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DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-1						
	Title: Clinical research protocol checklist.					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-CT-005/F01-01	01	Nov'21	Nov' 26		7.12.21	01 of 04

Name of the Assessor: S.M. Sabrina Yesmin Assessment Date: 31.01.2022 to 01.02.2022

Designation: Asst. Director

Title of the Protocol: "Assessing immunogenicity of intramuscular Sabin inactivated polio virus vaccine and non-inferiority of intradermal fractional inactivated poliovirus vaccine."

I. General information:

Sl No.	Checklist	Yes	No	Not Required	Remarks
1.	Application letter for protocol approval	✓			
2.	Name and designation of PI	✓			Prof. Dr. K Zaman
3.	Name and address of Sponsor	✓			
4.	Name and address of CRO	✓			icddr'b
5.	Name and contact information of a specific contact person	✓			Dr. k. Zaman 01713047100

II. Protocol Components:

Sl No	Checklist	Yes	No	Not required	Remarks
1.	Preclinical (non-clinical) study report			✓	Reference submitted
	• Study site and sponsor details		✓		

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	• Safety evaluation study/Toxicological study data (Single dose, repeated dose toxicity, others: carcinogenicity study, local tolerance)		✓		
	• Efficacy Study Data (Pharmacodynamics, Pharmacokinetics and immunogenicity)		✓		
	• Animal species details		✓		
	• Drug information: Investigational drug, control, vehicle		✓		
2.	Phase I/II/III Clinical Trial				
	• Study Title	✓			
	• Protocol version (if any)	1.1 ✓			
	• Protocol summary	✓			
	• Abstract		✓		Not submitted
	• Background and Rationale	✓			
	• Objectives (Primary and secondary objectives)	✓			
	• Hypothesis (if any)	✓			
	• Trial design (Superiority, non-inferiority trial, parallel group, crossover, randomized, double	✓			

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	blind, placebo controlled etc)				
	• End point/outcome	✓			
	• Study setting (eg: academic hospital, community clinic etc), Study period and Study method	✓			
	• Selection of Participants (Eligibility criteria: Inclusion & exclusion criteria, Withdrawal criteria)	✓			
	• Sample Size	✓			
	• Participants timeline (Recruitment, enrollment, visits etc)	✓			
	• Criteria for suspending/terminating the trial	✓			
	• Data collection procedure	✓			
	• Statistical analysis	✓			
3.	Investigator's Brochure (IB)		✓		Not Submitted
4.	Informed Written Consent form	✓			
	• English	✓			
	• Bangla	✓			
5.	Case Record Form	✓			

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6.	Specification of efficacy and safety parameters	✓			
7.	Procedure of assessment of efficacy and safety parameters	✓			
8.	Procedure of management, reporting and follow up of adverse event	✓			
9.	Ethical clearance letter (NREC/RRC/ERC)	✓			
10.	Independent Data Safety Monitoring Board (DSMB) information	✓			
11.	GMP Certificate of Investigational Product		✓		Not submitted
12.	Certificate of analysis of investigational product		✓		Not submitted
13.	GCP training certificate of the investigator(s)	✓			
14.	CV of Principal investigator and Co-Principal investigator	✓			
15.	Funding details of the study	✓			
16.	SOPs of different activities	✓			This CRO is approved by DGDA.
17.	Reference documents	✓			

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Comments of Clinical Trial Advisory Committee:
Meeting Date: 01/02/2022

(1) One ARM need to be included in the protocol – Existing poliovirus vaccine used in EPI need to compair with investigational polio vaccine.
(2) The reasons of switching oral to intramasculer poliovaccine need to be included in the protocol.
(3) This trial needs to be incorporated with EPI program.
(4) To identify the AE one surveillance system need to be incorporated.

