

Last updated on: 28/03/25

Site Info	
Site Name	Post Graduate Institute of Medical Education and Research, Chandigarh
Address	Phase 1 Unit, Block C, Level 2, Nehru Hospital, PGIMER, Sector 12, Chandigarh- 160012

Experience and Available Capacity	
Infrastructure	<p><u>Fully Equipped Phase 1 Unit</u></p> <ul style="list-style-type: none"> ● 4-bedded Phase 1 unit equipped with continuous monitoring capabilities, connected to a central monitoring station for real-time tracking of vital signs. ● Strategically located on the main hospital floor, with access to the hospital emergency, Main ICU as well as Emergency ward 22. ● The unit is fully equipped with emergency resuscitation facilities, including a crash cart, oxygen supply, and defibrillator to handle any medical emergencies. 24 * 7 support from on-call resident from the Department of Internal Medicine as well as Dept. of Anaesthesia and Critical Care to manage any emergency, and if needed transfer the subject to the Intensive unit. ● The Phase 1 unit maintains a comprehensive entry and exit log, ensuring strict access control and documentation of all personnel and participant movements. ● Outpatient set-up: Facilities for subjects to visit the fully functional OPD of the hospital, with access to laboratory and radiological services. <p><u>In-House Pharmacy</u></p> <ul style="list-style-type: none"> ● The dedicated in-house pharmacy features a separate entry and exit, ensuring controlled access and maintaining the integrity of investigational products (IP).

	<ul style="list-style-type: none"> It is equipped with a laminar flow hood for sterile drug preparation and a refrigerator with a data logger to continuously monitor and record temperature <p><u>Sample Processing & Archival Facilities</u></p> <ul style="list-style-type: none"> A dedicated space for sample processing ensures efficient handling of biological samples. A secure archival space for proper documentation and storage of trial records. <p><u>Participant Comfort and Consent Area</u></p> <ul style="list-style-type: none"> Dedicated informed consent area, with Audio-visual recording capabilities. Additionally, a separate washroom/shower area and a recreation room to enhance participant comfort during their stay Equipped with bedside alarm bells and additional emergency call buttons in the washroom area
Manpower	<ol style="list-style-type: none"> PI: Prof. Nusrat Shafiq, Clinical Pharmacology Unit, Dept of Pharmacology Principal Co-PI: <ol style="list-style-type: none"> Prof. Samir Malhotra, Clinical Pharmacology Unit, Dept of Pharmacology Dr. Ashish K. Kakkar, Clinical Pharmacology Unit, Dept of Pharmacology Co-investigators: <ul style="list-style-type: none"> Prof. Sandhya Yaddanapudi, Dept of Anaesthesia and Intensive Care Prof. Navneet Sharma, Dept of Internal Medicine Prof. Madhu Gupta, Dept of Community Medicine Prof. Pankaj Malhotra, Dept of Clinical Hematology and Medical Oncology Prof. Gaurav Prakash, Dept of Clinical Hematology and Medical Oncology Dr. Ankur Gupta, Dept of Cardiology Dr. Vivek Kumar, Dept of Nephrology Dr. Ashok K. Pannu, Dept of Internal Medicine Dr. Ritin Mohindra, Dept of Internal Medicine Dr. Nipun Verma, Dept of Hepatology Dr. Aastha Takkar, Dept of Neurology

- Dr. Aashima Arora, Dept of Obstetrics and Gynaecology

Collaborators:

- Central Drug Research Institute, Lucknow : Trial for novel antimalarial drug
- Indian Council of Medical Research: Phase 1 Unit Network, PLG Nanoparticle trial, Covishield/Covaxin trial, Hydroxychloroquine for Covid-19 prophylaxis
- Department of Science and Technology: sponsor for the HFNC trial (indigenous device)
- DBT-Wellcome trust: Towards accurate determination of burden of kidney disease in India- Development and validation of accurate equation to estimate glomerular filtration rate (GFR) for Indian population.
- Aurigene: sponsor for the AUR108 (ASHA) study

Project Staff:

1. Project Research Scientist- III (Med): Dr. Soumya Vij
2. Project Research Scientist- II (NM): Dr. Ashok Kumar
3. Project Research Scientist-I (NM): Ms. Himanshi Khera
4. Project Nurse-III: Ms. Priyanka
5. Project Technical Support III: Ms. Seema
6. Hospital Attendant: Mr. Sanjay Kumar

