



Index MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, INDORE

(Unit of Mayank's Welfare Society)
(Constituent Unit of Malwanchal University)

ACCREDITED BY NABH & NABL



NABL Certificate No. MC-3448
NABH Certificate No. PEH-2019-0966

IMCHRC/VAC/2024/08

Date – 1st June 2024

CIRCULAR

We are pleased to announce that a value added course on “**Drug Discovery & Clinical Research**” has been scheduled from 20th June to 22th June 2024 in the lecture hall no. 3 of index medical college, hospital and research centre, Indore.

It is being organized by the faculty of IMCHRC, Malwanchal University to train the MBBS – 2nd professional students about understanding the drug discovery & phases of clinical research. The course is free for all 2nd professional students. Interested students are requested to register for the course by 15th of June 2024.

Dean

IMCHRC, Indore

CC:

The Chairman

Vice Chairman

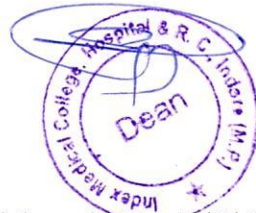
Vice Dean

Registrar – Malwanchal University

All Administrators

HODs of all Departments

Notice Board – college notice board, hostel – Boy's/Girl's, PG hostel



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Malwanchal University
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**MALWANCHAL
UNIVERSITY**

**INDEX MEDICAL
COLLEGE,
HOSPITAL &
RESEARCH
CENTRE, INDORE**

**“Drug Discovery
& Clinical
Research”**



ABOUT

Clinical trial is a prospective ethically designed investigation in human subjects to discover the new drugs.

REGISTRATION

ELIGIBILITY: MBBS 2ND YEAR

**Co-ordinator: Dr. Akash
Vishwe**

Registration fee: 0

**Dates: 20th to 22th June
2024**

**Venue: Lecture hall no. 3 of
index medical college**

RESOURCE PERSON

**Dr. Prem Nyati, Professor
(Pharmacology)
Dr. Suruchi Sharma,
Assistant Professor
(Pharmacology)**

MODULES:

- **Module 1 : Clinical Trial - Phase 0**
- **Module 2 : Clinical Trial - Phase I**
- **Module 3 : Clinical Trial - Phase II**
- **Module 4: Clinical Trial - Phase II**
- **Module 4: Clinical Trial - Phase IV**

OUTCOMES:

- **Clinical research Guidelines and Regulations**
- **Pre Clinical Trials/Animal trials**
- **Human Clinical Trials**
- **Compliance & Quality Assurance in clinical trials**
- **Pharmacovigilance**

Time-Table
Value Added Course
Topic: Drug Discovery & Clinical Research
For: - MBBS 2nd Year

Day-1 : (20/06/24)		
Title	Time	Speaker
Drug discovery & Clinical Trials-Introduction	09:00am – 10:00am	Dr. Prem Nyati
Clinical research Guidelines and Regulations:India & USA	10:00am – 11:00am	Dr. Suruchi Sharma
Tea	11:00 – 11:15am	
Clinical Trial Planning and design	11:15am – 12:15pm	Dr. Prem Nyati
Pre Clinical Trials/Animal trials	12:15pm – 01:15pm	Dr. Suruchi Sharma
Lunch	01:15pm – 02:00pm	
Clinical trials phase -1	02:00pm – 03:00pm	Dr. Prem Nyati
Clinical trials phase - 2	03:00pm – 04:00pm	Dr. Suruchi Sharma
Day-2 : (21/06/24)		
Clinical trials phase – 3	09:00am – 10:00am	Dr. Prem Nyati
Clinical trials phase – 4	10:00am – 11:00am	Dr. Suruchi Sharma
Tea	11:00 – 11:15am	
Compliance & Quality Assurance in clinical trials	11:15am – 12:15pm	Dr. Prem Nyati
Pharmacovigilance	12:15pm – 01:15pm	Dr. Suruchi Sharma
Lunch	01:15pm – 02:00pm	
Data Analysis and Management in Clinical Research	02:00pm – 03:00pm	Dr. Prem Nyati
Basic Safety & legal issues	03:00pm – 04:00pm	Dr. Suruchi Sharma
Day-3 : (22/06/24)		
The regulatory authorities in Clinical Trial- CDSCO, EMA &FDA	09:00am – 10:00am	Dr. Prem Nyati
Clinical Trial Calculations.	10:00am – 11:00am	Dr. Suruchi Sharma
Tea	11:00 – 11:15am	
Clinical SAS programming	11:15am – 12:15pm	Dr. Prem Nyati
Understanding Statistics in Clinical trial research	12:15pm – 01:15pm	Dr. Suruchi Sharma
Lunch	01:15pm – 02:00pm	
Applications of Clinical Trial in Healthcare	02:00pm – 03:00pm	Dr. Prem Nyati
Future prospects of Clinical Trials	03:00pm – 04:00pm	Dr. Suruchi Sharma



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Report: Drug Discovery & Clinical Research

A value added course on “**Drug Discovery & Clinical Research**” was conducted from 20th June to 22th June 2024 in the lecture hall no. 3 of index medical college, hospital and research centre, Indore. This course was conducted for 18 hrs., where each section was conducted for 6 hrs.