Final Comments by DGDA CT Cell head:

To submit IB, CoA of IMP & CMP certificate of IMP

Signature:

01.02.2022

S.M. SABRINA YESMIN
Asssitant Director
Directorate General of Drug Administration
Govt. of the People's Republic of Bangladesh
Dhaka

1/2/22

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

Name of the Assessor: S. M. Sabrina Yesmin
Designation: Assistant Director
Assessment Date: 31.01.2022
Title of the protocol:

"Assessing immunogenicity of intramuscular Sabin inactivated poliovirus vaccine and non-inferiority of intradermal fractional inactivated poliovirus vaccine."

I. General Information:

1. Application Letter for protocol Approval: Received on 03.01.2022.
2. Name and Designation of PI: Dr. K. Zaman, MBBS, MPH, PhD, FRCP Edin, Senior Scientist, Enteric and Respiratory Infections, Infectious Diseases Division.
3. Name and Address of Sponsor: CDC, USA.
4. Name and Adress of CRO: icddr,b, Mohakhali, Dhaka-1212.
5. Name and contact information of a specific contact person: Dr. K. Zaman, MBBS, MPH, PhD, FRCP Edin, Senior Scientist, Enteric and Respiratory Infections, Infectious Diseases Division.
   Email: kzaman@icddrb.org
   Cell # 880 1713047100

II. 1. Protocol Components:

Preclinical (non-clinical) study report: It's a non-inferiority Phase IV clinical Trial. The sponsor/ PI does not submitted any report. In their protocol they have informed that

"Preclinical study using sIPV manufactured by Institute of Medical Biology Chinese Academy of Medical Sciences, Kunming (IMBCAMS) has demonstrated immunogenicity of intradermal route for administration of the vaccine at 1/5 fractional dose".

Ref:

Ma, L., et al., *Analyzed immunogenicity of fractional doses of Sabin-inactivated poliovirus vaccine (sIPV) with intradermal delivery in rats.* Hum Vaccin Immunother, 2016. 12(12): p. 3125-3131.

2. Phase IV Clinical Trial:

- Study Title: "Assessing immunogenicity of intramuscular Sabin inactivated poliovirus vaccine and non-inferiority of intradermal fractional inactivated poliovirus vaccine"
- Protocol version (if any): 1.12
- Protocol Summary:
- Background and Rationale:

By May 2016, Sabin 2 was successfully withdrawn globally from essential immunization programs with replacement of trivalent OPV (tOPV) with bivalent OPV (bOPV). The switch from tOPV to bOPV was preceded by the introduction of inactivated poliovirus vaccine (IPV) in accordance with the Strategic Advisory Group of Experts on Immunization (SAGE) recommendation of at least one dose of IPV at age ≥14 weeks to provide type 2 immunity against paralytic polio. However, the two IPV manufacturers of WHO-prequalified stand-alone IPVs were unable to successfully scale-up production to meet the planned increased in demand. Therefore, 49 countries either delayed introduction of IPV or experienced a stock-out after introduction [1]. During this emergency phase of critical IPV supply constraint, WHO and CDC reviewed available evidence to identify an alternative schedule of two doses of intradermal fractional IPV (fIPV), one-fifth of the volume of intramuscular IPV, administered 2 months apart, instead of one dose of intramuscular IPV.

After OPV cessation, which is expected within a year of polio eradication certification, IPV will be the only polio vaccine used in essential immunization programs. SAGE has recommended a two-dose intramuscular IPV or intradermal fIPV schedule after OPV cessation, which could occur as early as 2023. While it is expected that there shall be sufficient IPV available – in large part because of several manufacturers establishing production of IPV using Sabin strains (sIPV) – it is dependent on these manufacturers being able to meet promised product development and manufacturing timeline and meet WHO prequalification. It is likely that

countries that have introduced intradermal fIPV pre-eradication will continue to use intradermal fIPV post-eradication. Therefore, it is important to generate evidence on immunogenicity of intradermal fractional sIPV in addition to intramuscular sIPV for the schedule recommended by SAGE.

