

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 Divion (NCSD), 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, Iccdr,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

SL	Name of the Protocol	Principal Investigator Name with institute	Name of CRO	Time extension approval date	Time Extended Up to
		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

SL	Name of the Protocol	Principal Investigator Name with institute	Name of CRO	Time extension approval date	Time Extended Up to
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

SL	Name of the Protocol	Principal Investigator Name with institute	Name of CRO	Time extension approval date	Time Extended Up to
	(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

SL	Name of the Protocol	Principal Investigator Name with institute	Name of CRO	Time extension approval date	Time Extended Up to
		icddr,b	ahmed soroni Mohakhali ,Dhaka-1212		
17.	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. QuaziDeenMohammad National Institute of Neuroscience and Hospital (NINS), Dhaka. 2.Zhahirul Islam Laboratory Science and services Division, icddr,b. 3. Prof. Dr. Khan AbulKalam Azad Dhaka Medical College Hospital.	International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).	05.12.2023	04.12.2024
18.	A Phase-III, double blind, randomized active controlled study to evaluate safety and immunogenicity of inactivated adjuvanted. Polio vaccine in comparison with licensed Inactivated Poliovirus vaccines.	Dr. K Zaman Senior Scientist and Principal Investigator Influenza vaccine study Infectious Diseases Division (IDD)icddr, b 68 Shaheed tajuddin ahmed soroni	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni	17.12.2023	16.12.2024
19.	“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).	02.02.2024	01.02.2025

SL	Name of the Protocol	Principal Investigator Name with institute	Name of CRO	Time extension approval date	Time Extended Up to
20	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, Department of Obstetrics and Gynecology.	Bangabandhu Sheikh Mujib Medical University (BSMMU)	09.05.2024	08.05.2024
21.	A Phase 2/3, Randomized, Observer-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of mRNA-1345, an mRNA Vaccine Targeting Respiratory Syncytial Virus (RSV), in Adult \geq 60 Years of Age.	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	23.06.2024	22.06.2023
22.	An effectiveness trial (phase iv) to evaluate protection of children and pregnant women by influenza vaccine in rural Bangladesh.	Dr. K Zaman Principal Investigator and Senior Scientist, Infectious Diseases Division. icddr,b	International Centre for Diarrheal Disease Research, Bangladesh (icddr,b). 68 Shaheed tajuddin ahmed soroni Mohakhali ,Dhaka-1212	15.07.2024	14.07.2025