

## List of Approved Protocol

Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
01	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 sononi Mohakhali , Dhaka-1212	8.11.2016
02	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 sononi Mohakhali , Dhaka-1212	11.01.2017
03	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 sononi Mohakhali , Dhaka-1212	11.01.2017
04	A Double blind, randomized, placebo-controlled trial of Cystisine, a novel tobacco cessation agent, in order to assess feasibility and acceptability of introducing Cystisine along with behavior support (BS) package as tobacco cessation strategies to TB control programme.	Dr. Rumana Haque ARK foundation	ARK foundation Mirpur DOHS.	21.03.2017
05	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	13.04.2017

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			Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	
06	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
07	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
08	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, IDD, icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	04.06.2017
09	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	Dr. Kazi Reshad Agaz Principal Investigator Beximco Bioequivalence Center, 290 Sonargaon Road,	M/S. Beximco Bioequivalence Center. Clinical site: Padma General Hospital	23.08.17

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	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.	Dhaka-1205, Bangladesh.	290 sonargaon road, Dhaka	
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 OlmesertanMedoxomil Tablets USP,40 mg of Beximco Pharmaceuticals Limited ,Bangladesh With Reference Product Olmetec 40 mg Tablets (OlmesertanMedoxomilTablets 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

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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 GuillainBarre Syndrome.	Prof. Dr. Quazi Deen Mohammad Principal Investigator Prof. of Neurology and Director, National Institute of Neurosciences and 15Hospital (NINS) Shere-e-Bangla Nagar, Dhaka-1 207 and Dr. Zahirul Islam Principal Investigator(icddr,b.) Associate Scientist, Laboratory Science and ServicesDivision,icdd r,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 Nutrition and Clinical Services Division NCSD), icddr,b 68 ShaheedTajuddin Ahmed SaraniMohakhali, Dhaka	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	23.10.17
	A multi-country, multicenter, two-arm, parallel, doubleblind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early and late preterm	Dr. Mohammad Shahidullah Principal Investigator and Professor, Department of	Projahnmo Research Foundation Administrative Office: Flat-	13.11.17

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16	period in hospitals in low resource countries to improve newborn outcomes (ACTION) Trial"	Neonatology Bangabandhu Sheikh Mujib Medical University (BSMMU) Dhaka	5D,House no- 37,Road no- 27,BlockA Banani,Dhaka- 1213 Hospital/Researc h site: Centre for Woman and Child Health (CWCH),Ashuli a,Dhaka-1349	
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. 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka 1212	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	18.12.17
18	A Phase-II, Randomized, Observer Blind, Placebo Controlled, Group-Sequentifil, 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, Dhaka- 1212.	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 #PR-15116, Principal Investigator and Senior Research Investigator, Centre for Child and Adolescent Health	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni	18.01.18

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		icddr,b.68 ShaheedTajuddin Ahmed Sarani Mohakhali, Dhaka 1212	Mohakhali, Dhaka-1212	
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 Shaheedtajuddin ahmedsoroni 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,	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	16.04.18

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		Infectious Diseases Division, icddr,b	68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212	
24	Micronutrient Supplementation Before And During 1 <sup>st</sup> Pregnancy To Improve Birth Outcomes (jiVitA-5)	Professor Keith P. west Jr. Dr. P.H. Principal Investigator JiVitA Maternal & Child Health Research Project Godown Road, Gaibandha, Bangladesh	M/s. Beximco Bioequivalence Centre. 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 Quadri, Principal Investigator Director, Infectious Diseases Division, Senior Scientist and Head Immunology Unit, icddr,b;	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin 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 ShaheedTajuddin 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 development (CRO)3/6 Asad Avenue,	Eminence associates for social development (CRO)3/6 Asad Avenue, Mohammadpur,	04.07.18

