



## K.E.M.HOSPITAL RESEARCH CENTRE

### LIST OF ONGOING PROJECTS

Sr. No.	Study title	PI	Sponsor/ CRO
1	Diabetes Reduction Assessment with Rampavil and Resiglitzone Medication (DREAM) Trial	Dr. S. Kale/ Dr. C Yajnik	Aventis Pharma
2	A Phase 1a study of the safety and clinical tolerability of attenuated measles vaccine administered as an aerosol to healthy adult males.	Dr. A. Pandit	WHO-ICMR
3	Establishment of hospital based surveillance of Rotavirus disease and strains at National Institute of Virology, Pune	Dr. A. Pandit	CDC & ICMR
4	Isolation, characterization and determination of neurogenic potential of human bone marrow stromal cells.	Dr. R. Manchanda	Department of Bio-Technology
5	Standardization of the procedure for the transport, processing and culture of donor tissues (Ocular and Skin)	Dr. S. Shah ( Ocular tissue) (A) & (B)-Dr.Y. Tawade (Skin tissue)	Reliance Life Sciences Pvt. Ltd
6	Protocol no. RLS/DER/2005/01: "Comparative assessment of efficacy and safety of wound cover ReliHeal™ and Jelonet in healing of graft donor site"	Dr. A. Deodhar	Reliance Clinical Research Services Pvt. Ltd. (RCRS)
7	Association between maternal vitamin B12 & folate status in pregnancy and adiposity, insulin resistance and cognitive performance in the offspring at 11 Y of age.	Dr. C. S. Yajnik	Department of Bio-Technology
8	EpiDREAM International epidemiological study	Dr. S. Kale/ Dr. C Yajnik	Aventis Pharma

9	Study of genetic susceptibility to neural tube defects and its association with maternal vitamin B12 and folate status.	Dr. K. Godbole	Department of Bio-Technology
10	Can developmental programming of adiposity and insulin resistance in rural Indian children be reversed during adolescent growth by Vitamin B12 supplementation? A pilot study	Dr. C. S. Yajnik	Wellcome Trust, UK
11	Evaluation of Oxidative stress in Diabetes mellitus	Dr. S. Ghaskadbi	Department of Bio-Technology
12	Phase IV Multicentric study with Centchroman	Dr. K. Coyaji	ICMR
13	Phase IV Multicentric study with Centchroman	Dr. K. Coyaji	ICMR
14	HIV-Cervical Cancer prevention research program.	Dr. S. Hirve/ Dr. V. Padbidri	NARI
15	A randomized, double-blind, placebo-controlled, parallel group study to determine whether, in patients with type 2 diabetes at high risk for cardiovascular and renal events, Aliskiren, on top of conventional treatment, reduces cardiovascular and renal morbidity and mortality	Dr. C. S. Yajnik	Novartis
16	Primary vaccination in subject aged 11-17 years to demonstrate the non-inferiority of ASK Biological Meningococcal vaccine ASK 134612 vaccine vs Mencevax ACWY	Dr. A. Bavdekar	GSK Biologicals
17	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	Dr. V. Pai	Pharma Net Clinical Services Pvt. Ltd.
18	Lilly protocol H7T-MC-TABY (a) A comparison of Prasugrel and Clopidogrel in subjects with unstable Angina / Non-ST-Elevation Myocardial infarction (UA/NSTEMI) acute coronary syndrome (ACS) who are medically managed.	Dr. M. Gadkari	Eli Lilly

