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Session #6

Dr. M. K. Bhan Memorial Session on

Clinical Research: Science, Significance, and Scope”

February 23rd 2025; 10:30 AM (IST)

Session White Paper

CHAIR, COMMUNICATIONS

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Introduction

The session successfully shed light on the journey that medical products—including drugs, vaccines, diagnostic tests, medical devices, and biological therapeutics—undergo before reaching patients. These products, collectively termed as ‘Medical Products’, are subjected to rigorous testing processes required for regulatory approval. While the specific protocols vary based on the type of product, the journey almost always begins with a proof of principle derived from foundational and translational research.

This session not only provided valuable insights to the general audience about the complex pathways involved in bringing medical products to patient use, but also offered students and young professionals a clear view of the career opportunities available within pharmaceutical and academic sectors involved in medical product development.

Kashmir Care Foundation through its Global Kashmir Connect initiative was proud to host **Dr. Arshad Hussain Khuroo, Dr. M. Amin Mir, Dr. Vijay Raina, Dr. Showkat Rasool Mir, and Dr. Mubashir Hussain Masoodi** — eminent Kashmiri experts in the field of medical product evaluation. Through their rich experiences in leading pharmaceutical companies and academia, they have significantly contributed to improving patient care both in Kashmir and globally, while mentoring numerous students and professionals in the field.

Moderated by **Dr. Aamir Nazir**, a senior principal scientist and Professor within the Division of Toxicology and Experimental Medicine at CSIR – Central Drug Research Institute, Lucknow and core team leader at Kashmir Care Foundation, the session featured an engaging and free-flowing conversation with these experts about their academic and professional journeys. The discussion offered an in-depth exploration of medical product development across both innovative and generic industries, covering topics such as pre-clinical research, phases 1–4 of clinical trials, and bioequivalence/bioavailability studies.

Pre-clinical studies are needed for regulatory approvals, which may include in-vitro (lab-based) studies designed to test potency of the medical product, testing of the medical products in small animal models for safety studies and when possible effectiveness studies (in animal models). These studies vary from studies that are done in a typical research lab, as the testing and documentation has to be done in compliance with regulatory agencies.

