

Bharati Vidyapeeth (DTU) Medical College, Pune
List of Research Projects for the year 2021-2022

Sr No.	Name of the Scheme/Project	Name of the Principal Investigator/ Co Investigator	Name of the Funding agency	Type (Government/ Non-Government)	Department
1	Prevenar phase IV: A Phase 4, Randomized, Open-Label Trial to describe the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine formulated in Multidose Vials when given with routine Pediatric Vaccines in healthy infants in India	PI: Dr. Sanjay Lalwani Coinvestigator- Dr. Sonali Palkar, Dr. Neeta Dr. Shilpa Gokhale Dr. Amruta Walimbe	Pfizer/ ICON	Non-Government	Pediatrics
2	q-HPV -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 Coinvestigator- Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale Dr. Amruta Walimbe Dr. Vaishali Pawar Dr. Supriya Barsode Dr. Vaishali Taralekar Dr. Tushar Panchanadikar Dr. Deepak Bhosale Dr. Arvind Narula Dr. Rishi Patel	SIIPL/ Diagnosearch	Non-Government	Pediatrics
3	Serum Tdap- 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.	PI: Dr. Jintendra Oswal Coinvestigator- Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	SIIPL/ JSS	Non-Government	Pediatrics

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4	SH6 00003- SHAN 6 Phase III: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 0	PI: Dr. Sonali Palkar Coinvestigator- Dr. Neeta Hanumante Dr. Shilpa Gokhale Dr.Amruta Walimbe	Shantha Biotech	Non-Government	Pediatrics
5	Birth Rota: A Phase 3, Multicenter, Open-Label, Randomized Clinical Trial To Evaluate Safety And Immunogenicity of ROTAVAC® -20°C And ROTAVAC 5cm administered at Birth (Neonatal Schedule) and additional dose versus Infant Schedule against Rotavirus Gastroenteritis	PI: Dr. Neeta Hanumante Coinvestigator- Dr. Sanjay Lalwani Dr. Sonali Palkar Dr. Shilpa Gokhale Dr. Tushar Panchanadikar	Bharat Biotec	Non-Government	Pediatrics
6	Rotarix Liquid:A phase III, randomized, open study to assess the immunogenicity, reactogenicity and safety of two different formulations of GlaxosmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine, Rotarix, when given as a two dose Primary vaccination in healthy infants with no previous history of rotavirus illness or Vaccination.	PI: Dr. Sanjay Lalwani Coinvestigator- Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	GSK	Non-Government	Pediatrics
7	PCV-10-004 study: 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.	PI: Dr. Sanjay Lalwani Coinvestigator- Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	SIPL	Non-Government	Pediatrics

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8	HBI Hep A study: A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of HBI Inactivated Hepatitis-A Vaccine with Havrix® Vaccine when Administered to Two Age Groups of Healthy Subjects ”	PI: Dr. Sonali Palkar Coinvestigator- Dr. Neeta Hanumante Dr. Shilpa Gokhale Dr. Arundhati Diwan Dr. Supriya Barsode	Human Biologicals Institute	Non-Government	Pediatrics
9	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 HEXASIIL™ (DTwP-HepB-IPV-Hib) Vaccine in comparison with SIIPL PENTAVAC (DTwP-HepB-Hib) + Poliovac (IPV) Vaccines administered as separate injections.	PI: Dr. Sanjay Lalwani Coinvestigator- Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	SIPL	Non-Government	Pediatrics
10	HAV ISS- Hepatitis Sero Prevalence study: Sero-prevalence of Anti-Hepatitis A antibodies in four cities from different parts of India	PI: Dr. Sanjay Lalwani Co-investigator: Dr. Sonali Palkar	GSK	Non-Government	Pediatrics
11	GSK Pertussis: Evaluation of Pertussis Disease in Young Infants in India - A Hospital Based Multi-centric study	PI: Dr. Sanjay Lalwani Co-investigator: Dr. Sanjay Mankar Dr. Sonali Palkar Nandini Malshe Disha Dhamale	Medclin /GSK	Non-Government	Pediatrics
12	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 Co-investigator: Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Tushar Panchanadikar Dr. Vaishali Taralekar Dr. Supriya Barsode Dr. Rishi Patel Dr. Shilpa Gokhale Dr. Amruta Walimbe	SIPL	Non-Government	Pediatrics


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13	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 Coinvestigator: Dr. Neeta Hanumante Dr. Shilpa Gokhale	Sanofi Healthcare Ltd	Non-Government	Pediatrics
14	ICMR COVISHIELD vaccine study:A Phase 2/3 Observer-Blind, Randomized, Controlled Study To Determine The Safety and Immunogenicity of COVI SHIELD (Covid-19 Vaccine) In Healthy Indian Adults	PI: Dr. Sanjay Lalwani Coinvestigator: Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Purwa Doke Dr. Rishi Patel	SI IPL in collaboration with ICMR	Non-Government	Pediatrics
15	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	SI IPL	Non-Government	Pediatrics
16	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	Pediatrics
17	Pfizer Nosocomial Pneumonia Caz-Avi study: A Phase 1, Open-Label, Single-Dose Study To Assess The Pharmacokinetics, Safety And Tolerability Of Ceftazidime-Avibactam (Caz-Avi) In Children From 3 Months To Less Than 18 Years Of Age Who Are Hospitalized And Receiving Systemic Antibiotic Therapy For Suspected Or Confirmed Nosocomial Pneumonia, Including Ventilator-Associated Pneumonia	PI: Dr. Vijay Kalrao Co-Investigator: Dr. Sonali Palkar Dr. Ajay Walimbe Dr. Bhakti Sarangi	Pfizer /	Non-Government	Pediatrics