In China, sIPV has been licensed and used in immunization programs in China since 2015 and is manufactured by the Institute of Medical Biology Chinese Academy of Medical Sciences, Kunming (IMBCAMS) and Beijing Bio Institute Biological Products (BBIBP). We will study the immunogenicity of sIPV from both manufacturers for both full and fractional dose delivered at 14 weeks and 9 months. The Sabin antigen content of the two vaccines is different therefore direct comparisons will not be made.

- Abstract: The sponsor/PI does not submit any abstract.
- Objectives:

Primary Objectives:

1. To assess if two doses of intramuscular sIPV at 14 weeks and 9 months of age are immunogenic for poliovirus types 1, 2, and 3, with at least 90% of participants having an immune response.
2. To assess if two doses of fractional intradermal sIPV are non-inferior to two full doses of intramuscular sIPV given at 14 weeks and 9 months of age.

Secondary Objectives:

1. To assess the immune response including priming after a single dose of intramuscular sIPV at 14 weeks of age.
2. To assess if a single dose of fractional intradermal sIPV is non-inferior to a single full dose of intramuscular sIPV at 14 weeks (Arm A vs. B and Arm C vs. D).

- Hypothesis:
    1. Two 2 full doses of sIPV at 14 weeks and 9 months are immunogenic for poliovirus types 1, 2 and 3 with at least 90% of participants having an immune response [Primary objective].
    2. Two doses of fractional (1/5) intradermal dose of sIPV at 14 weeks and 9 months are non-inferior to 2 full doses of sIPV at 14 weeks and 9 months [Primary objective].
    3. A single full dose of sIPV at 14 weeks is immunogenic for poliovirus types 1, 2, and 3 [Secondary objective].

4. A single fractional (1/5) intradermal dose of sIPV at 14 weeks is non-inferior to a single full dose of sIPV at 14 weeks [Secondary objective]

- Trial design (Superiority, non-inferiority trial, parallel group, crossover, randomized, double blind, placebo controlled etc):
  This is a non-inferiority, open label, phase IV, randomized clinical trial.
- End Point/outcome:

To assess if two doses of intramuscular sIPV at 14 weeks and 9 months of age are immunogenic for poliovirus types 1, 2, and 3 with at least 90% of participants having an immune response (Arm A, Arm C; end point 10 months).

To assess if two doses of fraction intradermal sIPV is non-inferior to two full doses of intramuscular sIPV given at 14-weekand 9 months of age (Arm A vs. B and Arm C vs. D; end point 10 months).

- Study setting (eg. academic hospital, community clinic etc): This study will be conducted in Mirpur and Mohakhali area, icddr,b Dhaka.

Study period: 01 December 2021 to 31 March 2023.

Study method:

This is an open label, phase IV, randomized clinical trial. Infants will be enrolled and randomized at 6 weeks of age to one of four arms:

1. IMBCAMS full dose sIPV at 14 weeks and 9 months
2. IMBCAMS fractional dose sIPV at 14 weeks and 9 months
3. BBIBP full dose sIPV at 14 weeks and 9 months
4. BBIBP fractional dose sIPV at 14 weeks and 9 months

Total target enrollment is 1224 with 306 infants per arm.

- Selection of Participants (Eligibility criteria: Inclusion & exclusion criteria, Withdrawal criteria):

Inclusion criteria

1. Healthy infants 6 weeks of age (range: 42-48 days).
2. Parents that consent for participation in the full length of the study (i.e., 34 weeks).
3. Parents that are able to understand and comply with planned study procedures.

Exclusion criteria

1. A diagnosis or suspicion of immunodeficiency disorder either in the infant or in an immediate family member.
2. A diagnosis or suspicion of bleeding disorder that would contraindicate parenteral administration of sIPV or collection of blood by venepuncture.
3. Acute diarrhoea, infection or illness at the time of enrollment (6 weeks of age) that would require infant's admission to a hospital.
4. Acute vomiting and intolerance to liquids within 24 hours before the enrollment visit (6 weeks of age).
5. Evidence of a chronic medical condition identified by a study medical officer during physical exam.
6. Receipt of any polio vaccine (OPV or IPV) before enrollment based upon documentation or parental recall.
7. Known allergy/sensitivity or reaction to polio vaccine, or its contents.
8. Infants from multiple births. Infants from multiple births will be excluded because the infant(s) who is/are not enrolled would likely receive OPV through routine immunization and transmit vaccine poliovirus to the enrolled infant.
9. Infants from premature births (<37 weeks of gestation).

