

Clinical trials and research

* Are all the clinical trials registered with CTRI (Clinical Trials Research of India)?

Yes. As per Government of India Regulations (Amendments dated 13th February, 2013, the IEC of SRU is registered with DCGI. The Registration number is ECR/203/inst./TN/2013 dated 20.04.13. Further all clinical trials are registered with the ICMR - Clinical Trials Research Registry.

* List a few major clinical trials conducted with their outcomes:

Over 33 trials have been conducted from 2009- 2013 listed below

Year	2009	2010	2011	2012	2013
No. of Trials	10	4	7	9	3

A sample of the details for the trials in 2013 is given below

S. No	Title of the R & D project	Name of the Project Leader	Name of the agency	Year in which started & duration	Total (Rs. in Lakhs)
1.	Protocol: EGF114299: A Phase III trial to compare the safety and efficacy of lapatinib plus trastuzumab plus an aromatase inhibitor (AI) versus trastuzumab plus an AI versus lapatinib plus an AI as first-line therapy in postmenopausal subjects with hormone receptor positive, HER2-positive metastatic breast cancer (MBC) who have received trastuzumab and endocrine therapy in the neo/adjuvant setting	Dr.Anita Ramesh Medical Oncology	GSK Pharmaceuticals	2013	1.05
2.	Protocol No: RI-01-002 “A Randomized, Multi – centre, Double- blind, Parallel Group Study to Compare the Pharmacokinetics, Pharmacodynamics, safety and Efficacy of Two Anti-CD20 Monoclonal Antibodies in Combination with CHOP in Patients with CD20 – +ve Diffuse Large B-Cell Lymphoma”.	Dr.Anita Ramesh Medical Oncology	Dr. Reddys lab	2013	2.08
3.	An 8 week, Placebo-controlled, Double-Blind, Randomised, fixed- Dose Efficacy and Safety Trial of	Dr.Sathianathan Psychiatry	Schering-Plough Research Institute	2013	2.08

	Asenapine in Adolescent Subjects with schizophrenia (Phase 3b Protocol No: P05896)				
--	---	--	--	--	--

The outcome of these trials has been international validation of the trial drugs which have helped in most of them getting approved for manufacture.