ONGOING TRIALS						
Sr. No	**Name of Project**	**Protocol No**	**Principal Investigator**	**Department**	**Date of submission**	**Date of final approval**
1	A Randomized, Double-Blind, Placebo-Controlled Study of Galcanezumab in Patients 6 to 17 Years of Age with Episodic Migraine – the REBUILD-1 Study.	**I5Q-MC-CGAS**	Dr. Meenakshi Girish	Paediatrics	19/07/2021	13-Oct-21
2	A Randomized, Double-Blind, Placebo-Controlled Study of Galcanezumab in Adolescent Patients 12 to 17 Years of Age with Chronic Migraine – the REBUILD-2 Study.	**I5Q-MC-CGAT**	Dr. Meenakshi Girish	Paediatrics	19/07/2021	13/10/2021
3	A phase 3, randomized, double-blind, parallel group, multicenter study to compare efficacy, safety, pharmacokinetics, and immunogenicity of BP0% versus EU- approved lucentis® in patients with wet (Neovascular)age-related macular degeneration.	**CR213-20**	Dr. Puja Bang	Opthalmology	8/8/2022	12/9/2022
4	A randomized, assessor-blind, placebo controlled, multi-center, clinical endpoint bioequivalence study to compare efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44 mcg (Glenmark Pharmaceuticals Ltd) to Flovent HFA (Fluticasone propionate inhalation aerosol) 44 mcg (GSK group of companies) in treatment of patients with bronchial asthma.	**GLK-2101**	Dr. Amol Dube	General Medicine	7/2/2023	15/03/2023
5	A multi-center, open-label, randomized, phase III clinical trial to evaluate efficacy and safety of PF-114 versus imatinib at 600 or 800 mg daily in adult patients with Philadelphia chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) in the chronic phase (CP) resistant to Imatinib at daily doses of 400 or 600 mg.	**PF-114-02**	Dr. Vishvdeep Khushoo	Medical Hematology	9/2/2023	15/03/2023

6	A real-world prospective study to evaluate the geographical distribution of prevalence, sensitization rate, and utilization of prophylactic treatment of Rh-negative women in India.	**BSV-01-2021**	Dr. Shuchita Mundle	OBGY	25-8-2022	26-9-2022
7	A prospective, multicenter, open label, phase IV, interventional study to assess the safety and efficacy of capmatinib in Indian patients with mesenchymal-epithelial transition (MET) exon 14 skipping mutation positive advanced non small cell lung cancer (NSCLC)	**CINC280AIN01**	Dr. Vandana Singh Kushwaha	Radiotherapy	18-8-2022	4/10/2022
8	A non-randomized, open label, multi-country, cohort study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies (RSV MAT-001, RSV MAT-004, RSV MAT-010, RSV MAT-011, RSV MAT-009, RSV MAT-012 and RSV MAT-039) during any pregnancy conceived post vaccination/control.	**219510 (RSV MAT-015)**	Dr. Shuchita Mundle	OBGY	2/2/2023	15/03/2023
9	A randomized, double-blind, placebo-controlled multicenter study to evaluate the effect of inclisiran on preventing major adverse cardiovascular events in high-risk primary prevention patients (VICTORION-1 PREVENT).	**CKJX839D12302**	Dr. Sunita Kumbhalkar	General Medicine	6/3/2023	30/05/2023
10	A prospective, randomized, multicenrer, comparative, double-blind, parallel study to evaluate the efficacy, safety, pharmacokinetics and immunogenecity of biosimilar Pertuzumab (ENZENE) with reference Pertuzumab (Perjeta®, Genentech Inc.,) in previously untreated patients with HER2 positive metastatic breast cancer.	**ALK28/ENZ130-PER1**	Dr. Vandana Singh Kushwaha	Radiotherapy	1/5/2023	6/7/2023

