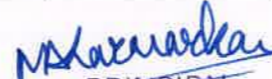


Bharati Vidyapeeth (DTU) Medical College, Pune
List of Research Projects for the year 2022-2023

Sr No	Name of the Scheme/Project/ Endowments/ Chairs	Name of the Principal Investigator/ Co Investigator (if applicable)	Name of the Funding agency	Type (Government/ Non-Government)	Department
1	Shan6 (SH600004) - SHAN 6 Phase III-Phase III, randomized, open-label, multicenter study evaluating the immunogenicity and safety of Shan6 vaccine administered, concomitantly with or without Measles-Mumps Rubella (MMR) vaccine, to healthy toddlers in India.	PI: Dr. Sonali Palkar	Sanofi Healthcare India Pvt Ltd	Non-Government	Paediatrics
2	Serum qHPV -A Phase-II/III: Partially Double-blind, Randomized, Active-controlled, Multicentric Study to Assess the Immunogenicity and Safety of SIIPL's qHPV Vaccine Administered Intramuscularly in Healthy Volunteers According to a Two-dose Schedule to Cohort 1 (Girls and Boys Aged 9-14 years) and a Three-dose Schedule to Cohort 2 (Women and Men Aged 15-26 years) as Compared to Merck's HPV6/11/16/18 vaccine (Gardasil®)	PI: Dr. Sanjay Lalwani	Serum Institute of India Pvt Ltd	Non-Government	Paediatrics
3	BBIL CHIKV: A Seamless Phase II/III, Observer-blind, Multi-centre, Randomized Clinical Trial to Evaluate Immunogenicity and Safety of BBV87, an Inactivated Chikungunya Virus Vaccine in Healthy Subjects 12-65 Years of Age.	PI: Dr. Sonali Palkar Coinvestigators: Dr. Prachee Makashir Dr. Neeta Hanumante Dr. Purwa Doke Dr. Rishi Patel Dr. Shilpa Gokhal Dr. Anuj Darak	Diagnosearch Life Sciences Pvt Ltd	Non-Government	Paediatrics
4	HBI Hep A study: A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of HBI Inactivated	PI: Dr. Sonali Palkar	Human Biologicals Institute	Non-Government	Paediatrics


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	Hepatitis-A Vaccine with Havrix® Vaccine when Administered to Two Age Groups of Healthy Subjects ”				
5	HBI MR vaccine study: A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of Measles and Rubella Vaccine (Live) of HBI with MR-VAC® Vaccine in Healthy Subjects	PI:Dr. Rahul Jahagirdar Co-investigator: Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale Dr. Rishi Patel	Human Biologicals Institute	Non-Government	Paediatrics
6	HBI CHIKV- CHIKUNGUNYA Phase I Vaccine study: A Phase I Randomized Single Blind Placebo Controlled Study to Evaluate the Safety and Immunogenicity of Chikungunya Vaccine (Inactivated) of HBI when administered by two different dosage schedules to Healthy Subjects of 19 To 49 Years of Age.	PI: Dr. Sonali Palkar Co-investigator: Dr. Neeta Hanumante, Dr. Shilpa Gokhale, Dr. Purwa Doke, Dr. Prachee Makashir , Dr. Vaishali Pawar	Human Biologicals Institute	Non-Government	Paediatrics
7	GSK Pertussis: Evaluation of Pertussis Disease in Young Infants in India - A Hospital Based Multi-centric study	PI: Dr. Sanjay Lalwani	Medclin Research Pvt Ltd	Non-Government	Paediatrics
8	rBCG study : A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study To Evaluate The Efficacy Of Recombinant BCG VPM1002 In Reducing Infection Incidence And Disease Severity Of SARS-COV-2/COVID-19 Among High-Risk Subjects	PI: Dr. Sanjay Lalwani	Serum Institute of India Pvt Ltd	Non-Government	Paediatrics
9	Serum aPENTA vaccine Study:A Phase II/III, Multicentre, Randomized, Open-Label, Active-Controlled Study to Assess the Immunogenicity and Safety of DTaP-IPV+Hib Vaccine Manufactured by Serum Institute of India Pvt. Ltd. in Comparison with Pentaxim® in Indian Toddlers and Infants.	PI: Dr. Jitendra Oswal Coinvestigator: Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	IQVIA RDS(India)Pvt Ltd	Non-Government	Paediatrics
10	Cadila nCOV vaccine: A phase III, randomized, multi-centre, double blind, placebo controlled, study to	PI - Dr Sanjay Lalwani	Cadila Healthcare Ltd.	Non-Government	Paediatrics