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		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,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka- 1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddi n Ahmed soroni, Mohakhali, Dhaka-1212.	29.07.18
29	Evaluation of TaqMan Array Card for environmental Surveillance of Polio Virus and antimicrobial Resistance genes	Dr. Rashidul Haque MBBS, Phd. Senior Scientst, icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka- 1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddi n Ahmed soroni, Mohakhali, Dhaka-1212.	14.10.18
30	Randomized Double-Blinded, Active Controlled 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 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka- 1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddi n Ahmed soroni, Mohakhali, Dhaka-1212.	14.10.18
31	Intestinal and Humoral Immunity of monovalent oral poliovirus Vaccine type 1 (mOPV1) when administered with and without fractional inactivated poliovirus vaccine (fIPV)	Dr. K Zaman Principal Investigator and Senior Scientist, Influenza Vaccine study Infectious Diseases Division (IDD), icddr,b; 68 ShaheedTajuddin	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	14.10.18



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		Ahmed soroni, Mohakhali, Dhaka-1212.	68 ShaheedTajuddin 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; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	05.03.19
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 83, Flat: A1, Road 12/A, Dhanmondi, R/A, Dhaka	Dev. Care Foundation House 88, Flat A1, Road 12/A, Dhanmondi, R/A, Dhaka	14.08.19
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-1212	14.08.19
	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	14.10.19

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35		study Infectious Diseases Division (IDD), icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	Research, Bangladesh (icddr,b). 68 ShaheedTajuddin 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 Disease Division (IDD), icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin 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 MBBS, Phd. Senior Scientist, icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	03.10.19
38	A Phase 1b Study to Evaluate the Safety, tolerability and Drug-Drug Interactions of ANX005 and Intravenous Immunoglobulin (IVIg) ing Subjects with Gullain-Barre 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.  2) Dr. Zhahirul Islam, PhD Principal Investigator of research protocol	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	04.12.19

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		PR-19087, Laboratory Science and Services Division, icddr,b;		
39	Effect of influenza vaccination on recurrent cardiovascular events among Myocardial Infraction (MI) patients in Bangladesh: A multicounty, randomized clinical trial	Dr. Zubair Akhtar Senior Research Investigator Principal Investigator of research protocol #PR19005 Infectious Diseases Division (IDD), icddr,b; Mohakhali, Dhaka- 1212, Bangladesh.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddi n 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 ShaheedTajuddi n 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 (IDD), icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka- 1212.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddi n Ahmed soroni, Mohakhali, Dhaka-1212.	05.05.2020
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	Dhaka Medical College and Hospital, 100 Romna, Central	07.05.2020

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		Medicine, Dhaka Medical College and Hospital	Shaheedminar area, Bakshibazar, Dhaka-1000.	
43	Hydroxy Chloroquine and Azithromycin in combination or ivermectin alone for the treatment of adult Bangladeshi patients hospitalized for COVID-19: a randomized, double-blind, placebo-controlled trial. <span style="color: red;">(This Protocol has been revised and amendment protocol has been approved enlisted in report no-46)</span>	Dr. Wasif Ali Khan Scientist, icddr,b; Mohakhali, Dhaka, bangladesh.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.	11.05.2020
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
46	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
	The safety and efficacy outcome of Ivermectin plus Doxycycline in treatment	Professor Md Tarek Alam	This trial is conducted by	26-08-2020

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47	of RT-PCR positive adult mild Covid-19 cases: a randomized double blind placebo controlled trail	Department of Medicine Bangladesh Medical College & Hospital	Bangladesh Medical College & Hospital on the purpose of Covid-19 without DGDA approved CRO.	
48	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
49	A randomized, double-blind placebo-controlled phase2/3 study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of ANX005 in subjects with GuillainBarre Syndrome	1. Professor Dr. QuaziDeenMohamm od National Institute of Neuroscience and Hospital (NINS), Dhaka. 2. Zahirul Islam Laboratory Science and services Division, icddr,b. 3. Prof. Dr. Khan AbulKalam Azad Dhaka Medical College Hospital.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	01/11/2020
50	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
51	A multicenter phase III double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of VPM1002 in the prevention of tuberculous (TB) recurrence in pulmonnary 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
	Comparative efficacy and performance evaluation trial of ventilator manufactured	Proffesor. Dr. Uttam Kumar Barua	Clinical Research	1/11/2020

