

**Government of the People's Republic of Bangladesh**  
**Directorate General of Drug Administration**  
**Aushad Bhavan**  
**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>Amendment 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 icddr,b.	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 16014 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. Farausi Qadri, PhD Senior Scientist and head Principal Investigator of research protocol# PR 18003 Mucosal Immunology and Vaccinology Laboratory International Centre for diarrhoeal Disease Research, Bangladesh (icddr,b) 68 Shaheed Tajudding 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.	18-11-2018
05	A randomized double-blind placebo controlled trial for the evaluation of a polycap, low dose aspirin and vitamin D supplementation in primary prevention The International Polycap Study 3 (TIPS n3)	Dr. Shamim Hayder Talukder, Principal Investigator of TIPS 3 Eminence 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 Syndrome.	Dr. Zahirul Islam Principal Investigator (icddr,b) ANX005-GBS-01 trial in Bangladesh Scientist, Laboratory Sciences and Services Division, icddr,b 68 Shageed Tajudding Ahmed Sorone Mohakhali, Dhaka-1212 and Prof. Dr. Quazi Deen Mohammad External Principal Investigator (NINS), ANX005-GBS-01 trail in Bangladesh Professor of Neurology and Director National Institute of Neurosciences and Hospital (NINS), Sher-e-Bangla Nagar, Khaka-1207.	16-04-2019
07	Assessing the impact of a vipolysaccharide conjugate Vaccine in Prevention typhoid infection among Bangladeshi children-a Phase III b 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 Diarroal Research, Bangladesh (icddr,b) 68 Shadeed Tajudding Ahemd 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-Labite Toxin LTR192G/L211A (dmLT) from Entrotoxicogenic 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 Diarroal Research, Bangladesh (icddr,b) 68 Shadeed Tajudding Ahemd Soroni, Mohakhali, Dhaka	16-04-2019
09	An Open label, Randomized, Clinical trial of two regiments 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 Tajudding ahemd 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 Lijposome (Auromedics Pharma LLC, USA)	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)	02-07-2019

	in Visceral Leishmaniasis Patients under fed	68 Shadeed Tajudding Ahemd 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 LTR192/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 Toxine LTR192/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 Participants with Guillain Barre Syndrome.	Prof. Dr. Quazi Deen Mohammad External Principal Investigator of ANX005-GBS-01 Professor, Neurology and Director National Institute of Neurosciences and Hospital (NINS) Sher-e-Bangla Nagar, Dhaka-1207. And Dr. Zhahirul 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 COID-19, a randomized 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 Shadeed Tajuddin Ahmed Soroni, Mohakhali, Dhaka	01-06-2020

15	Effectiveness of calcium channel blockade for organophosphorus and carbamate pesticide poisoning and open pragmatic, 3ar, 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 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. Zhahirul Islam Principal Investigator and scientist Laboratory Sciences and Service Division, icddr,b 68 Shadeed Tajuddin Ahmed Soroni, Mohakhali, Dhaka	29-07-2020
17	An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care (WHO Public health emergency SOLIDARITY TRIAL or 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 Assess 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 (adixa) 40mg 0.4 ml of Incepta	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

	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.		
21	An international randomized trial of additional treatments for COVID-19 in hospitalized 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
22	Efficacy & demonstration of Intravenous Iron for Anemia in Pregnancy version V.1.0 date 07.12.21	Dr. Jena Derakhshani Hamadani Emeritus Scientist Material & Child Health Division, icddr,b	19-02-2023
23	A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adult $\geq$ 60 Years of Age version V.1.3 date 23.06.22	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	19-02-2023
24	A phase 3 study to evaluate Zimberelimab (AB122) Monotherapy Compared to Standard Chemotherapy or Zimberelimab Combined with AB154 in Front-Line, PD-LI-Positive, Locally Advanced or Metastatic Non-Small Cell Lung Cancer Version 2.0 dated 23.02.2023	Dr. Zahirul Islam, PhD Principal Investigator (icddr,b) ARC-10 study Scientist, Laboratory Science and Services Division icddr,b.	12.06.23
25	A Phase 2. Randomized. Observer-Blind. Controlled. Age De-escalation. Dosage Escalation Study to Assess the Safety and Immunogenicity of a Novel Live Attenuated Type I Oral Poliovirus Vaccine in Healthy Young Children. Infants. and Neonates in Bangladesh, Version V.1.1 dated 24.01.2023	Dr. K Zaman MBBS,MPH, PHD FRCP Edin Principle investigator and senior scientist infectious Diseases Division	19-02-23

