

## List of Approved Protocol

| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                        | Principal Investigator Name with institute                        | Name of the 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 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       |
| 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                                                                                                          | 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       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Principal Investigator Name with institute                                                                                    | Name of the CRO                                                                                                                         | Date of Approval |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------|
|                | Neulastim 6 mg/ 0.6ml of Roche in Healthy, Adult, Human Subject by subcutaneous injection.                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                               |                                                                                                                                         |                  |
| 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<br>Senior Scientist,<br>IDD, icddr,b                                                                       | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>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<br>Principal Investigator<br>Beximco Bioequivalence Center, 290 Sonargaon Road, Dhaka-1205, Bangladesh.  | M/S. Beximco Bioequivalence Center.<br>Clinical site: Padma General Hospital 290 sonargaon road, Dhaka                                  | 23.08.2017       |
| 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<br>Principal Investigator<br>Beximco Bioequivalence Center<br>290 Sonargaon Road, Dhaka-1205 Bangladesh. | M/S. Beximco Bioequivalence Center.<br>Clinical site: Padma General Hospital 290 sonargaon road, Dhaka                                  | 23.08.2017       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                             | Principal Investigator Name with institute                                                                                                                                                                                                                                                         | Name of the CRO                                                                                                                         | Date of Approval |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------|
| 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).<br>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).<br>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).<br>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.                                                                                                                                                          | 1) Prof. Dr. Quazi Deen Mohammad Principal Investigator Prof. of Neurology and Director, National Institute of Neurosciences and 15Hospital (NINS) Shere-e-Bangla Nagar, Dhaka-l 207 and<br>2) Dr. Zhahirul Islam (icddr,b) Associate Scientist, Laboratory Science and Services Division, icddr,b | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 23.10.2017       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                            | Principal Investigator Name with institute                                                                                                                                                                            | Name of the CRO                                                                                                                                                                                                                  | Date of Approval |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| 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<br>MBBS, MD, PhD<br>Senior Scientist<br>Nutrition and<br>Clinical Services<br>Division NCSD),<br>icddr,b                                                                                            | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                       | 23.10.2017       |
| 16.            | 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 period in hospitals in low resource countries to improve newborn outcomes (ACTION) Trial"                                                                     | Dr. Mohammad<br>Shahidullah<br>Professor,<br>Department of<br>Neonatology<br>Bangabandhu<br>Sheikh Mujib<br>Medical University<br>(BSMMU) Dhaka                                                                       | Projahnmo Research<br>Foundation<br>Administrative Office:<br>Flat-5D,House no-<br>37,Road no-27,BlockA<br>Banani,Dhaka-1213<br>Hospital/Research site:<br>Centre for Woman and<br>Child Health<br>(CWCH),Ashulia,Dhak<br>a-1349 | 13.11.2017       |
| 17.            | Determination of booster dose effect trivalent inactivate influenza vaccine following primary vaccination with live attenuated influenza vaccine in children.                                                                                                                                                                                                   | Dr.K Zaman<br>Senior Scientist,<br>Influenza vaccine<br>study Infectious<br>Diseases Division<br>(IDD), icddrb.                                                                                                       | International Centre for<br>Diarrheal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                        | 18.12.2017       |
| 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<br>Principal<br>Investigator and<br>Senior Scientist,<br>Influenza vaccine<br>study Infectious<br>Diseases Division<br>(IDD), icddr,b<br>68 Shaheed<br>Tajuddin Ahmed<br>Sarani Mohakhali,<br>Dhaka-1212. | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                       | 18.12.2017       |
| 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<br>Masudur Rahman,<br>Research protocol<br>#PR-15116,<br>Principal<br>Investigator and<br>Senior Research<br>Investigator,<br>Centre for Child and<br>Adolescent Health                                  | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                       | 18.01.2018       |

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|                |                                                                                                                                                          | icddr,b.68<br>ShaheedTajuddin<br>Ahmed Sarani<br>Mohakhali, Dhaka<br>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,<br>Director, Infectious<br>Disease Division<br>icddr,b                                                                                             | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212 | 18.02.2018       |
| 21.            | Study on the immunogenicity of Oral Polio Vaccine (OPV) and Oral Cholera Vaccine (OCV) when co-administered (PR# 17120)                                  | Dr. Firdausi Qadri,<br>Principal<br>Investigator<br>Director, Infectious<br>Disease Division<br>icddr,b                                                                | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212 | 18.02.2018       |
| 22.            | Bioequivalence study of glyburide and metformin hydrochloride tablets usp (2.5 mg / 500 mg)                                                              | Dr. Kazi Reshad<br>Agaz<br>Principal<br>Investigator<br>Beximco<br>Bioequivalence<br>Center<br>290 Sonargaon<br>Road, Dhaka-1205<br>Bangladesh.                        | M/S. Beximco<br>Bioequivalence Center.<br>Clinical site: Padma<br>General Hospital<br>290 sonargaon road,<br>Dhaka                                         | 18.02.2018       |
| 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<br>Bhuiyan,<br>Principal<br>Investigator,<br>Post-Doctoral<br>Fellow, Enteric and<br>Respiratory Unit,<br>Infectious Diseases<br>Division, icddr,b       | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212 | 16.04.2018       |
| 24.            | Micronutrient Supplementation Before And During 1 <sup>st</sup> Pregnancy To Improve Birth Outcomes (jiVitA-5)                                           | Professor Keith P.<br>west Jr. Dr. P.H.<br>Principal<br>Investigator JiVitA<br>Maternal & Child<br>Health Research<br>Project Godown<br>Road, Gaibandha,<br>Bangladesh | M/s. Beximco<br>Bioequivalence Centre.<br>Clinical site: Padma<br>General Hospital 290<br>sonargaon road, Dhaka                                            | 17.05.2018       |
| 25.            | A Phase 1 Double-Blinded, Placebo-Controlled, Dose Escalation Study to                                                                                   | Dr. Firdausi Quadri,<br>Principal<br>Investigator                                                                                                                      | International Centre for<br>Diarrhoeal Disease                                                                                                             | 04.07.2018       |