In this era of bewildering new drug introduction and rapid attrition of older drugs, the doctor needs to have an overall idea of the manner in which new drugs are developed and marketed. Drug development now is a highly complex, tedious, competitive, costly and commercially risky process. From the synthesis/ identification of the molecule to marketing, a new drug takes at least 10 years and costs 500-1000 million US\$. As such invention and development of new drugs is now possible only in the set up of big pharmaceutical houses that alone have the resources, infrastructure and dedicated teams of scientists to carry out the multiple specialized stages of the process. Though the pharmaceutical industry is often regarded as cunning, greedy, unscrupulous, deceptive and fleecing the people, there is no denying that it is responsible for most of the progress in therapeutics as well as pharmacological knowledge of today.

Clinical trials

When a compound deserving trial in man is identified by animal studies, the regulatory authorities are approached who on satisfaction issue an 'investigational new drug' (IND) licence. The drug is formulated into a suitable dosage form and clinical trials are conducted in a logical phased manner. To minimize any risk, initially few subjects receive the drug under close supervision. Later, larger numbers are treated with only relevant monitoring. Standards for the design, ethics, conduct, monitoring, auditing, recording and analyzing data and reporting of clinical trials have been laid down in the form of 'Good Clinical Practice' (GCP) guidelines by an International Conference on Harmonization (ICH).

National agencies in most countries, including ICMR in India, have also framed ethical guidelines for clinical trials. Adherence to these provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected as enunciated in the *Helsinki Declaration* of the World Medical Association. The requirements and regulations for the conduct of clinical trials on a new drug in India have been laid down in the schedule Y of the Drugs and Cosmetics Rules. The clinical studies are conventionally divided into 4 phases.

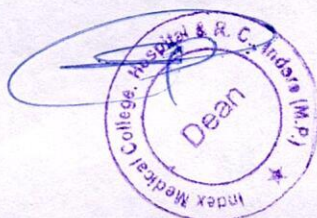
Modules:

Phase 0: Microdosing study

Phase I: Human pharmacology and safety

Phase II: Therapeutic exploration and dose ranging

Phase IV: Therapeutic confirmation/Comparison



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Phase IV: Postmarketing surveillance/data gathering studies

Clinical trial is a prospective ethically designed investigation in human subjects to objectively discover/verify/compare the results of two or more therapeutic measures (drugs). Clinical trials are designed to answer one or more precisely framed questions about the value of treating equivalent groups of patients by two or more modalities (drugs, dosage regimens, other interventions). Depending on the objective of the study, clinical trial may be conducted in healthy volunteers or in volunteer patients. Healthy volunteers may be used to determine pharmacokinetic characteristics, tolerability, safety and for certain type of drugs (e.g. hypoglycaemic, hypnotic, diuretic) even efficacy. For majority of drugs (e.g. antiepileptic, antipsychotic, antiinflammatory, antitubercular, etc.) therapeutic efficacy can only be assessed in patients.

At the end of the course, participant will learnt about:

- **Clinical research Guidelines and Regulations**
- **Pre Clinical Trials/Animal trials**
- **Human Clinical Trials**
- **Compliance & Quality Assurance in clinical trials**
- **Pharmacovigilance**

Course coordinator

Soodkand
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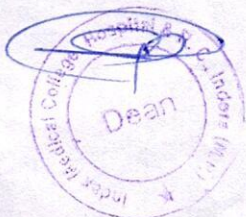
Department of Pharmacology

