

Clinical Trials at Institute of Medical Science and SUM Hospital

(Siksha 'O' Anusandhan Deemed to be University)

SINO	Principal Investigator Name	Department	Title of study proposal	Year	Status	National / International
1.	Dr. Chandan Das	Internal Medicine	A multicentric, open label, randomized, comparative, parallel group, active control phase iii clinical trial to evaluate safety and efficacy of arbekacin sulfate injection versus vancomycin injection in patients diagnosed with mrsa infection	2016	Closed	National
2.	Dr. Jyoti Ranjan Parida	Immunology	International comparative multicenter double blind randomized clinical study of efficacy and safety of bcd-055 (CJSC Biocad, Russia) and remicade in combination with methotrexate in patients with active rheumatoid arthritis.	2016	Closed	International
3.	Dr. Soumya Surath Panda	Medical Oncology	A Prospective, Multicenter, Randomized, Double-blind, Parallel group Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when given in combination with Paclitaxel in	2017	Closed	National

			Patients Diagnosed with HER2 Positive Metastatic Breast Cancer.			
4.	Dr.Manisha Sahu	Gynecology	A Prospective, Multicentric, Phase IV Clinical Study evaluating safety and efficacy of Leuprorelin 3.5mg injection plus Enzomac Tablet (Trypsin 96 mg + Bromelain 180 mg +Rutoside Trihydrate 200 mg) versus Leuprorelin 3.5mg injection in the treatment of patients diagnosis with Endometriosis	2017	Closed	National
5.	Dr.Manisha Sahu	Gynecology	An Open label, Prospective, Comparative, Randomized, Phase IV Clinical Study evaluating safety and efficacy of Menojoy capsule Versus Soya isoflavones capsule Versus Primarine 0.3 mg Tablets in patients with postmenopausal	2017	Closed	National
6.	Dr. Jagannath Sahoo	Orthopedic	A Randomized, Double blind, Three-arm, Parallel, Placebo-controlled, Clinical Study to Evaluate the Bioequivalence using Clinical Endpoint of Diclofenac Sodium Gel, 1% (Mylan Inc.) to Voltaren® Gel (Diclofenac Sodium Topical Gel) 1% (Novartis Consumer Health, Inc.) in Patients with Osteoarthritis (OA) of the Knee	2017	Closed	International

7.	Dr. Sourav Kumar Mishra/Dr Soumya surath Panda	Medical Oncology	A Phase-I/II, Open Label, Dose-Finding Study of DO-013 Alone and In Combination with Gemcitabine among Patients with Advanced Carcinoma of Pancreas.	2017	Closed	National
8.	Dr. Abhay Kumar Sahoo	Endocrinology	A randomised, multi-centric, double blinded, comparative study to evaluate efficacy and safety of fixed dose combination of Pregabalin and Amitriptyline in comparison to monotherapy of Pregabalin and Amitriptyline in patients having Neuropathic Pain in India	2017	Ongoing	National
9.	Dr. Bikash ranjan Kar	Skin & VD	A multi-centric open label, single arm study to evaluate efficacy and safety of High Dose of Desloratidine (10 mg) in the treatment of Chronic Idiopathic Urticaria in India	2017	Closed	National
10.	Dr. Bikash ranjan Kar	Skin & VD	A Multicenter Comparative Randomized Double-blind Study of the Efficacy and Safety of BCD-057 (INN: Adalimumab, CJSC BIOCAD, Russia) and Humira® (INN: Adalimumab, Vetter Pharma) in Patients with Moderate to Severe Plaque Psoriasis	2018	Closed	International
11.	Dr. Ayaskanta Singh	Gastroenterology	A randomized, multi-centric, active controlled, parallel, open-label, comparative study to	2018	Closed	National