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18	Perampanel study : A Multicenter, Double-Blind, Randomized, Placebo- Controlled Trial With an Open-Label Extension Phase of Perampanel as Adjunctive Treatment in Subjects at Least 2 years of Age with Inadequately Controlled Seizures Associated with Lennox- Gastaut Syndrome.	PI: Dr. Kavita Srivastava Co-Investigator: Dr. Jitendra Oswal Dr. Neeta hanumante	Sponsor – EISAI CRO- PPD	Non-Government	Pediatrics
19	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	Pediatrics
20	Birth Rota vaccine extended study: To Evaluate the Long-term Persistence of Rotavirus Antibody Responses in Children Previously Vaccinated With a 3-Dose Infant Schedule or 4-Dose Neonatal Schedule with ROTAVAC® - 20°C or ROTAVAC 5D®	PI: Dr. Neeta Hanumante Co-investigator Dr. Sanjay Lalwani Dr. Sonali Palkar Dr. Vaishali Pawar Dr. Shilpa Gokhale	Bharat Biotech	Non-Government	Pediatrics
21	Evaluation of activity profile of asparaginase based therapies in acute lymphoblastic leukemia	Mr Bijoy Kumar Panda	BVU Funded	Non-Government	Biochemistry and Pediatrics
22	Behavioral and biological risk factors of non communicable diseases among adults in urban slums of Pune using STEPS Approach.	Dr Sudhanshu Mahajan	BVU funded	Non-Government	Community Medicine
23	Evaluation of antidepressant effect of Drakshasava in wistar rats	Dr. Jayshree Dawane	BVU funded	Non-Government	Pharmacology
24	Co-relates of COVID 19 vaccine hesitancy/ acceptance among adult population: A Community based study	Dr Sanjivani Patil	BVU funded	Non-Government	Comm Medicine

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25	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 Coinvestigator: Neeta Hanumante Shilpa Gokhale Dr. Prachee Makashir Dr. Arundhti Diwa, Dr. Anuj Darak Dr. Rishi Patel Purwa Doke	Genova Biopharmaceuticals Limited	Non-Government	Pediatrics
26	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 Co-investigators: Dr. Sonali Palkar Shilpa Gokhale Dr. Amruta Walimb Ramdas Dahiphale	Cadila Healthcare Ltd.	Non-Government	Pediatrics
27	Preventive and Therapeutic Potential of Swarna and Jasad Bhasma in Diabetic Retinopathy and Nephropathy	Dr.Pallawi Khatavkar	ICMR Extrameural Project	Government	Pharmacology
28	Pneumosiil PCV-10-003- 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.	PI: Dr. Sanjay Lalwani Co-investigator: Dr. Sonali Palkar Dr. Neeta Hanumante Dr. Shilpa Gokhale	SIILP	Non-Government	Pediatrics

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29	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	SIILP/PPD	Non-Government	Pediatrics
30	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 Gokhale Dr. Anuj Darak	Bharat Biotech	Non-Government	Pediatrics
31	Augmentin: A Multicentre, Open-label, Non-comparative Phase IV Clinical Study to Evaluate the Safety and Clinical Efficacy of Augmentin Extra Strength (ES)-600 (amoxicillin/potassium clavulanate 14:1 combination) in Children with Acute Respiratory Tract Infections (ARTIs) in India.	PI : Dr. Neeta Hanumante Co-investigators : Dr. Sonali Palkar Dr. Shilpa Gokhale Dr. Amruta Walimbe Dr. Vishwanath Gowda Dr. Kartikeya Chauhan Dr. Purva Artham	GSK	Non-Government	Pediatrics
32	CBCC- A randomized, double-blind, multicenter, parallel-group, phase 3 study to compare the safety and efficacy of Phenobarbital Sodium for Injection, USP, at two different dose strengths, in cvEEG proven neonatal seizures	PI: Dr. Nandini Malshe Coinvestigator: Dr. Pradeep Suryavanshi Dr. Sonali Palka Dr. Surprabha Patnaik	Nivagen Pharmaceuticals Inc.	Non-Government	Neonatology

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33	Pfizer Covid vaccine- A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study To Evaluate The Safety, Tolerability, Immunogenicity, And Efficacy Of SARS-COV-2 RNA Vaccine Candidates Against Covid-19 In Healthy Individuals.	PI: Dr. Sanjay Lalwani Coinvestigators: Dr.Sonali Palkar Dr. Neeta Hanumante Dr. Vaishali Pawar Dr. Supriya Barsode Dr. Purwa Doke Dr. Rishi Patel	BioNTech/Pfizer	Non-Government	Pediatrics
34	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	CURATEQ BIOLOGICS PRIVATE LIMITED,	Non-Government	Medicine
35	An interventional efficacy and safety, phase 2/3, double blind,, 2 arm study to investigate orally administered PF07321332/ritonavir compared with placebo in nonhospitalized symptomatic adult participants with covid19 who are at increased risk of progressing to severe illness Protocol Number: C4671005	PI- DR. Jignesh Shah	PARAXEL international clinical research PVT LTD	Non-Government	Critical Care Unit


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