

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,LUCKNOW.

List of Multicentric Drug /Device trials : (1994-till date :27.2.09)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1.	Evaluation of Immunoferon As a Biological Response Modifier In Carcinoma Breast”.	Prof.S.Ayyagari Radiotherapy	NIL	NIL	INFAR	One year (1994)	2,36,000=00
2.	Percutaneous closure of atrial septal defect by the Das Transcatheter self centering device.”	Prof. S.Srivastava Cardiology	25.1.1995	23.2.1995	Microvena Corporation, USA	Six Month (1995)	42,000 US\$ 19,74,000=00
3.	Fragmin ® in acute myocardial infarction	Prof. N.Sinha Cardiology	19.4.1996	NIL	FAMI,Bangalore	One Year (1996)	2,35,000=00
4.	Development of standarisation of modified radioresperometric technique for faster detection of microorganisms & assessment of antibiotic sensitivity	Dr. A.K.Shukla Nuclear Medicine	31.8.1996	15.3.1997	REI, USA	Three years (1996)	Nil
5.	International research on efficacy and safety of prolonged tomoxifen trement for women with a history of breast cancer	Prof. S.K.Mishra Endocrinology (Surg)	31.8.1996	NIL	Atlas,U.K.	Two Year (1996)	Nil

6.	Surveillance of Methicilin Resistant Staphylococci and Haemophilus infection at SGPGI”.	Prof.A.Ayyagari Microbiology	31.8.1996	NIL	Eli Lilly,Ranbaxy, Ltd.	Six Months (1996)	1,50,000=00
7.	Cefamandole versus cefotaxime in surgical prophylaxis of Billiary tract surgery-Multicentric Trial.	Prof.S.P.Kaushik Surgical Gastroenterology	16.1.1997	NIL	Eli Lilly,Ranbaxy, Ltd.	One year (1997)	50,000=00
8.	Phase-II double blind clinical trial with CDRI compound 80/574 in patients of hyperlipidaemia.	Prof.Nakul Sinha Cardiology	20.9.1997	NIL	CDRI	One year (1997)	2,39,200=00
9.	Comparative antimicrobial activity of six broad spectrum B-lactum at medical centers in India	Prof.A.Ayyagari Microbiology	12.5.2000	20.5.2000	Hoechst Marion Roussel Ltd.	One Year (2000)	68,110=00
10.	Prevalence of B-lactamase producing strains among clinical isolates obtained from hospital in-patients and comparison of antimicrobial susceptibility using disc-diffusion method	Prof.A.Ayyagari Microbiology	NIL	11.7.2000	Pfizer	One Year (2000)	19,750=00
11.	Evaluation of the efficacy and safety of leflunomide (HWA 486) in patients with active rheumatoid arthritis-multicenter study	Prof. R.N.Mishra Immununology	12.5.2000	24.2.2001	Hoechst Marion Roussel, Ltd.	One Year (2000)	3,00,000=00

12.	Evaluation and management of dyslipidemia in indian subjects with coronary artery disease	Prof.N.Sinha Cardiology	10.10.2000	25.1.2001	Dr.Reddy's Laboratory	Two Years (2000)	5,00,000=00
13.	Study on safety and efficacy of an indigenous human recombinant interferon 2 a (Shanferon) in hepatitis B and C patients.	Dr.Rakesh Aggarwal Gastroenterology	10.10.2000	10.11.2000	M/s Shanta Biotechnics Pvt. Ltd. Hyderabad.	One Year & three month (2000)	4,56,800=00
14.	Phase III Randomized Multicenter comparative study of peginterferon 2a vs Roferon A in chronic phase chronic myogenous leukemia, diagnosed recently and not previously received interferon.	Dr.Soniya Nitya- nand Hematology	12.5.2000	21.3.2001	Quintiles Spectral Ahmedabad	Five years (2001)	6,12,000=00
15.	Open-Label Evaluation of the efficacy and safety of etanercept in common rheumatology usage (ECRU).	Prof.R.N.Mishra Immununology	12.5.2000	13.4.2001	Wyeth Lederle Ltd. Mumbai	Two years (2001)	2,50,000=00
16.	An open level multicentre study to further characterize the clinical utility and safety of Rapamycin and cyclosporine combination treatment in doNovo Renal Allograft Recipient.	Prof.R.K.Sharma Nephrology	12.5.2000	16.3.2001	Wyeth Lederle Ltd. Mumbai	Two years (2001)	5,00,000=00
17.	A Randomized, Open Label, Comparative, Multicenter study of Voriconazole versus	Prof.V.K.Kapoor Surgical Gastroenterology	25.7.2001	02.8.2001	Pfizer Limited , Mumbai	Two years (2001)	7,13,750=00

	Conventional Amphotericin B Followed by Fluconazole in the Treatment of Candidemia in Non Neutropenic Subjects.						
18.	Glucose-Insulin-Potassium and reviparin in the management of acute myocardial infarction.	Prof. Nakul Sinha Cardiology	14.5.2001	NIL	St.John's Medical College,Bangalore	One year & six months (2001)	5,00,000=00
19.	Safety,Tolerability and Pharmacokinetics of single dose of RBx 2258 in patients with Benign Prostatic Hyperplasia.	Dr. Anant Kumar Urology	10.10.2000	31.10.2000	Ranbaxy Lab.Ltd. Gurgaon(Haryana)	Three months (2001)	1,33,950=00
20.	Efficacy and safety of RBx-2258 in patients with lower urinary tract symptoms (LUTS) due to Benign Prostatic Hyperplasia: A double blind placebo controlled study".	Dr. Anant Kumar Urology	08.12.2000	15.12.2000	Ranbaxy Lab.Ltd. Gurgaon(Haryana)	Six months (2001)	1,98,813=00
21.	Comparative Efficacy and Tolerability of Sustained Release (OD) Tablets and Conventional Release Tablets of Ciprofloxacin in Complicated Urinary Tract Infection-A double blind study.	Dr.Anant Kumar Urology	14.4.2001	15.6.2001	Ranbaxy Lab.Ltd. Gurgaon(Haryana)	One year & six months (2001)	4,41,500=00
22.	A comparative study of TURP Vs Transurethral anhydrous	Dr.Anant Kumar Urology	14.5.2001	09.8.2001	American Medical Systems	One year (2001)	16,500 US\$ 7,75,500=00

	alcohol injection for treatment of Benign Prostatic Hyperplasia.						
23.	Prospective Bicentric randomized Double Blind Placebo Controlled study to test the efficacy of veromax in patients with Erectile Dysfunction.	Prof.M.Bhandari Urology	10.4.2002	02.11.2002	German Pharmaceuticals, Ltd.	One year (2002)	4,68,750=00
24.	“In-vitro sensitivity of a new synthetic drug RBX 7644 in Gram positive isolates from patients in a tertiary care health Institute and its comparison with standard drugs”.	Prof.A.Ayyagari Microbiology	No Human Subject	12.2.2002	Astra Zeneca, Bangalore	Three months (2002)	41,000=00
25.	“Clinical Evaluation of the Efficacy and Safety of Dutasteride in BPH (Study code No. CP/13/02.	Prof. Anant Kumar Urology	05.2.2003	17.2.2003	Cipla Ltd.	Three months (2003)	2,87,500=00
26.	“A clinical study to evaluate the Efficacy and Safety of Cyclosporine (Imusporin) in Renal Transplant patients with stable graft function maintained on Cyclosporine preparation other than Imusporin”.	Prof. Anant Kumar Urology	01.11.2002	11.9.2003	Cipla Ltd.	Three months (2003)	5,98,000=00
27.	“To determine safety and efficiency of indigeneous	Prof. R.K.Sharma Nephrology	05.2.2003	11.5.2003	Shantha Biotech. Pvt. Ltd.	One year (2003)	2,84,500=00

	recombinant human erythropoietin in patients of anaemia of chronic renal failure”.						
28.	“VIpe study Valproate in partial epilepsy”.	Prof.U.K.Misra Neurology	05.2.2003	14.5.2003	Sanofi- Synthelabo Ltd.	Tow years (2003)	47,000=00
29.	“Efficacy & Tolerability of Tacrolimus in patients of renal transplantation”.	Prof. R.K.Sharma Nephrology	05.2.2003	24.7.2003	Panacea Biotec Ltd. New Delhi	One year (2003)	2,38,750=00
30.	An open,multicentric, post-marketing surveillance study of GlaxoSmithKline Biologicals combined hepatitis A-hepatitis B vaccine (TWINRIX), injected as a three dose Primary vaccination course in healthy children and adults”.	Dr Rakesh Aggarwal Gastroenterology	02.8.2003	02.10.2003	Smith Kline Biologicals Ltd.	Ten Months (2003)	2,06,250=00
31.	An open label, Non-comparative multicentric clinical trial of Lamotrigine once a day preparation to evaluate the safety and efficacy in the treatment of epilepsy (Primary generalized, partial (simple/Complex) with or without secondary generalization) as a monotherapy or as an add on therapy or as a switched over	Dr. Sunil Pradhan Neurology	02.8.2003	29.10.2003	Torrent Pharmaceuticals Ltd.	Six months (2003)	75,000=00