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|                | 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               | Director, Infectious Diseases Division, Senior Scientist and Head Immunology Unit, icddr,b;                                                                                                            | Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                             |                  |
| 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<br>Principal Investigator icddr,b;                                                                                                                                                | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 04.07.2018       |
| 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.<br>Principal Investigator<br>Eminence associates for social development (CRO), 3/6Asad Avenue, Mohammadpur, Dhaka-1207.                                                    | Eminence associates for social development (CRO)3/6 Asad Avenue, Mohammadpur, Dhaka-1207, Bangladesh                                    | 04.07.2018       |
| 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.<br>Principal Investigator & Senior Scientist<br>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).<br>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.<br>Senior Scientist, icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                                                   | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 14.10.2018       |
| 30.            | Randomized Double-Blinded, Active Controlled trial to assess the                                                                                                                                                                                        | Dr. K Zaman                                                                                                                                                                                            | International Centre for Diarrhoeal Disease                                                                                             | 14.10.2018       |

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|                | immunogenicity, Safety and tolerability of NBP615 Vaccine in healthy female participants aged 19 to 26 years and adolescent aged 9 to 13 years                                                             | Principal Investigator and Senior Scientist, Influenza Vaccine study Infectious Diseases Division (IDD), icddr,b;                                                                  | Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                             |                  |
| 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<br>Principal Investigator and Senior Scientist, Influenza Vaccine study Infectious Diseases Division (IDD), icddr,b;                                                   | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 14.10.2018       |
| 32.            | Mucosal associated Invariant T (MAIT) cells in Vibrio Cholera infection and vaccination                                                                                                                    | Dr. Toufiquur Rahman Bhuiyan<br>Scientist & Principal Investigator of research protocol #PR-18012 Enteric and Respiratory Infections, Infectious Diseases Division (IDD), icddr,b; | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 05.03.2019       |
| 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,<br>Principal Investigator, Toxicology society of Bangladesh of Dev Care Foundation. House 83, Flat: A1, Road 12/A, Dhanmondi, R/A, Dhaka                  | Dev. Care Foundation<br>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<br>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                    | 14.08.2019       |
| 35.            | Immunogenicity of intramuscular (IM) and intradermal (ID) Inactivated                                                                                                                                      | Dr. K Zaman<br>Principal Investigator and Senior Scientist,                                                                                                                        | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).                                                             | 14.10.2019       |

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|                | Poliovirus Vaccine (IPV) in routine immunization- Phase (IV) Clinical Trial.                                                                                                                                                                   | Influenza Vaccine study Infectious Diseases Division (IDD), icddr,b; 68 ShaheedTajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                                                                                                                                                                   | 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. | Dr. Wasif Ali Khan Scientist, Infectious Disease Division (IDD), icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                                                                                                                                                             | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 14.10.2019       |
| 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 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) 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.<br><br>2) Dr. Zhahirul Islam, PhD Principal Investigator of research protocol PR-19087, Laboratory Science and Services Division, icddr,b; | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 04.12.2019       |
| 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                                                                                                                                                                                                                            | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed Tajuddin Ahmed Soroni,                        | 27.01.2020       |



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|                |                                                                                                                                                                                                                                                                                                                | Infectious Diseases Division (IDD), icddr,b; Mohakhali, Dhaka-1212, Bangladesh.                                                                                                                                                               | Mohakhali , Dhaka-1212                                                                                                                  |                  |
| 40.            | Development of an effective treatment of Cryptosporidiosis in Bangladeshi Children                                                                                                                                                                                                                             | Dr. Zannatun Noor, PhD<br>Assistant Scientist and Principal Investigator of research protocol #PR-19079<br>Emerging Infections and Parasitology Laboratory<br>Infectious Diseases Division (IDD), icddr,b; Mohakhali, Dhaka-1212, Bangladesh. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>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<br>Principal Investigator and Senior Scientist, Polio study, Infectious Diseases Division (IDD), icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                                | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin 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<br>Favipiravir Clinical Trial Department of Medicine, Dhaka Medical College and Hospital                                                                                                       | Dhaka Medical College and Hospital, 100 Romna, Central Shaheedminar 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 randomized, double-blind, placebo-controlled trial.<br>(This Protocol has been revised and amendment protocol has been approved enlisted in report no-46) | Dr. Wasif Ali Khan<br>Scientist, Infectious Disease Division (IDD), icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                                                                         | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 11.05.2020       |