11	Redefine 3: The cardiovascular safety of cagrilintide 2.4 mg s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg s.c.) once- weekly in participants with obesity and established cardiovascular disease.	**NN9838-4942**	Dr. Sagar Makode	Cardiology	2/5/2023	6/7/2023
12	A multi-centre, prospective , randomized, open label, active controlled, clinical trial evaluating the efficacy and safety of Paracetamol 1000mg/4ml intravenous bolus injection vs Paracetamol intravenous infusion 1% w/v (100ml) for the treatment of post-operative pain.	**CT/55/01/22**	Dr. Sucheta Bhowate Meshram	Anaesthesiology	3/5/2023	21/06/2023
13	An adaptive phase 2a/2b, randomized, double-blind, placebo-controlled study of LY3871801 in adult participants with moderately to severely active Rheumatoid Arthritis.	**J3P-MC-FTAF**	Dr. Rajashree Khot	General Medicine	12/7/2023	28/11/2023
14	A randomized, double-blind, multicenter, three-arm, placebo-controlled, parallel-design, bioequivalence study with clinical endpoints comparing Diclofenac Diethylamine Gel 1.16% of Encube Ethicals Private Limited, India with Voltaren Schmerzgel 11.6 mg/g (Diclofenac Diethylamine Gel 1.16%) of GlaxoSmithKline GmbH & Co. KG, 80258, Munich, Germany in patients with Osteoarthritis (OA) of the Knee.	**ENC-002-DIC-OST**	Dr. Samir Dwidmuthe	Orthopaedics	6/12/2023	23/01/2024
15	A phase 3, randomized, double-blind study to investigate the efficacy and safety of once-daily oral LY3502970 compared with placebo in adult participants with obesity or overweight with weight related comorbidities (ATTAIN-1).	**J2A-MC-GZGP**	Dr. Rajashree Khot	General Medicine	11/11/2023	5/12/2023
16	A randomized, double-blind, placebo-controlled, multicentric, phase III study to evaluate efficacy, safety and tolerability of ianalumab on top of standard of care therapy in patients with systemic lupus erythematosus (SIRIUS-SLE 2).	**CVAY736F12302**	Dr. Rajashree Khot	General Medicine	19/05/2023	21/02/2024

17	A randomized, multicenter, double-blind, 4-arm, parallel-group, active controlled, phase-3 study to compare efficacy, safety, and immunogenicity of ADL-018 150mg and 300mg with EU-approved Xolair® 150mg and 300mg administered through subcutaneous route every 4 weeks in patients with Chronic Idiopathic Urticaria (CIU) who remained symptomatic despite treatment with approved doses of H1 Antihistamines.	**KBS/OMA/01**	Dr. Sanjiv Choudhary	Dermatology	28/7/2023	14/9/2023
18	A phase IIb/III, randomized, double-blind, placebo-controlled, multi-centre study of CA-170 in combination with Chemotherapy in patients with Stage IV Non-Squamous Non-small Cell Lung Cancer (ASIAD-3).	**CA-170-302**	Dr. Vandana Singh Kushwaha	Radiotherapy	4/8/2023	26/9/2023
19	A multicenter, prospective, randomized, double-blind, sham controlled clinical study aimed to determine efficacy of CardiaCareTM RR2 (wearable home-care neuromodulation system) in reducing AF burden and symptoms in Paroxysmal AF patients	**DRL-CAR-008**	Dr. Gunjan Ghodeshwar	Cardiology	7/9/2023	17/10/2023
20	A phase 1, open label, dose escalation, dose expansion, multicenter study evaluating the safety, pharmacokinetics and pharmacodynamics of oral AUR108 in patients with Relapsed Advanced Lymphoma (ASHA-1).	**AUR108-101**	Dr. Vishvdeep Khushoo	Medical Hematology	11/10/2023	6/11/2023
21	A non-randomized, non-interventional, prospective, multicenter, post marketing surveillance study to assess the antibacterial effectiveness and safety of 0.5% Moxifloxacin Hydrochloride Ophthalmic Solution in Perioperative (Preoperative and Postoperative) sterilization in patients undergoing Ophthalmic Surgery.	**CUKG489C1IN01**	Dr. Puja Bang	Ophthalmology	4/8/2023	6/11/2023