MBBS 2nd Year

Value Added Course: Drug Discovery & Clinical Research

Attendance Sheet

S. No.	Name of the Student	Date		
	K.shitijJadhav	<u>Present</u>	<u>Present</u>	<u>Present</u>
	KunalGajbhiye			
	KushalSourashtriya			
	LavinaManghani			
	Laxmi Singh	<u>Laxmi</u>	<u>Laxmi</u>	<u>Laxmi</u>
	MadhusudanMuniya			
	MadhviVerma			
	MonaliKushwah	<u>Monali</u>	<u>Monali</u>	<u>Monali</u>
	Monika Rawat			
	Moorti Patel			
	MurtazaShabbir Kanchwala	<u>Murtaza</u>	<u>Murtaza</u>	<u>Murtaza</u>
	Mustafa Anis	<u>Anis</u>	<u>Anis</u>	<u>Anis</u>
	Nainshi Bhardwaj	<u>Nainshi</u>	<u>Nainshi</u>	<u>Nainshi</u>
	Nandini Tiwari	<u>Nandini</u>	<u>Nandini</u>	<u>Nandini</u>
	Neeraj Kumar Shah	<u>Neeraj</u>	<u>Neeraj</u>	<u>Neeraj</u>
	NidhiRaghuwanshi			
	Nikunj Gupta	<u>Nikunj</u>	<u>Nikunj</u>	<u>Nikunj</u>
	Patel Shiv Dharmeshbhai			
	PiyushMadaan	<u>Piyush</u>	<u>Piyush</u>	<u>Piyush</u>
	Pooja Balondiya			
	Pooja Jarman			
	Prachi Thakur	<u>Prachi</u>	<u>Prachi</u>	<u>Prachi</u>
	Prakash Mehta			
	PrasunPatidar	<u>Prasun</u>	<u>Prasun</u>	<u>Prasun</u>
	PremBhawar	<u>Prem</u>	<u>Prem</u>	<u>Prem</u>
	PurnaKathii			
	Rakhi Dev : Sonkar	<u>Rakhi</u>	<u>Rakhi</u>	<u>Rakhi</u>
	RamchandraBhagora	<u>Ram</u>	<u>Ram</u>	<u>Ram</u>
	RamitaSenani			
	Rani Bhawel	<u>Rani</u>	<u>Rani</u>	<u>Rani</u>
	Kareena Jindal	<u>Kareena</u>	<u>Kareena</u>	<u>Kareena</u>
	Khanak Solanki	<u>Khanak</u>	<u>Khanak</u>	<u>Khanak</u>
	Khushi Gupta	<u>Khushi</u>	<u>Khushi</u>	<u>Khushi</u>
	Kiran Mahajan			
	Krishna Fansay	<u>Krishna</u>	<u>Krishna</u>	<u>Krishna</u>
	KrutanshHedau			
	Manoj Singh Ashokant	<u>Manoj</u>	<u>Manoj</u>	<u>Manoj</u>
	MayankMahobe			
	Meet Pachisiya			
	Meet Sethi			
	MishikaPareta	<u>Mishika</u>	<u>Mishika</u>	<u>Mishika</u>

