

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Aushad Bhavan
Mohakhali, Dhaka-1212, Bangladesh

List of Protocol Amendment approval

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
1.	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
2.	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
3.	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. 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
4.	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
5.	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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
6.	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. Zhahirul Islam 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
7.	Assessing the impact of a vopolsaccharide 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
8.	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 Entrotoxigenic 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
9.	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 and 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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
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) 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 Research, Bangladesh (icddr,b) 68 Shadeed Tajudding Ahemd Soroni, Mohakhali, Dhaka	02-07-2019
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

SL	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
14.	Ivermectin and doxycycline in combination or ivermectin alone for the treatment of adult Bangladeshi Patients hospitalized for COVID-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 and 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. Zahirul 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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
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 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
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,D haka-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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
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 Principal 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@icddr.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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
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@icddr.org. 01730093257	21.08.2023
31.	Early clinical development of live attenuated combination vaccine against shigella and ETEC diarrhea version 1.0 dated 19 July 2023	DR. Rubhan Raqib Principle Investigator Senior Scientist(Emeritus),infectious Diseases Division icddr,b rubhana@icddr.org 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 ≥ 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

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
36.	"A Randomized, Double-blind, Parallel, Active controlled study (non-inferiority Trial) to compare the Efficacy and Safety between Ranibizumab 10mg/ml Injection of Incepta Pharmaceuticals Ltd. and Lucentis (Ranibizumab 10mg/ml) of Novartis in patients with Diabetic Macular Edema (DME) by intravitreal injection."	Dr. Niaz Abdur Rahman Principal Investigator and Managing Director Bangladesh Eye Hospital and Institute 78 Satmasjid Road, Dhanmondi, Dhaka	29.01.2024
37.	"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
38.	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	25.03.2024
39.	The WHO Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns (ACTION) Trials ACTIONS III: A multi-country, multi-center, three arm, parallel group, double blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in hospitals in low resource countries to improve newborn outcomes.	1) Prof. Dr. Mohammad Shahidullah, Professor, Neonatology Department, Bangabandhu Sheikh Mujib Medical University (BSMMU) 2) Prof. Dr. Saleha Begum Chowdhury, Professor, Department of Obstetrics and Gynecology.	09.05.2024

SL No	Name of the Protocol	Principal Investigator Name with Institute	Amendment Approval Date
40.	Early clinical development of live attenuated combination vaccine against shigella and ETEC diarrhea.	DR. Rubhan Raqib Principle Investigator Senior Scientist(Emeritus),infectious Diseases Division icddr,b rubhana@icddr.org 01713040942	09.05.2024
41.	“ 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
42.	“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 1.5, date 13june 2024]	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	11.08.2024
43.	An Observer-blind, Randomized, Active-controlled, Multi-centric Phase III Study in Infants and Toddlers to assess the Immunogenicity and Safety of SIPL HEXAVALENT (DTwp-HepB-IPV-Hib) Vaccine Containing Reduced Dose IPV in comparison with SIPL HEXASIIIL	Dr. K. Zaman Principal Investigator and Senior Scientist Infectious Diseases Division, icddr,b	15.09.2024
44.	"A Phase 1/2, 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	30.09.2024
45.	A Randomized, Double-Blind Placebo-Controlled, Safety,	Dr. Wasif Ali Khan	29-10-2024

	Tolerability and Pharmacokinetic phase I Study of Escalating Single Doses of VPO-227 in Healthy Volunteers”	Principal Investigator and Emeritus Scientist Infectious Diseases Division, icddr,b	
--	---	--	--