22	A Phase 3, randomized, double-blind study to investigate the efficacy and safety of once-daily oral LY3502970 compared with placebo in adult participants with obesity or overweight and type 2 Diabetes (ATTAIN-2).	**J2A-MC-GZGQ**	Dr. Rajashree Khot	General Medicine	11/10/2023	29/11/2023
23	A Phase 3, randomized, double-blind study to investigate the efficacy and safety of once daily Oral LY3502970 compared with Placebo in adult participants with Type 2 Daibetes (T2DM) and inadequate Glycemic control with Diet and Exercise Alone (ACHIEVE-1).	**J2A-MC-GZGT**	Dr. Udit Narang	General Medicine	11/10/2023	29/11/2023
24	A phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Pegozafermin in subjects with severe Hypertriglyceridemia (SHTG).	**BIO89-100-231**	Dr. Sunita Kumbhalkar	General Medicine	2/9/2023	28/12/2023
25	A Phase I/II, observer-blind, randomized, placebo-controlled study to assess the safety, immunogenicity, and efficacy of GSK S. aureus candidate vaccine when administered to healthy adults (dose-escalation) and to adults 18 to 64 years of age with a recent S. aureus skin and soft tissue infection (SSTI).	**208833 (STAPH AUREUS BIOCONJ-001 STG)**	Dr.Siddharth Dubhashi	Surgery	27-6-2022	16-8-2022

Closed Trials							
Sr. No	**Name of Project**	**Protocol No**	**Principal Investigator**	**Department**	**Date of submission**	**Date of final approval**	**Close out Date**
2021 Closed Trials							
1	A randomized open-label study to evaluate the efficacy and safety of Favipiravir and Umifenovir as compared to Favipiravir alone in moderate hospitalized adult Indian COVID-19 patients.	**GPL/CT/2020/004/III**	Dr. Rajashree Khot	General Medicine	6/7/2020	9/7/2020	15/01/2021
2	A randomized, open- label 2-treatment group clinical trial evaluating the efficacy and safety of 2-Deoxy-D-Glucose as an adjunctive therapy to standard of care, in comparison to standard of care alone, in the Acute Treatment of moderate to severe COVID-19 patients.	**CVD-02-CD-002**	Dr. Sunita Kumbhalkar	General Medicine	6/1/2021	11/2/2021	27/07/2021
3	A randomized, double-blind, two arm, placebo controlled clinical trial to evaluate the efficacy and safety of Mycobacterium w in preventing COVID-19 in subjects at risk of getting infected with COVID-19.	**CRSC20005**	Dr. P. P. Joshi	General Medicine	8/7/2020	13/01/2021	27/10/2021
4	A randomized, double-blind, two arm, controlled clinical trial to compare the efficacy and safety of Mycobacterium w (Mw) administered along with standard of care versus placebo administered along with standard of care, in adult, COVID-19 positive patients hospitalized but not critically ill.	**CRSC20006**	Dr. P. P. Joshi	General Medicine	8/7/2020	13/01/2021	27/10/2021
2022 Closed Trials							
5	A randomized, double- blind placebo-controlled, multicenter study of ensovibep (MPO421) in ambulatory adult patients with symptomatic COVID-19	**MP0420-CP302**	Dr. P.P. Joshi	General Medicine	15/05/2021	9/8/2021	30/09/2022

