintaining compliance, etc. Also, we should look into the benefit risk analysis.

The subject matter experts should weigh up the pharmacology of the product being tested right from the QSAR, drug interactions, adverse events, etc. at the time of designing the trial in order to evaluate whether it would be the right choice for decentralised trial design.

5. Remote data collection and unique designs that are adapted post-pandemic – How does it impact the quality of data from clinical trials?

Before designing a clinical trial, it is crucial to gather comprehensive patient information, identify necessary data points, determine outcome measures, and establish safety laboratory evaluations.

Additionally, understanding the type of sample specimens required, such as blood or urine samples, is essential. These factors should be verified by experts in regulatory affairs to ensure successful implementation of decentralized trials. Proper design considerations help ensure that all aspects of data collection, quality, and regulatory compliance are maintained and helps to avoid legal or ethical concerns.

Seeking expert opinions and adhering strictly to regulatory guidelines are critical steps to guarantee the success of the study, as it can provide valuable insights into the critical challenges and helps optimize the trial design. By carefully considering patient information, data requirements, outcome measures, safety evaluations, sample collection, and expert opinions, a well-designed clinical trial can be executed effectively. This approach contributes to data quality, legal compliance, and ethical integrity, ultimately increasing the likelihood of a successful study outcome.

6. Last week, the Union Health Ministry has released a draft of The Drugs, Medical Devices and Cosmetics Bill, 2022. Once implemented, it will bring in new definitions and changes to the current Drugs and Cosmetics Act, 1940. How do you think this will impact the clinical trial operations in India?

I have not gone through the amendments in detail yet. But what I can say from my experience is that whenever a government regulatory body releases amendments to previous laws or acts it meant to improve or tackle the current issues faced by the stakeholders as well as benefit of the patients. The process of releasing amendments in clinical research regulations involves a thorough evaluation by expert committees. These committees consider inputs from the industry, current challenges, and issues to formulate new amendments. The primary objective of these amendments is to achieve regulatory compliance, prioritize patient safety, and ensure the efficacy of clinical trials.

Additionally, the aim is to maintain the highest standards of quality to produce reliable and accurate results. By incorporating these amendments, the regulatory framework evolves to address emerging needs and challenges in the field of clinical research. The focus of amendments is to achieve regulatory compliance, patient safety, and efficacy and to ensure good quality of results.

7. There have been various comments on the quality of clinical trials that are conducted in India. How Lambda, as a big CRO handling 100s of trials handles the quality aspect of trials? Is there a centralised quality control system in place?

At Lambda, we prioritize the implementation of periodic monitoring for clinical trials. Our goal is to achieve 100% quality assurance by diligently reviewing and verifying data collection and documentation processes. We understand the significance of accurate and reliable data in ensuring the integrity and validity of clinical trial results.

To ensure consistent quality across our operations, we have established a centralized quality control system. This system enables us to effectively monitor and evaluate various aspects of the trial, including data collection, documentation practices, and adherence to regulatory guidelines. By centralizing our quality control efforts, we can streamline processes, identify potential errors or deviations, and take prompt corrective actions.
By conducting periodic monitoring and maintaining a centralized quality control system, we ensure that our clinical trials adhere to rigorous quality standards, thereby enhancing data accuracy, reliability, and ultimately contributing to the success of the trials we conduct.

8. Recently we saw an issue with Cough syrup supplied to Uzbekistan where 18 children died because of the quality of the product. CDSCO has issued a warning and probe into the matter. Though violations from Good Manufacturing Practice (GMP) is implied, could such issues hint on the quality of Clinical Trials in Indian clinical trials? What new steps can be taken to avoid such issues in the future?

According to me no new steps are required. In a clinical trial, multiple stakeholders, including the sponsor, CRO, ethics committee, investigators, and study team, play vital roles in ensuring compliance with Good Clinical Practice (GCP) guidelines. Collaboration and shared responsibility among these stakeholders are key to maintaining quality and patient safety. The sponsor provides clear protocols and resources, while the CRO offers support and efficient project management. The ethics committee safeguards participant rights and ethical principles. Investigators and site teams execute the trial diligently, collecting accurate data and reporting any deviations. A robust quality assurance program identifies and addresses non-compliance issues. Overall, adherence to GCP throughout the trial ensures quality, reliable data, and safe medications. I think that is the key to ensure quality and with good quality assurance, we can avoid safety issues with the new medications after approval.

9. You have years of experience in conducting clinical trials. Only in recent years, clinical research has evolved as a dedicated academic program. In this new era of clinical trials, what are the areas that we should focus and get strengthened to land on the right career path?

As a student in clinical research, it is essential to focus on the following areas:
GCP and Ethical Understanding: Develop a solid grasp of Good Clinical Practice (GCP) guidelines and ethical principles that govern clinical trials, ensuring patient safety, informed consent, and data integrity.
Data Management Skills: Acquire proficiency in data management tools and techniques, including electronic data capture (EDC) systems, data validation, database management, and analysis to effectively handle and analyze clinical trial data.

Regulatory Compliance and Documentation: Understand the regulatory landscape and compliance requirements in clinical research. Learn how to ensure adherence to regulations and maintain accurate documentation throughout the research process.

Utilization of Tools and Aids: Stay updated on the latest tools and technologies available in the market that can enhance clinical research. These may include electronic trial master files (eTMFs), risk-based monitoring approaches, remote monitoring technologies, and digital health solutions.

Therapeutic Knowledge: Develop a strong foundation of therapeutic knowledge relevant to clinical research, including disease areas, treatment modalities, and emerging trends. This knowledge will enable effective design and conduct of clinical trials in specific therapeutic areas.
By focusing on these areas, you will establish a solid foundation in clinical research, equipped with the necessary skills, ethical understanding, regulatory compliance knowledge, and therapeutic expertise to contribute to the field and advance healthcare through high-quality research.

10. In your point of view, what is the most important skill one should develop to sustain in the field of clinical research?

Effective communication skills are vital in clinical trials for conveying information accurately and fostering collaboration. Professionals need to communicate with various stakeholders, including sponsors, investigators, ethics committees, and patients. Clear communication ensures understanding of trial objectives, protocols, and requirements. It facilitates teamwork, problem-solving, and decision-making. Effective communication is crucial when addressing patient concerns, obtaining informed consent, and maintaining compliance. It also plays a significant role in presenting trial data and results to stakeholders. Strong communication skills enhance overall trial management and contribute to successful clinical research.

The important technical skills are understanding of GCP, trial details, investigational product information, supportive data and patient information, good communication skills, resolution skills, writing skills, team building skills, negotiation skills, and data analytics must be known.

11.What were the challenges faced in the past conducting clinical trials in India and what are the current challenges faced by the clinical research professionals

In the past, conducting clinical trials in India faced challenges including a lack of awareness and understanding of Good Clinical Practice (GCP) guidelines, complex regulatory processes, difficulties in patient recruitment and retention, as well as limited availability of interested investigators and infrastructure to conduct trials. The shortage of experienced and motivated investigators, particularly in certain therapeutic areas, posed a significant challenge to the timely and efficient execution of clinical trials. Additionally, inadequate infrastructure in some regions, such as research facilities, laboratories, and data management systems, hindered the smooth conduct of trials. However, efforts have been made to address these challenges and improve the clinical research landscape in India.

Currently, clinical research professionals in India face challenges such as the increasing complexity of trial designs, evolving regulatory requirements, patient recruitment and retention, and the need for advanced technological infrastructure.

To overcome these challenges, professionals focus on enhancing their knowledge and skills, staying updated with regulatory changes, implementing innovative recruitment strategies, and investing in digital solutions and data management systems. Collaborative efforts among stakeholders, including regulatory authorities, research institutions, and industry partners, are vital in tackling these challenges and ensuring the conduct of high-quality clinical trials in India.

12. Considering all the new amendments brought by the government and the general population being more aware of the aspects of Clinical Research, what is the Future of Clinical Trials in India?

The future of clinical trials in India holds tremendous opportunities for growth and advancement. With a vast patient population, skilled professionals, and robust infrastructure, India has the potential to become a global leader in this field. However, realizing this potential requires a collective commitment from all stakeholders to adhere to Good Clinical Practice (GCP) principles and regulatory guidelines.

By prioritizing ethical conduct, data integrity, and quality assurance, India can attract more trials, foster innovation, and contribute to medical advancements on a global scale. Collaboration, continuous learning, and investments in training and capacity building will further strengthen India's position, ensuring a bright future for clinical trials in the country.By upholding the highest standards of GCP and regulatory compliance, India can establish itself as a preferred destination for conducting clinical trials. The adherence to ethical and legal guidelines, along with maintaining the integrity and quality of data, will be instrumental in driving India's success in this field. With a growing pool of patients, experienced investigators, and state-of-the-art infrastructure, India has the potential to lead the way in clinical research. By nurturing a supportive ecosystem that encourages collaboration, innovation, and continuous improvement, India can shape the future of clinical trials and make significant contributions to global healthcare advancements. With a focused approach and collective efforts from all stakeholders, India's clinical trial landscape is poised for a bright and promising future.

Cover Page - Regulatory Bodies

National Regulatory Bodies

- Central Drugs Standard Control Organisation, India
- Ministry of Health, Labour and Welfare (MHLW), Japan
- Medicines Control Council, South Africa
- Indian Council of Medical Research
- Federal Institute for Drugs and Medical Devices, Germany
- Medicines Control Authority of Zimbabwe
- Indian Pharmacopoeia Commission
- Pan American Health Organization, USA
- Medicines Evaluation Board Agency (MEB), The Netherlands
- United States Food and Drug Administration
- Health Canada
- Medicines and Healthcare products Regulatory Agency, UK
- National Agency for Food and Drug Administration and Control, Nigeria
- Brazilian Health Regulatory Agency
- Swiss Agency for Therapeutic Products
- Saudi Food and Drug Authority
- European Medicines Agency
- National Medicines Regulatory Authority, Srilanka
- Ministry of Food and Drug Safety, Republic of Korea

International Regulatory Bodies

- World Trade Organization
- World Intellectual Property Organization
- United Nations Organization
- International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use

CONSIDERATIONS FOR AI IN HEALTHCARE AND CLINICAL RESEARCH

– A FUTURE PERSPECTIVE

AI (Artificial Intelligence) is Getting worldwide attention and expecting to be a Breakthrough in the future concept of technology. Along the way people also inspired about the integration of AI in Health care and Research; though it had many potential benefits it also had many complicated BARRIERS such as ethical concerns about Algorithmic bias to Legislative concerns. It is clearly noticeable that need for the clear and updated guidelines for both Inventors and early adopters. This article will give considerations for AI Implementation with Health care and Clinical research

Artificial Intelligence means ability of the computer system to simulate the Human Intelligence process including the process of Learning, Reasoning and self correction. The strength of an AI depends on the ability to emphasize flexibility and expressivity of traditional statistical techniques, solving problems which has Inputs and outputs are highly multi-dimensional and complex

'Would AI be appropriate for the research question at hand?'

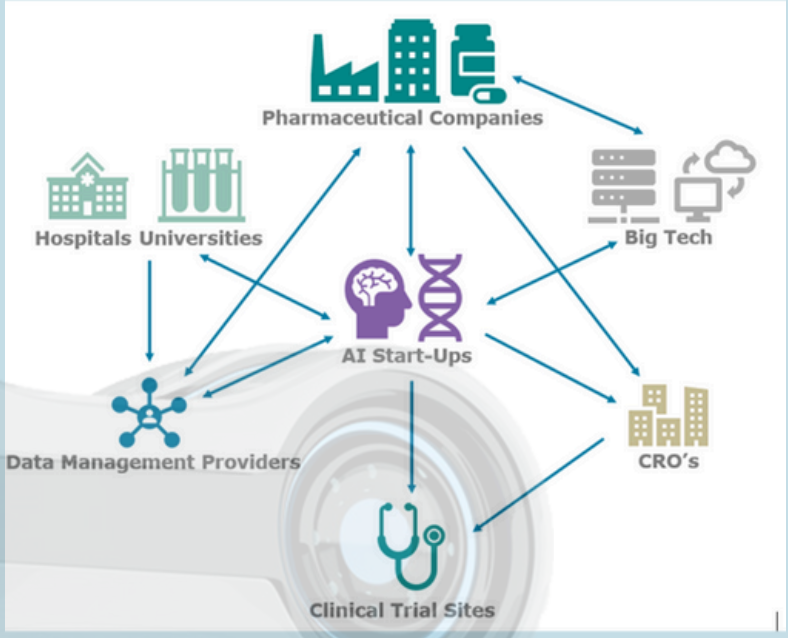
This is the fundamental complexity of AI implementation, AI is useful when the inputs are highly complex, where hypothesis space cannot be determined and for questions which supposed to have complex answers.

An example of High Input is imaging data

AI may be used to expand the scope of research by enabling the automation of routine tasks; for example, if a team wished to explore the prevalence of pulmonary nodules, the time and financial costs required to manually annotate a large dataset of computed tomography (CT) could exceed the resources available to a small research group. However, using AI, if enough data were already accurately labeled, the researchers could train a classifier that could be used to analyze the remaining images. Similarly, AI may be applied to interpret other investigations or even to analyze clinic letters using natural language processing tools.

Not all problems need AI solutions. A common issue is not considering problems which is out of the AI circle but the solution for that problem enhances the opportunity for the success of destroying boundaries

First, large datasets often lack diversity and studies based on these datasets may not reflect the target population; For instance,the UK biobank excludes young people and has a low number of several common diseases of interest, such as stroke.Although the algorithms may demonstrate superior performance on a limited set of test data, they may perform poorly when subjected to external validation on unseen data.This algorithmic bias can be observed with any predictive model, but AI models are particularly vulnerable because they can discriminatecertain patient groups while maintaining very high overall performance measures, such as accuracy and area under the receiver's operating characteristic curve (AUC).