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52	in Bangladesh (WPB-560) in patients who require mechanical ventilation support.	Department of Respiratory Medicine , ShaheedSuhrawardi Medical College, Dhaka	Organization Ltd.	
53	“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
54	“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
55	“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
56	“Bioequivalence study of test product Esomeprazole Magnesium 40 mg Tablet (MUPS) of Beximco Pharmaceuticals Limited, Bangladesh with reference product Nexium (Esomeprazole Magnesium) 40 mg tablet (MUPS) of Astrazenca GmbH, Germany in health adult human Subjects under fasting conditions”.	Dr. Kazi Reshad Agaz Novus Clinical Research Services Limited, 1/1/B, Paribagh, Dhaka- 1000	Novus Clinical Research Services Ltd. (NCRSL),	02/12/2020
57	“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	Prof. Abdullah Al Shafi Majumder Novus Clinical Research Services Limited, 1/1/B, Paribagh, Dhaka- 1000	Novus Clinical Research Services Ltd. (NCRSL). 1/1/B, Paribagh, Dhaka-1000	02/12/2020

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	adult human subjects under fasting conditions”.			
58	“ 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
59	“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
60	“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
61	“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
62	“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
63	“Performance evaluation of GR COVID-19 rapid dot blot IgG antibody kit and GR COVID-19 ELISA IgG kit with other EUA-	Rubhana Raqib, Phd, Principal Investigator and Senior Scientist,	International Centre for Diarrhoeal Disease	02/02/2021

## List of Approved Protocol

Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
	certified kits for detection of antibodies against COVID-19".	Infectious Diseases Division (IDD), icddr,b	Research, Bangladesh (icddr,b).	
64	"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 (Cecolin) 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
65	"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
66	"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
67	"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
68	"A randomized, double-blinded, active controlled, single dosing, crossover clinical trial to investigate the pharmacokinetics, pharmacodynamics and safety of GBPD002 and Eprex <sup>R</sup> 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



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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
69	“A randomized, double-blinded, active controlled, single dosing, crossover clinical trial to investigate the pharmacokinetics, pharmacodynamics and safety of GBPD0002 and EprexR 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
70	Safety, Tolerability and effects on the microbiome of neonatal administration of Lactobacillus Plantarum ATCC 202195 with or without fructooligosaccharide for one or seven days; a phase II randomized placebo-controlled trial in Dhaka, Bangladesh.	Dr. Md. Shafiqul Alam Sarkar Principal Investigator and Senior Scientist, Nutrition and clinical Services Division, icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	28.07.2021
71	Bioequivalence study of test product Famotidine 20 mg tablet of Beximco Pharmaceuticals Limited, Bangladesh with Reference of product pepcid 20 (Famotidine 20 mg) Tablet of Valeant Pharmaceuticals North America LLC Bridge water NJ 08807, USA in healthy adult human subjects under fasting conditions.	Dr. Uttom K Bhowmik, MBBS, PhD, Novus Clinical Research Services Limited, 1/1/B, Paribagh, Dhaka- 1000	Novus Clinical Researd services Limited	11.08.21 Received Date (Via E-Mail): 07.06.2021
72	A Phase-III, Randomized double-blind, placebo-controlled multi-country study to demonstrate efficacy of a single dose of unadjuvanted RSV Maternal Vaccine, administrated IM to pregnant woman 18 to 49 year of age, for prevention of RSV associated LRTI in their infants upto 6 months of age.	Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD)icddr, b 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka- 1212 Mobile: 01713047100 E-Mail: kzaman@icddrb.org	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	11.08.21
73	An open label randomized controlled trial to observe the safety & efficacy of biosimilar Filgrastin in chemotherapy induced neutropenic patients (Phase-IV) study for Evaluation.	Prof. Dr. Md Mahbubur Rahman, VC, Sheikh Hasina Medical University, Khulna.		11.08.21
74	Safety & efficacy evaluation of low-cost CPAP device for Hypoxemic COVID-19 Patients: A pilot study.	Dr. Taufic Hasan Al banna, Associate Prof. Dept. of BME, BUET.		11.08.21