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| 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 <sup>TM</sup> 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       |
| 47.            | 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       |
| 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. QuaziDeenMohammod National Institute of Neuroscience and Hospital (NINS), Dhaka.<br>2. Zhahirul Islam Laboratory Science and services Division, icddr,b.<br>3. Prof. Dr. Khan Abul Kalam Azad Dhaka Medical College Hospital. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).                                                                                             | 01/11/2020       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                   | Principal Investigator Name with institute                                                                            | Name of the CRO                                                             | Date of Approval |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|------------------|
| 50.            | Immunogenicity of novel monovalent oral poliovirus vaccine type 2 (nOPV2) with and without bivalent OPV                                                                                                                                                                                                | Dr. K Zaman<br>Infectious Diseases Division (IDD),<br>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 pulmonary TB patients after successful TB treatment.                                                                     | Dr. K Zaman<br>Infectious Diseases Division (IDD),<br>icddr,b                                                         | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 1/11/2020        |
| 52.            | 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<br>Department of Respiratory Medicine ,<br>Shaheed Suhrawardi Medical College, Dhaka | Clinical Research Organization Ltd.                                         | 1/11/2020        |
| 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<br>Emeritus Scientist,<br>Infectious Diseases Division (IDD),<br>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<br>Infectious Diseases Division (IDD),<br>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<br>Infectious Diseases Division (IDD),<br>icddr,b                                                         | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 01/11/2020       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                             | Principal Investigator Name with institute                                                                                               | Name of the CRO                                                             | Date of Approval |
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| 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<br>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 adult human subjects under fasting conditions”. | Prof. Abdullah Al Shafi Majumder<br>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       |
| 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 Jamaludddin<br>Chief Operating Officer<br>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<br>Deputy Asst. Director (Medical Services)<br>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,<br>Principal Investigator and Senior Director, Nutrition and                                               | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 03/01/2021       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                         | Principal Investigator Name with institute                                                                                          | Name of the CRO                                                             | Date of Approval |
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|                |                                                                                                                                                                                                                                                                                                                                              | Clinical Services Division, icddr.b                                                                                                 |                                                                             |                  |
| 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<br>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<br>Principal Investigator of Research Protocol# PR-20117<br>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-certified kits for detection of antibodies against COVID-19”.                                                                                                                                                            | Rubhana Raqib, Phd,<br>Principal Investigator and Senior Scientist, Infectious Diseases Division (IDD), icddr,b                     | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 02/02/2021       |
| 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<br>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<br>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                                                                                                                                                             | Dr. Zannat Kawser, M.Phil<br>Principal Investigator and Assistant Scientist,                                                        | Institute for developing science and health initiatives (ideSHi)            | 01/06/2021       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                        | Principal Investigator Name with institute                                                                                  | Name of the CRO                                                             | Date of Approval                                      |
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|                | 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”                                                                                                                                       | Institute for Developing Science & Health Initiatives.                                                                      |                                                                             |                                                       |
| 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                                            |
| 69.            | “A randomized, double-blinded, active controlled, single dosing, crossover clinical trial to investigate the pharmacokinetics, pharmacodynamics and safety of GBPD0002 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                                            |
| 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 Research services Limited                                    | 11.08.21<br>Received Date (Via E-Mail):<br>07.06.2021 |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                              | Principal Investigator Name with institute                                                                                                                                               | Name of the CRO                                                                                                                        | Date of Approval |
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| 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<br>Senior Scientist and Principal Investigator<br>Influenza vaccine study Infectious Diseases Division (IDD)icddr, b                                                         | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 11.08.2021       |
| 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.                                                                                                              |                                                                                                                                        | 11.08.2021       |
| 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.                                                                                                                           |                                                                                                                                        | 11.08.2021       |
| 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,<br>Professor of Medicines (Retired),<br>Former Director General of Health Services, Dhaka, Bangladesh.                                                          | M/S Dev Care Foundation.<br>1501/B, O/R Nizam Road, Mehediabag, 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.<br>MDDS, MPH,<br>Division, icddr,b                                                                                                                                       | icddr,b<br>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,<br>Professor of Medicine,<br>Bangabandhu Sheikh Mujib Medical University, Dhaka.<br>2) Prof. Dr. Md Titu Miah,<br>Dhaka Medical College Hospital, Dhaka | Dhaka Medical College and Hospital,<br>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,<br>Infectious Diseases Division (IDD),<br>icddr,b, Mohakhali, Dhaka-1212.                                                                                              | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b).                                                             | 12.09.2021       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                                   | Principal Investigator Name with institute                                                                                                                              | Name of the CRO                                                                                                                     | Date of Approval |
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|                |                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                         | 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                                                            |                  |
| 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                                              | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 26.10.2021       |
| 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       |
| 83.            | The WHO Antenatal Corticosteroids for Improving Outcomes in Preterm Newborns (ACTION) Trials ACTIONS III: A multicountry, multi-center, threearm, 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. | 1.Prof. Dr. Mohammad Shahidullah, Professor, Neonatology Department, Bangabandhu Sheikh Mujib Medical University (BSMMU) 2.Prof. Dr. Saleha Begum Chowdhury, Professor, | Projahnmo Research Foundation                                                                                                       | 14-03-2022       |



