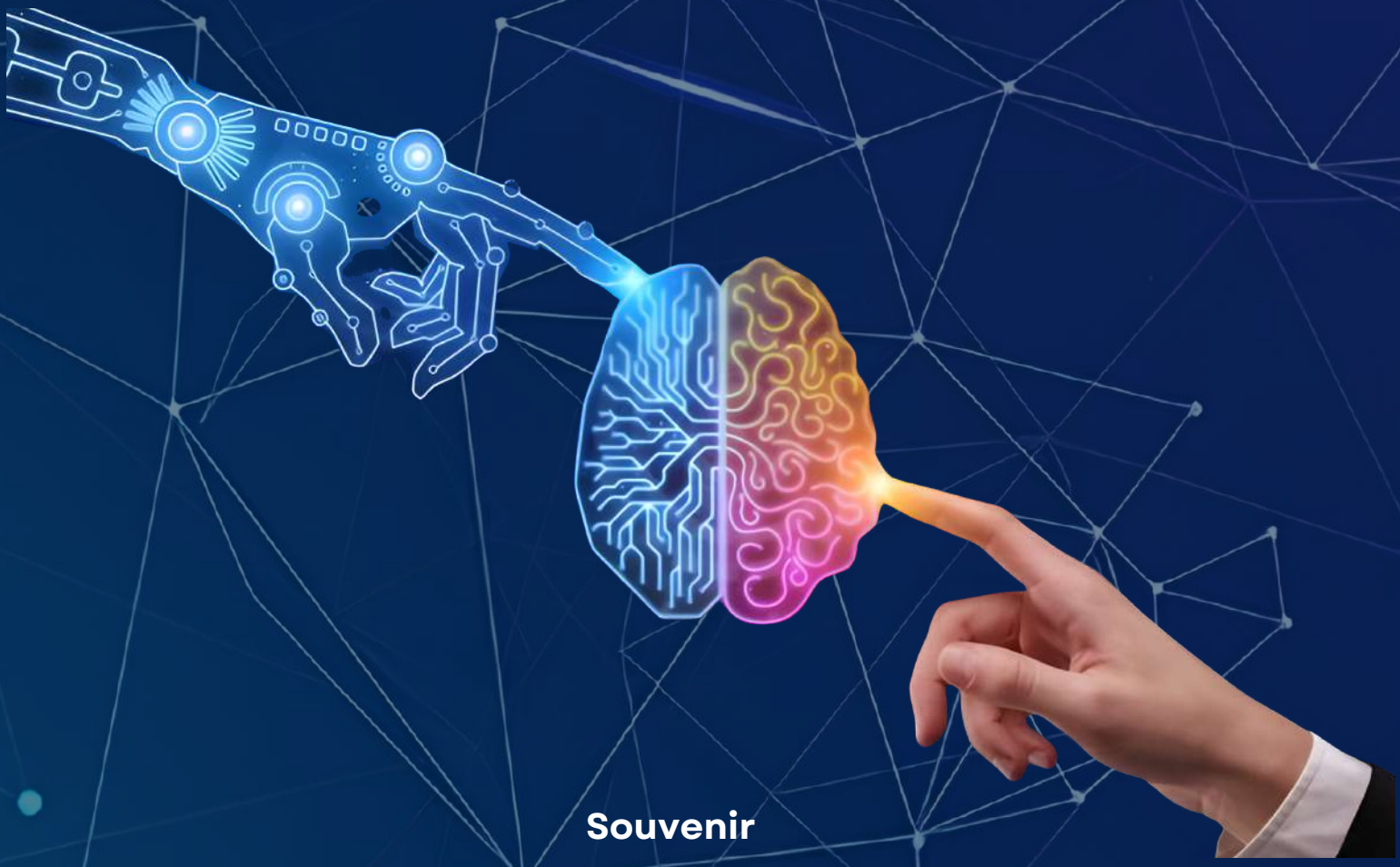
South Asian College of Clinical Pharmacology, an Affiliate of American College of Clinical Pharmacology 14th Annual International Conference

4th-6th January 2024, Hyderabad, India

"Role of clinical Pharmacology in the development of transformative medicines in this era of digital and Artificial Intelligence technologies"



Souvenir

Thank you for your support

We sincerely thank following organizations for providing financial support and sponsorships for the 14th annual SAC-ACCP conference

•Zydus Lifesciences Ltd , Ahmedabad , India
Avant Sante India Private Ltd Hyderabad, India
• Tech Observer India Private Limited Thane India
• Serum Institute of India Ltd., Pune, India
Techsol Lifesciences group company Hyderabad, India
• Glorant India (Octalsoft) Ahmedabad , India
• ClinoSol Research

CONTENTS

14th Annual Conference Scientific Program

Pre-conference Workshops

Workshop-I

Title: Basic Clinical Pharmacokinetic Analysis and Interpretation with PumasCP

Date: January 4, 2024

Venue: Hotel Avasa, Hyderabad, TS, India

Time: 9.00 pm to 12.45 pm IST

Workshop Director: Dr Vijay Ivaturi, PhD

Objectives

The objective of this one-day course is to introduce participants to basic pharmacokinetic data analysis using PumasCP and learn to answer critical questions based on the results.

Requirements

- **PumasCP access (to be provided closer to the date of the course)**
- **Students are expected to bring their laptops to the workshop**
- **Basic knowledge about pharmacokinetics**

Who is this course for

This course is designed for new users to Pumas and anyone who wants to efficiently learn pharmacokinetics and its applications in the clinic and drug development.

Workshop Agenda

Time	Topic	Speaker
9:30 – 10:30 am	Introduction to NCA in PumasCP	Dr Vijay Ivaturi
10:30 – 11:30 am	Introduction to BE in PumasCP	
11.30-11.45 am	Coffee/Tea Break	
11:45 – 12:45 am	Introduction to Integrated Workflows in Pumas CP	Dr Vijay Ivaturi
12.45 - 1.55 pm	Lunch Break	

Workshop-II

Title: PK/PD modeling in Drug Development

Date: January 4, 2024

Venue: Hotel Avasa, Hyderabad, TS, India

Time: 2.00 pm to 5.00 pm IST

Workshop Director: Jagannath Kota, PhD

Faculty: Jayant Sancheti, PhD; Samarth Dharmesh Thakore, PhD; Falguni Pradeep Pankhania, M Pharm

Pharmacokinetic and pharmacokinetic modeling enables early interventions to optimize through model informed drug development. The approach has proven record of reducing the steps and enabling efficient clinical trials in terms of number of trials and/or subjects. The application of tools like Winnonlin enable building strong strategy to prioritize the key trials to decision making point and thereafter, need based trials.

The application of modeling in drug development is currently being applied effectively in designing the first in human strategy through combination of physicochemical and physiological characteristics.

Who should attend:

- **Clinicians, Clinical pharmacology professionals**
- **PhD, M. Pharm scholars, early career faculty**

Workshop Agenda

Time	Topic	Speaker
2:00-2:15 pm	Introduction to the workshop	Dr. Jagannath Kota
2.15-2:30 pm	PK/PD modelling in drug development – introductory note	Dr. Jayant Sancheti
2:30-2:45 pm	Overview of case study – setting expectations	Dr. Samarth Thankore
2:45-3:45 pm	Group activity – Case study 1 and 2	Falguni Pankhania
3:45-4:45 pm	Group presentations	Dr Samarth Thakore and Falguni Pankhania
4:45 pm	Workshop conclusion	

14 th Annual SAC- ACCP Conference

Role of Clinical Pharmacology in the Development of Transformative Medicines in This Era of Digital and Artificial Intelligence Technologies

5 - 6th January 2024

Venue: Hotel Avasa, Hyderabad, India

In -Person Conference

Day 1: Jan 5th, 2024 (Friday)		
Time	**Topic**	**Speaker**
8.00 - 9.00 am -- Registration & Breakfast		
9.00-9.10 am	Opening Remarks	Dr. Deven Parmar President SAC-ACCP
9.10 - 10.35 am -- Session 1 RWE/RWD Contribution in Drug Approval Process Chairpersons: Dr. Deven Parmar and Dr. Sitaramaraju Yarramraju		
9.10 – 9.35 am	Real World Evidence in Global Health	Dr. Sunil Modali Novartis,Hyderabad, India
9.35 – 10.00 am	FDA's Real-World Evidence Program	Dr. John Concato US-FDA, Maryland, USA (V)
10.00 – 10.25 am	Demystifying Real World Evidence: Methodological Consideration for RWE Studies	Dr. Mahender Rai, Eversana, Singapore
10.25- 10.35 am --- Discussion		
Tea Break		
11.00- 12.45 pm -- Session 2 Inauguration, Felicitations, and Keynote Address		
12.00-12.15 pm	Keynote Address -1	Mr. Jayesh Ranjan IAS Principal Secretary Govt of Telangana (TBC)
12.15-12.40 pm	Greetings from the American College of Clinical pharmacology	Dr. Dionna Green President, ACCP, Maryland, USA
12.45- 1.45 pm -- Lunch break		

Time	Topic	Speaker
1.45-3.10 pm Session 3 **AI- ML in Early Drug Discovery, and Clinical Pharmacology** **Chairpersons: Dr. Ayyappa Chaturvedula and Dr.Vikas Dighe**		
1.45-2.10 pm	Opportunities and Challenges for Generative AI in the Drug Development Lifecycle	Dr. Tushar Nitve, Vivpro Illinois,USA
2.10-2.35 pm	Unlocking the Power of Omics for Combating Multidrug Resistant Pathogens	Dr. Vasundhara Bhandari, NIPER,Hyderabad India
2.35-3.00 pm	AI in drug development: A peek into the clinical side	Dr. Mahesh Iyer, Pfizer, Hyderabad, India
3.00-3.10 pm -- Discussion		
3.10- 3.30 pm --Tea break		
3.30-5.20 pm Session 4 **Model Informed Drug Development Applications in Infectious Diseases** **Chairpersons: Dr Nilima Kshirsagar and Dr. Bikas Medhi**		
3.30-3.55 pm	Clinical Pharmacology of Analgesics	Dr. Shrikant C Nallani Maryland, USA
3.55-4.20 pm	Early ADME of PAXLOVID using 19F-NMR	Dr. Ravi Singh Pfizer, Massachusetts, USA (V)
4.20-4.45 pm	Discovery and Development of a New TB Drug Candidate: TBA7371	Dr. R. K Shandil FNDR, Bangalore India
4.45-5.10 pm	Scaling up, Validation and Regulatory approval (Licencing) of Medical Diagnostics	Dr. Vinay Saini, IIT Mumbai, India
5.10 – 5.20 pm	Discussion	
5.30 – 6.30 pm --- Session 5 Poster Presentations		

Day 2: Jan 6th, 2024 (Saturday)		
Time	**Topic**	**Speaker**
8.00 - 9.00 am -- Breakfast Session 5: Free Papers/Poster Presentations		
9.00- 10.25 am -- Session 6 Current Advances in Clinical Pharmacology Chairpersons: Dr. Rama Sivasubramaniam and Dr. Sanish Davis		
9.00-9.25 am	Clinical Pharmacology in Drug Development	Dr Aashish Sharma, Boehringer Ingelheim Connecticut, USA
9.25-9.50 am	Applications of Pharmacometrics Models in Drug Development	Dr. Ayyappa Chaturvedula, Arcus Biosciences, Texas, USA
9.50-10.15 am	Patient adherence: Why do we keep ignoring it?	Dr. Michael Fossler, Cytel, Maryland, USA (V)
10.15- 10.25 am --- Discussion		
10.25-10.50 am Keynote : Big Data is a Big Deal in Pediatrics & Rare Diseases Dr. Brian Tseng- USA		
Tea Break		
11:05 am-11:50am ---Panel Discussion Integrating AIM/ML/RWE for Better Human Health Moderator: Dr. Sauren Das Panelists: Mr. Mahesh Iyer, Mr. Satya Sagi, Dr. Jignesh Patel, Mr. Nirnith Devireddy, Dr. Gangadhar Sunkara		
11.50 - 1.05 pm ---Session 7 Modelling & Simulations in Drug Development Chairpersons: Dr. Kiran Marthak and Dr. Jagannanth Kota		
11.50--12.15 pm	Model Informed Precision Dosing for Oncology Therapeutic Management	Dr. Vijay Ivaturi, Pumas AI, Maryland, USA
12.15-12.40 pm	Applications of PBPK and PBBM in Drug Product Development	Dr. Anant Ketkar, Simulations Plus Mumbai, India
12.40-1.05 pm	ICMR's initiative and perspectives on AI based drug development	Dr. Taruna Madan, ICMR, New Delhi, India
1.05 - 1.15 pm --- Discussion		
1.15 -2.15 pm -Lunch break		

2.15 - 3.30 pm --Session -8 **The AI Alchemy: Transforming Drug Development and Product Lifecycle Management with AI & ML** **Chairpersons: Dr. Nirmala Rege & Dr. Mira Desai**		
2.15 – 2.40 pm	**Digital Precision: Personalizing NAFLD Treatment with Digital Biomarker**	**Dr. Mihir Gharia Mumbai, India**
2.40-3.05 pm	**Navigating the Post-Authorization Landscape with AI**	**Dr. Vivek Ahuja, Eversana, Delhi, India**
3.05- 3.30 pm	**AI & ML in Product Lifecycle Maintenance**	**Col (Dr) Prafull Mohan, AFMC, Pune, India**
3.30-3. 40pm -- Discussion		
3.40-4.25 pm **Valedictory Function, Award Ceremony** **Tea/ Coffee**		

Jayesh Ranjan IAS
Principal Secretary to Government

Information Technology, Electronics &
Communications (ITE&C) Department,
Government of Telangana

Date: 06-12-2023

It is pleasure to learn that South Asian College of Clinical Pharmacology (SAC-ACCP)

(An affiliate of American College of Clinical Pharmacology), Mumbai is organizing an International conference and workshop on 4th-6th January 2024 at Hyderabad and publishing a conference souvenir. The conference on "Role of Clinical Pharmacology in the Development of Transformative Medicines in this era of Digital and Artificial Intelligence Technologies" entails participation from both industry and academia. I hope that this conference will have fruitful deliberations for the benefit of practices in Clinical drug development.

It is expected that participants will be greatly benefitted with the experiences learned speakers India and abroad and scientific talents will apply their learning from this event to take their research endeavors to the next level I extend my best wishes for the successful completion of this conference and workshop organized by SAC–ACCP at Hyderabad.

Yours faithfully

(JAYESH RANJAN)

Room # 24, 3rd Floor, Dr. BR Ambedkar Telangana State Secretariat, Hyderabad-500022.
Ph : +91 40-223456401 | +91 40 - 23450103, email : secy_itc@telangana.gov.in | jayesh_ranjan@hotmail.com

SAC ACCP President Message

Dr Deven V Parmar MD, FCP
Chief Medical Officer & Head – Clinical RnD
Zydus Therapeutics INC, New Jersey

1st Jan 2024,

Artificial Intelligence (AI) is already having a pervasive impact on our daily lives. However Generative AI relatively new will reorient the way we think and work unlock creativity and scientific discoveries and allow us to serve mankind.

USFDA recognizes the significance of AI/ML in drug development, citing the more than 100 drug and biological product applications—submitted in 2021 alone—that included AI/ML components, and the areas of drug development where AI/ML efforts are already active, including clinical trial design, use of digital health technologies ("DHTs"), and real-world data ("RWD") analytics.

I am glad the 14th SAC ACCP conference is covering the relevant topics of AI/ML in Drug development.

Modelling and Simulation are gaining much attention as they provide a platform to integrate current understanding of a disease, patient characteristics, and pharmacology, using dosage optimization and selection, the design of clinical program and trials, identification of supportive evidence of efficacy, and new policy development.

The Scientific & Organizing Committee have made the program educative with the recent trends and regulations.

We remain committed in growing need to spread the discipline of clinical pharmacology across the region.

This program wouldn't have materialized but for the scientific & organizing committee members, our learned speakers, and chairpersons, & our sponsors.

A special mention to local administration committee – Jagan, Rama and Laxman and all volunteers who have ensured smooth workflow of the event.

We look forward for growing and fostering the clinical pharmacology discipline in INDIA and Across.

Wishing YOU ALL A GREAT LEARNING EXPERIENCE
Thank you

Dr Deven V Parmar MD, FCP
President – SAC ACCP

SAC ACCP Vice President Message

Dec 1st, 2023, Hillsborough, New Jersey, USA

Dear Delegates,

Pleasant greetings from New Jersey, USA!

I extend a warm welcome and thank you all for joining us for the 14th annual conference of the South Asian College (earlier chapter) of Clinical Pharmacology held between 4 to 6, January 2024, first time in India's HITECH CITY i.e. Hyderabad!

The theme of this year's conference is "Role of Clinical Pharmacology in the Development of Transformative Medicines in this era of Digital and Artificial Intelligence Technologies".

With a core objective of excellence in science and fostering clinical pharmacology education in the South Asian region, the 14th annual program scientific committee, worked diligently to design a well-rounded scientifically rich program that meets the needs of a pharmaceutical professional, basic and applied scientist, pharmacologist, and clinical pharmacologist with applications in all stages of drug development research and optimizing patient care.

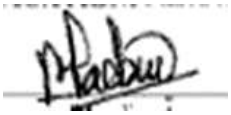
This conference spans over 3 days with 2 pre-conference hands-on workshops focusing on application of modelling and simulation in drug development, followed by 7 scientific sessions ranging from RWE/RWD contributions to drug approval process, AI/ML in early drug discovery and clinical pharmacology, model informed drug development in infectious diseases, current advances in clinical pharmacology and how AI/ML is transforming the drug development and product lifecycle management using these tools. The intent is to get oriented to cutting edge advances in the field of clinical pharmacology in combination with how these novel technological advances can speed up the drug and biologic development.

The conference is going to be a great scientific event with opportunities for the delegates to connect, collaborate and contemplate during these three highly energetic days and I am confident that you will go back with enriched scientific confidence, willingness to do better and something new to shape up your professional career.

For the young scientists, this is an opportunity to get exposed to the best scientific community focusing on drug development and clinical pharmacology. This College will give you an opportunity to develop your scientific and leadership skills and seek guidance and mentoring from the senior Members of the College! Feel free to reach out to me, happy to speak, meet with you.

Thank you and best wishes to the organizers for planning this wonderful scientific feast!

Best Regards,



Manoj Jadhav, M. Pharm, PhD, FCP
Vice President– SAC-ACCP
Founder and CEO ISHA Therapeutics LLC,
Hillsborough, New Jersey, USA.

SAC ACCP SOC chairman Message

Jan 4th, 2024,

Dear Students and Early-Stage Professionals,

Greetings ...!!

On behalf of the Student Outreach Committee, I extend a warm welcome and thank you all for attending this 14th annual international conference of the South Asian College (earlier chapter) of Clinical Pharmacology (SAC-ACCP) held first time in India's City of Pearls, Hyderabad...!

I am associated with this College since last 12 years, when I was pursuing my clinical pharmacology training and doctoral degree. Since then, I have evolved from a student member to full member of the American College of Clinical Pharmacology. I have got one of the most wonderful platforms to showcase my scientific, administrative, leadership and global outreach skills through this College. The reason to this success is my keen interest to contribute to the mission and vision of the College and unique guidance received from SAC-ACCP members and several finest Indian and global scientists from academia, and industry.

We are living in one of the most advanced age in the history of mankind and have been blessed with the most advanced technology and the scientific resources to do best research. This is the age and time of your life where you, as a young and budding students and early-stage professionals, need to be extremely focused and confident to plan for your future. This can be done by exposing yourself and engaging into active interactions, learning, planning with help of the leaders, teachers, and mentors in your area of interest. And this organization and the conference are one of such a unique platform where you can get exposed to all these resources. You will witness in the conference a variety and global science-rich interactions happening through discussions and deliberations. Please plan to interact positively and share your scientific activities during all the sessions of the conference!

I invite you all to join to the Student Outreach Committee of SAC-ACCP and get going on new journey! Be exposed to the best scientific community focusing on clinical pharmacology and drug development. This College will give you an opportunity to develop your scientific and leadership skills and seek guidance and mentoring from the senior Members of the College.

also invite you to follow SAC-ACCP website (https://sacaccp.org/) and LinkedIn page (https://in.linkedin.com/company/south-asian-college-of-clinical-pharmacology-sac-accp) to keep updated with recent college and clinical pharmacology opportunities, news and updates. I look forward to your constant involvement and support.

I am committed to serve your needs, so please feel free to write to us about your thoughts, ideas, and suggestions on how we can serve you better to polish your professional development.

Thank you and best wishes to the organizers for planning this wonderful scientific feast!

Best Regards,

Sagar S Bachhav, M. Pharmacy, Ph.D.
Chair, Student Outreach Committee, SAC-ACCP.
Senior Clinical Pharmacologist,
Clinical Pharmacology, AbbVie Inc. USA.
Email: sagarbachhav25@gmail.com

ACCP President Message

ACCP
American College of Clinical Pharmacology
Advancing Clinical Care through Pharmacology®
PO Box 1758 | Ashburn, VA 20146
Phone: 571.291.3493 | Fax: 571.918.4167 | www.ACCP1.org

14th Annual Conference

"Role of Clinical Pharmacology in the Development of Transformative Medicines in This Era of Digital and Artificial Intelligence Technologies"

January 5-6, 2024

Dear Distinguished Attendees, Colleagues and Friends,

It is with great pleasure that I welcome you to the 14th Annual Conference of the South Asian College, an affiliate of the American College of Clinical Pharmacology® (ACCP). I bring you greetings and best regards from the ACCP Executive Committee, the Board of Regents and Members.

ACCP takes great pride in the accomplishments of the South Asian Affiliate (SAC-ACCP) as it seeks to adopt cutting-edge principles in clinical pharmacology, provide scientific education and training to aid in the dissemination of information and to improve drug discovery and development, regulation, and patient care. In supporting the Affiliate, the Leadership and Members of the ACCP look forward to the continuation of a prosperous and mutually-beneficial relationship.

We have great excitement regarding the state-of-the-art theme of the 14th Annual Conference of the SAC-ACCP: "Role of Clinical Pharmacology in the Development of Transformative Medicines in This Era of Digital and Artificial Intelligence Technologies" and look forward to another outstanding meeting, including critical scientific topics presented by an exceptional global Faculty. We wish to express our gratitude for the efforts of the Organizing Committee and the Scientific Committee in putting together the meeting.

We sincerely hope that you will find this meeting to be informative and that you will seek to apply the principles you learn in your daily work. If you are not a currently a Member of SAC-ACCP, please consider joining this rapidly growing scientific community.

Yours sincerely,

Dionna Green, MD, FCP
President, American College of Clinical Pharmacology®

SAC-ACCP OFFICE BEARERS

(2023 - 2025)

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President

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Ms. Amruta Gadade , Ms.Shruti Desai , Mr. Anirudh Tiwari ,
Ms Diksha Agarwal

Organizing committee of SAC ACCP 14th Annual international Conference

SAC ACCP Organizing Committee

Dr Deven Parmar

Dr Manoj Jadhav

Dr Nilima Kshirsagar

Dr Nirmala Rege

Dr Taruna Madan

Dr Vikas Dighe

Dr Jagannath Kota

Dr Bikash Medhi

Dr Chetna Desai

Dr Gurusharan Dumra

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Clinical Pharmacology: Integrating AI/ML, RWE for better human health

Authors:
Manoj Jadhav 1*, Deven Parmar 2, Rajesh Krishna 3, Vijay Ivaturi 4, Sagar Bachhav 5, Nirmala Rege 6, Nilima Kshirsagar 7
Affiliations:
1. Vice President, SAC-ACCP, Mumbai, India
2. President, SAC-ACCP, Mumbai, India
3. Certara Distinguished Scientist, Drug Development Solutions, Certara USA, Inc., Princeton, NJ 08540
4. Principal Scientist, PumasAI, Inc., Dover, DE, USA
5. Chair, SOC, SAC-ACCP, Mumbai, India
6. Past President, SAC-ACCP, Mumbai, India
7. Founder President, SAC-ACCP, Mumbai, India

Background:

Artificial Intelligence (AI) commonly describes the automation of performing complex tasks, which historically were considered to require human intelligence (1) Machine learning (ML), or deep learning are set of methods (algorithms) that learn from 'big data' to enable AI. Although it is a concept with historical roots which goes back in 1950s, where a scientist called John McCarthy 2, coined the term "artificial intelligence" as the "science and engineering of making intelligent machines." Since then, AI has travelled through the peak and valley pattern of interest which is typically called the "hope-hype cycle".(3,4) Artificial intelligence isn't science fiction anymore. It's reshaping our world, from chessboards to boardrooms, transforming the way we live, work, and even think.

In recent years there has been a rapid expansion of AL/ML applications in therapeutic drug development and biomedical research. In 2019, a team of scientists led by Liu et al(5), performed a landscape analysis of the application of AI/ ML in regulatory submissions for drugs and biologics. The authors envisioned that there would be a significant contribution of AI/ML in the space of drug development. The US-FDA team at office of Clinical Pharmacology, office of Translational Sciences, Center for Drug Evaluation and Research, performed a detailed analysis consisting of drugs and biologics which were approved during 2016-to-2021-time frame, and which had used AI/ML as a component of their drug development submission package. The US-FDA's internal database was searched using the key terms "machine learning and AI" for the investigational New Drug Applications (INDs), Abbreviated New Drug Applications (ANDA), Biologic License Applications (BLA) as well as submission or Critical Path Innovation Meeting and Drug Development Tools Programs from 2016 to 2021. The analysis reported that there was only a single submission in the years 2016, 2017, and since then from 2018 to 2020 the submission increased to 3, 7 and 14 respectively. Astonishingly, there were 132 submissions made in 2021 were approximately 10-fold vs 2020 submissions(6).This tremendous growth in use of AI/ML in drug and biological development is an indicative of strong collaboration between the pharmaceutical and technology industries. These AI/ML tools are being used to improve efficiency of diagnosis and support new treatment modalities across different therapeutic areas including oncology, immunology, rare diseases, psychiatry, gastroenterology, and neurology.

These tools were used across the drug development cycle right from drug discovery, preclinical studies, clinical drug development and also at the post marketing stages. Key analysis types of AI/ML applications are summarized in Figure 1 below. For example, AI/ML was used for prediction of clinical outcomes, including diseases prognosis and treatment response for efficacy and safety based on the characteristic of patient and treatments e.g. drug and dose. Few other applications are like covariate selection/confounding adjustment, pharmacometrics modelling, anomaly detection, imaging, video, and voice analysis etc. Real world data (RWD) phenotyping and natural language processing used AI/ML was used to support the phenotyping of real-world data from certain sources.

Current status and progress:

The prominent US legislation 21st Century Cures Act 2016, created a framework for drug developers to benefit from the use of real-world data for regulatory decision making. In addition to finding new drugs, this legislation created a pathway for use of RWE in new indications. Because big data, whether they be observational data from patient electronic health records or other data from patient registries are difficult to process, the use of neural networks, machine/deep learning, natural language processing and the like can be advantages in understanding trends or in generating new hypotheses with more analytic insights. AL can facilitate the conceptual deviance from descriptive analyses to predictive analyses. It is gratifying to note that the US FDA has approved several medical devices incorporating AI/ML functionality as a result of availability of large language models (LLMs). LLMs are AI models that are trained on large datasets. The US FDA has authorized these medical devices (via 510(k), De Novo request, or premarket approval). However, no device has been authorized that uses generative AI or artificial general intelligence as of Oct 19, 2023 according to the US-FDA. These applications can be used to diagnose diseases earlier and with precision, and as such the “patient” can be better defined. By defining the patient better, clinical trials for chosen indications can potentially yield clinically meaningful information.

