

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

Time extension of Clinical Trial

| SL | Name of the Protocol | Principal Investigator Name with institute | Name of CRO | Time extension approval date | Time Extended Up to |
|----|---|---|--|------------------------------|---------------------|
| 01 | 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 Principal investigator and senior scientist, Polio Study, Infectious disease division icddr,b. 68 Shaheed Tajuddin Ahmed Soroni, Mohakhali, Dhaka-1212, Bangladesh. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 16-10-2018 | 15-10-2019 |
| 02 | 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 Principal Investigator & Senior Scientist, Nutrition and Clinical Services Division (NCS), icddr,b, 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212, Bangladesh. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 16-10-2021 | 15-10-2023 |
| 03 | 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 Principle investigator and senior scientist, HEV Study, Infectious disease division, Icdrr,b, 68, shaheed Tajuddin Ahmed Sarani, Mohakhali, Dkaka-1212, Bangladesh. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 16-10-2018 | 15-10-2020 |
| 04 | A Phase 1/ Phase 2 Study to evaluate the safety, tolerability Efficacy, Pharmacokinetics, and pharmacodynamics of ANX005 in participants with Guillain Barre Syndrome. | Prof. Dr. Quazi Deen Mophammad Principal Investigator (External) of research protocol# PR-17015, Professor of Neurology and Director, National Institute of Neurosciences and Hospital (NINS), Shere-e-Bangla nagar, Dhaka-1207, | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni | 16-10-2018 | 15-10-2020 |

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| | | And Dr. Zhahirul Islam Principal Investigator (icddr,b) ANX005 GBS trial Associate Scientist, Laboratory Science and Services Division, icddr,b, 68 Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212. Bangladesh. | Mohakhali ,Dhaka-1212 | | |
| 05 | 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 Principle investigator and senior scientist, Influenza Vaccine Study, Infectious disease division, icddr,b, 68, shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka-1212, Bangladesh. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 16-10-2018 | 15-10-2020 |
| 06 | A Double blind, randomized, placebo controlled trial of Cytosine, a novel tobacco cessation agent, in order to assess feasibility and acceptability of introducing Cytosine along with behavior support (BS) package as tobacco cessation strategies to TB control programmer. | Dr. Rumana Haque Principal Investigator & Executive Director, ARK Foundation, Flat C4, House-6, Road-109, Gulsan-2, Dhaka-1212. | ARK Foundation, Flat C4, House-6, Road-109, Gulsan-2, Dhaka-1212. <i>(They have notified DGDA that they will take the responsibilities of human subject, if any health hazard occurred due to clinical trial)</i> | 18-11-2018 | 17-11-2019 |
| 07 | A multi-country, multicenter, two-arm, parallel, double blind, placebo-controlled, randomized trial of antenatal corticosteroids for women at risk of imminent birth in the early and late preterm period in hospitals in low resource countries to improve newborn outcomes (ACTION Trial) | Prof. Dr. Mohammed Shahidullah Co-Principal Investigator and Professor, Department of Neonatology, Bangabandhu sheikh Mujib Medical University (BSMMU), Dhaka. | M/S Projahnmo Research Foundation Administrative Office: Flat-5D,House no-37,Road no-27,BlockA Banani,Dhaka-1213 | 18-11-2018 | 17-11-2020 |

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| 08 | A Phase 3, Randomized, Observer Blind, Placebo Controlled, Group-Sequentifil, Virus (RSV) F Nanoparticle Vaccine with Aluminum in Healthy Third-trimester Pregnant Women; and Safety and Efficacy of maternally Transferred Antibodies in Preventing RSV Disease in their Infants. | Dr. K Zaman Principal Investigator & Senior Scientist, Infectious Disease Division, International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 23-12-2018 | 22-12-2019 |
| 09 | Micronutrient Supplementation Before and During 1 st Pregnancy to Improve Birth Outcomes (JiVitA-5). | Professor Keith P. West Jr. Dr. P.H, Principal Investigator, JiVitA Maternal & Child Health Research Project, Godown Road, Gaibandha, Bangladesh. | M/S. Beximco Bioequivalence Center | 15-09-2020 | 30-06-2021 |
| 10 | An Open label, Randomized, Clinical Trial of Two Regimens to assess the Safety and Efficacy for Treatment of PKDL Patients in Indian subcontinent. | Dr. Dinesh Mondal Senior Scientist and Principal Investigator, Nutrition and Clinical Services Division, icddr,b. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 23-05-2021 | 22-05-2022 |
| 11 | A randomized, double-blind placebo-controlled phase2/3 study to evaluate the efficacy, safety, pharmacokinetics and pharmacodynamics of ANX005 in subjects with Guillain Barre Syndrome | 1.Professor Dr. Quazi Deen Mohammad National Institute of Neuroscience and Hospital (NINS), Dhaka. 2.Zhahirul Islam Laboratory Science and services Division, icddr, b. 3.Prof. Dr. Khan Abul Kalam Azad Dhaka Medical College Hospital. | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 04.12.23 | 03.12.24 |
| 12 | “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 | Dr. Rashidul Haque Emeritus Scientist, Infectious Diseases Division (IDD), icddr,b | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 19.10.23 | 18.10.2025 |

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| | (rDEN230-7169) attenuated Strain in a Dengue Endemic Population in South Asia”. | | | | |
| 13 | “An effectiveness trial (Phase IV) to evaluate protection of children and pregnant women by influenza vaccine in rural Bangladesh”. | Dr. K Zaman Infectious Diseases Division (IDD), icddr,b | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 30.07.2023 | 29.07.2024 |
| 14 | “A Phase 3 Randomized, Active-Comparator Controlled, Open-Label Trial to Evaluate the Immunogenicity and Safety of Alternate Two-Dose Regimens of a Bivalent Human Papillomavirus (HPV) Vaccine (Cecolin) Compared to a Licensed Quadrivalent HPV Vaccine (Gardasil) in Healthy 9-14 Year-Old Girls in Low and Low-Middle Income Countries”. | Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division (IDD), icddr,b | International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). | 02.02.23 | 01.02.2025 |
| 15 | A Phase-III, double blind, randomized active controlled study to evaluate safety and immunogenicity of inactivated adjuvanted Polio vaccine in comparison with licensed Inactivated Poliovirus vaccines | Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD)icddr, b 68 Shaheed tajuddin ahmed soroni Mohakhali, Dhaka-1212 Mobile: 01713047100 E-Mail: kzaman@icddrb.org | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212 | 01.11.23 | 31.10.2024 |
| 16 | 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, | International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin | 02.11.2023 | 01.11.2025 |

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