Trial Info: Early-Phase Trials Conducted				List FIH trials conducted, if any (in the table below) Mention other early phase trials, if any (in the table below)			
Year of start	Title	Therapeutic Area	Status	PI	Regulatory/Academic	Sponsor	CTRI Number
ICMR Sponsored/co-sponsored trials							
2016	Phase 1 Clinical Study with Poly-Co-Glycolide (PLG) Nanoparticles Encapsulating Antitubercular Drugs (Isoniazid, Rifampicin, Ethambutol and Pyrazinamide)	Antitubercular	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Academic	ICMR, New Delhi	CTRI/2016/10/007356
2020	Population pharmacokinetics of hydroxychloroquine sulphate in healthcare workers given for prophylaxis against Corona Virus Disease 2019 (COVID 19) pandemic in India	Anti-infective	Completed	Co-PI: Prof. Nusrat Shafiq	Regulatory	ICMR, New Delhi	CTRI/2020/05/025242

2022	Bioevaluation of PLGA loaded with radio-labeled Rifampicin: A prospective study	Antitubercular	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Academic	ICMR, New Delhi	CTRI/2022/02/040372
2022	Safety, tolerability and immunogenicity after administration of Covid-19 vaccine in homologous prime/boost schedule Covishield Covishield or Covaxin Covaxin as compared with heterologous prime/boost Covishield Covaxin or Covaxin Covishield schedule among adults in North India	Vaccine	Completed	PI: Prof. Madhu Gupta Co-PI: Prof. Nusrat Shafiq	Regulatory	ICMR, New Delhi	CTRI/2022/06/043447
2025	A Phase 1, Open Label, Dose Escalation, Dose Expansion, Multicenter, First in	Oncology	Ongoing	PI: Dr. Gaurav Prakash Co-PI: Prof.	Regulatory	ICMR, New Delhi	CTRI/2023/05/052954

	Human (FIH) Study Evaluating the Safety, Pharmacokinetics and Pharmacodynamics of Oral AUR107 in Patients with Relapsed Advanced Malignancies (SHAKTI-1)			Nusrat Shafiq			
Other Trials							
2012	Phase 1 Single dose pharmacokinetic study of CDRI compound 97/78, a novel antimalarial drug in healthy human volunteers	Antimalarial agent	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Regulatory	CDRI, Lucknow	CTRI/2012/07/002832
2012	Phase 1 study of the safety, tolerability and pharmacokinetic of CDRI Compound 97/78, a novel antimalarial drug in normal healthy human volunteers	Antimalarial agent	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Regulatory	CDRI, Lucknow	CTRI/2012/07/002812

2013	A study on Hydroxychloroquine efficacy as an antiplatelet agent in healthy volunteers: comparison with aspirin and clopidogrel	Cardiovascular	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Academic	NA	CTRI/2013/03/003485
2020	A randomized, double blind, cross over, single center study to evaluate the oral sensory attributes of placebo tablet coatings	-	Completed	PI: Prof. Nusrat Shafiq Co-PI Dr. Shivani Acharya	Academic	Abbott Healthcare Pvt Ltd	CTRI/2020/11/029406
2024	Clinical Efficacy of the Indigenously Developed High Flow Nasal Cannula Device (TrueOxy+ HFNC Device): A Pilot Study.	Respiratory, Critical Care	Completed	PI: Dr. Shiv Lal Soni Co-PI: Prof. Nusrat Shafiq	Regulatory	DBT/Wellcome Trust, New Delhi	CTRI/2024/02/062209
2024	Quality Control Testing and Bio-Equivalence Study of Amoxicillin-Clavulanic Acid Generic Tablets Procured by A	Anti-infective	Completed	PI: Prof. Samir Malhotra Co-PI: Prof. Nusrat Shafiq	Academic	UT DST	CTRI/2024/02/062668

	Tertiary Care Centre in India						
2024	A Phase I, Open Label, Dose Escalation, Dose Expansion, Multicenter Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics of Oral AUR 108 in Patients with Relapsed Advanced Lymphoma (ASHA).	Oncology	Ongoing	PI: Dr. Gaurav Prakash Co-PI: Prof. Nusrat Shafiq	Regulatory	Aurigene Oncology Ltd	CTRI/2023/08/056321

Certifications/accreditations	<p>Certifications/accreditations:</p> <ul style="list-style-type: none"> • All Project staff are trained in Basic Life Support. • All Investigators are GCP certified <p>Central trial inspection was carried out by the CDSCO for the Covishield/Covaxin trial was conducted in the Phase 1 Unit, PGIMER in 2023</p>
Point of Contact	<p>Name: Dr. Nusrat Shafiq, Professor and Incharge, Clinical Pharmacology Unit, PGIMER, Chandigarh</p> <p>Email: shafiq.nusrat@pgimer.edu.in</p>