	Therapy”.						
32.	A Randomized double blind trial of LdT (Telbivudine) virus Lamivudine in Adults with Compensated Chronic Hepatitis B	Dr. G. Choudhari Gastroenterology	27.8.2003	27.1.2004	Novartis India Ltd.	Three years (2003-2006)	4,97,500=00
33.	An multicentre randomized open lable study of the efficacy and safety of 2 doses of Ferrlecit versus oral iron to treat iron deficiency anaemia in peritoneal dialysis patient receiving erythropoietin	Prof. Amit Gupta Nephrology	02.8.2003	17.3.2004	Quintiles Research (India) Private Ltd.	Two years (2004-2005)	12,00,000=00
34.	Safety & efficacy of recombinant HB vaccine in healthy adults.	Prof. G.Choudhuri Gastroenterology	14.5.2004	07.7.2004	Shreya Life Sciences, Pvt. Ltd.	Two years (2004-2006)	3,70,000=00
35.	An evaluation of safety and efficacy of recombinant erythropoietin (EPO) (IPL-P03) in the treatment of anemia in patients with chronic kidney disease (CKD). A prospective, Non-comparative, Open Label, Multicenter study	Prof. R.K.Sharma Nephrology	14.5.2004	21.7.2004	Intas Pharmaceuticals Ltd. Ahmedabad	One year (2004-2005)	3,62,500=00
36	A Randomized open label, multicentre phase 4 study to evaluate the efficacy and safety of Magnex in	Prof. V.K.Kapoor Surgical Gastroenterology	14.5.2004	05.9.2004	Pfizer Ltd.	Nine months (2004)	3,37,880=00

	comparison with Ceftazidime plus Amikacin and Metronidazole in the treatment of Intra-abdominal Infections”.						
37.	An evaluation of safety and efficacy of IPL-PO2 (Interferon Alfa 2-b) in patients with chronic hepatitis B & C infection	Prof. G.Choudhuri Gastroenterology	14.5.2004	24.9.2004	Intas Pharma. Ahamadabad	One year (2004)	3,62,500=00
38.	A Ramdp,oozed. Two Arm, Double Blind, Comparative, Multicentric Clinical Trial to evaluate efficacy and safety of Nebivolol in Patients with Chronic Stable Angina in Comparison with Metoprolol	Prof. Nakul Sinha Cardiology	23.9.2004	18.2.2005	Torrent Pharmaceuticals Ltd. Ahmedabad	One year six months (2005)	2,02,250=00
39.	Open randomized study to evaluate efficacy and safety of oral val ganciclovir versus IV ganciclovir for the treatment of CMV disease in solid organ transplant recipient.	Prof. R.K.Sharma Nephrology	14.5.2004	16.3.2005	F.Hoffmann-La Roche Ltd.	Two years (2005)	6,56,250=00
40.	“A Phase 3, Randomized, Double-blind, Comparative study of micafungin (FK463) versus caspofungin as antifungal treatment in patients with invasive candidiasis or candidemia”.	Prof. V.K.Kapoor Surgical Gastroenterology	23.9.2004	16.3.2005	Quintiles Research (India) Pvt. Ltd.	One year (2005)	1,20,000=00

41.	“Evaluation of efficacy and safety of Lanthanum Carbonate in Patients of Hyperphosphatemia”.	Prof. R.K.Sharma Nephrology	23.9.2004	06.5.2005	Panacea Biotec Ltd. New Delhi	One year (2005)	1,87,500=00
42.	“Assesment of Everolimus in addition to calcineurin inhibitors reduction in maintenance renal transplant recipients- Ascertain”.	Prof. R.K.Sharma Nephrology	09.3.2005	20.6.2005	Novartis Ltd.	Two years (2005-2007)	9,40,000=00
43	“Dose ranging study to evaluate the safety & efficacy of olmesartan medoxomil in Children and Adolescents with Hypertension”.	Prof. R.K.Sharma Nephrology	09.3.2005	20.6.2005	Quintiles Ltd.	Three years (2005-2008)	1,68,500=00 (per patients)
44	“The Surgical Treatment for Ischemic Heart Failure (STICH)”.	Prof. Nakul Sinha Cardiology	27.12.2004	20.6.2005	Clini Rx Research Pvt. Ltd.	Three years (2005-2008)	38,88,000=00
45	“An open Non comparative study to evaluate the efficacy & safety of fixed dose combination of Dutasteride (0.5mg) & Tamsulosin (0.4mg) in patients with benign prostatic Hyperplasia”.	Prof. Anant Kumar Urology	09.5.2005	28.7.2005	Cipla Ltd. Mumbai	Six months (2005-2006)	3,47,563=00
46.	“A Phase III, randomized, multi-centre, double-blind, parallel group, active comparator study to compare the efficacy and safety of	Prof. G.Choudhuri Gastroenterology	09.3.2005	28.7.2005	Shire Pharma. Developopt UK	Two years (2005-2007)	30,00,000=00

	SPD476 (mesalazine) 2.4g/day once daily (DQ) with Asacol® 1.6g/day twice daily (BID) in the maintenance of remission in patients with ulcerative colitis”.						
47.	“Phase III multicentric double blind clinical trials in patients of hyperlipidemia (CDRI compound 80/574).	Prof. Nakul Sinha Cardiology	23.9.2004	30.10.2005	Cadila Pharmaceuticals	One year (2005-2006)	3,50,000=00
48.	“An open label, multicentric clinical trial to assess the efficacy and tolerability of Sevelamer in the treatment of hyperphosphatemia in end stage renal disease patients”.	Prof. R.K.Sharma Nephrology	09.3.2005	27.11.2005	Emcure Pharma. Ltd.	Six months (2005-2006)	33,375=00
49.	“A randomized, double blind, placebo controlled, parallel group study to assess the effect of the endothelin receptor antagonist avosentan on time to doubling of serum creatinine, end stage renal disease or death in patients with type-2 diabetes mellitus and diabetes nephropathy”.	Prof. R.K.Sharma Nephrology	18.8.2005	27.11.2005	Speedel Pharma Ltd.	Three years (2005-2008)	2,08,110=00 (per patients)
50	“A randomized, double-blind trial of Ldt (Telbivudine) versus Lamivudine in Adults	Prof. G.Choudhuri Gastroenterology	25.8.2005	23.3.2006	Idenix Pharma. Inc.	Two years (2006-2008)	2,00,000=00

	with Decompensated Chronic Hepatitis B and Eviudence of Cirrhosis: NV-02B-011”.						
51.	“An Open Label Trial of Telbivudine (LdT) in Adults with Chronic Hepatitis B Previously Treated in Idenix-Sponsored Telbivudine Studies”.	Prof. G.Choudhuri Gastroenterology	26.11.2006	23.3.2006	Quintiles	One Year (2006-2007)	3,90,000=00
52.	“(Protocol 1160.26) Randomized of Long Term anticoagulant therapy (RE-LY) comparing the efficacy and safety of two blinded doses of dabigatran etexilate with open label warfarin for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation: Prospective, multi-centre, parallel group, non-inferiority trial”.	Prof. Nakul Sinha Cardiology	27.2.2006/0 6.6.2006	27.3.2006	Boehringer Ingelheim Korea Ltd.	Five Years (2006-2011)	6,12,000=00
53.	“A Multicentre, Open-Label, Randomized Comparative Study of Tigecycline Us Ceftriaxone Sodium Plus Metroindazole for the treatment of Hospitalized Subjects with Complicated	Prof. V.K.Kapoor Surgical Gastroenterology	11.8.2005	02.6.2006	Quintiles (Wyeth)	Two years (2006-2008)	90,488=00 per patient