Second, common AI models, such as deep neural networks, have internal logic that is inherently difficult to interpret.This "black box" problem makes the models more difficult to explain to patients, to question when clinical intuition contradicts them and to improve systematically and rigorously.For this reason, AI is subject to greater regulatory scrutiny, which can present additional hurdles and uncertainties compared to conventional solutions.There is, however, active research into the development of methods of producing AI models avoiding the "black box" phenomenon, including the use of Local Interpretable Model Independent (LIME) explanations.

Third, there are times when clinical decisions are left to healthcare professionals and the use of AI may be inappropriate; examples include withdrawal decisionslife-saving treatments, decisions involving particularly sensitive clinical data (such as sexual history or infectious status) and decisions involving a risk of discriminatory bias.

Reference:
Lovejoy, C. A., Arora, A., Buch, V., & Dayan, I. (2022). Key considerations for the use of artificial intelligence in healthcare and clinical research. Future healthcare journal, 9(1), 75–78. https://doi.org/10.7861/fhj.2021-0128

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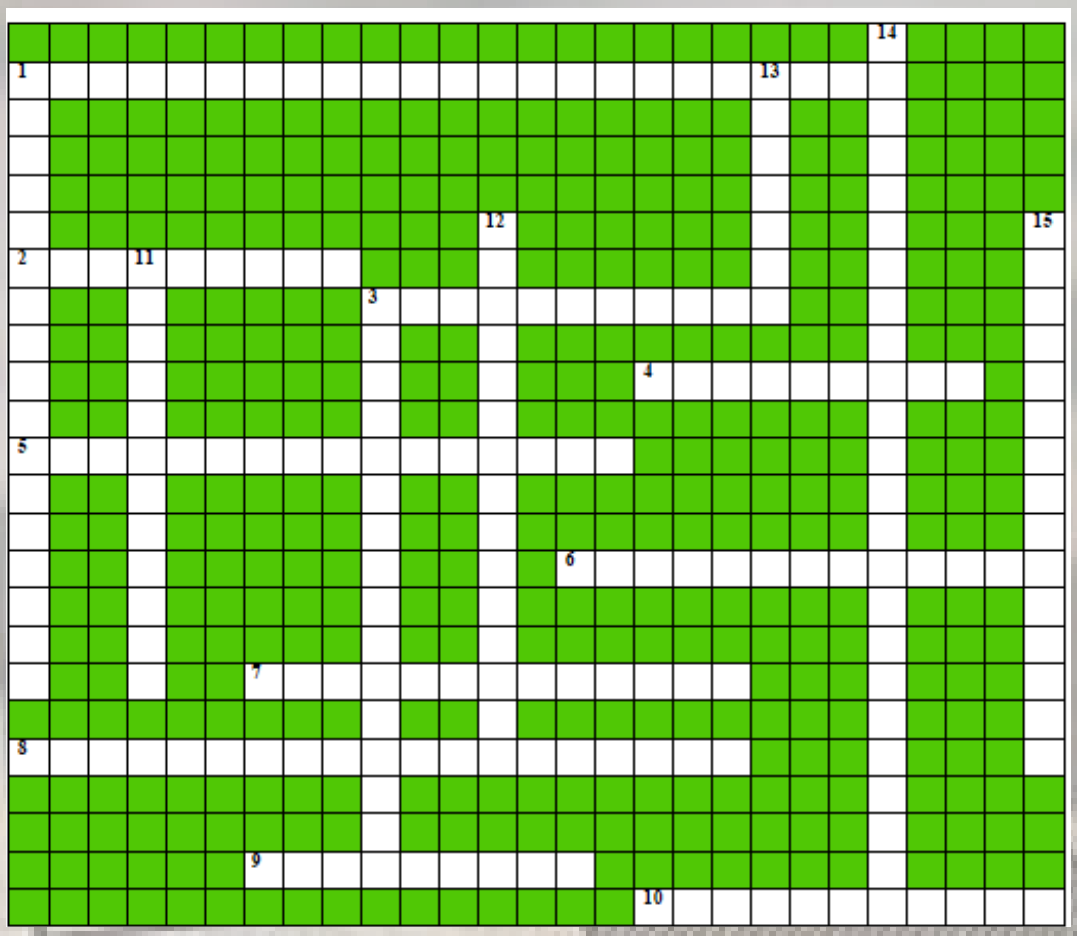
https://www.google.com/amp/s/itchronicles.com/artificial-intelligence/artificial-intelligence-in-healthcare/amp/

By
HARRISH VIKRAM
MSc. Clinical Research
2021-2023

CROSSWORD



ACROSS

1.A non-random experimental method aims to establish cause and effect relationship and does not have control over treatment.

2. It is generally reported as the number of new cases occurring within a certain period of time.

3. An observational study in which the investigator determines the exposure status of subjects and then follows them for subsequent outcomes.

4. A type of intellectual property consists of sign, design, symbol, word, phrase that identifies your goods or services.

5. This is a meticulous summary of all the available primary research in response to a research question

6. It is the process of assigning participants to treatment and control groups assuming that each participant has an equal chance of being assigned to any group.

7. This is the type of study in which the unit of observation is a group not separate individuals for one or more study variables.

8. A chemical or biological substance that has been tested in the laboratory and approved by the FDA for testing in people during clinical trials.

9. A legal term used to describe the rights that creators have over their literary and artistic works.

10. A time period after inclusion, but before randomization, used to exclude certain patients.

DOWN

1. It is a systemic process of documenting, auditing and reporting product or service quality levels.

3. This type of study proceed from the effects of a disease to its cause.

11. A person who is involved in conducting a clinical trial according to the protocol.

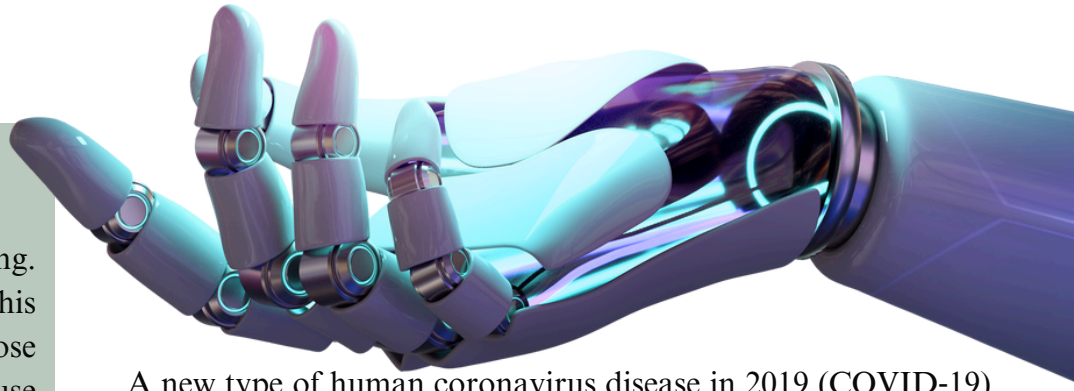
12. A study design in which participants are randomly allocated to one treatment for a period of time and then switched to the other treatment for the second period of time.

13. In phase 3 clinical trials, what is evaluated along with efficacy to compare the new treatment against the current standard treatment.

14. A comprehensive document summarizing the information about the investigational product obtained during a clinical trial.

15. This type of trial is performed to find better ways to prevent disease in people and to prevent disease recurrence using vaccines, etc.

ARTIFICIAL INTELLIGENCE DIAGNOSES COVID



Artificial intelligence (AI) is a popular topic in medical imaging. It certainly revolutionized this diagnostic systems, especially those involved in imaging. Currently, the use of AI in thoracic imaging facilitates diagnostic practices, like the evolution of pulmonary nodules, detection of interstitial lung diseases, and diagnoses of tuberculosis and pneumonia. Recently, certain studies investigated the efficiency of AI within the diagnostic processes for COVID-19 pneumonia and reported high diagnostic outputs in the related applications. It's also been shown that an AI-based quantitative CT analysis can be an objective tool in demonstrating the severity of the disease.

A new type of human coronavirus disease in 2019 (COVID-19) first reported in Wuhan, China, at the top of December 2019, resulted in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), This has spread aggressively round the world, significantly affecting people's health and lifestyle . Community-acquired pneumonia (CAP) is that the pulmonary parenchyma infection and it is associated with COVID-19 since both has common characteristics. The gold standard method for diagnosing COVID-19 is reverse transcriptase-polymerase chain reaction (RT-PCR), which aims to reveal the RNA of the virus in respiratory samples like bronchial aspirates or nasopharyngeal swabs. Thorax CT has been shown to possess a higher sensitivity than RT-PCR samples in the diagnosis of COVID-19.

This is a retrospective study. Patients older than 18 were included within the study and no gender difference was regarded between the patients. Patients were analyzed retrospectively using the hospital electronic record system. For the COVID-19 group, patients whose SARS-COV-2 PCR tests were positive were analyzed retrospectively. Patients with no or normal chest CT and nonpneumonic disease findings on CT were excluded from the study. 553 COVID-19 pneumonia patients, who had confirmed positive RT-PCR results for SARS-COV-2, and CT images, which were according to COVID-19 pneumonia, were included within the study. For the CAP group, patients who were admitted nd were diagnosed with pneumonia were analyzed retrospectively. Accordingly, within the study, 334 CAP patients were included following the exclusion of patients without thoracic CT and people with signs of disease other than pneumonia on CT.

Thorax CT images of the study were evaluated independently by four pulmonologists, who are experienced. In thorax CT scans, to exclude the extrapulmonary sites, the lung was manually segmented. Then, the full data set was subjected to preliminary processing by adjusting the width of the CT window and the level of the lung window. Furthermore, the lesion sections in COVID-19 or CAP patients were labelled manually and utilized as references for the training of the deep neural network of the AI. Four pulmonologists analyzed the test set of 251 CT images, scoring each image as COVID-19 or CAP. Each CT image was scored by pulmonologists, with “0” representing CAP and “1” representing COVID- 19. The pulmonologists weren't given any information about the patients and all the identification information was extracted from the CT images. All pulmonologists, then, knowing the prediction result from the AI, analyzed the test set again and presented their scores for every patient.

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“1” representing COVID- 19. The pulmonologists weren't given any information about the patients and all the identification information was extracted from the CT images. All pulmonologists, then, knowing the prediction result from the AI, analyzed the test set again and presented their scores for every patient.

Atypical involvements in COVID-19 pneumonia aren't uncommon, and as seen during this study, even pulmonologists experienced within the diagnosis of COVID-19 disease can be mistaken in some patients. AI support can minimize these errors and make important contributions to clinicians within the diagnostic process. AI applications and related implementations can provide vital contributions within the fight against COVID-19, especially by reducing the workload and improving the diagnostic performance of front-line physicians like pulmonologists.

Reference:

*İ*n E, Geçkil AA, Kavuran G, Şahin M, Berber NK, Kuluöztürk M. Using artificial intelligence to improve the diagnostic efficiency of pulmonologists in differentiating COVID-19 pneumonia from community-acquired pneumonia. J Med Virol. 2022 Aug;94(8):3698-3705. doi: 10.1002/jmv.27777. Epub 2022 May 2. PMID: 35419818; PMCID: PMC9088454.

By
NIVEDITHA
MSc Clinical Research
2021-2023

WORD GUESS

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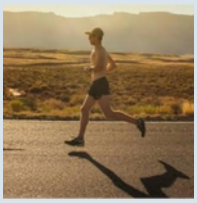



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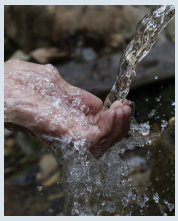

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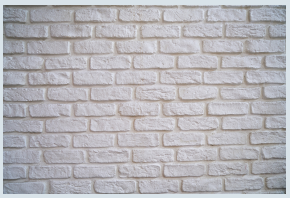


By
HEMA PRIYA
BSc Clinical Research
2020-2023

INHALED VACCINE FOR COVID

- clinical research perspective

In this fast-moving world, healthcare developments are moving faster to keep up with the pace. From the discovery of new drugs to diagnostic tools and treatment remedies, the blooming medical science sector has never failed to impress us. Amongst them is the discovery of vaccines, they range from oral, subcutaneous, intramuscular and intranasal. Although traditional approaches for the administration of vaccines are intramuscular and oral, these days intranasal vaccines interests the pharmaceutical industry more because of least invasive, more effective and easier self-administration.

Ever since COVID-19 spread has been reported, clinical research studies for the discovery of effective vaccines are on the run. As a result, 24 various types of COVID vaccines were approved and brought into the market. But with the population that has to be covered for vaccianation, the healthcare sector is laid under the necessity of discovering alternative methods for vaccination, which are more feasible for administration, easily storable, less invasive and more effective. Hence, world countries like US, UK, China, India and many other are investing their time and money in the development of safer and effective COVID vaccines. Few of these involves intranasal vaccines.

When considering airborne diseases like COVID, pneumonia, tuberculosis, etc the main route of transmission of virus is through the upper respiratory tract. While intramuscular vaccines induce intense IgG serum reflux in the lower respiratory tract along with humoral immunity, the subject of argument here is the upper respiratory tract where the viral entry is first made.