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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                 | Principal Investigator Name with institute                                                                                                                                                                                                 | Name of the CRO                                                                                                                        | Date of Approval |
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|                |                                                                                                                                                                                                                                                      | 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<br>Senior Scientist and Principal Investigator<br>Influenza vaccine study Infectious Diseases Division (IDD) icddr, b 68<br>Shaheed tajuddin ahmed soroni<br>Mohakhali, Dhaka1212 Mobile: 01713047100 E-Mail: kzaman@icddr.org | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b).<br>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<br>Enteric and Respiratory Infections Programme, Infectious Research Division, icddr,b                                                                                                                                      | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 11-05-2022       |
| 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<br>Principal Investigator and Senior Scientist, Infectious Disesses Division. icddr,b                                                                                                                                          | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b).<br>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 | Prof. Dr. Liaquat Ali,<br>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       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                         | Principal Investigator Name with institute                                                                                                                                   | Name of the CRO                                                                                                                     | Date of Approval |
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|                | (Boehringer Ingelheim N.Z. Limited, Auckland) in healthy adult human subjects under fasting conditions.                                                                                                                      |                                                                                                                                                                              |                                                                                                                                     |                  |
| 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       |
| 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 Industrial Research (BCSIR)                                        | Bangladesh council of scientific and clinical Research (BCSIR)                                                                      | 08-08-2022       |
| 93.            | Performance evaluation of BRICM Multiple RT-PCR kit for the detection of SARS-COV-2 infection                                                                                                                                | Mahmudul Hasan Razu, Scientific officer, Bangladesh Reference institute for chemical Measurements (BCICM) Dr. Qudrat-e-Khuda Road,(Laboratory Road) Dhanmondi , Dhaka- 1205. | Institute for developing science and health initiatives(idestli)                                                                    | 03-08-2022       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                              | Principal Investigator Name with institute                                                                                                                     | Name of the CRO                                                            | Date of Approval |
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| 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(icddr,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 (IDD), icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                             | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212        | 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,1212, Bangladesh | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212        | 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<br>01708462727<br>info@Novuscro net                                                               | M/S Novus clinical Research Services Ltd, 1/1/B Paribag, Dhaka, Bangladesh | 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,Bangladesh<br>01708462727<br>info@Novuscro net                                  | M/S Novus clinical Research Services Ltd,1/1/B paribag, Dhaka, Bangladesh  | 24.01.2023       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                             | Principal Investigator Name with institute                                                                                                                   | Name of the CRO                                                                                                     | Date of Approval |
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| 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<br>Senior scientist<br>infectious Diseases<br>Division                                                                                           | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                       | 24.03.2023       |
| 101.           | Stop the transmission of Leprosy the PEP++ Project in Bangladesh.                                                                                                                                                                                                | Abu sufian<br>Chowdhury<br>01713362720<br>dr.sufian@tembangl<br>adesh,org                                                                                    | The Leprosy Mission<br>international,<br>Bangladesh.<br>House#488A, Road-32,<br>Mohakhali, New<br>DOHS, Dhaka-1206. | 09.01.2023       |
| 102.           | Does additional clofazimine for smear positive multi Bacillary border line and leprometous leprosy cases at high risk of Erythema Nodosum Leprosus reaction improve their prognosis/outcome over 2 years.                                                        | Dr.vv pai ,Director,<br>Bombay leprosy<br>project,vidnyanBha<br>ban11,vv purav<br>marg, sion<br>chunabltti, Mumbai-<br>400022,india                          | The Leprosy mission<br>international<br>Bangladesh, House No<br>32 Mohakhali, New<br>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<br>Scientist, Infectious<br>Disease Division<br>(IDD), icddr,b; 68<br>Shaheed Tajuddin<br>Ahmed soroni,<br>Mohakhali, Dhaka-<br>1212.     | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                       | 02.04.2023       |
| 104.           | Early clinical development of live attenuated combination vaccine against shigella and ETEC diarrhea                                                                                                                                                             | DR. Rubhan Raqib<br>Principle<br>Investigator Senior<br>Scientist(Emeritus),i<br>nfectious Diseases<br>Division icddr,b<br>rubhana@icddrb.org<br>01713040942 | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                       | 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<br>MBBS,Ms<br>(Singapore)<br>info@Novuscro.net                                                                                             | M/S Novus clinical<br>Research Services<br>Ltd,1/1/B paribag,<br>Dhaka, Bangladesh<br>01708462727                   | 12.04.2023       |