Discontinuation criteria

1. Withdrawal of consent for participation for any reason.
2. Request by parents of participant to terminate all study procedures.
3. Identification of immunodeficiency disorder, bleeding disorder or another medical condition for which continued participation, in the opinion of the principal investigator, would pose a risk to the participant.
4. Receipt of immunosuppressive medications.
5. Receipt of any polio vaccine (OPV or IPV) outside of study after enrollment (as per parent's report). Study activities will not be discontinued if any polio vaccination campaigns are implemented in the study area. Participants who received polio vaccines outside of the study, including any polio vaccine administered in polio campaigns, would be excluded from further study procedures.
6. Allergic reaction to a prior dose of polio vaccine, or its contents.
7. Premature termination of the study.

- Sample size:

  Proposed Sample Size:

  Sub-group (Name of subgroup e.g. Men, Women) and Number

Name	Number	Name	Number
(1) IMBCAMS sIPV	306	(3) BBIPB sIPV	306
(2) IMBCAMS f-sIPV	306	(4) BBIPB f-sIPV	306
		Total sample size	1224

- Participants timeline (Recruitment, enrollment, visits etc):

Study design with study visits

Arm	Manufacturer	Sample Size	Enrollment Target	6 weeks	14 weeks	18 Weeks	9 months	9 months + 7 days	10 months
A	IMBCAMS	275	306	Enrollment	•sIPV	•	•sIPV	•	•
B	IMBCAMS	275	306	Enrollment	•f-sIPV	•	•f-sIPV	•	•
C	BBIBP	275	306	Enrollment	•sIPV	•	•sIPV	•	•
D	BBIBP	275	306	Enrollment	•f-sIPV	•	•f-sIPV	•	•
Total		1100	1224						
• Blood draw									

- Criteria for suspending/terminating the trial: N/A

- Data collection procedure:

Study objective	Study Arms	End point	Serological results included in analysis
Primary			
To assess if two doses of intramuscular sIPV at 14 weeks and 9 months of age are immunogenic for poliovirus types 1, 2, and 3, with at least 90% of participants having an immune response	A C	Seroconversion/boosting A: 10 months C: 10 months	A: 14 week, 18 weeks, 9 months, 10 months C: 14 week, 18 weeks, 9 months, 10 months
To assess if two doses of fractional intradermal sIPV is non-inferior to two full doses of intramuscular sIPV given at 14-weekand 9 months of age.	A vs. B C vs. D	Seroconversion/boosting A and B: 10 months C and D: 10 months	A and B: 14 week, 18 weeks, 9 months, 10 months C and D: 14 week, 18 weeks, 9 months, 10 months
Secondary			
To assess the immune response after a single dose of intramuscular sIPV at 14 weeks of age	A C	Seroconversion A: 18 week C: 18 weeks	A: 14 week, 18 weeks C: 14 week, 18 weeks
		Seroconversion/boosting A: 9 months	A: 14 week, 18 weeks, 9 months

Study objective	Study Arms	End point	Serological results included in analysis
		C: 9 months	C: 14 week, 18 weeks, 9 months
		Priming A: 9 months + 7 days C: 9 months +7 days	A: 14 weeks, 18 weeks, 9 months +7 days C: 14 weeks, 18 weeks, 9 months +7 days
To assess if a single dose of fractional intradermal sIPV is non-inferior to a single full dose of intramuscular sIPV at 14 weeks	A vs. B C vs. D	Seroconversion A and B: 18 weeks C and D: 18 weeks	A and B: 14 week, 18 weeks C and D: 14 week, 18 weeks
		Seroconversion/boosting A and B: 9 months C and D: 9 months	A and B: 14 weeks, 18 weeks, 9 months C and D: 14 weeks, 18 weeks, 9 months
		Priming A and B: 9 months +7 days C and D: 9 months +7 days	A and B: 14 weeks, 18 weeks, 9 months +7 days C and D: 14 weeks, 18 weeks, 9 months +7 days

