

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

Name of approved protocol:

SI.No	Protocol name	Principal investigator name with Institute	Name of CRO	Date of approval
1.	A phase I/II dose escalation study to evaluate safety, tolerability and immunogenicity of '2-dose primary series' single strain (Hikojima serotype) inactivated Oral Cholera Vaccine formulations (two formulations based on total O1 LPS content), in sequential age descending population of healthy adults and children.	Dr. Firdausi Qadri, Director, Infectious Disease Division icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	8.11.2016
2.	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 Senior scientist IDD,icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	11.01.2017
3.	A phase I randomized, double-blinded, placebo-controlled, dose escalation study to assess the safety ,tolerability and immunogenicity of live attenuated oral shigella WRSS 1 vaccine in Bangladeshi toddlers (12 to 24 months old)	Dr. Rubhana Raqib Senior scientist icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni, Mohakhali ,Dhaka-1212	11.01.2017
4.	A Double blind, randomized, placebo controlled trial of Cytisine, a novel tobacco cessation agent, in order to assess feasibility and	Dr. Rumana Haque ARK foundation	ARK foundation Mirpur DOHS.	21.03.2017

	acceptability of introducing Cytisine along with behavior support (BS) package as tobacco cessation strategies to TB control programme.			
5.	Benefits and Risks of Iron interventions in Children (BRISC): a randomized controlled trial in Rupgonj- rural Bangladesh.	Dr. Jena Derakhshani Hamadani ,Senior scientist , icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	13.04.2017
6.	Phase 1, open-label study to assess the safety of growth hormone releasing peptide 6 (GHRP6), as anti-fibrotic drug, for the treatment of patients with liver cirrhosis in Bangladesh.	Dr. Mamun-Al-Mahtab Associate professor Dept. of Hepatology BSMMU	M/S. Clinical Research Organization Ltd. Clinical site :Farabi General Hospital Road-14(New), House-8/3, Dhanmondi.	24.04.2017
7.	A Comparative, Randomized, Double blind, Single dose, Cross over, Phase I, Pharmacokinetic & Pharmacodynamic (PK/PD) and Safety study of PEG-Filgrastim (Incepta) 6 mg/ 0.6 ml of Incepta Pharmaceuticals Ltd with Neulastim 6 mg/ 0.6ml of Roche in Healthy, Adult, Human Subject by subcutaneous injection''	Dr. Mamun-Al-Mahtab Associate professor Dept. of Hepatology BSMMU	M/S. Clinical Research Organization Ltd. Clinical site: Farabi General Hospital Road-14(New), House-8/3, Dhanmondi.	04.06.2017
8.	A double-blind, randomized controlled trial of the effect of vaccine inoculum on oral rotavirus vaccine (Rotarix, GlaxoSmithKline) take and immunogenicity in Dhaka, Bangladesh''-A phase II study.	Dr. Rashidul Haque Senior Scientist icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	04.06.2017

9.	An Open Label, Pilot ,Randomized, Laboratory Blind, Single Dose ,Two Period, Two Treatment, Two Sequence, Two-Way Crossover, Comparative Oral Bioavailability Study of Test Product Minocycline Hydrochloride Tablets USP,100 mg of Beximco Pharmaceuticals Limited ,Bangladesh With Reference Product Minocycline Hydrochloride Tablets USP,100 mg (Minocycline Hydrochloride Tablets USP,100 mg) of Par Pharmaceutical Companies Inc. Spring Valley, NY 10977 In Healthy Adult human Subjects Under Fasting Conditions.	Dr. Kazi Reshad Agaz Principal Investigator BeximcoBioequivalence Center,290 Sonargaon Road, Dhaka-1205 Bangladesh.	M/S. Beximco Bioequivalence Center. Clinical site: Padma General Hospital 290 sonargaon road,Dhaka	23.08.17
10.	An Open Label, Pilot ,Randomized, Laboratory Blind, Single Dose ,Two Period, Two Treatment, Two Sequence, Two-Way Crossover, Comparative Oral Bioavailability Study of Test Product Olmesertan Medoxomil Tablets USP,40 mg of Beximco Pharmaceuticals Limited ,Bangladesh With Reference Product Olmetec 40 mg Tablets (Olmesertan Medoxomil Tablets USP,40 mg) which is supplied in Australia by :Merck sharp & Dohme (Australia) Pty. Limited ® Registered Trademark of Daiichi sankyo company Ltd, in healthy adult human subjects under fasting conditions.	Dr. Kazi Reshad Agaz Principal Investigator Beximco Bioequivalence Center 290 Sonargaon Road, Dhaka-1205 Bangladesh.	M/S. Beximco Bioequivalence Center. Clinical site: Padma General Hospital 290 sonargaon road,Dhaka	23.08.2017
11.	A randomized observer-blinded controlled non-inferiority trial to evaluate the immunogenicity of locally manufactured Meningococcal ACWY vaccine ‘Ingovax ACWY’ in Bangladeshi healthy adults.	Dr. Mohiul Islam Chowdhury Scientist and Principal Investigator ,Enteric and Respiratory Unit Infectious Diseases Division (IDD) icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23.08.2017