AI/ML can also be meaningfully applied in drug discovery and healthcare research, were solutions for most of the challenges are multi-dimensional or complex. ML algorithms could provide an extraordinary path forward in several different complex challenges and problems like preclinical research in neuroscience, oncology, rare disease etc. To support preclinical evaluation of new candidates and disease pathophysiology in neurological diseases, several AI/ML approaches have been developed to perceive the behavioral patterns during the preclinical studies in the rodents.ML algorithm CEBRA, based on brain activity (behavioral and neural data) in mice, was developed which could predict what mice see based on decoding its neural activity(7). AI/ML has also significant potential in clinical and translational research for diagnosis, biomarker selection, protocol optimization, study conduct, etc. Use of AI/ML algorithms to digitized radiology outputs including images of biopsies can assist in understanding heterogeneity in tumors because of driver mutations.A state-of-art biomarker discovery tool, BioDiscML, used a large variety of ML algorithms to identify biomarkers for predicting study outcomes from highly complex datasets (e.g., clinico-pathological information with omics data)(8) With an aim of generating more

efficient and reliable clinical trials, AL/ML tool was leveraged by Unlearn to generate a trial patient's digital twin, which a comprehensive longitudinal forecast of patient record predicted through probabilistic deep learning model of disease progression (e.g. Alzheimer's disease). These digital twins will be used in clinical trial called TwinRCTs, which are randomized controlled trials that use a PROCOVA framework (regulatory qualified) to include the study participant's 'digital twins' into the pivotal Phase2/3 trials with an aim to deliver more power with relatively smaller control groups (9). Overall, there are several leading breakthroughs of AI/ML in healthcare and drug development. However, there still exists multiple challenges for AI/ML implementation in drug development, and one needs to take those into account before applying and utilizing the results.

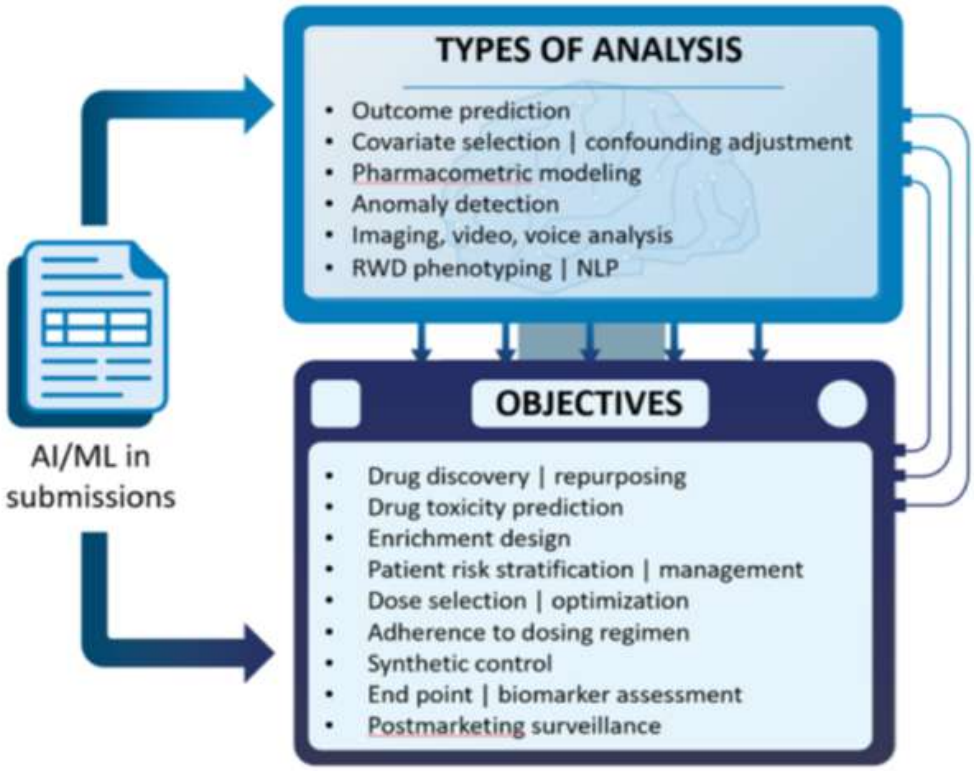

Figure 1. Common types of application of AI/ML in drug development.
(Adopted from Liu et al, 2023, Clinical Pharmacology and Therapeutics.)

How clinical pharmacology can contribute to this evolving landscape?

Clinical pharmacologists have made major contributions to discovery, development, regulation, and utilization of medicines and in teaching rational therapeutics to current and future medical professionals, combining laboratory research, desk work and hands-on clinical consultation.(10-12). There has been a transformation in the role of the clinical pharmacologist, with a demand especially in developing countries for their contribution to public health.(13, 14) AI/ML has an ability to transform many core areas of clinical pharmacology, in addition to medical diagnostics, biomarker development etc. AI will also be going to contribute to drug discovery and development, clinical trials, medicine management, personalized medicines and precision dosing, pharmacovigilance, clinical toxicology etc.(15) While AI may appear promising in healthcare, recognizing both its strengths and weaknesses is essential before using it in patient settings. To ensure safety and efficacy, clinical pharmacologists and clinicians should be involved throughout the development and evaluation process. Clinical pharmacologists sit at the nexus of drug development, evaluation, and regulation, making them uniquely positioned to champion the safe and effective deployment of AI in drug development.

While the promise of AI extends beyond individual disciplines, its true value lies in fostering integrated, collaborative sciences. This evolution may ultimately transcend traditional medical specializations, giving rise to a new breed of data-driven "integrators." South Asia, with India at its vanguard, stands poised to revolutionize drug development in the AI/ML era. India's bedrock of IT prowess, computational expertise, and deep mathematical grounding, coupled with a vibrant pool of highly-skilled pharmacy and medical graduates, presents an unprecedented opportunity. We have the power to dramatically accelerate the discovery of safe and effective treatments for both infectious and lifestyle diseases. But unlocking this potential demands bold action. We must foster cross-pollination of knowledge and embrace AI/ML on a scale never seen. Let's rise to the challenge and claim our rightful place as global leaders in this transformative era of healthcare.

While we aim for this bigger goal, it is also imperative that we design and implement continuing professional development programs for physicians to be trained as well-informed prescribers, astute evaluators of information on new drugs, accredited investigators for clinical trials, innovative clinical researchers to identify local needs for research and clinical trials, and finally as leaders contributing to policy making.

A scoping review regarding application of AI in medical education by Nagi, et al, 2023 has revealed that AI based training enhances the skill development of learners from different disciplines(16). Training in Clinical Pharmacology should not be an exception. It is possible to create case scenarios using AI (e.g. GPT-4, a chatbot) to provide a variety of engaging learning experiences (17) to all the above-mentioned categories viz. physicians, investigators, regulators. These experiences can be in form of scenarios pertaining to ADR reporting, seeking informed consent in simple and complex situations, communicating prescribing information, decision making during clinical trials, ethical issues arising during drug development etc. Such training helps learning and practice clinical pharmacology skills in safe and protected environment. AI based training can provide personalized training as suitable to the learner, assessing his/her strengths and weaknesses and providing real-time feedback so that a learner can self-monitor the progress in the field16. AI can serve as an assessor too(17). This is particularly important at places where faculty trained in clinical pharmacology is not sufficient to cope up with the growing number of learners or not able to supervise the learner's progress closely. In such situations, AI can help as an accessible "virtual faculty". Faculty in turn can get benefitted from the AI generated analytics of learners, which helps in planning the teaching strategy as per the learners' requirement(11). Though still in infancy, the educators will grow with technology and find appropriate and optimum use of this new tool (12). However, it must be noted that GPT-4 is developed to attain general purpose cognitive ability and data available from open sources have been fed to it. Though GPT-4 has answered a battery of questions from USMLE correctly more than 90% of the time(18), it may not understand nuances of clinical pharmacology. The best thing is GPT-4 is not an end and future AI systems are expected to be more efficient and effective(18). Hence creation of simulated volunteers /patients to provide real-life experiences in clinical pharmacology is not far away.

Future scope for SAC-ACCP, India

The South Asian College of the American College of Clinical Pharmacology (an affiliate of the American College of Clinical Pharmacology, USA) has been in existence since 16 yrs. in Mumbai, India. The SAC-ACCP has made significant contributions to foster the discipline

of clinical pharmacology in the region and trained several students, faculty and professional through the workshops, annual conferences and provided platforms to several students across the country to showcase their scientific research work. The SAC-ACCP aspires to be a leader in the evolution of AI in drug development, and we feel this could be further strengthened by developing a common platform for scientific meetings and interactions for all those who are involved in drug development programs in the region. It plans to enlighten pharmacy, pharmacology and clinical pharmacology faculty about applications of AI in clinical pharmacology as well as their role in development and evaluation of forthcoming AI tools in the field of clinical pharmacology. Through its network it is also possible to develop scenario-based certificate courses on specified Clinical Pharmacology Skills using AI technology for those who aspire to become clinical pharmacologists.

*Corresponding Author:
Dr. Manoj Jadhav, M. Pharm., PhD, FCP
Email: manojpjadhav@yahoo.com

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Dr. Deven V Parmar MD,FCP
Chief Medical Officer & Head Clinical RnD
Zydus Therapeutics Inc

Clinical Pharmacologist with more than 30 years of experience
Fellow of the American College of Clinical Pharmacology
Currently – Chief Medical Officer & Head Clinical RnD
Member Working Group ICH M11 : Clinical Electronic Structured Harmonized Protocol
Chairman Medical Committee IDMA (2022- 2024)
Editorial Advisory Board Member Endocrinology Diabetes and Metabolism
More than 100 publications in Indexed Journals

Dr. John Concato
US FDA

Dr. John Concato, MD, MS, MPH, is Associate Director for Real-World Evidence Analytics in the Office of Medical Policy, Center for Drug Evaluation and Research (CDER), U.S. FDA. His responsibilities focus on FDA's Real-World Evidence (RWE) Program, including internal Agency processes, external stakeholder engagement, demonstration projects, guidance development, and serving as Chair of CDER's RWE Subcommittee.

Dr. Concato joined FDA in 2019 after 27 years at Yale School of Medicine and the U.S. Department of Veterans Affairs (VA), where he was Professor of Medicine, Director of the VA Clinical Epidemiology Research Center, and one of two founding principal investigators of the VA Million Veteran Program mega-biobank.

Dr Mahendra Rai
Regional Head & Senior Director , EVERSANA APAC

Dr. Mahendra Rai is a Regional thought leader in HEOR & RWE with over 18 years of experience. At EVERSANA, he heads the overall HEOR, PMA & RWE practice for the APAC& EU region.

Mahendra's core responsibility is to provide actionable insights to Healthcare clients, based on real world data, in the process facilitating informed decision-making at both strategic and tactical levels. He has over 18 years of experience in pricing and market access, outcomes research, health economics, real world insights and observational research spanning across the healthcare spectrum covering pharmaceuticals, medical devices and diagnostics and OTC categories.

Mahendra has been part of various early HTA engagement programs and has successfully managed over 50+ HTA submission globally including US, EU and APAC markets. He has been instrumental in early regulatory and HTA scientific advice with various regulators and HTA bodies including EMA/MHRA and EUnetHTA/ NICE/ GBA/HAS.

Mahendra's academic training includes a M. Pharma in Hospital Pharmacy and a PhD in in Clinical Research. Mahendra is currently the President for ISPOR India, Mumbai chapter and Ex-Chair for the RWE Council of Indian Society for Clinical Research (ISCR). He is also an adjunct faculty at MAHE, India for Health Economics Post Graduate program.

Dr.Sunil Modali
GMAD, Global Health (APac)
GH&S

Dr.Sunil Modali is Global Medical Affairs Director, in Global Health leading Medical Affairs activities for Leprosy Flagship and Avoidable Blindness Program. Prior to this role, he was the clinical/medical lead for Neglected Tropical Diseases, which includes Fascioliasis, Leprosy, MDR-TB and Non Tubercular Mycobacterial infections. Sunil also had experience in the field of regulatory writing, where he used to head the regulatory and submission group in Hyderabad and Shanghai in Novartis. He has experience working in various therapeutic areas which includes Neurology, Immunology, Cardio-metabolic and Infectious Diseases domains; and has been part of various submissions during his tenure in regulatory writing in Novartis.

He is a medic by training with Masters in Pharmaceutical Medicine. He joined his present role of in Nov-2020. Prior to this role Sunil has worked extensively, over 15+ years in clinical development, regulatory, safety, submission and publication writing domains.

Dr. Ayyappa Chaturvedula,
Sr. Director, Clinical Pharmacology,
Arcus Biosciences USA.

Dr.Ayyappa is currently working as Sr. Director, Clinical Pharmacology, Arcus Biosciences, Hayward, CA, USA. Ayyappa has more than 18 years of combined academic, consulting and pharmaceutical industry experiences. He is a current fellow of American College of Clinical Pharmacology (ACCP). He was the recipient of Tanabe Young Investigator by ACCP in 2020. He implemented model informed drug development approaches in a variety of drug development programs ranging from small molecules, vaccines, RNA therapeutics, and monoclonal antibodies in therapeutic areas such as anti-infectives, oncology, rare diseases.

He mentored several graduate students and postdoctoral fellows in his full time academic career, currently holds a part-time Associate Professor appointment at the University of North Texas Health Science Center, Fort Worth, Texas to teach online certificate program in pharmacometrics.

Dr. Vikas Dighe
Scientist ‘F’ & In-charge,
National Centre for Preclinical Reproductive and Genetic Toxicology
ICMR- National Institute for Research in Reproductive and Child Health

Dr. Vikas Dighe works as Scientist `F’ and heading the National Centre for Preclinical Reproductive and Genetic Toxicology at ICMR-National Institute for Research In Reproductive and Child health a premier institution of Indian council of Medical Research, Department of health Research, Government of India. He is a veterinary graduate and Doctorate in Animal Biotechnology

Dr. Dighe has more than two decade of experience in animal experimentation mainly the drug development process and has undertaken more than 30 project where in efficacy, safety of the novel molecules has been undertaken following the OECD/ICH guidelines. He is having expertise in animal model development for PCOS, diabetic, hypothyroidism, Oligospermia etc. His current area of research is molecular toxicology and novel drug delivery. Apart from managing the service mandate, he is guiding PhD students and Post-doctoral fellows and instrumental in human resource development in the area of preclinical reproductive and genetic toxicology. He has shouldered the responsibility of conduction of training workshops and organised national / international conferences in the area of laboratory animal science, clinical pharmacology.

He has published 42 research papers in high impact factor peer reviewed journals and 10 research papers in national journals and also has two book chapters to his credit.

Mr. Tushar Nitave
Staff Software Engineer,
Vivpro Corp

Tushar Nitave is a Staff Software Engineer at Vivpro Corp, a provider of R&D Intelligence Assistant (RIA). Tushar holds a master's degree in computer science from Illinois Institute of Technology, Chicago. Tushar has more than three years of professional experience. Tushar started his career with Tata Consultancy Services (TCS) where he worked as a data scientist and made significant contributions to Conversational AI.
He also led a regulatory intelligence project at GHD Group where he worked on building a tool for experts using software engineering solutions.

Dr. Vasundhra Bhandari
Assistant Professor
Faculty Incharge , Pharmacoinformatics
NIPER Hyderabad

Name: Dr Vasundhra Bhandari, PhD (Biological Sciences)
Designation: Assistant Professor, Faculty Incharge (Pharmacoinformatics and Biopharamceuticals)
Department: Biological Sciences (Pharmacoinformatics)
Affiliation: National Institute of Pharmaceutical Education and Research, Hyderabad
Post-PhD Experience: >8 years
Area of Research: Antimicrobial resistance (ESKAPE Pathogen), Epigenomics, Resistomics, Pharmacogenomics and Drug Discovery.
H-index: 19
i10 index: 28
International Peer-reviewed Publications: 48
Awards and Professional Recognitions
TWAS selected participants for International Conference for Young Scientists on Infectious Diseases, 2017; DST INSPIRE Faculty Award-2015; Fast Track Young Scientist – (DST-SERB) 2014; Won the Sri Ramachari Young Scientist Award -on May 15th 2012; Won International Travel Grant Award from the European Commission- FP7,2010.
Biomed Central Microbiology Editor, Review editors for several international peer reviewed journals.

Dr. Mahesh Iyer, Head of Stats, AI/ML, Quantitative Digital Sciences, and Innovation, Pfizer (India-Philippines)

Mahesh is currently Head of Stats, AI/ML, Quantitative and Digital Sciences, and Innovation, India-Philippines at Pfizer. Mahesh Iyer has over 25 years of experience in research and development in healthcare and has been responsible for guiding many products through the development life-cycle throughout his career at Novartis, Bristol Myers Squibb and Boehringer-Ingelheim.

Prior to his current role at Pfizer, Mahesh was VP at Parexel, responsible for heading the Innovation and Technology function for Parexel, and was also India Head for Global Data Operations. Mahesh has also been a co-founder of Sineflex Solutions LLP, a consulting firm focused on enabling and accelerating innovation in the healthcare space. He was also the head of the BIRAC funded med-tech accelerator located at the Centre for Innovation and Entrepreneurship, IIIT Hyderabad. Mahesh continues to be responsible for mentoring startups in the med-tech space, and helping them scale their products and solutions.

Mahesh brings a strong analytical mind-set, deep insights into healthcare development and a proven record of implementing innovative solutions in the healthcare domain.

Mahesh is passionate about enhancing industry academia collaboration; he set up one of the first part-time Ph.D. program in Statistics for Novartis associates, teaches at a number of Indian universities and has chaired multiple conferences over the years. He is Past-President of the Indian Association for Statistics in Clinical Trials and Past-President of the International Indian Statistical Association, India Chapter. He was recently featured in the Top-100 AI leaders in India.

Apart from his functional activities, Mahesh has led various organizational developmental activities and trainings. He is a certified coach in the areas of emotional intelligence, assessment centers, and psychometric evaluations. Mahesh has completed his Ph.D. in Statistics from Temple University, Philadelphia.

Dr Nilima Kshirsagar
President, South Asian College an Affiliate of ACCP (SAC-ACCP), National Chair in Clinical Pharmacology, ICMR

Positions held

Current: National Chair Clinical Pharmacology, ICMR, New Delhi, Member Drug Technology Advisory Board of Govt. of India, President, South Asian College, an Affiliate of American college of clinical Pharmacology, Member of WHO Committees on Medicine Safety, Product development, Drug statistics Methodology, Fellow of Royal College of Physicians, Faculty of Pharmaceutical Medicine UK and Fellow of American College of Clinical Pharmacology, USA, fellow of National Academy of Sciences, National Academy of Medical Sciences India.

Former: Acting Vice-Chancellor, Maharashtra State Health Science University, Director Medical Education, Dean at GS Medical and KEM Hospital, Mumbai, Dean, ESI-PGIMSR, MGM Hospital, Govt. of India, Mumbai President, Indian Pharmacology society and Infectious Disease society, India.

Awards: University topper, gold medalist, B.C. Roy National Award, Vasvik Award for industrial research developing and patenting liposomal drug delivery system, Mayor's award thrice, Glaxo oration of NAMS, S.B. Pande oration of IPS, P. K. Devi oration of Kasturba Trust, S. Sharma oration Neurology India, Silver jubilee oration AIIMS, B. N. Ghosh oration IPS, Gujarat Bhavgara oration, Anandibai Joshi oration University of Mumbai.

Publications: Over 200 publications including in Lancet, BJCP, Am. J. Trop. Med. Hyg., WHO publications on safety of Medicines in public Health, paediatrics.

Areas of expertise: Clinical trials, Drug development, Tropical diseases. Pharmacovigilance.

Dr Bikash Medhi
Professor Department of Pharmacology, PGIMER, Chandigarh.

Professor Department of Pharmacology, PGIMER, Chandigarh.
Editor-In-Chief, Indian Journal of Pharmacology
Editor-In-Chief, International Journal of Pharmaceutical Sciences and Nanotechnology (IJPSN) and PGIMER Drug Bulletin
Ex-Additional Medical Superintendent, Founder of Experimental Pharmacology and Neurobehavioral laboratory
Coordinator PGIMER Pharmacovigilance and Materiovigilance Centre
Regional Coordinator, NADA (North Zone), Ministry of Youth and Sports, Government of India.
Co-Convener India Initiate Programme, Lead GCP ,GLP,NABH,CPCSEA,NMC Assesers
Ex Secretary Clinical Pharmacology of Indian Pharmacology Society.
Awards:
Dr. D N Prasad memorial award with Gold medal (ICMR), New Delhi.
Dr. V K Bhargava Award with Gold medal (NAMS)
Dr. B N. Ghosh and Col. Ram Nath Chopra Oration from Indin Pharmacological Society (IPS), VAIDA AWARD 2023
Prof. Bikash Medhi has been dedicated in 2% scientist across the world conducted by Elsevier & Stanford University.
Nominated as member executive committee of IUPHAR for Global coverage IUPHAR activities in coordination with WHO (2023-2026)
Member of Codex Committee, USA,DSMB MEMBERS FOR SEVERAL MULTINATIONAL TRIALS
He has published 5 books and more than 500 research papers.

Dr. Ravi Shankar Singh,
Senior Director,
Clinical Pharmacology, Pfizer

Dr. Ravi Shankar Singh, PhD, is a Senior Director of Clinical Pharmacology at Pfizer. Currently, he leads development of various projects in inflammation and immunology and anti-infective including oral protease inhibitor for COVID-19. Before joining Pfizer, he worked at Abbvie, University of Florida, Central Drug Research Institute and Dr. Reddy's lab in India. His experience spans from discovery to late phase drug development across various organizations in various therapeutic areas including inflammation and immunology, anti-infective, oncology and HCV.

Dr. Singh received his M. Pharm from BITS Pilani, India and PhD in pharmacokinetics at the University of Saskatchewan, Canada. He has more than 35 publications in peer reviewed journals and has authored five book chapters. He has presented his research work in several international conferences and his work has received several awards.

Dr Srikanth C. Nallani,
Clinical Pharmacologist
Maryland, USA

Dr. Nallani has extensive knowledge pertaining to the clinical pharmacology of opioids, opioid antagonists, analgesics, anesthetics, and treatments for various substance use disorders; as well as the clinical pharmacology issues pertaining to pediatrics and maternal health, and drug-drug interactions.
Dr. Nallani received his doctoral, and post-doctoral training at the University of Cincinnati, College of Pharmacy and now works at the US FDA since 2003.

Dr. R.K. Shandil
Co-founder & CSO,
FNDR Bangalore

Dr. Shandil is PhD in immunology with twenty-five years of R & D experience in drug discovery of infectious diseases. He has a strong track record of scientific, project and organizational leadership skills. He did his postdoctoral training in Astra AB, a Swedish company. He is a infectious disease specialist has lead pharmacology of various TB and malaria programs at AstraZeneca R & D India that found way to clinical development. He is inventor of two TB drug candidates: AZD5847 that completed Phase2 A clinical trial and TBA 7371 that has just completed phase2A clinical trial in human TB patients in South Africa that was fully funded and developed by GATB and Gates Medical Research Institute (GMRI), USA.

Dr. Shandil and has significant interest in neglected tropical diseases relevant to developing world. He co-founded Foundation for Neglected Disease Research (FNDR) in 2014 in Bangalore and is currently, Director and Chief Scientific Officer of this small but vibrant R&D group of 30 scientists engaged in drug discovery. He manages infectious disease programs and drug discovery portfolio across bacterial, viral and fungal therapeutics at FNDR and with several national and international collaborators. He has ~50 publications and 10 patents to his credit. Shandil and his team has generated
funding worth ~5 Mn USD in last 10 years. He is scientific advisor and consultant to many
discovery and pharma companies and visiting Prof. to University of Transdisciplinary Sciences and Technology, India.

Dr. Vinay Saini
Managing Director, Ostic Pharma Pvt Ltd
Founding Director, TUMAAS (Foundation for TB, Malnutrition & AIDS)
Senior Scientist (OS), BSBE, IIT Mumbai

Positions:
Managing Director, Ostic Pharma Pvt Ltd (Startup), SINE, IIT Bombay, Powai
www.osticpharma.com
Founding Director, TUMAAS (Foundation for TB, Malnutrition & AIDS, Mumbai)
www.tumaasfoundation.ngo
Senior Scientist (OS), BSBE, IIT Bombay, Powai, Mumbai
Contact- drvinays14@gmail.com/ info.ostic@gmail.com
Mobile - +91-9987253095/ 8657104859
Research Interest: In Vitro Diagnostics – Rapid, ELISA and Molecular
Rapid TB Diagnostics, Covid-19 diagnostics, CRISPR Based Diagnostics, Real Time Screening and Monitoring of Child Malnutrition, AI tools for screening of Covid-19 and TB
Marketed Products – Rapid Covid Test, Malaria, Dengue, Pregnancy, Hepatitis B, Hepatitis C and HIV, Syphilis
Products in Pipeline- Rapid TB Diagnostics, Neglected Tropical Diseases, Sickle Cell of Anemia, Rapid Test Kit for Paragonimiasis, Device for Screening of Soil transmitted Helminth infections in Children and Animals, Rapid Molecular Diagnostics - Multiplex detection
Funding Received for Startup
 Nidhi 4 Covid Grant (DST)- 35 Lacks Grants cum loan (2021) – Paper based Molecular Test for Covid-19
 Rapid Covid-19 Tests (DST-CAWACH)- 75 Lacs Grants + 75 Lacs cum Loan (2020)- Rapid Covid Diagnostics (Rapid Covid antigen and antibody tests)
 CRISPR Based Covid-19 Tests (Indo US- IUSSTF- 25 Lacs each) (2020)- Covid Ignition grant - University of Florida, USA
 Rapid TB Tests (DST SEED Grant) (2019)- 20 Lacs
 DST- Nidhi Prayas- 2.55 Lacs for Prototype Development (2019) -2.55 Lacs
 Project investigator (Co-I) with Brazil for grant under BRICS countries (May, 2020- 2.0 Cr)

Grant Recipient as Investigator - IIT Bombay:
1. On TB Therapeutics: (2.0 Crore: March, 2017- Dec, 2020): India Health Fund (TATA TRUST): as a - Development of Aerosol formulations for MDR TB.
2. On TB Diagnostics: (2.30 Crore: March, 2017- March, 2022): IMPRINT INDIA (MHRD & MHFW), as a co-PI- Rapid TB Tests in urine, blood and sputum with European Company, Germany
3. Centre of Excellence in Child Malnutrition under DBT Twinning program between North East States and IIT Bombay (4.88 Cr) (2021 -2022)- co-PI

Social Innovation Projects:
Completed project on Generation of real time data of children (No. 800) malnutrition (0-6 years- WHO Anthropometric Parameters) using smart scale (ICDS & district administration, Jhansi, Uttar Pradesh, India)
Awards:
1. Startup Award - STARTUP Award in International Conference (UKICINDIA) on Coronavirus - Past, Present and Future | 10-11 May 2022 (ICCoVs-India-22) held at Srinagar, Kashmir.
2. SARTHI Award - Selected as one of the top 10 winners under Dialogue on Role of Innovations in Disaster Risk Reduction (DRR) (“Building Resilience in the New Normal”) and
(the Bill and Melinda Gates Foundation, FICCI and ADPC, Bali, Indonesia on May 27, 2022)
3. Aarohan Social Innovation Award (Infosys Foundation – 20 Lacs)- Gold Award for TUMAAS foundation (2020) – By Honble Smt. Sudha Murthy and Shri Nandan Nilekani

Dr. Ashish Sharma
Site Head of Clinical Pharmacology, Boehringer Ingelheim, USA.