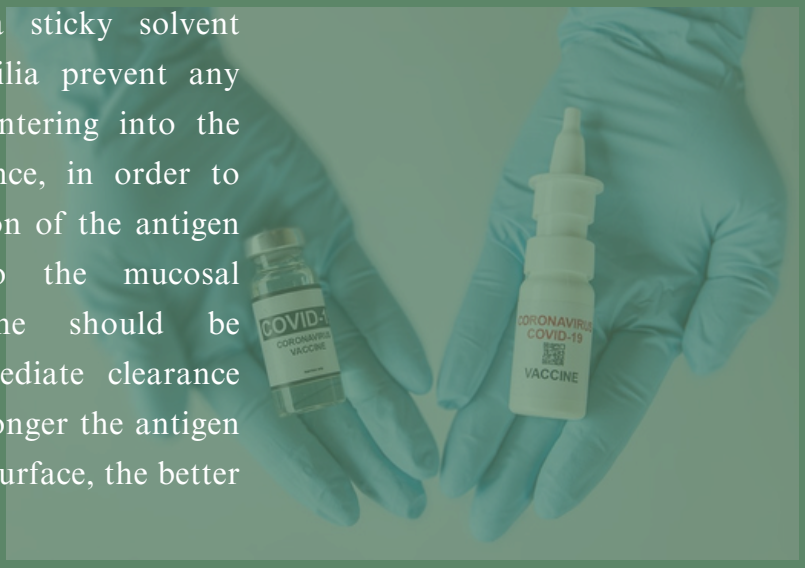
This is believed to be met by intranasal vaccines, which provide with the advantage of producing immune

response at the first entry of the viral particles i.e.) mucosal barrier alongside with systemic immune response. Intranasal vaccines also provide with the advantage of preventing viral transmission from an infected individual. Also, they can be stored in ambient temperature unlike intramuscular vaccines which requires cold storage4.

With all these advantages in hand, one might ask - what could be the possible reason impeding the development of intranasal vaccines?

The important challenges faced during the development of intranasal vaccine are as follows,

Clear nasal surface: Mucous in the nasal pathways is a sticky solvent material while the cilia prevent any foreign body from entering into the mucosal surface. Hence, in order to enhance the absorption of the antigen (from vaccine) into the mucosal surface, the vaccine should be prevented from immediate clearance by the mucous. The longer the antigen stays on the mucosal surface, the better the absorption is.



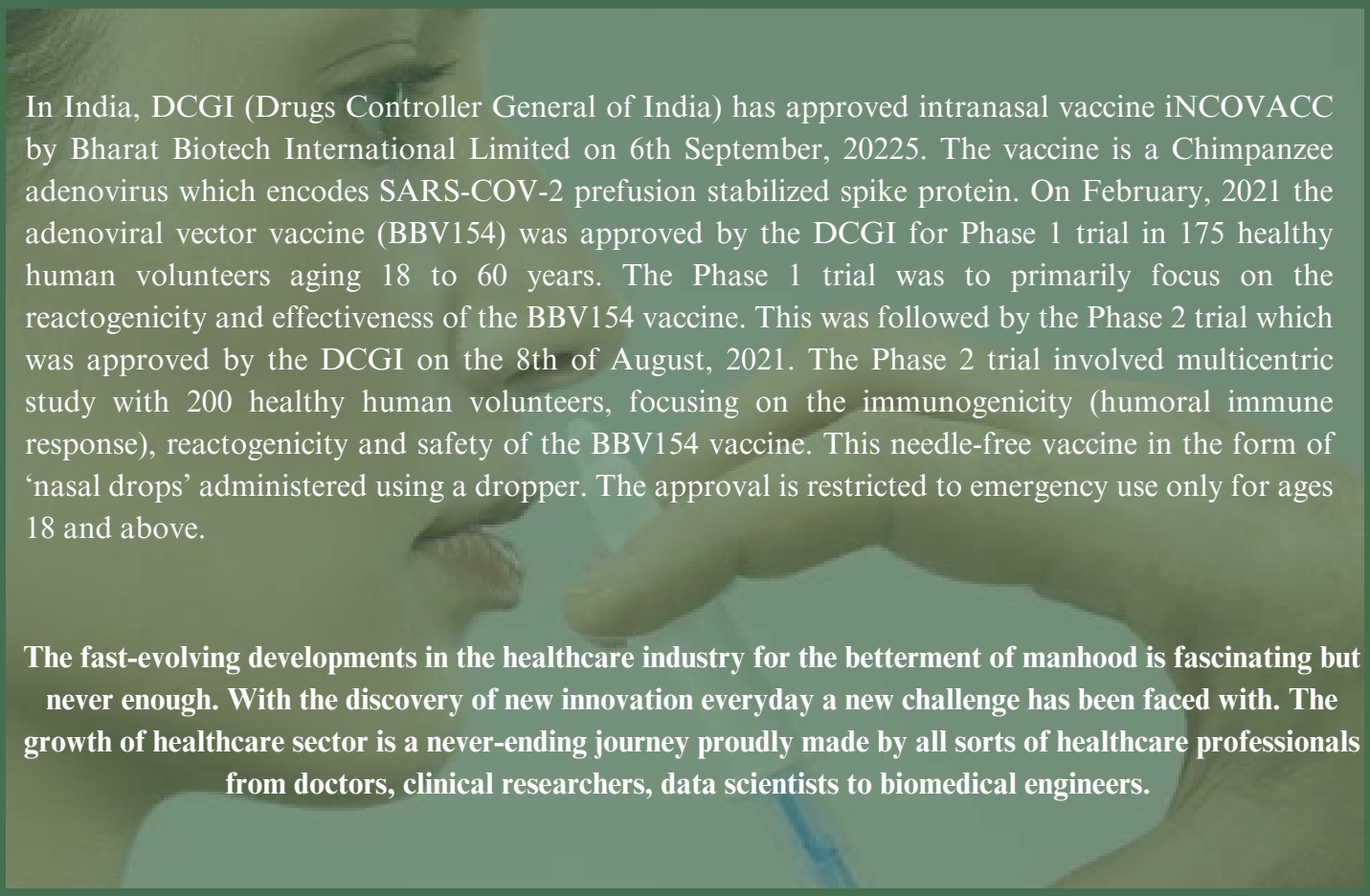
Delivery system: Choosing the right delivery system which ensures sufficient residence of the antigen in the mucosal surface and protecting the antigen till it reaches the lymphatic system to stimulate humoral response also remains a challenge.

Hence the intranasal vaccine developments are scrutinized for their effectiveness and safety in various populations by various pharmaceutical industries. Currently 12 different intranasal vaccines are under development in countries like USA, India, UK and China. The vaccines are under various stages of clinical study, but two industries had succeeded in the making of intranasal vaccines, which are India and China.

China has approved their first inhaled vaccine for COVID-19 developed by Beijing Institute of Biotechnology, Beijing, China and CanSino Biologics, Tianjin, China. This vaccine (Ad5-nCoV) is administered in the form of mist and shall be given as an alternative to parental vaccines as a booster dose. The aerosol vaccine utilizes common cold virus (adeno virus type5) as the vector to carry SARS-COV-2 viral spike protein1. The adeno virus is made replication-defective and is made to carry the full-length spike of the wild-type SARS-COV-2 viral gene.

> **“intra-nasal vaccines will be a global game changer”**

The trial began with animal models, which showed effective inhibition of SARS-COV-2 viral proliferation in the upper respiratory tract. Followed by clinical trial for Ad5-nCoV in Zhongnan Hospital, Wuhan, China with 130 eligible participants in July, 2021. The participants were divided into 5 groups and administered with 2 doses of vaccines (aerosol/parenteral or both) at an internal of 28 days. Based on the trial results, one shot of inhaled vaccine followed by two shots of intramuscular vaccine has been proven to be more effective than three shots of intramuscular vaccines.



In India, DCGI (Drugs Controller General of India) has approved intranasal vaccine iNCOVACC by Bharat Biotech International Limited on 6th September, 20225. The vaccine is a Chimpanzee adenovirus which encodes SARS-COV-2 prefusion stabilized spike protein. On February, 2021 the adenoviral vector vaccine (BBV154) was approved by the DCGI for Phase 1 trial in 175 healthy human volunteers aging 18 to 60 years. The Phase 1 trial was to primarily focus on the reactogenicity and effectiveness of the BBV154 vaccine. This was followed by the Phase 2 trial which was approved by the DCGI on the 8th of August, 2021. The Phase 2 trial involved multicentric study with 200 healthy human volunteers, focusing on the immunogenicity (humoral immune response), reactogenicity and safety of the BBV154 vaccine. This needle-free vaccine in the form of 'nasal drops' administered using a dropper. The approval is restricted to emergency use only for ages 18 and above.

The fast-evolving developments in the healthcare industry for the betterment of manhood is fascinating but never enough. With the discovery of new innovation everyday a new challenge has been faced with. The growth of healthcare sector is a never-ending journey proudly made by all sorts of healthcare professionals from doctors, clinical researchers, data scientists to biomedical engineers.

References:

1) Wu, S., Huang, J., Zhang, Z., Wu, J., Zhang, J., Hu, H., ... & Chen, W. (2021). Safety, tolerability, and immunogenicity of an aerosolised adenovirus type-5 vector-based COVID-19 vaccine (Ad5-nCoV) in adults: preliminary report of an open-label and randomised phase 1 clinical trial. The Lancet Infectious Diseases, 21(12), 1654-1664.

2) Yusuf, H., & Kett, V. (2017). Current prospects and future challenges for nasal vaccine delivery. Human vaccines & immunotherapeutics, 13(1), 34-45.

3) Chavda, V. P., Vora, L. K., Pandya, A. K., & Patravale, V. B. (2021). Intranasal vaccines for SARS-CoV-2: From challenges to potential in COVID-19 management. Drug discovery today, 26(11), 2619-2636.

4) Dhama, K., Dhawan, M., Tiwari, R., Emran, T. B., Mitra, S., Rabaan, A. A., ... & Al Mutair, A. (2022). COVID-19 intranasal vaccines: current progress, advantages, prospects, and challenges. Human Vaccines & Immunotherapeutics, 1-11.

5) https://www.bbc.com/news/health-62793078

6) https://edition.cnn.com/2022/09/06/china/china-covid-19-vaccine-cansino-intl-hnk/index.html

7) Chavda, V. P., Vora, L. K., Pandya, A. K., & Patravale, V. B. (2021). Intranasal vaccines for SARS-CoV-2: From challenges to potential in COVID-19 management. Drug discovery today, 26(11), 2619-2636.

By
Dr. ROJA SK
MSc Clinical Research
2021-2023

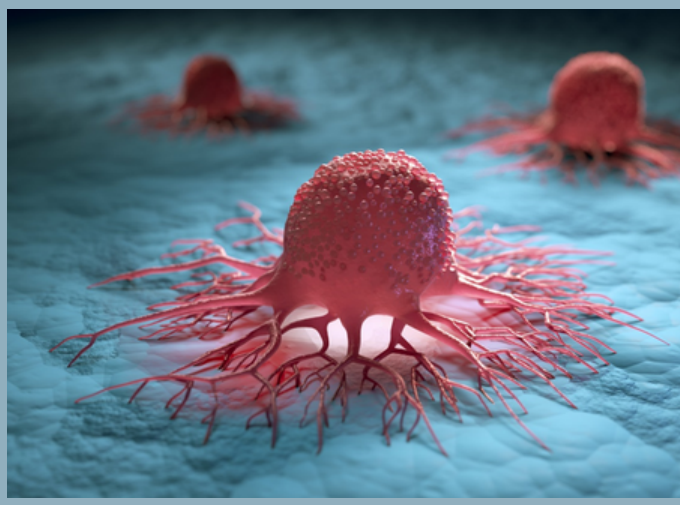
In a breakthrough clinical experiment, the first human patient is injected with a cancer-killing virus.

Modified poxviruses work by entering cells and replicating themselves. After the infected cells rupture and release thousands of new virus particles that act as antigens, they stimulate the immune system to attack nearby cancer cells. Meanwhile, previous studies in animal models have shown that the drug can use the immune system to hunt down and destroy cancer cells in this way, but so far it has not been tested in humans.

The drug's co-developers, the City of Hope Cancer Treatment and Research Center in Los Angeles and the Australian biotech company Imugene, recently announced that the first clinical trial in human patients is underway.
For the first time, an experimental cancer-killing drug has been administered to a human patient. Scientists hope the trial will eventually provide information about new alternatives to successfully fight cancerous tumors in the human body

The drug candidate CF33-hNIS (an oncolytic virus), also known as Vaxinia. Scientists say it's a genetically engineered virus designed to selectively infect and kill cancer cells while sparing healthy cells.

Previous research has shown that oncolytic viruses can engage the immune system to respond to cancer, destroy cancer, and trigger the immune system to respond to other immunotherapies more effectively. CF33 -We believe hNIS has the potential to improve patient outcomes," said Daneng Li, an oncologist and principal investigator at City of Hope. However, the results of whether CF33-hNIS is safe to take depend on the first phase of research focusing on the safety and tolerability of the drug.



By
KAVITHA
MSc Clinical Research
2021-2023

After enrollment in the study, these participants will receive low-dose experimental treatment by direct injection or intravenous administration. If the initial results are successful and CF33-hNIS is deemed safe and well-tolerated, additional testing will explore how the drug compares with pembrolizumab, an existing antibody therapy already used in cancer immunotherapy. You can check if it is combined like this.