19	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
20	Health Economic study to estimate the incremental cost effectiveness ratio of delivery of measles vaccine with an aerosol device as compared to delivery with traditional subcutaneous injection	Dr. A. Bavdekar	WHO/Serum Institute of India Ltd.
21	Influenza disease burden in rural communities in India	Dr. S. Hirve	CDC
22	A phase IIIb, open, randomized, multicentre, primary study in healthy children to establish the non inferiority of Glaxo Smith Kline (GSK) Biologicals MeMuRu-OKA vaccine (administered at 9 and 15 months) Vs Priorix™ (9 months) & Priorix™ Co-administered with Varilix™ at 15 months of age (comparator) & also to evaluate the non-inferiority of Priorix™ (9 months) & MeMuRu-OKA vaccine (15 months) versus the comparator, all administered subcutaneously as 2 dose primary vaccination course	Dr. A. Bavdekar	GSK Biologicals
23	A phase 3, randomized, placebo controlled, blinded, multicenter, study of the induction & maintenance of clinical response and remission by MLN0002 in patients with moderate to severe ulcerative colitis	Dr. B. Kalambe	Millenium Pharmaceuticals Inc. USA/ Quintiles Ltd.
24	A phase 3, open label study to determine the long term safety and efficacy of MLN0002 in patients with ulcerative colitis and Crohn's disease	Dr. B. Kalambe	Millenium Pharmaceuticals Inc. USA/ Quintiles Ltd.
25	An open-label, multicenter, followup trial to evaluate the long term safety and efficacy of brivaracetam used as adjunctive treatment at a flexible dose up to a maximum of 150 mg/day in subjects aged 16 years or older suffering from epilepsy. NO1199	Dr. N. Yardi	UCB Pharma, Belgium/ PPD India Ltd.

26	Protocol HGT-GCB-044: An open label extension study of Gene Activated® Human Glucocerebrosidase (GA-GCB) Enzyme Replacement Therapy in patients with Type 1 Gaucher Disease.	Dr. A. Bavdekar	Shire Human Genetic Therapies. Inc
27	Early life antecedents of type 2 diabetes and polycystic ovary syndrome in young Indian adults	Dr. C. S. Yajnik	Wellcome trust
28	Named patient program with levetiracetam oral solution, for paediatric patients suffering from epilepsy having previously participated in study No 1148	Dr. N. Yardi	UCB Pharma, Belgium/
29	A clinical trial comparing Cangrelor to Clopidogrel in subjects who require percutaneous coronary intervention	Dr. M. Gadkari	Quintiles Ltd.
30	Integration of Ayurveda with Genomics: a novel approach in systems biology for predictive medicine	Dr. S. Juvekar	CSIR
31	Phase 3 b, randomized, double blind placebo controlled, multicenter study to assess the safety and efficacy of Conivaptan in Symptomatic Acute Decompensated Heart Failure (ADHF) subjects with hyponatremia	Dr. M. Gadkari	Astellas Pharma Inc./ ClinSys Clinical Research Pvt. Ltd.
32	Study L00070 IN305B0, A phase III study of vinflunine + capecitabine versus capecitabine alone in patients with advanced breast cancer previously treated with or resistant to an anthracycline and who are taxane resistant	Dr. M. Jain	Chiltern (CRO)
33	Study A0081143 A randomized, doubleblind, parallel group multicenter comparative flexible trial of pregabalin versus gabapentin as adjunctive therapy in subjects with partial seizures.	Dr. N. Yardi	Pfizer
34	A randomized, active controlled, parallel group, multi-center, two stage, open label, study comparing safety and immunogenicity of Insugen® & insurgen® with actrapid and Insulatard® in patients with type 1 diabetes mellitus	Dr. C. S. Yajnik	Biocon / CLINIGEN