			evaluate efficacy and safety of pantoprazole dual-release Gastro-resistant tablet in comparison to Pantoprazole tablet in patients having refractory moderate to severe GERD (Gastro Esophageal Reflux Disease) in India			
12.	Dr. Sourav Kumar Mishra/ Dr Priyanka Samal	Medical Oncology/Haematology	A phase 3 randomized, controlled, open-label study of selinexor, bortezomib, and dexamethasone (SVD) versus bortezomib and dexamethasone (Vd) in patients with relapsed or refractory multiple myeloma (RRMM)	2018	Closed	International
13.	Dr. Sourav Kumar Mishra/ Dr Priyanka Samal	Medical Oncology/Haematology	A phase 2b open-label study of selinexor (KPT-330) in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL)	2018	Closed	International
14.	Dr. Debadarshi Rath	Urology	A randomized, multi-centric, double blind, comparative study to evaluate efficacy and safety of fixed dose combination of Alfuzosin hydrochloride extended release and Tadalafil in comparison to Alfuzosin hydrochloride extended release in patients having Benign Prostatic Hyperplasia (BPH) and Lower urinary tract symptoms (LUTS) in India	2018	Ongoing	National
15.	Dr. Sourav Kumar Mishra /Priya P Nayak	Medical Oncology	A single arm, multicentric, open label, efficacy and safety study of		Ongoing	National

			Docetaxel Lipid Suspension for Injection of Intas Pharmaceuticals Limited, India in patients with Metastatic Castration Resistant prostate cancer	2018		
16.	Dr. Debadarshi Rath	Urology	A Phase-III, Multicentric, Randomized, Double Blind, Placebo-Controlled, Comparative Clinical Study to Evaluate the Efficacy and Safety of Tadalafil 10 mg plus Dapoxetine 30 mg Tablets, Tadalafil 20 mg plus Dapoxetine 30 mg Tablets and Tadalafil 20 mg plus Dapoxetine 60 mg Tablets in the treatment of subjects with co-existing Erectile Dysfunction and Premature Ejaculation.	2018	Ongoing	National
17.	Dr. Swati Samant	Ophthalmology	A Comparative, Randomized, Two Arm, Double Blind, Parallel group, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v Vs Timolol Maleate Eye Drops 0.5% w/v in Subjects Suffering from Ocular Hypertension / Glaucoma.	2018	Ongoing	National
18.	Dr. Abhay Kumar Sahoo	Endocrinology	Fixed dose combination (Fdc) of repaglinide (0.5gm/1mg) + Voglibose (0.2mg/0.3mg) Phase 3 clinical Trial	2018	Closed	National

19.	Dr. Abhay Kumar Sahoo	Endocrinology	A 12 month prospective observational study assessing the real world clinical effectiveness, safety and health economic benefits of Toujeo Initiation after oral antidiabetic drug failure in Insulin-Naïve Patient With Type-2 Diabetes.	2018	Closed	International
20.	Dr. Swati Samant	Ophthalmology	A Phase III, Multicenter, Comparative, Randomized, Double blind, Two arm, Parallel group Clinical Study to evaluate Efficacy and Safety of Fixed dose combination of Alcaftadine 0.25% w/v and Ketorolac Tromethamine 0.4% w/v Eye Drops compared with Alcaftadine Ophthalmic Solution 0.25% w/v for the treatment of Subjects with Ocular Itching associated with Allergic Conjunctivitis.	2018	Ongoing	National
21.	Dr. Sourav Kumar Mishra/Dr. Priyanka Samal	Medical Oncology/ Haematology	A Randomized, Assesor-blind, multicentre, Parallel group, two arms, clinical study to assess the efficacy, pharmacokinetics, pharmacodynamics, Immunogenecity and safety study of Rituximab (test product, Zydus) with Rituximab (Reference Product, Roche/Genetech) in patients with	2018	Ongoing	National