Ashish Sharma is the Site Head of Clinical Pharmacology at Boehringer Ingelheim, USA. He is a pharmacist by training (Hamdard University, India) and obtained a Masters in Pharmaceutics at the Memorial University, Canada and a PhD in Clinical Pharmacology at the Laval University in Quebec, Canada in 2003. He has worked in the field of Clinical Pharmacology for almost 20 years of which 18 years were at Boehringer Ingelheim in different roles and locations. He worked as a clinical pharmacologist in Canada – 2 years, Germany – 12 years and USA - 6 years. He is actively involved in the various activities of the IQ organ impairment group and is a member of the IQ Clinical Pharmacology Leadership Group.

Dr Michael J. Fossler
Executive Consultant and Vice-President, Strategic Consulting Cyte

Michael J. Fossler is Executive Consultant and Vice-President, Strategic Consulting at Cytel. He received the Pharm. D. (1992) and Ph. D. (1995) degrees from the University of Maryland. From 1995 to 2000, Dr. Fossler was employed by the FDA as a clinical pharmacology reviewer in the Division of Metabolic and Endocrine Drug Products.

In 1998, he was promoted to Senior Reviewer, and joined the Pharmacometrics group at FDA, where he was responsible for reviewing and performing population PK/PD analyses. He left the Agency in 2000 and joined the Clinical Pharmacokinetics Group at DuPont Pharmaceuticals, where he had major responsibility for PK/PD analyses in the cardiovascular and anti-inflammatory areas. In November, 2001, he joined GlaxoSmithKline, where he continued to work in the cardiovascular area, and eventually headed a group of nine pharmacometrics scientists. He left GSK in 2015 to join Trevena, Inc., a late-stage small biotech company, where he led clinical pharmacology, clinical development, biostatistics, programming and data management.

He assumed his present role at Cytel in April 2022, where he provides strategic consulting services in the areas of clinical pharmacology, and pharmacometrics.

Dr. Fossler is a Fellow of the American Foundation for Pharmaceutical Education, a Fellow of the American College of Clinical Pharmacology, a past President of the College and is an Honorary Regent and Councilor to the current President. He holds an adjunct faculty appointment at the University of North Texas where he teaches in the school's Pharmacometrics program and is on the faculty of the University of California's American Course on Drug Development and Regulatory Science.

Dr Rama Sivasubramanium
Director
Clinical Development, Novartis
Hyderabad India

Rama Sivasubramanian is a currently Clinical Development Director in Clinical Development at Novartis Healthcare Pvt. Ltd. Hyderabad with over 17 years of experience in drug development. She is currently the clinical lead for a clinical study with a complement inhibitor for rare kidney disease and has led the pediatric strategy for this asset. She has contributed to pediatric hypertension and heart failure programs and submissions to the EMA and FDA. Her experience spans all phases of clinical studies as well as Life-cycle management of mature brands.
She started her career as a Lecturer and moved to the Industry post her PhD and worked at Nektar Therapeutics in the Bioanalytical and Pharmacokinetics division. She joined Novartis in 2008 as a Research Scientist and led the Global Pharmacokinetics / Pharmacodynamics team. Since 2015, she has been in clinical development. Rama received her B.Pharm and M.Pharm degrees from Department of Pharmaceutical Sciences, Nagpur University, India and holds a PhD in Pharmacokinetics and Drug Metabolism from the University of Pittsburgh, Pittsburgh, USA.
Her areas of specialization are PK-PD modeling, clinical Drug-Drug Interaction (DDI) studies and pediatric drug development. She is a member of South Asian College of American College of Clinical Pharmacology (SAC-ACCP) and an organizing committee member of the Society for Study of Xenobiotics-India (SSX-I). She has been an invited speaker to several conferences in India and has presented at the European Society for Developmental Perinatal and Paediatric Pharmacology (ESDPPP) in Basel, Switzerland in 2019, International Pediatric Nephrology Association conference in Calgary, Canada in September 2022 and the World Congress of Nephrology, Thailand, March –April 2023.

Dr Sanish Davis
R&D Director,
Janssen (J&J) Pharmaceuticals, India

Dr Sanish Davis is a R&D Director, Janssen (J&J) Pharmaceuticals, India
President, Indian Society for Clinical Research (ISCR), the nodal stakeholder organization for CR in India
Clinical Pharmacologist (DM) by training and Fellow of ACCP, USA
~ 20 years of experience in Pharmaceutical Industry (Clinical Development, Clinical Pharmacology, Medical Affairs, New Product Development Strategy & Planning in both India and Emerging Markets)
Passion – CR Educational Philanthropy, operationalizing Ethics in the context of Clinical Trials; Clinical Development for Rare Diseases

Dr.Brian Tseng
Chief Scientific Officer
The Polymerase Gamma (POLG) Foundation

As a board-certified MD/PhD pediatric neurologist/neuromuscular physician-neuroscientist, Brian Tseng is currently the Chief Scientific Officer for The Polymerase Gamma (POLG) Foundation, a non-profit rare mitochondrial disease research advocacy organization. In previous roles, he has led large global cross-functional teams (Novartis, Avexis, Vertex) to develop and bring forward new medicines for infants and children including rare genetic disorders. As a retired Vice-President from two top R&D companies, Brian has deep experience in translational, operational and clinical development of novel molecules (small, biologics, cell-based, AAV genetic replacement, and CRISPR-mediated gene editing) for children. He is also currently an expert consultant with NDA Partners, LLC. His most recent clinical/academic practice has been at Massachusetts General Hospital – Harvard Medical School and previously Colorado Children's Hospital.

His Physiology undergrad degree is from UC Berkeley and he has a MD/PhD in molecular biology from MD Anderson Cancer Center – Univ of Texas at Houston McGovern Medical School.

Dr. Tseng serves as teaching faculty in several medical schools including previously with the Gates Foundation at The Univ of Sienna and volunteers on several Boards of non-profit rare Patient Advocacy and Patient Foundations. Additionally, he is Vice-President of the Board of Directors for the Estes Valley Fire Protection District in Colorado. He is also a trained NOLS Wilderness Medicine Provider and serves as a volunteer Parkmedic with the Dept of Interior Rocky Mountain National Park - Search and Rescue division.

Dr.Saurendra Das

Dr Saurendra Das Have over 32 years of experience in clinical practice, teaching, clinical research, digital health and health innovation. Extensive experience in managing clinical
research projects of new drugs, vaccines and biologicals. Worked on designing apps for managing research projects, innovative drug device combinations and diagnostics, digital health tools, and other healthcare products.

- A seasoned start-up specialist, has set up 8 major healthcare and research organizations across India.
- Trained by Harvard Medical International, USA. Successfully trained around 20,000 investigators, physicians, dentists, ethics committee members, CRC's & CRAs' lab and pharmacy personnel on research. Wet lab trainer for SCS route of administration for ophthalmologists across India, Taiwan, Korea, Thailand, Malaysia and Australia.
- Been actively involved in clinical research conceptualization, bids and proposals, design, set up, logistics, coordination to close out and publication.
- Managed the 4 sites which became the first clinical trial sites in India to be inspected by US FDA and of another 4 sites inspected by EMA.
- And loves to click pictures – wildlife, birds, & nature, sports, astronomy

Dr. Jignesh Patel
Chief Scientific Officer,
ClinNext Core Lab & CRO
Professor, PhD Guide & Head,
Clinical Research
Parul University Baroda

Dr. Jignesh Patel is pharmaceutical and clinical research scientist with more than 20 years of experience in pharmaceutical and medical device clinical research.

• He has done bachelor & master in pharmacy from L. M. College of Pharmacy, India, and PhD in Pharmacology in 2006 involving application of Artificial Intelligence (AI) in Pharma and Medical Field. He had published >40 scientific papers in various scientific journals. He has received many national and international awards for his research work and scientific publications.

• He had worked with Sun Pharma's Global R & D Centre, Vadodara, India for 10 years as "In-charge of Phase 1 clinical trial unit". Dr. Jignesh is pioneer of setting up phase 1 clinical trial unit of Sun Pharma and Phase 1 clinical trial unit & Pharmacodynamics Labs of CBCC Global Research, at India & USA.

• During his early career, he has worked for clinical trials of Sanofi, GSK, Pfizer, BMS, Boehringer Ingelheim, J & J, Medtronic, AstraZeneca, Novartis etc. for various CROs like Quintiles, Covance, ICON, PPD etc. and have handled EU and UK sites.

• He has directly led the clinical development of more than 10 NCEs-based INDs, more than 14 NDDS, 37 medical devices, 3 Biosimilars, 2 Biologics, 2 vaccines & more than 140 generic products for USFDA, EMA, MHRA, ANVISA, CDSCO, Malaysia and many other regulated markets.

Mr Nirnith Devireddy
CEO & Founder , InSilicoMinds
San Diego | Hyderabad

The Founder and CEO of InSilicoMinds (Ikimind Pvt Ltd.), a company focused on providing AI, Modeling, & Simulation solutions for Pharma & Life Sciences. Nirnith is a seasoned tech entrepreneur with over a decade of entrprenurial experience. He also Co-founded Anipanion, the world's leading veterinary virtual care platform.He has completed his Executive Education at Harvard Medical School in Implementing AI Solutions in Healthcare & has a BBA from Babson College with a concentration in Technology, Entrepreneurship & Design.

Dr Gangadhar Sunkara
Novartis Pharmaceuticals, USA.

Dr Gangadhar Sunkara works as the Global Program Head in Global Health Development Unit supporting Transplant and Neglected Tropical Disease Established Product Programs at Novartis pharmaceuticals, USA. Dr Sunkara Ganga obtained B.Pharm degreed followed by Master's degree in Pharmaceutics/pharmacokinetics from Kakatiya University, India. He holds a PhD in Pharmaceutical sciences from the University of Nebraska Medical Center, USA. He also has an MBA degree from Fairleigh-Dickinson University, USA. Ganga has authored/coauthored more than 70 research publications.

Dr Kiran Marthak
Veeda C R Ltd.

At present Member of the Board of Director in Veeda C R Ltd. Fellow of American College of Clinical Pharmacology. Into Clinical Research for nearly 40 years. Have conducted clinical Trials- from Phase-1 to Phase-4 in MNCs and in CROs. Co-chairman of Medical Committee in IDMA Chairman of Inter System Biomedical Ethics Committee Invited to deliver talks on International and National Conferences. Invited Faculty in various universities.

Dr. Jagannath Kota
Novartis India

Dr. Jagannath Kota is the site head for Novartis Institutes for BioMedical Research in India; heading a group of 21 scientists, with experts in clinical pharmacology, toxicology, modelling & simulation and analytical sciences. Jagannath received his PhD in pharmaceutical sciences from Victoria College of Pharmacy, Monash University, Australia. Prior to PhD he worked in Dr Reddy's Laboratories in the drug discovery division for three years.

Dr. Jagannath is very passionate about sharing knowledge and experience and has done this at various academic institutions including Kakatiya University, Warangal; National Institute for Pharmaceutical Education and Research (NIPER); and also at various national pharmaceutical conferences.

Dr. Anant Ketkar
‘Scientific Lead – India’. Simulations Plus, inc.

Anant Ketkar is working with Simulations Plus, inc., as a Principal Scientist in the role of‘Scientific Lead – India’. He is involved in the application of PBPK/PBBM modelling and simulation to meet the objectives of various client projects. He also provides scientific input both in terms of software applications and project proposals to the Indian distributor to support their marketing and sales efforts.

In partnership with Indian distributor, Electrolab, he supports Simulations Plus’s many customers in India and serves as a thought leader to increase awareness and adoption of PBBM/PBPK modelling throughout the country. He delivers modelling and simulation projects to address client objectives and inform regulatory interactions.

Anant earned his doctorate in Pharmaceutical Sciences from Poona College of Pharmacy (Bharati Vidyapeeth Deemed University), Pune, India. He carries 20+ years of experience in formulation research, including 8+ years of experience in PBPK/PBBM modelling and biorelevant dissolution method development for modified complex generics and enabled formulations for poorly soluble NCEs.

Prior to joining Simulations Plus, Anant was Head of Technical Services at IQGEN-X Pharma, where he led a team of formulation team leaders and scientists for development of solid and liquid orals, and injectables for the global market. Prior to that he worked in positions of increasing seniority with pharmaceutical research companies, including Bioved Pharmaceuticals Inc., Ranbaxy (now Sun Pharma), Pfizer Animal Health (now Zoetis), Sandoz and Sun Pharma Advanced Research Company (SPARC). He has also served as a PBPK/PBBM modelling consultant for one of the leading Indian multinational pharma companies and worked as a freelance PBPK modeller for Indian generic pharma client on US-FDA submission of a PBPK modelling project.

Dr Vijay Ivaturi

A clinical pharmacologist and pharmacometrician by training, Vijay has led project Pumas from the front and the beginning, nurturing the idea for a game-changing modeling and simulation platform since 2017. His primary research interest is in developing tools and methods to bridge the gap between decision-makers and scientists, with a special focus on clinical therapeutics in pediatrics.

After completing his doctorate in Experimental and Clinical Pharmacology from the University of Minnesota, Vijay went on to pursue a post-doctoral fellowship in Pharmacometrics at Uppsala University in Sweden. He has more than 12 years of experience with pharmacometrics modeling and simulation and has worked at the US FDA as an ORISE research scholar on pharmacometrics projects. Further, he is also a graduate faculty at the University of Maryland Baltimore School of Pharmacy since 2012.

Dedicated to advancing the discipline of pharmacometrics, Vijay is the President-Elect of the International Society of Pharmacometrics (ISoP) and will serve a two-year term upon assuming Presidency in 2024.

Dr. Taruna Madan, M.Pharm. PhD
Scientist G and Head,
Development Research,
Indian Council of Medical Research,
New Delhi.

With a PhD in Pharmacy from CSIR-IGIB and College of Pharmacy, University of Delhi (now DIPSAR, DPSR University), Dr. Madan did her post-doctoral training with Professor KBM Reid, MRC Immunochemistry Unit, University of Oxford, UK; and Dr. Raina Fichorova, Brigham and Women's Hospital, Harvard Medical School, USA.

She is President, Indian Immunology Society, a recipient of 2022- ISSRF-Mridula Kamboj Oration, 2018-IUSSTF-WISTEMM-Senior Scientist Fellowship Award; 2016-ACBI-Mrs. and Dr. G. P. Talwar Oration Award; 2003-CSIR Young Scientist and 1998-INSA Young Scientist Medal.

Her group has over 100 peer-reviewed publications, 8 granted patents, 1 multi-institution validated product and an ICMR policy brief at the intersection of immuno-regulatory, pattern recognition proteins (PRRs) and human health with a focus on host-defense, cancer and reproductive disorders.

Dr Nirmala N Rege
Professor in Pharmacology
Era's Lucknow Medical College.

Dr. Nirmala N. Rege is a visiting faculty (Professor in Pharmacology) at Era's Lucknow Medical College. She completed her graduation and MD in Pharmacology from the Seth GS Medical College & KEM Hospital and secured DNB in Clinical Pharmacology. Subsequently she was awarded PhD from University of Mumbai. She served her alma mater as faculty in Pharmacology department and superannuated as Professor and Head of Department of Pharmacology and Therapeutics. She has been continued her association with the same department as Professor Emeritus since December 2018. She is a member of Expert group instituted by National Medical Commission's UG Medical Education Board. She is a senior advisor and past President, South Asian College an affiliate of the American College of Clinical Pharmacology (SAC- ACCP) and Executive Committee Member and past-President of Academy of Health Professions Educators. She is also a member of task force for the online prescribing skills course developed by ICMR to enhance Prescribing Skills of an Indian Medical Graduate.

She was a recognised University teacher for MD and PhD (Pharmacology), and MSc and PhD (Applied Biology). She has been a principal investigator for projects sponsored by Dept. of AYUSH; NMITLI, CSIR; DST and ICMR and co-investigator for projects by Dept. of Biotechnology and ICMR. She is a recipient of more than 40 awards for her research in the field of pharmacology and Ayurveda. She has to her credit 120 research papers on experimental & clinical pharmacology as well as Ayurveda and medicinal plants in National & International journals and 2 textbooks viz. Satoskar-Bhandarkar's 'Pharmacology and Pharmacotherapeutics' and 'Practical Pharmacology for Medical Students'. She is also a co-editor of 13 books & manuals on research methodologies, medical education and Ayurveda including 'The Art of Teaching Medical Students' and 'SLOs in Pharmacology'.

Dr Rege was a coordinator of Medical Education Unit of KEM hospital, Convenor of MCI Regional Centre for Faculty Development and Co-director of Regional institute of Foundation of Advances in Medical Education and Research (FAIMER), USA. She has contributed to designing of undergraduate and postgraduate pharmacology curricula, participated in research in medical education and is instrumental in organizing the national level workshop for postgraduates of pharmacology-PHARMATECH.

Dr Mira Desai
Professor & Head of pharmacology
M K Shah Medical College Ahmedabad

Clinical Pharmacologist with 34 years of experience in Medical Education, Drug Safety
Monitoring, Clinical Research, Research Ethics & Medical Writing. Scientific publications: 78, Google Scholar citations: 980, h-index:19, i10-index:26 Member of Signal Review Panel & National Faculty for Skill development programme, Pharmacovigilance Programme Of India, IPC, MOHFW. Member, Multi Technical Group Committee, WHO for technical expertise of Pharmacology and Pharmacovigilance Chairperson, Expert data review committee for pragmatic clinical trials on DRTB by ICMR
Member of the Course Advisory Group and Resource person for course on 'Rational use of medical products' by WHO, India
Chairperson & member of DSMB & Safety adjudication committee of phase I, II Clinical trials of drugs and vaccines
CDSCO appointed GCP expert for inspection of clinical research facility, Clinical trial sites & Ethics Committees
Member, Expert Committee to assess FDCs de novo by CDSCO
Core committee member of formulating Essential Medicines List and Standard Treatment Guidelines for Gujarat State. Prepared first edition of STG for Gujarat State.
Received CDRI oration award for outstanding contribution in scientific research, publications and academics by Indian Pharmacological Society,2017
Awarded Certificate Of Appreciation for outstanding contribution to PvPI by Scientific Director, IPC, MOHFW, 2023

Dr. Mihir Gharia
Tatvacare.

With over a decade of expertise in the pharmaceutical industry and a recent pivot into the dynamic world of Healthtech, Dr. Mihir Gharia stands out as a visionary in the intersection of healthcare and technology. Currently leading as the Lead Medical Services & Content at Tatvacare, Dr. Gharia has been instrumental in bridging traditional pharmaceutical practices with innovative digital solutions since early 2020.

Dr. Gharia's pharmaceutical journey is marked by significant accomplishments and novel Projects across various roles. His tenure in the industry is spanning across Specialty divisions creating Fragility fracture treatment algorithms at MSD Pharma, enabling Medico-Regulatory function at BI Pharma for the CHC division and during his tenure at Zydus Lifesciences in the vaccines and immunology therapeutic area by launching Indians Quadrivalent Flu-vaccine, setting up and conducting the world's first adalimumab biosimilar patient registry and conducting RWE studies on novel UV-B filter cream for Psoriasis and Vitiligo.

Transitioning his focus to HealthTech, Dr. Gharia now heads the clinical development initiatives for Digital therapeutics and EMR Platforms. His work is paving the way for integrating AI and digital tools in healthcare, transforming how RWE and Remote Patient Monitoring Studies (RPMS) are delivered and experienced.

A prolific academic contributor, Dr. Gharia has over 25 publications on across Ortho, Vaccines and Immunology and his role as a Reviewer for Springer and Bentham further showcases his strides in the field of Medical Science.

Dr. Vivek Ahuja
Senior Vice President Eversana

Dr. Vivek Ahuja . a seasoned professional in the pharmaceutical industry, pioneered the introduction of pharmacovigilance as a subject and science in India in the year 2003. With his vision he established the country's first global pharmacovigilance unit in Ranbaxy and scaled up several such organizations in this field. He has more than twenty-two years of experience spanning over diverse areas like pharmacovigilance, clinical research, public health and technology. With experience in working in worldwide pharmacovigilance regulations related to drugs, vaccines and devices and having worked closely with several global regulatory authorities on technology related aspects, Vivek brings hands on experience and insights in these areas. He currently works for Eversana as Senior Vice President for Delivery excellence, strategy and growth for the pharmacovigilance, regulatory and quality businesses.

Prior to joining Eversana, Dr. Vivek Ahuja was Vice President – Medical Affairs & Global Head of Pharmacovigilance at SunPharma. His responsibilities include managing the Global Pharmacovigilance function with teams from US, EU, Japan, South Africa and India supporting him to maintain compliance to global regulations. Prior to this, he worked at a global technology company i.e. ArisGlobal, where he was Vice President for Global Pharmacovigilance and headed the safety business unit. His responsibilities included strategy, operations, managing the profit and loss of this software technology business. Prior to joining ArisGlobal, Vivek worked as Director, Research and Development at PATH. He was overseeing PATH's work of driving transformative global health innovation to save and improve lives, through multiple projects involving public health and vaccine safety. PATH is a Seattle based international nonprofit organization working to accelerate health equity and also the world's largest public health partner to the Bill & Melinda Gates foundation. Dr. Ahuja is a MBBS from Government Medical College, Chandigarh, India and MD from All India Institute of Medical Sciences, New Delhi. He is also an Executive MBA (Post Graduate Diploma in Business Management) from one of the leading Business Schools in India (Management Development Institute, Gurgaon). Vivek actively contributes to policy making for the government. In particular, he co- authored the Pharmacovigilance Program of India (Government of India) in 2010 and supported the Nepal and Bangladesh governments by conceptualizing focused pharmacovigilance programs for neglected drugs. In China, he helped establish the vaccine safety systems of the largest government vaccine manufacturer. He has avid interest in technology and its applications particularly cognitive computing.

Col (Dr) Prafull Mohan
Clinical Pharmacologist
Armed Forces Medical Services

MBBS and MD (Pharmacology) (2006): AFMC Pune
DM (Clinical Pharmacology) (2015): AIIMS New Delhi
Teaching exp: 12 years (AFMC Pune and ACMS New Delhi)
Currently: Incharge of Combat medical Care infra in eastern sector
Visiting Faculty at AIIMS Guwahati
Area of Interest – Illustrative biostatistics, Data management, Clinical Pharmacokinetics, Wilderness medicine, Pharmacoeconomics
Number of Publications - 35
Fellowships/Additional Qualification- Advance Course in Medical Education, Advance Certificate Course in AI and Medical Imaging: Pursuing
Memberships – NAMS, Indian Pharmacological Society, APPI
Other- Modern Indian history and Indian music

Dr Manoj P Jadhav

Dr. Jadhav is responsible for strategic, scientific planning and business functions for the organization.Dr. Jadhav brings more than 15 years of experience in academic and industry research, pharmaceutical drug development and regulatory affairs experience in the US, India with small molecules and peptides therapeutics.

Before starting ISHA Therapeutics, he served as the Vice President clinical development and business strategy at CRC Pharma based in Parsippany, New Jersey. He has contributed to several drug development programs for both NCEs and 505(b) (2) across different therapeutics areas. At ISHA Therapeutics, he is leading a robust pipeline of novel repurposed drug developed program for lifestyle and infectious diseases.

He is a trained clinical pharmacologist with extensive experience in planning, designing, execution and interpretation of clinical studies (prospective, retrospective, interventional and observational) in the area of infectious diseases, cancer, cardiovascular diseases. He was part of successful team which developed first Indian liposomal amphotericin B (Fungisome TM) which is launched in Indian market.

Dr. Jadhav has represented the Sponsors at the US-FDA for several formal meetings e.g., pre-IND meetings, at the Division of Anti-infective, Cardiovascular and Renal products, CNS, Dermatology, Pharmaceutical Quality, Oncology etc.

Dr. Jadhav has over twenty-five peer-reviewed publications, co-edited a book, have made numerous posters and oral presentations internationally.

Dr. Jadhav received his PhD in Pharmaceutics from Bombay College of Pharmacy and KEM Hospital at the University of Mumbai, India and did his Post-Doctoral Fellowship at the Colleges of Pharmacy and Medicine Univ. of Florida, Gainesville, Florida. He did his M. Pharmacy from DIPSAR, New Delhi (gold medalist).

List of Awards for Oral and Poster Presentations

1. Dr. U. K. Sheth award as first prize for Clinical Oral presentations.
2. Dr. Ashok Vaidya award as second prize for Clinical Oral presentations.
3. Dr. S. M. Karandikar award as third prize for Clinical Oral presentations.
4. Dr. G. B. Parulkar award as first prize for Clinical Poster presentations.
5. Dr. A. S. Nanivadekar award as second prize for Clinical Poster presentations.
6. Dr. R. D. Kulkarni award as third prize for Clinical Poster presentations.
7. Dr. K. G. Nair award as first prize for Pre-clinical Poster presentations.
8. Dr. R.S. Satoskar award as second prize for Pre-clinical Poster presentations.
9. Dr. B. K. Bacchawat award as third prize for Pre-clinical Poster presentations.
10. Dr. Arun Sanghani award as first prize in Pre-clinical Oral presentations.
11. Pre-clinical Studies Oral presentations (Category-1)- Second prize.
12. Pre-clinical Studies Oral presentations (Category-1)- Third prize.
13. Dr. A. D. Joseph award for Best All-round Presenter.
14. Dr. Sonal Vora award for Best All-round Woman Presenter.
15. Young Researcher Award -- Dr. Hartmut Derendorf Memorial Award

Oral Presentations: Clinical

Abstract No.	Presenting Author	Mode of Presentation	Title of abstract
CO-01	Sai Prasad	Oral	Naloxone Dose Recommendation for Opioid Overdose treatment: Modeling and Simulation Approach
CO-02	Ritu Modi	Oral	Assessment of Attitude, Knowledge, and Practice of Cosmetovigilance Among Dermatologists Of Gujarat.
CO-03	Damini H Prajapati	Oral	An Evaluation of Prescribing Pattern of Antimicrobial Drugs According to the WHO Aware Classification at A Tertiary Care Teaching Hospital.
CO-04	Shashank N Asara	Oral	An Analysis of Adverse Events Due to Intravenous Catheter at A Tertiary Care Teaching Hospital
CO-05	Madhuri Doke	Oral	Evaluation of Prescription Pattern of Drugs and Drug Awareness and Adherence to Treatment in Post Myocardial Infarction Patients.
CO-06	Ajay Gattani	Oral	Evaluation of Patient Awareness, Prescription Pattern and Adverse Drug Reactions Profile Of Secondary Prophylactic Drug Treatment in Stroke Patients Visiting A Tertiary Care Hospital
CO-07	Radhika Bindu	Oral	A Comparitive Study of Correlation of Random Blood Glucose with Glycated Haemoglobin Using Roc – A Single Centre Study
CO-08	Mir Mansoor Sultan	Oral	Integration of Artificial Intelligence in Clinical Pharmacology: Current Status and Future Prospects
CO-09	Farheen Sultan	Oral	A Cross Sectional Study to Assess Knowledge, Attitude and Practice towards E- Learning among Medical Undergraduates in Tertiary Care Teaching Hospital in Telangana
CO-10	Nageshwar Swamy	Oral	A comparative Study of Efficacy of Oral Contraceptive Containing Ethinyl estradiol Combined with Drospirenone Versus Desogestrel on Clinical and Metabolic Parameters in Patients with Polycystic Ovarian Syndrome at Tertiary Care Hospital Telangana
CO-11	Sharika Pillay	Oral	Evaluation of Awareness to Drug Treatment, Prescription Pattern and Adverse Drug Reactions in Patients with Psoriasis
CO-12	Simran Khatri	Oral	A Cross Sectional Observational Study to Evaluate Awareness of Patients to Drug Treatment and Adherence to Statin and Antiplatelet Therapy in Patients Suffering from Cardiovascular Diseases
CO-13	Ruby R	Oral	Utility and Feasibility of Antibiotic Disposal Boxes at a Tertiary Care Hospital in Telangana
CO-14	Mudra Patel	Oral	To Assess the Prescription of Antiretroviral Agents and Study of Adverse Drug Reactions Profile in Patients Attending ART Centre in A Tertiary Care Hospital
CO-15	Mohd Moosa Quadri	Oral	Knowledge, Attitude and Practices Study on Antimicrobial use and Resistance among Indian Medical Graduates in A Tertiary Care Centre.