	Intra-Abdominal Infection”.						
54.	“The Effect of Eplerenone Versus Placebo on Cardiovascular Mortality and Heart Failure Hospitalization in Subjects with NYHA Class II Chronic Systolic Heart Failure”.	Prof. Nakul Sinha Cardiology	26.10.2004	03.5.2006	Pfizer Pvt. Ltd.	Four Years (2006-2010)	14,42,500=00
55.	“Comparison of Three Regimens of PEG-Intron plus Ribavirin in the Treatment of Chronic Hepatitis C, Genotype 2 or 3, in Previously Untreated Patients”.	Prof. G.Choudhuri Gastroenterology	11.8.2005	27.7.2006	Fulford (India), Ltd.	One year eight months (2006- 2008)	US\$ 950 per patient 42,750=00
56.	“A 13-week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group study to Evaluate the Efficacy, Safety and Tolerability of Pregabalin (150-600 mg/day) Using A Flexible Dosing Schedule in the Treatment of Subjects with Central Post-Stroke Pain (CPSP)”.	Prof. U.K.Misra Neurology	06.06.2006	30.8.2006	Pfizer Ltd.	Three months (2006)	4,66,250=00
57.	“A randomized, phase 3, controlled, double-blind, parallel-group, multicentre	Prof. R.N.Misra Immunology	06.6.2006	10.8.2006	Roche Pvt. Ltd.	Four years (2006- 2010)	1,08,790=00

	study to evaluate the safety and efficacy of rituximab in combination with methotrexate (MTX) compared to MTX along, in methotrexate naïve patients with active rheumatoid arthritis”. Code No. A-06: PGI/DT/EC/34/6/6/2006						
58.	“A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a fully Human Anti-TNF α Monoclonal Antibody, Administered Subcutaneously, in Methotrexate-naïve Subjects with Active Rheumatoid Arthritis”.	Prof. R.N.Misra Immunology	06.6.2006	22.7.2006	Centocor Pvt. Ltd.	Six years (2006-2012)	25,097,57 USD 11,29,391=00
59.	“A Randomized, Double-Blind Placebo-Controlled, Four Arm, Parallel-Group, Multicenter, Multinational, Safety and Efficacy trial of 100 mg, 300 mg and 900 mg of Abetimus Sodium in Systemic Lupus Erythematosus (SLE) patients with a history of Renal Disease”.	Prof. R.K.Sharma Nephrology	06.6.06	10.8.06	La Jolla Pharmaceutical	Two years (2006-2008)	1,38,825=00 per patients

60	“A Phase III, open label, multicentric, parallel group, randomized study to evaluate the safety and efficacy of Abciximab in Indian patients scheduled for Percutaneous Coronary Intervention”. Code no. A-08: PGI/DT/EC/35/19.9.06	Prof. Nakul Sinha Cardiology	19.9.2006	10.1.2007	CRO-Manipal Acunova Ltd. (Lupin)	Six months (2007)	2,25,000=00
61.	“A 12-Week, Open Lable, Safety Trial of Pregabalin in Patients with Fibromyalgia”. Code no. A-02 (a)- PGI/DT/EC/35/19.9.2006	Prof. R.N.Misra Immunology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	Ten months (2007)	2,76,100=00
62.	“A 14-Week, Randomized, Double-Blind, Placebo-Controlled Trial of Pregabalin Twice Daily in Patients with Fibromyalgia”. Code no. A-02 (b)-PGI/DT/EC/35/19.9.2006	Prof. R.N.Misra Immunology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	Nine months (2007)	4,95,000=00
63.	“A randomized, comparative, double-blind, parallel-group, multicenter, monotherapy, study of Pregabalin (Lyrica) and Lamotrigine (Lamictal) in patients with newly diagnosed partial seizures”. Code no. A-01-PGI/DT/EC/35/19.9.2006	Prof. U.K.Mishra Neurology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	One year (2007)	8,12,000=00

64.	“Clinical Protocol IM103008: Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial (BENEFIT)”. Code no. A-04: PGI/DT/EC/36/13.12.2006.	Prof. R.K.Sharma Nephrology	13.12.2006	21.4.2007	Bristol-Myers Squibb India Pvt. Ltd. (CRO Quintiles)	Three years (2007-2010)	24,47,200=00
65.	“Randomized, multinational, double-blind study, comparing a high loading dose regimen of clopidogrel versus standard dose in patient with unstable angina or non-ST segment elevation myocardial infarction managed with an early invasive strategy”. Code no A-02: PGI/DT/EC/36/13.12.2006	Prof. Nakul Sinha Cardiology	13.12.2006	05.6.2007	ICON Clinical Research India Pvt. Ltd.	One year (2007)	24,000=00 per patient
66.	“A randomized double-blind controlled trial of the efficacy and safety of POLYCAP versus its components in subject with at least one additional cardio-vascular risk factor”. Code No. A-09: PGI/DT/EC/35/19/9/2006	Prof. Nakul Sinha Cardiology	19.9.2006	2007	Cadila Pvt. Ltd.	Six months (2007)	1,25,000=00
67.	Protocol CL3-18886-012 “Prevention of cerebrovascular and cardiovascular events of	Prof. U.K.Mishra Neurology	13.12.2006	25.6.2007	Quintiles Pvt. Ltd.	2 and half years (2007-2010)	5,80,000=00

	<p>ischaemic origin with teRutroban in patients with a history of ischaemic stroke or tRansient ischaeMic stroke- The PERFORM study”. Code no. A-01: PGI/DT/EC/36/13.12.2006</p>						
68.	<p>“A phase 3 randomized study to evaluate survival of patients treated with talaporfin sodium (LS11) and interstitial light emitting diodes (LED) as compared to the standard of care therapies in the treatment of unresectable Hepatocellular Carcinoma (HCC)”. Code no. A-20: PGI/DT/EC/37/20/3/2007</p>	<p>Dr. Neeraj Rastogi Radiotherapy</p>	20.3.2007	26.6.2007	<p>Light Science Oncology, USA (CRO-Reliance Clinical Research Services, Mumbai</p>	<p>One year (2007-2008)</p>	7,74,089=00
69.	<p>“Phase III Clinical evaluation of safety and efficacy of HD-03/ES in Hepatitis B Virus”. Code No. A-21: PGI/DT/EC/38/10.5.2007</p>	<p>Prof. G.Choudhuri Gastroenterology</p>	10.5.2007	11.7.2007	<p>Himalayan Drug Company</p>	<p>One year (2007-2008)</p>	3,47,500=00
70.	<p>“Phase III clinical evaluation of safety and efficacy of NCB-02 in Ulcerative Colitis”. Code No. A-22: PGI/DT/EC/38/10.5.2007</p>	<p>Prof. G.Choudhuri Gastroenterology</p>	10.5.2007	11.7.2007	<p>Himalayan Drug Company</p>	<p>One year (2007-2008)</p>	4,78,750=00

