



K.E.M.HOSPITAL RESEARCH CENTRE

LIST OF COMPLETED PROJECTS

Sr. No.	Study title	PI	Sponsor/ CRO
1	Insulin Lispro low mixture (LM) as compared to Human Insulin 30/70 in treatment of type 2 diabetes in elderly patients.	Dr. C. S. Yajnik	Eli Lilly Ranbaxy Ltd.
2	Safety & efficacy of Propofol lipid free as an intravenous anaesthetic in comparison with Propofol emulsion	Dr. A. Bhatia	Bharat Serums & vaccines Ltd.
3	Trial of drug esomeprazole in acid suppression therapy	Dr. S. Wagle	Torrent P`ceuticals
4	Clinical trial of Tab Montelukast in patients of bronchial asthma	Dr. M. Kale	Dr. Reddy's Lab
5	A study of L-arginine supplementation in PIH & foetal growth restoration	Dr. K. Coyaji	University of Pennsy Ivania, USA
6	Clinical trial of Product HP11 for hepato protection in alcoholic liver disease	Dr. V. Pai	Bioved P`ceuticals
7	Trial on open label randomized comparative clinical trial of 3 oral anti diabetic drugs (OAD) Gliclazide, malformin and piolitozone	Dr. C. S. Yajnik	Population Council
8	Misoprostol for menstrual regulation/ early termination of pregnancy	Dr. K. Coyaji	
9	A sensitive parameter for early diagnosis & sepsis in new borns	Dr. R. Manchanda /Dr. S. Oswal	Southampton
10	To assess immediate needs of HIV patients, women and men, in rural Maharashtra, India- A rapid study (2 months)	Dr. L. Garda	Pharmacia India
11	Efficacy & safety of dalacin C in acute & recurrent streptococcal pharyngotonsillitis	Dr. N. Vaid	
12	Efficacy & safety of Gourdin in diabetic subjects	Dr. C. S. Yajnik	Pfizer
13	"Cytogenetic Studies in cases of Megaloblastic Anemias and myelodys	Dr. R. Manchanda	Departmental Project

	plastic Syndromes"		
14	The prevalence of vitamin b6 deficiency in infants & proposal to conduct b6 assays on the breast milk (in mothers) and blood (of infants) of about 350 mother- infant diads	Dr. S. Hirve	
15	Evaluation of immunogenicity & safety of an indigenously developed DTPw-HB combination vaccine	Dr. S. Bhave	Shanta Biotechnics Pvt. Ltd.
16	Phase III clinical trial of Tazarotone (0.5%) gel on patients with psoriasis	Dr. Y. Tawade	M/s Allergen (india) Ltd.
17	Sexual behaviour resolving unwanted pregnancies in unmarried & married males & females in the age group 15 to 24 years	Dr. L. Garda/ Savita Kanade/ Dr. M. Alexander	Population Council
18	Assessment of immunogenicity and safety of Hepatitis B vaccination in neonates using a novel pre- filled immunization device uniject	Dr. S. Bhave	Shanta Biotechnics Pvt. Ltd.
19	Preliminary trial of Vitamin B12 and green leafy vegetables supplementation to reduce homocysteine levels in India	Dr. C. S. Yajnik	MRC (South ampton)
20	Clinical trial Phase II with RBX-7796 as per protocol No. RX/MACR/2003-21	Dr. M. Kale	Ranbaxy Labs Gurgaon
21	Protocol No 3074A1-301-WW A. Multicentre, double blind, randomized, comparison study of the efficacy and safety of tigecycline to imipenen / cilastatin to treat complicated intra-abdominal infections in hospitalised subjects	Dr. M. Y. Bapaye	Quintiles Ltd.
22	Protocol No. 3074A1-300-US. A multicentre, double blind, randomized, double blind comparison of the safety and efficacy of tigecycline to those of Vancomycin with Aztrenam to treat complicated skin and skin structure infections	Dr. A. Deodhar	Quintiles Ltd.
23	Safety & efficacy of NP-002 (Hepatitis B immuno prophylaxis of Hepatitis B infection) to infants of HBSAg positive mothers	Dr. A. Pandit / Dr A. Bavdekar	SIRO Clinpharm Pvt. Ltd
24	A double blind randomized comparison between Genevac B and Energix - B immunogenicity & reactogenicity in infants	Dr. A. Pandit	Serum Institute of India Ltd.

25	Effects of early versus late oral iron supplementation in preterm infants with birth weight less than 2 kgs	Dr. A. Pandit / Dr. U. Vaidya	Magnachem Pharmaceuticals Pvt. Ltd
26	Sprinkles Project	Dr. A. Pandit	CIHR Canada
27	Saccharomyces boulardii in the treatment of acute diarrhea in infants and children.	Dr. S. Bhave	Dr. Reddy's Lab
28	Open, Phase III b multicentric, safety and reactogenicity study of Glaxo SmithKline Biologicals' reduced antigen content combined diphtheria-tetanus-acellular pertussis vaccine (BOOSTRIX-TM) administered as a booster dose to healthy children 4-6 years of age according to the international recommended prescribing information	Dr. A. Pandit	GSK Biologicals
29	Evaluate the immunogenicity and safety of a trivalent DTPw-HB vaccine	Dr. A. Pandit	Shanta Biotechnics Pvt. Ltd.
30	Studies 030 A & 030 B (Pleuromutilin Study) Protocol SB 275833/030	Dr. B. Kalambe	GSK Biologicals
31	Prevalence of obstructive lung disease in general medicine wards	Dr. M. Kale	Cipla
32	Functionality and safety of the Humapen (R) Memoir in patients with Type-I or Type-II diabetes on multiple daily injection therapy (ITAA)	Dr. C. S. Yajnik	Eli Lilly USA
33	Evaluation of immunogenicity and tolerability of a live attenuated hepatitis A vaccine in healthy Indian children	Dr. A. Pandit	Wockhart India Pvt. Ltd.
34	RCH (EC Project)	Dr. G. A. Panse	State Family Welfare Bureau, Pune
35	Socio Economic Status assessment of population for understanding health equity in HDSS Vadu	Dr. S. Juvekar	INDEPTH
36	Handwashing compliance and risk of Acute Respiratory Infections - a study in Pune, India	Dr. S. Hirve	London School of Hygiene & Trop. Med.
37	The genetic and environmental influences on plasma triglyceride concentrations in Indians and their impact on type 2 diabetes, insulin resistance and fetal growth	Dr. C. S. Yajnik	Wellcome Trust, UK
38	Phase IV clinical trial on Cilanem (Imipenem + Cilastatin) in lower respiratory tract infection patients	Dr. P. Khatavkar	Ranbaxy Labs Ltd.