## List of Approved Protocol

| Protocol 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 | 16.05.2023       |
| 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 | 16.05.2023       |
| 110.           | A Prospective, single-blinded, randomized control, comparative study of allogeneic umbilical cord derived Mesenchymal stem calls with standard Treatment for knee osteoarthritis.                                                                                                  | Dr.Ahmedul kabir AMG Hospital, Progoti Soroni Badda,Dhaka 01713379706                                                  | AMG Hospital, Progoti Soroni Badda,Dhaka 01713379706                                                                                 | 16.05.2023       |
| 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, Dhaka                                | DMC                                                                                                                                  | 16.05.2023       |
| 112.           | An open label, balanced, single Centre two, period, two-treatment, , two sequence, randomized, laboratory blind, single oral dose, cross-over                                                                                                                                      | DR. Uttom K Bhowmik Novus Clinical Research Ltd.                                                                       | Novus Clinical Research Ltd. 1/1/B Paribag,Dhaka 01920512655                                                                         | 16.05.2023       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Principal Investigator Name with institute                                                                                                                                | Name of the CRO                                                                                                                         | Date of Approval |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------|
|                | 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.                                                                                                                                                                                                                                        | 1/1/B Paribag,Dhaka 01920512655                                                                                                                                           |                                                                                                                                         |                  |
| 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<br>Nutrition & clinical services Division<br>icddr,b<br>mohakhali,Dhaka,12 12,<br>Bangladesh                                                          | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 16.05.2023       |
| 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<br>KYAMCH Bio-Research Services<br>Enayetpur Sharif, Chowhali, Sirajgonj                                                                       | KYAMCH Bio-Research Services<br>Enayetpur Sharif, Chowhali, Sirajgonj                                                                   | 09.08.2023       |
| 115.           | "An open label, randomized, laboratory blind, single dose, two period, two treatment, two sequence, two-way 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". | Dr. Uttom K. Bhoumik<br>Principal Investigator<br>Operation Incharge<br>Diagonostic and Molecular Lab<br>Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka. | Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka.                                                                        | 26.10.2023       |
| 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<br>Principal Investigator<br>Project coordinator<br>Nutrition Research Division, icddr,b                                                                | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                                                     | 26.10.2023       |
| 117.           | "A Phase IV open-label, randomized, parallel-group study to evaluate                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Dr. K. Zaman                                                                                                                                                              | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni,                                                                                            | 26.10.2023       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                                      | Principal Investigator Name with institute                                                                                                         | Name of the CRO                                                     | Date of Approval |
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|                | pharyngeal immunity to poliovirus type-2 in healthy bOPV- versus IPV-vaccinated infants."                                                                                                                                                                                                                                                                                                                 | Principal Investigator and Senior Scientist Infectious Diseases Division, icddr,b                                                                  | Mohakhali , Dhaka-1212                                              |                  |
| 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<br>Principal Investigator and Senior Scientist Infectious Diseases Division, icddr,b                                                  | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 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 Novartis in patients with Diabetic Macular Edema (DME) by intravitreal injection."                                                                         | Dr. Niaz Abdur Rahman<br>Principal Investigator and Managing Director Bangladesh Eye Hospital and Institute<br>78 Satmasjid Road, Dhanmondi, Dhaka | Institute for developing science and health initiatives(idestli)    | 15.11.2023       |
| 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<br>Principal Investigator Professor of Medicine (Retired) Former Director General of Health Services, Dhaka, Bangladesh    | Dev Care Foundation                                                 | 27.11.2023       |

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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Principal Investigator Name with institute                                                                                                                                | Name of the CRO                                                     | Date of Approval |
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| 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<br>Principal Investigator<br>Operation Incharge<br>Diagonostic and Molecular Lab<br>Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka. | Novus Clinical Research Service Limited<br>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<br>Principal Investigator and Senior Scientist<br>Infectious Disease Division, icddr,b                                                                 | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 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 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." | Dr. Uttom K. Bhoumik<br>Principal Investigator<br>Operation Incharge<br>Diagonostic and Molecular Lab<br>Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka. | Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka.    | 24.01.2024       |
| 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<br>Principal Investigator<br>Operation Incharge<br>Diagonostic and Molecular Lab<br>Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka. | Novus Clinical Research Service Limited<br>1/1/B Paribag, Dhaka.    | 24.01.2024       |



