# FUNDED RESEARCH PROJECTS

| Sr | Project title | Principle Investigator | Sponsor |
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| 1 | Evaluation of Typhoid Conjugate Vaccine (TCV) introduction program-Navi Mumbai, India (PI Dr Rajesh Rai, Professor & Head, Department of Pediatrics) | Dr. Rajesh Rai, Prof. and Head, Pediatrics | WHO- India, CDC- Atalanta & Stanford University, USA |
| 2 | A Phase III, multicenter, randomized, observer blind,parallel group, three arm, controlled clinical trial to evaluate the efficacy and safety of topically applied Calocipotriol/ AKV ANO 50 µg/g Cutaneous solution against Diavonex® 50 µg/g Crème, LEO and placebo in patients with mild to moderate plaque psoriasis. | Dr. Sharmila Patil, Prof and Head, Dermatology | Cadila Pharmaceuticals |
| 3 | Pharmacodynamic (PD) Study to demonstrate the equivalence of Sevelamer Hydrochloride Tablets 800 mg (Test Drug) with Renagel Tablets 800 mg (Reference Drug) in patients of Hyperphosphatemia receiving Hemodialysis. | Dr. Avinash Chaudhary | Cadila Pharmaceuticals |
| 4 | A Prospective, Randomized, Parallel group Study to Evaluate the Safety and Efficacy of FDC of Mupirocin calcium, Neomycin Sulfate & HT61 HCL in Patients with infected skin lesions by Staphylococcus aureus including Methicillin-resistant Staphylococcus aureus (MRSA) and/or S. Pyogenes. | Dr. Sharmila Patil, Prof and Head, Dermatology | Cadila Pharmaceuticals |
| 5 | A prospective, observational, post marketing surveillance study to evaluate the effectiveness and safety of secukinumab in Indian patients with moderate to severe plaque psoriasis requiring systemic therapy. | Dr. Kiran Godse, Asst. Prof., Dermatology | Novartis CAIN457AIN01 |
| 6 | A Phase III, Randomized, Open-Label, Multiple-Dose, Parallel-Group Study to Determine Efficacy, Safety, Pharmacokinetics and Immunogenicity of Recombinant Human FSH of Cadila Healthcare Limited, India as compared to Gonal-FTM Administered Subcutaneously in Female Patients Undergoing Assisted Reproductive Technology. | Dr Pallavi Vishwekar, , Asst. Prof., Obs. and Gynecology | Cadila Pharmaceuticals |

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| **7** | A Randomized, Double Blind, Placebo Controlled, Three Arm, Parallel Group, Multicentric Clinical Study to Evaluate the Therapeutic Bioequvalance of Two tarcrolimus 0.03% Topical Ointment Formulations In Adult Patients With Moderate To Severe Atopic Dermatitis. | Dr. Sharmila Patil, Prof and Head, Dermatology | Intas Pharmaceuticals |
| **8** | Open Label, Randomized, Multicentric, Two Treatments, Single Dose, Parallel Group, Bioequivalence Study Of Test Leteprednol Etabonate Opthalmic Suspension 0.5%, Manufactured By Indoco Remedies Ltd., For Watson Pharma Pvt Ltd. With Reference LOTEMAX® (Leteprednol Etabonate Opthalmic Suspension 0.5%) Manufactured By Bausch And Lomb Inc. In Aqueous Humor Of Patients Undergoing Indicated Cataract Surgery. | Dr. Nita Shanbhag, Prof. and Head, Ophthalmology | Indoco Remedies Ltd |
| **9** | Open Label Clinical Study To Determine The Specificity And Sensitivity Of Algorithm (Software) Developed By Bosch Using Bosch Mobile Non-Mydriatic Fundus Camera Comparing It With Mydriatic 7- Standard Field Stereoscopic Digital Color Fundus Photography (EDTRS) Done In Patients In Undiagnosed Diabetic Retinopathy (Symptomatic/Asymptomatic) | Dr. Nita Shanbhag, Prof. and Head, Ophthalmology | Bosch |
| **10** | An Open Label, Prospective, Single Arm Study to Evaluate Safety and Efficacy Of Heme – Iron In Pregnant Women. | Dr Shriram Gopal, Prof. and Head, Obs. and Gynecology | Wockhardt Pharmaceuticals |
| **11** | A prospective, post marketing surveillance study to study the safety and effectiveness of Omalizumab in Indian patients with Chronic Spontaneous Urticaria refractory to standard of care. | Dr. Kiran Godse, Asst. Prof., Dermatology | Novartis |
| **12** | An open label, prospective, comparative, assessor blind, single centric study for evolution of tolerability and efficacy of Zinderm BPO gel and Epiduo gel in management of Acute Vulgaris. | Dr. Kiran Godse, Asst. Prof., Dermatology | Wockhardt Pharmaceuticals |

