

(F) MAIN CLINICAL TRIALS**A. Investigator-initiated trials: Clinical**

IRB No	Title of Project	Investigators	Date of approval	Status	Budget	Funding agency
270	Optimizing the physical and biological parameters in craniospinal irradiation (CSI) for average risk medulloblastoma: a feasibility study	<u>Gupta T,</u> Jalali R, Sarin R, Muzumdar D, Sanghavi D, Merchant N	July 2006	Ongoing; 19 pts accrued; 1 remaining	Rs 3.4 Lakhs	CRC- ACTREC
200	A prospective study of concurrent carboplatin and radiotherapy followed by adjuvant chemotherapy in patients with newly diagnosed high-risk central nervous system embryonal tumours	<u>Kurkure PA,</u> Arora B, Bhagwat R, Gupta T, Sarin R, Jalali R, Muzumdar D, Kumar C, Kane S	June 2004	Ongoing; Over 50 patientts accrued	Rs 4.5 lakhs	CRC- ACTREC
197	Intensity modulated radiotherapy (IMRT) for craniospinal irradiation (CSI) in pediatric brain tumours- a dosimetric and feasibility study	<u>Jalali R,</u> Sharma D, Sarin R, Gupta T, P Reena, Shrivastava SK, Dinshaw KA	July 2004	Ongoing; 19 pts accrued, 1 remaining	Rs 3.0 lakhs	CRC- ACTREC
556	Feasibility of a low cost image based approach for safe and optimal resection of brain tumours.-A pilot study	<u>A Moiyadi,</u> Thakur MH, R Sarin, R Jalali, T Gupta, A Munshi	March 2008	Await of equipmeting procurement	Rs 60 Lakhs	DAE
653	Safety and efficacy of oral valproate in recurrent /progressive brain tumours	<u>T Gupta,</u> V Gota, S Gupta, R Jalali, A Munshi, R Sarin, A Moiyadi, H Menon, P Kurkure, S Medhi, N Merchant	Conditional approval granted in July 2009	Yet to receive final HEC clearance	Rs 5 Lakhs	To be sought
408	Head-Shaving in Neurosurgery – Implications on Surgical Site Infection and Cosmesis - A Feasibility Study	<u>A Moiyadi</u>	2008	Ongoing; initial accrual over; permission for extended accrual obtained	Rs 1 lakh	Intramural grant
53	Efficacy of stereotactic conformal radiotherapy (SCRT) compared to conventional radiotherapy in minimising late sequelae in children and young adults with brain tumour: a randomised clinical trial (SCRT trial).	<u>Sarin R, Jalali R,</u> Merchant N, Goswami S, Shah N, Dinshaw KA	2001	Ongoing	Rs 14 lakh approx	Terry Fox

B. Investigator-initiated trials: Basic/Translational

329	Genome wide expression profiling to determine the molecular basis of sensitivity to temozolomide in patients with glioblastoma multiforme	<u>N Shirsat, R Jalali,</u> R Sarin, T Gupta, A Moiyadi	Mar 2008 Grant as ICMR Centre of Excellence Genomics Proteomics	Ongoing	Rs 20.32 lakhs	ICMR
495	Proteomic analyses of medulloblastoma to identify sensitive biomarkers to detect, diagnose, and monitor disease: a biological correlative link-up study to currently ongoing clinical trials in medulloblastoma	<u>P Venkatraman,</u> T Gupta, P Kurkure, A Moiyadi, B Arora, R Jalali, R Sarin	July 2008 Grant as part of ICMR Centre of Excellence Genomics Proteomics	Ongoing	NK	ICMR
385	Identification of molecular sub-classes of medulloblastomas by genome wide expression analysis coupled with array-CGH	<u>N Shirsat,</u> R Sarin, R Jalali, T Gupta, A Moiyadi		Ongoing	NK	

C. Industry-sponsored trials:

694	Cilengitide for subjects with newly diagnosed glioblastoma multiforme and methylated MGMT gene promoter - a multicenter, open-label, controlled Phase III study, testing cilengitide in combination with standard treatment (temozolomide with concomitant radiation therapy, followed by temozolomide maintenance therapy) versus standard treatment alone (CENTRIC)	<u>T Gupta, R Jalali,</u> R Sarin, A Munshi, A Moiyadi, H Menon, S Epari, N Merchant, S Juvekar	January 2010	Site initiated; Patients being pre-screened	Rs 43.5 Lakhs approx	Merck- Serono
687	Efficacy and safety of AP 12009 in adult patients with recurrent or refractory anaplastic astrocytoma (WHO grade III) as compared to standard treatment with temozolomide or BCNU: a randomized, actively controlled, open-label clinical phase III study (SAPPHIRE)	<u>A Moiyadi,</u> T Gupta, R Jalali, A Munshi, R Sarin	October 2009	Site initiated; patients being pre-screened	Rs 20 Lakhs approx	Antisense Pharma