- Statistical analysis:

This is an open-label phase IV randomized clinical trial that will 1) assess the immunogenicity of two different sIPV formulations given at 14 weeks/9months and 2) compare the immunogenicity of full dose sIPV to fractional sIPV given at 14 weeks/9 months. In addition, we will assess the immunogenicity of a single dose of sIPV given at 14 weeks and compare the immognencity of a full-dose to fractional dose at 14 weeks. The study will recruit 1224 participants in four arms. Participants will be enrolled at 6 weeks of age and followed until 10 months of age for a total follow-up period of 8.5 months.

3.Investigator's Brochure (IB): The sponsor/PI does not submit any Investigator's Brochure (IB).

4. Informed Written Consent form:

English: The sponsor/PI has submitted English Informed Written Consent form.

Bangla: The sponsor/PI has submitted Bangla Informed Written Consent form.

5.Case Record Form:

The sponsor/PI has submitted a hard copy of Case Record Form.

Socio-demographic, physical examination, and clinical information will be recorded on the corresponding electronic case report form (eCRF).

6.Specification of efficacy and safety parameters:

Safety monitoring

Sabin IPV has a strong safety record with no trial reporting any serious adverse events associated with receipt of sIPV. Two studies comparing sIPV to Salk IPV found an increased prevalence of fevers in infants receiving sIPV, especially when receiving high DU antigen content vaccines [7, 8]. A phase III clinical trial that directly compared sIPV to Salk IPV also detected higher prevalence of systemic adverse events (51.5% vs. 44.5%) among infants receiving sIPV and Salk IPV, respectively, but there was no difference in reported serious adverse events [8]. Increased monitoring for fevers and other systemic adverse events (rash, cough, diarrhoea, vomiting, and decreased appetite) immediately following vaccination will be conducted.

All participants will be observed for 30 minutes after vaccination with sIPV to monitor for any immediate adverse reactions to the vaccine including site of injection. Properly skilled medical personnel will be immediately available in the event of an unexpected adverse reaction. However, adrenaline (for anaphylactic reaction) or equipment for endotracheal intubation will not be available at the site considering the safety record and low risk of reaction of the study vaccines. After the 30-minute observation period, the medical officer will record the presence of any potential reaction to the vaccine on the corresponding eCRF. At the end of each study visit, the physician will provide the parents with a phone number to call if they have any questions or if the infant experiences any reactions to the vaccines.

Since sIPV is a new vaccine to be used in Bangladesh and this is the first study to assess intradermal sIPV, as an additional safety monitoring measure, study staff will contact the parents of vaccine recipients to inquire and record any potential adverse events after the two vaccination visit; this will take place 24–48 hours after vaccination.

Should a serious illness occur while the infant is enrolled in the study (requiring a physician's visit or hospitalization), parents will be instructed to seek medical care immediately and to notify study staff as soon as possible. Medical care for study participants will be provided free of charge for expected minor illnesses that develop during the follow up period, such as diarrhea and respiratory infections, as well as any adverse outcomes judged to be possibly, probably or definitely related (detailed below) to study vaccines or vaccination.

8. Procedure of assessment of efficacy and safety parameters:

9. Procedure of management, reporting and follow up of adverse event:

During each study clinic visit, study staff will ask the parents about possible adverse events (AE) experienced by the participant since the previous study visit or telephone inquiry. This information will be recorded on the corresponding eCRF. Reported AE will be recorded in the AE form. The AE form will include a description of the event, time of onset, assessment of severity, relationship to study product, and time of resolution/stabilization of the event.

