

**Government of the People's Republic of Bangladesh**  
**Directorate General of Drug Administration**  
**Aushadh Vaban**  
**Mohakhali, Dhaka-1212, Bangladesh**

**List of Protocol Amendment Approval**

<b>SL</b>	<b>Name of the Protocol</b>	<b>Principal Investigator Name with institute</b>	<b>Approval date</b>
01	An effectiveness trial to evaluate the protection of pregnant women with a hepatitis E vaccine in rural Bangladesh and the risk factors for severe hepatitis E infection.	Dr. K Zaman Principal Investigator of research Protocol# PR 16014 Infections Diseases Division (IDD)	23-02-2017
02	A double-blind, randomized controlled trial of the effect of vaccine inoculum on oral rotavirus vaccine (Rotarix, GlaxoSmithKline) take and immunogenicity in Dhaka, Bangladesh, Phase II Study	Dr. Rashidul Haque, MBBS, PHD, Senior Scientist, Principal Investigator of research Protocol# PR 16072 Infections Diseases Division (IDD), icddr,b.	31-07-2017
03	A Phase I Double-Blinded, Placebo-Controlled, Dose Escalation Study to Evaluate the Safety and Immunogenicity of Double Mutant Heat-Labile Toxin LTRI92G/L211A (dmLT) from Enterotoxigenic Escherichia coli (ETEC) by Oral, Sublingual, or Intradermal Vaccination in Adults Residing in an Endemic Area,	Dr. Firdausi Qadri, PhD Senior Scientist and head Principal Investigator of research Protocol# PR 18003 Mucosal Immunology & Volcanology Laboratory International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka.	18-11-2018
04	A multicounty, multicenter, two-arm, parallel. double blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early and late preterm period in hospitals in low resource countries to improve newborn outcomes (ACTION Trial)	Prof. Dr. Mohammad shahidullah Co-Principal Investigator and Professor, Department of Neonatology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka.	18-11-2028
05	A randomized double-blind placebo-controlled trial for the evaluation of a polycap, low does aspirin and vitamin D supplementation in primary prevention – The International Polycap Study 3 (TIPS n3)	Dr. Shamim Hayder Talukder, Principal Investigator of TIPS 3 Eminenee associates for social development (CRO), 3/6 Asad Avenue, Mohammadpur, Dhaka-1207. Bangladesh.	18-11-2018
06	A Phase 1/ A Phase 2 Study, to evaluate the Safety, Tolerability, Efficacy, Pharmacokinetics, and Pharmacodynamics of ANX005 in Participants with Guillain Barre	Dr. Zhahirul Islam Principal Investigator (icddr,b) ANX005-GBS-01 trial in Bangladesh Scientist, Laboratory Sciences and Services Division, icddr,b.	16-04-2019

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	Syndrome.	68 Shageed Tajuddin Ahmed Soroni Mohakhali, Dhaka-1212 and Prof. Dr. Quazi Deen mohammad External Principal Investigator (NINS), ANX005-GBS-01 trail in Banladesh Professor of Neurology and Director National Institute of Neurosciences and Hospital (NINS), Sher-e-Bangla Nagar, Dhaka-1207.	
07	Assessing the impact of a Vi-Polysaccharide conjugate Vaccine in preventing typhoid infection among Bangladeshi children-a Phase IIIb trial.	Dr. Firdausi Qadri Head & Senior Scientist, Mucosal Immunology & Vaccinology Laboratory, Principal Investigator of research Protocol# PR 17115, Infectious Diseases Division (IDD), International Centre for Diarrhoeal Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka.	16-04-2019
08	A Phase I Double-Blinded, Placebo-Controlled, and Dose Escalation Study to Evaluate the Safety and Immunogenicity of Double Mutant Heat-Labile Toxin LTR192G/L211A (dmLT) from Enterotoxigenic Escherichia coli (ETEC) by Oral, Sublingual, or intradermal Vaccination in Adults Residing in an Endemic Area.	Dr. Firdausi Qadri Head & Senior Scientist Mucosal Immunology & Vaccinology Laboratory, Principal Investigator of research Protocol# PR 17115, Infectious Diseases Division (IDD), International Centre for Diarrhoeal Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka.	16-04-2019
09	An Open label, Randomized, Clinical Trail of Two Regimens to Assess the safety and Efficacy for Treatment of RKDL Patients in the indian subcontinent.	Dr. Dinesh Mondal MBBS, MD, PhD Senior Scientist Principal Investigator of research Protocol# PR 17067 Nutrition and Clinical Services Division (NCSD), International Centre for Diarrhoeal Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka.	16-04-2019
10	A Multi9-Center, Open –Label, Randomized, Two treatment, Parallel, Single period, Multiple-Dose, Steady state, Global Bioequivalence study of Amphotericin D Liposome (Auromedics Pharma LLC, USA) in Visceral Leishmaniasis patients under fed	Dr. Dinesh Mondal. MBBS, MD, PhD Senior Scientist Principal Investigator of research Protocol# PR 17067 Nutrition and Clinical Services Division (NCSD), International Centre for Diarrhoeal	02-07-2019