26	Multi –country, Multi-center, open labelled, Randomized controlled, extended phase clinical trial to evaluate the immunogenicity and tolerability of Sabin strain inactivated poliovirus vaccine Administered with or without routine infant vaccine.	Dr. Wasif Ali khan Scientist and PI Infectious Diseases Division icddr,b wakhan@icddrb.org	30.4.23
27	Effectiveness of calcium channel blockade for organophosphorus and carbamate pesticide poisoning an open, pragmatic 3 arm randomized controlled trial repurposing two widely available licensed medicines.	Professor Md. Abul Faiz, Principal Investigator, Toxicology society of Bangladesh of Dev Care Foundation. House 83, Flat: A1, Road 12/A, Dhanmondi, R/A, Dhaka	06.06.2023
28	An open label, balanced, single Centre two, period, two-treatment, , two sequence, randomized, laboratory blind, single oral dose, cross-over bioequivalence study of test product LEVOTHROXINE SODIUM (100*6) mg tablet o Nuvista Pharma L:td,Bangladesh Comparing with reference product ELTROXIN (100*6) mg tablets containing LEVOTHYROXINE Sodium 100mg of GIAXOSMITMCLIWE IN healthy adult Human subjects under fasting condition.	DR. Uttom K Bhowmik Novus Clinical Research Ltd. 1/1/B Paribag, Dhaka 01920512655	03.07.2023
29	A Randomized, Double Blind, Placebo Controlled Phase 3 Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of ANX005 in Subjects with Guillain-Barré Syndrome [Protocol version 3.0; Dated 13 June, 2023]	Dr. Zhahirul Islam Principal Investigator, Senior Scientist, Infectious Diseases Division, icddr,b Mohakhali, Dhaka 1212	03.08.2023
30	Multi –country, Multi-center, open labelled, Randomized controlled, extended phase clinical trial to evaluate the immunogenicity and tolerability of Sabin strain inactivated poliovirus vaccine Administered with or without routine infant vaccine. Version 1.5 dated 06, Aug2023	Dr. Wasif Ali khan scientist and PI infectious Diseases Division icddr,b wakhan@icddrb.org. 01730093257	21.08.2023

31	Early clinical development of live attenuated combination vaccine against shigella and ETEC diarrhea version 1.0 pated 19 July 2023	DR. Rubhan Raqib Principle Investigator Senior Scientist(Emeritus),infectious Diseases Division icddr,b <a href="mailto:rubhana@icddr.org">rubhana@icddr.org</a> 01713040942	21.08.2023
32	A phase 2, Randomized observer Blind controlled, Age –De-escalation , Dosage escalation study to assess the safety and immunogenicity of a Novel Live Attenuated Type 1 oral poliomyelitis vaccine in healthy young children infants and neonates in Bangladesh.	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	10.09.2023
33	“A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adult $\geq$ 60 Years of Age”	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	11.09.2023
34	"A Phase 2. Randomized. Observer-Blind. Controlled. Age De-escalation" Dosage Escalation Study to Assess the Safety and Immunogenicity of a Novel Live Attenuated Type I oral Poliomyelitis vaccine in Healthy young children. infants. and Neonates in Bangladesh".	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	15.11.2023
35	A Phase IV open-label, randomized, parallel-group study to evaluate pharyngeal immunity to poliovirus type-2 in healthy bOPV-versus IPV-vaccinated infants."	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	16.01.2024
36	“A Phase ½ Randomized, Observer-Blind, Active-Controlled, Age De-escalation, Dose Combination Ranging Study to Assess the Safety and Immunogenicity of Co-administered Novel Live Attenuated Trivalent Oral Poliomyelitis Vaccine in Healthy Adults, Young Children and Neonates and Co-administered Novel Live Attenuated Monovalent Oral poliomyelitis Vaccines 1 and 2 in Neonates in Bangladesh.”	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	25.03.2024

37	“ A Multi –country, Multi-center, open labelled, Randomized controlled, extended phase clinical trial to evaluate the immunogenicity and tolerability of Sabin strain inactivated poliovirus vaccine Administered with or without routine infant vaccines.”	Dr. wasif Ali khan scientist and PI infectious Diseases Division icddr,b wakhan@icddr.org. 01730093257	12.06.2024
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