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Site Info	
Site Name	SRM Center for Clinical Trials and Research(CCTR)
Address	3rd Floor, E Block, SRM Medical College Hospital And Research Centre (SRM MCH & RC), Mahatma Gandhi Rd, Potheri, SRM Nagar, Kattankulathur, Tamil Nadu 603211

Experience and Available Capacity	
Infrastructure	<p>The Centre for Clinical Trials and Research (CCTR) at SRM Medical College Hospital and Research Centre is a state-of-the-art facility designed to support high-quality clinical research across various therapeutic areas.</p> <p>Phase 1 Unit CCTR houses a dedicated Phase 1 Clinical Trial Unit, compliant with regulatory standards, equipped with 6 inpatient beds, one bed in emergency resuscitation room, continuous monitoring facilities, and a controlled environment for first-in-human (FIH) and bioequivalence studies.</p> <p>Inpatient & Outpatient Setup The Clinical Research Centre operates within a 1200+ bed tertiary care hospital, ensuring seamless access to inpatient facilities. A well-structured outpatient research clinic supports participant recruitment and follow-up, integrating multi-specialty care for diverse study requirements.</p> <p>Laboratory The research laboratory at CCTR , featuring advanced bioanalytical, molecular, and immunology testing capabilities. It is equipped with digital PCR, western blot, ELISA, and biochemistry analyser, hormone analyser, haematology analyser to support pharmacokinetic, biomarker, and genomic studies.</p> <p>Pharmacy A GCP-compliant research pharmacy with temperature-controlled storage and secure drug dispensing systems ensures accurate investigational product management.</p> <p>ICU Backup & Emergency Support A fully equipped ICU and emergency department are available 24/7 for safety monitoring in high-risk trials, including first-in-human and complex interventional studies.</p>

	<p>CCTR's robust infrastructure, combined with a dedicated clinical research team, ensures excellence in conducting early to late-phase clinical trials while maintaining the highest ethical and safety standards.</p>	
Manpower	<p>Principal Investigator:</p> <p>Dr. Satyajit Mohapatra, Director, SRM CCTR, Professor , Department of Pharmacology, SRM MCH & RC</p> <p>Co-PI's:</p> <ol style="list-style-type: none"> Dr. Sangeetha Raja: Professor, Department of Pharmacology, SRM MCH & RC Dr. Preethika. A. Assistant Professor, SRM CCTR, SRM MCH & RC <p>Investigators</p> <ul style="list-style-type: none"> Dr. Muralidharan: Professor, Cardiologist Dr. J. S Kumar: Professor, General Medicine Dr. Subramanian: Professor, General Medicine Dr. Nalini Jayanthi: Professor , Respiratory Medicine Dr. Saswati Tripathy: Professor , Obstetrics & Gynecology Dr. V. Vijayanand, Professor, Orthopedics Dr Athira Gopinathan, Professor, Surgery Dr Karthikeyan S, Asst professor, Medical Oncology Dr Senthil Kumar, Professor, Urology <p><u>COLLABORATORS</u></p> <p>Government funding: ICMR , DHR, BIRAC, TamilNadu Apex Skill Development Center for Healthcare</p> <p>Pharmaceutical & Biotech Companies – Industry collaborations for drug/device trials: Sanofi, GSK, Bharat Biotech, Serum Institute of India, Hetero Biopharma, Glenmark, Gennova, IQVIA, ICON, Takeda, Zydus Cadila, Clantha research, JCDC, Veeda , Cliwis and DNDi, Patanjali research Foundation, MSMF, many more</p>	

	<p>Academic Institutions – Joint research with national/international universities</p> <p>Project Staff:</p> <ol style="list-style-type: none"> Project research scientist III (Med): Under Recruitment Project research scientist II (Non Med): Ms. Nayak Deeksha Dayanand Project Nurse III: Ms. Jeyanthi Aruldoss Project Research Scientist I (Non Med): Mr. Parvatha Raja kumaran V S Project Research Scientist I (Non Med) Under recruitment Project Technical support III: Dr. Uma S <p>Other site staffs at CCTR: Site Manager, Medical officer, senior quality reviewer, Clinical Research Coordinators , Research Associates, Scientific Writer, Research Assistants (Bioanalytical Lab), Research nurses, phlebotomists, Lab technicians , Office Executive .</p> <p>This multidisciplinary team ensures seamless execution of early to late-phase clinical trials while maintaining regulatory and ethical standards.</p>	
<p>Trial Info: Early-Phase Trials Conducted</p>	<p>List FIH trials conducted, if any (in the table below) Mention other early phase trials, if any (in the table below)</p>	

Year of start	Title	Therapeutic Area	Status	PI	Regulatory/Academic	CTRI Number	SPONSOR
2020	An adaptive , seamless, phase I, followed by phase II randomised, double-blind, multicentre study to evaluate the safety, reactogenicity, tolerability and immunogenicity of a whole-virion inactivated SARS-CoV 2 vaccine in healthy volunteers	Covid-19 vaccine	completed	Dr. Satyajit Mohapatra	Regulatory	CTRI/2020/07/026300	Bharath Biotech
2021	An adaptive , seamless, phase I, followed by phase II randomised, double-blind, multicentre study to	Covid-19 vaccine	completed	Dr. Satyajit Mohapatra	Regulatory	CTRI/2021/04/032942	Bharath Biotech

	evaluate the safety, reactogenicity, tolerability and immunogenicity of a whole-virion inactivated SARS-CoV 2 vaccine in healthy volunteers						
2024	A single dose , double - blind, parallel arm, comparative pharmacokinetic study of DRL_AB, US licensed, reference Abatacept (Orencia) and EU approved reference(Orencia) administered by the subcutaneous route to male normal healthy volunteers.	Biological		Dr. Satyajit Mohapatra	Regulatory	CTRI/2024/05/067154	Dr. Reddy's

Certifications/accreditations	<p>List certifications/accreditations</p> <p>Mention any specific regulatory approvals or audits passed in the last 5 years :</p> <p>We were audited from the pharmaceutical companies like Dr. Reddy's, Takeda, GLK, Hetero</p>
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