			Diffuse Large B cell Lymphoma (DLBCL).			
22.	Dr. Chandan Das	Internal Medicine	A multi-centric, open label study to evaluate safety and efficacy of fixed dose combination of Olmesartan Medoxomil, Chlorthalidone and Cilnidipine Tablet in the treatment of essential hypertension in India.	2019	Ongoing	National
23.	Dr. Abhay Kumar Sahoo	Endocrinology	A Phase III Randomized, Double Blind, Parallel Group, Placebo Controlled, Multicentre, Multinational Study to Evaluate Efficacy and Safety of TRC150094 as an Add On to Standard of Care in Improving Cardiovascular Risk in Subjects with Diabetes, Dyslipidemia and Hypertension	2019	Closed	International
24.	Dr.E Venkata Rao	Community Medicine	Immune lot-to-lot consistency and non-inferiority of SHAN6™ vaccine in comparison to SHAN 5® + SHANIPV™ when administered as three doses at 6-8, 10-12 and 14-16 weeks of age in healthy Indian infants concomitantly with oral rotavirus vaccine	2019	Closed	National
25.	Dr. Abhay Kumar Sahoo	Endocrinology	Pemafibrate to Reduce cardiovascular outcomes by reducing triglycerides IN patients with diabetes (PROMINENT).		Closed	International

26.	Dr. Abhay Kumar Sahoo	Endocrinology	A multicentric, open label, randomized, case-control study on Safety and Efficacy of Sofinox Hydrogel (Fusidic acid gel) in Diabetic wound healing.	2019	Ongoing	National
27.	Dr. Jyoti Ranjan Parida	Immunology	A Randomized, Double Blind, Double- Dummy, Multi Center, Parallel, Phase III Study to Evaluate the Efficacy and Safety of Tacrolimus Lipid Tablets (Manufactured by Intas Pharmaceuticals Ltd) Compared to Prograf (Tacrolimus Immediate Release Capsules-Astellas Pharma Canada, Inc) in Adult Patients with Active Rheumatoid Arthritis Who have resistance OR Intolerance to DMARDs.	2019	Ongoing	National
28.	Dr Priyanka Samal	Haematology	A Prospective, Multi Centre, Observational, Data Collection Registry Study to Monitor The Routine Clinical Use Of Mabtas (Rituximab 100 Mg / 500 Mg Concentrate For Solution For Infusion, Manufactured By Intas Pharmaceuticals Ltd) In Indian Patients.	2019	Ongoing	National
29.	Dr. Soumya Surath Panda	Medical Oncology	A single arm, multicentric, open-label, efficacy, and safety study of Doceaqualip (Docetaxel Lipid Suspension for Injection of Intas Pharmaceuticals Limited, India)	2019	Ongoing	National

			based regimens in metastatic gastric adenocarcinoma patients.			
30.	Dr. Tapas Ranjan Behera	Nephrology	A Phase III, Multi-center, Multi country, Open label, randomized, active controlled clinical trial to evaluate the efficacy and safety of Desidustat versus Darbopoetin for the treatment of Anemia in patients with chronic kidney disease (CKD) who are not on Dialysis.	2019	Ongoing	National
31.	Dr.Rakhi Ludam	Pulmonary Medicine	An Open label, Multi-centric, Prospective, Clinical Trial to Evaluate safety and efficacy of Fixed Dose combination of Montelukast 10Mg plus Acebrophylline SR 200Mg Tablets in Patients having Bronchial Asthma in India	2019	Ongoing	National
32.	Dr.E Venkata Rao	Community Medicine	A Phase IV Study to Evaluate the immunogenicity and Safety of Purified Vi capsular polysaccharide of Salmonella typhi, Ty2 skain) tetanus toxoid conjugate vaccine; Typbar-TCV@ in Adults	2019	Ongoing	National
33.	Dr Priyanka Samal	Haematology	A Phase III, Multicenter, Randomized, Double-blind study to assess Efficacy and Safety of Two Doses of Crizanlizumab versus Placebo, With or Without Hydroxyurea/ hydroxycarbamide	2019	Ongoing	International