71.	<p>“International, randomized, double-blind clinical study evaluating the efficacy and safety of clopidogrel 0.2 mg/kg once daily versus placebo in neonates and infants with cyanotic congenital heart disease palliated with a systemic-to-pulmonary artery shung (e.g. modified Blalock Taussing shunt)”.</p> <p>Code. No. A-18: PGI/DT/EC/38/10.5.2007.</p>	Dr. Nirmal Gupta CVTS	10.5.2007	07.8.2007	Sanofi-Synthelabo Recherche, France	One year (2007-2008)	1,71,320=00
72.	<p>“Comparison of the Efficacy and Safety of Entecavir Versus Adefovir in Subjects Chronically Infected with Hepatitis B Virus and Evidence of Hepatic Decompensation”.</p> <p>Code. No. A-23: PGI/DT/EC/37/20.3.2007.</p>	Prof. G.Choudhuri Gastroenterology	20.3.2007	07.8.2007	Bristol-Myers Squibb India Pvt. Ltd.	One year (2007-2008)	1,36,813=00 per patient
73.	<p>“A Randomized Double-Blind, Placebo-Controlled Evaluation of the Safety, Efficacy and Pharmacokinetics of multiple doses of Basiliximab with Concomitant Corticosteroids in Steroid-Refractory Ulcerative</p>	Dr. U.C.Ghoshal Gastroenterology	14.8.2007	26.9.2007	Cerimon Pharmaceuticals Pvt. Ltd.	Two years (2007-2009)	4,35,260=00

	Colitis". Code No. A-15: PGI/Dt/EC/39/14.8.2007.						
74.	“An open label, response adaptive study of Telbivudine in adults with HBeAg positive compensated chronic hepatitis B”. Code No. A-14: PGI/DT/EC/39/14.8.2007.	Prof. V.A. Saraswat Gastroenterology	14.8.2007	03.10.2007	Novartis India Ltd.	Three years (2007-2010)	12,18,750=00
75.	“A1463-080 Randomized observational study of Entecavir to assess long term outcome associated with nucleoside/nucleotides monotherapy for patients with chronic HBV infection: The REALM study”. Code No. A-24: PGI/DT/EC/37/20/3/2007	Prof. G.Choudhuri Gastroenterology	20.3.2007	13.11.2007	Bristol Myers Squibb India Pvt. Ltd.	Three years (2007-2010)	41,028/- per patients
76.	“A Multicenter, randomized, Double-Blinded, Placebo-Controlled, dose-ranging study to assess the efficacy and safety of TZP-101 when administered as a 30 minute IV infusion for post operative ileus to subjects undergoing major open abdominal surgery”. Code No. A-21: PGI/DT/EC/40/7/11/2007	Prof. V.K.Kapoor Surgical Gastroenterology	7.11.2007	26.12.2007	Tranzyme, Inc. USA (CRO-QED Pharmaceutical Services Pvt.Ltd.	Six months (2007-2008)	1,00,000=00 per patient

77	<p>“Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndrome: A Randomized, Placebo-Controlled Trial Evaluating the Clinical Benefits of Early Front-Loaded Eptifibatide in the treatment of Patient with Non-ST-Segment Elevation Acute Coronary Syndrome (EARLY ACS)”. Code No. A-22: PGI/DT/EC/37/20/3/2007</p>	Prof. Nakul Sinha Cardiology	20.3.2007	24.8.2007	Millennium Pharmaceuticals	Two years (2007-2009)	22,00,000=00
78	<p>“Study for Monitoring Antimicrobial Resistance Trends”. Code No. A-16: PGI/DT/EC/40/7/11/2007</p>	Prof. T.N.Dhole Microbiology	7.11.2007	24.7.2007	MSD Pharmaceuticals Pvt. Ltd. Gurgaon.	One year (2008)	1,33,603=00
79	<p>“Protocol C0524T17-A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-Blind study to evaluate the safety and efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in subjects with Moderately to Severely Active Ulcerative Colitis”. Code No. PGI/DT/EC/39/14.8.2007</p>	Prof. G.Choudhuri Gastroenterology	14.8.2007	04.4.2008	Centocor (CRO- Quintiles)	One year (2008-2009)	81,259/- per patient

80	“Protocol C0524T18-A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind study to evaluate the safety and efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in subjects with Moderately to Severely Active Ulcerative Colitis”.	Prof. G.Choudhuri Gastroenterology	14.8.2007	04.4.2008	Centocor (CRO-Quintiles)	Five years (2008-2013)	2,85,060/- per patient
81	“A clinical trial comparing cangrelor to clopidogrel in subjects who require percutaneous coronary intervention”. Code No. A-18: PGI/DT/EC/40/7/11/2007	Prof. Nakul Sinha Cardiology	7.11.2007	21.2.2008	The Medicines Company, USA	One year (2008-2009)	15,00,000=00
82	“PICTURE SUDY-the place of reveal in the care pathway and treatment of patient with unexplained recurrent syncope”. Code No. PGI/DT/EC/Registry/39/14.8.2007.	Prof. Nakul Sinha Cardiology	14.8.2007	22.2.2008	India Medtronic Pvt. Ltd., Mumbai	Four months (2008)	84,000=00
83	“A Phase IIb/III-Multi-centre, double-blind, randomized, placebo-controlled, dose ranging study of tamsulosin hydrochloride (low, medium and high dose) as treatment	Prof. Rakesh Kapoor Urology	28.2.2008	30.4.2008	Boehringer Ingelheim International GmH (“BII”).	Eighteen months (2008-2009)	93,500=00 per patient

	children with neuropathic bladder for three months”. Code No. A-20: PGI/DT/EC/41/28.2.2008						
84	“Clinical Investigation Plan No. 07-377 SPRIT Women Clinical Evaluation: A clinical Evaluation of the XIENCEV Everolimus Eluting Coronary Stent System in the treatment of Women with de novo Coronary Artery Lesion (single Arm Study Protocol)”. Code No. A-17: PGI/DT/EC/40/7/11/2007.	Prof. P.K.Goel Cardiology	7.11.2007	16.5.2008	M/s Abott Cardiovascular System Inc, USA	Five years (2008-2013)	800 Euro per patient @ 46,400=00
85	“A1463-110-A comparative study of chronic Hepatitis B subjects treated with Entecavir plus Tenofovir combination therapy vs Entecavir Monotherapy in Adults who are treatment naïve to Nucleosides and Nucleotides: The Be-Low study”. Code no. A-11: PGI/DT/EC/39/14.8.2007	Prof. G.Choudhary Gastroenterology	14.8.2007	22.5.2008	Bristol Myers Squibb	Two years (2008-2010)	4,86,378=00
86	“A randomized, open level two arm, multicenter study to evaluate the safety and	Prof. R.K.Sharma Nephrology	28.2.2008	12.5.2008	SIRO Clinpharm Pvt. Ltd.	One year (2008-2009)	11,33,625=50

	efficacy of the darbapoetin as compared to erythorpoetin in predialysis patient with anemia of chronic kidney disease (CKD). Code No. A-77: PGI/DT/EC/41/28.2.2008						
87	“a1463-111-A comparative study of Entecavir us Adefovir vs the combination in Lamivudine Refractory Chronic Hepatitis B SUBJECTS: The Define study”. Code no. A-10: PGI/DT/EC/39/14.8.2007	Prof. G.Choudhuri Gastroenterology	14.8.2007	30.5.2008	Bristol Myers Squibb	Two years (2008-2010)	4,30,395=00
88	“A multicenter, randomized, double-blind, assessor-blind, non-inferiority study comparing the efficacy and safety of once-weekly subcutaneous biotinylated idraparinux (SSR126517E) with oral adjusted-dose warfarin in the prevention of stroke and systemic thromboembolic events in patients with atrial fibrillation”. Code No. PGI/DT/EC/41/28.2.2008	Dr. Aditya Kapoor Cardiology	28.2.2008	9.6.2008	Sanofi-Sythelabo (India) Ltd. Mumbai	Two & Half year (2008-2011)	15,75,000=00