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	evaluate efficacy, safety and immunogenicity of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited.				
11	Cadila TCVMR - A prospective, randomized, parallel, three-arm,open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid Vi conjugate vaccine with Measles and Rubella vaccine administered to healthy infants	PI: Dr. Neeta Hanumante	Zydus LifeSciences Ltd (formerly known as Cadila Healthcare Ltd.)	Non-Government	Paediatrics
12	Reliance Covid-19: A prospective, open label, dose escalation phase I clinical study to evaluate the safety, tolerability and immunogenicity of Reliance Life Sciences SARS-CoV-2 Recombinant protein subunit vaccine in healthy volunteers.	PI- Dr. Prachee Makashir Co-investigator- Dr. Sonali Palkar Dr. Purwa Doke Dr. Swati Chouhan Dr. Bhabatosh Saha	Reliance Life Sciences Pvt. Ltd.	Non-Government	Medicine
13	Reliance Growth Hormone:A prospective, multi-centre, phase IV study to evaluate safety and efficacy of SomatoReITM (recombinant human growth hormone manufactured by Reliance Life Sciences Pvt. Ltd.) in growth hormone deficient children	PI-Dr. Rahul Jahagirdar	Reliance Life Sciences Pvt. Ltd	Non-Government	Medicine
14	GSK RSVMAT-009:A Phase III, randomized, double-blind, placebo-controlled multi-country study to demonstrate efficacy of a single dose of unadjuvanted RSV Maternal vaccine, administered IM to pregnant women 18 to 49 years of age, for prevention of RSV associated LRTI in their infants up to 6 months of age.	PI: Dr. Sanjay Lalwani	GSK Pharma India Pvt. Ltd.	Non-Government	Paediatrics
15	GSK RSVMAT-012:A Phase III, double-blind, randomized, placebo-controlled study to evaluate the safety, reactogenicity and immune response of a single intramuscular dose of unadjuvanted RSV Maternal	PI: Dr. Sanjay Lalwani	GSK Pharma India Pvt. Ltd.	Non-Government	Paediatrics

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	vaccine, in high risk pregnant women aged 15 to 49 years and infants born to the vaccinated mothers.				
16	Genova Covid 19 Vaccine- A Prospective, Multicentre, Randomized, Active-controlled, Observer-blind, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy subjects	PI: Dr. Sonali Palkar	Diagnosearch Life Sciences Pvt Ltd	Non-Government	Paediatrics
17	Serum Covovax Vaccine: A phase 2/3, 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 aged ≥18 years and children aged 2 to 17 years.	PI: Dr Sanjay Lalwani Coinvestigators: Dr. Sonali Palkar , Dr. Neeta Hanumante, Dr. Shilpa Gokhale, Dr. Amruta Walimbe, Dr. Ramdas Dahiphale	PPD Pharmaceutical Development India Pvt Ltd	Non-Government	Paediatrics
18	Serum Covovax Booser: A phase 3, observer-blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of COVOVAX in Indian adults who have received primary vaccination against COVID-19	PI-Dr. Sanjay Lalwani	PPD Pharmaceutical Development India Pvt Ltd	Non-Government	Paediatrics
19	Serum Heterologous Booster: A PHASE 3, observer-blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of covovax in children aged ≥ 12 to < 18 years who have received primary vaccination against covid-19	PI-Dr. Sanjay Lalwani Coinvestigator-Dr. Sonali Palkar, Dr. Neeta Hanumante, Dr. Shilpa Gokhale, Dr. Ramdas Dahiphale	PPD Pharmaceutical Development India Pvt Ltd	Non-Government	Paediatrics
20	Serum Homologous Booster:A phase 3, observer-blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of COVOVAX in children aged ≥ 7 to < 18 years.	PI-Dr. Sanjay Lalwani Coinvestigator - Dr. Sonali Palkar	PPD Pharmaceutical Development India Private Limited	Non-Government	Paediatrics