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Protocol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
75	Approval of a protocol entitled "A multi - centre randomized controlled non-inferiority trial to compare the efficacy safety & triple artemisinin based combination the rapies versus first-line ACTs + placebo for the treatment of uncomplicated plasmodium falciparaum malaria in Asia.	Professor Md. Abul Faiz, Professor of Medicines (Retired), Former Director General of Health Services, Dhaka, Bangladesh.	M/S Dev Care Foundation. 1501/B, O/R Nizam Road, Mehedibag, Chattogram, Bangladesh.	06.09.2021
76	Effects of Oral Intake of olive leaf Extract on hematological parameters: Phase-I, A Double-blinded Randomized, Placebo-controlled study among young adults in Bangladesh.	Dr. Masud Alam. MDDS, MPH, Division, icddr,b	icddr,b Mohakhali, Dhaka.	12.09.2021
77	Efficacy & safety of Baricitinib in patients with moderate & severe Covid-19 A multicenter randomized double Blind placebo controlled clinical trial in Bangladesh	1) Prof. Dr. Md. Mujibur Rahman, Professor of Medicine, Bangabandhu Sheikh Mujib Medical University, Dhaka. 2) Prof. Dr. Md Titu Miah, Dhaka Medical College Hospital, Dhaka	Dhaka Medical College and Hospital, 100 Romna, Central Shaheed minar area, Bakshi bazar, Dhaka-1000.	12.09.2021
78	The role of the Giant microbiome in shaping immune response to the oral cholera vaccine euvichol.	Dr. Jasmin Akter, Infectious Diseases Division (IDD), icddr,b, Mohakhali, Dhaka-1212.	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	12.09.2021
79	A Phase-III, double blind, randomized active controlled study to evaluate safety and immunogenicity of inactivated adjuvanted. Polio vaccine in comparison with licensed Inactivated Poliovirus vaccines	Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD)icddr, b 68 Shaheed tajuddin ahmed soroni	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni	26.10.2021

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Protocol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
		Mohakhali, Dhaka-1212 Mobile: 01713047100 E-Mail: kzaman@icddr.org	Mohakhali, Dhaka-1212	
80	Tebipenem pivoxil as an alternative to ceftriaxone for clinically non-responding children with shigellosis: a randomized non-inferiority trial.	Dr. Sharika Nuzhat, Assistant Scientist and Principal Investigator, Nutrition and clinical services division, icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	26.10.2021
81	Efficacy & demonstration of Intravenous Iron for Anemia in Pregnancy	Dr. Jena Derakhshani Hamadani Emeritus Scientist Material & Child Health Division, icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	07.12.2021
82	Azithromycin & cefixime combination Verses azithromycin alone for the outpatient treatment of clinically suspected or confirmed uncomplicated Typhoid fever in South Asia: a randomized controlled trial (The ACT South Asia Trial)	Dr. Md. Shabab Hossain, Assistant Scientist, Nutrition & clinical Services Division, icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212	30.12.2021
	The WHO Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns (ACTION) Trials ACTIONS III: A multicountry, multi-center, threearm,	1.Prof. Dr. Mohammad Shahidullah, Professor,	Projahnmo Research Foundation	14-03-2022