39	Phase III study of recombinant human erythropoetin	Dr. F. F. Wadia	VHB Life Services
40	Non-Communicable Diseases Surveillance Project	Dr. S. Juvekar	INDEPTH
41	A multicentre randomized, double blind, active controlled study to compare the effects of 24 weeks treatment with combination therapy of LAF 237 and pioglitazone to LAF 237 monotherapy or pioglitazone monotherapy in drug naïve patients with type 2 diabetes as per Protocol No. CLAF 237A2355	Dr. C. S. Yajnik	Novartis
42	A study of glycaemic response in diabetic and non-diabetic subjects	Dr. C. S. Yajnik	GSK Consumer Healthcare Ltd. Haryana
43	Evaluation of safety, tolerability and immunogenicity of vaccination with VARIVAX in healthy Indian children	Dr. S. Bhave	Clinigen Inter national Pvt. Ltd
44	Follow-up serial infusions of Natrecor (nesiritide) for the management of patients with heart failure (FUSION II)	Dr. M. Gadkari	Synchron Research/ Quintiles
45	Assessing quality of care in Family Planning Services in rural Maharashtra, India	Patrice L. Yang/ Indian Supervisor / Dr. Annie Gibson/ Dr. S. Juvekar	Student from Emory University, Atlanta, USA
46	Women's decision making power and perceptions of contraceptive methods in rural India: is it a choice?	Jennifer Scharff Indian Supervisor/ Dr. M. Alexander /Dr.L. Garda	Student of Emory Univ. Atlanta, USA
47	Study of Pitavastatin 2mg vs. Atorvastatin 10 mg and Pitavastatin 4 mg vs. Atorvastatin 20 mg (Following Up Titration) in patients with primary hypercholesterolemia or combined dyslipidemia.	Dr. V. Pai	Pharma Net Clinical Services Pvt. Ltd.

48	A prospective, randomized, double-blind, placebo controlled, dose ranging, multi-centre study of the safety and efficacy of three days continuous intravenous infusion of GR270773 in the treatment of suspected or Gram-negative severe sepsis in adults.	Dr. B. Kalambe	GSK Pharmaceuticals Ltd.
49	Prevalence of GJB2 (Connexin26) mutations in Autosomal Recessive - Non - Syndromal hearing loss: a pilot study in India	Dr. K. Godbole	Departmental Project
50	TOPMAT-PEP 3001;"A randomized, double-blind, placebo-controlled, fixed dose- ranging study to asses the safety, tolerability and efficacy of topiramate oral liquid and sprinkle formulation as an adjunct to concurrent anticonvulsant therapy in infants (1 to 23 months of age, inclusive) with refractory partial onset seizures, with open- label extension	Dr. N. Yardi	Johnson & Johnson Pharmaceutical Research & Development, L.L.C./
51	GSK Biologicals' live attenuated human rotavirus (HRV) vaccine (RIX 4414) (Rotarix TM) Rota 044 Protocol No. 103792 version 12.1 dt. Nov 29, 2004	Dr. A. Pandit	GSK Biologicals
52	A comparative clinical trial on two DTP-HB vaccines (Serum Institute of India Ltd. & Glaxo SmithKline Beecham) for immunogenecity and reactogenecity in infants	Dr. A. Pandit	Serum Institute of India Ltd.
53	Life Style Program for prevention of obesity & related disorders in school children.	Dr. A. Pandit	Venkys
54	A multicentre, double blind, comparative study evaluating clinical efficacy & tolerance of Ketorolactrometha mine 0.5% and Ketorolac trometh amine 0.5% + Ofloxacin 0.3% combination ophthalmic solutions in treatment of conjunctivitis of different etiology & post operative inflammatory conditions of anterior segment of the eye.	Dr. S. Shah	Dr. Bhavana Doshi