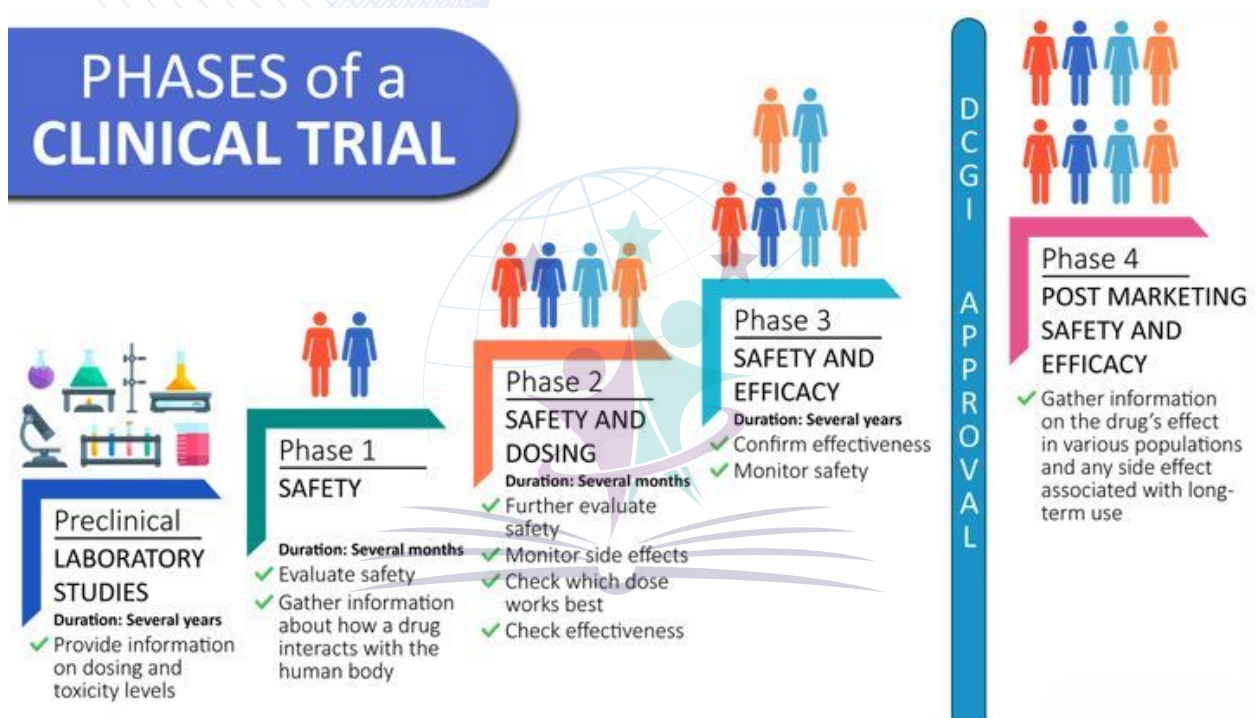


Preclinical Studies





Phase 1 study is done in limited number of healthy humans to determine the safety and tolerability using doses determined through prior studies. Following successful Phase 1 study, the Phase 2 study is done in patients (lesser sample size as compared to phase 3) using dose (level of drug and dosing regimen) derived through the human Phase 1 studies, and finally Phase 3 studies in a large number of patients (at different sites) to determine the safety and efficacy of the medical product. Phase 4 studies are done after the launch of the product in the market and has different objectives, depending on the product and regulatory requirements. Bioequivalence and Bioavailability studies are conducted generally in healthy human subjects, with main objective of proving equivalence of generic product with innovator product.

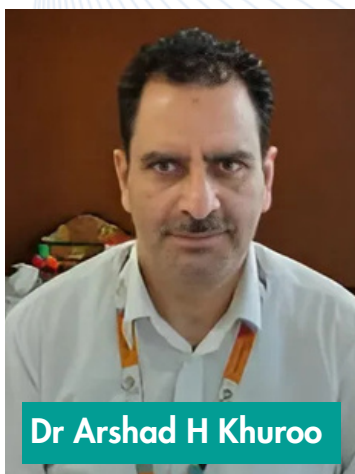


These studies are conducted using protocols that are compliant with regulatory guidance of countries where the medical product is to be used, and the entire process can take **5-10 years** depending on the medical product and countries where testing has to be done. The cost of taking a medical product through R&D and clinical research can be between **\$100 million to a \$1 Billion**.

During the session, the experts shared their personal and professional experiences with the aim of inspiring and guiding medical and pharma students, as well as young professionals, toward careers in clinical research. Through their insights, they fostered a spirit of inquiry and collaboration, encouraging attendees to envision a future where more students and physicians from Kashmir actively engage in the field of clinical research and contribute to the testing and evaluation of medical products.



Know the panelists

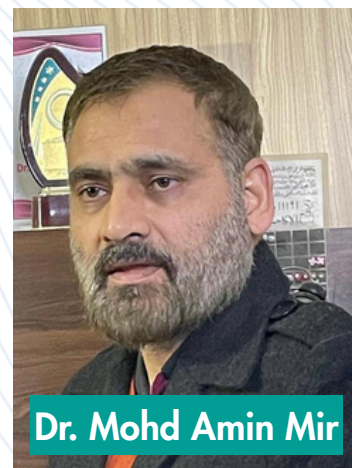


Dr Arshad H Khuroo

Dr Arshad H Khuroo is currently heading **Bioequivalence and Bioavailability function in R&D unit of SUN Pharma, India**. He was born in a village in district Baramulla, did his basic education from the same village school. After completing his graduation in Pharmacy from Jamia Hamdard, Dr. Arshad joined Ranbaxy Research Labs as trainee chemist. He was the first graduate hired by the pharma giant, owing to the fact that this pharma company was never hiring any student below PG level in its R&D division.