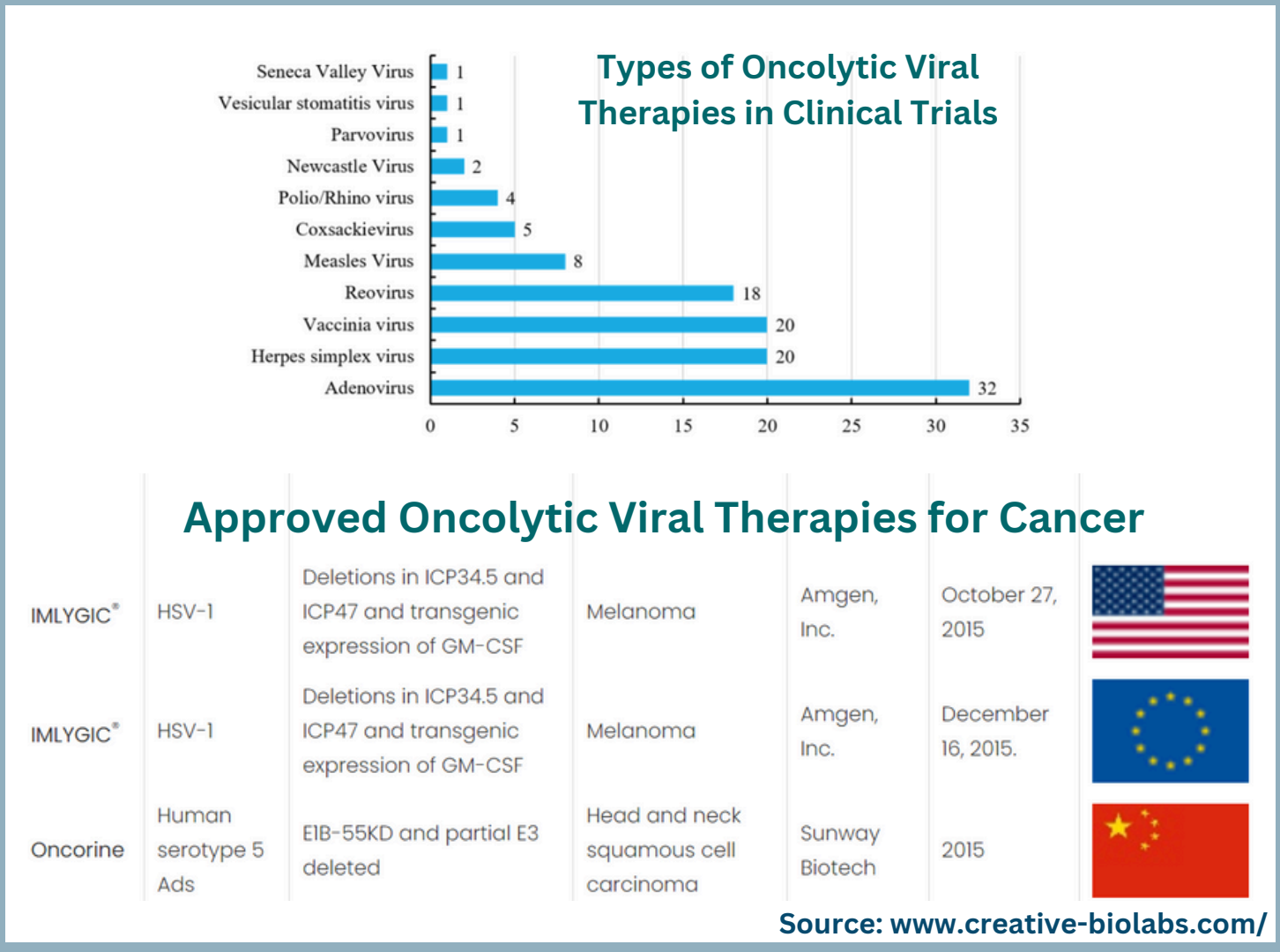
If this drug proves to be safe and well-tolerated, it will become an effective anti-tumor drug defined as a 'breakthrough' in its potency and ability to recruit and activate immune cells. We can explore new tools that are useful," said the team, which has previously studied the effects of CF33 on tumors in mice.

If successful, CF33-hNIS will be his second FDA-approved tumor-to-cancer after Talimogene laherparepvec (T-VEC), a modified version of the herpes simplex virus used to treat melanoma. It has been reported to be a lytic virus therapy.

References:
1.https://d.newsweek.com/en/full/2043024/cancer-cell.jpg

2.https://www.financialexpress.com/healthcare/news-healthcare/first-human-patient-injected-with-cancer-killing-virus-in-new-clinical-trial/2537555/

3. Lin, D., Shen, Y. & Liang, T. Oncolytic virotherapy: basic principles, recent advances and future directions. Sig Transduct Target Ther 8, 156 (2023)



Unveiling the Promise of Digital Biomarkers in Clinical Trials

Issue 2
May 2024

In the realm of modern medicine, the integration of technology has been nothing short of revolutionary. Among the most promising advancements is the emergence of digital biomarkers, transforming the landscape of clinical trials. These digital indicators, harnessed from various devices and platforms, offer profound insights into patient health and treatment efficacy, propelling the field towards more personalized and efficient healthcare solutions. Let's delve into how digital biomarkers are reshaping clinical trials and their potential game-changing applications, along with insights from recent research over the past decade.

Digital biomarkers encompass a diverse array of physiological, behavioural, and environmental data collected through digital devices such as smartphones, wearables, and sensors. From heart rate variability to sleep patterns, these markers provide real-time, objective measurements, enabling continuous monitoring of patient health outside traditional clinical settings.

Unlike conventional methods reliant on intermittent observations, digital biomarkers offer a holistic perspective, capturing nuances that may otherwise go unnoticed.

The utilization of digital biomarkers in clinical trials holds immense promise, offering several key advantages.

Firstly, they enable remote patient monitoring, reducing the burden of frequent clinic visits and enhancing participant compliance. This seamless integration of technology enhances data accuracy and reliability, facilitating more robust analyses. Moreover, digital biomarkers offer insights into patient behaviour and lifestyle factors, enriching researchers' understanding of disease progression and treatment response.

Over the past decade, numerous studies have highlighted the transformative potential of digital biomarkers in clinical research. For instance, a study published in Nature Biotechnology in 2017 demonstrated how smartphone-based digital biomarkers could accurately predict symptom severity in Parkinson's disease patients, offering a non-invasive tool for disease monitoring. Similarly, research published in JAMA Cardiology in 2020 showcased the efficacy of wearable devices in detecting atrial fibrillation, paving the way for early intervention and personalized treatment strategies.

Looking ahead, the future of digital biomarkers appears increasingly promising. With ongoing advancements in sensor technology, artificial intelligence, and data analytics, the scope and sophistication of digital biomarkers are poised to expand dramatically. From predicting disease onset to optimizing medication dosages, these markers hold the potential to revolutionize healthcare delivery, fostering a paradigm shift towards proactive, preventative medicine.

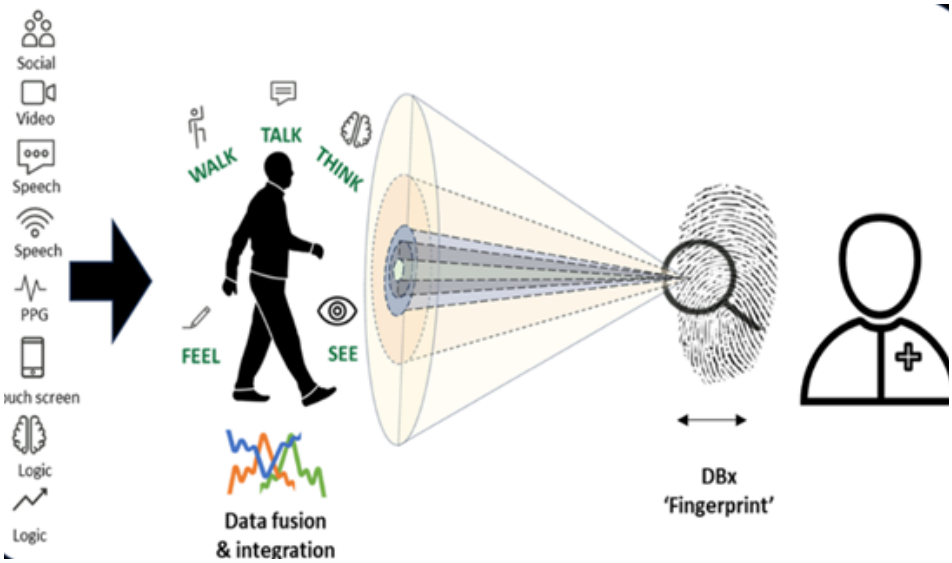
The applications of digital biomarkers extend far beyond clinical trials, promising transformative impacts across various healthcare domains. In mental health, for instance, wearable devices capable of monitoring physiological and behavioral metrics offer invaluable insights into mood fluctuations and stress levels, facilitating personalized interventions and improving patient outcomes. Similarly, in chronic disease management, digital biomarkers empower patients to take control of their health through real-time feedback and personalized coaching, ultimately reducing healthcare costs and enhancing quality of life.

In conclusion, the advent of digital biomarkers represents a watershed moment in clinical research and healthcare delivery. As we embark on this journey towards a digital future, embracing these innovative tools holds the key to unlocking unprecedented insights into human health and disease. With continued research and collaboration, digital biomarkers are poised to revolutionize medicine, ushering in a new era of personalized, precision healthcare.

References:

1. Bhidayasiri, R., Truong, D. D., Pal, P. K., Lee, L. V., & Tan, A. H. (2017). Smartphone-based digital biomarkers in Parkinson's disease: From objective measurement to management. Nature Biotechnology, 35(10), 1034–1036.

2. Steinhubl, S. R., Waalen, J., Edwards, A. M., Ariniello, L. M., Mehta, R. R., Ebner, G. S., ... & Topol, E. J. (2020). Effect of a home-based wearable continuous ECG monitoring patch on detection of undiagnosed atrial fibrillation: The mSToPS randomized clinical trial. JAMA, 323(5), 146-155.



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By
AISHWARYA S
MSc Clinical Research
1st year

DECENTRALISED CLINICAL TRIALS IN INDIA

SCI BUZZ >

OVERVIEW OF DCTS IN INDIA

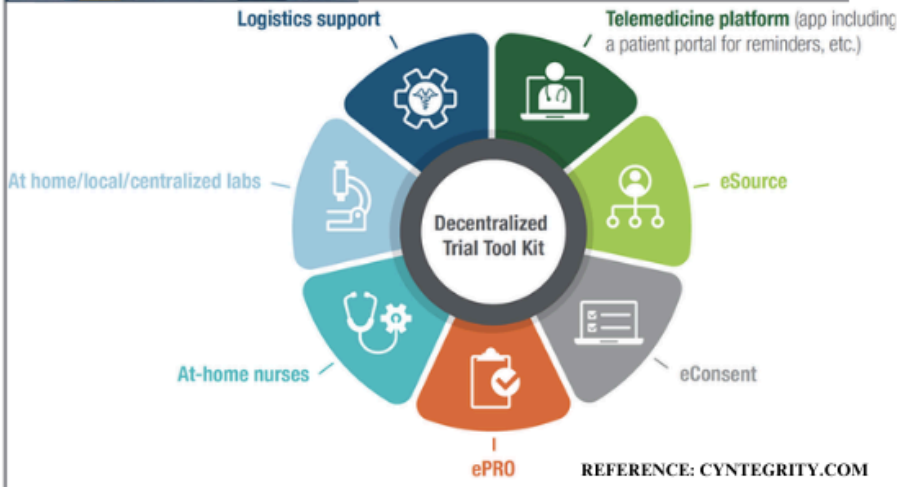
Decentralized clinical trials (DCTs) Leverage digital tools to conduct studies remotely, improving patient access and offering flexibility in participation. They streamline recruitment, enhance data accuracy, and adapt to unforeseen circumstances like pandemics. Challenges such as data security, infrastructure development, regulatory compliance, and ethical considerations persist. Successful implementation relies on strong partnerships and careful navigation of regulatory requirements. While DCT adoption in India isn't specified, globally, there was a 9% decline in 2022 compared to 2021, but usage exceeded 2020 levels, with a projected 17% increase by 2023. Regulatory clarity poses challenges, with compliance difficulties including training for new data capture methods and a lack of fast-track approval for medical devices. Government initiatives like the Draft IoTs Policy and data protection laws aim to address these challenges. Indian pharmaceutical companies and Contract Research Organizations (CROs) have successfully implemented DCTs, resulting in enhanced participant access, retention, and real-time data collection. Initiatives to improve access to clinical trials

REFERENCES:

INDUSTRY >

OPPORTUNITES FOR DCT IN INDIA

The adoption rate and growth of Decentralized Clinical Trials (DCTs) in India aren't specified, but regulatory clarity poses challenges, with 45% finding it clear and 5% not. Compliance difficulties include training for new data capture methods and a lack of fast-track approval for medical devices..



REFERENCE: CYNTEGRITY.COM

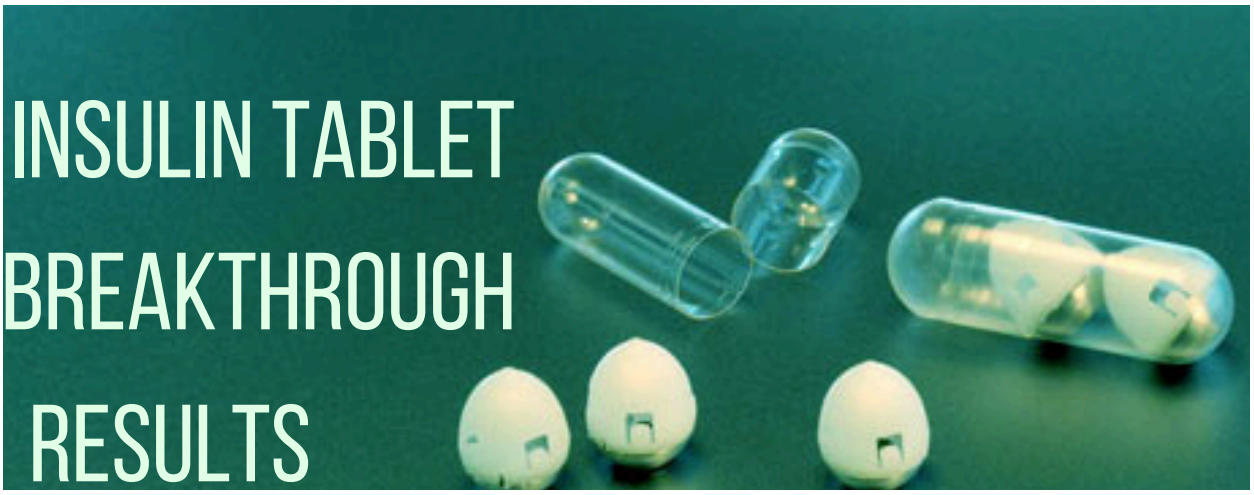
CURRENT LANDSCAPE

Decentralized trials are rapidly evolving due to COVID-19 and initiatives to promote inclusion have led to a rapid evolution of decentralized trials. 76% of professionals adopted more quickly overall. Difficulties include high participant retention (50%) and delays in recruiting (85%), with 70% of eligible participants residing more than two hours away from research facilities.