12.	Increasing influenza vaccine immunization coverage for pregnant women and children: A study of hospital-based epidemiological surveillance for influenza among pregnant women and newborns and assessment of serological effectiveness, safety and acceptability of inactivated influenza vaccine in rural and urban Bangladesh.	Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD) icddr, b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23.08.2017
13.	Duration of priming and antibody decay with full-dose inactivated poliovirus vaccine (IPV) administered with or without bivalent oral poliovirus vaccine (bOPV)"	Dr. K Zaman Senior Scientist and Principal Investigator Polio study Infectious Diseases Division (IDD) icddr, b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23.08.2017
14.	A Phase 1/ 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 Principal Investigator Prof. of Neurology and Director, National Institute of Neurosciences and Hospital(NINS) Shere-e-Bangla Nagar, Dhaka-1207 and Dr. Zahirul Islam Principal Investigator (icddr,b.) Associate Scientist, Laboratory Science and Services Division, icddr,b.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23.10.17
15.	An Open label, Randomized, Clinical* Trial of Two Regimens to Assess the Safety and Efficacy for Treatment of PKDL Patients in the Indian subcontinent	Dr. Dinesh Mondal MBBS, MD, PhD Senior Scientist Principal Investigator	International Centre for Diarrhoeal Disease Research, Bangladesh	23.10.17

		Nutrition and Clinical Services Division NCSD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka	(icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	
16.	A multi-country, 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)"	Dr. Mohammad Shahidullah Principal Investigator and Professor, Department of Neonatology Bangabandhu Sheikh Mujib Medical University (BSMMU) Dhaka	Projahnmo Research Foundation Administrative Office: Flat-5D,House no-37,Road no-27,BlockA Banani,Dhaka-1213 Hospital/Research site: Centre for Woman and Child Health (CWCH),Ashulia, Dhaka-1349	13.11.17
17.	Determination of booster dose effect trivalent inactivate influenza vaccine following primary vaccination with live attenuated influenza vaccine in children.	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine study Infectious Diseases Division (IDD), icddr.b. 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka 1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.12.17
18.	APhase3,Randomized,Observer Blind, Placebo Controlled, Group-Sequential, Study to Determine the Immunogenicity and Safety of a Respiratory Syncytial Virus (RSV) F Nanoparticle Vaccine with Aluminum in Healthy Third-trimester Pregnant Women; and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in their Infants.	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine study Infectious Diseases Division (IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.12.17

19.	Assessing the appropriate dose and efficacy of bovine lactoferrin to correct iron deficiency anaemia in pregnancy: a series of community-based randomized controlled trials in Mirpur, Dhaka	Dr. Mohammad Masudur Rahman ,Research protocol#PR15116 ,Principal Investigator and Senior Research Investigator, Centre for Child and Adolescent Health icddr,b.68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka 1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.01.18
20.	Assessing the impact of a Vi-Polysaccharide Conjugate Vaccine in preventing typhoid infection among Bangladeshi children – a Phase IV trial	Dr. Firdausi Qadri, Director, Infectious Disease Division icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.02.18
21.	Study on the immunogenicity of Oral Polio Vaccine (OPV) and Oral Cholera Vaccine (OCV) when co-administered (PR# 17120)	Dr. Firdausi Qadri, Principal Investigator Director, Infectious Disease Division icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.02.18
22.	Bioequivalence study of glyburide and metformin hydrochloride tablets usp (2.5 mg / 500 mg)	Dr. Kazi Reshad Agaz Principal Investigator Beximco Bioequivalence Center 290 Sonargaon Road, Dhaka-1205 Bangladesh.	M/S. Beximco Bioequivalence Center. Clinical site: Padma General Hospital 290 sonargaon road, Dhaka	18.02.18