55	A randomized, 2 - period, multicenter, double-blind, parallel-group study comparing the effects of 2 doses of Montelukast granules & placebo in the treatment of respiratory symptoms associated with Respiratory Syncytial Virus- induced bronchiolitis in children aged 3 to 24 months.	Dr. A. Bavdekar	SIRO Clinpharm Pvt. Ltd
56	Protocol no. RLS/DER/2005/02: "Comparative assessment of efficacy and safety of interactive wound cover ReliDerm E™ and Jelonet in healing of graft donor site"	Dr. A. Deodhar	Reliance Clinical Research Services Pvt. Ltd. (RCRS)
57	A multicentric randomized single blind trial to compare the immunogenicity and safety of indigenously developed Hib (Liq) conjugate vaccine with Act - HIBR (Lyo) and Hiberix™ (Lyophilized) in Indian subjects.	Dr. S. Bhave	Shanta Biotechnics Pvt. Ltd.
58	A Phase 3, open- label, parallel group study to evaluate the efficacy and safety of Human Insulin Inhalation Powder (HIIP) compared to pre-prandial injectable Insulin in Insulin-naïve patients with Type 2 Diabetes mellitus	Dr. C. S. Yajnik	Eli Lilly & Co.
59	A Phase III, randomized, double-blind study of Ceftobiprole Medocaril versus Vancomycin with Ceftazidime in the treatment of complicated skin and skin structure infections	Dr. A. Deodhar	Johnson & Johnson Pharmaceutical Research & Development, L.L.C./
60	A comparison of the Brass-V Excellent Fixable Drape™ and a modified WHO blood measurement protocol for the measurement of blood loss during vaginal delivery	Dr. K. Coyaji	Gynuity Health Projects
61	Efficacy and safety of SII r-HuEPO in patients with anaemia of chronic renal failure on maintenance haemodialysis	Dr. V. Lobo	Serum Institute of India Ltd.
62	World health survey study on global ageing - Vadu rural health programme supplement	Dr. S. Hirve/Dr. S. Juvekar	WHO
63	Relationship between maternal folate and B12 status, size of the offspring at birth and its growth in infancy	Dr. C. S. Yajnik	IAEA, Vienna

64	A prospective open-label, uncontrolled, single-centre, evaluation of viremia in healthy flavivirus seronegative adults after primary vaccination with JE SA14-14-2 live attenuated vaccine	Dr. F. F. Wadia	Health Ministry, GOI & ICMR
65	LCPUFA Status and Birth Outcome in India	Dr. A. Pandit	ICMR/ Dept of Health & Human Services, USA
66	Phase I A randomized open label multicentric study, with open label extension of the pharmacokinetics and safety of topiramate administered as oral liquid and sprinkle formulation, as an adjunct to concurrent therapy in infants (aged 1-24 months, inclusive) with refractory partial onset seizures.	Dr. N. Yardi	Johnson & Johnson Pharmaceutical Research & Development, L.L.C./
67	Improving parent child communication, on SRH issues	Dr. L. Garda / S. Kanade	DFID
68	NK-104-307: Open-label, long term (1 year) extension study of Pitavastatin 4 mg OD in patients with primary hypercholesterolemia or combined dyslipidemia	Dr. V. Pai	Pharma Net Clinical Services Pvt. Ltd.
69	Comparative evaluation of safety & efficacy of WCK 771 with Vancomycin & Linezolid in treatment of infections caused by Methicillin Resistant Staphylococcus aureus.	Dr. B. Kalambe	Reliance Clinical Research Services Pvt. Ltd. (RCRS)
70	A multicenter, randomized, double-blind, placebo controlled, phase 3 trial to evaluate the efficacy and safety of saxagliptin (BMS-477118) in combination with thiazolidinedione therapy in subjects with type 2 diabetes who have inadequate glycaemic control on thiazolidinedione therapy alone. (CV 181 013)	Dr. S. Kale	Bristol Mayers Squibb
71	A multicenter, randomized, double-blind, active controlled, phase 3 trial to evaluate the efficacy and safety of saxagliptin in combination with Metformin IR as initial therapy compared to saxagliptin monotherapy and to Metformin IR monotherapy in subjects with T2DM who have inadequate glycaemic control (CV181039)	Dr. S. Kale	Bristol Mayers Squibb

72	A pivotal open-label, parallel study to evaluate the safety and efficacy of human insulin inhalation powder (HIIP) compared to injectable insulin in patients with diabetes and COPD or asthma	Dr. C. S. Yajnik	Eli Lilly & Co./Quintiles Ltd.
73	A one year multicentre, international, randomised, double-blind study with comparison of benfluorex (150 mg bid or 150 mg tid) versus pioglitazone (30 mg od or 45 mg od) in combination with sulfonylurea administered orally for the treatment of type 2 diabetes	Dr. C. S. Yajnik	IRIS/ Chiltern
74	Evaluation of safety, tolerability and immunogenicity of quadrivalent human papilloma virus vaccine in healthy females 9 to 15 years of age in India.	Dr. S. Bhave	Clinigen International Pvt. Ltd
75	A multicenter, double blind, placebo and active controlled, randomized study to evaluate the safety and efficacy of the addition of Sitagliptin 100 mg. once daily in patients with type-2 diabetes with inadequate glycaemic control on metformin monotherapy.	Dr. C. S. Yajnik	Clinigen International Pvt. Ltd
76	A Phase II, multi-centre, double blind, randomised, parallel design, placebo-controlled study to evaluate the efficacy and safety of two different dosage regimens of LL-4218 of Lupin Ltd. In moderate to severe chronic stable plaque type of psoriasis	Dr. Y. Tawade	Lupin Ltd
77	A randomized, double blind active controlled, multicenter, study to compare the effects of 24 weeks treatment with fixed dose combination therapy of vildagliptin /metformin to individual monotherapies in drug naïve patients with T2DM as/ protocol No. CLMF 237A2302	Dr. C. S. Yajnik	Novartis
78	Developing a prototype for data sharing, building capacity in data management across India, Thailand and Papua New Guinea	Dr. S. Juvekar	Indepth