India's growing economy and Digital India initiatives bolster Decentralized Clinical Trials (DCTs), employing remote data capture and wearables for enhanced participant access and real-time data collection. Regulatory clarity and data privacy challenges are tackled by government efforts like the Draft IoTs Policy and data protection laws. Pharmaceutical firms are establishing teams to manage remote data efficiently, stressing the need for nationwide technology access to ensure effective DCT implementation.

By
AMEER DEEN A &
AKSHAYA J
MSc Clinical Research
1st year

ORAL INSULIN TABLET SEES BREAKTHROUGH RESULTS



In the University of British Columbia, a team of researchers have developed oral insulin tablets (buccal route) as a replacement of insulin injections in the view to eliminate pain and discomfort caused to patients and to eradicate the use of plastic syringes and needles. This is because the use of plastic syringes and needles create a lot of environmental waste which have to be recycled then and there. They conducted the pre clinical studies in rats which showed great results. The oral insulin tablets (buccal route) is absorbed in the same way as of injected insulin by the rats.

Dr.Anubhav Pratap Singh , Principal Investigator told that his team is on the right way of developing the insulin tablet which will improve the quality of life and also will eliminate the use of insulin injection before every meal. He explains that his father was injected with insulin 3-4 times per day for the past 15 years. So why he was inspired to prepare a non- insulin injection with high absorption rate.

In their previous attempts, to prepare an oral insulin, most of the insulin will get accumulated in the stomach. After several improvements in their techniques , they found that liver is the target site and found this latest version of insulin tablet (buccal route administration).

This means the tablet must be placed between the inner cheek and gums (back of the lips).It distributed all the insulin present in one dose without wasting or decomposing any of the insulin to the liver and showed high bioavailability.

Dr.Yigong Guo said, "There is no insulin found in the stomach of the rat after two hours of delivery. When insulin's route of administration is through intravenous it needs 100iu per shot and when administered through oral administration (tablets) it needs 500iu of insulin, from which most of the insulin are wasted which is considered as a major issue".

Dr. Baldelli says that the results of the oral insulin tablet in comparison with insulin injection showed that the tablet is been absorbed completely after half an hour and it's action lasts for two to four hours long. He explains that this would reduce the cost of insulin per dose since their oral alternative could be cheaper, sustainable and easy to make.

Meanwhile, Dr. Nicholas J Hunt and team in Australia has been working for a decade to develop oral insulin. They had developed, characterized and proven that it orally controls blood glucose without hypoglycemic episodes in rats, mice and non-human primates (baboons).

The clinical trial design used for the study in animals is now going to be implemented in healthy people with the phase 1a trial, followed by a phase 1b trial in participants with diabetes. Importantly, the same dosages used in the animals will be tested.

If oral insulin is approved after completing clinical trials, would reduce the cost of insulin per dose since their oral alternative would be cheaper, sustainable and easy to make.

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Reference:

- https://news.ubc.ca/2022/08/30/ubc-team-developing-oral-insulin-tablet-sees-breakthrough-results/
- Guo, Y., Baldelli, A., Singh, A. et al. Production of high loading insulin nanoparticles suitable for oral delivery by spray drying and freeze drying techniques. Sci Rep 12, 9949 (2022).
- Hunt, N.J., Lockwood, G.P., Heffernan, S.J. et al. Oral nanotherapeutic formulation of insulin with reduced episodes of hypoglycaemia. Nat. Nanotechnol. 19, 534–544 (2024).

By,
RESHMI. S & SNEHA. J
BSc Clinical Research
2020-2023

QUIZ

1. In which phase of clinical trial of drug ethical clearance is not required?

2. Good Clinical Practice (GCP) seen in all aspect except ……. study.

3. Combined phase 1 and 2 trials are done in which condition / disease ……

4. Proof of concept studies are also called as phase …… studies of Clinical trial.

5. When was the clinical trial started in India?

6. On average it take how many years to make the new drug from research to market?

7. What is considered a major concern for study delay?
a. Budget concerns b. Recruitment problems
c. FDA holdups d. Safety and toxicity issues

8.what kind of Personally identifiable Health Information protected by HIPAA privacy rule?
a. Paper B. Electronic C. Spoken word

9. A clinical research study can be conducted in how many phases ……

10. The type of Clinical trial which focus on a single person is called ……

POORNIMA
MSc. Clinical Research
2021-2023
&
SUTIRTHA MAJI
BSc. Clinical Research
3rd year

Breaking Ground in Diabetes Research: Tailoring Treatment for the Indian Population

Diabetes poses a significant challenge in India, with an estimated 77 million adults affected, earning the country the title of the diabetes capital of the world. Researchers have been actively exploring innovative methods to tackle this issue, focusing on the distinct genetic and environmental factors prevalent in the Indian population. Clinical trials conducted over the past decade have played a crucial role in identifying new targets to address insulin resistance and improve diabetes management. Let's delve into recent trials that offer promise in combating the diabetes epidemic in India.

Genetic predisposition significantly influences diabetes development and progression, with certain genetic variations more common in the Indian populace. Recent trials have aimed to understand how different genotypes respond to various medications. For instance, the INDIAN Study (Prasad et al., 2019) examined the effectiveness of sulfonylureas versus metformin as initial therapy for newly diagnosed type 2 diabetes in Indian patients. Results showed that individuals with specific genetic variants linked to sulfonylurea sensitivity experienced better glycemic control with sulfonylurea therapy, suggesting the potential for personalized treatment strategies based on genotype.

Traditional Indian medicinal systems like Ayurveda and Siddha have long been respected for their holistic approach to health. Clinical trials have sought to validate the efficacy of traditional herbal formulations in managing diabetes and enhancing insulin sensitivity. The CURES Trial (Ramachandran et al., 2021) evaluated a polyherbal formulation containing fenugreek, bitter gourd, and Indian gooseberry in reducing insulin resistance and improving glycemic control in patients with prediabetes and early-stage diabetes. Results indicated significant improvements in insulin sensitivity and beta-cell function, highlighting the potential integration of traditional medicines into mainstream diabetes care.

Environmental and lifestyle factors, such as diet and physical activity, greatly influence diabetes risk and insulin sensitivity. Clinical trials have investigated the effectiveness of lifestyle interventions tailored to the Indian context in preventing and managing diabetes. For example, the Diabetes Community Lifestyle Improvement Program (D-CLIP) trial (Thankappan et al., 2019) implemented a community-based lifestyle intervention program, incorporating dietary changes, physical activity promotion, and behavioral counseling among high-risk individuals in India.

Results showed notable reductions in insulin resistance and improvements in cardiovascular risk factors, emphasizing the importance of culturally sensitive lifestyle interventions in addressing diabetes.

Advancements in digital health technologies have created new opportunities for diabetes management, particularly in resource-limited settings like India. Clinical trials utilizing mobile health (mHealth) interventions have shown promise in enhancing glycemic control and insulin sensitivity. The mWellcare Trial (Sathish et al., 2020) assessed the effectiveness of a smartphone-based diabetes self-management program in rural Indian communities. Participants receiving the mHealth intervention experienced significant reductions in insulin resistance and improvements in diabetes self-care behaviors, indicating the transformative potential of digital health solutions in overcoming barriers to diabetes care.

As India faces the escalating burden of diabetes, the search for effective strategies to address insulin resistance and enhance diabetes management becomes increasingly urgent. Recent clinical trials, tailored to the unique genetic, cultural, and environmental factors prevalent in India, provide renewed hope in the fight against diabetes. From personalized therapies and traditional herbal medicines to culturally adapted lifestyle interventions and digital health solutions, these trials underscore the importance of a comprehensive approach in combating the diabetes epidemic. As we navigate the complexities of diabetes care, these pioneering efforts pave the way for a future where personalized, accessible, and effective treatments revolutionize the lives of millions affected by this chronic disease.s

Blessy.Nalluri
MSc.Clinical Research
1st year

References:

- Prasad RB, Groop L. Genetics of Type 2 Diabetes—Pitfalls and Possibilities. Genes (Basel). 2015;6(1):87-123.
- Ramachandran A, Snehalatha C, Bhaskar AD, et al. Polyherbal formulation Cogent db® improves insulin sensitivity and β-cell function in subjects with prediabetes and early-stage type 2 diabetes mellitus: a double-blind, randomized placebo-controlled crossover study. Diabetology. 2021;64(1):50-60.
- Thankappan KR, Sathish T, Tapp RJ, et al. A peer-support lifestyle intervention for preventing type 2 diabetes in India: A cluster-randomized controlled trial of the Kerala Diabetes Prevention Program. PLoS Med. 2019;16(6):e1002857.

Word Scramble

Let us see how many you can find!!

Clue: Related to Clinical Trials

MRTNINOIGO	_____
RIEEVOLIAINCMGTA	_____
LEOACPCNIM	_____
ENNECIALFNMCEO	_____
ORIITNNTENVE	_____
ITYNEOANFIILTCD	_____
OTNEERNLM	_____
FGOUNIONDCN	_____

RESEARCHERS DEVELOP MESSENGER RNA THERAPY FOR OVARIAN CANCER, MUSCLE WASTING

Specialists at Oregon State College and Oregon Wellbeing and Science College have fostered a promising, first-of-its-sort courier RNA treatment for ovarian malignant growth as well as cachexia, a muscle-squandering condition related with disease and other ongoing sickness.

The treatment depends on similar standards utilized in SARS-CoV-2 antibodies, and the researchers say that mRNA innovation, while still in its outset regarding helpful application, has colossal clinical potential for the treatment of sicknesses includes. Courier RNA advises cells how to make proteins.

The discoveries, accomplished through a mouse model and distributed today in the diary little, are significant in light of the fact that ovarian malignant growth is an especially dangerous type of disease, with a five-year endurance pace of under 30% assuming it has spread past the ovaries.

"Regularly, patients don't realize they have ovarian disease until it's high level and has arrived at the stomach cavity," said oleh Taratula, a teacher at the OSU School of Drug store in Portland.
"Therapy was restricted to careful evacuation of however much of the disease as could reasonably be expected, trailed by chemotherapy. Most patients at first answer chemotherapy, however the reaction by and large doesn't keep going long."

Notwithstanding malignant growths of the ovaries, stomach, lungs and pancreas, cachexia is related with numerous other constant ailments including different sclerosis, renal disappointment, cystic fibrosis, Crohn's sickness, rheumatoid joint inflammation and HIV. Individuals with cachexia get more fit even they eat, and simply fat, yet muscle also. The crippling condition kills up to 30% of disease patients experiencing it.

The new treatment created by Taratula, Daniel Characteristics of OHSU and associates at the two colleges depends on lipid nanoparticles, or LNPs, fit for conveying mRNA that sets off the development of the follistatin protein inside malignant growth bunches. The examination is important for a five-year, $2.3 million Public Foundations of Wellbeing award that came about because of a coordinated effort among Taratula and Imprints. The LNPs are directed through infusion into the peritoneal pit, which contains the stomach organs.

The follistatin delivered following infusion neutralizes another protein, activin A, whose raised numbers are connected with forceful ovarian malignant growth and its related cachexia.

"By changing the properties of the malignant growth cells, mRNA treatment can prompt number of beneficial outcomes,"Taratula said. "It forestalls the development of ascites - stomach liquid that contains disease cells.

It likewise defers illness movement and prompts the arrangement of little, strong cancers that don't stick to organs and are thusly simpler to eliminate. Furthermore, it battles cachexia by assisting with keeping up with bulk."

Cachexia and unhealthiness have immense ramifications for disease patients, he makes sense of. A significant number of those patients are "In a condition of wholesome chapter 11 and ongoing squandering," and that harms their capacity to profit from treatment.

"Chemotherapy stays the cutting edge treatment for metastatic infection, however it accompanies significant expenses - loss of bulk, exhaustion of fat stores, weakness and fundamental Inflammation,"Marks said.

"There is an unmistakable need to find new treatments and medication blends that work on the viability and bearableness of chemotherapy, and we accept we have made a significant stage that way."

The mouse model showed that mRNA treatment functioned admirably in mix with cisplatin, the ongoing norm of care chemotherapy therapy for ovarian malignant growth. Mice getting the two treatments in show lived longer and had less muscle decay than those getting only one of the medicines.

Reference:

https://indiaeducationdiary.in/oregon-state-university-oregon-state-researchers-develop-messenger-rna-therapy-for-ovarian-cancer-muscle-wasting/

By
E. SNEKHA SRI (BSc Clinical Research 3rd year)
RAJESHWARI (BSc Clinical Research 3rd year)
S. VARSHINI (BSc Clinical Research 3rd year)

Gene Editing Tool improves vision

From Mice to Humans

Researchers have developed a new gene editing technique that has been successful in reversing vision loss in mice. This innovative technique could potentially be used to treat inherited retinal diseases, which are the leading cause of blindness in people under the age of 60.