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
83	parallel group, doubleblind, 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 lowresource countries to improve newborn outcomes.	Neonatology Department, Bangabandhu Sheikh Mujib Medical University (BSMMU) 2.Prof. Dr. Saleha Begum Chowdhury, Professor, Department of Obstetrics and Gynecology.		
84	Assessing immunogenicity of intramuscular Sabin inactivated poliovirus vaccine and non-inferiority of intradermal fractional inactivated poliovirus vaccine.	Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD) icddr, b 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka1212 Mobile: 01713047100 E-Mail: kzaman@icddrb.org	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	28-03-2022
85	A randomized open label, two way, single dose, crossover study to compare the bioequivalence of AZIMEXTM (Azithromycin 500 mg Tablet; Pfizer, USA) in healthy adult male volunteers.	Dr. Md. Zulfikar Ali, KYA Bio-Research Services, Professor and Head of the Department of Medicine, Khwaja Yunus Ali Medical College and Hospital.	Khwaja Yunus Ali Medical College and Hospital.	04-04-2022
86	Acceptability and Efficacy of Entered (VS001) in Children at Risk for Environmental Enteric Dysfunction in Bangladesh.	Dr. Masud Alam Enteric and Respiratory Infections Programme, Infectious Research Division, icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	11-05-2022

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
87	“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 Disesses Division. icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23-06-2022
88	Bioequivalence Study of test product Empagliflozin 25 mg Tablet of Beximco Pharmaceuticals Limited, Bangladesh with reference product Jardiance 25 mg (Empagliflozin 25 mg) Tablet Boehringer Ingelheim Pharmaceuticals Pty Limited Sydney Australia (Boehringer Ingelheim N.Z. Limited, Auckland) in healthy adult human subjects under fasting conditions.	Prof. Dr. Liaquat Ali, Novus Clinical Research Services Limited, 1/1/B Paribagh, Dhaka-1000.	Novus Clinical Research Services Ltd. (NCRSL). 1/1/B, Paribagh, Dhaka-1000	23-06-2022
89	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.	Dr. Zahirul Islam, PhD Principal Investigator (icddr,b) ARC-10 study Scientist, Laboratory Science and Services Division icddr,b.	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23-06-2022

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
90	A double blinded phase I clinical trial to investigate the safety and immunogenicity of an mRNA-based vaccine (GBPD060) against SARS-CoV-2 in healthy adult volunteers.	Professor. Dr. Mamun Al Mahtab Chairman, Department of Hepatology Bangabandhu Sheikh Mujib Medical University Shahbag, Dhaka-1000	Department of Hepatology Bangabandhu Sheikh Mujib Medical University Shahbag, Dhaka-1000	17-07-2022
91	Methotrexate & Prednisolone Study in Erythema Nodosum Leprosum	Dr samsun nahar Residential Medical officer, Danish Bangladesh Leprosy Mission Hospital	Leprosy Mission International	03-08-2022
92	"Clinical trial to determine and validate the effectiveness of a locally developed diagnostic kit (BCSIR-COVID Kit) for the detection of SARS-CoV-2 infection"	Professor Dr. Md. Aftab Ali Shaikh Principal Investigator & Chairman Bangladesh Council of Scientific and Industri a l Research (BCSIR)	Bangladesh council of scientific and clinical Research (BCSIR)	08-08-2022
	Performance evaluation of BRICM Multiple RT-PCR kit for the detection of SARS-COV-2 infection	Mahmudul Hasan Razu, Scientific officer, Bangladesh Reference institute	Institute for developing science and	03-08-2022