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	condition.	Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka.	
11	A Phase I Double-blinded, placebo-Controlled, dose escalation Study to Evaluate the Safety and Immunogenicity of Double Mutant heat Labile Toxine LTR192G/L211A (dmLT) from Enterotoxigenic Escherichia Coli (ETEC) by Oral, Sublingual or Intradermal Vaccination in Adults residing in an endemic Area.	Dr. Firdausi Qadri, PhD Senior Scientist and Head Principal Investigator of research protocol# PR 18003, Mucosal Immunology & Vaccinology Laboratory, International Centre for Diarrhoeal Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka	17-10-2019
12	A Phase I Double- Blinded, Placebo-controlled, Dose Escalation Study to Evaluate The Safety and Immunogenicity of Double Mutant heat-Labile Toxin LTR192G/L211A (dmLT) from Enterotoxigenic Escherichia coli (ETEC) by Oral, Sublingual, or Intradermal Vaccination in Adults Residing in an Endemic area	Dr. Firdausi Qadri, PhD Senior Scientist and Head Principal Investigator of research protocol# PR 18003, Mucosal Immunology & Vaccinology Laboratory, International Centre for Diarrhoeal Research, Bangladesh (icddr,b) 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka	05-12-2019
13	A phase /Followed by Phase 2 study, to Evaluate the Safety, Tolerability, Efficacy, Pharmacokinetics, and Pharmacodynamics of ANX005 in Participants with Guillain Barre Syndrome.	Prof. Dr. Quazi Deen Mohammad External Principal Investigator of ANX005-GBS-01 Professor of Neurology and Director National Institute of Neurosciences and Hospital (NINS) Sher-e-Bangla Nagar, Dhaka-1207. And Dr. Zahirul Islam Principal Investigator and scientist Laboratory Sciences and Service Division, icddr,b 68 shadeed Tajuddin ahmed Soroni, Mohakhali, Dhaka.	27-01-2020
14	Ivermectin and doxycycline in combination or ivermectin alone for the treatment of adult Bangladeshi patients hospitalized for COVID-19: a randomised, double-blind, placebo-controlled trial.	Dr. Wasif Ali Khan Scientist Enteric and Respiratory Infections Principal Investigator of research protocol# PR-20039 Infectious Diseases Division (IDD) International Centre for Diarrhoeal Diseases Research, Bangladesh (icddr,b) 68 shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka.	01-06-2020

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15	Effectiveness of calcium channel blockade for organophosphorus and carbamate pesticide poisoning –an open pragmatic, 3arm randomized controlled trial repurposing two widely available licensed medicines.	Professor Md. Abul Faiz Principal Investigator Professor of Medicine (Retired & Former director General of Health Services President, Toxicology Society of Bangladesh. Dev Care Foundation House 83, Flat 41, Road 12/A, Dhanmondi R/A, Dhaka.	29-07-2020
16	A Phase Ib Study to Evaluate the safety, Tolerability and Drug-Drug Interactions of ANX005 in Combination with Intravenous Immunoglobulin (IVIg) in subjects with Guillain-Barre Syndrome, (PR-19087)	Prof. Dr. Quazi Deen Mohammad Principal Investigator (NINS), ANX005-GBS-03 trial in Bangladesh Professor of Neurology and Director National Institute of Neurosciences and Hospital (NINS), Sher-e-Bangla Nagar, Dhaka-1207 and Dr. Zahirul Islam Principal Investigator (icddr,b) ANX005-GBS-03 trial in Bangladesh Scientist, Laboratory Sciences and Services Division, icddr,b 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali, Dhaka-1212.	29-07-2020
17	An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care (“WHO Public health emergency- SOLIDARITY TRIAL” for Covid-19 therapeutics trial”)	Prof. Dr. Meerjady Sabrina Flora PhD Principal Investigator and National Coordinator ADG (Planning and Development). DGHS, MOHFW.	17-11-2020
18	A Phase III Study with a ventilator manufactured in Bangladesh (WPB-560) in patients who require mechanical ventilation support.	Professor Dr. Uttam Kumar Barua Head, Department of Respiratory Medicine, Shabeed Suhrawardi Medical College, Dhaka.	19-11-2020
19	An Open label, Randomized, Clinical Trial of Two Regimens to Asses the Safety and Efficacy for Treatment of PKDL Patients in Indian subcontinent.	Dr. Dinesh Mondal Senior Scientist and Principal Investigator Nutrition and Clinical Services Division, icddr,b.	23-05-2021
20	A Prospective, Randomized, Double blind, Active controlled study to compare PK & Safety of biosimilar Adalimumab (Advixa) 40mg/ 0.4 ml of Incepta Pharmaceuticals Ltd. With Humira 40 mg/ 0.4 ml of Abbvie Ltd. in Healthy, Adult, Human subject by single subcutaneous injection followed by Efficacy & Safety Study in patients with rheumatoid arthritis.	Dr. Zannat Kawser Principal Investigator and Assistant Scientist Institute for Developing Science & Health Initiatives Hosaf High tower, 9, Mohakhali C/A, Dhaka-1212.	01-06-2021

<b>SL</b>	<b>Name of the Protocol</b>	<b>Principal Investigator Name with institute</b>	<b>Approval date</b>
21	An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care (SoC)	Prof. Dr. Meerjady Sabrina Flora PhD Principal Investigator, Solidarity Trial PLUS ADG, DGHS. MOHFW, Mohakhali, Dhaka-1212.	01-06-2021