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| Protocol SL No | Name of the protocol                                                                                                                                                                                                                                           | Principal Investigator Name with institute                                                                                                                                             | Name of the CRO                                                           | Date of Approval |
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| 125.           | "Testing the role of thermal jacket in attaining and maintaining Euthermia among preterm and LBW neonates in clinical settings of Bangladesh."                                                                                                                 | Anisuddin Ahmed<br>Principal Investigator and Project Coordinator<br>Maternal and Child Health Division<br>icddr,b GPO 128,<br>Dhaka-1000<br>Mohakhali, Dhaka-1212                     | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-1212 | 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<br>Principal Investigator<br>Department of Medicine, Rajshahi Medical College Hospital                                                                             | BCTL                                                                      | 13.03.2024       |
| 127.           | An Observer-blind, Randomized, Active-controlled, Multi-centric Phase III Study in Infants and Toddlers to assess the Immunogenicity and Safety of SIIPL HEXAVALENT (DTwp-HepB-IPV-Hib) Vaccine Containing Reduced Dose IPV in comparison with SIIPL HEXASIIIL | Dr. K. Zaman<br>Principal Investigator and Senior Scientist<br>Infectious Diseases Division, icddr,b                                                                                   | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-1212 | 30.05.2024       |
| 128.           | Bioequivalence clinical study of "Test product", tablet ROSTATIN 10 mg manufactured by Drug International Limited, Bangladesh and "Reference product", tablet CRESTOR 10mg manufactured by AstraZeneca, UK in healthy Bangladesh adult volunteers."            | Prof. Dr. Md. Saiful Islam<br>Principal Investigator<br>KYAMCH Bio-Research Services<br>Professor and Head (Department of Cardiology)<br>Khwaja Yunus Ali Medical College and Hospital | KYAMCH Bio-Research Services                                              | 30.05.2024       |
| 129.           | A Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability and Pharmacokinetic Study of Escalating Single Doses of VPO-227 in Healthy Volunteers.                                                                                                    | Dr. Wasif Ali Khan<br>Scientist, Infectious Disease Division (IDD), icddr,b; 68 Shaheed Tajuddin Ahmed soroni, Mohakhali, Dhaka-1212.                                                  | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-1212 | 16.07.2024       |

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| Protocol SI Name | Name of the Protocol                                                                                                                                                                                                                                                                                                                  | Principal Investigator Name with institute                                                                                                              | Name of the CRO                                                                  | Date of approval |
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| 130.             | Bioequivalence study of test product Sacubitril 24 mg and Valsartan 26 mg tablet of Beximco Pharmaceuticals Limited, Bangladesh with reference product Entresto 50 mg tablet i.e Sacubitril 24 mg and Valsartan 26 mg of Novartis Pharmaceuticals Australia Pty Ltd/ Europe in healthy adult human subjects under fasting conditions. | Dr. A K M Monwarul Islam, MBBS, FCPS (Medicine), M.D (Cardiology), FACC, FESC, FESC, FASE, FACP, FRCP (Edin). Email: info@novuscro.net                  | Novus Clinical Research Services Limited, 1/1/B Paribag, Dhaka-1000, Bangladesh. | 02.12.2024       |
| 131.             | A Phase 1b, Open-Label, Single-Arm, Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Effect of ANX1502 in Participants with Primary Cold Agglutinin Diseases.                                                                                                                                | Dr. Zhahirul Islam, Principal Investigator and Senior Scientist, icddr,b<br>Phone: 01710957036                                                          | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212              | 02.12.2024       |
| 132.             | A randomized, double-blind, placebo-controlled Phase III clinical trial evaluating the protective efficacy, immunogenicity, and safety of the S. Flexneri-S. Sonnei bivalent conjugate vaccine in infants and children aged 6 months to 5 years in Bangladesh.                                                                        | Dr. Rubhana Raquib Principal Investigator Senior Research Division icddr,b<br>Email: rubhana@icddr.org                                                  | icddr,b Mohakhali Dhaka-1212, Bangladesh                                         | 02.12.2024       |
| 133.             | Efficacy of Eltrombopag & Prednisolone Versus Prednisolone Monotherapy in Newly Diagnosed Immune Thrombocytopenia-A Randomized Control Trial.                                                                                                                                                                                         | Dr Mohammad Monirul Islam, MBBS, FCPS (Hematology), Associate Professor, Department of Hematology & BMT Unit, Dhaka Medical College and Hospital, Dhaka | Dhaka Medical College and Hospital, Dhaka                                        | 02.12.2024       |
| 134.             | Evaluation of typhoid conjugate vaccine (TCV) effectiveness among Bangladeshi children using the test-negative design.                                                                                                                                                                                                                | Dr Farhana Khanam, PI of the study Infection Diseases Diseases Division icddr                                                                           | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212              | 02.12.2024       |

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| Protocol SI Name | Name of the Protocol                                                                                                                                                                                                                                                                                                                                                | Principal Investigator Name with institute                                                                                                                                           | Name of the CRO                                                     | Date of approval |
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| 135.             | Evaluation of serum phosphate following intravenous iron (ferric carboxymaltose) treatment of anaemic pregnant women in their second trimester in Bangladesh (EDIVA-PHASE)                                                                                                                                                                                          | Dr. Jena Derakhshani Hamadani MBBS, DCH, PhD (UK), Emeritus Scientist and Principal Investigator of the Project Maternal and Child Health Division, icddr,b<br>Email: jena@icddr.org | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 02.12.2024       |
| 136.             | Ability of VE818 to reduce enteropathogen colonization and improve environmental enteropathy in pregnant women: a proof of concept and phase II randomized placebo-controlled trial in Bangladesh, Pakistan, Zambia and Burkina Faso.                                                                                                                               | Dr. S.M Tafsir Hasan, Associate Scientist, Nutrition Research Division, icddr,b<br>Phone: 01709651470                                                                                | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 02.12.2024       |
| 137.             | Immunogenicity of different primary immunization schedules with inactivated poliovirus vaccine (IPV) plus pentavalent vaccine (DTwP-HBV-Hib) or with hexavalent vaccine (DTwP-HBV-Hib-IPV).                                                                                                                                                                         | Dr. K Zaman, Principal Investigator and Senior Scientist, wP-Hexavalent Study Infectious Diseases Division                                                                           | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212 | 02.12.2024       |
| 138.             | Sensitivity, specificity, and acceptability of a bedside formate assay as a diagnostic tool in methanol poisoning: prospective observational and randomized studies.                                                                                                                                                                                                | Prof. Aniruddha Ghose Professor, Department of Medicine, Chittagong Medical College and Hospital Chittagong, Bangladesh                                                              | Dev Care Foundation                                                 | 06.02.2025       |
| 139.             | A randomized, double- blinded, balanced, two-treatments, two-periods, two-sequences, single dose, crossover, pharmacokinetics and pharmacodynamics (PK/PD), safety and immunogenicity study of Epoetin (Erythropoietin 4000 IU Injection) for subcutaneous injection manufactured by Incepta Pharmaceuticals Ltd with Eprex 4000 (Epoetin Alfa) injectable solution | Dr. Firdausi Qadri, Principal Investigator Director, Infectious Disease Division icddr,b                                                                                             | Institute for developing science and health initiatives (ideSHi)    | 11.03.2025       |