79	A Phase 2/3, randomized double blind, placebo and active comparator controlled, parallel group, multicenter study to determine the safety and efficacy of metaglidasen (MBX-102) in the treatment of type-2 diabetes in patients sub optimally controlled on insulin.	Dr. S. Kale	Metabolex
80	A multicenter, randomized, double blind study comparing the clinical effects of intravenous montelukast with placebo in pediatric patients (age 6 to 14 yrs) with acute asthma.	Dr. A. Pandit	SIRO Clinpharm Pvt. Ltd
81	Relationship between patient knowledge and control of type 1 diabetes: A study in India and UK.	Dr. C. S. Yajnik	collaboration Southampton Hospital, UK
82	A Phase III controlled, open-label, randomized, parallel group, multicentric, comparative study to assess the efficacy and safety of oral rehydration therapy (ORT) in combination with spores of Bacillus clausii in the treatment of acute diarrhoea in children	Dr. A. Bavdekar	Sanofi Aventis
83	An international, multicenter, randomized, double-blind, double-dummy, parallel group, study of 3-months or 6-months treatment with SSR126517E (3.0 mg s.c once weekly) versus oral INR-adjusted warfarin in the treatment of patients with symptomatic pulmonary embolism, with or without symptomatic deep venous thrombosis	Dr. S. Kalashetti	Sanofi Aventis
84	Pune low birth weight study - birth to adult hood	Dr. S. Chaudhari	ICMR
85	Sexual initiation in India: Among married and unmarried youth and further experience of physical violence among married young women	Dr. M. Alexander Dr. L. Garda	WHO
86	A multi center, open label, long term follow- up study of the safety and efficacy of Levetiracetam in children with partial onset seizures	Dr. N. Yardi	UCB
87	A phase III, multi centre, placebo-controlled double blind, randomized, parallel group study to establish the efficacy of LLL-2011 administered as a 1% nasal spray in the preventive treatment of common migraine	Dr. A. Alurkar	Lupin Ltd

88	A randomized, double blind, placebo-controlled, multicenter, parallel study assessing the efficacy, safety and dose response of ramipril for the treatment of hypertension in children and adolescents.	Dr. M. Otiv	King pharmaceutical/Quintiles Ltd.
89	Protocol CV185030: A phase 3, active (warfarin) controlled, randomized double blind, parallel- arm study to evaluate efficacy and safety of Apixaban in preventing stroke and systemic embolism in patients with nonvalvular atrial fibrillation.	Dr. M. Gadkari	Bristol Mayers Squibb
90	A phase 3, randomized , active - controlled, double blind trial evaluating the safety, tolerability and immunogenicity of a 13 valent pneumococcal conjugate vaccine in healthy infants given with routine paediatric vaccinations in India.	Dr. A. Bavdekar	Wyeth
91	Evaluation of safety, tolerability and immunogenicity of vaccination with rota teq [™] in healthy infants in India	Dr. S. Bhave	Apothecaries
92	Clinical study of ocular problems in preschool children and evaluation of strategies employed.	Dr. V. S. Padbidri	IMPACT, UK
93	Efficacy of NaFeEDTA fortified wheat flour in improving haemoglobin & iron status & total body iron of school children.	Dr. C. S. Yajnik	Department of Bio-Technology
94	Follow up evaluation of long-term immunogenicity of a live attenuated Hepatitis A vaccine (Biovac A) in healthy Indian Children.	Dr. A. Pandit	Wockhardt Limited
95	Inhaled preprandial human insulin with the AERx® iDMS versus subcutaneous injected insulin aspart in subjects with Diabetes and asthma: a 52- week, open- label, multinational, randomized, parallel trial to investigate long term safety	Dr. C. S. Yajnik	Novo Nordisk
96	Inhaled preprandial human insulin with the AERx® iDMS versus subcutaneous injected insulin aspart in subjects with Diabetes and asthma: a 52- week, open- label, multinational, randomized, parallel trial to investigate long term safety	Dr. C. S. Yajnik	Novo Nordisk

97	A multicentric, randomised, open label study to compare efficacy and safety of intravenously administered doripenem injection with cilanem (Imipenem-Cilastatin) injection in the treatment of Nosocomial Pneumonia.	Dr. P. Khatavkar	Ranbaxy Labs Ltd.
98	A randomized, double blind, parallel, placebo or amlodipine- controlled study of the effects of losartan on proteinuria in pediatric patients with/ without hypertension.	Dr. S. Bhave	Merck & co. / Clinigen International Pvt. Ltd
99	An international randomized, double-blind, parallel-group, placebo controlled, flexible dose study: evaluation of the safety and efficacy of brivaracetam in subjects (> 16 to 70 years old) suffering from localization related or generalized epilepsy.	Dr. N. Yardi	UCB
100	Protocol 39039039AFL3001/BAY59 - 7939/11630: A randomized, double-blind, double dummy, parallel- group, multicenter non-inferiority trial comparing the efficacy and safety of once daily oral rivaroxaban (Bay59-7939) with adjusted dose oral warfarin for the prevention of stroke and non-central nervous system systemic embolism in subjects with non-valvular atrial fibrillation.	Dr. M. Gadkari	Bristol Mayers Squibb
101	A phase II/III, observer-blind, randomized, active controlled study to compare the safety and immunogenicity of a mein gococcal a conjugate vaccine (PsATT) with meningogoccal ACYW polysaccharide vaccine administered in healthy children 2-10 years of age.	Dr. A. Pandit	WHO/ SIIL PATH
102	Protocol No. RCRS/CT/Ind Swift/PRU : A randomized, multicenter, open labelled study to assess the safety & efficacy of Prulifloxacin Vs Augmentin in patients with acute exacerbation of chronic bronchitis (AECB)	Dr. P. Khatavkar	Reliance Clinical Research Services Pvt. Ltd. (RCRS)
103	Protocol No. RCRS/CT/Ind Swift/IVA: An open labelled, randomized, parallel group, multicenter study to evaluate the anti-anginal efficacy and safety of Ivabradine as compared to Atenolol in patients with chronic stable angina pectoris.	Dr. S. Kalashetti	Reliance Clinical Research Services Pvt. Ltd. (RCRS)