35	A randomized, double-blind, placebo and active controlled, parallel-group, multicenter study to determine the efficacy and safety of albiglutide administered in combination with metformin and glimepiride compared with metformin plus glimepiride and placebo and with metformin plus glimepiride and pioglitazone in subjects with type 2 diabetes mellitus	Dr. C. S. Yajnik	GSK Biologicals (Sponsor)/ PPD (CRO)
36	Sprinkles' supplementation in infancy and mental development in early childhood (EDIS)	Dr. A. Pandit	H J Heinz Company Foundation
37	A Randomized, Placebo Controlled Clinical Trial to Evaluate cardiovascular Outcomes after Treatment with Sitagliptin in Patients with Type 2 Diabetes Mellitus & Inadequate Glycemic Control on Mono- or Dual Combination Oral Antihyperglycemic Therapy.	Dr. C. S. Yajnik	Jubilant Clinsys Limited (CRO)
38	An open label extension phase of the double blind, placebo controlled, dose escalation, parallel-group studies to evaluate the efficacy and safety of E2007 (perampanel) given as adjunctive therapy in subjects with refractory partial seizures (revised as per amendment 01)	Dr. N. Yardi	Eisai Medical Research, Inc
39	A multicenter, randomized, double blind, parallel group, placebo controlled study to evaluate the 6 mths efficacy and safety of aliskiren therapy on top of standard therapy, on morbidity and mortality when initiated early after hospitalisation for acute decompensated heart failure. CSPP 100A2368	Dr. M. Gadkari	Novartis
40	A Phase 2/3, placebo controlled, efficacy and safety study of once-weekly subcutaneous LY2189265 compared to Sitagliptin in patients with type 2 diabetes mellitus on metformin.	Dr. C. S. Yajnik	Eli Lilly
41	Growth and body composition in undernourished Indian children effect of vitamin B <sub>12</sub> supplementation.	Dr. U. Deshmukh	International Atomic Energy Agency ,Vienna & Diabetes Unit

42	Characterization of type 1 diabetes patients with special reference to peri-pubertal growth, body composition	Dr. K. Godbole	Departmental project
43	A 2- year, randomised, double blind, placebo controlled, multi- center, phase II-III study to evaluate the efficacy and safety of oral ranirestat (40 and 80 mg) in mild to moderate diabetic sensorimotor polyneuropathy	Dr. C. S. Yajnik	Eisai Medical Research, Inc
44	A multicenter, randomised, double blind, parallel group, active controlled study to evaluate the efficacy & safety of both aliskiren monotherapy & aliskiren /enalapril combination therapy compared to enalapril monotherapy on morbidity & mortality in patients with chronic HF(NYHA class II-IV).	Dr. V. Pai	Novartis
45	CLR_09_10, A phase I safety, tolerability and pharmacokinetic study of Docetaxel nano-dispersion: A randomised, open label, dose ranging, active controlled comparative, parallel groups and multicentric study.	Dr. M. Jain	Sun Pharma Advanced Research Company Limited, India/ Max Neeman International
46	A phase III, open, controlled study to assess the persistence of antibodies after one dose of GSK Biological's meningococcal serogroup ACWY conjugate vaccine (MenACWY-TT) given intramuscularly versus one dose of Mencevax <sup>TM</sup> ACWY given subcutaneously to healthy subjects aged 11 through 17 years in the primary study 109069 (MenACWY-TT-036)	Dr. A. Bavdekar	GSK Biologicals
47	Cooling efficacy of PCM mattress for therapeutic hypothermia in neonatal encephalopathy – A pilot study	Dr. S. Kadam	Departmental project
48	Multi drug resistant TB	Dr. S. Sanghavi	Department of Bio-Technology
49	An Observational, Case – control study to evaluate if surgical gastric Bypass done for ulcer diathesis is protective for wt. gain as well as onset of diabetes in long term follow-up.	Dr. C. S. Yajnik	Departmental Project

