

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, Icddr,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

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