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21	Sanofi MET-55: Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adults, Adolescents, Children, and Toddlers in India and Healthy Adolescents and Children in the Republic of South Africa	PI: Dr. Sonali Dr. Neeta Hanumante Dr. Shilpa Gokhale	IQVIA RDS India Pvt. Ltd.	Non-Government	Paediatrics
22	HBI Dengue: a phase i single blind randomized placebo controlled study to evaluate the safety and immunogenicity of live attenuated tetravalent recombinant dengue vaccine of hbi in healthy adults of 18 to 50 years of age	PI-Dr. Sonali Palkar	Abiogenesis Clinpharm Pvt Ltd	Non-Government	Paediatrics
23	Pfizer PCV-20(Pediatric)-A Phase 3 Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-valent Pneumococcal Conjugate Vaccine Given in a Series of 3 Infant Doses and 1 Toddler Dose in Infants in India and Taiwan.	PI-Dr. Sonali Palkar	ICON Clinical Research India Private Limited	Non-Government	Paediatrics
24	Lung Cancer- A Multicenter, Randomised, Double blind, Parallel, Phase III Global Study to Assess the Efficacy and Safety of BP01 (Bevacizumab) when compared to Avastin®-EU in Combination with Carboplatin and Paclitaxel during Induction phase and Bevaciz-umab alone during the Maintenance phase in patients with newly diagnosed or recurrent Stage IIIB/IV Non Squamous (ns) Non-Small Cell Lung Cancer (NSCLC)	PI: Dr.Shreeniwa Raut Coinvestigator: Dr. Ashwin Rajbhog	Clintrisearch Healthcare Pvt Ltd	Non-Government	Medicine
25	RCC - A Multicentric, Open-label, Randomized, Two Period, Two Treatment, Two Sequence, Crossover, Multiple Dose, Steady state Bioequivalence Study of Pazopanib tablets 200 mg of Eugia Pharma Specialities Limited, India (Test) with VOTRIENT® (pazopanib) tablets 200 mg of Novartis Pharmaceuticals Corporation, USA (Reference) in adult patients with advanced renal	PI- Dr. Shreeniwas Raut Coinvestigator- Dr. Tushar Patil	Raptim Research Pvt Ltd	Non-Government	Medicine

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	cell carcinoma already receiving Pazopanib HCl tablets in standard therapy, and who are tolerating a stable dosing regimen of 800 mg/day (4 × 200 mg) under fasting conditions.				
26	Ashwagandha-Repeated Dose Toxicity study	PI-Dr. Jayashree Dawane	Clinsearch Healthcare Solutions Pvt Ltd	Non-Government	Pharmacology
27	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	PI-Dr. Girija Wagh	Eversana India Pvt Ltd	Non-Government	OBGY
28	Diagnostic Potential of Intestinal permeability markers in irritable bowel syndrome	Dr Gayatri Gawade	BVU funded	Non-government	Biochemistry
29	A comparative study of Subacute Repeated Dose Toxicity of Ashwagandha Root extract vs. Leaf extract in Rats	Dr. Jayshree Dawane	External funded	Non-government	Pharmacology
30	Synergistic activity of ceftazidime-avibactam plus aztreonam against carbapenemase producing enterobacteriaceae and its clinical implications	Dr. Aishwarya B.	BVU funded	Non-government	Microbiology
31	Healthcare Access for Rural Community via Telemedicine	Dr. Varsha Vaidya	BVU funded	Non-government	Community Medicine
32	Community Behavior Change Communication (CBCC) for improving childhood immunization coverage among children in urban slums and brickkilns in rural area	Dr Sujata Murarkar	BVU funded	Non-government	Community Medicine
33	Co-relates of COVID 19 vaccine hesitancy/ acceptance among adult population: A Community based study	Dr Sanjivani Patil	BVU funded	Non-government	Community Medicine
34	Prevalence of biological and behavioural risk factors of non-communicable diseases among adults in urban slums of Pune using STEPPS approach	Dr Sudhanshu Mahajan	BVU funded	Non-government	Community Medicine

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35	Assessment of the prevalence of psychological and spiritual health in cancer chemotherapy patients.	Dr. Shilpa Patankar	BVU funded	Non-government	Surgery
36	Performance evaluation of rpr and elisa with tpha for detection of syphilis in blood donors	Dr. Brinda Kakkar	BVU funded	Non-government	Immunohematology
37	Can IgG specific column agglutination cards replace Dithiothreitol (DTT)	Dr. Brinda Kakkar	BVU funded	Non-government	Immunohematology
38	Prevalence of APOA5 and CD36 gene polymorphisms in lipid metabolizing genes in patients with Type 2 diabetes mellitus - A pilot study	Anu Chiristopher	BVU funded	Non-government	Pathology

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