23.	Investigation of innate immune responses to <i>Salmonella</i> Typhi in typhoid fever in children and adults patients and vaccinees in Dhaka, Bangladesh.	Dr. Md Saruar Bhuiyan Principal Investigator Post-Doctoral Fellow, Enteric and Respiratory Unit, Infectious Diseases Division, icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	16.04.18
24.	Micronutrient Supplementation Before and During 1st Pregnancy to Improve Birth Outcomes (JiVitA-5)	Professor Keith P. west Jr., Dr. P.H. Principal Investigator JiVitA Maternal & Child Health Research Project GodownRoad, Gaibandha, Bangladesh	M/S. Beximco Bioequivalence Center. Clinical site: Padma General Hospital 290 sonargaon road, Dhaka	17.05.18
25	A Phase 1 Double-Blinded, Placebo-Controlled, Dose Escalation Study to Evaluate the Safety and Immunogenicity of Double Mutant Heat-Labile Toxin LTR192G/L211A (dmLT) from Enterotoxigenic <i>Escherichia coli</i> (ETEC) by Oral, Sublingual, or Intradermal Vaccination in Adults Residing in an Endemic Area	Dr. Firdausi Qadri Principal Investigator Director, Infectious Diseases Division, Senior Scientist and Head Immunology Unit, icddr,b;	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	04.07.18
26	A randomized observer-blinded non inferiority trial to evaluate the immunogenicity and safety of locally manufactured Hepatitis B Vaccine 'Hepa B' in Bangladeshi healthy adults (PR#18020)	Dr. Fahima Chowdhury Principal Investigator icddr,b;	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	04.07.18
27	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 3)	Dr. Shamim Hayder Talukder Principal Investigator Eminence associates for social	Eminence associates for social development (CRO) 3/6Asad Avenue, Mohammadpur,	04.07.18

		development (CRO)3/6 Asad Avenue, Mohammadpur, Dhaka-1207, Bangladesh	Dhaka-1207 Bangladesh	
28	A Multi-Center, Open-Label, Randomized, Two treatment, Parallel, Single period, Multiple-Dose, Steady state, Global Bioequivalence study of Amphotericin B Liposome (Auromedics Pharma LLC, USA) in Visceral Leishmaniasis patients under fed condition	Dr. Dinesh Mondal Principal Investigator & Senior Scientist Protocol number:PR17116 Nutrition and Clinical Services Division, icddr 68 Shaheed Tajuddin Ahamed Sarani Mohakhali, Dhaka-1212, Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	29.07.2018
29	Evaluation of TaqMan Array Card for environmental Surveillance of Polio Virus and antimicrobial Resistance genes”.	Dr. Rashidul Haque MBBS, Phd. Senior Scientist, icddr,b, 68 Shaheed Tajuddin Ahamed Sarani Mohakhali, Dhaka-1212, Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	14.10.2018
30	Randomized, Double-Blinded, Active Controlled, phase I/II Clinical trial to assess the immunogenicity, Safety, and tolerability of NBP615 Vaccine in healthy female participants aged 19 to 26 years and adolescent aged 9 to 13 years”	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine study Infectious Diseases Division (IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	14.10.2018
31	Intestinal and Humoral Immunity of monovalent oral poliovirus Vaccine type 1 (mOPV1) when administered with and without fractional	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine study Infectious	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68	14.10.2018

	inactivated poliovirus vaccine (fIPV)	Diseases Division (IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	
32	Mucosal associated Invariant T (MAIT) cells in Vibrio Cholera infection and vaccination	Dr.Toufiqur Rahman Bhuiyan Scientist Principal Investigator of research protocol# PR-18012 Enteric and Respiratory Infections Infectious Diseases Division (IDD),icddr,b Mohakhali, Dhaka-1212, Bangladesh.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	5.3.19
33	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 88, Flat A1, Road 12/A, Dhanmondi, R/A, Dhaka	Dev. Care Foundation House 88, Flat A1, Road 12/A, Dhanmondi, R/A, Dhaka	14.08.2019
34	Novel triple-dose tuberculosis retreatment (TriDoRe) regimens : how to overcome resistance without creating more:”	Dr. Aung Kya Maug 106, Damien Foundation supported IB Clinics and hospitals apartment# 201, House #10, Road # 96, Gulshan-2, Dhaka-1212	106, Damien Foundation supported IB Clinics and hospitals apartment# 201, House #10, Road # 96, Gulshan-2, Dhaka-121	14.08.2019
35	Immunogenicity of intramuscular (IM) and intradermal (ID) Inactivated Poliovirus Vaccine (IPV) in routine immunization-Phase (IV) Clinical Trial.	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine	International Centre for Diarrhoeal Disease Research, Bangladesh	14.10.19