CO-01

Naloxone Dose Recommendation for Opioid Overdose Treatment: Modeling and Simulation Approach

Sai Prasad Boddu, Hindu Kalluru
Pfizer Healthcare India Pvt. Ltd., Chennai
SaiPrasad.Boddu@pfizer.com

Aim:

Naloxone, essentially a pure opioid antagonist is the recommended treatment for acute opioid toxicity. To treat highly potent, fast-acting synthetic opioid overdose (fentanyl, carfentanil, etc.), there is a need to evaluate the required high dose from the currently available naloxone products.

Objectives:

Develop a population pharmacokinetic model for Naloxone to estimate pharmacokinetic parameters and perform simulations and understand the best route of administration and dose of naloxone for treatment of acute opioid toxicity.

Methods:

The POP PK model was developed based on the data from a relative bioavailability study performed to compare a single naloxone HCl 5 mg autoinjector IM injection with a single naloxone HCl 2 mg (1 mg/mL) IM injection (1 mg in each gluteus maximus) and a single bolus of naloxone HCl 2 mg (1 mg/mL) IV injection in healthy adult participants. POP PK analysis was undertaken using NONMEM 7.5.0 with FOCE interaction method. The final model was used to perform simulations using Mrgsolve package.

Results:

The results indicate that the PK of naloxone was adequately characterized by a two-compartment model with first-order absorption. Inter-individual variability in various PK parameters was modeled using a multiplicative exponential function. Residual variability was modeled using a proportional error model. Simulations of 1000 individuals for a range of IV, IM, and IN doses of naloxone are performed.

Conclusion:

Pfizer proposed Naloxone IM Autoinjector (QuickShot™) showed better concentration profile for longer periods and it can be safely, readily, and rapidly administered and can readily reach higher concentration (<1 min).

CO-02

Assessment of attitude, knowledge, and practice of cosmetovigilance among dermatologists of Gujarat.

Dr. Ritu Modi, Dr. Gurusharan H. Dumra

Narendra Modi Medical College, Ahmedabad – 380008, Gujarat

ritumodi98@gmail.com

Aim & Objectives:

To assess attitude, knowledge, and practice of cosmetovigilance among dermatologists of Gujarat by using a questionnaire.

Methodology:

A Cross-sectional, observational, questionnaire-based study was conducted among dermatologists of Gujarat. The questionnaire was validated (CV ratio = 0.98) and copyrighted (L-134516/2023) by the Copyright Office of India. The questionnaire contained 17 questions and a score was given for each question. The questionnaire was distributed manually or through a digital web link and responses were collected. Analysis of data was carried out using SPSS 20.0 software.

Results:

A total of 117 dermatologists responded amongst these 49 (41.9%) were resident doctors, 24 (20.5%) were faculty in teaching institutes, and 44 (37.6%) were private practitioners. A significant difference ($p < 0.05$) was seen in the knowledge and practice domain among them. According to years of experience, a significant difference ($p<0.05$) was seen in the knowledge and practice domain. Although 71.8% of dermatologists had patients who experienced cosmetic-induced adverse events, only 27.3% had reported it. But, 96.6 % agreed that reporting of cosmetic-induced adverse events is necessary.

Conclusion:

This study showed a positive attitude and adequate knowledge towards cosmetovigilance but a lack of practice in adverse event reporting was seen among dermatologists.

CO-03

An Evaluation of Prescribing Pattern of Antimicrobial Drugs According to the Who Aware Classification at A Tertiary Care Teaching Hospital

Dr Damini H Prajapati, Dr Megha H Shah, Dr. Hemlata Ninama, Dr Chetna K Desai
Department of pharmacology B.J Medical college, Ahmedabad
daminiprajapati511@gmail.com

Aim & Objectives:
In India, 297,000 deaths were attributable to antimicrobial resistance (AMR) in the year 2019.The WHO has classified antibiotics into Access, Watch, and Reserve (AWaRe) categories to monitor antimicrobial consumption. We aimed to evaluate the prescribing pattern of antibiotics using the AWaRe classification.

Materials and Methods:
This was prospective, observational, single centre study in a tertiary care hospital. Patients admitted to Medicine and Surgery wards and prescribed antibiotics were enrolled based on inclusion criteria. The prescribing pattern of antibiotics was evaluated using the WHO AWaRe classification on 2nd and 7th day of starting antibiotics. Selected indicators (hospital and prescribing) for antimicrobial use in hospitals were also analysed.

Results:
A total 307 patients enrolled. The most common age group of patients was 19-44years (51.46%). The average number of antibiotics prescribed per patient was 1.58 and 1.52 during 2nd and 7th day of starting antibiotics respectively. The Watch category of antibiotics was prescribed in a high number, among these Ceftriaxone was the most commonly prescribed antibiotic (26.18%). 29.48% & 30.70% of prescribed antibiotics belonged to Access, 60.62% &57.36% to Watch 1.24%&1.49% to Reserve and 8.66% &10.45% to Not recommended categories respectively on 2nd and 7th day. The Access to Watch ratio was 0.5, which is below the WHO recommended ratio of 1.5. Total 80.41% antibiotics were prescribed under generic names. Total 98.97 % prescribed antibiotics from the state EML.

Conclusion:
Prescription of Access group antibiotics need to be increased to reach the WHO goal of 60% prescribed antibiotics should be from Access group. The balance among the different categories, as recommended by the WHO, need to be maintained.

CO-04

An Analysis of Adverse Events Due to Intravenous Catheter at A Tertiary Care Teaching Hospital

Dr Shashank N Asara, Dr Prakruti P Patel, Dr Chetna K Desai
Department of Pharmacology, B.J Medical College, Ahmedabad
shashank.asara@gmail.com

Aim and Objectives:
Intravenous catheters (IVCs) are commonly used medical devices. The aim of this study was to determine the incidence, type of adverse events (AEs) and identify the risk factors associated with IVCs.

Methodology:
This prospective observational study was conducted at two medicine wards in 200 patients, older than 15 years of age and having at least one intravenous catheter inserted. Patients were observed at 24 hours, 48 hours and 72 hours after insertion of IVCs. Suspected adverse event if any was recorded and analysed. Morbidity was assessed by Charlson Morbidity Index.

Result:
Out of 260 intravenous catheters in 200 patients, 64 adverse events in 64 patients were reported with incidence of adverse event as 24.6%. The mean age of patients who developed AEs was 44.17 ± 16.84 years and male: Female ratio was 1.36. Adverse events (38) were mainly mechanical in nature which included 21 obstructions/occlusions followed by 11 accidental removal/wrenching and 6 fluid leaks. Clinical AEs (26) were phlebitis (19), isolated edema (4) and hematoma (3). About 90% (58) AEs were reported within 48 hours of insertion. Charlson comorbidity index (0.94) and mean drug number administered (7.26 ± 1.47) were significantly higher in patients with AE as compared to those having no AEs ($p<0.05$).

Conclusion:
AEs were common due to IVCs with most AEs reported within 48 hours. AEs are associated with increased morbidity and directly related to the number of drugs administered.

CO-05

Evaluation of Prescription Pattern of Drugs and Drug awareness and Adherence to treatment in Post Myocardial Infarction Patients.

Dr. Madhuri Doke, Dr. Yashashri Shetty, Dr. Ajay Mahajan*, Dr. Dhiraj Kumar*, Dr. Vinoodh Kumar K
Department of Pharmacology & Therapeutics, Department of Cardiology*, Seth G S Medical College and KEM Hospital (KEMH) ,Mumbai – 400012
madhuridoke09@gmail.com

Aims & Objectives:
Prescription pattern studies gives us insight about the trends of drugs commonly used in primary /secondary prevention of myocardial infarction. Limited prescription audit studies in India on drugs used for secondary prevention of MI, made us do this study aiming to evaluate the prescription pattern of drugs in post myocardial infarction patients along with their adherence, awareness, and probable clinical outcomes.

Methodology:
After approval from ethics committee (EC), a prospective, cross-sectional, observational, single-centered, questionnaire-based study was conducted in 100 post MI patients. The prescription patterns, adherence and awareness were analyzed using descriptive statistics.

Results:
100 patients' prescriptions had an age range of (32-79 years), gender (M: F - 3.76:1) consisted of 739 drugs and each prescription had at least 7.39 drugs (7.39 □ 1.36). Drugs for secondary prevention were 580 (78.48%) and rest were concomitant medication 159 (21.51%). 47 prescriptions were complete and incompleteness was seen in dose unit and lifestyle instructions in 53 and 76 prescriptions respectively. 227 drugs were prescribed in generic name. Most common prescribed drug was Atorvastatin followed by Aspirin. Concomitant medication most commonly found was Pantoprazole. FDCs prescribed were 99 and commonest for MI was furosemide and spironolactone and in concomitant medication, most common FDC was Dapagliflozin and Metformin. Adherence for polytherapy was 93% and awareness regarding therapy was only 52%. Only 5 % had restenosis and 2% had stroke as outcome.

Conclusion:
Polytherapy is a practice for secondary prevention of MI, with good adherence and less awareness.

CO-06

Evaluation of patient awareness, prescription pattern and adverse drug reactions profile of secondary prophylactic drug treatment in stroke patients visiting a tertiary care hospital.

Dr. Ajay Gattani, Dr. Sharmila Jalgaonkar, Dr. Raakhi Tripathi, Dr. Neeraj Jain, Dr. Rishikesh Joshi
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai.
kgsaaa@gmail.com

Introduction:

Stroke is a leading cause of mortality across the globe, In India, stroke accounts for 3.5% DALYs and has crude prevalence- 26 -757 per 100,000 ppy. One in every four strokes is recurrent suggesting insufficient prevention strategies or poor awareness. Keeping this in view, this study was planned with the following objectives

Objectives:

1-To evaluate the awareness of patients towards secondary prophylactic drug treatment of stroke. **2-**To evaluate prescription pattern and ADRs preceding last 1 month.

Methodology:

A cross-sectional observational study [IEC(II)/542/2023] was conducted on 18–65-year stroke patients attending Neurology OPD. Drug Treatment awareness was assessed using pre-validated 11 item questionnaire with 5 domains (total score:11). Prescription pattern and the reported ADRs were evaluated and analysed. Statistical analysis was done using descriptive statistics.

Results:

For 100 patients included, overall score for drug treatment awareness was 4.98±2.185. Highest score was in 'Current Prescription' and minimum in 'Side Effects' domain. Total 430 drugs were prescribed of which 298 drugs were prescribed in generic name and each prescription had an average of 3.98 drugs (3.98±1.53). 43 prescriptions were complete, and incompleteness was seen in drug related and lifestyle instructions. Most common prescribed drug was Atorvastatin (22.32%) followed by Aspirin (22.79%). Total 12 ADRs were reported and analysed.

Conclusion:

Awareness to treatment was lacking indicating the need for patient education programs. Multiple drugs are used in secondary prophylactic treatment of stroke. Majority of prescription were lacking drug related and lifestyle instructions.
Adverse drug reactions seen in 12% (12/100) of the prescriptions.

CO-07

A Comparitive Study of Correlation of Random Blood Glucose with Glycated Haemoglobin Using Roc – A Single Centre Study

Dr. Radhika Bindu, Dr. Abhay Dharamsi
Parul Institute of Pharmacy, Faculty of Pharmacy, Parul University,
Vadodara, (Gujarat) India- 391760
radhikasaddu94@gmail.com

Background:

Before the development of glycated haemoglobin (HbA1c), a new baseline for measuring blood sugar, blood sugar estimate was the primary method of diagnosing, managing, and treating diabetes for many years. The ability to reflect the cumulative glycemic history of the previous two to three months makes HbA1c an essential biomarker of long-term glycemic control. HbA1c hasn't been used much, though, especially in smaller hospital settings, due to expense. Data from earlier studies produced conflicting findings about the relationship between RBS and HbA1C.

Objective:

To determine if random blood sugar (RBS) and HbA1c correlate, as well as to show that RBS is sensitive to and specific for HbA1c.

Methodology:

We acquired prospective, one-year data on diabetic patients who had HbA1c and RBS investigations. Data was prepared for analysis to look for a relationship between RBS and HbA1c. ROC (Receiver Operating Characteristics) was drawn using both the sets of data to find the predictive values.

Results:

Significant correlation was observed between HbA1c and RBS with the Area Under Curve (AUC) as 0.7 which is closer to 1. The sensitivity of both test is high and agreement between both these exists. The p value is also significant.

Conclusion:

RBS do have higher clinical correlation with HbA1c.

CO-08

Integration of Artificial Intelligence in Clinical Pharmacology: Current Status and Future Prospects

Mir Mansoor Sultan
Sultan ul Uloom College of Pharmacy,
JNTU Hyderabad Telanagana 500034
mmsultan@sucp.ac.in

Driven by Artificial Intelligence, Clinical Pharmacology is transforming. This presentation will explore how AI is reshaping key areas like drug discovery through in silico target identification using deep learning algorithms, and optimizing clinical trial design with virtual patient populations.

Our research leverages natural language processing to mine scientific literature, aiming to answer the question: Can NLP be used to identify novel drug targets with greater accuracy than traditional methods, potentially accelerating the development of life-saving medications?

To address this, our research utilizes a convolutional neural network trained on a curated database of biomedical literature. Analyzing complex relationships between genes, proteins, and diseases, uncovering promising drug targets with 25% greater accuracy than traditional methods. The contribution speeds up the discovery of life-saving medications, bringing them to bedside faster. Virtual patient populations, powered by AI simulations, are revolutionizing trial design. These digital surrogates, built on real-world data, predict drug efficacy and safety across diverse demographics, allowing us to refine protocols and accelerate the path to effective therapies. No longer a one-size-fits-all approach, machine learning models trained on individual genomic and clinical data are enabling personalized drug dosing. Initial trials demonstrate a 10% reduction in treatment failure rates, paving the way for safer, more effective therapies tailored to each patient. While challenges like data quality and regulations remain, AI's potential for revolutionizing drug development is undeniable.

This presentation envisions a future with common AI advancements like drug-drug interaction prediction and explores critical steps to achieve a safer, more effective, and truly personalized era of medications for all.

CO-09

A Cross Sectional Study to Assess Knowledge, Attitude and Practice Towards E-Learning Among Medical Undergraduates in Tertiary Care Teaching Hospital in Telangana.

Dr Farheen Sultana, Dr P. Srujana Dr N. Karunasree Dr Meher Kounen Fatima
Osmania Medical College, Koti, Hyderabad.
aleenafarheen63@gmail.com

Introduction:

E-learning is a method of gaining knowledge using electronic media which is getting popularity among students. E -learning can be used in medical education to improve the efficiency of academic deliverance and make the learning sessions more captivating and retainable. E -learner is a person who can use the online material for learning purposes, according to his time and space**.**

Aim:

The Present Study Was Aimed to Assess Knowledge, Attitude and Practice Towards E-Learning Among Medical Undergraduates.

Methodology:

A cross sectional pre validated questionnaire-based study consisting of 19 questions was conducted among 500 medical UGs at Osmania medical college and hospital after ethics approval. Out of 19 questions,1-7 were knowledge based,8-12 were attitude-based questions from 13-19 included practice related questions. Statistical analysis was done using Excel sheet. Chi square test was used to compare variables with p value less than 0.05 was considered statistically significant.

Result and Discussion:

Out of 484 responses (54% were females) 87% of medical undergraduates are aware of term E-learning and possess good knowledge, with positive attitude and 93% had practice.

Conclusion:

The study has emphasized that E-Learning can be a useful tool in enhancing the learning experience and students are more open towards the upcoming change in teaching methods. The lack of knowledge in computer skills along with poor technological infra structure and resource can be a challenge for implementation of E – learning.

CO-10

A Comparative Study of Efficacy of Oral Contraceptive Containing Ethinyl Estradiol Combined with Drospirenone Versus Desogestrel on Clinical and Metabolic Parameters in Patients with Polycystic Ovarian Syndrome at Tertiary Care Hospital Telangana

Nageshwar swamy, Dr. N Karunasree
Dept of Pharmacology, Osmania Medical College, Osmania Tertiary Care Hospital Telangana
nageshwarswamy@gmail.com

Background:
A prospective randomized trial was conducted to compare the efficacy of drospirenone-containing combined oral contraceptives (COC) with desogestrel-containing COC in women with polycystic ovary-syndrome (PCOS).

Study design:
Sixty (60) women were randomized into the study group [ethinylestradiol (EE) 30 mcg+drospirenone 3 mg] and control group (EE 30 mcg+desogestrel 150 mcg), treated for 6 months and were followed up at 1 month, 3 months, 6 months, during the treatment and at 3rd and 6th months post-treatment. Acne and hirsutism scoring, bodyweight, blood pressure (BP), body mass index (BMI), ultrasound parameters, glycemic profile, lipid profile, and hormonal profile were compared in this study.

Results:
Cycles were regular in both the groups during treatment. Effect of regular cycles persisted in 44.93% (13/30) vs. 17.34% (5/30) in study vs. control group at 6 months post-treatment with 33.6% decreased hirsutism score in the study group (versus no change in control group) even at 6 months after stopping the treatment. With treatment, BMI fell by 0.54 kg/m(2) in the study group; systolic and diastolic BP fell in the study group while it subsequently rose in the control group. Low-density lipoprotein (LDL) significantly decreased and high-density lipoprotein (HDL) was elevated in the study group ($p<.05$). The study group showed a significant fall in fasting/postprandial blood sugar (FBS/PPBS) and insulin and total testosterone against a rise in the control group.

Conclusion:
In women with polycystic ovarian syndrome, a drospirenone containing COC has better outcome in terms of persistent regular cycles, anti-androgenic effect, fall in BMI and blood pressure, better lipid profile, favourable glycemic and hormonal profile than desogestrel-containing COC.

CO-11

Evaluation of Awareness to Drug Treatment, Prescription Pattern and Adverse Drug Reactions in Patients with Psoriasis

Dr. Sharika Pillay1, Dr. Raakhi Tripathi1, Dr. Sharmila Jalgaonkar1, Dr. Sunanda Mahajan2, Dr. Prachi Gole2

1Department of Pharmacology and Therapeutics, 2Department of Dermatology & Venereology, Seth GS Medical College and KEM Hospital Mumbai

sharika.rockz@gmail.com

Introduction:

1.multi-drug therapy is involved in management of Psoriasis so variability within the prescription pattern is seen. **2.**Drug and treatment Awareness contributes towards drug compliance. **3.**Side effects with treatment of Psoriasis need to be analysed to reduce incidence of comorbidities.

Objectives:

1. Evaluation of Drug Awareness in Patients with Psoriasis. **2.** Evaluation of prescription pattern used in treatment of patients with Psoriasis. **3.** Assessment of causality, severity, and preventability of ADRs in patients taking Psoriasis treatment.

Methodology:

1. Institutional EC permission & informed consent taken; demographic details & current prescription of the participant captured in a Case Record Form.

2. A pre-validated Drug Awareness Questionnaire, with 7 domains & 22 questions was used.

3. Adverse events experienced in the last 3 months were captured & assessed for causality, severity and preventability.

Results:

1.150 patients were enrolled, 71.3 % (N=107) took treatment for >1 year. Comorbidities seen in 29.6% (N=44). Average awareness score=11±0.24 (total score=22), 58% (N=87) scored >50%. **2.** 1070 drugs were prescribed, average number of drugs per encounter=7.13±0.13, most common drug=Mometasone cream (topical corticosteroid), (N=135, 90%). **3.** 50 Adverse Drug Reactions were reported, 52% (26/50) were Gastrointestinal, which included, Nausea 14% (7/50) and diarrhea 14% (7/50). Apremilast, accounted for 40% (20/50) of the adverse drug reactions.

Conclusion:

1. Awareness to Psoriasis treatment was lacking indicating the need for patient education programs.**2.** Treatment of Psoriasis involves multiple drugs (7.13 ±0.13)indicating polypharmacy. **3**. Adverse drug reactions seen in 33% (50/150) of the prescriptions.

CO-12

A Cross Sectional Observational Study to Evaluate Awareness of Patients to Drug Treatment and Adherence to Statin and Antiplatelet Therapy in Patients Suffering from Cardiovascular Disease.

Dr. Simran Khatri1, Dr. Padmaja Marathe1, Dr. Ajay Mahajan2, Dr. Dhiraj Kumar2
1Department of Pharmacology and Therapeutics
2 Department of Cardiology Seth GS Medical College and KEM Hospital Mumbai.
Simrankhatri844@gmail.com

Background:
1. LDL is a major contributor to ASCVD. **2.** Prevalence of dyslipidemia is 79% in Indians. **3.** Lack of knowledge about treatment of dyslipidemia and importance of statin therapy affects compliance and optimum management to dyslipidemia.
Objectives:
1. To evaluate drug awareness and adherence to statins and antiplatelet therapy in patients receiving statins. **2.** To evaluate control of hyperlipidemia in patients receiving statins. **3.**To analyze the prescription pattern.
Methodology:
1. 180 patients aged 18 to 75 years, receiving statin therapy for > 6 months were enrolled after Ethics Committee approval & informed consent. **2.** Demographic information & prescription details were collected. **3.** A pre-validated 23-question 'Drug Awareness & Adherence' questionnaire was administered.
Results:
1. A total of 180 patients(115M,65F) were enrolled (mean age of 58.36 ± 8.02 yrs.) **2.** For statin therapy, drug awareness score 3.6 ± 1.24 (Maximum score 10), adherence score was 3.2 ± 0.62. (Maximum score 5) & for aspirin adherence score was 3.6 ± 1.46 (Maximum score 5). **3.** Statins prescribed were Atorvastatin (40 mg) and Rosuvastatin (20 mg). **4.** Majority patients showed reduction in LDL cholesterol with statins. **5.** Most common drugs prescribed were Aspirin 75mg, Metoprolol 50mg, Ramipril 5mg and Pantoprazole 40mg.
Conclusion:
1. Awareness to statin therapy was lacking and adherence was suboptimal stating the need for patient education. **2.** Use of high intensity statins achieved better control of hyperlipidemia in patients. **3.** Most common drugs prescribed apart from Statins and Antiplatelet were Beta-blockers, ACE-inhibitors and Proton Pump Inhibitors.

CO-13

Utility and Feasibility of Antibiotic Disposal Boxes at a Tertiary Care Hospital in Telangana

Ruby R and C Prabhakar Reddy
Dept of CP & T, Nizams Institute of Medical Sciences, Punjagutta, Hyderabad, Telengana
drrubyraphael@gmail.com

Introduction:

The misuse and overuse of antibiotics substantially increases the level of antibiotics in the environment. It accelerates the evolution of Antibiotic Resistant Bacteria and Antibiotic Resistance Genes resulting in multidrug resistant organisms and antimicrobial resistance. Therefore, by adopting an appropriate antibiotic disposal practice, the amount of antibiotics in the environment can be reduced. The aim of this study is to create awareness and assess the quantity of unused antimicrobials among the public and health-care professionals.

Methods:

This was an observational study, conducted at Nizams Institute of Medical Sciences, Hyderabad to estimate the proportion of antimicrobials disposed by the public and health-care professionals. Antibiotic Disposal Boxes were custom made by a local vendor, in rectangular shape with the dimensions of height - 3 feet and width - 2 feet. It was made of transparent acrylic material. “Kindly dispose of unused/ unwanted/ expired antibiotics here” is written in 3 different languages (English, Telugu, Hindi) in front, and at either side of the box. It has a small door at one side with locking system for accessing the drugs. Antibiotic Disposal Boxes were placed at two different locations in the hospital, one at old OPD block and the other at specialty block, near patient waiting area. It was securely placed and monitored by CCTV. They were easily accessible for all patients, public and health-care workers. All drugs disposed in the Antibiotic Disposal Boxes were included in this study. Drugs from disposal box were collected in yellow bags. The antimicrobials were manually segregated from the other drugs. The total no of antimicrobials disposed, unused and expired antibiotics were analyzed. After analysis these drugs were sent for incineration.

Results:

A total 2763 antimicrobials were collected from both the disposal boxes after 8 months. Among these antimicrobials, 2455 (88.8%) were Antibiotics, 141 (5.1%) were antifungals, 59 (2.1%) were antivirals, 33(1.1%) were anti-helminthic, 75 (2.7%) antimalarials. Out of all the antibiotics disposed, includes 773 (27.9%) of Antitubercular drugs. According to Aware classification, 889 (32.5%) antibiotics belonged to Access group, 1421(52%) in Watch and 50 (1.83%) in Reserve group. 1856 (67.9%) antimicrobials disposed were expired drugs, 729 (26.3%) unused and 178 (6.4%) uncertain.

Conclusion: Antibiotic Disposal box can decrease the antibiotic pollution in the environment. This is a simple effective measure to prevent antimicrobial resistance. Hence Antibiotic Disposal box at every hospital and a campaign for appropriate disposal of antibiotics is warranted.

CO-14

To Assess the Prescription of Antiretroviral Agents and Study of Adverse Drug Reactions Profile in Patients Attending ART Centre in a Tertiary Care Hospital

Dr. Shruti Bhide, Dr.Vijayadhaarani, **Dr. Mudra Patel**, Dr. Kavita Joshi
mudrapatel2121996@gmail.com

Introduction:
In today's world HIV, developing a vaccine for the unique HIV virus has been challenging due to its rapid replication, mutagenesis, immune system evasion, and ability to create host reservoirs. India's Antiretroviral Therapy (ART) program strives to improve life quality, reduce viral loads sustainably, and revitalize the immune system. Recent WHO guidelines endorse dolutegravir-based HIV treatments for their potency, fewer side effects, and simpler dosing. Evaluating adverse drug reactions and prescription patterns amid this regimen shift is crucial for patient care.

Methodology:
From September 2021 to July 2022, a study at a Tertiary Care Hospital's Outpatient Antiretroviral Treatment Centre assessed HIV-diagnosed patients above 18 in ART clinics, analyzing clinical or lab-confirmed ADRs. Ethical clearances were obtained, recruiting 97 participants through convenience sampling for six months.

