

CONSULTANCY SERVICES - Apr 2020 - Dec 2021

CLINICAL TRIAL DIVISION

S.No	Trial A/C No	Name of the Project, Clinical Trial, Endowment, Chairs	Name of the Principal Investigator/ Co Investigator	Name of the Funding agency	Type (Government /Non-Government etc)	Department of Principal Investigator/ Co Investigator	Year of Award	Funds provided (INR in Lakhs)	Total Received Amount	Received Amount in 2020 - 2021	Received Amount in 2021 - 2022 (Apr to Dec)	Duration of the project
1	10083	Protocol Number: NN9536-4373 Effect and safety of semaglutide 2.4 mg once-weekly in subjects with overweight or obesity.	Dr. Shriram Mahadevan	Novo Nordisk India Pvt. Ltd.	Non Govt.	Endocrinology	2018-2020	46.00000	738482.00	70935.00	238464.00	24 months
2	28152	Protocol No: VB066P/2017-CT4 "A randomised, controlled, comparative, open-label, multicenter study on the safety and efficacy of PEG-Neutrogen and Neulastim in prevention of chemotherapy-induced neutropenia."	Dr.Lakshmi Narasimhan	Virchow Biotech Pvt. Ltd	Non Govt.	Medical Oncology	2019-2020	6.87320	236439.00	0.00		1 year
3	28092	Protocol No. PCV-10-003 "A Phase 3, Randomized, Double-Blind Study to Evaluate the Safety, Tolerability, Immunogenicity and Non-Interference with Concomitant Vaccinations of Serum Institute of India's 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants."	Dr. Padmasani Venkat Ramanan	DiagnoSearch Life Sciences Pvt. Ltd.	Non Govt.	Pediatrics	2019-2020	13.65000	1781956.00	0.00	330317.00	1 year
4	28172	Protocol No: SII-Tdap/IN-02, Protocol Title: A phase II/III, multicenter, randomized, open label, active controlled, clinical study to assess the immunogenicity and safety of tetanus toxoid, diphtheria toxoid, and acellular pertussis (Tdap) vaccine manufactured by Serum institute of India pvt. Ltd. (SIIPL) in comparison with Boostrix® vaccine of GSK in healthy adults, adolescents and children in India.	Dr. Saji James	Serum Institute of India Ltd.	Non Govt.	Pediatrics	2019-2020	23.81250	2484150.00	896325.00	378247.00	1 year

5	28232	0851-17; Version No. 1.1; Date: 15 May 2018 "A randomized, open label, multicenter, parallel group, multiple dose, steady state study to compare the bioavailability and characterize the pharmacokinetic profile of the sponsor's test formulation [Paliperidone Palmitate extended release injectable suspension, (156 mg/ml)] relative to that of the reference formulation [Invega® Sustenna® (Paliperidone Palmitate extended release injectable suspension, 156 mg/ml), Janssen Pharmaceuticals, Inc., Titusville, New Jersey] and establish bioequivalence in patients of Schizophrenia already receiving a stable regimen of paliperidone palmitate extended release injectable suspension.	Dr. R. Sathianathan	Lambda Therapeutic Research Ltd.	Non Govt.	Psychiatry	2019-2020	29.62500	5318955.00	0.00	5318955.00	8 months
6	28176	Protocol No: TOL3033A A Pivotal, Single-Dose, Pharmacokinetic Bioequivalence Trial Comparing Generic to Reference Medicinal Product of Paliperidone Palmitate Prolonged-Release Injectable Suspension (100 mg) in Patients with Schizophrenia.	Dr. R. Sathianathan	CBCC Global Research LLP	Non Govt.	Psychiatry	2019-2020	27.66375	1788474.00	436716.00	0.00	1 year
7	28198	Protocol No: TOL3033B Study Title: A Pivotal Multiple-Dose, Pharmacokinetic Bioequivalence Trial Comparing Generic to Reference Medicinal Product of Paliperidone Palmitate Prolonged-Release Injectable Suspension (100 mg) in Patients with Schizophrenia.	Dr. R. Sathianathan	CBCC Global Research LLP	Non Govt.	Psychiatry	2019-2020	56.13850	3078527.00	2580981.00	0.00	1 year