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|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|------------|
|      | for subcutaneous injection manufactured by Janssen-Cilag Ltd in 56 healthy adult subjects under fasting condition.                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                   |            |
| 140. | A prospective, randomized, parallel, three-arm, open-label, clinical trial to evaluate the immunological non-interference of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s Zydus Lifescience Ltd with Yellow fever vaccine administered to Bangladeshi healthy infants aged 9-12 months. | Dr. Umme Kulsum, Assistant Scientist, Institute for Developing Science and Health Initiatives (ideSHi)                                                                                                                                                                                                                                | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                               | 11.03.2025 |
| 141. | A Phase IIa immunogenicity and safety study of a Nipah virus vaccine, ChAdOx1 NipahB, in healthy volunteers aged 18 to 55 years in Bangladesh.                                                                                                                                                           | Dr. K Zaman Principal Investigator and Senior Scientist, Influenza vaccine Study Infectious Diseases Division (IDD) icddr,b                                                                                                                                                                                                           | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                               | 12.08.2025 |
| 142. | Efficacy of probiotic supplementation in preterm and small for gestational age infants: A multi-center, placebo-controlled, individually-randomized trial (Probiotic in preterm and small for gestational infants, PROPS trial).                                                                         | 1) Dr. Salahuddin Ahmed Executive Director and Scientist, Projahnmo Research Foundation<br>2) Prof. Dr. Mohammad Shahidullah, Senior Scientist and Advisor, Projahnmo Research Foundation<br>3) Prof. Dr. Abdullah H. Baqui Professor, Johns Hopkins University Director, International Center for Maternal and Newborn Health, JHSPH | Projahnmo Research Foundation Administrative Office: Flat-5D, House no-37, Road no-27, Block A Banani, Dhaka-1213 | 06.11.2025 |

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| 143. | Asymptomatic Bacteriuria in Pregnant Individuals in Low- and Middle-Income Countries: The ABLE Study – A Randomized Placebo-Controlled Trial of Treatment of Asymptomatic Bacteriuria on the Incidence of Small Vulnerable Newborns and Stillbirth. | Dr. Rashidul Haque<br>Senior Scientist,<br>Head of<br>Parasitology<br>Laboratory, Enteric<br>and Respiratory<br>Infectious Diseases<br>Division, icddr,b          | International Centre for<br>Diarrhoeal Disease<br>Research, Bangladesh<br>(icddr,b).<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212 | 06.11.2025 |
| 144. | A Phase III, double-blind, randomized, placebo-controlled study to evaluate the mucosal intestinal immunity to poliovirus type-2 of nOPV2 at birth dose in healthy IPV vaccinated infants.                                                          | Dr. K Zaman<br>Principal<br>Investigator and<br>Senior Scientist,<br>Influenza vaccine<br>Study<br>Infectious Diseases<br>Division (IDD)<br>icddr,b               | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                              | 22.02.2026 |
| 145. | Feasibility and effectiveness evaluation of Small Intestinal MicroBiome Aspiration (SIMBA) Capsule Technology in a pilot Study of Environmental Enteric Dysfunction in Bangladesh.                                                                  | Dr Mehjabin Tisha<br>Mahfuz<br>Assistant Scientist<br>Maternal Research<br>Division, icddr,b<br>68 Shaheed<br>Tajuddin Ahmed<br>Soroni, Mohakhali ,<br>Dhaka-1212 | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                              | 22.02.2026 |
| 146. | An Open-Label, Randomized Non-Inferiority Trial Comparing Safety and Immunogenicity of Intradermal versus Intramuscular Administration of Registered Rabies Vaccine Manufactured by Popular Pharmaceuticals PLC in Healthy Bangladeshi Adults.      | Dr. Shomik Maruf<br>Assistant Scientist<br>Nutrition Research<br>Division, (NRD),<br>icddr,b<br>68 Shaheed<br>Tajuddin Ahmed<br>Soroni, Mohakhali ,<br>Dhaka-1212 | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                              | 22.02.2026 |
| 147. | Caffeine for Hypoxic Ischemic Encephalopathy (CHIME Trial): A Randomized Controlled Trial of the Global Network for Women's and Children's Health Research.                                                                                         | Dr. Rashidul Haque<br>Senior Scientist and<br>Head of<br>Parasitology<br>Laboratory, Enteric<br>and Respiratory<br>Infections Diseases<br>Division, icddr,b       | icddr,b<br>68 Shaheed Tajuddin<br>Ahmed Soroni,<br>Mohakhali , Dhaka-<br>1212                                                                              | 22.02.2026 |