6	A randomized, double-blind, parallel arm, multicenter study to evaluate the efficacy and safety of nitric oxide nasal spray combined with standard supportive care in adult non-hospitalized patients with COVID- 19.	**GPL/CT/2021/ 004/III**	Dr. Sunita Kumbhalkar	General Medicine	25/8/21	11/9/2021	3/6/2022
7	A Phase 3, Multicentre, randomized, double-blind, double-dummy,parallel-group, active controlled study to compare the efficacy and safety of a fixed dose combination of Metformin hydrochloride 1000mg ER, Sitagliptin phosphate 100mg and Dapagliflozin Propanediol 10 mg tablets versus Janumet XR CP (Combipa k of Metformin hydrochloride 1000 mg SR and Sitagliptin Phosphate 100mg) in patients with Type 2 Diabetes Mellitus (T2 DM)"	**ALK23-MSD 1**	Dr. Sunita Kumbhalkar	General Medicine	18/11/20 21	20/1/2022	14/11/2022
8	A Prospective, Multi-centre ,Phase -IV study for post marketing safety evaluation of recombinant Anti- Rho(D) immunoglobulin in the preservation of Maternal Rh-isoimmunization	**NV-05-1226-2021/BSV-ANTID -21-03**	Dr. Shuchitra Mundle	OBJY	#######	24/1/2022	23/11/2022
2023 Closed Trials							
9	A randomized, double- blind placebo-controlled, phase 2 study of LY3471851(NKTR-358) in adults with systemic lupus erythematosus.	**J1P-MC-KFAJ/SLE**	Dr. Rajashree Khot	General Medicine	#######	25/8/21	19/06/2023

10	A Phase III , Prospective , Randomized, open lable , Active controlled, Parallel group , Multicentre Clinical Study to Evaluate the Efficacy, Safety and Tolerability of a fixed Dose Combination of Vildagliptin and Dapagliflozin Tablet 50mg/5mg of USV Private Ltd, India as compared to Concomitant Administration of Reference Product, Galvus 50mg tablet (Vildagliptin) of Novartis Pharmaceuticals UK Ltd , along with Forxiga 5mg tablet(Dapagliflozin) of AstraZeneca Pharmaceuticals , USA in patients with type 2 Diabetes Mellitus Inadequately Controlled on earlier metformin containing dual therapy .	**SB-IND-CT-003**	Dr. Amol Dube	General Medicine	4/2/2022	10/3/2022	4/8/2023
11	A Comparative, Double blind randomized multicentre, phase study to compare the safety and efficacy of ENZ105 of Enzene Bioscience Ltd with Innovator Ranibizumzb in subject with Neovascular (Wet) age related macular degeneration (AMD).	**ALK21/ENZ105-RANI1**	Dr. Rajesh Pattebahadur	Opthalmology	4/1/2022	2/2/2022	6/10/2023
12	A randomized ,double- blind, placebo-controlled, multicentre, phase III clinical trial to evaluate the efficacy and safety of Prandial Technosphere® insulin inhalation powder versus placebo inhalation powder in patients with type 2 diabetes mellitus inadequately controlled with oral anti-diabetic drugs over a 24-week treatment period.	**CP/01/19**	Dr. Bharat Singh Rathod	General Medicine	23-5-2022	21-6-2022	6/10/2023

13	Multi-center, randomized, parallel-group, active-controlled, open label clinical trial to evaluate efficacy and safety of fixed dose combination syrup of Bilastine 3.3mg, Dextromethorphan 10 mg and Phenylephrine 5 mg per 5 ml in patients with cough associated with common cold orallergy.	**GPL/CT/2022/ 001/III**	Dr. Ganesh Dakhale	Pharmacology	5/4/2023	2/8/2023	20/12/2023
14	A phase III, randomized , double-blind, placebo-controlled multi-country study of demonstrate efficacy of a single dose of RSV MAT (RSVpreF3) vaccine (GSK3888550A), administered IM to healthy pregnant women 18 to 49 years of age, for prevention of RSV LRTI in their infants up to 6 months of age.	**(212171) RSVMAT-009**	Dr. Shuchita Mundle	OBJY	9-Jan-21	27/7/21	close out report not submitted

