Last updated on: (23/04/25)

Site Info	
Site Name	Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai
Address	Department of Clinical Pharmacology, New MS Building, First Floor, Seth GS Medical College and KEM Hospital, Acharya Donde Marg, Parel, Mumbai-400012,Maharashtra
Experience and Available Capacity	
Infrastructure	Key Facilities Department Ward: The Clinical Pharmacology Department has a dedicated 20-bedded ward. (including 3 bedded Phase I Unit) Phase I Unit: Our facility includes a well-equipped, three-bedded Phase I unit with Fowler beds and ICU facilities, such as multipara monitors, defibrillators, a transport ventilator, an emergency crash cart, a phlebotomy chair, and a 12-lead ECG machine. The department conducts pharmaceutical industry and government-sponsored clinical trials (Phase I, II, III, and IV) as well as academic projects. Pharmacy Room: The pharmacy room is equipped with a 24-hour electricity backup system for deep freezers and refrigerators used for IP and sample storage. Additionally, we have a 24-hour cloud-based temperature monitoring system. Archival Room: The department has an archival facility for storing clinical trial and academic study documents. Laboratories: The laboratories are equipped with instruments and all are calibrated annually to support clinical trials, patient care, and academic studies. • Therapeutic Drug Monitoring (TDM): Estimations are done using HPLC. • Biosafety Level 2 Lab: Equipped with biosafety cabinets, a CO2 incubator, and a liquid nitrogen tank. • Routine Biochemistry and Hematology: Fully and semi-automated biochemistry analyzers, a 5-part hematology analyzer, an electrolyte analyzer, and a cooling/research centrifuge. • Pharmacogenetics: PCR and RT-PCR machines, gel electrophoresis, and a gel documentation system. • Malarial Parasite Screening: Microscopes. Outpatient Setup: • Annually, we analyze approximately 1,500 patients on various antiepileptic drugs such as Phenytoin, Phenobarbital, Carbamazepine, Valproate Sodium, Levetiracetam, Lamotrigine, Vancomycin, Voriconazole, and Lithium (anti-manic drug). • In the Pharmacogenetics OPD, approximately 1,000 patients are referred to us annually for genotyping for drugs like Warfarin (CYP2C9, VKORC1), Tacrolimus (CYP3A5), Clopidogrel (CYP2C19), Azathioprine (NUDT15), and TPMT. • In the Malaria OPD, we screen approximately 2,500 patients annually.
Manpower	Principal Investigator : Dr. Nithya Gogtay Project Research Scientist –II (NM) : Dr. Sheetal Kudtarkar Project Research Scientist – I (NM) : Vipin Mokalkar

	Project Nurse –III	: Shraddha Jagushte

Early phase trial Info:						
Year of start	Title	Therapeutic Area	Status	PI	Regulatory/ Academic	CTRI Number
Other trials						
2020	A randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) following a single-subcutaneous dose administration of ZYBK2 to patients with rheumatoid arthritis aged between 18-65 years old	Rheumatoid Arthritis	Completed	Dr. Nithya Gogtay	Regulatory	CTRI/2021/09/036874
2017	Phase-I open label dose-escalation clinical trial to evaluate the safety, tolerability and immunogenicity of Chikungunya vaccine in healthy adults of 18 to 50 years age.	Infectious Diseases	Completed	Dr. Nithya Gogtay	Regulatory	CTRI/2017/02/007755
2013	A Phase 1, Prospective, Randomized, Two-Arm, Active Controlled, Double-Blind, Study to Evaluate the Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (SIILPCV10) in Healthy Indian Young Adult	Infectious Diseases	Completed	Dr. Nithya Gogtay	Regulatory	CTRI/2013/09/003961
2008	Open Label, Dose Escalation Phase I Study in Healthy Adult Volunteers to Evaluate the Safety and Pharmacokinetics of a Human Monoclonal Antibody to Rabies (MBL-RAB1) Administered in Conjunction with Rabies Vaccine (RABIVAX).	Animal Bites	Completed	Dr. Nithya Gogtay	Regulatory	CTRI/2009/091/000465

2004	A Phase I, double blind, randomized study to evaluate the safety and immunogenicity of a new Meningococcal A conjugate vaccine versus a Meningococcal Polysaccharide A+C reference vaccine and a Tetanus Toxoid control vaccine, given as single intramuscular injections in healthy adults from 18 to 35 years of age	Infectious Diseases	Completed	Dr. Nilima Kshirsagar	Regulatory	
Certifications/accreditations /Audits		1. CMC Vellore External QC for Biochemistry 2. AIIMS, New Delhi External QC for Hematology Regulatory approvals / audits passed in the last 5 years -Saudi FDA Inspection in February 2024. The department cleared the inspection without findings.				
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