89	“Effects of ivabradine on cardiovascular events in patients with moderate to severe chronic heart and left ventricular systolic dysfunction”. Code No. A-16: PGI/DT/EC/41/28/2/2008	Prof. Nakul Sinha Cardiology	28.2.2008	9.6.2008	Institut De Recherches Internationals Server (IRIS)	Two years (2008-2010)	20,15,518=00
90	“ST-ANAM-207-A randomized, double-blind, placebo-controlled, multicenter Phase II Anamorelin HCI Dose Range study to evaluate the safety & efficacy of Anamorelin HCI in Patients with NSCLC”. Code No. A-12: PGI/DT/EC/42/7.5.2008	Dr. Neeraj Rastogi Radiotherapy	07.5.2008	16.7.2008	Sapphire Therapeutics, Inc. (CRO-Reliance Clinical Research Services, Pvt. Ltd.)	One year (2008-2009)	3,41,200=00
91	“SPD467-304-A Phase III, randomized, multi-centre, double-blind, parallel group, active comparator study to compare the efficacy and safety of SPD467 (mesalazine) 2.4g/day once daily (QD) with Asacol® 1.6g/day twice daily (BID) in the maintenance of remission in patients with ulcerative colitis”. Code No. A-19: PGI/DT/EC/41/28.2.2008	Dr. S.Mohindra Gastroenterology	28.2.2008	18.7.2008	Shire Pharmaceu. Development Ltd. (CRO-ICON)	Two years (2008-2010)	1,29,200=00 per patient

92	“Heart Outcomes Prevention Evaluation (Hope)-3”. Code No. PGI/DT/EC/41/28.2.2008	Prof. Nakul Sinha Cardiology	28.2.2008	23.7.2008	Population Health Research Institute. (CRO-St. John Academy of Health Sciences, Bangalore	Five years (2008-2013)	34,58,700=00
93	“A Phase IIIB Multicenter, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Abatacept Administered Subcutaneously and Intravenously in Subjects with Rheumatoid Arthritis, Receiving Background Methotrexate, and Experiencing an Inadequate Response to Methotrexate”. Code No. A-15: PGI/DT/EC/42/7.5.2008.	Dr. Amita Aggarwal Immunology	7.5.2008	4.8.2008	Briston-Myers Squibb R&D	Two years (2008-2010)	14,52,196=00
94	“A randomized, double blind, placebo-controlled study to evaluate the efficacy and safety of Fesoterodine as an “Add-on” therapy in men with persistent overactive bladder symptoms under monotherapy of alpha blocker for lower	Prof. Rakesh Kapoor Urology	13.8.2008	22.9.2008	Pfizer Pvt. Ltd.	One year (2008-2009)	2,65,000=00

	urinary tract symptoms”. Code No. A-17: PGI/DT/EC/43/ 13.8.2008						
95	“A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Darbepoetin alfa Treatment on Mortality and Morbidity in Heart Failure (HF) Subjects with Symptomatic Left Ventricular Systolic Dysfunction and Anemia-20050222 Amendment 1”. Code No. A-13: PGI/DT/EC/42/7.5.2008	Prof. Nakul Sinha Cardiology	7.5.2008	22.9.2008	Amgen Inc.	Three years (2008-2011)	70.20,625=00
96	“A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging study to assess the Efficacy and Safety of TZP-101 when Administered as a 30 Minute I.V. Infusion to Subjects with Severe Gastroparesis due to Diabetes Mellitus”. Code No. A-20: PGI/DT/EC/43/13.8.2008	Dr. U.C. Ghoshal Gastroenterology	13.8.2008	22.9.2008	Tranzyme Inc. Dehradun	Six months 2008-2009	1,24,625=00 per patient
97	“A Phase III, Randomized, Placebo-controlled, Double-	Dr. Anil Mandhani	7.5.2008	3.10.2008	Astra Zeneca	Five Years 2008-2013	18,96,000=00

	Blind study to assess the Efficacy and Safety of Once-daily Orally Administered ZD4054 10mg in Non-metastatic Hormone-resistant Prostate Cancer Patients”. Code No. A-16: PGI/DT/EC/42/7.5.2008	Urology					
98	“A Multinational, Multicenter, Randomized, Double Blind Study comparing the Efficacy and Safety of AVES5026 with Enoxaparin for the Prevention of Venous Thrombo-embolism in Patients Undergoind Major Abdominal Surgery”. Code No. A-16: PGI/DT/EC/43/13.8.2008.	Prof. V.K.Kapoor Surgical Gastroenterology	13.8.2008	28.11.2008	ICON Clinical Research India Pvt. Ltd.	15 Months 2008-2009	1,00,000=00 Per patients
99	“CABG Off or On Pump Revascularization Study”, (Coronary). Code No. A-15: PGI/DT/EC/41/28.2.2008.	Prof. Nakul Sinha Cardiology	28.2.2008	01.12.2008	Canadian Institute of Health Research, Canada	30 months 2008-2011	60,15,625=00
100	“The Best Combination for Coronary Revascularization-Optimal Platelet Inhibition, Effective Cholesterol Lowering, The PronoVa XR Stent, and Effective Disease Management (BELIEVE)	Dr. Satyendra Tewari Cardiology	28.2.2008	01.12.2008	Vascular Concepts Ltd.	6 months 2008-2009	Only Device (Stent)

	Trial”. Code No. A-23: PGI/DT/EC/41/28.2.2008						
101	“A screening protocol to characterize the Disease status of Gaucher type 1 Patients for Potential Inclusion in a Subsequent Phase 3 Clinical Study”. Code No. A-25: PGI/T/EC/44/28.11.2008	Prof. Shubha R Phadke Medical Genetics	28.11.2008	19.1.2009	SIRO Clinpharm Pvt. Ltd.		34,262=00 per patient
102	“A Randomized, Double-Blind Placebo-Controlled study of the safety and Tolerability of E5555 and its effects on clinical events and biomarkers in patients with non-ST-segment elevation acute coronary syndrome”. Code No. A-22: PGI/DT/EC/44/28.11.2008	Prof. Nakul Sinha Cardiology	28.11.2008	19.1.2009	Eisai Ltd.	One month (2009)	5,98,604=00
103	“109MS302-A Randomized, Multicenter, Placebo-Controlled and Active Reference (Glatiramer Acetate) Comparison study to evaluate the efficacy and safety of BG00012 in subjects with Relapsing-Remitting Multiple Sclerosis”. Code No. A-24:	Prof. U.K. Misra Neurology	28.11.2008	16.1.2009	Biogen Idec Ltd.	Two years (2009-2011)	2,34,919=00 per patient

	PGI/DT/EC/44/28.11.2008						
104	“RELY-ABLE long term multi-center extension of dabigatran treatment in patients with atrial fibrillation who completed the RE-LY trial and a cluster randomized trial to assess the effect of a knowledge translation intervention on patient outcomes”. Code no. A-21: PGI/DT/EC/44/28.11.2008	Prof. Nakul Sinha Cardiology	28.11.2008	23.1.2009	Boehringer Ingelheim Pharmaceuticals	Two & Half year (2009-2011)	6,47,640=00
105	“Evaluation of Efficacy and Tolerability of Fixed Dose Combination of Losartan (50 mg) and Ramipril (2.5mg/5mg) in managing Hypertension and Controlling the progression of renal insufficiency in patients of non diabetic Chronic Kidney Disease”. Code No. I-59: PGI/DT/EC/43/13.8.2008.	Prof. R.K.Sharma Nephrology	13.8.2008	13.2.2009	Unichem Laboratories Ltd.	Six months (2009)	1,87,500=00
106	“A comparison of Prasugrel and Clopidogrel in Subject with Unstable Angina/Non-ST-Elevation Myocardial Infarction (UA/NSTEMI)	Prof. Nakul Sinha Cardiology	13.8.2008	13.2.2009	Eli Lilly and Company, USA CRO-Quintiles	Two & half years (2009-2011)	16,24,311=00