50	Identifying variants causal for Type 2 Diabetes in Major human populations U01DK085545	Dr. C. S. Yajnik	NIH USA/ EU
51	Hospital based surveillance of Female Genital Fistula	Dr. K. Coyaji	ICMR
52	A multicenter, randomised, double blind, placebo controlled study to evaluate cardiovascular outcomes following treatment with alogliptin in addition to standard of care in subjects with type 2 diabetes and acute coronary syndrome.Syr 322-402	Dr. M. Gadkari	Takeda Global Research Ltd.
53	Hospital Admissions under Department of Paediatrics	Dr. A. Pandit	Departmental Project
54	A phase 3, randomized, double blind, multinational, placebo controlled study to evaluate efficacy & safety of Teplizumab (MGA031), a humanized, FcR non-binding, anti-CD3 monoclonal antibody, in children & adult with recent onset T1DM	Dr. C. S. Yajnik	Diagnosearch Life Sciences Pvt. Ltd./ Macro Genics Inc
55	A randomized, multicenter, double blind, parallel, placebo- controlled study of the effects of JNJ-28431754 (Canagliflozin) on cardiovascular outcomes in adult subjects with type-2 diabetes mellitus.	Dr. C. S. Yajnik	Johnson & Johnson Pharmaceutical Research & Development, L.L.C./
56	Vitamin B 12 absorption in Vitamin B 12 deficient subjects, before and after B 12 supplementation	Dr. C. S. Yajnik	Departmental Project
57	A study of teenage pregnancy and its outcome	Dr. K. Coyaji	ICMR
58	A phase 3 multicenter, randomized, double blind, parallel group, placebo controlled Study of cardiovascular outcomes to evaluate the potential of Alogliptin to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes (T2D)	Dr. M. Gadkari	Roche/ GIIH India
59	Assessment of total energy expenditure using Doubly Labelled Water technique in Indian rural pregnant women	Dr. C. S. Yajnik	IAEA

60	Fitting to outcomes expert (FOX™) adult study A computer assisted fitting approach to improve clinical efficiency	Dr. N. Vaid	A B Clinical Research Dept. Europe
61	Growth of infants who are supplementary fed/mixed fed with probiotics – containing formula in India.	Dr. U. Vaidya	Nestec SA
62	The Pune Photovoice Project: Mera Shahar, Mera Sawasta, Mera Jeevan	Dr. C. S. Yajnik	Departmental Project
63	Clinical evaluation of the Nucleus® C12422 cochlear implant(Nucleus straight array cochlear implant)	Dr. N. Vaid	Cochlear Ltd, Australia
64	A double blind, randomized, placebo-controlled, parallel group study to establish therapeutic equivalence of 1000 mg mesalamine rectal suppositories and Canasa ® Rectal suppositories (100 mg Mesalamine, USP) in the treatment of mild to moderate ulcerative proctitis.	Dr. B. Kalambe	Sandoz Inc. USA/ Clinsys
65	Use of a multidrug pill in reducing cardiovascular events	Dr. M. Gadkari	Imperial College
66	A prospective, multi-centric, open label, randomized, controlled study to evaluate the safety and efficacy of teriparatide (rhPTH1-34) in postmenopausal osteoporosis	Dr. K. Coyaji	Cadila healthcare ltd.
67	A Phase III randomised, double blind, active controlled parallel group efficacy and safety study of BI 10773 compared to glimepiride administered orally during 104 weeks in patients with type 2 diabetes mellitus and insufficient glycemic control despite metformin treatment	Dr. C. S. Yajnik	Boehringer Ingelheim/ SIRO clinpharm Pvt Ltd.
68	A Phase III randomised, double blind, placebo controlled, parallel group, efficacy and safety study of BI 10773(10mg and 25mg administered once daily) as add on to pre-existing antidiabetic therapy over 52 weeks in patients with T2DM & renal impairment & insufficient glycemic control.	Dr. C. S. Yajnik	Boehringer Ingelheim/ Siro clinpharm Pvt Ltd.