104	248:525: A double blind, double-dummy, placebo- controlled, randomized, three parallel groups study comparing the efficacy, safety and tolerability of Pramipexole ER versus placebo and Vs Pramipexole IR administered orally over a 26-week maintenance phase in L-Dopa + treated patients with advanced Parkinson's disease(PD).	Dr. A. Alurkar	Pharma Net Clinical Services Pvt. Ltd.
105	Protocol P04230 A randomized placebo-controlled efficacy & safety study of 1 Yr treatment duration with high and medium dose inhaled mometasone furoate /formoterol combination formulation compared with formoterol & high dose inhaled mometasone furoate monotherapy in sub. with moderate to severe COPD	Dr. P. Khatavkar	SPRI (Quintiles CRO)
106	(Study PO4073) A 26-week placebo-controlled efficacy and safety study of Mometasone furoate/ formoterol fumarate combination formulation compared with mometasone furoate and formoteril monotherapy in subjects with persistant asthma previously treated with Low dose inhaled glucocorticosteroids.	Dr. M. Kale	SPRI (Quintiles CRO)
107	(Study PO4334) A 26-week placebo-controlled efficacy and safety study of Mometasone furoate/ formoterol fumarate combination formulation compared with mometasone furoate and formoteril monotherapy in subjects with persistant asthma previously treated with medium dose inhaled glucocorticosteroids.	Dr. M. Kale	SPRI (Quintiles CRO)
108	Protocol TAR-ORI-SD001 titled Nuvocid (oritavancin) at single or infrequent doses for the treatment of complicated skin and skin structure infections (SIMPLIFI)	Dr. B. Kalambe	Targanta Therapeutics Corporation
109	A Multicenter, Randomized, Double-Blind, Parallel-Group 2-Dose study of Gene-Activated®Human Glucocerebrosidase(GA-GCB) Enzyme Replacement Therapy Compared with Imi glucerase in Patients with type I Gaucher Disease.	Dr. A. Bavdekar	Shire Human Genetic Therapies. Inc

110	A randomized, double blind, placebo controlled study to assess the safety and efficacy of KRP-104 in patients with Type-2 diabetes inadequately controlled on Metformin alone.	Dr. S. Kale	Activ X Biosciences
111	A randomized, double blind, parallel-group, multicenter study to compare the glycemic effects, safety & tolerability of exenatide long acting release to those of sitagliptin and pioglitazone in subjects with T2DM treated with metformin. (BCB106)	Dr. S. Kale	Amylin Pharmaceuticals, Inc/ Medpace (CRO)
112	Evaluation of the anti-anginal efficacy and safety of oral administration of Ivabradine compared to placebo on top of a background therapy with a calcium antagonist (Amlodipine or Nifedipine) in patients with stable angina pectoris, a 6 week randomized double blind parallel group international multicentric study.	Dr. M. Gadkari	IRIS
113	A double-blind , randomized, placebo-controlled, parallel, multicenter study of the safety & efficacy of 2 dosages of bicifadine SR in adult outpatients with chronic neuropathic pain associated with diabetic peripheral neuropathy	Dr. C. S. Yajnik	XTL Development Inc
114	An open label 52 week safety study of bicifadine SR in adult outpatients with chronic neuropathic pain associated with diabetic peripheral neuropathy	Dr. C. S. Yajnik	XTL Development Inc
115	Surveillance for prevention of anaemia in children under 5 - ICDS administration of Low dose "Sprinkles"	Dr. A. Pandit	Heinz India Ltd.
116	Multinutrient supplementation in school children: Effects on nutritional status and cognitive development	Dr. A. Pandit	Heinz India Pvt. Ltd.
117	Protocol: TMC-CAN-05-03, A Clinical trial comparing treatment with Cangrelor (in combination with usual care) to usual care, in subjects who require percutaneous coronary intervention."	Dr. M. Gadkari	The Medicines Co
118	Multicenter, randomized, parallel Group Efficacy superiority study in hospitalised medically ill patients comparing rivaroxaban with enoxaparin	Dr. M. Gadkari	BayerHealth Care AG, Germany