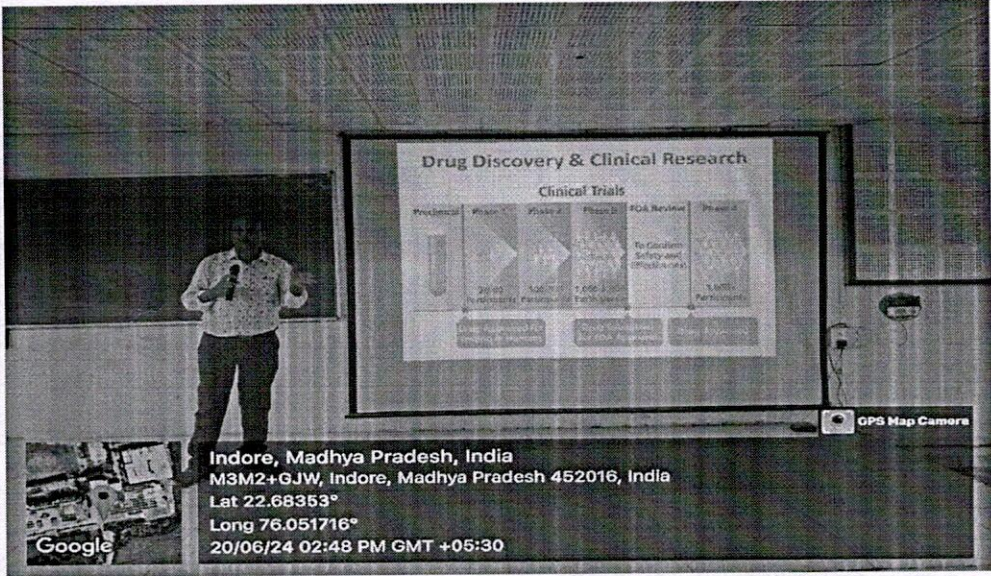



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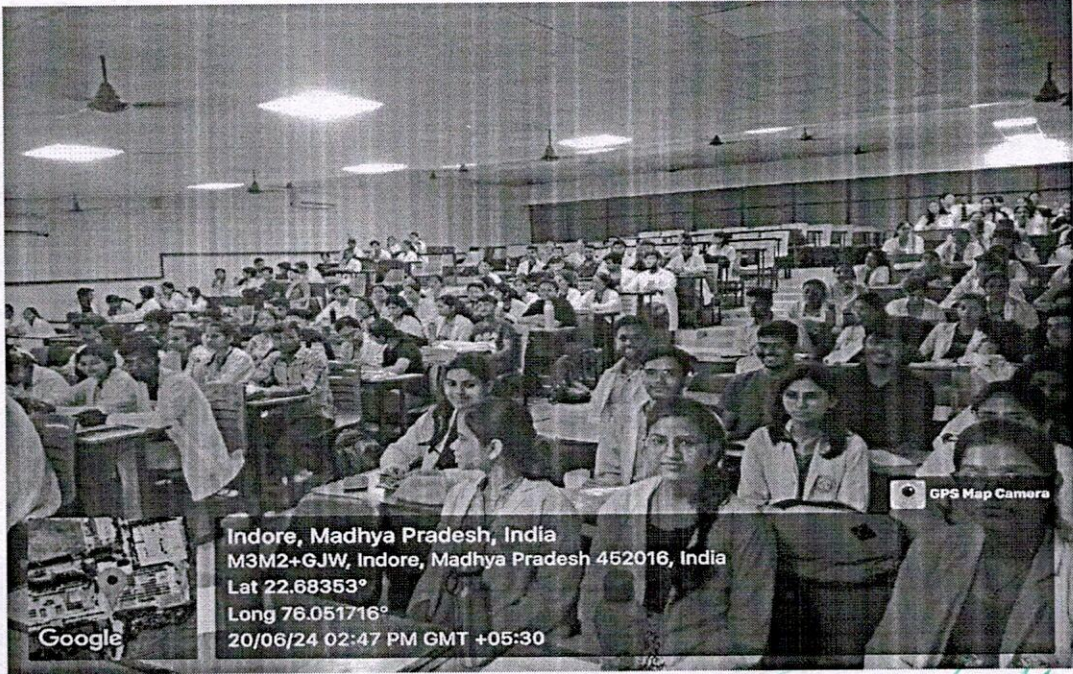
Varsha Nargawe	Varsha	Varsha	Varsha
Varun Sharma	Varun	Varun	Varun
Vedant Sahu	Vedant	Vedant	Vedant
Vedika Patidar	Vedika	Vedika	Vedika
Vijay Jaiswal	Vijay	Vijay	Vijay
Vikas Rathore	Vikas	Vikas	Vikas
Vikas Tanwar	Vikas	Vikas	Vikas
Vinit Shiwalkar	Vinit	Vinit	Vinit
Shailendra Chhiroliya	Shailendra	Shailendra	Shailendra
Shantik Pasari	Shantik	Shantik	Shantik
Shatakshi Yadav	Shatakshi	Shatakshi	Shatakshi
Shekh Hasrat Hamza	Shekh	Shekh	Shekh
Shivani Achale	Shivani	Shivani	Shivani
Shivani Lathi	Shivani	Shivani	Shivani
Shourya Dalmia	Shourya	Shourya	Shourya
Shraddha Patidar	Shraddha	Shraddha	Shraddha
Shrikant Pardhi	Shrikant	Shrikant	Shrikant
Shruti Bele	Shruti	Shruti	Shruti
Sujal Chouhan	Sujal	Sujal	Sujal
Sumit Patel	Sumit	Sumit	Sumit
Sur Singh Baraniya	Sur	Sur	Sur
Suruchi Yadav	Suruchi	Suruchi	Suruchi
Suyash Bramhane	Suyash	Suyash	Suyash
Vaidehi Patidar	Vaidehi	Vaidehi	Vaidehi
Vaishnavi Chaudhary	Vaishnavi	Vaishnavi	Vaishnavi
Vandana Harinkhede	Vandana	Vandana	Vandana
Vansh Pankaj Agrawal	Vansh	Vansh	Vansh
Shruti Prajapat	Shruti	Shruti	Shruti
Shruti Sen	Shruti	Shruti	Shruti
Shruti Soni	Shruti	Shruti	Shruti
Shruti Yadav	Shruti	Shruti	Shruti
Shubham Bargah	Shubham	Shubham	Shubham
Shubham Damor	Shubham	Shubham	Shubham
Shubham Parrnar	Shubham	Shubham	Shubham
Shweta Rathor	Shweta	Shweta	Shweta
Sourabh Patidar	Sourabh	Sourabh	Sourabh
Subham Kumar Chauhan	Subham	Subham	Subham
Subhash Prajapati	Subhash	Subhash	Subhash
Vaibhav Dubey	Vaibhav	Vaibhav	Vaibhav
Vaibhav Patidar	Vaibhav	Vaibhav	Vaibhav
Vaibhavi Patidar	Vaibhavi	Vaibhavi	Vaibhavi



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