Results and conclusion:
The study found Tenofovir + Lamivudine + Dolutegravir as the most prescribed regimen, following WHO and NACO guidelines. Dolutegravir-related adverse reactions included increased alkaline phosphatase, hyperglycaemia, and dyslipidaemia, mostly linked to Dolutegravir and TLD. Mean ART drugs per prescription averaged 3.08 ± 0.298, predominantly featuring Lamivudine, in line with NACO guidance. Notably, 91.7% of ADRs were lab-based, contrasting studies reporting more patient-reported ADRs. WHO-UMC causality suggested 60.2% possible associations, limited by fixed drug combinations and ethical considerations. Regimen changes aligned with NACO guidelines, driven by immune/viral failures or toxicity. The study's strength in evaluating post-guideline changes was affected by sample size and single-centre focus, impacting causality assessment. Continuous monitoring is crucial during ongoing dolutegravir regimen implementation for a comprehensive understanding of their use and associated ADRs.

CO-15

Knowledge, Attitude and Practices study on Antimicrobial use and Resistance among Indian Medical Graduates in a Tertiary Care Centre.

Dr. Mohd Moosa Quadri, Dr. N. Karunasree.
Osmania Medical College, Koti, Hyderabad.
moosa2q@gmail.com

Aims:

To measure the extent of knowledge, attitude and practices on antimicrobial use and resistance among Indian medical graduates.

Objectives:

To assess the knowledge, attitude, and practices on antibiotic use and resistance among Indian medical graduates using study questionnaire. To improve awareness and understanding of AMR through effective communication, education, and training.

Methodology:

A validated structured study questionnaire was used for capturing respondent particulars, antimicrobial prescribing habits, knowledge of antimicrobial resistance, ways of choosing and learning about antibiotics, agreement or disagreement with certain perceptions regarding antibiotics, selection of antibiotics in specific settings, and suggestions regarding rationalizing antimicrobial use in the practice setting. Summary statistical analysis of the pooled data was done.

Results:

200 respondents participated in the study. The theoretical knowledge about antimicrobials was satisfactory, but areas of concern were noted in the attitude and practice domains. A substantial proportion of participants failed to identify the correct choice of antibiotics in case-based scenarios. Statistically significant differences were not observed in KAP quotient scores between house surgeons and medical graduates.

Conclusion:

Despite satisfactory background knowledge regarding the rational use of antimicrobials and AMR patterns, there are discrepancies in the respondents prescribing attitude and thus strengthen the case for instituting specific interventions to improve antimicrobial prescribing.

Oral Presentations: Pre-Clinical

Abstract No.	Presenting Author	Mode of Presentation	Title of abstract
PCO-01	Abhijeet Shinde	Oral	In-Vivo Studies on Efficacy of Bio-Enhanced Curcumin in Dementia
PCO-02	Abhishek Joshi	Oral	Mechanism of Action of Hesperidin and Diosmin in Varicose Vein Activity
PCO-03	Bisht Khushboo	Oral	Comparing Effects of Arglabin On NFκB/MAPK and Inflammasome Pathways: A Clash of Pathways (CAN-COP Study)
PCO-04	Syed Bilal Ali	Oral	Investigation of Antifungal Activity of Tinospora Cordifolia in Wistar Rats
PCO-05	Soham Sinha	Oral	Evaluation of The Antiepileptic Effect of N-Acetyl Cysteine in Pentylene-Tetrazole-Induced Kindling Model in Wistar Rats.
PCO-06	Anirudh Tiwari	oral	Evaluation of Safety of Curcumin, Nano-curcumin, and Alpha-Linolenic Acid for Improved Pregnancy Outcomes
PCO 07			

PCO-01

In-Vivo Studies on Efficacy of Bio-Enhanced Curcumin in Dementia

Mr.Abhijeet Shinde, Dr.Vaishali Kilor, Ms.Ashika Rewatkar

Department of Pharmaceutics, Gurunanak college of Pharmacy, Behind C.P. Foundry, Near Dixit Nagar, Kamptee road, Nari, Nagpur , Maharashtra 440026 (India)
shindeabhijeet774@gmail.com

Background:

Alzheimer's disease is a disorder that slowly destroys memory and thinking ability to carry out the simplest tasks. It is the cause of 60–70% of cases of dementia. The bioactive compound curcumin extracted from the turmeric plant (Curcuma longa), is gaining popularity due to its curative properties for cognitive disorders and treating dementia.

Aim & Objectives:

The purpose of this study is to overcome curcumin's limited aqueous solubility as well as to improve its permeability to make it cross the blood brain barrier to be effective in treating dementia.

Method:

Ionic salts of curcumin were prepared using Choline chloride and tetrabutylammonium bromide (TBAB) as anions. These salts were converted into nanofibers for bioavailability enhancement using electrospinning technique.

Results and Discussion:

Resulting ionic liquids were found to possess low melting points 80– 85°C and 90–95°C respectively. Partition coefficient of Curcumin choline salt observed to be log P=3.77, may contribute to enhanced permeability. Curcumin chloride nanofibers showed improved aqueous solubility as well as dissolution rate as compared to pure curcumin. Curcumin nanofibers and pure curcumin were used in treating scopolamine induced dementia in male wistar rats by using Y-maze model. It was observed that Curcumin nanofibers not only prevented disruption but improved memory significantly, when compared with pure curcumin and untreated/treated group.

Conclusion:

The results of in-vivo animal studies shows that conversion of curcumin to curcumin choline nanofibers has potential to be effective in the treatment of dementia due to its improved solubility and permeability

PCO-02

Mechanism of action of hesperidin and diosmin in varicose vein activity

Abhishek Joshi, Kajal Bais**,** Nidhi Sapkal.
*Department of Pharmaceutics, Gurunanak College of Pharmacy, Nagpur – 440026
abhibja25@gmail.com

Background & Objective:
Citrus bioflavonoids namely, diosmin and hesperidin are used for the treatment of venous diseases like hemorrhoids. The activity of these flavonoids is reported in the ratio of 9:1 as micronized purified flavonoid fraction (MPFF). Both flavonoids exhibit poor solubility that results in low bioavailability. In the proposed work it was envisaged to hydrolyze these flavonoids and compare the activities of these hydrolyzed fractions with that of MPFF.

Methodolgy:
Both diosmin and hesperidin were hydrolyzed separately using concentrated sulfuric acid and the anti-hemorrhoidal activity was evaluated using croton oil induced hemorrhoid model in rats. The dose of test and standard compounds was 200 mg/kg and it was administered by oral route for five days. During the study period, change in body weight and change in extent of insertion of cotton swab were measured every day. The histopathological examination was carried out at the end of the study.

Results:
The study data revealed that the gain in weight in hydrolyzed hesperidin group was significantly higher than the standard and hydrolyzed diosmin group. Further, on day 4, the hydrolyzed hesperidin group showed complete reversal of hemorrhoid as measured by extent of insertion of cotton swab in the anal region. The histopathology confirmed these results.

Conclusion:
It can be concluded that the hydrolyzed hesperidin is more effective in treating hemorrhoids than hydrolyzed diosmin or the marketed MPFF. Hence there is a need to develop a suitable formulation for hydrolyzed hesperidin for this purpose.

PCO-03

Comparing effects of Arglabin on NFκB/MAPK and inflammasome pathways: A Clash of Pathways (CAN-COP study)

Bisht Khushboo, Arya Dharam Vir
Department of Pharmacology, All India Institute of Medical Sciences, New Delhi
khushboobisht12@gmail.com

Background
Arglabin is a plant alkaloid, a sesquiterpene lactone which is used an anticancer drug and proclaimed to have shown potential anti-diabetic and anti-atherogenic effects. It was developed anticancer drug against H-Ras oncoproteins at International Research and Production Holding "Phytochemistry", Kazakhstan. In the present study, effects of Arglabin on NFκB/MAPK pathway and mediators of inflammasome pathways in myocardium were studied.

Methods
Institutional Animal Ethics Committee (IAEC) approval was obtained for the study (50/IAEC-1/18) following this, Albino male Wistar rats were randomly classified into nine groups (n=6 per group) of which six groups were pre-treated with different doses (2.5 µg.kg-1, 5 µg.kg-1 and 10 µg.kg1) of intraperitoneal Arglabin for 21 days. Remaining three groups were normal, vehicle (0.01% DMSO) and isoproterenol control groups [2]. On the 22nd day, 85 mg.kg-1.day-1 isoproterenol was injected to induced myocardial ischemia. Hemodynamic analysis, histopathological examination, electron microscopy, biomarkers, cardiac parameters, oxidative stress (MDA, GSH, SOD, and CAT), inflammatory mediators (Interleukin-6 and Tumor necrosis factor-α), apoptotic markers (Bax, bcl2, and caspase-3), inflammasome mediators (Interleukin-1β and caspase-1) and western blot analysis (NFκB/MAPK pathway) was performed and results were evaluated.

Results
Upon, evaluation of recorded findings, the hemodynamic parameters like systolic, mean and diastolic arterial pressure were reduced after myocardial injury induced by isoproterenol ($p<0.01$) as compared to normal group. A 21 day treatment with arglabin 2.5 µg.kg-1 showed improvement in hemodynamic parameters compared to isoproterenol group ($p<0.05$). The level of inflammatory cytokines CK-MB and LDH were found to be increased in all the arglabin pre-treated groups (2.5 µg.kg-1, 5 µg.kg-1 or 10 µg.kg-1) as compared to the normal group ($p<0.001$). Histopathological examination revealed decreased neutrophilic infiltration in 2.5 µg.kg-1 arglabin pre-treated groups that correlated with electron microscopic findings

Conclusions
Arglabin administration showed mixed-effects on myocardial ischemia suppression. A partial protective response was observed via NLRP3 inflammasome mediators. However, inflammation altered myocardial structure and modulated myocardial function via activation of NFκB/MAPK pathway. Thus, Arglabin shows mixed effects on suppression and activation of inflammation in rat model of isoproterenol-induced myocardial ischemia.

PCO-04

Investigation of antifungal activity of *Tinospora cordifolia* in wistar rats."

Syed Bilal Ali[1], Viplav Raj Gunjan [2] ,Avinash Singh Mandloi,
Asher John Mohan, Vipin V. Dhote
Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India
Email: syedbilalali0037@gmail.com

Background:
Oral candidiasis, also known as oral thrush, is a fungal infection of the mouth caused by *Candida albicans*. Treatment usually involves antifungal medications that are associated to certain obnoxious. This has led to the search for new drug candidates of herbal origin.

Objective:
The objective of this study was to evaluate the antifungal effect of *Tinospora cordifolia (TC)* using rat model of oral candidiasis.

Methods:
Candidiasis was induced in rats with 2.5 × 107 viable cells/mL of *Candida albicans* introducing a cotton swab in the oral cavity of animals. The animals were grouped as negative control (*Candida albicans*), standard (amp B), TC-1 (50 mg/kg), TC-2 (100 mg/kg), TC-3 (200 mg/kg). *Candida* colonies were estimated by well agar diffusion method. Furthermore the antifungal evaluation was carried out by observing tongue scores, colony forming units and histopathological study.

Results and Discussion:
The HPTLC analysis revealed the phytoconstituents tinosporine and berberine possess anti-fungal potential, thus *TC* was found to be an effective antifungal when compared to standard Amphotericin B in terms of less or no nephrotoxicity. The dose of 400 mg/kg exhibited significant reduction in tongue scores (0.33±0.33) and CFU (21.50±1.19) after 14 days treatment. Similarly it improved histological observation in tongue and kidney. However upon histopathological examinations, an undesired nephrotoxic effect was observed in kidney samples of rats that is the group treated with standard Amphotrecin B .

Conclusion:
The herbal extract was found to be equally efficacious as antifungal when compared to conventional synthetic treatments. This could be due to the presence of berberine and tinosporine. Additionally the toxicities associated with synthetic first line treatments could be alleviated upon substitution with TC. However further in depth investigations are always a requirement to translate this research into clinical scenarios.

PC0-05

Evaluation of The Antiepileptic Effect of N-Acetyl Cysteine in Pentylenetetrazole-Induced Kindling Model in Wistar Rats.

Dr. Soham Sinha, Dr. Sandhya Kamat
Department of Pharmacology & Therapeutics, Seth GS Medical College and KEM Hospital, Parel, Mumbai 400012
sohamsinha1217@gmail.com

Aims & Objectives:
The objective of the study was to evaluate the antiepileptic effect of N-acetyl cysteine (NAC) in the pentylenetetrazole (PTZ)-induced kindling model in Wistar rats.
Methodology:
After approval from the Institutional Animal Ethics Committee, 48 male Wistar rats were divided into 6 groups: normal control, disease control, positive control, and three test dose groups of NAC (200, 300, and 400 mg/kg). In all the groups except normal control, 35 mg/kg PTZ was administered intraperitoneally every 48 hours and the rats were observed for 30 mins for the appearance of seizures. The study drug/vehicle was administered 30 mins before every PTZ injection and the antiepileptic effect was evaluated using seizure latency and severity. The seizure severity was classified and scored according to the Racine scale. Seizure latency and severity were analysed among the different groups using the Kruskal Wallis test (GraphPad InStat version 3.06). $p< 0.05$ was considered as significant.
Results:
The low dose of NAC (200 mg/kg) did not change the seizure latency while the intermediate dose (300 mg/kg) and high dose (400 mg/kg) of NAC showed a significant increase in seizure latency as compared to the disease control group ($p<0.001$). All the three test doses showed a significant difference in the seizure severity as compared to the disease control group.
Conclusion:
The results demonstrated that both intermediate dose and high dose of NAC were efficacious in exerting an antiepileptic effect in the pentylenetetrazole-induced kindling model of epilepsy.

PC0-06

Evaluation of Safety of Curcumin, Nano-curcumin, and Alpha-Linolenic Acid for Improved Pregnancy Outcomes.

Mr. Anirudh Tiwari, Ms. Shruti Desai, Mr. Sudhir Jadhav, Ms. Amruta Gadade, Mr.Pravin Salunke and Dr. Vikas Dighe*
ICMR-National Institute for Research in Reproductive and Child Health.
Jehangir Merwanji Street, Parel, Mumbai 400012
dighev@nirrch.res.in

Aims-
To Evaluate the Safety of Curcumin, Nano-curcumin, and Alpha-Linolenic Acid in Pregnancy.

Objectives-
To assess the effect of oral dosing of Curcumin, Nano-curcumin, Alpha-Linolenic Acid, and a combination of Nanocurcumin and ALA on fertility and sexual maturation of F1 and F2 offsprings

Methodology-
Sixty rats were randomly assigned to five groups of twelve rats each. Group-I Vehicle Control (0.5% CMC solution), Group-II Curcumin (400 mg/Kg-BW), Group-III Nano-Curcumin (400 mg/Kg-BW) Group IV ALA (150 mg/Kg-BW) and Group-V Nano-Curcumin (400 mg/Kg-BW) + ALA (150 mg/Kg-BW). The rats received respective dosages from 14 days before conception until PND 13. Of the twelve rats in each group, six were sacrificed at GD20 to determine pre-implantation loss and post-implantation loss, and the remaining animals were allowed to deliver pups. Hematological parameters of blood and biochemical parameters from serum were also analyzed. 0-day, 4-day, and 13-day weight and anogenital distance (AGD) of pups were recorded. Vaginal opening (VO) and testicular descent (TD) days of pups were also recorded. Pups were followed until PND-75 and weekly body weight was recorded and then sacrificed. We measured the levels of reproductive hormones like testosterone progesterone and estradiol from serum samples. Further remaining pups were followed till F2 generation to asses any transgenerational effect of treatment.

Results-
There was no discernible pre-implantation loss or post-implantation loss was found in F0 and F1 pregnant females as compared to the control. Reproductive hormone profile was found to be well within the range, and biochemical and hematological parameters also showed no discernible change. Growth and sexual maturation parameters were assessed till F2 generation and found to be normal as compared to the control.

Conclusion-
It was found that curcumin, nano-curcumin, ALA, and a combination of nano-curcumin and ALA administration are safe during pregnancy. Additionally, the combination of nano-curcumin and ALA was found to be improving pregnancy outcomes.

PCO-7

Dexamethasone primed mesenchymal stem cells conditioned media immunomodulates immune responses and ameliorates clinical pathology in lupus mice model.

Khushbu Priya1, Manaswi Chaubey2, Sonali Rawat3, Kiran Giri4, Sujata Mohanty2, Geeta Rai1*

1Department of Molecular and Human Genetics, Institute of Science, Banaras Hindu University, Varanasi, India.

2 Department of Medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.

3 Stem Cell Facility, DBT-Centre of Excellence for Stem Cell Research, AIIMS, New Delhi, India.

4 Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.

*Corresponding author

Background

Systemic lupus erythematosus (SLE), a chronic autoimmune disease, is governed by dysregulated immune mechanisms and cell death pathways. Cell-free secretome of Mesenchymal stem cells (MSCs) have been proposed as a potential treatment for SLE owing to their ability to modify immune cells and their functions.

Objectives

To prepare a Dexamethasone primed Wharton jelly MSC conditioned media (DW) (cell free) and assess its immunomodulatory effect and over all disease amelioration via *in vivo* studies in murine lupus model.

Methods

Lupus model was developed in female BALB/c mice. *In vivo* studies were performed and the mice were assessed for improvement of disease specific histopathology of kidney, spleen, lungs, liver and heart, autoantibody production, proteinuria, body weights, limb inflammation, adaptive immune system components; cytokines, TGF-β; ROS production and NET formation. To identify NETs, presence of extracellular DNA, MPO and citrullinated histone were visualized by immunofluorescence. Photoacoustic imaging to investigate the NET formation in acutely inflamed kidney, liver and heart of lupus mice was done using Vevo LAZR-x imaging systems.

Results

In pristane induced mice model, DW treatment significantly decreased ROS and NET release by neutrophils. Treatment improved the disease specific pathology of kidney, spleen, liver, lungs and heart along with reducing alopecia with notably visible reversed hair loss. It also significantly increased the body weight and reduced proteinuria, limb inflammation, circulating autoantibody, and deposition of NETs in the kidneys, liver, heart, lungs and spleen.

Conclusion

Pre-clinical studies showed improvement *in vivo* with DW. Our ongoing clinical studies would help evaluating it as a promising treatment option offering a shift from the currently available therapeutics.

Poster Presentations: Clinical

Abstract No.	Presenting Author	Mode of Presentation	Title of abstract
CP-01	Bisht Khushboo	Poster	Effect of Chrono-Modulation on Gemcitabine Elimination Kinetics and Cytidine Deaminase Enzyme in Metastatic Cancers: an Exploratory Trial
CP-02	J.Raghu Ram	Poster	Comparison of Diclofenac and Tramadol for Pain Management During the Post-Operative Period of Total Knee Replacement: A Prospective Study
CP-03	Mohammed Ashfaq Hussain	Poster	Innovative Approaches: AI Applications in Geriatric Pharmacotherapy and Patient Care.
CP-04	Syed Jaffer	Poster	Artificial Intelligence in Personalized Medicine for Pediatric Patients: Exploring Roles and Impact
CP-05	Jagriti Jha	Poster	A Cross-Sectional Observational Study to Assess Prescription Pattern, Awareness of Parents regarding Disease and Use of Antimicrobial agents and Cost of Treatment in Children Admitted in a Tertiary Care Hospital.
CP-06	Honshil V. Parikh	Poster	An Evaluation of Rationality of Fixed Dose Combinations Prescribed and their Prescription Pattern.
CP-07	Meher kounen	Poster	The Effect of Topical Versus Intraoperative Infiltration of Epinephrine Solution (1:100,000) on Intraoperative Visualisation and Bleeding During Functional Endoscopic Sinus Surgery (Fess) at Tertiary Care Centre, Telangana
CP-08	Rajvee Parekh	Poster	Dasatinib as A Probable Cause of Bilateral Chylothorax in Chronic Myeloid Leukaemia Patient: A Case Report
CP-09	Farheen Sultana	Poster	A Cross Sectional Study to Assess Knowledge, Attitude and Practice Towards E- Learning Among Medical Undergraduates in Tertiary Care Teaching Hospital in Telangana

CP-01

Effect of Chrono-modulation on Gemcitabine Elimination kinetics and Cytidine Deaminase enzyme in Metastatic Cancers: An Exploratory Trial

Bisht Khushboo1, Dhamija Puneet1, Sehrawat Amit2, Handu Shailendra1
1Department of Pharmacology, 2Department of Medical Oncology, All India Institute of Medical Sciences, Rishikesh, Uttarakhand.
khushboobisht12@gmail.com

Background:

Gemcitabine gets deaminated to its inactive metabolite difluorodeoxyuridine (dFdU) by cytidine deaminase enzyme (CDA) enzyme.

Objective:

The objective of this study was to lay a proof of concept regarding effect of chrono-modulation on gemcitabine elimination kinetics and CDA activity.

Methods:

In a single center, cross-over exploratory trial, fourteen patients were randomly allocated to two groups of morning and evening chronotherapy groups each to receive gemcitabine 1000 mg m-2 infusion over 30 minutes. Plasma concentration of gemcitabine and individual pharmacokinetic profile of each patient was determined. CDA activity was measured ex vivo in plasma samples.

Results:

After chronotherapy, gemcitabine kinetics remained unaltered. CDA activity was similar in both groups. Evening group participants reported an increase in adverse drug reactions.

Conclusion:

Our results confirm that chronotherapy does not alter gemcitabine kinetics and CDA activity. Hence. Gemcitabine can be infused at any time of the day.

CP-02

Comparison of Diclofenac and Tramadol for Pain Management During the Post-Operative Period Of Total Knee Replacement: A Prospective Study

Dr. J. Raghu Ram1*, Dr. N.Anitha2 and Dr. Syed Jaffer3
1,2,3 Department of Pharmacology, Sultan Ul-Uloom College of Pharmacy, Hyderabad, Telangana – 50034, India.
jampalaraghuram@sucp.ac.in

Back Ground

Total Knee Replacement:
It is a surgical treatment that replaces a damaged or diseased knee joint with an artificial joint called a prosthesis. The prosthesis, that is commonly comprised of metal, plastic, or ceramic materials, is intended to simulate the natural movement of a healthy knee joint

Aim:
The aim of this prospective study is to compare the effectiveness of the analgesics (diclofenac and tramadol) for pain management in patients after total knee replacement by making use of different parameters

Objectives:
1) To compare groups on diclofenac and tramadol in terms of patient satisfaction with pain treatment.
2) To assess the pain intensity at different points after surgery in patients receiving diclofenac or tramadol.

Methodology:
SAMPLE SIZE: The study was conducted on 120 who had undergone TKR.
ETHICAL CONSIDERATIONS: The Institutional Ethical Committee gave its approval for the study's beginning. The study's participants were kept anonymous at all times.

Results :
• Software utilized: SPSS software version 29.0.1.0 •Confidence interval 95%, hence a P value of 0.05 or higher is regarded as significant. • Test Performed: T test

Conclusion:
This study determined the prescribed drugs and concluded the safety, efficacy, and cost-effectiveness of analgesic drugs (diclofenac and tramadol) in TKR patients.

CP-03

Innovative Approaches: AI Applications in Geriatric Pharmacotherapy and Patient Care.

Dr.Mohammed Ashfaq Hussain

Department of Pharmacy Practice, Sultan ul Uloom College of Pharmacy, JNTU Hyderabad Telanagana 500034

mdashfaqhussain@sucp.ac.in

Background:
This study investigates innovative approaches through the application of artificial intelligence (AI) in geriatric pharmacotherapy and patient care. The aim is to optimize medication management and healthcare outcomes for the aging population. Recognizing the unique challenges associated with geriatric care, the research employs AI technologies to enhance medication adherence, reduce adverse drug events, and improve overall patient care.

Objectives:
AI-Optimized Medication Regimens: Evaluate the efficacy of AI algorithms in tailoring medication regimens for elderly patients based on individual health profiles, medical histories, and potential drug interactions.

Decision Support Systems:
Assess the impact of AI-driven decision support systems on healthcare providers' decision-making processes in geriatric pharmacotherapy, aiming to enhance precision and effectiveness in treatment plans.

Personalized Adherence Strategies:
Investigate the role of AI in developing personalized medication adherence strategies for older adults, taking into account cognitive and physical limitations to improve treatment compliance.

Methodology:
Encompasses a mixed-methods approach, combining quantitative analysis and qualitative assessments. Real-world patient data will be utilized to apply AI algorithms, and healthcare providers will engage in simulated scenarios to gauge the integration of AI recommendations into clinical decision-making. Patient and caregiver perceptions will be gathered through surveys and interviews to evaluate the acceptance and effectiveness of AI-supported interventions in geriatric care.

Results:
Anticipated Results aim to unveil AI-driven strategies that significantly enhance geriatric pharmacotherapy, contributing to improved medication management and overall patient care for the elderly population. This study strives to provide valuable insights into the practical implementation of AI applications in geriatric healthcare, fostering advancements in personalized and effective treatment approaches.

CP-04

Artificial Intelligence in Personalized Medicine for Pediatric Patients: Exploring Roles and Impact

Syed Jaffer
Department of Pharmacy Practice, Sultan ul Uloom College of Pharmacy,
JNTU Hyderabad Telanagana 500034
syedjaffer@sucp.ac.in

Background:
This study explores the dynamic role of artificial intelligence (AI) in revolutionizing personalized medicine for pediatric patients.

Objectives:
The objective is to harness AI technologies to customize healthcare strategies, thus improving treatment efficacy and minimizing potential risks. The research focuses on evaluating AI algorithms that consider genetic, medical, and environmental factors to tailor treatment plans for individual children. Additionally, it aims to assess the impact of AI-driven decision support systems on healthcare providers' ability to make informed, personalized decisions in pediatric medicine.

Methodology:
The methodology involves a comprehensive approach, combining quantitative and qualitative methods. AI algorithms will analyze diverse pediatric patient data sets, incorporating genetic information, medical histories, and environmental factors. Healthcare providers will participate in simulated scenarios to assess the practicality and effectiveness of AI-driven decision support systems. Moreover, surveys and interviews with parents or guardians will provide insights into the acceptance and satisfaction levels regarding AI-assisted personalized medicine for their children.

Results:
Anticipated results include the identification of AI-driven strategies that significantly enhance personalized medicine for pediatric patients. The study aims to contribute valuable insights into the integration of AI technologies in pediatric healthcare, emphasizing the improvement of treatment precision, reduction of risks,and promotion of positive healthcare outcomes for children.

CP-05

A Cross-Sectional Observational Study to Assess Prescription Pattern, Awareness of Parents regarding Disease and Use of Antimicrobial agents and Cost of treatment in Children Admitted in a Tertiary Care Hospital.

Dr. Jagriti Jha, Dr. Padmaja Marathe Dr. Sandhya Kamat, Dr. Abhilash Saravanan, Dr. Milind Tullu, Dr. Sunil Karande
Department of Pharmacology and Therapeutics and Department of Pediatrics, Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai.
jagritipjha@gmail.com

Backgroud:
Infectious diseases caused 9 million deaths worldwide and 58% of total deaths in children in 2018. Drug utilization studies in children are less owing to lack of standardized drug use indicators.

