



## CLINICAL TRIALS & BIOMEDICAL AND HEALTH RESEARCH - 2013 ONWARDS

### Clinical Trials

1. Project Title: Evaluation of Efficacy and Safety of Hydroxychloroquine Sulfate as an Adjunct to Diet and Exercise to Improve Glycemic Control in Type 2 Diabetes Patients Uncontrolled on Sulfonylurea + Metformin Combination. Protocol No : Ipca/HCQS/PIV-14
  - Principle Investigator : Dr Raj Mohan L, Department of Endocrinology
  - Status: Closed out
2. Project Title: A multicenter, randomized, 52-week, double-blind, parallel group, active controlled study to compare the efficacy and safety of QVM149 with QMF149 in patients with asthma. Protocol ID : CQVM149B2302
  - Principle Investigator: Dr Kesavan Nair V, Department of Respiratory Medicine
  - Status: Closed out
3. Project Title: A prospective, multicentric, randomized, open label, parallel group, comparative, two arms, safety, efficacy and pharmacokinetic study of Trastuzumab, (Manufactured by Intas Pharmaceuticals Limited, Biopharma Division, Ahmedabad, India) in comparison with Reference Biologic (Trastuzumab, Marketed by Roche) in the patients with HER2- Overexpressing Metastatic Breast Cancer. Protocol ID :625-14
  - Principle Investigator : Dr Boben Thomas, Department of Oncology
  - Status: Closed out
4. Project Title: a prospective, adaptive, randomized, open label ,multicenter clinical trial to assess the efficacy and safety of fixed dose combination of capecitabine&cyclophosphamide in patients of metastatic breast cancer with failure of anthracycline and/ or taxane chemotherapy.
  - Principle Investigator: Dr Boben Thomas, Department of Oncology
  - Status: Closed out
5. Project Title: A Multicenter, Observational, Post Marketing Surveillance to evaluate the Safety of Trastuzumab intravenous infusion (marketed as CANMAb of Biocon Limited, India/Hertraz™ of Mylan Pharmaceuticals Pvt. Ltd., India) administered as per the approved prescribing information in patients with HER2 overexpressing Metastatic Breast Cancer. Protocol ID: BIINTR001.

- Principle Investigator: Dr Boben Thomas, Department of Oncology
  - Status: Trial Terminated by the sponsor
6. Project Title: The CREDENCE Trial (Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation Trial). A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy. Protocol Number: 28431754DNE3001.
- Principle Investigator: Dr Satish Balan, Department of Nephrology
  - Status: Closed out
7. Project Title: A Randomized, Open Label, Parallel-group, Multi-center Phase 3 Study to Compare Efficacy and Safety of Recombinant Insulin Aspart (Manufactured by BioGenomics Limited) with NovoRapid® (Manufactured by Novo Nordisk), in Adult Patients with Diabetes Mellitus.
- Principle Investigator: Dr. Thushanth Thomas, Dept. of Endocrinology
  - Status: Closed out
8. Project Title: An Indian multi-centre, prospective, open-label, single-arm, non-interventional, post marketing surveillance study of Fiasp® to evaluate safety and effectiveness in patients with diabetes mellitus in routine clinical practice.
- Principle Investigator: Dr Thushanth Thomas, Dept of Endocrinology
  - Status: ongoing

## **Biomedical and Health Research**

1. Project Title: Dyslipidemia International Study II (DYSIS II): Lipid target achievement in high risk patients with Coronary Heart Disease (DYSIS II ACS/CHD)
  - Principle Investigator: Prof. G. Vijayaraghavan, Department of Cardiology
  - Status: Closed out
2. Project Title: Open-label, Multicentre, Observational, Prospective, Real-time data capturing of Usage, Outcome & Physician satisfaction of Coseal in Cardio-Vascular-Thoracic Operative and Re-operative procedures.
  - Principle Investigator : Dr. Fazil Mohamed Azeem, Department of Cardiac Surgery
  - Status: Closed out
3. Project Title: Helios Trial – Human Prospective anti-restenosis randomized trial utilizing the Vasmed “Rapstrom” Stirlimus local drug delivery Stent”
  - Principle Investigator: Dr. Ramakrishna Pillai V, Department of Cardiology
  - Status: Closed out
4. Project Title: Clinical Experience with Ertapenem in acute Pyelonephritis due to ESBL producing enterobacteriaceae in India.
  - Principle Investigator: Dr. Praveen Murlidharan, Department of Nephrology
  - Status: Closed out
5. Project Title: Project Title: Global Anticoagulant Registry In the FIELD (GARFIELD): Prospective, multicentre, international Registry of male and female patients newly diagnosed with atrial fibrillation. REGISTRY NUMBER: TRI08888.
  - Principle Investigator : Prof. G. Vijayaraghavan, Department of Cardiology
  - Status: Closed out
6. Project Title: A registry of Primary Percutaneous Coronary Interventions for Acute elevation ST Elevation Myocardial Infarction in Kerala (PARK Registry).
  - Principle Investigator : Dr. Ramakrishna Pillai V, Department of Cardiology
  - Status: Closed out
7. Project Title: The Indian Bronchiectasis Registry based on EMBARC: The European Bronchiectasis Registry Protocol and Governance Structure.
  - Principle Investigator : Dr. Arjun P, Department of Respiratory Medicine
  - Status: Closed out