Dr. Arshad set the trend and did not just stop here. He completed his post-graduation from BITS Pilani, followed by his Ph.D. from BIT Ranchi. His hard work, sincerity, and zeal for learning, helped him to climb to the ladder of success career. He is currently managing more than 250 scientists across India and Eastern Europe. Dr Arshad is author/co-author of more than 100 scientific publications, has successfully faced more than 100 regulatory inspections and has 30 years of experience in conduct of pharmacokinetic studies for all regulated markets across globe. Dr Arshad is passionate about conducting management development programs. Till date he has conducted more than 60 workshops on self-motivation, effective communication skills, collaboration, challenging status quo, in India as well as at overseas locations. Dr. Arshad has also authored a book, entitled, ***"Echoes of Experience: 30 Insights from Life's Journey."***

Dr. Mohd Amin Mir is currently working as **General Manager, medical safety, safety evaluation and risk management at Qinecsa Solutions India Pvt Ltd** and primarily involved in pharmacovigilance activities related to investigational medicinal products. Dr. Mir was born in small village (Logripora) which is around 10 kms from Sopore. He completed his schooling from Islamia Model School Bomai (1981-85) and Tujar(1986-88) and his High School from Govt Higher Secondary School Bomai (1989-1994).



Dr. Mohd Amin Mir



He completed his UG (1995-2001) and PG (2002-2005) from AMU Aligarh and Cranfield UK (2006-08). He is Post-graduate in clinical research (M.Sc.) and surgery (M.S.) with around 15 years of experience in Research and Development especially Medical Safety (Pharmacovigilance).

Dr. Mir brings extensive experience in leading teams to advance research molecules from lab to pharmacy, ensuring strong oversight on safety profiles. He led the Clinical Research Division at Venus Remedies Ltd for seven years, guiding activities across drug development phases, including Clinical Operations, Medical Writing, Medical Affairs, and Pharmacovigilance. Earlier, at Fortis Clinical Research Limited, he focused on Clinical Operations, Regulatory Affairs, and Phase I studies.

A published author of over 15 scientific papers and a reviewer for multiple journals, Dr. Mir is recognized as a subject matter expert in clinical drug development. Passionate about promoting clinical research, he regularly conducts GCP workshops nationwide. He currently serves as Chairman of the Clinical Research Committee at ARAP India and is a Steering Committee member for the GCP Professionals Certification Scheme (GCPPCS) by CDSA-THSTI.



Dr. Vijay Raina

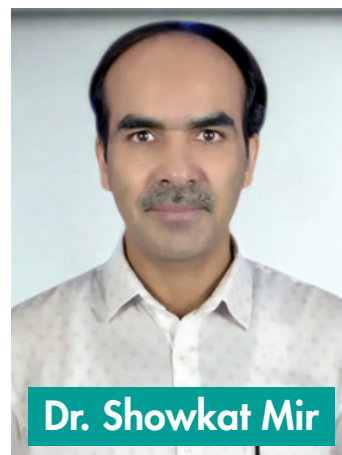
Dr. Vijay Raina has Ph.D. in clinical chemistry and over 30 years of experience in India and US based organisations. He is currently **heading clinical research operations in Aizant Hyderabad, India**. His expertise is clinical research, bioanalytical research, drug discovery, drug development, toxicokinetic, invitro studies, DMPK studies, analytical research, large molecule assays and quality management system. He completed his schooling from Happy Home High School, Anantnag, Bachelor of Science from Government Degree College Anantnag and Master's in Chemistry from the University of Kashmir, Srinagar.