Objectives:
1. To analyze prescription pattern of antibiotics in hospitalized children using WHO derived pediatric drug use indicators. **2.** To find out awareness of parents, cost of treatment and clinical outcome.

Methodology:
•A cross-sectional observational study [IEC(II)/519/2023; CTRI/2023/09/057669] in 106 hospitalized children (1month to 12 years of age) receiving antibiotics is being conducted at a tertiary care hospital. Statistical analysis has been done using descriptive statistics. •Variables: average number of drugs/ prescription, prescribed daily dose (PDD), Child Defined Daily Dose (cDDD), PDD/cDDD ratio, Child Drug Utilization Index (cDUI), awareness of parents using as pre-validated questionnaire (CVR-1.0), treatment cost analysis and treatment outcome.

Results:
•Number of drugs prescribed was 8.85 per child. Ceftriaxone(20%), Vancomycin(10%), Amoxycillin-clavulanate and Metronidazole(8.6%) and Cefotaxime(7.14%) were commonly prescribed. cDUI of Ceftriaxone was in prescribed range for pre-school children(1.00-1.49), higher for toddlers(1.53-2.04) and school-going children(1.63-2.16). cDUI of Vancomycin was in range for toddlers(0.89-1.19) and school-going children(0.93-1.24), but lower for infants(0.27-0.54) and pre-school children (0.60-0.89). While cDUI of Amoxycillin-clavulanate was in range for all the age groups. •Diseases' awareness among parents was 96.85% (Score: 3.33±1.21, total-4), however drug awareness during hospitalization and at discharge were 48% [3.29±1.72 (total-6)] and 36% [1.25±1.15 (total-3)] respectively. •Average direct and indirect cost were ₹14347.5±7841.95 and ₹10119.79±5051.87 per child respectively. •Clinical improvement was seen in 8.95±5.81 days and 50% children improved with empirical therapy.

Conclusion:
Antibiotics dosing pattern varied for majority of the children vis-à-vis pediatric range of WHO defined daily doses. Awareness regarding use of antibiotics was less satisfactory.

CP-06

An Evaluation of Rationality of Fixed Dose Combinations Prescribed And Their Prescription Pattern.

Dr. Honshil V. Parikh, Dr. Bhavesh M. Vyas
Narendra Modi Medical College Maninagar, Ahmedabad – 380008, Gujarat.
hvparikh9@gmail.com

Objectives:
To evaluate the prescribing practices of fixed dose combinations used.
To assess the rationality of different fixed dose combinations prescribed in Ahmedabad city.

Methodology:
A Cross-sectional study was conducted over a period of 2 months, after ethical approval. The principle investigator visited several pharmacy stores in Ahmedabad. The prescription data was collected and entered into a pre-designed data record form. The FDCs prescribed were evaluated for their rationality and checked for their inclusion in WHO-EML-2021 and NLEM-2022 of India.

Results:
Out of 188 prescriptions, 37 did not have any FDCs. Only one FDC was prescribed in 42.02% of prescriptions. Among all prescriptions, 66 different FDCs were prescribed. Highest numbers of FDCs (15) were prescribed for disorders of Cardio-vascular system. Rational FDCs prescribed were 53(80.3%). Only 5 FDCs and 3 FDCs were prescribed from WHO-EML and NLEM of India respectively.

Conclusion:
FDCs are prescribed very often in clinical practice. Majority of FDCs prescribed had rational combination of drugs. But only few prescribed FDCs belonged to different essential medicines list.

CP-07

The Effect of Topical Versus Intraoperative Infiltration of Epinephrine Solution (1:100,000) on Intraoperative Visualization And Bleeding During Functional Endoscopic Sinus Surgery (Fess) at Tertiary Care Centre, Telangana

Dr.Meher kounen Fatima, Dr.T.Chakradhar, Dr.Karuna Sree, Dr.sudarshan Reddy and Dr.Farheen Sultana

Department of pharmacology, Department of ENT, Osmania medical college, Koti,Hyderabad, Telanagana.

meherkounen@gmail.com

Background:

Adequate surgical field visualization is among the most important factors in preventing complications in functional endoscopic sinus surgery (FESS).

Aim

The aim of this study was to assess the effect of topical cocaine vs adrenaline on surgical field visualization and intraoperative bleeding during FESS.

Methods:

A prospective, randomized, study was performed. Thirty patients undergoing FESS were randomized to have topical application of epinephrine and thirty had irrigation with (1:100,000) epinephrine in normal saline during surgery. Outcomes measure included the Boezaart grading scale to assess the intraoperative surgical field, surgeon's satisfaction with field visualization and bleeding which was evaluated in a 10 cm visual analog scale, estimated blood loss as well as hemodynamic parameter changes.

Results:

There was no statistically significant difference in the studied variables between both groups. However, in patients with higher than 12 Lund-Mackay score (LMS) the volume of blood loss was significantly less in the epinephrine infiltration group. All surgical procedures were completed and there were no operative complications or any reported perioperative cardiovascular events

Conclusions:

Intraoperative irrigation with saline–epinephrine solution at a concentration of (1:100,000) is safe but having not much impact on hemodynamic parameter with better surgical field visualization than topical application of epinephrine.

CP-08

Dasatinib as a Probable Cause of Bilateral Chylothorax in Chronic Myeloid Leukaemia Patient: A Case Report

Dr. Rajvee Parekh1, Dr. Gurusharan Dumra**1**, Dr. Pradip Dabhi**2**
1Pharmacology department, Narendra Modi Medical College, Ahmedabad, India
2 Consultant Pulmonologist Sparsh hospital, Ahmedabad, India.
rkpprakash@gmail.com

Aim:
To present the real-world data of chronic myeloid leukaemia (CML) patient on dasatinib who developed bilateral chylothorax.

Objective:
To assess dasatinib as a cause of bilateral chylothorax using casualty assessment methods.

Methodology:
After obtaining the patient's written informed consent, all data and photos were taken. Expert opinion taken before reporting.

Results:
A 65-year-old male with underlying CML in major molecular response on regular tablet dasatinib 100 mg once daily since November, 2020; presented with breathlessness. Chest X-ray showed bilateral pleural effusion, complemented with chest tomography. There was no evidence of trauma, pulmonary or mediastinal lesions. Dasatinib was withheld. A right intercostal drainage tube (ICD) was inserted and 2.3 litres of pleural fluid aspirated. Pleural fluid analysis revealed exudative effusion with triglyceride of 141 mg/dl, negative for malignant cells and tuberculosis. Lymphoscintigraphy was performed for further chylothorax evaluation. A left sided pleuroscopy was performed, ICD inserted and 1 litre of pleural fluid aspirated revealed exudative effusion with triglyceride of 137 mg/dl. No recurrence on follow up.

Conclusion:
Expert judgement and assessment with Naranjo scale revealed dasatinib as a probable cause of bilateral chylothorax. This case study adds to evidence that dasatinib treatment should be considered as one of the causes of bilateral chylothorax.

CP-09

A Cross Sectional Study to Assess Knowledge, Attitude and Practice Towards E-Learning Among Medical Undergraduates in Tertiary Care Teaching Hospital in Telangana."

Dr Farheen Sultana, Dr P. Srujana Dr N. Karunasree Dr Meher Kounen Fatima

Osmania Medical College, Koti, Hyderabad.

aleenafarheen63@gmail.com

Background:
E-learning is a method of gaining knowledge using electronic media which is getting popularity among students. E -learning can be used in medical education to improve the efficiency of academic deliverance and make the learning sessions more captivating and retainable. E -learner is a person who can use the online material for learning purposes, according to his time and space.

Aim:
the present study was aimed to assess knowledge, attitude and practice towards e-learning among medical undergraduates.

Methodology:
A cross sectional pre validated questionnaire-based study consisting of 19 questions was conducted among 500 medical UGs at Osmania medical college and hospital after ethics approval. Out of 19 questions,1-7 were knowledge based,8-12 were attitude-based questions from 13-19 included practice related questions. Statistical analysis was done using Excel sheet. Chi square test was used to compare variables with p value less than 0.05 was considered statistically significant.

Result and Discussion:
Out of 484 responses (54% were females) 87% of medical undergraduates are aware of term E-learning and possess good knowledge, with positive attitude and 93% had good practice.

Conclusion:
The study has emphasized that E-Learning can be a useful tool in enhancing the learning experience and students are more open towards the upcoming change in teaching methods. The lack of knowledge in computer skills along with poor technological infra structure and resource can be a challenge for implementation of E – learning.

Poster Presentations: Pre-Clinical

Abstract No.	Presenting Author	Mode of Presentation	Title of abstract
PCP-01	Sagar Rajput	Poster	Enhancing Neuroprotection: Metformin and Coenzyme Q10 in Post-Stroke Injury Recovery
PCP-02	Shantanu R Joshi	Poster	To Evaluate the effect of Cap. PCOSNIL ® , a Polyherbal Formulation on Reproductive and Developmental Toxicity
PCP-03	Ajinkya Bavlecha	Poster	Evaluation of Neuroprotective Effect of Phyllanthus Emblica and Allium Sativum in Rotenone Induced Parkinson's Disease in Drosophila Melanogaster
PCP-04	Vinoodh Kumar K	Poster	Evaluation of the Hypolipidemic Effect of Pueraria Tuberosa Extract on High-Fat Diet-Induced Hyperlipidemia in Wistar Rats
PCP-05	Shruti Desai	Poster	Evaluation of cytotoxicity and genotoxicity of Nanocurcumin, Alpha-linolenic acid, and a combination of Nanocurcumin + ALA.
PCP-06	Shubham Kamble	Poster	Formulate and Evaluate the Topical Preparation for the Skin Burn.
PCP-07	Dinker Raj	Poster	Exploring the Antihyperlipidemic Potential of Traditional Indian Therapy in MSG-Induced Hyperlipidemia in mice.
PCP-08	Sushma Kewat,	Poster	Effect of Omega-3 & CoQ10 on Ischemic Cerebral Injury
PCP-09	Lokendra Yadav	Poster	Anti –arthritic Potential of Bioactive Fractionate of Lagerstroemia Speciosa
PCP-10	Sabhyata Chatterjee	Poster	Noscapine Exhibit Neuroprotection in Ovariectomized Female Exposed to Cerebral Ischemic Injury
PCP-11	Komal Gorakshanath Kurhade	Poster	Evaluation of Cardioprotective Effect of S-Adenosyl L-Methionine (Same) on Isoproterenol Induced Chronic Heart Failure (CHF) Model in Wistar Rats.
PCP-12	Sakshi R. Dhonge	Poster	Comparison of Antihemorrhoidal Activity of Oral and Topical Formulations of Dolichandrone Falcata Leaf Extract

PCP-13	Nayan Dinesh Ghime	Poster	In Vivo and In Vitro Studies of Formulation of Citric Acid and Cowry for Treatment of Kidney Stones and Calcium Deficiency
PCP-14	Amruta Gadade	Poster	Evaluation of Efficacy of Kaklarakshak Yog in an Experimental Model of Hypothyroidism
PCP-15	Ayush Kumar Pandey	Poster	Investigation of Acute Pre-injury Treatment of Metformin and Vitamin E in Ischemic Reperfusion Injury
PCP-16	Vipendra Singh	Poster	Exploring the Cognitive Benefits of Banaba in Scopolamine-Induced Dementia
PCP-17	Shanu Rajput	Poster	To Evaluate the Effect of CoQ-10 drug against PTZ Induced Seizure using Zebrafish Model
PCP-18	Mohammad Shahadat	Poster	Evaluation of Curcumin Buccal Formulation against Scopolamine Induced Dementia in Mice
PCP-19	Kapil Baraskar	Poster	Exploring the Therapeutic Potential: Jasminum sambac and β-sitosterol in Rheumatoid Arthritis
PCP-20	Zoya Ali	Poster	Effectiveness of Alendronate and Ketorolac in a TNBS Model of Rat Ulcerative Colitis
PCP-21	Sejal Haldkar	Poster	Evaluation and comparison of Jasminum Sambac and its Phytoconstituent against Oral Candidiasis
PCP-22	Unnati Sahu	Poster	Enhanced Neuroprotection in Cerebral Ischemia-Reperfusion Injury: Evaluating the Combined Effects of Metformin and Vitamin E in a Rat Model
PCP-23	Sahana Parween	Poster	Mitigating Cyclophosphamide-Induced Nephrotoxicity: Investigating the Renoprotective Potential of Dolichos biflorus in rats
PCP-24	Vipin Singh	Poster	Effect of Nicotinamide on Methotrexate Toxicity in Arthritic rats
PCP-25	Apurva Fasate	Poster	Exploratory Studies on Efficacy of Herbal Components for the Treatment of Aphthous Stomatitis.

PCP-01

Enhancing Neuroprotection: Metformin and Coenzyme Q10 in Post-Stroke Injury Recovery

Sagar Rajput1, Vinay Kumar Patel1, Avinash Singh Mandloi1,2, Aman B. Upaganlawar2,
Vipin Dhote1
1Faculty of Pharmacy, VNS Group of Institutions, Neelbud, Bhopal, MP India
2SNJB's SSDJ College of Pharmacy, Chandwad, Nashik, MH, India
rajput28sagar@gmail.com

Introduction:
Stroke, a major cause of death and disability . While Metformin (MET) and Coenzyme Q10 (CoQ10) have shown neuroprotective effects in stroke, limited data exist on their impact on post-stroke disability. This study explores the neuroprotective potential of MET and CoQ10, individually and in combination, on post-stroke brain injury in rats.

Material and Methods:
Using a Bilateral Common Carotid Artery Occlusion (BCCAO) model to induce cerebral ischemia-reperfusion injury in Wistar rats, The groups (n=6) were divided and assigned
treatment as Sham operated and ; Reperfusion Injury (IR) received vehicle [i.m] while
other received MET [200mg/kg/day i.m] CoQ10 [200mg/kg/day i.m] and MET+CoQ10
[200mg/kg/day i.m] respectively . Treatments were administered for 7 consecutive post-stroke days. The study assessed neurological scores NORT , infarct volume, inflammatory markers (Myeloperoxidase enzyme), AChE activity, NO activity, and histological examination.

Results:
MET and CoQ10, both individually and in combination, improved neurological scores and discrimination ratios, indicating a positive impact on post-stroke injury compared to IR. Coadministration significantly reduced infarct volume compared to IR and MET groups indicating advantage of CoQ10 and MET when administered together .

Conclusion:
These findings suggest that co-administration of MET and CoQ10 treatments enhanced the neuroprotective effects exhibited by individual treatment of CoQ10 and MET . However, further studies are needed to elucidate the detailed mechanism responsible for this improved outcome .

PCP-02

To Evaluate the Effect of Cap. PCOSNIL®, A Polyherbal Formulation on Reproductive and Developmental Toxicity

Joshi Shantanu*1, Gogtay Nithya1, Amruta Gadade2, Shruti Desai2and Dighe Vikas2
1 Department of Clinical Pharmacology, Seth GS Medical college & KEM Hospital,, Mumbai, 2National Institute of Research in Reproductive and Child Health, ICMR, Mumbai.
drjoshisr@gmail.com

Background –
Polycystic Ovarian Syndrome (PCOS) is an important cause of infertility. As insulin resistance is a fundamental common pathway in PCOS, metformin is commonly prescribed for this condition in non-obese women. Cap. PCOSNIL® which is a polyherbal formulation marketed for PCOS is marketed but data on its developmental and reproductive toxicity (DART) are lacking.

Objective –
To evaluate safety of Cap. PCOSNIL® on DART in F0 (Parent animals), F1 (Firstgeneration) and F2 (Second generation).

Methods –
Two groups of Wistar rats (6 males and 12 females) were fed Cap. PCOSNIL® in doses of 103 and 206 mg/kg body weight for 14 days and then mated. The control group was given 0.05% Carboxy methyl cellulose. Standard OECD (Organization for Economic Cooperation and Development), guidelines (2001) No. 414 and 421 were followed for DART studies. The blood was tested for haematology and biochemistry. The pups of F1 and F2 generation were sacrificed to check organogenesis and ossification.

Results –
No difference was found in both the groups in hematological, biochemical, histological and hormonal levels in treated animals as compared to control group on PND 75 and organogenesis in pups of F1 and F2 generation was found to be normal post-natal.

Conclusion –
Cap. PCOSNIL® was found to be safe during pregnancy and lactation in Wistar rats

PCP-03

Evaluation Of Neuroprotective Effect of *Phyllanthus Emblica* and *Allium Sativum* in Rotenone Induced Parkinson's Disease in *Drosophila Melanogaster*

Dr. Dnyaneshwar G. Kurle **Dr. Ajinkya Bavlecha,** Mr. Arun Shankar, Dr. Ajinkya Parhe
Department of Pharmacology & Therapeutics, Seth GS Medical college & KEM Hospital, Mumbai, Parel-12
ajinkya.schumi@gmail.com

Aims and Objectives:

Parkinson's disease is a common neurodegenerative condition seen in the elderly and the current measures only address the symptoms. *Phyllanthus emblica* and *Allium sativum* possess antioxidant and anti-inflammatory properties along with neuroprotective functions which this study aims to evaluate.

Methods:

7 days old male Drosophila melanogaster (CsBz) were divided into seven groups (n=30): Normal control, disease control, positive control (L-dopa 1mM), and high & low doses of *Phyllanthus emblica* (0.5 & 0.25%) and *Allium sativum* (0.25 & 0.125%). Parkinson's disease was induced by dissolving Rotenone 125µM in the cornmeal medium. *Drosophila* flies were exposed to the study drugs through the medium for 7 days. On the 8th day, climbing assay was performed followed by estimations of Malondialdehyde, TNF- alpha, and Dopamine levels in the *Drosophila* brain.

Results:

Both high & low doses of *P. emblica* & *A. sativum* showed significant improvement ($p<0.001$) in the climbing ability of *Drosophila* compared to the disease group. They also significantly increased Dopamine and decreased Malondialdehyde levels ($p<0.05$) in the *Drosophila* brain. In particular, a high dose of *P. emblica* was found to be the most effective. However, these effects were less marked than those of the L-dopa group. *P. emblica* & *A. sativum* did not change TNF-alpha levels significantly. ($p>0.05$)

Conclusion:

Phyllanthus emblica & *Allium sativum* were found to be neuroprotective in Rotenone-induced Parkinson's Disease in *Drosophila Melanogaster* with high dose of *P. emblica* being the most effective. They exert a protective influence on dopaminergic neurons probably by reducing oxidative stress.

PCP-04

Evaluation of the Hypolipidemic effect of *Pueraria tuberosa* extract on High-fat diet- Induced Hyperlipidemia in Wistar rats

Dr Vinoodh Kumar K , Dr Shirish S Joshi , Dr Yashashri Shetty, Dr Madhuri Doke
Department of Pharmacology & Therapeutics, Department of Cardiology, Seth G S Medical College and KEM Hospital (KEMH), Mumbai – 400012
mail2vinoodhkumar@gmail.com

Aims and Objective:
Dyslipidemia is the most important factor in the pathogenesis of atherosclerosis. Lifestyle interventions along with high-intensity statin therapy are the first-line management. Only about 20–30% of patients on maximally tolerated statins reach recommended low-density lipoprotein cholesterol (LDL-C) goals. The main aim is to evaluate the hypolipidemic effect of Pueraria tuberosa extract on high-fat diet-induced hyperlipidemia in Wistar rats.

Methodology:
IAEC permission was sought (IAEC/GSMC/05/2022). Wistar rats of either sex around 150-200 grams were divided into 5 groups (n= 8). Group I (Normal control) received a normal diet while Group II (disease control), Group III (Atorvastatin 10mg/kg/day), Group IV (PTE 50mg/100g/day) and Group V (PTE 100mg/100g/day) received high-fat diet for 45 days. Atorvastatin and *Pueraria tuberosa* aqueous extract (PTE) were given from the 15th day to the 45th day to the respective groups. Lipid profile, and atherogenic index, were analyzed and compared between groups using one-way ANOVA followed by post hoc analysis ($p<0.05$).

Results:
Aqueous extract of PTE (100mg/100g/day) had significantly decreased total cholesterol, and LDL-C, compared to the disease control group.

Conclusion:
Pueraria tuberosa aqueous extract has a hypolipidemic effect.

PCP-05

Evaluation of cytotoxicity and genotoxicity of Nanocurcumin, Alpha-linolenic acid, and a combination of Nanocurcumin + ALA.

Ms. Shruti Desai, Mr. Anirudh Tiwari, Ms Shilpa Kerkar, Mr. Sudhir Jadhav, Ms. Amruta Gadade, Dr. Ganesh Aderao and Dr. Vikas Dighe*,
ICMR-National Institute for Research in Reproductive and Child Health, Parel, Mumbai
dighev@nirrch.res.in

Aim:
To study the cytotoxic and genotoxic effects, and antioxidant potential of Alpha-Linolenic acid (ALA), Nano-curcumin (NC), and their combination.
Objectives: i)To study cytotoxicity of NC, ALA, and its combination using MTT assay, ii)To study the genotoxicity of NC, ALA, and its combination using *in-vivo* comet assay, iii)To study the impact of NC, ALA, and its combination on oxidative stress
Methodology:
(i) HTR8/SVneo human placental trophoblast cells were incubated overnight at 10000 cells/ well in 96 well plates. Cells were treated with different concentrations of NC, ALA, and a combination dose of NC and ALA in triplicate for 24 hours. Cell viability was analyzed using MTT reagent. **(ii)** Sixteen female Wistar rats were divided into four groups (Vehicle control, NC, NC+ALA, and Positive control) each of four rats. And dosed with respective doses for six days and on the seventh day blood samples were collected and processed for the comet assay. **(iii)** Thirty animals were inducted for the study group as Vehicle control, Curcumin, NC, ALA, and NC+ALA. Animals were dosed from preconception day 14 and continued until GD 20. The liver samples collected were snap-freeze and kept at -80 ℃ till further analysis. Snap-frozen liver samples were further homogenized and supernatants were used for the estimation of oxidative stress markers.
Results:
NC ALA and normal Curcumin promote cell proliferation and cell viability at dosages up to 50µM for NC and normal Curcumin at up to 10µM for ALA in the HTR8/SVneo cell line. There were no significant changes observed in the treatment group after 6 days of daily dosages. However, the positive control group (injected with cyclophosphamide) exhibited significantly higher DNA damage in terms of higher no. of comet cells compared to other groups. The MDA levels were decreased in the treatment groups compared to the control group. Superoxide Dismutase level was increased in ALA treated group as compared to the control group.
Conclusion: Nano-curcumin (NC) and Alpha-Linolenic acid (ALA) combination was found to be non-cytotoxic and non-genotoxic, and with antioxidant properties.

PCP-06

Formulate and Evaluate the Topical Preparation for the Skin Burn.

Mr. Shubham Kamble, Dr. Govind Lohiya, Mr. Mohit Saktel

Department of Pharmaceutics, Gurunanak college of pharmacy, Behind C.P. Foundry,Near Dixit Nagar , Kamptee road , Nari , Nagpur , Maharashtra 440026 (India)
shubhkamble121@gmail.com

Background:
Addressing skin burns in healthcare poses a significant challenge, requiring specific interventions to facilitate effective wound healing and optimize resource allocation.

Aim:
The purpose of this study is to formulate and evaluate the topical preparation for the skin burn.

Method:
The Nano silver was synthesized using microwave-assisted synthesis with hyaluronic acid as a reducing agent. Design expert software was used to optimize the process, focusing on particle size and zeta potential.

Results and Discussion:
The study aimed to assess the synergistic antimicrobial effect of combining Neomycin with Nano silver to combat sepsis. Two formulations, a traditional spray, and a gel, were specifically developed for this purpose. Efficacy testing involved utilizing a burn wound model on rats and employing the hot plate method for evaluation. Antibacterial assessments included determining the minimum inhibitory concentration (MIC) and zone of inhibition against *S.Aureus*. It was found that the MIC of Neomycin and Nano silver individually was 10 µg/ml, while their combination significantly reduced the MIC to 0.1 µg/ml. Furthermore, the combined treatment exhibited a larger zone of inhibition compared to individual treatments. The study successfully demonstrates the synergistic antimicrobial effects of combining Neomycin and Nano silver against *S.Aureus*.

Conclusion:
Histopathological examination revealed superior wound healing in the spray-treated group compared to the gel-treated group. Future research could explore the development of a film-forming spray incorporating Poloxamer 407 and a novel combination of Nano silver, Neomycin, and hyaluronic acid for treating skin burns.

PCP-07

Exploring the Antihyperlipidemic Potential of Traditional Indian Therapy in MSG-Induced Hyperlipidemia in mice.

Dinker Raj, Anish Kumar, Kapil Baraskar Avinash Singh Mandloi
VNS Group of Institutions, Faculty of Pharmacy, Bhopal, MP, India
rajdinakar10@gmail.com

Background:
Hyperlipidemia, a prevalent disorder in developed countries, is a major contributor to coronary heart disease. Traditional Indian therapy has shown promise in addressing hyperlipidemia. This study aims to assess the antihyperlipidemic potential of traditional therapy (fresh *Zingiber officinale* (ZO), dried *Zingiber officinale* (ZO), and *Terminalia chebula* (TC)) in mice with monosodium glutamate (MSG)-induced hyperlipidemia.

Methods:
Hyperlipidemia was induced in mice by administering MSG (4mg/kg, orally) for 28 days. Animals were divided into different groups: Control (Vehicle); MSG; Standard (fenofibrate 20 mg/kg; p.o.), Traditional therapy (Fresh ZO + Dried ZO+ TC, 12.5mg/kg, 10 mg/kg, 20mg/kg, respectively; p.o.), Dried ZF (10mg/kg; p.o.), TC (20mg/kg; p.o.). Treatments were administered from the 14th to the 28th day. On the 28th day, various parameters, including lipid profile, ALT, AST, oxidative stress, and histopathology, were assessed.

Results:
Traditional therapy groups significantly ($p<0.05$) reduced lipid profile (LDL, VLDL, TG, Cholesterol) compared to the MSG group. Further, HDL levels were significantly increased in the Traditional therapy group compared to the MSG group. Similarly, ALT and AST levels were significantly reduced in the Traditional therapy groups. Moreover, Lipid peroxidation (LPO) was significantly lower in the Traditional therapy group than in the MSG group. Liver histology in the Traditional therapy groups showed less steatosis compared to the MSG group.

Conclusion:
These findings suggest that the traditional therapy of fresh ZO, dried ZO, and TC exhibits antihyperlipidemic potential, possibly due to its potent antioxidant activity. Further studies are warranted to explore the detailed mechanism of action of this therapy.

PCP-08

Effect of Omega-3 & CoQ10 on Ischemic Cerebral Injury

Sushma Kewat, Priyanshi Kapoor, Avinash Singh Mandloi, Asher John Mohan, Vipin Dhote
VNS Group of Institutions, Faculty of Pharmacy, Bhopal, MP, India
imsushikewat410@gmail.com

Background:
Cerebral ischemia, characterized by impaired blood supply to the brain, results in neuronal injury. However, quick reperfusion of ischemic cells exhibits extensive cell death due to exacerbated inflammatory and free radical reactivity. We hypothesized additional benefits in reperfusion injury with simultaneous administration of Omega-3 & CoQ10.