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| **13** | An open label, prospective, comparative, multicenter, two weeks study to assess the device handling, human factors, ease of use, errors & participant perception on use of Synchrobreath- a breath actuated inhaler versus pressurized metered dose inhaler in healthy volunteers & in patients with Asthma or COPD | Dr Keya Lahiri, Prof. of Pediatrics | CiplaPharmaceuticals |
| **14** | Registry in the Management of Acute Diarrhea in children: Observational study in daily practice 2(REMAD 2) | Dr Keya Lahiri, Prof. of Pediatrics | SanofiPharmaceuticals |
| **15** | A Multicentre, double blinded, active controlled, parallel group,two arm, bioequivalence study with clinical end pointcomparing Brinzolamide 1% ophthalmic suspension (manufactured by Indoco Remedies Ltd) to Brinzolamide 1 %suspension (Azopt@, manufactured by Alcon Laboratories) , in the treatment of chronic open angle glycoma or occular hypertension in both eyes. | Dr. Nita Shanbhag, Prof. and Head, Ophthalmology | Alcon Laboratories |
| **16** | A randomized, double blind, double dummy, placebo with controlled, multi-center study of Secukinumab to demonstrate efficacy after 12 weeks of treatment compared to placebo, etanercept & to access the safety, tolerability &long time efficacy up to 1 year in subjects with moderate to severe chronic plaque type psoriasis. | Dr. Sharmila Patil, Prof and Head, Dermatology | NovartisPharmaceuticals |
| **17** | A Randomized, Double-Blind, Placebo-Controlled, three arm, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence and Safety of Tacrolimus Ointment, 0.1%(Encube Ethicals Private Limited) with Protopic (tacrolimus) ointment, 0.1%(Astellas Pharma US, Inc.) in the Treatment of Moderate to Severe Atopic Dermatitis | Dr. Sharmila Patil, Prof and Head, Dermatology | Encube Ethicals ARL-CT-18-002 |
| **18** | A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of AS012 in Subjects with Non-segmental Vitiligo | Dr. Sharmila Patil, Prof and Head, Dermatology | AS012 |

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| **19** | A Randomized, Double-Blind, Placebo-Controlled, three arm, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence and Safety of Pimecrolimus Cream, 1% (Encube Ethical's Private Limited) to Elidel (pimecrolimus) Cream 1%(Valeant Pharmaceuticals North America LLC) in the Treatment of Mild to Moderate Atopic Dermatitis | Dr. Sharmila Patil, Prof and Head, Dermatology | Encube Ethicals ARL-CT-18-003 |
| **20** | A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AK VANO 50 ug/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, sandoz and placebo in patients with mild to moderate plaque psoriasis | Dr. Sharmila Patil, Prof and Head, Dermatology | CRSC16004 |
| **21** | A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines | Dr. Kiran Godse, Asst. Prof., Dermatology | Novartis |
| **22** | A Randomized, Double blind, Multicentre, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel (Encube Ethical's Private Limited, India) to DUAC Gel ( Clindamycin Phosphate 1.2% and Benzoyl Peroxide 5% Gel ) (Stiefel Laboratories, Inc. Research Triangle park. NC 27709) in Subjects with Acne Vulgaries | Dr. Sharmila Patil, Prof and Head, Dermatology | |
| **23** | A Multicenter, Randomized, Double Blind, Placebo Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib in Adult Patients with Moderate to Severe Atopic Dermatitis | Dr. Kiran Godse, Asst. Prof., Dermatology | Eli-lily (JAH-L) |
| **24** | A Phase 3 Multicenter, Double-Blind Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Adult Patients with Atopic Dermatitis | Dr. Kiran Godse, Asst. Prof., Dermatology | Eli-lily (JAH-N) |

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| **25** | A Randomized, double - blind , placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT)and Zinc versus Placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute Diarrhoea in children | Dr Keya Lahiri, Prof. of Pediatrics | KIDDIE/LPS1414 |
| **26** | A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Three-arm, Parallel Study to Evaluate the Bioequivalence using Clinical Endpoint of Mupirocin Cream USP 2% (Encube Ethicals Private Limited, India) to Mupirocin Cream USP 2% (Glenmark Pharmaceuticals Inc., USA) in the Treatment of Subjects with Secondarily Infected Traumatic Skin Lesions | Dr. Sharmila Patil, Prof and Head, Dermatology | Encube |
| **27** | A randomized, double-blind, placebo control, multicenter, clinical trial to evaluate the efficacy and safety of intravenous (IV) Rabeprazole in prevention of pulmonary acid aspiration during surgery in patient under general anesthesia | Sandesh Deolekar, Prof., Surgery | Cadilla |
| **28** | A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of AdaliRel(R) in patients with moderate to severe plaque psoriasis | Dr. Sharmila Patil, Prof and Head, Dermatology | RLS/PMS/2016/07 |
| **29** | A randomized, double-blind, placebo-controlled, parallel group, multicenter, comparative study to assess the efficacy and safety of spores of Enterogermina in combination with oral rehydration therapy (ORT) and Zinc versus placebo in combination with ORT and Zinc administered for 5 days in the treatment of acute diarrhea in children | Dr Keya Lahiri, Prof. of Pediatrics | KIDDIE/LPS1414 Amedment |
| **30** | A multicenter, randomized, double-blind, placebo-controlled phase 2b dose-finding study to investigate the efficacy and safety of ligelizumab (QGE031) in adolescent patients with Chronic Spontaneous Urticaria (CSU) | Dr. Kiran Godse, Asst. Prof., Dermatology | Novartis (QGE031) |