		study Infectious Diseases Division (IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	(icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	
36	A randomized, Open Phase I/II to evaluate the inactivated enterovirus type 71 Vaccine Safety in healthy adults followed by safety and immunogenicity administered in two consecutive doses one month apart among children aged 6 to 71 months.	Wasif Ali Khan Scientist Infectious Diseases Division (IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	14.10.19
37	Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor (in low- and middle-income countries): a randomized controlled trial	Dr.Rashidul Haque Principle Investigator icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	03.10.2019
38	A Phase 1b Study to Evaluate the Safety, Tolerability and Drug-Drug Interactions of ANX005 and Intravenous Immunoglobulin (IVIg) in Subjects with Guillain-Barré Syndrome	1)Prof. Dr. Quazi Deen Mohammad Principal Investigator Prof. of Neurology and Director, National Institute of Neurosciences and Hospital(NINS) Shere-e-Bangla Nagar, Dhaka-1207 and Dr. Zhahirul Islam Principal Investigator (icddr,b.) Associate Scientist, Laboratory Science and Services Division, icddr,b. 2)Dr.Zhahirul	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	04.12.2019

		Islam, PhD Principal Investigator of research protocol PR-19087, Laboratory sciences and services division, icddr, b		
39	Effect of influenza vaccination on recurrent cardiovascular events among Myocardial Infarction (MI) patients in Bangladesh: A multicounty, randomized clinical trial	Dr. Zubair Akhtar Senior Research Investigator Principal Investigator of research protocol# PR-19005 Infectious Diseases Division (IDD), icddr, b Mohakhali, Dhaka-1212, Bangladesh.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr, b).68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	27.01.2020
40	Development of an effective treatment of Cryptosporidiosis in Bangladeshi Children	Dr. Zannatun Noor, PhD Assistant Scientist and Principal Investigator of research protocol# PR-19079 Emerging Infections and Parasitology Laboratory Infectious Diseases Division (IDD), icddr, b Mohakhali, Dhaka-1212, Bangladesh.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr, b).68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	27.01.2020
41	A Phase II clinical trial to evaluate the safety and immunogenicity of novel oral polio type 2 vaccine candidate in healthy newborns in Bangladesh	Dr. K Zaman Principal Investigator and Senior Scientist, Polio study, Infectious Diseases Division	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr, b).68 Shaheed tajuddin	05.05.2020

		(IDD), icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka-1212	ahmed soroni Mohakhali ,Dhaka-1212	
42	Study on safety and efficacy of Favipiravir (Favipira) on COVID-19 patient in selected hospitals of Bangladesh	Professor Ahmedul Kabir Principal Investigator Favipiravir Clinical Trial Department of Medicine Dhaka Medical College and Hospital	Dhaka Medical College and Hospital 100 Romna,Central shaeed minar area ,Bakshibazar Dhaka 1000	07.05.2020
43	Hydroxy chloroquine and Azithromycin 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, Icddr,b Mohakhali, Dhaka, Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	11.05.2020