Objective and Methodology:
This study aims to assess the combined impact of CoQ10 and Omega-3 on cerebral ischemia-reperfusion injury. IR is induced by a 15-minute bilateral common carotid artery occlusion followed by 24 hours of reperfusion. Animals are grouped as Sham-operated, IR, Omega (10mg/kg p.o.), CoQ10 (200mg/kg p.o.), and combination (Omega+CoQ10). All animals receive oral treatment for 14 days before reperfusion injury induction. After 24 hours, assessments include neurological score, locomotion, anxiety parameters, infarct size, blood-brain barrier permeability, and oxidative stress.

Results:
Combination of Omega and CoQ10 significantly ($p<0.05$) ameliorates the neurological score, % infarcted area (13.20±3.4 vs 79.89±7.6) and BBB permeability (43.7±3.7 vs 85.6±0.8 µg/ml) as compare to IR group. Further, Combination treatment attenuates the LPO (1.20±0.06 vs 2.30±0.11) as compare to IR group, whereas SOD and GSH level were significantly augmented by combination treatment.

Conclusion:
The study highlights the neuroprotective potential of the CoQ10 and Omega-3 combination, which could be the result of potent antioxidant activity. Further studies are required to explore the detailed mechanism of this combination.

Keywords:
Co-enzyme Q10, Omega fatty acid, Ischemia reperfusion, oxidative stress, Blood brain barrier.

PCP-09

Investigating of Banaba on CFA Induced Rheumatoid Arthritis in Rats"

Lokendra Yadav, Akhilesh Kumar Gupta, Kapil Baraskar
Faculty of Pharmacy, VNS Group of Institutions, Bhopal, Madhya Pradesh, India
lokendray367@gmail.com

Background:

Rheumatoid arthritis (RA) significantly affects quality of life, with structural deformities and inflammatory signs adding to patient inconvenience. A multipronged approach addressing inflammation, bone destruction, and pain sensation is crucial. *Lagerstroemia speciosa* (Banaba) is reported to be effective in inflammatory and glucose dysregulation disorders. We hypothesized *Banaba's* potential benefits in an experimental RA rat model, exploring its therapeutic outcomes in experimental induced RA in rats.

Materials and method:

RA was induced by injecting complete Freund's adjuvant (CFA) 0.1% intradermally in the base of the rat tail. The animals were divided into different groups (n=6), Vehicle control (Vehicle, p.o.), Adjuvant Induced Arthritis (AIA) (0.1% CFA), Diclofenac sodium (10mg/kg p.o.), Banaba-5 (Banaba 5mg/kg p.o.), and Banaba-10 (Banaba 10 mg/kg p.o.). After 28 days of CFA administration, various parameters were evaluated including paw swelling, arthritis score, body weight, spleen & thymus weight, oxidative stress, Hb & ESR level, and histology of joints.

Results:

Banaba extract notably reduced paw volume (2.09±0.04 Vs 2.51±0.16) and ESR levels (13.75±0.62 Vs 6.50±0.50) compared to the AIA group. Additionally, SOD (0.39±0.20 Vs 1.51±0.80) and GSH levels (1.39±0.32 Vs 5.21±0.96) were significantly elevated compared to the AIA group. Banaba treatment resulted in a significant ($p<0.05$) reduction in LPO level (108.22±34.52 Vs 35.42±8.53) compared to AIA. Furthermore, ESR and Hb levels were significantly restored compared to the AIA group. Histologically, Banaba treatment indicated an increased joint space compared to the AIA group.

Conclusion:

This study provides scientific evidence of the effectiveness of methanolic extract of *Banaba* leaves as anti-inflammatory and anti-arthritic medication supporting the common traditional beliefs and uses.

PCP-10

Noscapine Exhibit Neuroprotection in Ovariectomized Female Exposed to Cerebral Ischemic Injury

Sabhyata Chatterjee*, Shraddha Mishra, Kapil Baraskar, Avinash Singh Mandloi
VNS Group of Institutions, Faculty of Pharmacy, Neelbud, Bhopal, MP, India
Sabhyata.chatterjee10@gmail.com

Background:

Estrogen imparts additional neuroprotection in female rats exposed to cerebral or cardiac ischemic injury. We explored the role of noscapine on gender specific neuroprotection in cerebral ischemia reperfusion injury (IR) in ovariectomized rats.

Objective and Methodology:

To investigate additive or synergistic effect (if any) of noscapine in rats exposed cerebral IR injury. IR was induced by 2 hours of middle cerebral carotid artery occlusion, followed by 72 hours of reperfusion. Rats were divided into sham-operated, IR, noscapine (10mg/kg i.p.), and noscapine (10mg/kg i.p.) ovariectomized groups. Treatment preceded IR injury by 7 days. After 72 hours of reperfusion, evaluations included neurological deficit, infarct analysis, oxidative stress (SOD, LPO, and GSH), Myeloperoxidase (MPO), BBB permeability, and histopathology.

Result:

Noscapine treatment improved neurological scores, reduced brain infarction, and enhanced BBB permeability in intact and ovariectomized female rats. Additionally, SOD and GSH were significantly restored, while LPO and MPO were significantly reduced in noscapine-treated intact and ovariectomized female rats as compared to IR. Brain histology indicated fewer signs of pyknosis and cellular injury in noscapine-treated rats compared to IR. No significant differences were recorded in all outcomes between intact and ovariectomized female rats.

Conclusion:

Neuroprotection was equally observed in ovariectomized and intact female after 7 day noscapine treatment. It could be attributed to potent effect on free radical & inflammation through its bradykinin receptor antagonistic activity.

PCP-11

Evaluation of cardioprotective effect of S-Adenosyl L- Methionine (SAMe) on isoproterenol induced Chronic Heart Failure (CHF) model in Wistar rats

Dr. Komal Gorakshanath Kurhade1, Dr. Sharmila Jalgaonkar1, Dr. Raakhi Tripathi1.

Dr. Pradeep Vaideeswar2 and Dr. Pradip Chaudhari3
1 Department of pharmacology and therapeutics ,
2Department of Pathology, Seth GSMC and KEM Hospital, Mumbai,400012, India
3Tata Memorial Centre, Secor-22, Kharghar, Navi Mumbai.

komalkurhade25@gmail.com

Aims & Objectives:

The development and progression of CHF as well as hypertrophy and remodeling are strongly correlated with myocardial inflammation and oxidative stress.

S- adenosylmethionine(SAMe) available as a dietary supplement exerts anti-inflammatory and antioxidant effects. Protective effect of SAMe in animals or humans is not reported in literature. The study objective was to investigate the cardioprotective effect of SAMe in isoproterenol induced CHF and to explore the anti-inflammatory and antioxidant property of SAMe in this model.

Methods:

After Animal ethics permission(IAEC/GSMC/04/2020), CHF was induced using isoproterenol(ISO) of 10 mg/kg for 14 consecutive days in 18 wistar rats. The animals were randomly divided into 4 groups of 6 rats in each group, Sham Control(SC),Disease Control (DC),ISO+SAMe 100mg/kg ,ISO+ SAMe 200mg/kg (SAMe administered simultaneously from Day1-14). The variables assessed were Heart to body weight percent ratio(HW/BW%), biodistribution of 18FDG in heart tissue, PET imaging followed by TNFα & GSH levels in heart tissue and histopathology(Grading by veterinary pathologist: Distribution of Lesions- Focal, Multifocal, Diffuse, Severity of lesions: Mild, Moderate, Marked). The variables were assessed using Repeated measures ANOVA($p<0.05$) followed by post-hoc Tuckey test using graph pad 3.06.

Result:

SAMe in ISO induced CHF animals showed significant decrease of percent heart to body weight ratio compared to DC group ($p<0.001$).18F-FDG uptake was significantly reduced by SAMe in CHF-induced rats compared to disease control rats for both doses ($p<0.001$).Values of TNF α significantly reduced while GSH were significantly increased when compared with DC group for SAMe in both doses100mg/kg and 200mg/kg($p<0.001$).SAMe in both doses showed good histopathological improvement.

PCP-12

Comparison of Antihemorrhoidal Activity of Oral and Topical Formulations of *Dolichandrone Falcata* Leaf Extract

Ms. Sakshi R. Dhonge , Dr.Vaishali Kilor, Ms. Pragati M. Jibhkate
Department of Pharmaceutics, Gurunanak college of Pharmacy, Behind C.P. Foundry,Near Dixit Nagar, Kamptee road, Nari, Nagpur, Maharashtra 440026 (India)
dhongesakshi@gmail.com

Background and Objective:
The *Dolichandrone falcat*a leaves have been traditionally used by healers of India for the treatment of hemorrhoids due to their anti-inflammatory and antioxidant activity. However, no studies have been reported that compare the activity of these leaves when given by different route of administrations. Therefore, in the present work, it was envisaged to compare the activity of oral and topical formulations.

Method:
For topical route, gel formulation was developed using ethanolic extract of D. falcata with Carbopol 934, sodium CMC and HPMC K100 polymer. For oral route, tablets were formulated containing D. Falcata extract, lactose, MCC, sodium starch glycolate, magnesium stearate and talc, using direct compression method. The activity of both the formulations was compared using croton oil induces hemorrhoid model in rats. The croton oil solution induced in ano-rectal region of wistar rats for five days. Two standard groups received Pilex ointment and tablets by topical and oral routes. Similarly, two treatment groups received test formulations. The parameters measured swelling index, body weight, and histopathological changes.

Results:
The in-vivo study on day 6 of treatment D. falcata tablets exhibited maximum reduction in swelling (0.38+0.06). D. falcata gel exhibited maximum weight gain. Histopathology indicated healing in all groups' ano-rectal tissues.

Conclusion:
It can be concluded that D. falcata extract is effective by both topical and oral routes however, the efficacy is slightly higher by topical route. for the treatment of hemorroids.

PCP-13

In-Vivo and In-Vitro Studies of Formulation of Citric Acid and Cowry for Treatment of Kidney Stones and Calcium Deficiency

Mr. Nayan Dinesh Ghime, Mr. Manmay Makkad , Dr. Govind K. Lohiya , Dr. Sheelpriya R.Walde

Department of Pharmaceutics, Gurunanak College of Pharmacy, Behind C.P. Foundry , Near Dixit Nagar , Kamptee road , Nari , Nagpur , Maharashtra-440026

nayanghime5@gmail.com

Background:

Kidney stones cause urinary tract blockage, resulting in severe pain, haematuria, vomiting, and painful urination. Around 80% of the global population suffer from this condition, primarily Calcium Oxalate Stones. A calcium-restricted diet is advised to minimize stone formation risk, potentially causing calcium deficiency. Treatment involves Citric Acid and Cowry combination.

Aim and Objective:

The primary purpose of this study is to treat kidney stones and to minimize the calcium level depletion.

Methodology:

Sodium Oxalate induced kidney stones rat model was used. Solutions of different concentrations containing Cowry in Citric acid were prepared and were subjected to evaporation in sunlight. The obtained powder was granulated using PVP K-30 as binder and granules were compressed to form tablets. The in-vitro study of this tablets was performed. The solutions of different concentrations were orally administered to the rats and in-vivo investigations were carried out using renal ultrasonography.

Results and Discussion:

The optimum concentration of Citric Acid to dissolve Cowry was found to be 5% w/v. Renal ultrasonography showed and confirmed the complete dissolution and removal of kidney stones from the kidney.

Conclusion: Citric Acid and Cowry can be used for the effective treatment of Kidney Stones and Calcium Deficiency.

PCP-14

Evaluation of Efficacy of Kaklarakshak Yog in an Experimental Model of Hypothyroidism

Ms. Amruta Gadade1, Mr. Anirudh Tiwari1, Ms. Shruti Desai1, Mr. Sudhir Jadhav1, Mr.Pravin Salunke1 , Mukesh Chawda2 and Dr. Vikas Dighe1*
1ICMR-National Institute for Research in Reproductive and Child Health. Jehangir Merwanji Street, Parel, Mumbai 400012, 2Shree Dhootapapeshwar Limited, Mumbai
dighev@nirrch.res.in

Background:
Hypothyroidism is one of the most communal pathological conditions in current clinical practice. Various therapeutic modalities are being employed for the treatment.

Aim and Objective:
To evaluate the efficacy of Ayurved formulation **Kaklarakshak Yog** in methimazole-induced hypothyroidism model of female Wistar rats

Materials and Method:
A total of 42 Female Wistar Rats aged 6-8 weeks were selected and 36 rats were randomly selected for induction of hypothyroidism using 0.04% Methimazole in drinking water for 28 days. The remaining 6 rats were administered vehicle(0.002% Gum Acacia). The animals were divided into group **Group I** (Vehicle Control Group)**, Group II** -Positive Control Group (Hypothyroidism induced), **Group III Kaklarakshak Yog - Low Dose** (269 mg/kg BW), **Group IV: Kaklarakshak Yog - High Dose** (403 mg/kg BW). **Group V: Thyroxin** (20 mcg/kg BW), **Group VI: Thyroxin** (20 mcg/kg BW) + **Kaklarakshak Yog - Low Dose,** and **Group VII: Thyroxin** (20 mcg/kg BW) + **Kaklarakshak Yog - High Dose** [**THY + KRY-HD]**. The medications were gavaged orally for 28 days after Hypothyroidism induction. Weekly Body weights, feed intake, and water consumption was recorded. On the day of the sacrifice, the blood samples were collected to analyze biochemical and hematological parameters. Total serum T3, T4, and TSH levels were estimated by the ELISA method. The animals were sacrificed as scheduled for the collection of vital organs for histology.

Results:
KRY exhibited a promising hormonal effect in reversing methimazole-induced hypothyroidism, as evident from the reversal of altered T3, T4, and TSH levels. **KRY**, when administered alone, partially mitigated the effects of hypothyroidism, with higher **KRY** doses yielding more prominent results. **KRY** when administered alone was not as comprehensive as thyroxine treatment. Intriguingly, a synergistic effect emerged/was observed when **KRY** was combined with Thyroxine, significantly enhancing hypothyroidism normalization, particularly with a higher dose of **KRY**.

Conclusion:
This research suggests the potential of **KRY** in influencing thyroid hormone levels and holds significance for future investigations into Ayurved remedies for hypothyroidism management.

PCP-15

Investigation of Acute Pre-Injury Treatment of Metformin and Vitamin E in Ischemic Reperfusion Injury."

Ayush Kumar Pandey, Vishal Amrode, Asher John Mohan, Avinash Singh Mandloi
Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India
ayushpandey4053@gmail.com

Background:
Stroke is a prevalent global health issue, with ischemic strokes constituting 87% of cases, caused by blocked blood flow to the brain. Metformin (MET) and Vitamin-E (Vit-E) has been investigated for the ischemia brain injury. However, limited information is available for their combination effect. Current study aiming to assess their combined impact on cerebral ischemia-reperfusion injury (IR).

Methods:
Rats underwent 15-minute bilateral common carotid artery occlusion (BCCAO) followed by 24-hour reperfusion to induce ischemia-reperfusion (IR). Groups included Sham (no artery occlusion), IR (Vehicle), MET (200 mg/kg, p.o.), Vit-E (100 mg/kg, p.o.), and MET+Vit-E. Treatments were administered three days pre-BCCAO. Post-reperfusion, evaluations encompassed neurological score, infarct analysis, oxidative stress, Blood-Brain Barrier (BBB) permeability, and histopathology.

Results and Discussion:
Pre-injury MET and Vit-E combination treatment enhances neurological scores, significantly reduces brain infarct size (12.20±1.29 vs 44.11±0.76) compared to IR. BBB integrity notably improves with the combination (2.48±0.28 vs 4.54±0.09) versus IR. The combo boosts SOD (8.06±0.10 vs 3.71±0.07) and GSH (37.08±2.29 vs 11.08±0.48) levels, while lowering LPO (9.57±0.49 vs 15.24±0.61) compared to IR. Hippocampal histology in combination treated brains exhibits fewer pyknotic than in IR.

Conclusion:
The pre-injury combination treatment of MET and Vit-E indicates potent antioxidant action, contributing to the neuroprotective effect against IR brain injury. The combination demonstrates enhanced efficacy, warranting further evaluation to explore its detailed mechanism and its impact on post-injury treatment.

PCP-16

Exploring the Cognitive Benefits of Banaba in Scopolamine-Induced Dementia

Vipendra Singh, Avinash Singh Mandloi,
Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India
vipendrasingh0204@gmail.com

Background:

Dementia refers to a substantial decline in cognitive function, disrupting daily activities. Global estimates suggest up to 7% of individuals over 65 have dementia. Banaba (*Lagerstroemia speciosa*) is known for its anti-inflammatory and antioxidant properties, which can countering learning and memory impairment linked to dementia. This study investigates Banaba's impact on scopolamine-induced dementia in rats.

Methods:

Dementia was induced in rats by 7-day scopolamine injection (4mg/kg; i.p.).
Groups included Control (Vehicle), Scopolamine (4mg/kg; i.p.), Donepezil (3mg/kg; i.p.), Banaba100 (Banaba extract 100mg/kg; oral), and Banaba200 (Banaba extract 200mg/kg; oral). All treatments were administered for 7 days. Throughout the experiment, animals underwent training for novel object recognition, elevated plus maze, and Y-maze tests. On the last day, discrimination ratio, spontaneous alteration, transfer latency and histology were assessed.

Results and Discussion:

Banaba treated groups significantly augmented the discrimination ratio and % spontaneous alteration as compare to the only scopolamine treated group. Further, transfer latency was significantly reduced on elevated plus maze as compare to the scopolamine group. Notably in all cognitive parameters Banaba 100 mg/kg shows better effect as compare to the Banaba 200 mg/kg. Further, brain histology indicates less sing of cellular injury in Banaba treated groups as compare to the scopolamine treated group.

Conclusion:

Banaba treatment improves the learning and memory impairment associated with dementia. A lower dose of Banaba exhibits better efficacy compared to a higher dose, possibly due to the modulation of other physiological mechanisms at higher doses. Further studies are required to evaluate the complexity of Banaba's mechanism of action.

PCP-17

To Evaluate the Effect of CoQ-10 Drug against PTZ Induced Seizure using Zebrafish Model

Shanu Rajput, Mahima Gupta, Manisha Kawadkar, Avinash Singh Mandloi,
Faculty of Pharmacy, VNS ~~Group of Institution, Bho~~pal, Madhya Pradesh, India
shanu47rajput@gmail.com

Background:

Zebrafish have emerged as a high-throughput model for screening pharmacological activities. Epilepsy is often associated with disturbances in learning and memory. CoQ-10 has reportes of being efficient as a neuroprotective agent.

Objective:

To investigate the Anti-Convulsion effect of CoQ-10 drug against PTZ induced Seizures in Zebrafish model.

Methods:

Zebrafish were treated as per the groups; Control group (water), Negative control group (pentylenetetrazole, PTZ, 5mg/ml), Standard (Phenytoin group) (1mg/15ml)+PTZ (5mg/15ml), CoQ-10 varying doses (0.25mg/15ml, 0.50 mg/15ml, 0.75 mg/15ml, 1 mg/15ml, 1.25mg/15ml, 1.50 mg/15ml, 1.75 mg/15ml, 2 mg/15ml, 4 mg/15ml). The Seizure scores, T-maze test,of cognition light dark test, group behavioural task, Shoal Cohesion and locomotion tests were used to determine anticonvulsant effect and cognitive abilities.

Results and Discussion:

All varying doses of 1mg/15ml, CoQ-10 dramatically reduced the severity of PTZ-induced seizures in Zebrafish and increased their cognitive abilities. In Zebrafish, CoQ-10 increased motor coordination.

Conclusion:

Our present findings demonstrated the anticonvulsant potential of CoQ-10. We hence suggest that it could be employed in epilepsy treatment, however, further studies are required to verify its activity in other experimental seizure models.

PCP-18

Evaluation of Curcumin Buccal Formulation against Scopolamine Induced Dementia in Mice

Mohammad Shahadat, Avinash Singh Mandloi, Asher John Mohan, Vipin V. Dhote
Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India
mohdshahadat300@gmail.com

Background:
Memory loss and other cognitive problems are hallmarks of dementia. Curcumin has been found beneficial in the treatment of this illness. However, its limited oral bioavailability necessitated the development of formulations using nanotechnology.

Objective:
We designed this study wherein the effect of curcumin nano fibers was evaluated against scopolamine induced dementia in mice.

Methods:
Swiss albino mice were pre-treated with curcumin nano fiber (100 mg/kg) buccal dose and standard curcumin powder (50 mg/kg) orally for 14 consecutive days. Dementia was induced by scopolamine (2 mg/kg, i.p.) after pre-treatment for 14 consecutive days. Further behavioral, biochemical, and histopathological analyses were performed.

Result and Discussion:
Scopolamine (51.63 ± 3.16 seconds) was found to impair memory and cognition. The nano formulation of curcumin (94.13 ± 6.70 seconds) was found to be significantly superior as compared to conventional curcumin powder (72.63 ± 5.64 seconds) based on a behavioral probe employing the Y-maze. The level of Acetylcholinesterase activity was enhanced in the scopolamine group (7.77 ± 0.36) and decreased in the curcumin nanofiber treatment group (2.93 ± 0.11) and plain curcumin (4.31 ± 0.15). Supportive histopathological findings exhibited the fact that curcumin prevented the degeneration of pyramidal cells in the brain hippocampus.

Conclusion:
We have hence concluded that the use of curcumin nanofibers as a formulation strategy not only helped to produce a stable oral product, but additionally worked out to be far more advantageous than the traditional and standard form of powdered curcumin in terms of its ability to treat dementia. This approach could thus be considered as a potential application of utilising buccal nano formulations of curcumin for the treatment of dementia related to Alzheimer's.

PCP-19

Exploring the Therapeutic Potential: *Jasminum sambac* and β-sitosterol in Rheumatoid Arthritis

Kapil Baraskar, Rajat Rathore, Avinash Singh Mandloi
Faculty of Pharmacy, VNS Group of Institutions, Bhopal, MP, India
Kapilbaraskar017@gmail.com

Background:
Jasminum sambac (JS) is recognized for its potential anti-arthritic effects and traditional analgesic use. β-sitosterol (BS) is one of the constituents of JS which could be responsible for its antiarthritic potential. This study aims to compare the anti-arthritic effects of JS and BS in adjuvant-induced arthritis.

Materials and Method:
The rats injected with Complete Fruend's Adjuvant (CFA 10mg/ml; 0.1ml) and treatment (day 0 to 28) with vehicle (control), ethanolic extract of JS (JSE 400 mg/kg) and β- sitosterol (BS) (2 mg/kg). Parameters estimated were clinical signs, oxidative biomarkers and inflammatory markers along with ankle joint destruction, using CT scan technique.

Results:
JSE treatment significantly reduced paw volume (2.27±0.11 vs. 6.64±0.14), and BS groups also saw a significant reduction (5.27±0.04 vs. 6.64±0.14) compared to the CFA-induced group. Arthritis scores were markedly reduced in both JSE and BS treated groups. Additionally, Hb levels increased, ESR improved in both JSE and BS groups compared to the CFA group. SOD and GSH levels were elevated, while LPO levels were reduced in both JSE and BS groups. CT scans revealed normal joint space in both groups, and joint histology showed less leukocyte infiltration and a normal synovial membrane.

Conclusion:
The results show JSE's anti-arthritic activity, but β-sitosterol alone did not exhibit similar efficacy. This suggests that JSE's potent anti-arthritic activity is not solely due to β-sitosterol but may involve other essential chemical constituents contributing to observed relief in rheumatoid arthritis in rats.

PCP-20

Effectiveness of Alendronate and Ketorolac in a TNBS Model of Rat Ulcerative Colitis

Zoya Ali, Sandeep Sahu, Chanda Malviya, Kapil Baraskar, Avinash Singh Mandloi
Faculty of Pharmacy, VNS Group of Institutions, Bhopal, MP India
zoyaali96786@gmail.com

Background:
Inflammatory bowel disease (IBD) is a chronic remitting and relapsing inflammatory disorder encompassing ulcerative colitis and Crohn's disease. Alendronate (ALN) inhibits osteoclast activity and reduces bone resorption, whereas Ketorolac (KET) is a nonsteroidal anti-inflammatory drug (NSAID) that inhibits COX-II. In the present study, we are exploring the efficacy of ALN and KET on experimentally induced ulcerative colitis in rats.

Material and Methods:
Ulcerative colitis was induced in fasted rats under light anesthesia. TNBS (10mg/0.5 ml) dissolved in 50% ethanol was instilled into the colon (0.5 ml per rat) on day 1. Animals were randomized into four groups: Control (Vehicle), TNBS control (TNBS, 0.5 ml/rat), ALN (Alendronate 25mg/kg; oral), KET (Ketorolac 10mg/kg; oral). Treatments started on day 7 and continued until day 14 of TNBS induction. On day 14, animals were assessed for body weight loss, ESR, colon ulcer score, morphological assessment, oxidative stress, and histology.

Results:
Body weight loss and ESR significantly decreased in ALN and KET groups compared to TNBS. Both ALN and KET treatments resulted in significantly lower ulcer scores and less colon damage (ulceration and necrosis) than the TNBS group. Moreover, GSH levels were significantly elevated in ALN and KET groups compared to TNBS. Histology of ALN and KET-treated colons revealed less inflammatory cell infiltration and normal crypt structure.

Conclusion:
Present study demonstrated that ALN and KET were effective in the TNBS model of rat colitis, a widely employed preclinical models of IBD.

PCP-21

Evaluation and Comparison of *Jasminum sambac* and its Phytoconstituent against Oral Candidiasis

Sejal Haldkar, Avinash Singh Mandloi, Asher John Mohan, Vipin V. Dhote
Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India
haldkarsejal6@gmail.com

Background:
Oral candidiasis (OC), also known as oral thrush, is a fungal infection induced by candida albicans in oral cavity. The current treatments include Amphotericin B (AMB) & fluconazole, with reports of undesirable effects warranting the development new therapeutic options for OC. Herbs, with specific phytoconstituents (Beta-sitosterol) may resolve both purposes of the treatment. Hence, we emphasized on *Jasminum sambac* (*JS*) its constituents for systemic *in-vivo* & *in-vitro* investigation against *Candida albicans* (*C. albicans*).

Objective:
To investigate the antifungal effect of *JS* & its Beta-sitosterol (BIT) using rat model of oral candidiasis.

Method:
In vitro evaluation of *JS* was performed against *C. albicans* using well agar diffusion methods, following which Immunocompromised Wistar rats employing Prednisolone (50 mg/kg) were used *in-vivo* for the development of OC prior to the inoculation with *C. albicans*. The rats were given a 14-day treatment as per the groups; Control group (5% CMC), OCA (1.0*105 viable cells/mL of *C. albicans*), Standard (Amphotericin-B 5mg/Kg, PO, BID), *JS* (200 mg/kg, PO, OD), and Beta-Sitosterol (BIT 2 mg/kg, PO, OD). Body weight, feed weight, body temperature, Colony forming units (CFU), tongue scores and histology (tongue and kidney) were the parameters assessed.

Result and discussion:
JS was found to be equally efficacious as an anti-fungal when compared to standard AMB with respect to tongue scores 1 (0.5-1.5) and colony forming units (18700.00±547.50). No significant difference was found between the whole extract of *JS* and BIT. However, upon histopathological examinations an undesired nephrotoxic effect of AMB was observed in kidney samples of rats (such as deterioration of renal capsules, glomeruli, and interlobular rays). This absent in both the whole extract as well as its phytoconstituent.