			Therapy, in Adolescent and Adult Sickle Cell Diseases Patients with Vaso-Occlusive Crises(STAND)	2019		
34.	Dr. Tapas Ranjan Behera	Nephrology	A Phase III, Multi-center, Open label, randomized, active-controlled study to evaluate the efficacy and safety of Desidustat tablet versus Epoetin alfa injection for the treatment of Anemia in patients with chronic kidney disease (CKD) on Dialysis (DREAM-D)	2019	Ongoing	National
35.	Dr.E Venkata Rao	Community Medicine	A Phase IV Randomized, Controlled Study to Evaluate the Immunogenicity and Safety of Inactivated Japanese Encephalitis Vaccine in healthy Volunteers.	2020	Ongoing	National
36.	Dr.E Venkata Rao	Community Medicine	A prospective, randomized, two-arm, parallel, single-blind, active-controlled, multicentre, non-inferiority clinical study to evaluate the immunogenicity and safety of Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s. Cadila Healthcare Limited compared to Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s. Biological E Limited in healthy subjects.	2020	Ongoing	National
37.	Dr. Soumya Surath Panda	Medical Oncology	A Multicentre, Double-Blind, Randomized, Parallel-Group,		Ongoing	National

			Active-Controlled, Two Part, Phase III, Global Study to Evaluate the Pharmacokinetics, Efficacy and Safety of BP02 (Trastuzumab) in Comparison with Herceptin-EU in Patients with HER2-Positive Early Breast Cancer (EBC) and HER2 Positive Metastatic Breast Cancer (MBC).	2020		
38.	Dr Priyanka Samal	Haematology	An Open label, Multi-Centre, Randomized, Two-treatment, Multi dose, Parallel Comparative Bioavailability Study of Bortezomib Injection 3.5 mg/0.2 ml and VELCADE 3.5 mg powder for solution for injection at a dose of 1.3 mg/m ² in Multiple Myeloma patients.	2020	Ongoing	National
39.	Dr Priyanka Samal	Haematology	Phase IV Multi-center, Prospective, Interventional, Post-marketing Study in Hemophilia B Patients in India receiving RIXUBIS as On- demand or Prophylaxis Under Standard Clinical Practice.	2020	Ongoing	International
40.	Dr. Sandeep Kumar Panigrahi	Community Medicine	A Phase 3, Randomized, Observer-blind, Controlled, Multi-Center Study to Evaluate the Lot to Lot Consistency of SIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) and to Compare its Safety and	2020	Ongoing	National

			Immunogenicity with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Individuals 18-85 Years of Age.			
41.	Dr.E Venkata Rao	Community Medicine	An adaptive seamless Phase 1, followed by Phase 2 Randomized, Double-blind, Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers.	2020	Ongoing	National
42.	Dr. Suryaprakash Sibanarayan Choudhury	Neurology	A Phase III Randomized, Multi-centric, Double-blind, Doubledummy, Parallel-group Non-inferiority Study to Evaluate Efficacy and Safety of Fixed Dose Combination of Pregabalin and Duloxetine Capsule compared to Monotherapy of Pregabalin Capsule in Patients with Moderate to Severe Neuropathic Pain		Closed	National
43.	Dr Priya N Nayak	Medical Oncology	A randomized, open label, multi-center, two-treatment, two-period, two-sequence,two-way cross-over, multiple dose, steady-state Bioequivalence (BE) study ofPazopanib HCl 200mg Tablets at a dose of 800 mg (4 * 200 mg tablets) of TorrentPharmaceuticals Ltd., India with	2020	Ongoing	National

			VOTRIENT®(Pazopanib HCl 200mg) Tablets at adose of 800 mg (4 * 200 mg tablets) of Novartis Pharmaceuticals Corporation, USA in subjects with Advanced renal cell carcinoma under fasting condition.			
44.	Dr.E Venkata Rao	Community Medicine	An Event-Driven,Phase3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity,and Lot-to-Lot consistency of BBV152, a Whole- virion Inactivated SARS-CoV-2 Vaccine in Adults≥18Years of Age.	2020	Ongoing	National
45.	Dr. Ayaskanta Singh	Gastroenterology	A Multicenter, Randomized, Double-Blind. Parallel-Group, Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severely Active Crohn's Diseases.	2020	Closed	International
46.	Dr. Jyoti Ranjan Parida	Immunology	A prospective, multicenter, randomized, double blind, Phase III study to compare the efficacy and safety of Biosimilar Adalimumab injection of Enzene Biosciences Ltd. with HUMIRA® (adalimumab) injection in subjects with active Ankylosing spondylitis (AS).	2020	Ongoing	National