8	28162	Study Title: Protocol No: PCV-10-004 ” A Phase 3, Randomized, Double-blind study to evaluate the immunogenicity, Safety and Tolerability of Serum Institute of India’s 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants.	Dr. Padmasani Venkat Ramanan	DiagnoSearch Life Sciences Pvt. Ltd.	Non Govt.	Pediatrics	2019-2020	23.1022	2689720.00	847008.50	1596809.00	1 year
9	28195	Study Title: Protocol No: SII-wHEXA/IN-02 “An Open label, Randomized, Active-controlled, Multi-centric phase II/III Study in Indian Toddlers and Infants to Assess the Immunogenicity and Safety of SIIPL HEXASILT™ (DTwP-HepB-IPV-Hib) Vaccine in Comparison to SIIPL Pentavac (DTwP-HepB-Hib) + Poliovac (IPV) vaccines Administered as Separate Injections”.	Dr. Padmasani Venkat Ramanan	DiagnoSearch Life Sciences Pvt. Ltd.	Non Govt.	Pediatrics	2019-2020	62.1250	345712.00	104062.00	126450.00	1 year
10	28212	Controlled, Multi-Center Study to Evaluate the Lot to Lot Consistency of SIIPL Meningococcal ACYW X Conjugate Vaccine (NmCV-5) and to Compare its Safety and Immunogenicity with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Individuals 18-85 Years of Age.	Dr.K.Vengadkrishnan	DiagnoSearch Life Sciences Pvt. Ltd.	Non Govt.	General Medicine	2020-2021	47.00688	2465718.00	2465718.00		1 year
11	28213	Study Title: Protocol No: SII-rBCG/COVID-19/IN-01 A Multicenter, Phase Iii, Double-Blind, Randomized, Placebo- Controlled Study To Evaluate The Efficacy Of Recombinant Bcg Vpm1002 I Reducing Infection Incidence And Disease Severity Of Sars-Cov- 2/Covid-19 Among High-Risk Subjects.	Dr. T. V. Ramakrishnan	DiagnoSearch Life Sciences Pvt. Ltd.	Non Govt.	General Medicine	2020-2021	28.62000	3222441.00	2493916.00	728525.00	8 months

12	28244	Study Title: Protocol No: SAN-hMG-01 "A Prospective, Randomized, Open-Label, Controlled, Clinical Study to Compare the Clinical Efficacy and Tolerability of Two Highly Purified Human Menopausal Gonadotropin Preparations administered Subcutaneously in Women Undergoing In Vitro Fertilization."	Dr. N. Sanjeeva Reddy	Sciformix, A Covance Company	Non Govt.	Reproductive Medicine	2020-2021	23.10222	2877034.00	2453055.00	423979.00	6 months
13		Protocol No: SRPL/DFU/18-19/001 Protocol Title: A Label extension, Randomized, Double Blind, Placebo Controlled, Multicentre, Single Dose, Phase III Study Assessing the Efficacy and Safety of Peri-ulcer Administration of stempeucel® (Adult Human Bone Marrow Derived, Cultured, Pooled, Allogeneic Mesenchymal.	Dr. T. Mohanapriya	JSS Medical Research India Pvt. Ltd.	Non Govt.	General Surgery	2020-2021	6.37500				6 months
14	28276	Protocol No: I4V-MC-JAHU(a): Protocol Title: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less Than 18 Years Old with Systemic Juvenile Idiopathic Arthritis.	Dr. Mahesh Janarthana	Eli Lilly and Company (India) Pvt. Ltd.	Non Govt.	Pediatrics	2020-2021	17.94420			162000.00	6 months
15	28276	Protocol No: I4V-MC-JAHV(b): Protocol Title: A Randomized, Double Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 2 Years to Less Than 18 Years Old with Juvenile Idiopathic Arthritis (JIA).	Dr. Mahesh Janarthana	Eli Lilly and Company (India) Pvt. Ltd.	Non Govt.	Pediatrics	2020-2021	20.48472				6 months