69	A phase 2a, randomized, controlled, observer blind, age de-escalation, multicenter and multinational study of the safety, reactogenicity and immunogenicity of the NVGH glycoconjugate vaccine against <i>S.typhi</i> in adults, children, older infants and infants	Dr. A. Bavdekar	NVGH/ inVentiv pharma
70	Efficacy and safety of paclitaxel nano dispersion concentrate for injection(PICN) in subjects with metastatic breast cancer:A randomized , open label , active controlled, comparative,parallel group, and multi-centric study	Dr. M. Jain	Sun Pharma
71	A phase III randomised double blind placebo controlled trial to evaluate the protective efficacy of three doses of oral rotavirus vaccine (ORV) 116E, against severe rotavirus gastroenteritis in infants	Dr. A. Bavdekar	Bharat Biotech IL / PATH
72	INSUGCT300509" A Randomized Active Controlled , Parallel Group, Multicenter , Two Phase, Open Label Study Comparing the Safety and Immunogenicity of Insugen R and Insugen N with Actrapid and Insulatard in Patients with Type 1 Diabetes Mellitus	Dr. C. S. Yajnik	BIOCON / GVK
73	LUX BREAST-1,1200.0075, An open label, randomised phase III trial of BIBW 2992 and viorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment	Dr. M. Jain	Boehringer Ingelheim/ Manipal Ecron Acunova Ltd.
74	A phase II, 12 week randomised double blind, placebo controlled study to evaluate safety, tolerability, pharmacokinetic and effects of glycemic control of P1736-05 in subjects with type 2 diabetes mellitus	Dr. C. S. Yajnik	Piramal Life Sciences

75	PVRV rabies A randomized, open label, active controlled, phase I clinical study to assess the safety and immunogenicity of SIIIL's Purified Vero Cell Rabies Vaccine (PVRV) in healthy adults as a pre-exposure immunization.	Dr. A. Bavdekar	Serum Institute of India Ltd./ Diagno Search life sciences pvt. ltd.
76	SAVOR A multicentre, randomised, double-blind, placebo-controlled phase IV trial to evaluate the effect of Saxagliptin on the incidence of cardiovascular death, myocardial infarction or ischaemic stroke in patients with T2DM	Dr. C. S. Yajnik	Astra Zeneca
77	A population based surveillance of invasive disease caused by S.Pneumoniae or H. influenzae or N. meningitis in children < 5 years of age in India	Dr. A. Sapru	CMC
78	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy & safety of CLCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure & reduced ejection fraction.	Dr. M. Gadkari	Novartis
79	A phase 1 pharmacokinetic, safety and tolerability study of paclitaxel injection concentrate for nano-dispersion (PICN) administered once a week in subjects with advanced solid malignancies in Indian population.	Dr. M. Jain	Sun Pharma Advanced Research Company Limited, India
80	A trial comparing the efficacy and safety of Insulin degludec / liraglutide, insulin degludec and liraglutide in subjects with T2D (NN9068-3697)	Dr. C. S. Yajnik	Novo Nordisk
81	Effects of ivabradine in patients with stable coronary artery disease without clinical heart failure. A randomised double blind placebo-controlled international multicentre study.	Dr. M. Gadkari	IRIS, France / Gleagles

82	A 52 weeks, double blind, randomized, placebo controlled trial evaluating the effect of oral BIBF 1120, 150 mg twice daily on annual Forced Vital Capacity decline, in patients with Idiopathic Pulmonary Fibrosis (IPF). <b>IPF1199.34</b>	Dr. P. Khatavkar	Boehringer Ingelheim/ Manipal Acunova Ltd.
83	Seroprevalance study of Hepatitis A virus antibody in Indian children (EPO in AKI) Effect of recombinant Erythropoietin alfa in preventing Acute Kidney Injury (AKI) in patients with Septic Shock- A Randomized controlled Study.	Dr. S. Bhave	Wockhardt Limited/ Medclin Dept. Study
84		Dr. V. Lobo	
85	Milk Consumption and Child Growth in Pune, India: A Biocultural Investigation	Dr. C. S. Yajnik	Indiana University
86	Study OV-1004: Safety and Effectiveness of Open - Label Clobazam in Subjects with Lennox - Gastaut syndrome	Dr. N. Yardi	Ovation Pharmaceuticals, INC./ Quintiles Research (India) Pvt. Ltd.