Sl. No.	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
44.	Evaluation of GR COVID-19 Rapid Antibody Dot Test and GR COVID-19 Rapid Antigen Dot Test for detection of SARS-COV-2	Professor Dr. Shahina Tabassum, Department of Virology, BSMMU	M/S Bangabandhu Sheik Mujib Medical University (BSMMU) Shahabag Dhaka-1000.	16-05-2020
45.	Performance evaluation of Real Detect™ COVID -19 RT-PCR Kit for the detection of SARS-COV-2 virus.	Professor Dr. Rosy Sultana Head, Department of Immunology, Bangladesh University of Health Sciences.	Institute for developing science and health initiatives (ideSHi)	20-05-2020
47.	An international randomized trial of additional treatments for COVID-19 in hospitalized patients who are all receiving the local standard of care.	Professor Dr. Meerjady Sabrina Flora (MBBS, MPH, PhD). Director, IEDCR & NIC, MoHFW, Mohakhali, Dhaka-1212.	Sponsor of this trial is WHO and Ministry of Health and Family Welfare. This trial is conducted by DGHS and IEDCR on the purpose of Covid-19 without DGDA approved CRO.	19-08-2020
48.	The safety and efficacy outcome of Ivermectin plus Doxycycline in treatment of RT-PCR positive adult mild Covid-19 cases: a randomized double blind placebo controlled trail	Professor Md Tarek Alam Department of Medicine Bangladesh Medical College & Hospital	This trial is conducted by Bangladesh Medical College & Hospital on the purpose of Covid-19 without DGDA approved CRO.	26-08-2020
49.	A randomized, double-blind placebo-controlled trial to evaluate the safety and efficacy of a SARS-COV-2 inactivated vaccine among healthcare workers in Bangladesh.	Dr. K Zaman MBBS, MPH, PhD, FrCP Ed icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	27-08-2020
50.	A randomized, double-blind placebo-controlled phase2/3 study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of ANX005 in subjects with Guillain Barre Syndrome	1. Professor Dr. Quazi Deen Mohammad National Institute of Neuroscience and Hospital (NINS), Dhaka. 2. Zahirul Islam Laboratory Science and services Division, icddr,b. 3. Prof. Dr. Khan Abul Kalam Azad Dhaka Medical College Hospital.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	01/11/2020

Sl. No.	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
51.	Immunogenicity of novel monovalent oral poliovirus vaccine type 2 (nOPV2) with and without bivalent OPV	Dr. K Zaman Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	1/11/2020
52.	A multicentre phase III double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of VPM1002 in the prevention of tuberculous (TB) recurrence in pulmonary TB patients after successful TB treatment.	Dr. K Zaman Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	1/11/2020
53.	Comparative efficacy and performance evaluation trial of ventilator manufactured in Bangladesh (WPB-560) in patients who require mechanical ventilation support.	Proffesor. Dr. Uttam Kumar Barua Department of Respiratory Medicine , Shaheed Suhrawardi Medical College, Dhaka	Clinical Research Organization Ltd.	1/11/2020
54.	“A Phase II Evaluation of the Safety and protective Efficacy of a single Dose of the live Attenuated Tetravalent dengue Vaccine Tetra Vax-DV TV005 to Protect against infection with Live Recombinant DENV-2 (rDEN230-7169) attenuated Strain in a Dengue Endemic Population in South Asia”.	Dr. Rashidul Haque Emeritus Scientist, Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	01/11/2020
55.	“An effectiveness trial (Phase IV) to evaluate protection of children and pregnant women by influenza vaccine in rural Bangladesh”.	Dr. K Zaman Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	01/11/2020
56.	“A Phase III, Randomized, Observer-blind, Multicenter Study to Evaluate the Efficacy, Immunogenicity and Safety of Seqirus’ Cell-Based Quadrivalent Subunit Influenza virus Vaccine (QIVc) compared to a non-Influenza Vaccine when Administrated in Healthy Subjects aged 6 months through 47 months”	Dr. K Zaman Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	01/11/2020
57.	“Bioequivalence study of test product Esomeprazole Magnesium 40 mg Tablet (MUPS) of Beximco Pharmaceuticals Limited,	Dr. Kazi Reshad Agaz Novus Clinical Research Services Limited, 1/1/B,	Novas Clinical Research Services Ltd. (NCRSL),	02/12/2020