Terminated Trials							
Sr. No	**Name of Project**	**Protocol No**	**Principal Investigator**	**Department**	**Date of submission**	**Date of final approval**	**Remarks**
1	A multi-centre,prospective,open label,parallel,randomized,clinical trial to assess the efficacy and safety of molnupiravir 800mg capsules and standard of case (SoC) compared to standard of case (SoC) only in mild patients with polymerase chain reaction (PCR) confirmed COVID-19.	**NV05-1154-2021**	Dr. Rajashree Khot	General Medicine	7/6/2021	7/7/2021	Terminated
2	An interventional efficacy and safety, phase 2/3, double-blind, 2-arm study to investigate orally administered pf 07321332/ritonavir compared with placebo in non-hospitalized symptomatic adult participants with covid-19 who are at increased risk of progressing to severe illness.	**C4671005**	Dr. Sunita Kumbhalkar	General Medicine	24/8/21	8/9/2021	Terminated
3	A two-year, phase III randomized, double-blind, parallel-group, placebo-controlled trial to evaluate the safety, efficacy and tolerability of 300 mg s.c. secukinumab versus placebo, in combination with SoC therapy, in patients with active lupus nephritis.	**CAIN457Q12301**	Dr. Anand Chellappan	Nephrology	10/3/2023	10/4/2023	Terminated
4	A randomized double-blind placebo-controlled parallel group study assessing the efficacy and safety of dupilumab in patients with Allergic Fungal Rhinosinusitis (AFRS).	**EFC16724**	Dr. Sandeep Dabhekar	ENT	2/1/2023	15/03/2023	Terminated
5	A randomized, double-blind, placebo-controlled, multicenter trial, assessing the impact of inclisiran on major adverse cardiovascular events in participants with established cardiovascular disease (VICTORION-2 PREVENT).	**CKJX839B12302**	Dr. Sagar Makode	Cardiology	6/3/2023	10/4/2023	Terminated

6	A phase III, randomized , double-blind, placebo-controlled study to evaluate the safety ,reactogenicity and immune response of a single intramuscular dose of RSV Maternal vacine vaccine , in high risk pregnant women 15 to 49 years and infant born to vaccinated mothers."	**RSV MAT 012 (214725)**	Dr. Shuchitra Mundle	OBJY	17/11/2021	24/1/2022	Terminated
7	A multicenter, open label, balanced, randomized, two-treatment, two-sequence, single dose, crossover bioequivalence study between two formulations of Doxorubicin Hydrochloride Liposome Injection 20 mg/10ml (2 mg/ml) [Doxopeg® manufactured by FAPASA- Farmaceutica Paraguay S.A. and registered by Zodiac Produtos Farmaceuticos S.A. (test formulation) and Caelyx® manufactured by Janssen Pharmaceutica NV (reference formulation)] in Patients with Advanced Ovarian Cancer or Metastatic Breast Cancer.	**0063-22**	Dr. Vandana Singh Kushwaha	Radiotherapy			Terminated
8	A randomized, double-blind, multicenter, parallel group study to compare efficacy, safety, immunogenecity, pharmacokinetics and pharmacodynamics of BP08 (Tocilizumab) and RoActemta® in patients with moderate to severe Rheumatoid Arthritis (RA) with adequate response to Methotrexate.	**ICS/CUR/2022-006**	Dr. Samir Dwidmuthe	Orthopaedics	27/2/2023	28/3/2023	Terminated
9	Pediatric options for Migraine Relief: A randomized, double-blind, placebo-controlled study of Lasmiditan for acute treatment of Migraine: PIONEER-PEDS1 study.	**H8H-MC-LAHV**	Dr. Meenakshi Girish	Pediatrics	29/03/2023	9/5/2023	Terminated
10	A Phase 3, 12-Month, Open-Label study of Lasmiditan in Pediatric Patients with Migraine- PIONEER-PEDS2	**H8H-MC-LAHW**	Dr. Meenakshi Girish	Pediatrics	28/03/2023	18/05/2023	Terminated