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
93		for chemical Measurements (BCICM) Dr. Qudrat-e-Khuda Road,(Laboratory Road) Dhanmondi , Dhaka- 1205,	health initatives(idestli)	
94	A randomized, Multi-dose three-Treatment active controlled, comparative safety and efficacy study of cyclobenzaprine Nasal spray in subjects with pain due to lower back or Neck muscle spasm associated cute painful musculoskeletal conditions.	Dr. Md. Azizul Haque	M/S Novus clinical Research Services Ltd(NCRSL)	03-08-2022
95	A randomized, control, double blinded, no inferiority trial to evaluate the immunogenicity and safety of typhoid vi conjugated vaccine Typhocon in Bangladeshi healthy population	Incepta	International center for Diarrheal Disease Research Bangladesh(icdd r,b)	03-08-2022
96	An open level, single dose, single treatment, single period, safety and Bioavailability study of Fexofinadine hydrochloride topical lotion 1% in healthy, adult, male human subjects	Dr. Wasif Ali Khan Scientist, Infectious Disease Division, icddr,b; Dhaka	icddr,b	08-08-2022
97	Prevention of Iron Deficiency Anemia post-delivery (Priority Trial): A randomized controlled trial of the global network for women's and children's health research.	Dr. Rashidul Haque,MBBS,P.H.D senior scientist and PI infectious Diseases Division icddr,b 68 Shaheed Tajuddin Ahmed sarani ,mohakhali,Dhaka,12 12, Bangladesh	icddr,b 68 Shaheed Tajuddin Ahmed sarani ,mohakhali,Dha ka,1212,Banglad esh	27.02.2023
98	Bioequivalence study on linagliptin 2.5 mg and metformin 100mg tablet	Pro.Dr Liaquat ali, M/S Novus clinical Research Services Ltd 01708462727 info@Novuscro net	M/S Novus clinical Research Services Ltd1/1/B paribag,Dhaka,b angladesh	24.01.2023
99	Bicquivalence study of Dydrogesterone 10mg tablet	Dr.Nusrat Mahamud M/S Novus clinical Research Services Ltd,1/1/B paribag,Dhaka,Bangl adesh 01708462727	M/S Novus clinical Research Services Ltd,1/1/B paribag, Dhaka, Bangladesh	24.01.2023

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
		info@Novuscro net		
100	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 Senior scientist infectious Diseases Division	icddr,b 68 Shaheed Tajuddin Ahmed sarani , mohakhali, Dhaka,1212, Bangladesh	24.03.2023
101	Stop the transmission of Leprosy the PEP++ Project in Bangladesh.	Abu sufian Chowdhury 01713362720 dr.sufian@tembangla desh.org	The Leprosy Mission international, Bangladesh. House#488A,Ro ad-32, mohakhali, New DOHS ,Dhaka- 1206.	09.01.2023
102	Does additional clofazimine for smear positive multi Bacillary border line and leprometis leprosy cases at high risk of Erythema Nodosum Leprosium reaction improve their prognosis/outcome over 2 years.	Dr.vv pai ,Director, Bombay leprosy project,vidnyanBhaba n11,vv purav marg, sion chunabltti, Mumbai- 400022,india	The Leprosy mission international Bangladesh, House No 32 mohakhali, New DOHS , Dhaka- 1206.	24.01.2023
103	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. 01730093257	icddr,b 68 Shaheed Tajuddin Ahmed sarani ,mohakhali,Dha ka,1212, Bangladesh	02.04.2023
104	Early clinical development of live attenuated combination vaccine against shigella and ETEC diarrhea	DR. Rubhan Raqib Principle Investigator Senior Scientist(Emeritus),in fectious Diseases Division icddr,b <a href="mailto:rubhana@icddrb.org">rubhana@icddrb.org</a> 01713040942	icddr,b 68 Shaheed Tajuddin Ahmed sarani ,mohakhali,Dha ka,1212, Bangladesh	02.04.2023
105	Bioequivalence study of test product dienogest 2mg Tablets of Nuvista pharma lid Bangladesh comparing with reference product visanne containing dienogest 2mg tablets of Bayer pharma Germany in healthy adult human female subjects under fasting conditions	Dr. Nusrat Mahmud MBBS,Ms (Singapore) info@Novuscro.net	M/S Novus clinical Research Services Ltd,1/1/B paribag, Dhaka, Bangladesh 01708462727	12.04.2023