47.	Dr. Manisha Sahu	Gynecology	A randomized, double blind, parallel group, placebo-controlled, three arm, multicenter study to evaluate the Efficacy and Safety of Estradiol Vaginal Inserts USP 10 mcg in healthy postmenopausal women with symptoms of vulvar and vaginal atrophy [Group I (Test): Estradiol Vaginal Inserts USP 10 mcg of Aurobindo Pharma Ltd, India; Group II (Reference): Vagifem® (estradiol vaginal Inserts) 10 mcg of Novo Nordisk Inc., USA and Group III: Placebo].	2020	Ongoing	National
48.	Dr.Rakhi Ludam	Pulmonary Medicine	A phase 3, observer-blind, randomized, controlled study to determine the safety And immunogenicity of COVOVAX [sars-cov-2 recombinant spike protein Nanoparticle Vaccine (sars-cov-2 rs) with Matrix-M1™ adjuvant] in indian adults	2021	Ongoing	National
49.	Dr.E Venkata Rao	Community Medicine	A monolithic phase II –III double unknown, multicenter, and unresectable, clinical trial to evaluate immunogenicity and safety of an inactivated chikungunya virus vaccine BBV 87 in healthy participants aged 12 to 65 years.	2021	Ongoing	National

50.	Dr. Suryaprakash Sibanarayan Choudhury	Neurology	A Multicenter, open-label, non-comparative clinical trial to evaluate safety and tolerability of lacosamide injection in patients with partial onset seizures.	2021	Ongoing	National
51.	Dr.Rakhi Ludam	Pulmonary Medicine	A prospective, randomized, parallel, multicentric, Phase III clinical trial to assess the efficacy and safety of molnupiravir 800 mg capsules and standard of care (SOC) compared to standard of care (SOC) only in patients with polymerase chain reaction (RT-PCR) confirmed mild COVID-19 infection.	2021	Ongoing	National
52.	Dr.E Venkata Rao	Community Medicine	A Prospective, multicentre, Phase II Seamlessly Followed by Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to COVID-19-Negative Adult Subjects.	2021	Ongoing	National
53.	Dr. Chandan Das	Internal Medicine	A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against	2021	Ongoing	International

			COVID-19 in adults 18 years of age and older			
54.	Dr Dillip Kumar Dash	Pediatric	A phase 3, Observer blind, Randomized, Active-controlled trial evaluating the immunologic non-inferiority, safety and tolerability of a 15-valent pneumococcal conjugate vaccine in healthy infants given with routine pediatric vaccinations.	2021	Ongoing	National
55.	Dr Priyanka Samal	Haematology	Phase 3, prospective, multi-center, open label study to investigate safety, immunogenicity, and hemostatic efficacy of PEGylated factor VIII (BAX 855) in previously untreated patients (PUPs) < 6years with severe haemophilia A (FVIII < 1%).	2021	Ongoing	National
56.	Dr Lipilekha Pattnaik	Community Medicine	A Phase II/III Multicentric Randomized Single Blind Study to compare the Immunogenicity and Safety of Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents I.P of HBI with BE Td® Vaccine in two age groups of Healthy Subjects.	2021	Ongoing	National
57.	Dr Lolly Pattnaik	Ophthalmology	A Phase IV, Multicentre, Open Label Clinical Study to Evaluate The Safety and Efficacy of Intracameral Phenocaine Plus Injection for Anaesthesia and Mydriasis in Cataract Surgery	2021	Ongoing	National

58.	Dr.E Venkata Rao	Community Medicine	A Phase 2 randomized, multi-centric, Clinical Trial of Heterologus Prime-Boost Combination of SARS-CoV-2 Vaccines to evaluate the immunogenicity and safety of BBV152 (COVAXIN®) with BBV154 (Adenoviral Intranasal COVID-19 vaccine) in Healthy Volunteers.	2021	Ongoing	National
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