	Acute Coronary Syndromes (ACS) who are medically Managed”. Code No. A-21: PGI/DT/EC/43/13.8.2008						
107	“Protocol no. 310123-A multicenter, randomized, double-blind, crossover, phase 3 study to determine the safety and efficacy of gadobutrol 1.0 molar (Gadovist®) in patients referred for contrast-enhanced MRI of the central nervous system (CNS)”. Code No. A-20: PGI/DT/EC/44/28.11.2008	Prof. R.K.Gupta Radiodiagnosis	28.11.2008	16.2.2009	Bayer Health Care Pharmaceuticals	Three months (2009)	20,28,000=00
108	“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”. Code No. A-19: PGI/DT/EC/43/13.8.2008	Prof. A.K. Mahapatra Director	13.8.2008	21.2.2009	Antisense Pharma GmbH, Germany (CRO-ICON Clinical Research India Pvt. Ltd.	Two years (2009-2011)	10,99,020=00 per patient
109	“A prospective study evaluating the safety of two	Prof. Nakul Sinha Cardiology	28.11.2008	28.4.2009	Glaxo Smith Kline	Six Months (2009)	13,38,750=00

	regimens of adjunctive intravenous UFH during PCI in high risk patients with UA/NSEMI initially treated with subcutaneous fondaparinux and referred for early coronary anglography (OASIS 8)". Code no. A-23: PGI/DT/EC/44/28.22.2008.						
110	"A multi-centre randomized, double-blind, placebo-controlled, dose-ranging study to evaluate the safety, tolerability, efficacy, pharmacokinetics and immunogenicity of ART621 following multiple dose administration for 3 months in subjects with rheumatoid arthritis concomitantly taking methotrexate". Code. No. A-21: PGI/DT/IEC/45/7.3.2009	Dr. Able Lawrence Immunology	07.3.2009	08.7.2009	Arana Therapeutics Ltd. Australia	Six months (2009-2010)	2,00,000=00 per patient

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LIST OF DRUG TRIALS (2004)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1	A Randomized double blind trial of LdT (Telbivudine) virus Lamivudine in Adults with Compensated Chronic Hepatitis B	Dr. G. Choudhari Gastroenterology	27.8.2003	27.1.2004	Novartis India Ltd.	Three years (2003-2006)	4,97,500=00
2	An multicentre randomized open lable study of the efficacy and safety of 2 doses of Ferrlecit versus oral iron to treat iron deficiency anaemia in peritoneal dialysis patient receiving erythropoietin	Prof. Amit Gupta Nephrology	02.8.2003	17.3.2004	Quintiles Research (India) Private Ltd.	Two years (2004-2005)	12,00,000=00
3	Safety & efficacy of recombinant HB vaccine in healthy adults.	Prof. G.Choudhuri Gastroenterology	14.5.2004	07.7.2004	Shreya Life Sciences, Pvt. Ltd.	Two years (2004-2006)	3,70,000=00
4	An evaluation of safety and efficacy of recombinant erythropoietin (EPO) (IPL-P03) in the treatment of anemia in patients with chronic kidney disease (CKD). A prospective, Non-comparative,	Prof. R.K.Sharma Nephrology	14.5.2004	21.7.2004	Intas Pharmaceuticals Ltd. Ahmedabad	One year (2004-2005)	3,62,500=00

	Open Label, Multicenter study						
5	A Randomized open label, multicentre phase 4 study to evaluate the efficacy and safety of Magnex in comparison with Ceftazidime plus Amikacin and Metronidazole in the treatment of Intra-abdominal Infections	Prof. V.K.Kapoor Surgical Gastroenterology	14.5.2004	05.9.2004	Pfizer Ltd.	Nine months (2004)	3,37,880=00
						Total	26,32,880=00

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LIST OF DRUG TRIALS (2005)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1	A Ramdp,oozed. Two Arm, Double Blind, Comparative, Multicentric Clinical Trial to evaluate efficacy and safety of Nebivolol in Patients with Chronic Stable Angina in Comparison with Metoprolol	Prof. Nakul Sinha Cardiology	23.9.2004	18.2.2005	Torrent Pharmaceuticals Ltd. Ahmedabad	One year six months (2005)	2,02,250=00
2	Open randomized study to evaluate efficacy and safety of oral val ganciclovir versus IV ganciclovir for the treatment of CMV disease in solid organ transplant recipient.	Prof. R.K.Sharma Nephrology	14.5.2004	16.3.2005	F.Hoffmann-La Roche Ltd.	Two years (2005)	6,56,250=00
3	“A Phase 3, Randomized, Double-blind, Comparative study of micafungin (FK463) versus caspofungin as antifungal treatment in patients with invasive candidiasis or candidemia”.	Prof. V.K.Kapoor Surgical Gastroenterology	23.9.2004	16.3.2005	Quintiles Research (India) Pvt. Ltd.	One year (2005)	1,20,000=00

4	“Evaluation of efficacy and safety of Lanthanum Carbonate in Patients of Hyperphosphatemia”.	Prof. R.K.Sharma Nephrology	23.9.2004	06.5.2005	Panacea Biotec Ltd. New Delhi	One year (2005)	1,87,500=00
5	“Assesment of Everolimus in addition to calcineurin inhibitors reduction in maintenance renal transplant recipients- Ascertain”.	Prof. R.K.Sharma Nephrology	09.3.2005	20.6.2005	Novartis Ltd.	Two years (2005-2007)	9,40,000=00
6	“Dose ranging study to evaluate the safety & efficacy of olmesartan medoxomil in Children and Adolescents with Hypertension”.	Prof. R.K.Sharma Nephrology	09.3.2005	20.6.2005	Quintiles Ltd.	Three years (2005-2008)	1,68,500=00 (per patients)
7	“The Surgical Treatment for Ischemic Heart Failure (STICH)”.	Prof. Nakul Sinha Cardiology	27.12.2004	20.6.2005	Clini Rx Research Pvt. Ltd.	Three years (2005-2008)	38,88,000=00
8	“An open Non comparative study to evaluate the efficacy & safety of fixed dose combination of Dutasteride (0.5mg) & Tamsulosin (0.4mg) in patients with benign prostatic Hyperplasia”.	Prof. Anant Kumar Urology	09.5.2005	28.7.2005	Cipla Ltd. Mumbai	Six months (2005-2006)	3,47,563=00
9	“A Phase III, randomized, multi-centre, double-blind, parallel group, active comparator study to compare the efficacy and safety of	Prof. G.Choudhuri Gastroenterology	09.3.2005	28.7.2005	Shire Pharma. Developopt UK	Two years (2005-2007)	30,00,000=00

	SPD476 (mesalazine) 2.4g/day once daily (DQ) with Asacol® 1.6g/day twice daily (BID) in the maintenance of remission in patients with ulcerative colitis”.						
10	“Phase III multicentric double blind clinical trials in patients of hyperlipidemia (CDRI compound 80/574).	Prof. Nakul Sinha Cardiology	23.9.2004	30.10.2005	Cadila Pharmaceuticals	One year (2005-2006)	3,50,000=00
11	“An open label, multicentric clinical trial to assess the efficacy and tolerability of Sevelamer in the treatment of hyperphosphatemia in end stage renal disease patients”.	Prof. R.K.Sharma Nephrology	09.3.2005	27.11.2005	Emcure Pharma. Ltd.	Six months (2005-2006)	33,375=00
12	“A randomized, double blind, placebo controlled, parallel group study to assess the effect of the endothelin receptor antagonist avosentan on time to doubling of serum creatinine, end stage renal disease or death in patients with type-2 diabetes mellitus and diabetes nephropathy”.	Prof. R.K.Sharma Nephrology	18.8.2005	27.11.2005	Speedel Pharma Ltd.	Three years (2005-2008)	2,08,110=00 (per patients)
						Total	95,64,048=00