119	Serosurvey to assess Rubella IgG antibodies in teenaged girls in Maharashtra and to assess immunogenicity and reactogenicity of Rubella Vaccine (R-Vac)	Dr. V. S. Padbidri	Serum Institute of India Ltd.
120	International, multicenter, randomized, double blind study to compare the overall mortality in acutely ill medical patients treated with Enoxaparin versus placebo in addition to graduated elastic stockings	Dr. P. D'costa	Reliance Clinical Research Services Pvt. Ltd. (RCRS)
121	Radomised dabigatran etexilate dose finding study in patients with acute coronary syndromes post index event with additional risk factors for cardiovascular complications also receiving aspirin & clopidogrel: multicentre prospective, placebo controlled, group dose escalation trial	Dr. V. Pai	Boehringer Ingelheim
122	A phase III, randomized, multicenter, double blind, parallel group, active controlled study to evaluate the efficacy and safety of oral dabigatran etexilate (150 mg bid) compared to warfarin (INR 2.0-3.0) for the secondary prevention of venous thromboembolism	Dr. M. Gadkari	Quintiles Ltd.
123	A Phase III, randomized, double blind, parallel-group study of the efficacy & safety of oral dabigatran etexilate (150 mg bid) compared to warfarin (INR 2.0-3.0) for 6 month treatment of acute symptom venous thromboembolism, following initial treatment (5-10 days) parenteral anticoagulant approved for this indication. (RECOVER 1160.53)	Dr. M. Gadkari	Quintiles Ltd.
124	Open label, randomized, multicentric study to establish safety and efficacy of recombinant insulin glargine manufactured by Biocon Ltd. Compared to Lantus™ in Type I Diabetes Mellitus Patients.	Dr. C. S. Yajnik	Clinigen International Pvt. Ltd
125	248.634: Long term safety study of open-label Pramipexole extended release (ER) in patients with advanced Parkinson's disease (PD)	Dr. A. Alurkar	Pharma Net Clinical Services Pvt. Ltd.

126	A randomized, double blind placebo controlled, parallel group, study investigating the safety and efficacy over 12 weeks treatment period of MAP0010 in asthmatic infants and children 12 months to 8 years of age	Dr. A. Pandit	MAP Pharmaceuticals, Inc.
127	Clinical trial A0081171: A randomized, double blind multicenter dose ranging study of the efficacy and safety of pregabalin compared to placebo in the adjunctive treatment of post surgical pain after primary inguinal hernia repair symptoms.	Dr. B. Kalambe	Pfizer
128	Amended Protocol: RLS/Oph/2005/01; Assessment of safety & efficacy of ReliNethra™ C Au (an Autologous bioengineered conjunctiva) in the treatment of Conjunctival disorders".	Dr. S. Shah	Reliance Life Sciences
129	Efficacy and tolerability of Ramelteon for treatment of Insomnia (an open-label, randomized, comparative study)	Dr. S. Pant/ Dr. V. Parlikar Update status/	Ranbaxy Labs Ltd.
130	A simple behavioural intervention to reduce episiotomy rates- an ICMR task force study	Dr. K. Coyaji	ICMR
131	Effects of ivabradine on cardiovascular events in patients with moderate to severe chronic heart failure & left ventricular systolic dysfunction. A 3year randomized double blind placebo controlled international multicentre study.	Dr. M. Gadkari	IRIS
132	A phase IV, open label comparative, comparative, parallel group, clinical study to evaluate the safety & immunogenicity of Haemophilus influenzae Type-B vaccine (SII Hib P _{RO}) of serum institute of India limited in indian infants	Dr. S. Hirve	Serum Institute of India Ltd.
133	Study of prevalence of chronic obstructive pulmonary disease (COPD) and phenotypic characterization of smoking and non-smoking COPD in a rural population in the region of Pune district, India	Dr. S. Juvekar	Imperial College, London

134	A multicentre, double-blind, parallel - group, placebo controlled randomized study: evaluation of the efficacy and safety of brivaracetam in subjects (> 16 to 70 years old) with partial onset seizures.	Dr. N. Yardi	UCB Pharma Belgium/ PPD India Ltd. Mumbai
135	Pivotal study to evaluate the immunogenicity and safety of a measles vaccine given by aerosolised inhalation: randomized controlled trial	Dr. S. S. Hirve/ Dr. A. Bavdekar	WHO & SII/ Diagnosearch Life sciences Pvt. Ltd.
136	A randomized double blind active controlled phase 3 extension study investigating the safety and efficacy over 40 weeks treatment of 2 doses of MAP0010 in asthmatic children (12 months to 8 years at enrolment into the MAP0010-CL-P301 study)	Dr. A. Pandit	MAP Pharmaceuticals, Inc.
137	TAK-442-202 : A phase 2, double-blind, randomized, placebo-controlled study of the safety and efficacy of TAK-442 in subjects with Acute Coronary Syndromes	Dr. M. Gadkari	Takeda
138	Efficacy and tolerability of Uro-vaxom in reduction of UTI episodes in recurrent lower urinary tract infection (rUTI)	Dr. D. Kirpekar	Ranbaxy Labs Ltd.
139	A double-blind, dose- ranging, placebo controlled, randomized study to evaluate the safety and efficacy of INCB013739 plus metformin compared to metformin alone on glycemic control in type 2 diabetic subjects not adequately controlled by metformin monotherapy	Dr. C. S. Yajnik	Incyte Corporation
140	Study OV-1012: Double blind, placebo-controlled, efficacy and safety study of clobazam (0.25,0.5and 1.0mg/kg/day) in patients with Lennox - Gastaut syndrome	Dr. N. Yardi	Ovation Pharmaceuticals, INC./ Quintiles Research (India) Pvt. Ltd.
141	A randomized double blind, parallel group study evaluating the safety and efficacy of clindamycin / butoconazole vaginal cream in the treatment of mixed bacterial vaginosis / vulvovaginal candidiasis infections.	Dr. S. Otiv	K V Pharma