The study, which was published in the journal Nature, used a method called CRISPR-Cas9 to target a specific gene mutation that causes retinitis pigmentation, a degenerative eye disease that affects around 1 in 4,000 people worldwide.

The researchers were able to edit the gene and restore vision in the mice. CRISPR-Cas9 is a powerful gene editing tool that has been widely used in research since its development in 2012. It works by cutting DNA at a specific location and allowing researchers to insert, delete, or replace genes as needed. This technique has shown promise in treating a variety of genetic disorders, including sickle cell anemia and muscular dystrophy.

In this study, the researchers used CRISPR-Cas9 to target a gene called MERTK, which is known to play a role in retinitis pigmentosa.

The mice in the study had a mutation in this gene that caused them to develop the disease. The researchers were able to edit the gene in the mice and restore function to the photoreceptor cells in their eyes, which are responsible for vision.

The researchers found that the treatment was effective in restoring vision in the mice, and the effects lasted for at least six months. The treated mice were able to navigate a maze and respond to changes in light, indicating that their vision had been restored.

This study is significant because it shows that CRISPR-Cas9 can be used to treat inherited retinal diseases, which are currently untreatable. These diseases are caused by mutations in specific genes, so gene editing techniques like CRISPR-Cas9 have the potential to be a targeted and effective treatment.

However, there are still several challenges that need to be addressed before this technique can be used in humans. One concern is the potential for off-target effects, where the gene editing tool could unintentionally edit other genes in the body. Another challenge is the delivery of the gene editing tool to the eye, as it is a delicate and complex organ.

Despite these challenges, this study is a promising step towards developing new treatments for inherited retinal diseases.

Gene editing techniques like CRISPR-Cas9 have the potential to revolutionize the field of medicine and provide new hope for patients with genetic disorders.

A phase 1-2, open-label, single-ascending-dose study was conducred in persons 3 years of age or older with CEP290-associated inherited retinal degeneration. 14 participants received a subretinal injection of EDIT-101 therapy.

Six participants out of 14 have reported a meaningful improvement from baseline in the vision-related quality-of-life score.

The study was conducted at the Ocular Genomics Institute, Department of Ophthalmology, Mass Eye and Ear and Harvard Medical School, Boston and Editas Medicine. This study has opened up avenues for further research with in vivo CRISPR-Cas9 gene editing to treat inherited retinal degenerations.

Reference:

- Huan Qin H, Zhang W, Zhang S, et al., Vision rescue via unconstrained in vivo prime editing in degenerating neural retinas. J. Exp. Med. 2023 Vol. 220 No. 5 e20220776
- Pierce EA, Aleman TS, Jayasundera KT, et al. Gene Editing for CEP290-Associated Retinal Degeneration. N Engl J Med. 2024 May

SMART WOUND HEALING

Revolutionary Wound Dressing Unveils Infections Swiftly

Wound infections are a significant concern in healthcare settings, as they can lead to severe complications and prolonged healing times. Timely detection and treatment of infections are crucial for successful wound management. In a groundbreaking development, a novel wound dressing has emerged that not only aids in the healing process but also has the ability to reveal the presence of infection. This innovative solution revolutionizes the way we approach wound care, empowering healthcare providers to take proactive measures and mitigate potential complications. In this article, we delve into the unique features and benefits of this cutting-edge wound dressing.

DETECTING INFECTION: THE CHALLENGE

Identifying wound infections promptly can be challenging, as initial signs may be subtle and easily overlooked. Common indications of infection include increased redness, swelling, warmth, pain, and the presence of pus or foul odor. However, these symptoms often manifest at later stages when the infection has already progressed. Early detection is critical to prevent complications such as cellulitis, abscess formation, or even systemic infection.

INTRODUCING THE SMART WOUND DRESSING

The revolutionary wound dressing utilizes advanced technology to detect infection early, enabling healthcare providers to intervene promptly. Developed through extensive research and engineering, this intelligent dressing combines traditional wound care materials with innovative biosensors and color-changing indicators.

- Biosensors: Embedded within the dressing, biosensors actively monitor the wound environment by detecting the presence of specific biomarkers associated with infection. These biomarkers can include microbial toxins, enzymes, or inflammatory markers.
- Color-Changing Indicators: The smart dressing is equipped with a color-changing indicator system. When the biosensors detect the presence of infection-related biomarkers, the dressing undergoes a visual transformation. The indicator changes color, providing a clear visual cue to healthcare providers that infection is present.

By
JAYALAKSHMI.V
BSc. Clinical Research
3rd year

BENEFITS

Early Detection: The primary advantage of this smart wound dressing is its ability to detect infection at its earliest stages.

By capturing subtle changes in the wound environment, healthcare providers can take immediate action to prevent complications.

Real-Time Monitoring: Traditional wound dressings require regular removal for assessment, disrupting the wound healing process. With the smart dressing's continuous monitoring capability, healthcare providers can track infection progression without disturbing the wound, promoting uninterrupted healing.

Streamlined Care: The visual cue provided by the color-changing indicator simplifies wound assessment, making it easier for healthcare providers to identify infected wounds promptly. This efficiency translates into enhanced patient care, reducing the risk of delayed interventions.

Preventative Measures: By detecting infection early, healthcare providers can implement appropriate interventions promptly, such as targeted antimicrobial therapy or wound debridement, preventing the infection from worsening and spreading.

The advent of the smart wound dressing marks a significant advancement in wound care. By combining biosensors and color-changing indicators, this innovative solution enables early detection of infection, empowering healthcare providers to intervene promptly and mitigate potential complications. The benefits of this intelligent dressing range from real-time monitoring to streamlined care, enhancing patient outcomes and improving the efficiency of wound management.

As the field of wound care continues to evolve, the integration of technology and advanced materials holds promise for transforming patient care. The smart wound dressing exemplifies this potential, offering a glimpse into the future of wound management where proactive infection detection becomes the standard practice.

References:

- N. Pan, J. Qin, P. Feng, Z. Li, B. Song, Color-changing smart fibrous materials for naked eye real-time monitoring of wound pH, J. Mater. Chem. B, 7 (2019), pp. 2626-2633
- A. Pusta, M. Tertiș, C. Cristea, S. Mirel Wearable sensors for the detection of biomarkers for wound infection, Biosensors (Basel), 12 (2021)

Evolution of Regulatory Guidelines for Clinical Research in India

1945 — DRUGS&COSMETICS ACT
The first amendment to the Drug and Cosmetics Act, CSDCO

2004 — VACCINE GUIDELINES
1st Annex of Vaccine Guidelines, World Health Organization[WHO]

2005 — BA/BE GUIDELINES
Bioavailability (BA) and bioequivalence (BE) guidelines, CSDCO

2006 — ICMR GUIDELINES
Ethical Guidelines for Biomedical Research on Human Subjects, ICMR

2011 — PROBIOTICS GUIDELINES
Guidelines For Evaluation of Probiotics in humans, ICMR

2013 — AYUSH GUIDELINES
Good Clinical Practice Guidelines, Minister of AYUSH

2013 — MEDICAL DEVICE GUIDELINES
Guidelines for evaluation of Medical Devices, CDSCO

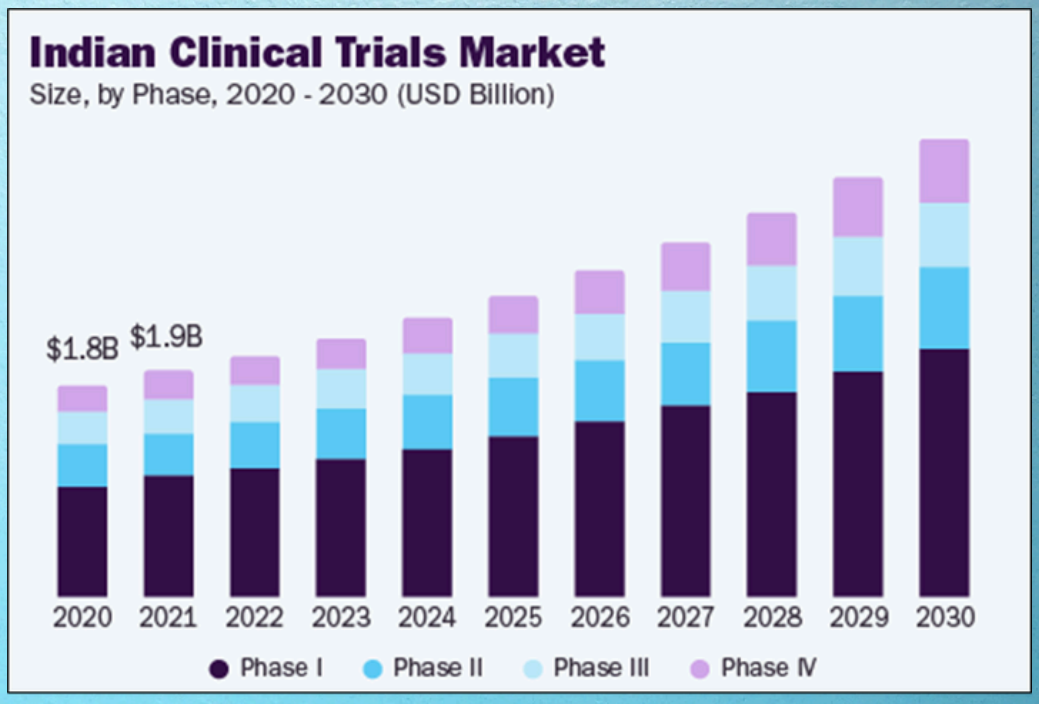
2017 — STEM CELL RESEARCH GUIDELINES
National guidelines for Stem Cell Research, DBT

2017 — ICMR GUIDELINES
National Ethical Guidelines for Biomedical Research Involving Children, ICMR

2018 — GUIDELINES FOR AYUSH PRODUCTS
Guidelines for Evaluation of AYUSH PRODUCTS, Minister of AYUSH

2019 — NEW REGULATIONS
The Indian government rolled out the New Drugs and Clinical Trials Rules on March 19, 2019.

By
AMEER DEEN A
MSc Clinical Research
1st year



Ref: Grand View Research, Report ID: GVR-2-68038-676-9

ETHICAL PRINCIPLES FOR PARTICIPANT SAFETY IN CLINICAL TRAILS

BENEFICENCE

The principle of beficence is to protect and defend the right of participants , prevent harm, remove conditions that cause harm and promote participant's welfare

NON MALEFICENCE

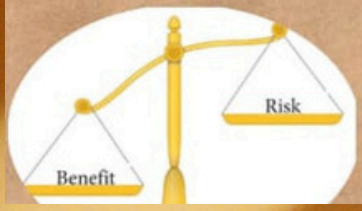
Do not kill, do not cause pain / suffering
Do not incapacitate, do not cause offence
Do not deprive others of the goods of life

JUSTICE

Fair, equitable and appropriate distribution of health care resources and treatments to all participants

AUTONOMY

Participant has the right to know what is being done with their body (adults)
Exception - vulnerable people like childrens, those with disabilities or disorders



RISK-BENEFIT ASSESSMENT

Benefits stated must be comparatively more than the risks posed for

By
Praveen J
BSc Clinical Research
2nd year

CANCER CELLS AS A WEAPON

Stanford Medicine scientists have made a breakthrough discovery that could transform cancer cells into weapons against the disease. Their groundbreaking research involves taking cancer cells, reprogramming them, and then reintroducing them to the body to target and destroy other cancer cells.

CANCER CELL THERAPY

This innovative approach could potentially revolutionize cancer treatment, as it allows for personalized medicine that targets a patient's unique cancer cells. The research team, led by Dr. Crystal Mackall, director of the Stanford Center for Cancer Cell Therapy, has already had promising results in preclinical studies.

The technique involves taking T-cells, which are the body's natural defense against disease, and reprogramming them to specifically target cancer cells. The researchers accomplish this by using a molecule called IL-15 to stimulate the T-cells and increase their ability to recognize and attack cancer cells.

Once the T-cells are reprogrammed, they are reintroduced into the patient's body, where they continue to replicate and attack cancer cells. This approach is known as adoptive cell transfer, and it has already been used successfully in treating certain types of blood cancers.

The Stanford Medicine researchers are now working on developing this technique for use in solid tumors, which are more challenging to treat. They have already seen success in preclinical studies, where they were able to reprogram T-cells to target and destroy multiple types of solid tumors.

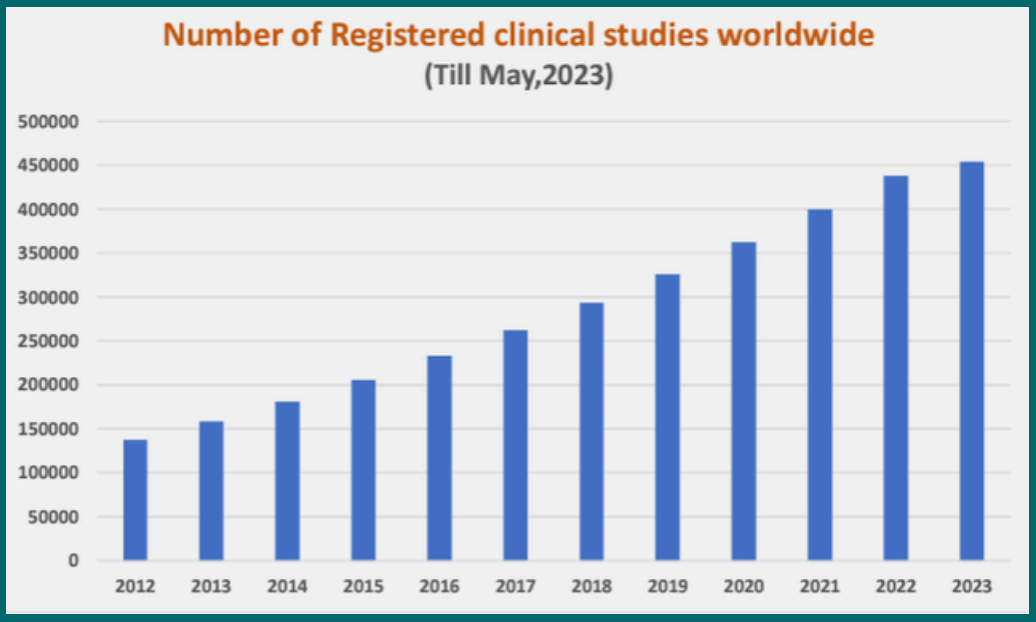
This approach is not without its challenges, however. One major issue is the potential for the reprogrammed T-cells to attack healthy cells as well as cancer cells. To address this concern, the researchers are working on developing methods to control the T-cells and ensure they only target cancer cells.