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LIST OF DRUG TRIALS (2006)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1	“A randomized, double-blind trial of Ldt (Telbivudine) versus Lamivudine in Adults with Decompensated Chronic Hepatitis B and Eviudence of Cirrhosis: NV-02B-011”.	Prof. G.Choudhuri Gastroenterology	25.8.2005	23.3.2006	Idenix Pharma. Inc.	Two years (2006-2008)	2,00,000=00
2	“An Open Label Trial of Telbivudine (LdT) in Adults with Chronic Hepatitis B Previously Treated in Idenix-Sponsored Telbivudine Studies”.	Prof. G.Choudhuri Gastroenterology	26.11.2006	23.3.2006	Quintiles	One Year (2006-2007)	3,90,000=00
3	“(Protocol 1160.26) Randomized of Long Term anticoagulant therapy (RE-LY) comparing the efficacy and safety of two blinded doses of dabigatran etexilate with open label warfarin for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation: Prospective, multi-	Prof. Nakul Sinha Cardiology	27.2.2006/0 6.6.2006	27.3.2006	Boehringer Ingelheim Korea Ltd.	Five Years (2006-2011)	6,12,000=00

	centre, parallel group, non-inferiority trial”.						
4	“A Multicentre, Open-Label, Randomized Comparative Study of Tigecycline Us Ceftriaxone Sodium Plus Metroindazole for the treatment of Hospitalized Subjects with Complicated Intra-Abdominal Infection”.	Prof. V.K.Kapoor Surgical Gastroenterology	11.8.2005	02.6.2006	Quintiles (Wyeth)	Two years (2006-2008)	90,488=00 per patient
5	“The Effect of Eplerenone Versus Placebo on Cardiovascular Mortality and Heart Failure Hospitalization in Subjects with NYHA Class II Chronic Systolic Heart Failure”.	Prof. Nakul Sinha Cardiology	26.10.2004	03.5.2006	Pfizer Pvt. Ltd.	Four Years (2006-2010)	14,42,500=00
6	“Comparison of Three Regimens of PEG-Intron plus Ribavirin in the Treatment of Chronic Hepatitis C, Genotype 2 or 3, in Previously Untreated Patients”.	Prof. G.Choudhuri Gastroenterology	11.8.2005	27.7.2006	Fulford (India), Ltd.	One year eight months (2006- 2008)	US\$ 950 per patient 42,750=00
7	“A 13-week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group study to Evaluate the Efficacy, Safety and Tolerability of Pregabalin	Prof. U.K.Misra Neurology	06.06.2006	30.8.2006	Pfizer Ltd.	Three months (2006)	4,66,250=00

	(150-600 mg/day) Using A Flexible Dosing Schedule in the Treatment of Subjects with Central Post-Stroke Pain (CPSP)".						
8	“A randomized, phase 3, controlled, double-blind, parallel-group, multicentre study to evaluate the safety and efficacy of rituximab in combination with methotrexate (MTX) compared to MTX along, in methotrexate naïve patients with active rheumatoid arthritis”. Code No. A-06: PGI/DT/EC/34/6/6/2006	Prof. R.N.Misra Immunology	06.6.2006	10.8.2006	Roche Pvt. Ltd.	Four years (2006-2010)	1,08,790=00
9	“A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, a fully Human Anti-TNF α Monoclonal Antibody, Administered Subcutaneously, in Methotrexate-naïve Subjects with Active Rheumatoid Arthritis”.	Prof. R.N.Misra Immunology	06.6.2006	22.7.2006	Centocor Pvt. Ltd.	Six years (2006-2012)	25,097,57 USD 11,29,391=00
10	“A Randomized, Double-Blind Placebo-Controlled, Four Arm, Parallel-Group, Multicenter,	Prof. R.K.Sharma Nephrology	06.6.06	10.8.06	La Jolla Pharmaceutical	Two years (2006-2008)	1,38,825=00 per patients

	Multinational, Safety and Efficacy trial of 100 mg, 300 mg and 900 mg of Abetimus Sodium in Systemic Lupus Erythematosus (SLE) patients with a history of Renal Disease”.						
						Total	46,20,994=00

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LIST OF DRUG TRIALS (2007)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1	“A Phase III, open label, multicentric, parallel group, randomized study to evaluate the safety and efficacy of Abciximab in Indian patients scheduled for Percutaneous Coronary Intervention”. Code no. A-08: PGI/DT/EC/35/19.9.06	Prof. Nakul Sinha Cardiology	19.9.2006	10.1.2007	CRO-Manipal Acunova Ltd. (Lupin)	Six months (2007)	2,25,000=00
2	“A 12-Week, Open Lable, Safety Trial of Pregabalin in Patients with Fibromyalgia”. Code no. A-02 (a)- PGI/DT/EC/35/19.9.2006	Prof. R.N.Misra Immunology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	Ten months (2007)	2,76,100=00
3	“A 14-Week, Randomized, Double-Blind, Placebo-Controlled Trial of Pregabalin Twice Daily in Patients with Fibromyalgia”. Code no. A-02 (b)-PGI/DT/EC/35/19.9.2006	Prof. R.N.Misra Immunology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	Nine months (2007)	4,95,000=00
4	“A randomized, comparative, double-blind, parallel-group, multicenter, monotherapy,	Prof. U.K.Mishra Neurology	19.9.2006	19.2.2007	Pfizer Pvt. Ltd.	One year (2007)	8,12,000=00

	study of Pregabalin (Lyrica) and Lamotrigine (Lamictal) in patients with newly diagnosed partial seizures”. Code no. A-01-PGI/DT/EC/35/19.9.2006						
5	“Clinical Protocol IM103008: Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial (BENEFIT)”. Code no. A-04: PGI/DT/EC/36/13.12.2006.	Prof. R.K.Sharma Nephrology	13.12.2006	21.4.2007	Bristol-Myers Squibb India Pvt. Ltd. (CRO Quintiles)	Three years (2007-2010)	24,47,200=00
6	“Randomized, multinational, double-blind study, comparing a high loading dose regimen of clopidogrel versus standard dose in patient with unstable angina or non-ST segment elevation myocardial infarction managed with an early invasive strategy”. Code no A-02: PGI/DT/EC/36/13.12.2006	Prof. Nakul Sinha Cardiology	13.12.2006	05.6.2007	ICON Clinical Research India Pvt. Ltd.	One year (2007)	24,000=00 per patient
7	“A randomized double-blind controlled trial of the efficacy and safety of POLYCAP versus its components in subject with at least one additional cardio-vascular risk	Prof. Nakul Sinha Cardiology	19.9.2006	2007	Cadila Pvt. Ltd.	Six months (2007)	1,25,000=00

	factor”. Code No. A-09: PGI/DT/EC/35/19/9/2006						
8	Protocol CL3-18886-012 “Prevention of cerebrovascular and cardiovascular events of ischaemic origin with teRutroban in patients with a history of ischaemic stroke or tRansient ischaeMic stroke- The PERFORM study”. Code no. A-01: PGI/DT/EC/36/13.12.2006	Prof. U.K.Mishra Neurology	13.12.2006	25.6.2007	Quintiles Pvt. Ltd.	2 and half years (2007-2010)	5,80,000=00
9	“A phase 3 randomized study to evaluate survival of patients treated with talaporfin sodium (LS11) and interstitial light emitting diodes (LED) as compared to the standard of care therapies in the treatment of unresectable Hepatocellular Carcinoma (HCC)”. Code no. A-20: PGI/DT/EC/37/20/3/2007	Dr. Neeraj Rastogi Radiotherapy	20.3.2007	26.6.2007	Light Science Oncology, USA (CRO-Reliance Clinical Research Services, Mumbai	One year (2007-2008)	7,74,089=00
10	“Phase III Clinical evaluation of safety and efficacy of HD-03/ES in Hepatitis B Virus”. Code No. A-21: PGI/DT/EC/ 38/10.5.2007	Prof. G.Choudhuri Gastroenterology	10.5.2007	11.7.2007	Himalayan Drug Company	One year (2007-2008)	3,47,500=00