142	A randomized, double blind, multicenter, placebo- controlled, phase III superiority study to assess the safety and efficacy of topical retapamulin ointment, 1% versus placebo ointment applied twice daily for 5 days in the treatment of adult and paediatric subjects with secondarily infected traumatic skin lesions	Dr. B. Kalambe	Paraxel
143	H80-IN-B009: a 16-week post marketing surveillance study on treatment emergent adverse event in patients with T2DM in India being started on exenatide (Byetta™)	Dr. C. S. Yajnik	Eli Lilly
144	A multicenter, double-blind, placebo-controlled, parallel group randomized, phase 2 trial to evaluate the glycemic efficacy, renal safety, pharmacokinetics and pharmacodynamics of Dapagliflozin in subjects with Type 2 diabetes mellitus and moderate renal impairment who have inadequate glycemic control	Dr. S. Kale	Bristol Mayers Squibb
145	Efficacy and safety of intravenous administration of conivaptan hydrochloride in the treatment of Euvolemic Hyponatremia	Dr. N. Bhalerao	Ranbaxy Labs Ltd.
146	Protocol -E5555-G000-202 A randomized, double blind, placebo controlled study of safety & tolerability of E5555 & its effects on clinical events and biomarkers in patients with non-ST-segments elevation acute coronary syndrome	Dr. M. Gadkari	Eisai Medical Research, Inc
147	F1K-MC-EVDP (1) efficacy and safety of drotrecogin alfa (activated) in adult patients with septic shock	Dr. M. Gadkari	Eli Lilly
148	A multicentric, prospective, phase III clinical study to evaluate the efficacy and safety of Zydus Recombinant Human Epoetin Alpha (r-HuEPO) in maintaining haemoglobin level in Chronic Renal Failure (CRF)	Dr. V. Pai	Zydus
149	Strategic approach to anemia-iron deficiency anemia- cross sectional survey of NCL school children	Dr. S. Tikekar / Dr. A. Patil/ Dr. R. Man chanda	NCL

150	A multinational, multicenter, randomized, double blind study comparing the efficacy and safety of AVE5026 with Enoxaparin for the Prevention of Venous Thromboembolism in patients undergoing major abdominal surgery.	Dr. B. Kalambe	ICON
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151	A phase IIa randomized, double blind, parallel group, placebo and active controlled, clinical trial to study the efficacy and safety of MK-0974 Co administered with Ibuprofen or acetaminophen in patients with migraine with or without aura	Dr. A. Alurkar	SIRO Clinpharm Pvt. Ltd
152	A double blind, placebo-controlled, dose escalation, parallel - group study to evaluate the efficacy and safety of E2007 (Perampanel) given as Adjunctive Therapy in Subjects with Refractory Partial Seizures.	Dr. N. Yardi	Eisai Medical Research, Inc
153	Protocol No. 1222.14 A randomized, double-blind, double-dummy, placebo - controlled, parallel group study to assess the efficacy and safety of 48 weeks of once daily treatment of orally inhaled BI 1744 CL (5 mg [2 actuations of 2.5 mg] and 10 mg (2 actuations of 5 mg)) delivered by the Respimat® inhaler and 48 weeks of twice daily Foradil®(12mg) delivered by the Aerolizer® Inhaler, in patients with Chronic Obstructive Pulmonary Disease (COPD)	Dr. P. Khatavkar	Boehringer Ingelheim
154	A Multicenter, randomized, doubleblind, placebo control study on IN-105 tablets (oral insulin) in patients with Type 2 diabets mellitus who have inadequate glycemic control on optimal doses of extended release metformin tablets.	Dr. C. S. Yajnik	BIOCON
155	A phase III, double-blind, randomized, active controlled study to evaluate the safety and consistency of immunogenicity of three consecutive lots of a Meningo coccal A Conjugate Vaccine administered as a single dose to healthy children at 5-10 years of age	Dr. S. Hirve	Path & SIIL/ CRO: Diagno Search Life Sciences Pvt. Ltd
156	A phase III, open-label, cross - sectional, study to evaluate eZscan as a tool for early detection of diabetic neuropathy in type 2 diabetic mellitus patients, as compared with standard methods of screening for the condition (IM/DM-03-08)	Dr. C. S. Yajnik	Impeto Medical, France

157	A randomized, double blind, placebo controlled, event driven multicenter study to evaluate the efficacy and safety of Rivaroxaban in subjects with a recent acute coronary syndrome	Dr. M. Gadkari	Johnson & Johnson Ltd.
158	Recover 1160.46: A Phase III randomized, double blind, parallel-group study of the efficacy and safety of oral dabigatran etexilate (150 mg bid) compared to warfarin (INR 2.03.0) for 6 month treatment of acute symptomatic venous thrombo embolism, following initial treatment for at least 5 days with a parenteral anticoagulant approved for this indication.	Dr. M. Gadkari	Quintiles Ltd.
159	Clinical study protocol CQAB149B2349 : A 12 week treatment multicentre randomized, parallel group, double blinded, double dummy study to assess the superiority of Indacaterol (150 mg o.d) via a SDDPI in patients with moderate to severe COPD, using Salmeterol (50 mg b.i.d) as an active comparator delivered via a DISKUS inhaler.	Dr. S. Kalashetti	Novartis
160	Safety and efficacy of Exenatide once weekly injection versus Metformin, Dipeptidyl Peptidase-4 inhibitor or Thiazolidine as monotherapy in drug naïve patients with Type 2 diabetes	Dr. C. S. Yajnik	Eli Lilly
161	Phase I safety, efficacy and pharmacokinetic study of Paclitaxel nano-dispersion injection in subjects with metastatic breast cancer: A randomized, open label, dose-ranging, active controlled, comparative, parallel group and multi-centric study.	Dr. M. Jain	Sun Pharma Advanced Research Company Ltd.
162	Management of severe sepsis in Asia's Intensive Care Units - MOSAICS	Dr. B. Bande	ISCCM
163	(Protocol no.= ROTA:01/09- part I} A randomized, double blind, placebo controlled, study to assess safety and tolerability of RotaVac vaccine (Live attenuated bovine- human (UK) reassortant pentavalent rotavirus vaccine)	Dr. A. Pandit	Serum Institute of India Ltd.