Despite the challenges, the potential benefits of this technique are enormous. Personalized cancer treatments that target a patient's unique cancer cells could significantly improve outcomes and reduce side effects associated with traditional cancer treatments like chemotherapy and radiation.

The Stanford Medicine researchers are continuing to refine their technique and conduct further preclinical studies. They hope to move on to clinical trials in the near future, with the ultimate goal of making this groundbreaking treatment available to cancer patients worldwide.

The discovery made by Stanford Medicine scientists in reprogramming cancer cells to fight cancer is a significant breakthrough in cancer research. The potential to develop personalized treatments targeting a patient's unique cancer cells could revolutionize cancer treatment and significantly improve outcomes. This innovative approach offers hope for the future of cancer treatment and underscores the importance of continued research and investment in the field.

By
VAMIKA
BSc. Clinical Research
3rd year



Study on CRO Sector of India, Ministry of Chemicals and Fertilizers Govt. of India, Aug'2023

SRI RAMACHANDRA
FACULTY OF CLINICAL RESEARCH

Symposium conducted on 10th May 2024

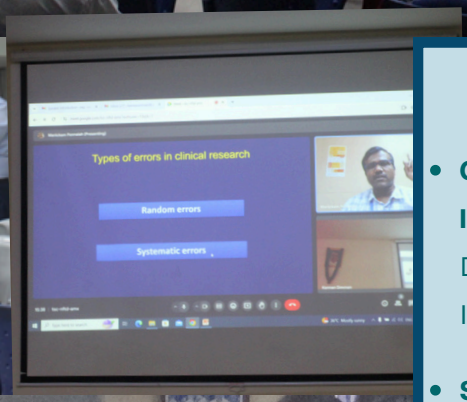
"Importance of Quality Assurance in Clinical Trials"

A symposium was organized by Faculty of Clinical Research to commemorate International Clinical Trials Day. Lectures focusing on Quality Assurance in Clinical Trials were attended by students and faculty members of various departments/colleges of SRIHER.

'International Clinical Trials Day'

20th May 2024

The day to recollect the first ever controlled clinical trial by Dr. James Lind



INVITED LECTURES

- **Overview of ICH-GCP Guidelines and ICMR Guidelines**
  Dr. R. Balaji
  ICMR – NIRT, Chennai

- **Salient Features of NDCT 2019**
  Dr. Alphienes Stanley Xavier
  AIIMS, Madurai

- **Roles and Responsibilities of IEC**
  Dr. Suthakaran C
  Saveetha Medical College, Chennai

- **Functions of DSMB**
  Dr. Melvin George
  SRM Medical College Hospital & Research Centre, Chennai

- **Responsibilities of researchers in data collection, analysis and documentation**
  Dr Manickam P
  ICMR – NIE, Chennai

STUDENT ACHIEVEMENTS

By
RESHMI
BSc Clinical Research
2020-2023

STUDENT ACHIEVEMENTS

Three student teams participated and one team won 3rd place in 'Millet Cookathon' organized by Department of Nutrition

Our students Lakshitha & Ashitha Fathima won 2nd Prize in the event 'Connexions' in the competitions organised for National Nutrition month by Department of Nutrition

Our students won 2nd Prize in the Rangoli Competition organized by Sri Ramachandra Centre for Women's Advancement (SRCWA)

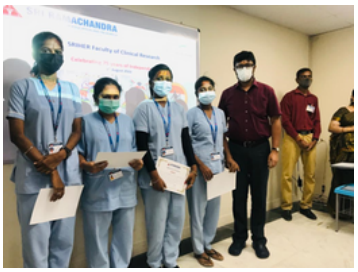
STUDENT ACTIVITIES

Students from SRIHER Faculty of Clinical Research participated in rangoli competition organized by the University for the Campus Environment Day, Women's Day and on Gender Equality

Students from SRIHER Faculty of Clinical Research participated in campus Eco Walk and in the tree planting event organized for 'Campus Environment Day' commemorating Smt Kamalam Udayar's passion for a green campus

AZADI KA AMRIT MAHOTSAV PROGRAM

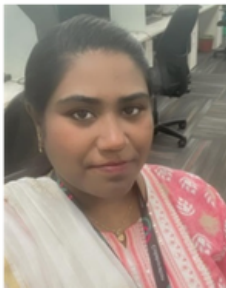
SRIHER Faculty of Clinical Research organized essay writing, rangoli and quiz competitions. Students participated enthusiastically and won exciting prize





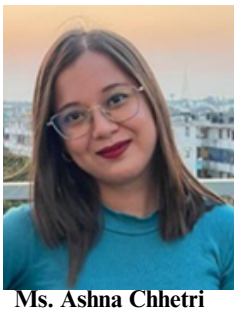
ALUMNI CORNER



Ms. Florence Priyashantini
Clinical Data Coordinator
ICON Plc.
M.Sc. Clinical Research
(2019-2021)

Currently, I am working in ICON plc as a Clinical Data Coordinator-1 at the site to complete the patient data in the database, maintain the site file and handle the monitoring visit. It has been a wonderful experience to have completed my M. Sc. Clinical Research in Ramachandra university, one of the renowned and best university. Clinical research is a competitive and growing field, it is a comprehensive program and gave a clear overview of clinical research with the concepts, research ethics and guidelines. This course enhanced my skills in information seeking, communicating, methodological skills and data analysis. It was an eye-opener experience which allowed me to have hands-on experience in the clinical trial department and in ICMR through internship. This course has changed my career path from a clinical Perfusionist to a Clinical Data Management, and doing this master's program was one of the wisest decisions I ever took in my life

Hi everyone, I am Ashna Chhetri. I am currently working as a Clinical Analyst at Navya Care Network Pvt. Ltd. I am a Clinical Research Master graduate from Sri Ramachandra Institute of Higher Education and Research. Clinical Research is an emerging field that gives you the detailed knowledge regarding clinical trials. I am more than happy to have been a part of this program. which gave me all the information on how trials are conducted and all the criteria that are to be considered. It also gave me the before and after circumstances, information that come in the path of the drug discovery & development, and its approval. Everyone should be acquainted with such a knowledgeable field.



Ms. Ashna Chhetri
Clinical Analyst
Navya Care Network
M.Sc. Clinical Research (2020-2022)

Mr. Vasanth. T
M.Sc. Data Analytics, SRIHER (2022-pursuing)
B.Sc. Clinical Research (2019-2022)

Hello, This is Vasanth, alumni of B.Sc. Clinical Research program. Now I am doing Masters in Data Analytics in SRER, SRIHER. The motive for choosing this course is to enter Clinical Data Management/Analytics field. I am happy that I chose Clinical Research in my UG. The field of Clinical Research is vast and diverse, ranging from drug development to clinical trials, due to this we get huge number of opportunities in research line. The only flaw in this field is, it takes a lot of time to get into a good position. Only experience or with PG or PhD might fetch you a good place in this field. As we know the market for drugs and trials is ever growing, so there is no need to worry about the opportunities and growth. The only thing required is dedication and hard work towards your loved field. All the best for your career and growth. Cheers…

"In my UG program, I had a comprehensive foundation on clinical research principles, research methodologies, data analysis, ethical considerations, regulatory requirements, and clinical trial management. The potential career opportunities for clinical research professionals in various sectors including the pharmaceutical industries attracted me a lot. I am currently pursuing masters in Medical Biotechnology and Molecular Medicine at University of Milan, Italy."

Ms. Krishnapriya Baskaran
MS Medical Biotech. & Molecular Medicine
University of Milan, Italy (2023- pursuing)
Clinical Analyst, Navya Care Network (2022-23)
B.Sc. Clinical Research (2019-2022)

From M.Sc. Clinical Research graduate to Founder of a Site Monitoring Organization (SMO)

Start of an enterpreneurial journey...

"If you don't build your dream, someone else will hire you to help them build theirs."

Dhirubhai Ambani

Embarking on the journey to establish my own Site Monitoring Organization (SMO) in the field of clinical research has been a testament to perseverance, dedication, and the invaluable support of SRIHER Faculty of Clinical Research, especially Dr. Meena Iyer from the Clinical Research Division.

My introduction to the world of clinical research came with a deep-seated passion for making a difference in healthcare outcomes. Recognizing the pivotal role that SMOs play in ensuring the success of clinical trials, I was determined to carve a niche in this specialized field.

It was during this pursuit that I discovered SRIHER, renowned for its excellence in clinical research education and training. The rigorous curriculum, provided me with the necessary skills and knowledge to navigate the complexities of the clinical research. From understanding regulatory requirements to mastering the intricacies of trial conduct, every aspect of the program was meticulously designed to prepare me for real-world challenges.

Dr. Meena Iyer's mentorship not only deepened my understanding of site monitoring practices but also instilled in me a sense of confidence and resilience needed to thrive in this demanding field. Today, as I stand at the helm of "ClinX Research Services", my own SMO, I am humbled by the progress made and the impact created. Each milestone achieved, is a testament to the education and mentorship that paved the way for my success.

I am immensely grateful to SRIHER for providing me with the foundation to realize my aspirations in the field of clinical research. My journey with SRIHER and Dr. Meena Iyer has been nothing short of transformative. Their unwavering support and guidance have been instrumental in shaping my path and empowering me to make a meaningful contribution to the world of clinical research. For that, I will be forever grateful.

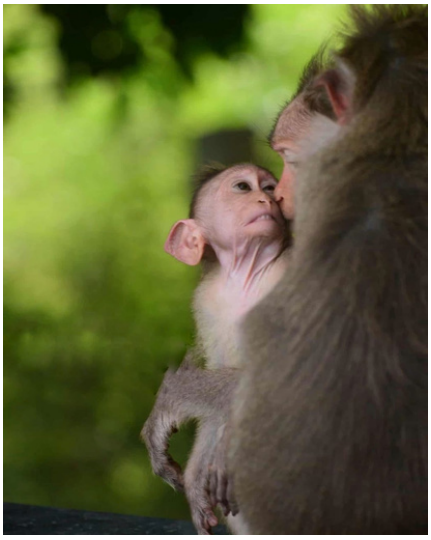
As my SMO continues to grow and expand its footprint in the clinical research landscape, I am excited to announce that we are actively seeking interns for our sites. We believe in nurturing talent and providing aspiring professionals with hands-on experience to develop their skills for upcoming trials.

If you are passionate about clinical research and eager to embark on a rewarding journey, we invite you to join us in shaping the future of healthcare. Together, we can make a difference.

With Warm Regards
Logeshwaran
M.Sc. Clinical Research (2020–2022)
Founder, ClinX Research Services (SMO)
Contact: https://linktr.ee/clinxreserach

clinX Research Services

PHOTOGRAPHY



By
SATHYA BARATHI P
MSc Clinical Research
2nd year

"CAPTURE THE MOMENT, RELIVE THE MEMORY"

PHOTOGRAPHY

VELAN R
MSc Clinical Research
1st Year

KAPISHA
MSc Clinical Research
1st Year

SNEGHA
MSc Clinical Research
1st Year

AISHWARYA
MSc Clinical Research
1st Year

PHOTOGRAPHY

DRISTANT KOUSHIK
BSc Clinical Research
3rdyear

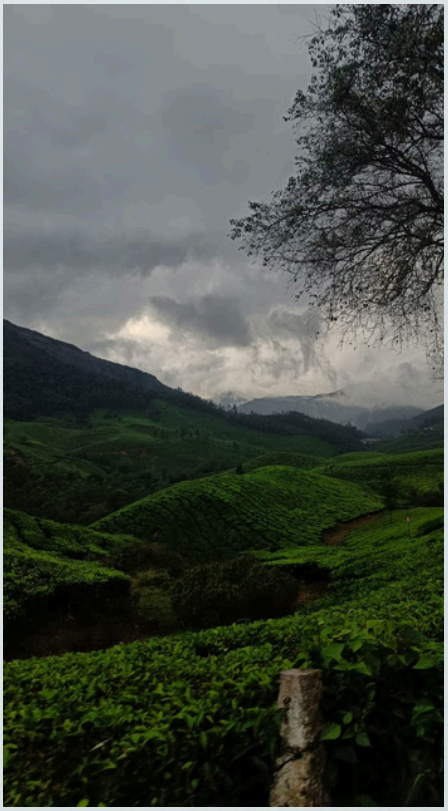
THIS PICTURE DESCRIBES THE SUNLIGHT SCATTERING THROUGH THE LITTLE GAPS OF MAGNIFICENT COCONUT TREES AROUND THE BEACH MAKING THE PICTURE LOOK LIVELY AND FRESH.