8. Project Title: 26 SEPSIS in India prevalence study
  - Principle Investigator: Dr Sujith Thomas, Department of Critical Care Medicine
  - Status: Patient recruitment stopped, officially not Closed out
9. Project Title: Assessing Microeconomic Impact of Dialysis for End-Stage Renal Disease in Kerala, India
  - Principle Investigator: Dr. Praveen Murlidharan, Department of Nephrology
  - Status: Ongoing
10. Project Title: To study the range of mean and absolute eosinophils counts in healthy Indian subjects and compare them with asthmatics and COPD patients.
  - Principle Investigator: Dr P Arjun, Department of Respiratory Medicine
  - Status: Ongoing
11. Project Title: Does maternal hypercholesterolemia influence cholesterol transport mechanisms across the placenta during gestation?
  - Principle Investigator : Dr P Rafeeka, Department of Obstetrics & Gynecology
  - Status: Ongoing
12. Project Title: To evaluate the feasibility of multigene panel for diagnosis and management of Autism Spectrum Disorder in early neonatal period (<7days).
  - Principle Investigator : Dr Reeba Ann Daniel, Department of Pediatrics
  - Status: Ongoing
13. Project Title: Multi-center cross sectional epidemiological study to characterize the prevalence and distribution of lipoprotein(a)levels among patients with established cardiovascular disease.
  - Principle Investigator: Dr G Vijayaraghavan, Department of Cardiology
  - Status: Ongoing
14. Project Title: Prevalence of cardiomyopathies in tertiary care hospitals in Kerala
  - Principle Investigator: Prof G Vijayaraghavan, Department of Cardiology
  - Status: Ongoing
15. Project Title: Prevalence of group B streptococcus and profile of microbiota in genito-rectal region of pregnant women in Kerala and relation to Neonatal outcomes.
  - Principle Investigator: Dr. Girija Gurudas, Department of Obstetrics & Gynecology
  - Status: Ongoing

16. Project title: “Indian Registry of Intensive Care (IRIS) study”
  - Principle Investigator: Dr V Deepak, Department of Critical Care Medicine
  - Status: Ongoing
17. Project Title: Effects of Timed Regular Exercise and physical activity in women diagnosed with gestational diabetes on pregnancy outcomes – a retrospective cohort study
  - Principle Investigator: Dr Raj Mohan L, Dept. of Endocrinology
  - Status: Ongoing
18. Project Title: Incidence of Type 2 Diabetes Mellitus 5 years after the diagnosis of Gestational Diabetes Mellitus
  - Principle Investigator: Dr Thushanth Thomas, Dept. of Endocrinology
  - Status: Ongoing
19. Project Title: Clinical, biochemical and histopathological profile in Patients with Primary Hyperparathyroidism at a tertiary care centre in South India: a retrospective analysis
  - Principle Investigator: Dr Thushanth Thomas, Dept. of Endocrinology
  - Status: Ongoing
20. Project Title: Ultra-Thin strUt versus XiencE in a diabetic pOpulation with Multi-Vessel disease-2-India study.
  - Principle Investigator: Dr Praveen SV, Dept of Cardiology
  - Status: Ongoing
21. Project Title: A Prospective, Multicentric, Non- Interventional, Real-World, Data Collection Registry to Evaluate the Effectiveness, Safety and Durability of SUPERA Stent for the Treatment of De Novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian patients
  - Principle Investigator: Dr Manish Kumar Yadav, Dept. of Radio Diagnosis
  - Status: Ongoing
22. To evaluate the feasibility of multigene panel for diagnosis and management of Autism Spectrum Disorder in early neonatal period (<7days).
  - Principle Investigator: Dr Reeba Ann Daniel, Dept of Pediatrics
  - Status: Ongoing
23. Characterization of the Molecular Genetic Spectrum and Identification of Novel Monogenic Etiologies for Congenital Hypothyroidism in India.
  - Principle Investigator: Dr Thushanth Thomas, Dept of Endocrinology

- Status: Ongoing
24. Effect of Lipoprotein(a) in the Modulation of Early appearance of Calcification in Placenta
- Principle Investigator: Dr Rafeekha P, Dept. of Obstetrics & Gynaecology
  - Status: approval awaited
25. Project Title: Differentiation of Liposuction derived Mesenchymal Stem Cells to different type of stem cells for regenerative medicine”.
- Principle Investigator : Dr. Manesh Senan, Department of Plastic Surgery
  - Status: Ongoing
26. Project title: Sleep-Apnoea Indian Registry (S-AIR)
- Principle Investigator: Dr P Arjun, Department of Respiratory Medicine
  - Status: Yet to be commenced