Conclusion:
This study hence proposes that the phytoconstituent BIT alone could not be efficacious as an antifungal. The need for further investigations involving the identification of phytoconstituents other than BIT to provide in-depth knowledge of *JS* for the treatment of OC is a necessity

PCP-22

Enhanced Neuroprotection in Cerebral Ischemia-Reperfusion Injury: Evaluating the Combined Effects of Metformin and Vitamin E in a Rat Model

Unnati Sahu1, Avinash Singh Mandloi1,2, Aman B. Upaganlawar2, Vipin V Dhote1
1Faculty of Pharmacy, VNS group of Institutions, Neelbad, Bhopal, MP, India
2SNJB's, SSDJ College of Pharmacy, Chandwad, Nashik, MH, India
unnatisahu21@gmail.com

Background:
Stroke disables more than it kills. Stroke survivors often experience impaired quality of life; cognitive disability. Metformin (MET) known to induce neuroprotection by regulating energy homeostasis while Vitamin E (Vit-E) neutralizes free radicals & limits neuronal injury.

Objective and Methodology:
Investigating pharmacological outcome of combined treatment of MET & Vit-E in cerebral ischemia reperfusion injury (IR) model in rats. The IR injury induced by bilateral common carotid artery occlusion (15min) followed by 7 days of reperfusion, groups included sham-operated, IR, Metformin (200mg/kg, i.m.) treated, Vitamin E (100 mg/kg i.m.) treated, and a coadministration group (Metformin and Vitamin E). Post-injury treatment for 7 days was followed by evaluation of its impact on learning and memory, neurological deficits, infarct size, BBB permeability, Acetylcholinesterase activity, and Nitric oxide.

Results:
The combination of MET & Vit-E significantly reduced cerebral injury. Infarct size was reduced (25.33±3.56 Vs 4.83±0.30) as compare to IR after 7 days of treatment. Similarly, the cognitive deficit was significantly reduced (p<0.05) and expressed by impaired discrimination ratio (46.08±3.58 Vs 69.91±4.08) in combination treatments group. The level of Acetylcholinesterase activity were enhanced (6.50± 0.29 Vs 2.34±0.31) in addition to Nitric oxide release (15.91±0.56 Vs 32.17±0.77).

Conclusion:
The improvement in various critical parameter of cerebral ischemia viz infarct size, BBB permeability, acetylcholinesterase and vasorelaxation could attribute to complementary effect of MET and Vit-E. The AMPK activation of MET may complement the endothelial protection regulated by Vit-E. However, further studies are required to zero on to specific mechanism to this enhanced neuroprotective activity.

PCP-23

Mitigating Cyclophosphamide-Induced Nephrotoxicity: Investigating the Renoprotective Potential of *Dolichos biflorus* in rats

Sahana Parween, Neha Gajbhiye, Avinash Singh Mandloi
Faculty pharmacy VNS Group of Institution, Neelbud, Bhopal, MP India
psahana22031999@gmail.com

Background

Nephrotoxicity is kidney harm caused by substances like drugs, contributing to 15–25% of acute kidney injury cases. Cyclophosphamide, an effective cancer treatment, and also leading to cause nephrotoxicity. *Dolichos biflorus* (DB), has been traditionally used for the treatment of kidney stones and urinary disorders. This research explores DB's benefits in managing nephrotoxicity.

Material and Method:

Nephrotoxicity was induced by injecting Cyclophosphamide (150 mg/kg, i.p.) for 7 days to all the animals except control group. Animals were divided into different groups (n=06), Control (Vehicle); CP (Cyclophosphamide 150mg/kg, i.p.); Standard (Cystone, 300mg/kg; p.o.); DB150 (*Dolichos biflorus extract*; 150mg/kg; p.o.); DB300 (*Dolichos biflorus extract*; 300mg/kg; p.o.). All the treatment were given for 7 days and on 8th day all animals subjected to evaluation of BUN, Creatinine, oxidative stress and histology assessment.

Results:

DB extract treated groups significantly ($p<0.05$) attenuates the level of BUN and Creatinine as compare to CP group. Furthermore, oxidative stress markers SOD and GSH were found to be significantly augmented all treatment groups as compare to the CP group. In addition, significant reduction in LPO was recorded in the treatment groups as compare to CP group. Further, Histology of kidney indicates less sing of injury as compare to the CP group.

Conclusion:

Dolichos biflorus shows potential to reduce nephrotoxicity induce by cyclophosphamide, which could be result of potent free radical scavenging activity. Further studies are required to evaluate the detailed mechanism.

PCP-24

Effect of Nicotinamide on Methotrexate toxicity in arthritic rats"

Vipin Singh, Priya Rani, Manisha Kawadkar, Avinash Singh Mandloi, Vipin V Dhote

Faculty of Pharmacy, VNS Group of Institution, Bhopal, Madhya Pradesh, India

vipinsingh2349@gmail.com

Background:

Arthritis is an acute and/or chronic joint inflammation that often co-exists with pain and structural damage to the synovial tissue. It is often characterized as an autoimmune disorder.

Objective:

The objective of the current study was to evaluate the toxicity of methotrexate in arthritic pain management in rats as well as the effect of nicotinamide on methotrexate toxicity in arthritic rat models.

Methods:

Induction of arthiritis by an intradermal injection of 0.25 ml of CFA at the subplantar surface. Paw volume measured by Plethysmograph at 0, 7, 14, 21, 28, days after the injection of CFA. Animal were divided into 5 groups, group I (control group) (normal saline), group II (AIA) received CFA (1 ml) intradermally on day 0, group III (NA) (CFA, 1 ml, intradermal + NA, 100 mg/kg, PO) from 14 days of induction, group IV (MTX) (CFA, 1 ml, intradermal + MTX, 0.075 mg/kg, IP) from 14 days of induction, group V MTX+NA (CFA, 1 ml, intradermal + MTX 0.075 mg/kg, IP + NA, 100 mg/kg, PO) from 14 day of induction. After the induction of CFA animal were subjected for continuous measuring of paw volume arthritic score on 0, 7, 14, 21, 28 days. The latter study involves evaluation of parameters such as hemoglobin level, ESR, TSI, serum activity, LPO, GSH and histopathology.

Results and Discussion: All treatment groups' show score improvement. However, both the treatment groups showed significant improvement in symmetry movement in the animal as compared to AIA group. Histology also reveals inflammatory signs and reduced cell infiltration

Conclusion: : Nicotinamide has shown to exert several anti-inflammatory properties, free radical scavenging, suppression of MHC class II expression, and intracellular adhesion molecule ICAM-1 expression on endothelial cells. Methotrexate has been proven to be a very effective, fast working, a second-line antirheumatic agent with the best efficacy but toxicity too.

PCP-25

Exploratory Studies on Efficacy of Herbal Components for the Treatment of Aphthous Stomatitis.

Ms. Apurva Fasate, Dr. Vaishali Kilor, Ms. Apurva Fasate
Department of pharmaceutics, Gurunanak college of pharmacy, Behind C.P. Foundry, Near Dixit Nagar, Kamptee road, Nari, Nagpur, Maharashtra 440026 (India)
fasateapurva@gmail.com

Background:

RAS is the repeated occurrence of lesions in the intraoral sites having diverse etiology leading to pain, inflammation, and difficulty in eating and speaking. Common treatment options available for RAS are analgesics, corticosteroids, local anesthetics, and antimicrobial agents. Literature reports, many herbal compounds are known for its activity in healing of mouth ulcer.

Aim:

Investigation of efficacy of suitable composition of some herbal ingredients for the treatment of aphthous stomatitis.

Method:

In a study, different combinations of guava leaf extract, chamomile essential oil, pumpkin seed oil, and Khadir were tested for effectiveness against aphthous stomatitis in rats using acetic acid-induced ulcers. The herbal compositions in gel form were applied to the ulcers three times a day for 8 days. Observations included Visual Analogue Scale assessments, ulcer size measurements, and monitoring of any changes in the animal's weight due to difficulty in food consumption.

Results and Discussion:

From the above study it was observed that Guava leaf extract, pumpkin seed oil, and chamomile oil in a 1:1:0.1 ratio effectively reduced ulcer size and pain within 3 days compared to the market product.

Conclusion:

Thus, it can be concluded that guava leaf extract + pumpkin seed oil+ Chamomile Oil in 1:1:0.1 ratio was found be effective for the treatment of mouth ulcers. As ingredients used in the said composition have various mechanism of action which might be contributing to the efficacy of the composition.

Poster Presentations: CMC

Abstract No.	Presenting Author	Mode of Presentation	Title of abstract
CMC-01	Bhumika sahu	Poster	Effective Utilization of Quality by Design Approach in Developing Model Drug Loaded Chitosan Nanogels for Better Wound Management
CMC-02	Akshay.V Ramteke	Poster	Formulation Development of Multipurpose skin cream with added amino acids
CMC-03	Dishant Dabhade	Poster	Ionic Liquids with N-Methyl-2-Pyrrolidonium Cation as an Enhancer for Topical Drug Delivery: Synthesis, Characterization, and Skin Penetration Evaluation
CMC-04	Mahesh Waghale	Poster	Formulation and Evaluation of Herbal products containing Probiotics for Oral Care
CMC-05	Ayesha Imtiaz	Poster	Personalized Drug Dosing: A Data-Driven Approach using Artificial Intelligence in Clinical Pharmacology
CMC-06	Mohammed Abdul Farhan	Poster	Predictive Modeling in Drug Development: Harnessing AI for Enhanced
CMC-07	Shaikh Obaid Alhilali	Poster	Development and Validation of RP-HPLC Method for determination of Ketamine in Spiked Drink Samples.
CMC-08	Astha Namdeo	Poster	Study of the Effectiveness of Antipressant Drug when Given as Nanoparticle

CMC-01

Effective Utilization of Quality by Design Approach in Developing Model Drug Loaded Chitosan Nanogels for Better Wound Management

Bhumika Sahu, Aman Singh
VNS Institute of Pharmacy Bhopal Madhya Pradesh
sahubhumika26@gmail.com

This study was planned to analyze the wound-healing potential of Terbinafine HCl-loaded Chitosan Nanogel. The micro and Nanospheres, hydrogel or nanogel manufactured from natural and artificial polymers are regularly applied in wound recuperation substances. The Nanogel was prepared by the crosslinking method. To prepare Nanogels, the necessary quantity of Chitosan powder was dissolved in 15 ml of 30% acetic aqueous solution to create a chitosan solution under magnetic stirring at room temperature and added span 80 into it along with TPP, which was dissolved in distilled water with various concentrations (0.2, 0.4, 0.6, 0.8, 1.0 mg/ml) further for the size reduction probe sonicator was use and leave the prepared for 24hrs at room temperature.

CMC-02

Formulation Development of Multipurpose Skin cream with Added Amino Acids

Akshay. V Ramteke*, Ayushi Chaudhary, Abhijeet Shinde , Abhishek Joshi , Atharva Thite ,Chinmay Thatte , Amitesh Bobade, Dr. Mitali Bodhankar
Department of Pharmaceutics, Gurunanak College of Pharmacy,
Nagpur – 440026
akshayramteke0666@gmail.com

Background- Amino acids and their salts are commonly utilized as cosmetic compounds, and they primarily serve as hair conditioners and skin conditioners Proteins are made up of the 21 most prevalent amino acids found in nature. Amino acids are therefore essential for life and metabolic function. Isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine are eight essential amino acids that cannot be produced by human cells and must be acquired through nutrition. Because amino acids are found in all living organisms and their general biology is well understood, they are not thought to constitute a substantial health risk when consumed orally, with the exception of people who have certain genetic diseases.

Objective - The formulation's main goal is to cure many skin-related problems with a single solution. The goal is to replace several products for multiple purposes with a single product that has multiple features such as anti-wrinkle, anti-ageing, restoring natural skin moisture, and nourishment. A single cream with multiple properties will also be more cost effective for users than purchasing a single cream for a single purpose.

Methodology - A pre-formulative survey was conducted, with 184 surveyees answering pertinent questions. Data analysis is critical for obtaining the knowledge and insights required to develop a more effective, and efficient formulation. **Results** - The spreadability of the formulated cream was good. PH paper shows a color shift in the 5 to 6 range. Stability Studies found no change in formulation after 6 months

CMC-03

Ionic Liquids with N-Methyl-2-Pyrrolidonium Cation as an Enhancer for Topical Drug Delivery: Synthesis, Characterization, and Skin Penetration Evaluation

Dishant Dabhade, Khusbu Sharma, Nidhi Sapkal
Department of Pharmaceutics, Gurunanak College of Pharmacy, Nagpur – 440026
dabhadedishant1999@gmail.com

Background and Objective - This research focuses on the development of novel ionic liquids utilizing the N-methyl-2-pyrrolidonium cation to enhance topical drug delivery. The study encompasses the synthesis, comprehensive characterization, and evaluation of the skin penetration properties of these innovative ionic liquids. The choice of N-methyl-2-pyrrolidonium as the cationic component aims to exploit its unique physicochemical properties, which may offer advantages in terms of drug solubility, stability, and skin permeation enhancement.

Methodology - The synthesis of the ionic liquids involves meticulous design to achieve optimal drug delivery properties. The physicochemical characteristics of the synthesized compounds, including viscosity, thermal stability, and solubility, are thoroughly characterized. Advanced analytical techniques such as nuclear magnetic resonance (NMR), Fourier-transform infrared spectroscopy (FT-IR), and mass spectrometry contribute to the comprehensive understanding of the molecular structure of the synthesized ionic liquids.

The study investigates the potential of these ionic liquids as enhancers for topical drug delivery through in vitro and in vivo skin penetration evaluations. The permeation studies involve the application of selected drugs in combination with the synthesized ionic liquids on ex vivo skin models to assess their penetration efficiency.

The findings from these experiments shed light on the ability of the developed ionic liquids to enhance drug delivery across the skin barrier.

Results and Conclusion - The results obtained from this research contribute valuable insights into the design and application of N-methyl-2-pyrrolidonium-based ionic liquids for improving topical drug delivery. The potential benefits of enhanced skin penetration, solubility, and stability offered by these ionic liquids may pave the way for the development of more effective and efficient topical drug formulations with implications for pharmaceutical and dermatological applications.

CMC-04

Formulation and Evaluation of Herbal products containing Probiotics for Oral Care

Mahesh Waghale, Umra Azam, Dr. Govind Lohiya,
Department of Pharmaceutics,Gurunanak College of Pharmacy,
Nagpur, Maharashtra, India
maheshwaghale1515@gmail.com

Abstract: According to the WHO, 3.8 billion people worldwide suffer from oral diseases, making it one of the main issues affecting personal well-being. Mouthwash containing alcohol is one of the available treatments to inhibit bacteria, however, it stains teeth while medications are ineffective on resistant bacteria. Pomegranate, mint leaves, clove oil, paan (Piper betel), licorice, piper mentha, neem, and other traditional herbal remedies have been utilized for dental care for a long time. The formulation strives to create a harmonious balance that promotes a comprehensive approach to oral care in addition to flavor and texture. The inclusion of probiotics in the herbal blend helps to preserve a balanced oral microbiota.

Methodology: The study includes a comprehensive assessment of the product that covers its sensory qualities, antibacterial activity, and effects on oral flora. The colony forming unit and colony characterization were analyzed for marketed as well as freshly prepared probiotics.

Results: It was interesting to know that the regeneration time for freshly prepared lactobacilli was found to be 24 hours whereas for marketed ones was to be between 36-48 hours. This might be due to the critical water activity film with Pomegranate Juice was somehow brittle and hence the result would be better if an extract of pomegranate was used. The film formulation showed promising results which may further need to be evaluated by animal activity.

CMC-05

Personalized Drug Dosing: A Data-Driven Approach using Artificial Intelligence in Clinical Pharmacology

Ayesha Imtiaz and Mohammed Abdul Farhan
Sultan-ul-Uloom College of Pharmacy, Banjara Hills, Hyderabad.
ayeshaimtiaz707@gmail.com

In the realm of clinical pharmacology, the paradigm of drug dosing is undergoing a transformative shift through the integration of artificial intelligence (AI). This paper delves into the intricate landscape of personalized drug dosing, presenting a data-driven approach that harnesses the power of AI. The traditional one-size-fits-all dosing model is being challenged by the nuanced understanding of individual patient characteristics, and AI emerges as a key catalyst in this evolution.

Through the amalgamation of vast patient datasets, AI algorithms analyze intricate patterns, incorporating factors ranging from genetics to lifestyle. This granular approach enables the identification of optimal drug dosages tailored to individual patients, thereby enhancing treatment efficacy while minimizing adverse effects. We will explores the intricacies between pharmacokinetics and pharmacodynamics, illustrating how AI refines dosing strategies in real-time based on dynamic patient responses.

The implications extend beyond mere dosage adjustments; AI-driven personalized dosing holds promise in mitigating drug resistance, reducing treatment-related toxicity, and improving overall patient outcomes. Furthermore, the paper addresses the regulatory considerations and ethical dimensions intertwined with implementing AI in clinical practice, underscoring the need for a balanced and patient-centric approach.

CMC-06

Predictive Modelling in Drug Development: Harnessing AI for Enhanced Clinical Pharmacology Studies

Mohammed Abdul Farhan,
Sultan-ul-Uloom College of Pharmacy, Banjara Hills, Hyderabad.

The utilization of Artificial Intelligence (AI) for predictive modeling in drug development, with a specific emphasis on augmenting clinical pharmacology studies is being discussed here. The increasing complexity of drug development processes has led to a growing need for advanced technologies to enhance efficiency and outcomes. We will explore the integration of AI algorithms to predict and optimize various facets of clinical pharmacology research.

The application of AI in this context aims to streamline the identification of potential drug candidates, optimize dosing regimens, and predict adverse effects. By leveraging machine learning and data-driven approaches, the study seeks to improve the precision of pharmacokinetic and pharmacodynamic modeling, offering a more comprehensive understanding of drug behavior within biological systems.

Furthermore, the abstract highlights the potential impact on trial design, as AI can contribute to the identification of relevant biomarkers and patient subpopulations, ultimately enhancing study outcomes. The utilization of AI in clinical pharmacology studies also holds promise for reducing development costs and timelines.

Through an exploration of case studies and emerging trends, this abstract aims to provide insights into the transformative role of AI in reshaping the landscape of drug development. The integration of predictive modeling powered by AI presents a paradigm shift, offering the pharmaceutical industry an innovative approach to enhance decision-making processes and accelerate the delivery of safe and efficacious therapeutics to patients

CMC-07

Development and Validation of RP-HPLC Method for Determination of Ketamine in Spiked Drink Samples.

Shaikh Obaid Alhilali1 Dr. Anupama Koneru1, Dr. Zahid Zaheer 2,
Ms. Adik Priyanka2
1 Sultan-ul-Uloom College of Pharmacy, Banjara Hills, Hyderabad.
2 Y. B. Chavan College of Pharmacy, Aurangabad.

Ketamine is a synthetic, fast-acting sedative and nonbarbiturate anaesthetic with potential misuse as a date rape drug, enabling individuals to compromise someone's self-defense or decision-making capacity for sexual assault.

A novel reversed-phase HPLC method was developed and validated for the detection and determination of Ketamine Hydrochloride in suspected samples of spiked cold drinks. Ketamine was extracted from spiked cold drink sample by using chloroform and the pH was adjusted to 11 with NaOH solution.

The method employed Agilent 1100 series HPLC system equipped with Photo diode array detector, Phenomenex Luna C18 Column 250 mm×4.6 mm stationary phase, a mobile phase of 0.05N Potassium dihydrogen phosphate : Acetonitrile (70:30) at a flow rate of 1.0 mL/min at 250C, and detection wavelength 268 nm. The method proves to be efficient, with a rapid retention time of 3.247 min.

Linearity in the concentration range of 5-25 µg/ml is evident from its correlation coefficient (r2 = 0.998). The limits of detection and quantification are 1.008866 µg/mL and 3.057172 µg/mL, respectively. The method demonstrates accuracy and precision, as reflected in the low %RSD values of 0.015808 and 0.07068 respectively, indicating reliability and reproducibility. Additionally, the method exhibits robustness, enhancing its suitability for routine analysis, thereby contributing to the control and

prevention of sexual violence.

CMC-08

Study of the Effectiveness of Antipressant Drug when Given as Nanoparticle

Astha Namdeo, Ankush Malviya, Dr. Ankit Mishra
VNS Group of Institutions - Faculty of Pharmacy, VNS Campus, Vidya Vihar, Neelbud,Bhopal - 462044 (M.P)
asthanamdeo251200@gmail.com

It is evident from available Literature that mirtrazapine efficiently cured a wide range of depression Symptoms, from mild to severe. These Symptoms might have induded insomnia, anorexia, anhedonia, andanxiety.
Mirtazapine film-coated are available in market, but there are various Side effects, like dry mouth, Sedation, appetite, Stimulation & weight gain. Nanoparticles were utilised in drug delivery Systems due to their properties, Size, Surface characteristics & adaptability For active and passive targeting. In preformulation study, no physicochemical interaction between drug and excipient evaluated by physical evaluation and confirmed by FTIR . UV-Spectrophotometric analysis, yielding linear regresion Coefficient (r^2=0.99). Nanoparticles were prepared spontaneous by mechanical Stirring (500rpm for 20 min.). The process variable were studied by Surface response methodology by QbD & box behnken design (BBD) selected. Design of expert software trial version 13.0 was used.Zeta potential evaluated by horina SZ100 range found 53.3 to 71.6nm, 0.035 to 0.68, and 13.7 to 0.2 mv respectively entrapment efficacy 51 % to 96.72 % . percentage drug release at 15 min from 17.84% to 48.28 % 280 min ranged 65.5 % to 100%.
Invivo study of antidepressed effect of optimized formulated studied by forced swim test in mice, most commonly employed method for evaluating antidepressant activity.

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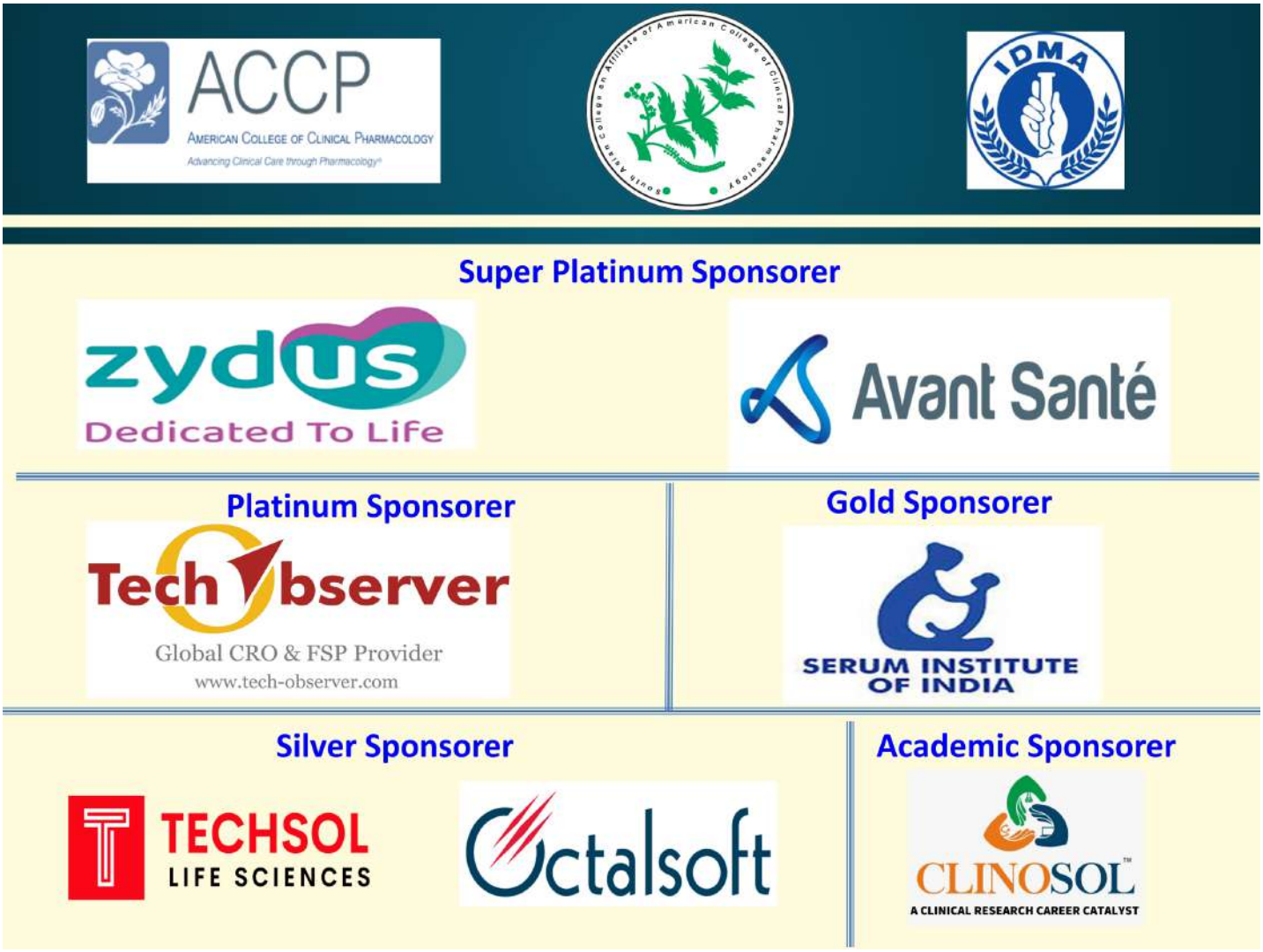

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• Clinical Study Protocols • ICD, IB, Study reference Manuals, CSR Writing • Clinical Investigation Plans • Patient Safety Narratives • CO / NCO, PDE Reports • Abstracts & Manuscripts • Medical & Scientific Editing • Literature Reviews & Pubs • Journal / Conference Content	• Phase I to IV Trials • Site Feasibility & Monitoring • Medical Device Clinical Investigations • Observational studies • IIT / IST Studies • RWD & RWE Studies • PASS / PMCF Studies • Registry Trials • Patient Surveys	• CRF Design & Annotation • DMP & DVP Preparation • Clinical Study Database Setup • Randomization & Trial Supplies • Edit Checks Programming • EDC UAT & Site Training • Medical Coding & SAE Mgmt • Interim Data Quality Review • Statistical Analysis & SAS • CDISC Data Transformation	• EU-MDR & IVDR Remediation • CER, PER, PMCF Plans, CIP Writing • EU PM510 (k),IDE,PMA submissions • Artwork, Labelling & CE Marking • S – FSCA Reporting • eCTD Authoring & Submissions (BLA,NDA,ANDA and CTA) • Import export/product registrations • Dossier Lifecycle Management • Regulatory & HA's Liasioning	• ICSR Case Processing • Safety Data & Signal Management • PSUR, PADER, PBRERs,RMP/REMS Writing • Aggregate Reporting • Medical Information Contact Center • EudraVigilance Services • EU QPPV & LPPVS • PSMF Management • Regulatory intelligence

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OUR COURSES

- Clinical Research
- Pharmacovigilance
- Clinical Data Management
- Medical Writing
- Regulatory Affairs
- Clinical SAS
- Medical Coding
- Clilical Data Science

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- Placement 800+
- Review Article 140+
- Blog 400+
- Presentations 520+
- Industry Expert Sessions, Webinar 120+
- Collaboration 80+
- Internships 150+
- Competitions 150+
- Workshops 20+

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9121151622 | 9121151623 info@clinosol.com

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