16	28276	Protocol No: 14V-MC-JAHX Prot Protocol Title: A Phase 3 Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients from 1 Year to <18 Years of Age with Juvenile Idiopathic Arthritis (JIA).	Dr. Mahesh Janarthana	Eli Lilly and Company (India) Pvt. Ltd.	Non Govt.	Pediatrics	2020-2021	46.86600				6 months
17	28291	Protocol Number - CBCC/2019/004 "A multicenter, open label, balanced, randomized, two-treatment, single-period, parallel, steady-state bioequivalence study of Paliperidone Palmitate injection 156mg/mL of Qilu Pharmaceuticals Co., Ltd. with INVEGA SUSTENNA® (Paliperidone Palmitate) ER Injectable Suspension 156mg/mL of Janssen Pharmaceuticals, Inc. Titusville, NJ 08560 in subjects with schizophrenia".	Dr. R. Sathianathan	CBCC Global Research LLP	Non Govt.	Psychiatry	2020-2021	22.97250	1408810.00		1408810.00	1 year
18	28216	Protocol No: NW-3509/008/II/2019 Protocol Title : A Phase II, Prospective, Multi-Center, Randomized, 4-Week, Double-Blind, Placebo-Controlled, Multiple-Dose Study, Designed To Determine the Safety, Tolerability, EEG Effects AND Preliminary Efficacy Of Fixed Oral Doses Of 7.5 and 15 mg BID Of EVENAMIDE (NW-3509) in Patients With Chronic Schizophrenia Who Are Symptomatic On Their Current Second-Generation Antipsychotic (Aripiprazole, Clozapine, Quetiapine, Olanzapine, Paliperidone OR Risperidone) Medication.	Dr. R. Sathianathan	Clinirx Research Pvt. Ltd.	Non Govt.	Psychiatry	2020-2021	14.17500	4753289.00	2304018.00	2449271.00	6 months

19	28253	Protocol Number: BBIL/BBV152D-B/2020; Version No: 3.0 &Date: 17-08-2020 Protocol Title: An Adaptive, Seamless Phase1, Ffollowed by a Phase 2, Rrandomized, Mmulticenter Study to Evaluate the Ssafety, Reactogenicity, and Iimmunogenicity of the Whole virion Inactivated SARS-CoV-2 Virus Vaccine, BBV152D Aadministered Intradermally in healthy volunteers.	Dr. R.B.Sudagar Singh	Bharat Biotech International	Non Govt.	General Medicine	2020-2021	20.00000	1316055.00	1316055.00	0.00	6 months
20	28238	Study No. - ICMR/SII-COVISHIELD Study Title - A phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVISHIELD (COVID-19 vaccine) in healthy Indian adults.	Dr. S. R. Ramakrishnan	PPD	Non Govt.	General Medicine	2020-2021	65.00700	5389965.00	5389965.00	0.00	8 months
21	28197	Study Title: Protocol No.: GBR 200-301 "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 Patients Diagnosed with HER2 Positive Metastatic Breast Cancer.	P.Jovita.M.M	Alkem Laboratories Ltd.	Non Govt.	Medical Oncology	2019 - 2020	700000	740617.00	0.00	0.00	
22	28188	Protocol No: 0486-17 Study Title: Version 03, Dated December 05, 2017 An open label, multicenter Post Marketing Surveillance Study in India to assess safety and efficacy of Intramuscular administration of stempeucel® in patients with critical limb ischemia due to Buerger's disease.	R.Radhakrish	Lambda Therapeutic Research Ltd.	Non Govt.	Vascular Surgery	2019-2020		367204.00	0.00	168075.00	