

## Last updated on: (28/04/24)

Site Info		
Site Name Advanced Centre for Treatment, Research and Education in Cancer		
Address       Sector 22, Utsav Chowk - CISF Rd, Owe Camp, Kharghar, Navi Mumbai, Maharashtra 410210		

<b>Experience and A</b>	vailable Capacity
Infrastructure	The Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) is the state-of-the-art R&D wing of the Tata Memorial Centre.
	ACTREC comprises the Cancer Research Institute (CRI), Clinical Research Centre (CRC) and Centre for Cancer Epidemiology (CCE), a setting that is unique in India and built and evolved with a vision to provide comprehensive cancer care to one and all.
	ACTREC can serve cancer patients with a capacity of 900 beds. The projects are technologically and thematically complex,
	including a Proton Beam Therapy Centre, a Centre to treat children's and hematological cancers, a Centre to treat solid tumors, and an advanced centre for nuclear medicine.
	The clinical pharmacology department in ACTREC focuses on the early phases of drug development and has been undertaking
	phase I clinical trials for more than 15 years. Phase I unit has the SOPs for undertaking the phase I clinical trials. The phase I unit has the latest equipment for the phase I clinical trials. The research team is experienced in handling Phase I
	clinical trials. The phase I unit is well supported by the clinical colleagues in the hospital who handle medical or surgical
	emergencies. Patient management is well supported by the presence of NABL accredited laboratory, which runs 24/7. In addition, ACTREC also handles patient emergencies with fully functional casualty and 16- independent ICU bedded facilities.
	In addition, the phase I unit is well supported by the hospital's nursing team, as well as research nurse availability. The Clinical Pharmacology Phase I unit has an independent research pharmacy.
	Radiology services (CT, PET, and MRI) are equipped with the latest and most advanced machines to support clinical research and hospital services.
	In addition, the department also has a well-established bioanalytical facility equipped with HPLCs and LCMSMS. Recently, High- resolution mass spectrometry was procured from the ICMR Centre for Advanced Research Project to undertake metabolomics
	analyses.



SI. No.	Name	Designation	Role
1	Dr. Vikram Gota	Professor Clinical Pharmacologist	Principal Investigator
			Officer in charge, Clinical Pharmacology department
2	Dr. Manjunath Nookala Krishnamurthy	Project Lead cum Clinical Pharmacologist	PI for CAR Phase I unit
3	Dr. Jaya Ghosh	Professor Medical Oncology	Medical Oncologist, Physician
4	Mrs. Sadhana Kannan	Officer in charge, Biostatistics department	Undertaking data analysis
5	Ms. Chital Naresh	Officer in charge, Quality control	Quality control of all the labs in ACTREC
		department	

	ICMR Project staff					
SI. No	Designation	N	Role			
1	Project research Scientist I – Non medical -Mr Ganesh Chepuri -Mrs Akshata Patil	02	<ul> <li>Undertaking screening, consenting the patients, keeping track of the patients in clinical trials, storage of samples, documentation, assist the PI in coordinating with other centres etc.</li> <li>communication with the regulators, submission of dossiers, IB preparation, project submission to the regulators.</li> </ul>			
2	Project research Scientist I – Non medical -Mrs Shraddha Jadhav	01	Undertaking the bioanalytical method development for the drugs			
3	Project research Scientist I – Medical	01	He/She will be playing a role in handling the clinical trials – patients' consenting, following patients' lab investigations, managing patients during the trials and occurrence of adverse events; communicating with the sponsors			
4	Research nurse	03	Providing nursing facilities for the patients In addition, hospital nursing team is cooperative to the research nurse team			
5	Pharmacometrician Dr Aswathy VS	01	Undertakes the pharmacometrics related research activities			



Year of	Title	Therapeutic	Status	PI	Regulatory/	CTRI
start		Area			Academic	Number
	ICMR Sponsored/co-sponsored trials					
2025	A Phase 1, Open Label, Dose Escalation, Dose Expansion, Multicentre, First in Human (FIH) Study Evaluating the Safety, Pharmacokinetics and Pharmacodynamics of Oral AUR107 in Patients with Relapsed Advanced Malignancies (SHAKTI-1)	All advanced solid tumors and multiple myeloma	Ongoing	Dr. Anbarasan Sekar	Regulatory	CTRI/202 3/05/052 954
	Other trials					
2014	A Phase I Clinical Study to evaluate the safety, pharmacokinetics and anti-tumor activity of NRC-2694-A in patients with advanced Solid Malignancies.	All Advanced solid tumors	Completed	Dr. Kumar Prabhash	Regulatory	CTRI/201 4/01/004 293
2017	Phase I Clinical trial of an oral therapeutic agent Bioplatin in patients with solid tumours refractory to conventional therapies and advanced metastatic tumours.	All Advanced solid tumors	Completed	Dr. Vikram Gota	Regulatory	CTRI/201 7/06/008 778
2022	A Single Ascending Dose, Phase I Trial to Assess Safety, Tolerability and Pharmacokinetic Profile of MSP008-22 in Patients with Advanced Solid Tumours	All Advanced solid tumors	Ongoing	Dr. Manjunath Nookala Krishnamurthy	Regulatory	CTRI/202 2/06/043 504
2017	A phase I study to determine Safety, Tolerability, Pharmacokinetics, and activity of K0706, a Novel tyrosine Kinase (TKI), in subjects with Chronic Myeloid Leukemia (CML) or Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ALL).	Acute lymphoblastic leukemia	Ongoing	Dr. Navin Khattry	Regulatory	CTRI/201 7/03/008 178
2021	Phase I study to evaluate the feasibility and safety of addition of ruxolitinib to a standard BFM-90 regimen in adolescent/adult Ph-like ALL.	Acute lymphoblastic leukemia	Ongoing	Dr. Hasmukh Jain	Academic	CTRI/202 1/02/031 251



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Certifications/accreditations List certifications/accreditations Mention any specific regulatory approvals or audits passed in the last 5 years	The clinical Pharmacology department successfully faced FDA inspection from March 19, 2018, to March 23, 2018, concerning a bioequivalence clinical trial conducted for the pharma industry.
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