164	A Multicenter Randomized, Double-Blind, Phase 3b Trial to Evaluate the Efficacy & safety of Saxagliptin Added to Insulin Monotherapy or to Insulin in Combination with Metformin in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Insulin Alone or on Insulin in Combination with Metformin. CV 181-057	Dr. C. S. Yajnik	Bristol Myers Squibb
165	A 24-Week National, Multi-centre, Randomized, Parallel-group, Double blind, Placebo-controlled, Phase III b study in India to evaluate the Efficacy & Safety of Saxagliptin in Adult Patients with T2Diabetes who have Inadequate Glycaemic Control with Diet & Exercise.	Dr. C. S. Yajnik	Astra Zeneca
166	Study of Phenotypic characterization of smoking and non-smoking COPD in a rural setting in India.	Dr. S. Juvekar	Collaborative project
167	An evaluation of the safety, efficacy and pharmaco kinetics of daptomycin in pediatric subjects aged 7 to 17 years with complicated skin and skin structure infections caused by gram-positive pathogens	Dr. M. Otiv	Cubist Pharmaceuticals, Inc
168	Study protocol AC-054-302: A prospective, multiple-centre, double-blind, randomized, placebo – controlled, parallel-group study to assess the efficacy and safety of Clazosentan in reducing vasospasm-related morbidity & all cause mortality in adult patients with aneurysmal subarachnoid hemorrhage treated by endovascular coiling.	Dr. A. Alurkar	ACTELION
169	Observational study to assess the rate of lactation failure after lactation counseling in mothers giving birth to term AGA infants	Dr. A. Bavdekar	Nestec
170	A multicentre, randomized, double blind, placebo-controlled study of AMG 785 in skeletally mature adults with a fresh unilateral tibial diaphyseal fracture status post definitive fracture fixation with an intramedullary nail	Dr. R. Nerlikar	Amgen

171	A prospective, multicentre, investigator-blinded, randomized, comparative study to estimate the safety, tolerability & efficacy of NXL104/Ceftazidime vs. Imipenem cilastatin followed by appropriate oral therapy in the treatment of complicated urinary tract infections in hospitalized adults.	Dr. B. Kalambe	Astra Zeneca formerly under Novexel/ Trident Clinical Research
172	A 26-week randomized, controlled, open label, multicentre, multinational trial comparing efficacy and safety of SIBA with sitagliptin as add on to current oral antidiabetic treatment in insulin-naïve subjects with type 2 diabetes mellitus inadequately controlled with 1-2 oral antidiabetic drugs (metformin, sulphonylurea, glinides or pioglitazone).	Dr. C. S. Yajnik	Novo Nordisk
173	Protocol NC25113- A randomized double blind, placebo controlled clinical trial to assess the effects of taspoglutide (RO5073031) on cardiovascular outcomes in subjects with inadequately controlled type 2 diabetes and established cardiovascular disease.	Dr. C. S. Yajnik	Roche
174	A double blind, randomized, placebo-controlled multi-centre study to assess the efficacy and safety of adjunctive zonisamide in paediatric partial onset seizures.	Dr. N. Yardi	Eisai Medical Research, Inc/Quintiles Research (I) Pvt. Ltd.
175	Multicenter, randomized, double blind, placebo controlled, parallel group, efficacy and safety study to evaluate the effects of oral administration of Lixivaptan in patients with congestive heart failure.	Dr. M. Gadkari	Chiltern
176	A phase II/III clinical trial to assess safety and immunogenicity of the influenza vaccine (whole virion, inactivated) A H1N1 (pandemic) administered at two dose levels in adults, elderly and pediatric populations.	Dr. A. Bavdekar	Serum Institute of India Ltd.

177	Clinical Trial Protocol 64,185-202; A phase 2b, multicenter, single-dose, blinded, randomized, placebo-controlled, dose–escalation, safety and efficacy trial of stannosoporphin in neonates with hyperbilirubinemia	Dr. S. Kadam	Infa Care Pharmaceuticals
178	A double-blind, placebo controlled clinical trial to evaluate the efficacy and safety of interferon Alfa-n3 therapy in addition to standard of care in adults hospitalized due to acute severe influenza	Dr. S. Kalashetti	Hemispherx Biopharma Inc./Max Neeman Medical International Ltd, New Delhi
179	Study Protocol SP921: A multicenter randomized, double blind, placebo controlled, 5-arm, parallel-group trial to assess rotigotine transdermal system dose response in subjects with advanced-stage Parkinson's disease	Dr. A. Alurkar	UCB Bio sciences Inc./Pharma Net(payment by CRO)
180	Survey of dengue specific antibodies in a rural population near Pune city: A pilot study	Dr. P. S. Shah	National Institute of Virology
181	A randomized, multicenter, open label, comparative study to evaluate the immunogenicity & reactogenicity of a new fully liquid hexavalent DTwP-Hepb-Hib-IPV vaccine (Easy six™, Panacea Biotech Ltd) with Pentavalent DTwP-Hepb-Hib vaccine (Tritanrix-HB™ reconstituted with Hiberix™, GSK) Co administered with Imovax Polio®(Salk Based Inactivated Polio Vaccine; Sanofi Pasterur India Pvt.LTd)in healthy infants.	Dr. A. Bavdekar	PANACEA Biotech Ltd