

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

SL	Name of the protocol	Principal Investigator Name with institute	Rejection Date	Reasons
1.	Epidemiological investigation of zoonotic tuberculosis in selected dairy farms of Dhaka and Mymensingh	Dr. Tanzina Begum Rumi Scientist Infectious Diseases Division, icddr,b.	05.03.2019	It is not considered as Clinical Trial.
2.	Evaluation of immunogenicity of a prototype Nipah Virus Vaccine in pigs under fed conditions	Dr. Mustafizur Rahman icddr,b.	DGDA meeting held on 21.10.2020	This is a preclinical study protocol. So this protocol was not recommended for approval by Clinical Trial Advisory Committee.
3.	Assessing acceptability and feasibility of introducing levonorgestrel releasing intrauterine system in the national family planning program of Bangladesh	Dr. Nurun Nahar Begum Line Director, CCSDP, DGFP	15.03.2021	This is not considered as Clinical Trial; this is an acceptability and feasibility trial.
4.	Stool Alkaline Phosphatase Test (STAP test)-A diagnostic test to predict vulnerability to Diabetes	Dr. Madhu.S. Malo IVD Development Pathway	09.01.2023	It does not follow the proper regulatory pathway for protocol submission
5.	A phase 3, randomized, double-blind, placebo-controlled study to evaluate the effect of Bi-26 (strain of Bifidobacterium longum, B ₄ infants) supplementation versus placebo on weight gain in underweight infants	Dr. Sharika Nuzhat Associate Scientist Nutrition Research Division, icddr, b.	07.08.2023	Bi-26 is not a drug; this is a functional food and nutraceutical food. This product is out of DGDA and this protocol has no approval of phase 1 & phase 2 from any drug regulatory authority.