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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
106	A Prospective randomized, double-group Active controlled study to compare PK immunogenic city and safety of trastuzamab (Roche) in Healthy, Adult, Human subjects by intravenous infusion under fasting conditions.	Prof. Dr. Manidranath Roy, PIQ Professor and Head (Biochemistry) United medical college median Avenue Satarkul, Dhaka.	M/S ESKEGEN Limited House NO:66,Road:08, Block:c,Niketon, Gulshan-1,Dhaka- 1212	02.04.2023
107	A phase (III) Randomized Observer blind multicenter study to evaluate the efficacy, immunogenicity & safety of squares cell based quadrivalent subunit influenza virus vaccine (QIVc) compared to a non-influenza vaccine when administered in healthy participants aged 6 months.	Dr. K Zaman Senior scientist infectious Diseases Division mohakhali, Dhaka-1212, Bangladesh. 01713047100	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	16.05.2023
108	Immunogenicity of novel oral poliovirus vaccine type 2 (nOPV2) bivalent oral Poliovirus vaccine (bOPV) & inactivated poliovirus vaccine (IPV) administered with different sequential or combination schedules.	Dr. K Zaman Senior scientist infectious Diseases Division mohakhali, Dhaka-1212, Bangladesh 01713047100	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	16.05.23
109	A Co-administration study of oral cholera vaccine (OCV), Typhoid Conjugate vaccine (TCV), Measles & Rubella (MR) vaccine in Bangladesh.	Dr. Firdausi Qadri Respiratory, Infctious Discases Division icddrb mohakhali, Dhaka-212, Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	16.05.23
110	A Prospective, single-blinded, randomized control, comparative study of allogeneic umbilical cord derived Mesenchymal stem	Dr.Ahmedul kabir	AMG Hospital, Progoti Soroni Badda,Dhaka	16.05.23

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
	calls with standard Treatment for knee osteoarthritis.	AMG Hospital, Progoti Soroni Badda,Dhaka 01713379706	01713379706	
111	Safety & efficacy evaluation of a low cost CPAP device for COVID-19 Patients: A Pilot study	Dr Taufiq Hasan al Banna Associate professor Dept of Biomedical Engineering,BUET,D haka	DMC	16.05.23
112	A 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	Novus Clinical Research Ltd. 1/1/B Paribag,Dhaka 01920512655	16.05.23
113	Ability of the probiotic Vivo mix to improve environmental enteropathy in pregnant women A proof of concept trial in Bangladesh, Pakistan , Senegal & Zambia,	Dr. SM Tafrin Hasan Nutrition & clinical services Division icddr,b mohakhali,Dhaka,12 12, Bangladesh	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali , Dhaka-1212	16.05.23
114.	Bioequivalence clinical study of “test product” tablet TENOBIS 5mg manufactured by Drug International Limited Bangladesh and “Reference product” , tablets ConCOR 5mg manufactured by merck Healthcare KGaA, Germany in healthy Bangladeshi adult Volunteers.	Prof. Dr. Md. Saiful Islam KYAMCH Bio- Research Services Enayetpur Sharif, Chowhali, Sirajgonj	KYAMCH Bio- Research Services Enayetpur Sharif, Chowhali, Sirajgonj	09.08.23
115.	"An open label, randomized, laboratory blind, single dose, two period, two treatment, two sequence, two-way	Dr. Uttom K. Bhoumik Principal Investigator	Novus Clinical Research Service Limited	26.10.2023

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Protoc ol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
	crossover, comparative oral bioavailability study of test product Empagliflozin and Metformin Hydrochloride tablets, 12.5/1000 mg of Beximco Pharmaceuticals Limited, Bangladesh with reference product Synjardy 12.5/1000 mg tablet i.e. Empagliflozin and Metformin Hydrochloride tablets, 12.5/1000 mg of Boehringer Ingelheim International GmbH, Germany in healthy adult human subjects under fed conditions".	Operation Incharge Diagonostic and Molecular Lab Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	1/1/B Paribag, Dhaka.	
116.	"Assessment of a novel fixed-dose combination (fdc) drug VR-AD-1005 for the treatment of acute watery diarrhea in cholera: a phase ii, randomized, placebo-controlled, double-blinded efficacy and safety trial" for your kind evaluation. "	Dr. Protim Sarker Principal Investigator Project coordinator Nutrition Research Division, icddr,b	icddr,b	26.10.2023
117.	"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	icddr,b	26.10.2023
118.	"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	icddr,b	26.10.2023
119.	"A Randomized, Double-blind, Parallel, Active controlled study ( <b>non-inferiority Trial</b> ) to compare the Efficacy and Safety between Ranibizumab 10mg/ml Injection of Incepta Pharmaceuticals Ltd. and Lucentis (Ranibizumab 10mg/ml) of	Dr. Niaz Abdur Rahman Principal Investigator and Managing Director Bangladesh Eye Hospital and Institute	Institute for developing science and health initatives(idestli)	15.11.2023