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	Bangladesh with reference product Nexium (Esomeprazole Magnesium) 40 mg tablet (MUPS) of Astrazenca GmbH, Germany in health adult human Subjects under fasting conditions”.	Paribagh, Dhaka-1000		
58.	“Bioequivalence study of test product Telmisartan USP 40 mg Tablet of Beximco Pharmaceuticals Limited, Bangladesh with reference product Micardis 40 mg (Telmisartan USP 40 mg) tablet of Boehringer Ingelheim Pharma GmbH & co. KG, Ingelheim an Rhein Germany for Boehringer Ingelheim International GmbH Ingelheim am Rhein Germany in Health adult human subjects under fasting conditions”.	Prof. Abdullah Al Shafi Majumder Novus Clinical Research Services Limited, 1/1/B, Paribagh, Dhaka-1000	Novas Clinical Research Services Ltd. (NCRSL).	02/12/2020
59.	“Performance evaluation of Afeabl Viral RNA extraction kit and afeabl Covid-19 real time RT-PCR kit for detection of severe Acute Respiratory Syndrome Coronavirus 2”	Mr. A.B.M Jamaluddin Chief Operating Officer AFC Agro Biotech Ltd., House#87-89, Road#4, Block# B, Niketon, Gulshan-1, Dhaka-1212	Institute for developing science and health initiatives (ideSHi).	15/12/2020
60..	“Bioequivalence study of Olaparib tablets 2 x 150 mg of Cadila Healthcare Ltd., India and LYNPARZA (Olaparib) Tablets 2x 150 mg of AstraZeneca Pharmaceuticals LP, in 16 female ovarian cancer and metastatic breast cancer patients under fed conditions”.	Dr. Kamrun Nahar Liza Deputy Asst. Director (Medical Services) Ahsania Mission Cancer and General Hospital (Uttara), Dhaka.	Bangladesh Clinical Trail Limited (BCTL)	23/12/2021
61.	“Clinical Trial to compare the efficacy and safety of a multiple amino-acid based ORS “VS002A” with the standard WHO-ORS in the management of non-cholera acute watery diarrhea in infants and young children”.	Dr. Tahmeed ahmed, MBBS, Phd, Principal Investigator and Senior Director, Nutrition and Clinical Services Division, icddr.b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	03/01/2021

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62.	“A Multi-center, open label, randomized parallel controlled evaluation on the efficacy and safety of BDB-001 injection in the treatment of progressive severe COVID-19 in Phase II/III”.	Dr. Rashidul Haque Principal Investigator and Emeritus Scientist, Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	06/01/2021
63.	“A double-blind randomized, controlled, non-inferiority trial to evaluate the immunogenicity and safety of new Rabies Vaccine ‘Rabix-VC’ on Bangladesh healthy adults”.	Dr. Taufiqur Rahman Bhuiyan Principal Investigator of Research Protocol# PR-20117 Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	12/01/2021
64.	“Performance evaluation of GR COVID-19 rapid dot blot IgG antibody kit and GR COVID-19 ELISA IgG kit with other EUA-certified kits for detection of antibodies against COVID-19”.	Rubhana Raqib, Phd, Principal Investigator and Senior Scientist, Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	02/02/2021
65.	“A Phase 3 Randomized, Active-Comparator Controlled, Open-Label Trial to Evaluate the Immunogenicity and Safety of Alternate Two-Dose Regimens of a Bivalent Human Papillomavirus (HPV) Vaccine 9Cecolin) Compared to a Licensed Quadrivalent HPV Vaccine (Gardasil) in Healthy 9-14 Year-Old Girls in Low and Low-Middle Income Countries”.	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division (IDD), icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	02/02/2021
66.	“Pancreatic Enzymes and Bile Acids: A Non-Antibiotic approach to Treat intestinal Dysbiosis in Acutely III Severely Malnourished Children”.	Dr. Mohammad Jobayer Chisti Principal Investigator and Senior Scientist, Nutrition and Clinical Services Division, icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	15/03/2021

Sl. No.	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
67.	“A Prospective, Randomized, Double, Active controlled study to compare PK & Safety of biosimilar Adalimumab (Advixa) 40 mg/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, M.Phil Principal Investigator and Assistant Scientist, Institute for Developing Science & Health Initiatives.	Institute for developing science and health initiatives (ideSHi)	01/06/2021
68.	“Optimizing place of treatment and antibiotic regimens for young infants presenting with signs of possible serious bacterial infection”	Professor Dr. Mohammad Shahidullah, Principal Investigator and Chair Department of Neonatology. BSMMU, Dhaka.	Projahnmo Research Foundation	30/05/2021
69.	“A randomized, double-blinded, active controlled, single dosing, crossover clinical trial to investigate the pharmacokinetics, pharmacodynamics and safety of GBP0002 and Eprex ^R after subcutaneous administration in healthy adult volunteers”	Professor Dr. Mamun Al Mahtab, Principal Investigator and Chairman, Department of Hepatology, BSMMU, Dhaka.	Clinical Research Organization Ltd.	30/05/2021