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| 148. | Bioequivalence clinical study of "Test product", tablet BETALOC-50 (Metoprolol tartrate 50 mg) manufactured by Drug International Limited, Bangladesh and "Reference product", tablet BETALOC® (Metoprolol tartrate 50 mg) manufactured by AstraZeneca, China in healthy Bangladeshi adult volunteers. | Prof. Dr. Md. Saiful Islam<br>Principal Investigator<br>KYAMCH Bio-Research Services.<br>Enayetpur sharif, Chowhali, Sirajgonj – 6751, Bangladesh | KYAMCH Bio-Research Services.<br>Enayetpur sharif, Chowhali, Sirajgonj – 6751, Bangladesh, Tel: +88075163761- 4 | 22.02.2026 |
| 149. | Randomized, Placebo-controlled, Antibiotic Treatment of Non-Dysentery Shigella Associated Diarrhea in children and feasibility, acceptance of a novel Shigella diagnostic test.                                                                                                                        | Dr. ASG Faruque<br>Emeritus Scientist<br>National Research Division, icddr,b                                                                      | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                             | 22.02.2026 |
| 150. | The BLAAAST Trial: Bangladesh Lung Auscultation AI for Antibiotic Stewardship Randomized Controlled Trial.                                                                                                                                                                                             | Salahuddin Ahmed<br>Executive Director and Scientist<br>Projahnmo Research Foundation, Dhaka                                                      | Projahnmo Research Foundation Dhaka                                                                             | 22.02.2026 |
| 151. | A Phase I/II, Randomized, Double-Blind, Single center, Multi site, Single-Dose Study to Assess the Safety, Tolerability, and Efficacy of <b>Subcutaneous EV25</b> Compared with Placebo and Oseltamivir in Adults with Uncomplicated Influenza Virus Infection.                                        | Mustafizur Rahman, PhD, Senior Director (Acting), Senior Scientist and Head, Virology Laboratory, IDD, icddr,b                                    | icddr, b68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                                | 18.05.2026 |
| 152. | Non-Inferiority Clinical Trial of the Safety and Immunogenicity of the Locally Produced TV003 Dengue Vaccine ( <b>Prodenga, by Incepta Pharmaceuticals Ltd.</b> ) Versus the Butantan-Dengue Vaccine in Dhaka, Bangladesh.                                                                             | Mohammad Shafiul Alam, PhD, Scientist, Emerging Infections & Parasitology Laboratory.                                                             | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                             | 18.05.2026 |
| 153. | Glucagon-like Peptide 2 (GLP-2) in Undernourished Women Improving from Histology-Confirmed Environmental Enteric Dysfunction (EED).                                                                                                                                                                    | Dr. Mustafa Mahfuz, MBBS, MPH, PhD, Scientist Maternal and Child Nutrition Nutrition Research Division, icddr,b                                   | icddr,b<br>68 Shaheed Tajuddin Ahmed Soroni, Mohakhali , Dhaka-1212                                             | 18.05.2026 |

## List of Approved Protocol

|      |                                                                                                                                                                                                                                          |                                                                                                                                                                                                                         |                                         |            |
|------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------|
| 154. | Immunogenicity of a fractional adult dose of the malaria vaccine R12/Matrix-M – A Noninferiority Trial.                                                                                                                                  | Professor Dr. Md. Abul Faiz, FCPS, FRCP, PhD, Professor of Medicine, Former Director General of Health Services, Dhaka, Bangladesh & Chairman, Dev Care Foundation, & President, Toxicology Society of Bangladesh (TSB) | Dev Care Foundation                     | 18.05.2026 |
| 155. | A Randomized, Double Blinded, Three-arm, Parallel Group, Placebo Controlled, 12-week, Phase 2a Study to Evaluate Tolerability, Safety and Pharmacodynamics of RNV-166 Capsules in Male Participants with Early Type 2 Diabetes Mellitus. | Dr. Md Azizul Haque, Principal Investigator, Department of Medicine, Rajshahi Medical College Hospital                                                                                                                  | BCTL Bangladesh Clinical Trial (BCTL)   | 18.05.2026 |
| 156. | An open-label randomised controlled trial comparing novel combination and currently used antibiotic regimens for the empiric treatment of neonatal sepsis with a run-in confirmatory pharmacokinetic phase: NeoSep1.                     | Professor ASM Nawshad Uddin Ahmed, FCPS, FRCP                                                                                                                                                                           | Child Health Research Foundation (CHRF) | 18.05.2026 |