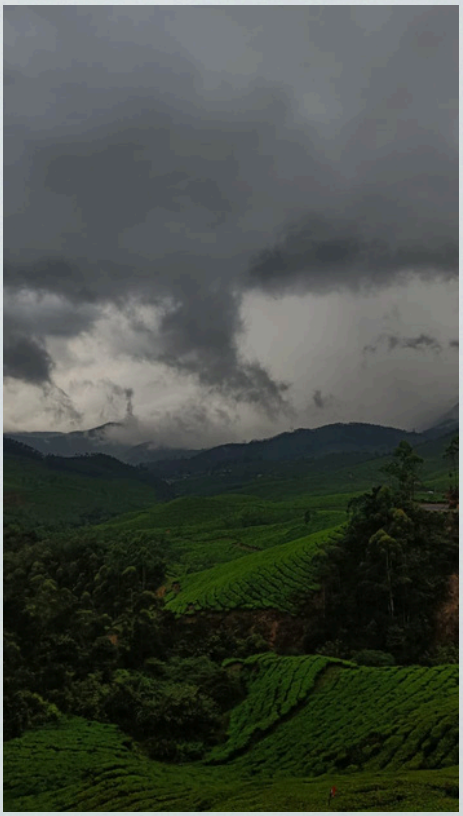
THIS PICTURE DESCRIBES THE TROPICAL NATURE OF MOTHER EARTH

PRIYADHARSHINI
MSc Clinical Research
2021-2023

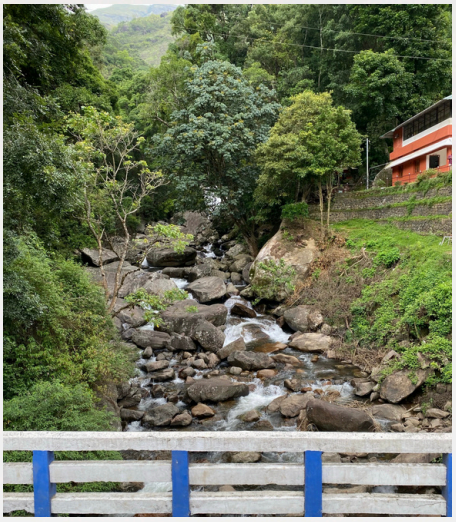
THERE ARE SUCH MOMENTS WHEN HEAVEN IS NONE OTHER THAN NATURE

PHOTOGRAPHY



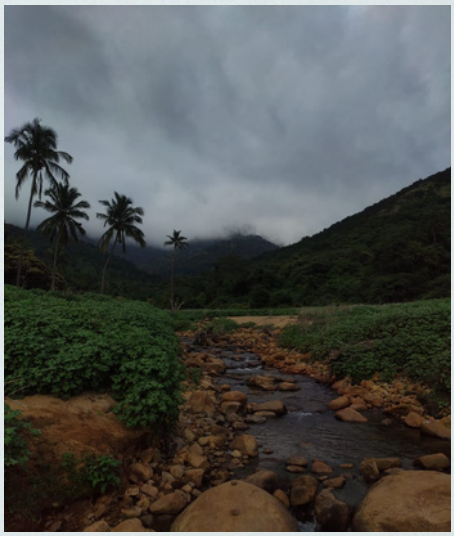


"NATURE- A HOPE FACTOR"



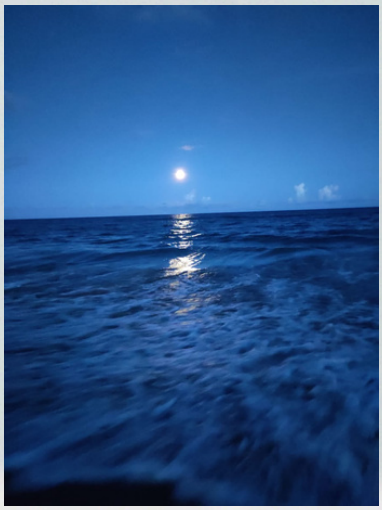
By
LAVANYA
MSc Clinical Research
2nd year

PHOTOGRAPHY



MYMOON SAFARIN
MSc Clinical Research
2nd year

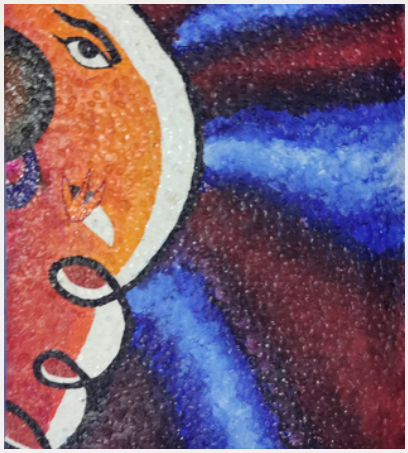
"GREEN MAGIC"



BALAJI K
MSc Clinical
Research
2nd year

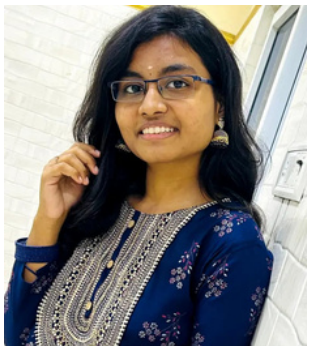
"NATURE NEVER GOES OUT OF STYLE"

ART AND CRAFTS



By
RESHMI
BSc Clinical Research
2020-2023

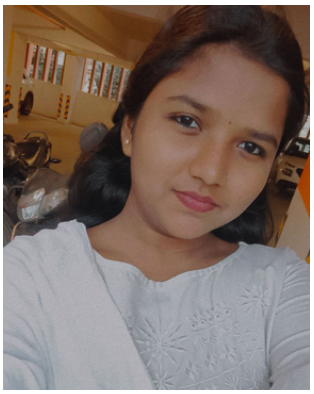
ART AND CRAFTS



By
NANDHINI G
MSc Clinical Research
1st year

YOUR JEWELRY INTRODUCES YOU BEFORE YOU SPEAK.....

tutty_threads



DHARSHINI S
MSc Clinical Research
1st year

ART AND CRAFTS

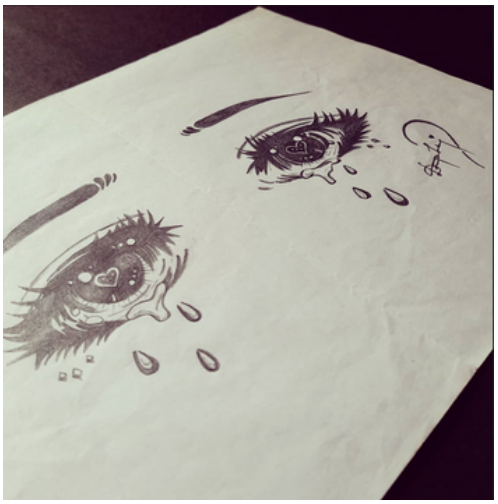
By
SARANAYA R
MSc Clinical Research
2nd year

"LIFE IS SHORT, BUT MY THREADS ARE LONG"

“ CRAFT IS PASSIONATELY CREATING SOMETHING WITH YOUR HANDS.”

By
ABINAYA S
MSc Clinical Research
1st year

ART AND CRAFTS



‘THE ESSENCE OF CRAFT IS CREATING SOMETHING BY HAND’

By
RAGUL V
&
DIVYALAKSHMI S
MSc. Clinical Research
1st year

POETRY

WE ENTER OUR COLLEGE WITH LOTS OF **FEAR,**
AND WE END UP IN CALLING MANY FRIENDS **DEAR.**

WE **REFORM** OURSELVES FROM A CHILD TO AN ADULT,
AND **PERFORM** THE TASKS FOR WHICH WE ARE RESPONSIBLE.

WE ATTEND THE ONLINE CLASSES THROUGH **MOODLE,**
AND WE CHAT, HAVE FUN AND SHARE **NOODLES.**

THE LIBRARY IS TO TAKE AND GAIN OUR **KNOWLEDGE,**
THE CAFETERIA TO SMALL AND TASTE COFFEE AND **FUDGE.**

THE HOSTEL IS TO MAKE MANY **ATROCITIES**
THE LAB IS THE PLACE TO EXPLORE THE ANSWERS TO OUR **CURIOSITIES.**

AT THE BEGINNING, WE WILL BE IN A **GLOOM** STATE AS A BUD,
BUT AT THE END, WE WILL **BLOOM** INTO FRUITFUL FLOWERS.

By
RESHMI
BSc Clinical Research
2020-2023

POETRY

BEING UNIQUE

BECAUSE I KNOW WHO I AM, I'M AT EASE AND FREE.

I CAN'T BE LIKE OTHERS, AND THEY CAN'T BE ME.

I'VE GOT FADING SCARS, AN UNUSUAL PHYSIQUE,

BUT IT ALL WORKS TOGETHER, TO MAKE ME UNIQUE.

I'VE GOT HIDDEN STRENGTHS, SOME OBVIOUS FLAWS.

STILL I AM WHO I AM, FOR BETTER OR FOR WORSE.

I DON'T HAVE TO BLEND IN; I WON'T LIVE A LIE.

I CAN'T PLEASE EVERYONE; I WON'T EVEN TRY.

SOME CALL ME PROUD; OTHERS STARE AT ME IN ALARM.

BUT I'M NOT ONE TO BOTHER, BECAUSE I KNOW WHO I AM.

By
MS. HIMANI SHARMA
BSc. Clinical Research
3rd year

ANSWERS TO PUZZLES

CROSS WORD

ACROSS

1) NON RANDOM EXPERIMENT
2) INCIDENCE
3) OBESERVATIONNAL STUDY
4)TRADEMARK
5) SYSTEMATIC REVIEW
6) RANDOMIZATION
7) GROUP LEVEL STUDIES
8) INVESTIGATIONAL DRUG
9) COPYRIGHT
10) SCREENING PERIOD

DOWN

1) QUALITY ASSURANCE
2) CASE-CONTROL STUDY
3) CLINICAL INVESTIGATOR
4) CROSSOVER STUDY
5) SAFETY PROFILE
6) INVESTIGATOR'S BROCHURE
7) PREVENTIVE TRIAL

WORD GUESS

1) CASE + REPORT + FORM = CASE REPORT FORM
2) RAN+DAM+MI+SAY+SUN = RANDOMIZATION
3) TRIAL+MASTER+ FILE = TRIAL MASTER FILE
4) WIT + DRAW + WALL = WITHDRAWAL
5) WASH + OUT + PERIOD = WASHOUT PERIOD

WORD SCRAMBLE

1.MONITORING
2.MATERIOVIGILANCE
3.COMPLIANCE
4.NONMALEFICENCE
5.INTERVENTION
6.CONFIDENTIALITY
7.ENROLMENT
8.CONFOUNDING

QUIZZ

1. PHASE 4(POST MARKETING SURVEILLANCE)
2. PRECLINICAL TRIALS
3. CANCER
4. PHASE 2
5. 2007
6. ABOUT 10 TO 15 YEARS
7. ALL
8. ALL
9. 3 MAIN PHASES
10. N-OF-1 CLINICAL TRIALS

SRI RAMACHANDRA
FACULTY OF CLINICAL RESEARCH

Programmes offered

B.Sc. Clinical Research

Eligibility criteria

Standard XII in Tamil Nadu State Board, CBSE or any board (Physics, Chemistry, Biological, Mathematics) or (Physics, Chemistry, Botany and Zoology)

M.Sc. Clinical Research

Eligibility criteria

B. Pharm/ Pharm. D/ MBBS/ BDS/ B. Sc. Nursing/ B. Sc. Biomedical Sciences/ Genetics/ Biotechnology/ Allied Health Sciences/ Clinical Research/ or any other Life Sciences degrees; B. Tech (Biotechnology/ Genetic Engineering)

M.Sc. Stem Cell and Regenerative Biology

Eligibility criteria

Bachelor's Degree (MBBS or B.Sc. (Hons) or B. Sc.) in Allied Health Sciences/ Biology/ Biochemistry/ Biomedical Sciences/ Biotechnology/ Botany/ Genetics/ Microbiology/ Life Sciences/ Zoology/ Agriculture / BDS / B. V. Sc. / B. Tech. (Biotechnology, Genetic Engineering)

Program Highlights

Clinical Research:

- Interdisciplinary Curriculum
- Strong foundation in core concepts
  - Clinical Trial Design and Documentation
  - Clinical Data Management
  - Pharmacovigilance
  - Clinical Trial Regulations
  - Good Clinical Practice
- Hands on Training through postings in clinical trials
- Industry Visits and Internships
- 100% Placement in M.Sc. Clinical Research – past 3 graduated batches

Stem Cell & Regenerative Biology:

- Hands on Training in 2D & 3D Cell Culture
- Isolation & Characterization of MSCs
- Fabrication & Characterization of 3D Scaffolds
- Flow Cytometry & Fluorescence Microscopy
- HPLC, HPTLC, NMR, Q-PCR & other molecular techniques
- Internships with Leading organisations

Top Recruiters of Our Students

Pfizer, novo nordisk, ZIFO RnD SOLUTIONS, HCL, Intellpat Patent Solutions, glr GLR Laboratories Pvt Ltd committed to scientific & service excellence, LYSINE BIOTECH PVT. LTD., DiagnoSearch, navya, Securra Health, ICON, accenture, SIMS SRM INSTITUTES FOR MEDICAL SCIENCE CHENNAI, stempeutics, MALLA REDDY UNIVERSITY, SCITUS, SRIHER, MAHER, CorroHealth

APPLY NOW

+91 70101 01510
dracademic@sriramachandra.edu.in
www.sriramachandra.edu.in
#1, Ramachandra Nagar, Porur, Chennai, Tamil Nadu - 600116

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

P.H.A.S.E.S

A Student Run Magazine on Clinical Research

nlclinicalresearch@gmail.com
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