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	Novartis in patients with Diabetic Macular Edema (DME) by intravitreal injection."	78 Satmasjid Road, Dhanmondi, Dhaka		
120.	"A cluster-randomized, open-label trial to compare the impact of combined Mass Vaccine and Mass Drug administrations, Mass Drug Administration alone, Mass Vaccination alone, and no vaccination or drug administration on Plasmodium falciparum malaria transmission."	Professor Md. Abul Faiz Principal Investigator Professor of Medicine (Retired) Former Director General of Health Services, Dhaka, Bangladesh	Dev Care Foundation	27.11.2023
121.	"An open label, randomized, laboratory blind, single dose, two period, two treatment, two sequence, two-way crossover, comparative oral bioavailability study of test product Montelukast Sodium 10 mg tablet of Beximco Pharmaceuticals Limited, Bangladesh with reference product Singulair 10 (Montelukast Sodium 10 mg) Tablet of Organo Pharma PTY Ltd, Australia, in healthy adult human subjects under fasting conditions."	Dr. Uttom K. Bhoumik Principal Investigator Operation Incharge Diagonostic and Molecular Lab Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	24.01.2024
122.	"Randomized Control Trial of Nitazoxanide for the Treatment of Cryptosporidium Infection in 6-12 months infant in Bangladesh."	Dr. Rashidul Haque Principal Investigator and Senior Scientist Infectious Disease Division icddr,b 68 Shaheed Tajuddin Ahmed Sarani Mohakhali, Dhaka- 1212.	icddr,b	24.01.2024
123.	"An open label, randomized, laboratory blind single dose two period two treatment two sequence, two-way crossover comparative oral bioavailability study of test product Telmisartan and hydrochlorothiazide (hctz) tablet 80/12.5 mg of Beximco Pharmaceuticals Limited, Bangladesh with reference product Micardis plus	Dr. Uttom K. Bhoumik Principal Investigator Operation Incharge Diagonostic and Molecular Lab Novus Clinical Research Service Limited	Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	24.01.2024

## List of Approved Protocol

Protocol SL No	Name of the protocol	Principal Investigator Name with institute	Name of the CRO	Date of Approval
	80/12.5 tablet ie Telmisartan and hydrochlorothiazide (hctz) 80/12.5mg of Boehringer Ingelheim PTY Limited, Sydney, Australia in healthy adult male subjects under fasting conditions."	1/1/B Paribag, Dhaka.		
124.	"An open label randomized laboratory blind single dose, two period, two treatment, two sequence, two - way crossover comparative oral bioavailability study of test product Vonoprazan Fumarate 20 mg tablet of Beximco Pharmaceuticals Limited, Bangladesh with reference product Takecab 20 mg tablet I.E Vonoprazan Fumar 20 mg of Takeda Pharmaceutical Company Limited, Japan in healthy adult human subjects under fasting conditions."	Dr. Uttom K. Bhoumik Principal Investigator Operation Incharge Diagonostic and Molecular Lab Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	Novus Clinical Research Service Limited 1/1/B Paribag, Dhaka.	24.01.2024
125.	"Testing the role of thermal jacket in attaining and maintaining Euthermia among preterm and LBW neonates in clinical settings of Bangladesh."	Anisuddin Ahmed Principal Investigator and Project Coordinator Maternal and Child Health Division icddr,b GPO 128, Dhaka-1000 Mohakhali, Dhaka-1212	icddr,b	24.01.2024
126	"A Randomized, Double-Blind, Placebo-controlled, Single-Ascending-Dose and Multiple-Ascending-Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetics of RNV-166 in Healthy Male Volunteers"	Dr. Md Azizul Haque Principal Investigator Department of Medicine, Rajshahi Medical College Hospital	BCTL	13.03.24