After masters, Vijay did a brief tenure as a Science teacher in Government High School, Anantnag until moving out of valley to Jammu in early 1990 where he joined Leo Pharmaceuticals Jammu as an Analytical Chemist. In 1992, he moved to Malti-Chem Research Centre Baroda, founded by the renowned scientist, Dr. Sukhdev and worked there as a Research Chemist for 7 years. From 1999 to 2005, Vijay worked in Pharmacokinetics division of SUN Pharma's Advanced Research Centre Baroda dedicated to Bioavailability and Bioequivalence clinical studies.



From 2005 to 2022, Dr. Vijay worked in a US based Biopharmaceutical company, Nektar Therapeutics Hyderabad and led drug discovery and drug development of Pegylated small and large molecules. Dr. Vijay did his Ph.D. in Nektar on Dry Blood Spot technique. Dr. Vijay has association with a reputed non-profit scientific organisation, has delivered several scientific talks in leading pharmaceutical institutes and international conferences.

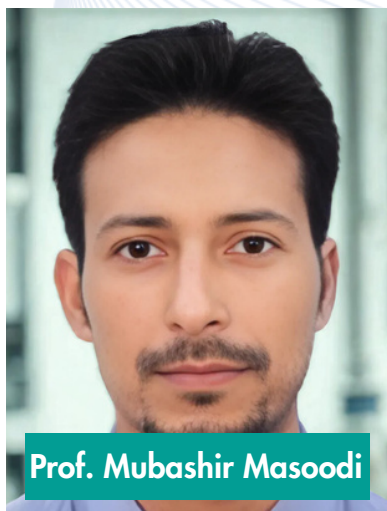
Dr. Showkat Rasool Mir was born in old town Baramulla on September 25, 1973. He completed his schooling from Noorul Islam High School, Baramulla (10th in 1989) and Govt. Boys Higher Secondary School, Baramulla (12th in 1992). He then joined Govt. Degree College, Baramulla for B. Sc. (1992-1995). He later moved to Delhi to pursue his studies in Pharmacy from Faculty of Pharmacy, Jamia Hamdard [B. Pharm. (1995-1999), M. Pharm. (1999-2001) and Ph.D. (2002-2006)].



Dr. Showkat is currently working as Professor of Pharmacognosy & Phytochemistry at School of Pharmaceutical Education and Research, Jamia Hamdard, New Delhi. He started his career in the Faculty of Pharmacy, Jamia Hamdard in 2002. He has more than 20 years of teaching experience. He teaches Pharmacognosy and Phytochemistry to under-graduate and post-graduate students. He has authored 4 books and several book chapters.

Currently he leads a team of dedicated researchers at Phyto-pharmaceutical Drug Research Laboratory. He has about 20 years of research experience in the field of drug discovery from natural products. He has more than 200 research papers in reputed journals to his credit with a cumulative impact factor is more than 300 and his h-index is 30. He has supervised 10 PhD and thirty PG scholars for their research projects. He has successfully completed several research projects funded by national agencies.

His field of expertise is the spectroscopic identification and characterization of natural products. He studies the role of plant-based products as drugs and health foods in the prevention and treatment of metabolic disorders.



Prof. Mubashir Masoodi

Prof. Mubashir Hussain Masoodi hails from district Baramulla and is presently **working at Department of Pharmaceutical Sciences, University of Kashmir, J&K.** After completing his schooling from St. Joseph Higher Secondary School, Baramulla, he completed his B. Pharm & M. Pharm from the Jamia Hamdard in 1999 and later joined Department of Pharmaceutical Sciences, University of Kashmir as faculty in 2000. Subsequently, he pursued his Ph.D. programme in Pharmaceutical Chemistry (2007) from Jamia Hamdard, New Delhi, India