11	<p>“Phase III clinical evaluation of safety and efficacy of NCB-02 in Ulcerative Colitis”.</p> <p>Code No. A-22: PGI/DT/EC/38/10.5.2007</p>	<p>Prof. G.Choudhuri Gastroenterology</p>	10.5.2007	11.7.2007	Himalayan Drug Company	One year (2007-2008)	4,78,750=00
12	<p>“International, randomized, double-blind clinical study evaluating the efficacy and safety of clopidogrel 0.2 mg/kg once daily versus placebo in neonates and infants with cyanotic congenital heart disease palliated with a systemic-to-pulmonary artery shung (e.g. modified Blalock Taussing shunt)”.</p> <p>Code. No. A-18: PGI/DT/EC/38/10.5.2007.</p>	<p>Dr. Nirmal Gupta CVTS</p>	10.5.2007	07.8.2007	Sanofi-Synthelabo Recherche, France	One year (2007-2008)	1,71,320=00
13	<p>“Comparison of the Efficacy and Safety of Entecavir Versus Adefovir in Subjects Chronically Infected with Hepatitis B Virus and Evidence of Hepatic Decompensation”.</p> <p>Code. No. A-23: PGI/DT/EC/37/20.3.2007.</p>	<p>Prof. G.Choudhuri Gastroenterology</p>	20.3.2007	07.8.2007	Bristol-Myers Squibb India Pvt. Ltd.	One year (2007-2008)	1,36,813=00 per patient
14	<p>“A Randomized Double-Blind, Placebo-Controlled Evaluation</p>	<p>Dr. U.C.Ghoshal Gastroenterology</p>	14.8.2007	26.9.2007	Cerimon Pharmaceuticals	Two years (2007-2009)	4,35,260=00

	of the Safety, Efficacy and Pharmacokinetics of multiple doses of Basiliximab with Concomitant Corticosteroids in Stroid-Refractory Ulcerative Colitis”. Code No. A-15: PGI/Dt/EC/39/14.8.2007.				Pvt. Ltd.		
15	“An open label, response adaptive study of Telbivudine in adults with HBeAg positive compensated chronic hepatitis B”. Code No. A-14: PGI/DT/EC/39/14.8.2007.	Prof. V.A. Saraswat Gastroenterology	14.8.2007	03.10.2007	Novartis India Ltd.	Three years (2007-2010)	12,18,750=00
16	“A1463-080 Randomized observational study of Entecavir to assess long term outcome associated with nucleoside/nucleotides monotherapy for patients with chronic HBV infection: The REALM study”. Code No. A-24: PGI/DT/EC/37/20/3/2007	Prof. G.Choudhuri Gastroenterology	20.3.2007	13.11.2007	Bristol Myers Squibb India Pvt. Ltd.	Three years (2007-2010)	41,028/- per patients
17	“A Multicenter, randomized, Double-Blinded, Placebo-Controlled, dose-ranging study to assess the efficacy and safety of TZP-101 when administered as a 30 minute IV infusion for post operative	Prof. V.K.Kapoor Surgical Gastroenterology	7.11.2007	26.12.2007	Tranzyme, Inc. USA (CRO-QED Pharmaceutical Services Pvt.Ltd.	Six months (2007-2008)	1,00,000=00 per patient

	ileus to subjects undergoing major open abdominal surgery”. Code No. A-21: PGI/DT/EC/40/7/11/2007						
18	“Early Glycoprotein IIb/IIIa Inhibition in Non-ST-Segment Elevation Acute Coronary Syndrome: A Randomized, Placebo-Controlled Trial Evaluating the Clinical Benefits of Early Front-Loaded Eptifibatide in the treatment of Patient with Non-ST-Segment Elevation Acute Coronary Syndrome (EARLY ACS)”. Code No. A-22: PGI/DT/EC/37/20/3/2007	Prof. Nakul Sinha Cardiology	20.3.2007	24.8.2007	Millennium Pharmaceuticals	Two years (2007-2009)	22,00,000=00
19	“Study for Monitoring Antimicrobial Resistance Trends”. Code No. A-16: PGI/DT/EC/40/7/11/2007	Prof. T.N.Dhole Microbiology	7.11.2007	24.7.2007	MSD Pharmaceuticals Pvt. Ltd. Gurgaon.	One year (2008)	1,33,603=00
						Total	1,10,21,413=00

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LIST OF DRUG TRIALS (2008)

S.N	Title	Name of PI & Department	E.C. Clearance	MOU	Funding Agency	Duration	Amount Sanctioned
1	“Protocol C0524T17-A Phase 2/3 Multicenter, Randomized, Placebo-controlled, Double-Blind study to evaluate the safety and efficacy of Golimumab Induction Therapy, Administered Subcutaneously, in subjects with Moderately to Severely Active Ulcerative Colitis”. Code No. PGI/DT/EC/39/14.8.2007	Prof. G.Choudhuri Gastroenterology	14.8.2007	04.4.2008	Centocor (CRO-Quintiles)	One year (2008-2009)	81,259/- per patient
2	“Protocol C0524T18-A Phase 3 Multicenter, Randomized, Placebo-controlled, Double-blind study to evaluate the safety and efficacy of Golimumab Maintenance Therapy, Administered Subcutaneously, in subjects with Moderately to Severely Active Ulcerative Colitis”.	Prof. G.Choudhuri Gastroenterology	14.8.2007	04.4.2008	Centocor (CRO-Quintiles)	Five years (2008-2013)	2,85,060/- per patient

3	“A clinical trial comparing cangrelor to clopidogrel in subjects who require percutaneous coronary intervention”. Code No. A-18: PGI/DT/EC/40/7/11/2007	Prof. Nakul Sinha Cardiology	7.11.2007	21.2.2008	The Medicines Company, USA	One year (2008-2009)	15,00,000=00
4	“PICTURE SUDY-the place of reveal in the care pathway and treatment of patient with unexplained recurrent syncope”. Code No. PGI/DT/EC/Registry/39/14.8.2007.	Prof. Nakul Sinha Cardiology	14.8.2007	22.2.2008	India Medtronic Pvt. Ltd., Mumbai	Four months (2008)	84,000=00
5	“A Phase IIb/III-Multi-centre, double-blind, randomized, placebo-controlled, dose ranging study of tamsulosin hydrochloride (low, medium and high dose) as treatment children with neuropathic bladder for three months”. Code No. A-20: PGI/DT/EC/41/28.2.2008	Prof. Rakesh Kapoor Urology	28.2.2008	30.4.2008	Boehringer Ingelheim International GmH (“BII”).	Eighteen months (2008-2009)	93,500=00 per patient
6	“A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Darbepoetin alfa Treatment on Mortality and Morbidity in	Prof. Nakul Sinha Cardiology	7.5.2008	22.9.2008	Amgen Inc.	Three years (2008-2011)	70.20,625=00

	Heart Failure (HF) Subjects with Symptomatic Left Ventricular Systolic Dysfunction and Anemia-20050222 Amendment 1”. Code No. A-13: PGI/DT/EC/42/7.5.2008						
7	“A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging study to assess the Efficacy and Safety of TZP-101 when Administered as a 30 Minute I.V. Infusion to Subjects with Severe Gastroparesis due to Diabetes Mellitus”. Code No. A-20: PGI/DT/EC/43/13.8.2008	Dr. U.C. Ghoshal Gastroenterology	13.8.2008	22.9.2008	Tranzyme Inc. Dehradun	Six months 2008-2009	1,24,625=00 per patient
8	“A Phase III, Randomized, Placebo-controlled, Double-Blind study to assess the Efficacy and Safety of Once-daily Orally Administered ZD4054 10mg in Non-metastatic Hormone-resistant Prostate Cancer Patients”. Code No. A-16: PGI/DT/EC/42/7.5.2008	Dr. Anil Mandhani Urology	7.5.2008	3.10.2008	Astra Zeneca	Five Years 2008-2013	18,96,000=00

9	“A Multinational, Multicenter, Randomized, Double Blind Study comparing the Efficacy and Safety of AVES5026 with Enoxaparin for the Prevention of Venous Thrombo-embolism in Patients Undergoing Major Abdominal Surgery”. Code No. A-16: PGI/DT/EC/43/13.8.2008.	Prof. V.K.Kapoor Surgical Gastroenterology	13.8.2008	28.11.2008	ICON Clinical Research India Pvt. Ltd.	15 Months 2008-2009	1,00,000=00 Per patients
10	“CABG Off or On Pump Revascularization Study”, (Coronary). Code No. A-15: PGI/DT/EC/41/28.2.2008.	Prof. Nakul Sinha Cardiology	28.2.2008	01.12.2008	Canadian Institute of Health Research, Canada	30 months 2008-2011	60,15,625=00
11	“The Best Combination for Coronary Revascularization-Optimal Platelet Inhibition, Effective Cholesterol Lowering, The PronoVa XR Stent, and Effective Disease Management (BELIEVE) Trial”. Code No. A-23: PGI/DT/EC/41/28.2.2008	Dr. Satyendra Tewari Cardiology	28.2.2008	01.12.2008	Vascular Concepts Ltd.	6 months 2008-2009	Only Device (Stent)
						Total	1,72,006,694=00