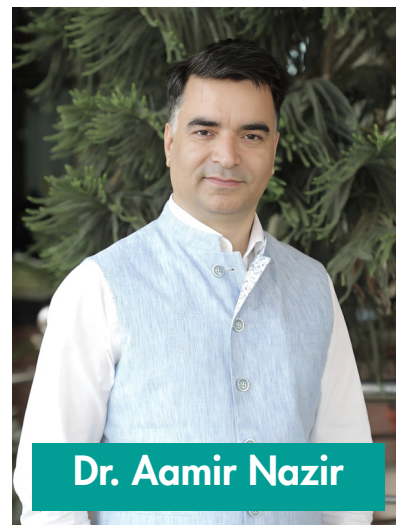
Later in 2013-14, he moved to National Center for Natural Products Research (NCNPR), University of Mississippi, USA for his postdoctoral studies. Prof. Mubashir has around 24 years of teaching & research experience and is recipient of several national and international fellowships and awards such as Indo-US UGC Raman Postdoctoral Fellowship, Young Scientist Award - 2010 by J&K State Science, Technology & Innovation Council and best publication award by Indian Drug Manufacturer's Association (IDMA), Mumbai. He has successfully carried out research projects sanctioned by CCRUM Ministry of AYUSH, UGC, ICMR, J&K ST&IC, SRISTI-BIRAC etc. and has published more than 90 research papers in peer-reviewed, national/international journals.

Prof. Masoodi has been awarded International travel grant by different funding agencies such as ICMR, DST, CICIS, CSIR & J&K State Science, Technology & Innovation Council for presenting his research findings and has travelled countries like, Austria, Hungary, Slovakia, USA, Turkey, Portugal, Thailand, etc.

Prof. Masoodi has supervised 05 PhD scholars, 20 M. Pharm scholars and is on editorial and review board of many reputed high-impact, international scientific journals. He has successfully headed the Department of Pharmaceutical Sciences, University of Kashmir from 2021 to 2024. His research group is involved in isolation and semi-synthetic modification of isolated bioactive compounds and their pharmacological evaluation.



Dr. Aamir Nazir is working as Senior Principal Scientist and Professor within the Division of Toxicology and Experimental Medicine at CSIR – Central Drug Research Institute (CDRI), Lucknow. His early education in Kashmir was at MET, Pulwama and Sainik School Nagrota, Jammu, followed by BSc from University of Kashmir and post-graduation in Toxicology from Jamia Hamdard, New Delhi. He obtained his Ph.D. from CSIR Indian Institute of Toxicology Research, Lucknow and then went on for Postdoctoral training to Medical College of Georgia USA where he studied Mechanism of anesthetic action employing genetic model system *C. elegans*. Thereafter,



Dr. Aamir Nazir

he has obtained advance trainings from Weizmann Institute of Science, Israel, University of Nottingham UK and University of Freiburg, Germany.

He joined CSIR-CDRI as Scientist and established research laboratory which focuses on the area of protein quality control employing functional genomics and epigenetics tools within powerful genetic model system *C. elegans*. He has established a very precious repository with more than 80 transgenic and mutant lines of the nematode which are used for addressing questions related to various aspects of neurobiology. His group holds the credit of discovering novel circular RNA molecule called circ-Zip-2 in *C. elegans* which has relevance in cause of Parkinson's disease.

His group has also identified and functionally characterized novel peptide conjugates and a novel Insulin Degrading Enzyme termed "ce-IDE-1" in *C. elegans* with relevance to neurodegenerative diseases. Dr. Nazir has numerous accomplishments to his credit; he has been awarded with prestigious "Raman Research Fellowship", by CSIR, Govt of India and the "India Distinguished Visiting Fellowship" by the University of Nottingham, UK. He is an elected Fellow of Society of Applied Biotechnology, India; he serves on Editorial board of several international journals and is associated with multiple scientific societies and other professional bodies. Dr. Nazir is an author on more than 75 scientific publications. The research work from his group has received wide recognition and has been well funded by the Council of Scientific and Industrial Research (CSIR), Department of Science and Technology (DST) and Indian Council of Medical Research, Govt. of India.



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A summary of the session has been published in **Daily Greater Kashmir** and can be accessed here.



Summary_GK Article

Click Here

The full recording of the session is also available to watch on the Kashmir Care Foundation **YouTube channel** via link given below



Session Recording

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