Reports of AE will be periodically discussed by the team of investigators. The study team will review the potential relationship and classify the relationship into:

- Unable to judge
- Not related
- Probably not related
- Possibly related
- Probably related
- Definitely related

Interpretation of vaccine-relationship to AE will be based on the type of event, the relationship of the event to the time of vaccine administration, the known biology of the vaccine and the investigators' medical judgment. In addition, the investigation team will also report clusters of AE (at least three) to the DSMB periodically for further evaluation.

An AE will be considered a serious AE (SAE) if it meets any of the following criteria:

1. Death during the study period
2. A life-threatening event
3. Hospitalization or prolongation of an existing hospitalization
4. Paralysis or severe disability/incapacity or substantial disruption of the ability to conduct normal functions
5. Anaphylaxis associated with vaccine administration

All SAEs will be notified by the principal investigator to the regulatory agencies, ethical review committees and Data Safety Monitoring Board (DSMB) and CDC within 24 hours of notification. A separate icddr,b SAE form will be completed for SAEs and submitted to the ERC for review.

10. Ethical clearance letter:(NREC/RRC/ERC): RRC approved this protocol on 23 August 2021.

11. Independent Data Safety Monitoring Board (DSMB) information:

    The study will be monitored by a DSMB constituted by icddr,b with input from the Ethical Review Committee (ERC). The DSMB will include representation outside of icddr,b. The DSMB is expected to convene once prior to the start of the study after ethical and regulatory approval of the study protocol. The DSMB will convene meetings near the middle of the study and at study completion. The DSMB will be responsible for establishing study stopping rules. Immunogenicity data will not be available for DSMB meetings because all blood specimens will be analyzed after the completion of the field activities.

12. GMP Certificate of investigational product: The sponsor/PI does not submit any GMP certificate of investigational product.
13. Certificate of analysis of investigational product: The sponsor/PI does not submit any certificate of analysis of investigational product.
14. CV of Principal investigator and co-principal investigator: Submitted.

15. Funding details of the study:

Name of the Project/Protocol:		SABIN IPV					
Budget Period:		1 Year					
Name of the PI:		Dr. K. Zaman					
Particulars		Pay level	Month Rate ($)	# of Staff	% Time	# of Month	Total Cost US$
Personnel:							
	Dr. K. Zaman	Intl	15,625	1	20%	12	40,500
	Dr. Md. Yunus	Intl	13,500	1	8%	12	13,997
	Senior Scientific Officer	NOA/1	1,826	1	20%	12	4,733
	Research Investigator	NOA/4	2,057	1	25%	12	6,665
	Senior Field Research Officer	GS6/1	1,144	1	40%	12	5,930
	Field Research Officer	GS5/1	897	1	80%	12	9,300
	Field Research Supervisor	GS4/1	698	3	100%	12	27,138
	Field Research Assistant	GS3/1	588	3	100%	12	22,861
	Female Field Worker / SW	UGL	292	14	100%	12	52,980
	Medical Officer	NOA/1	1,826	3	100%	12	70,995
	Nurse	GS5/1	1,035	2	100%	12	26,827
	Senior Research Officer (Lab)	GS6/2	1,206	1	25%	12	3,907
	Research Officer (Lab)	GS5/1	932	1	50%	12	6,039
	Analyst Programmer	NOB/2	2,364	1	25%	12	7,659
	Senior Data Management Officer	GS6/1	1,119	1	25%	12	3,626
	Senior Data Management Assistant	GS4/1	698	2	50%	12	9,046
	Asst. Coordination Manager	NOA/4	2,057	1	25%	12	6,665
	Assistant Programme Manager	NOA/4	2,057	1	25%	12	6,665
	Sr. Field Attendant	GS2/1	507	2	100%	12	13,141
	Field Attendant	GS1/1	451	3	100%	12	17,535
	Subtotal						356,211
Travel and Perdiem			$ Rate		No.		
	Local Transport including hiring vehicle	bulk					13,000
	ICDDR,B Transport		$ 950	per week			7,000
	Perdiem and Lodging		$ 50	per day			3,000
	International Travel with perdiem		$ 3,000	per trip			6,000
	Subtotal						29,000
Supplies:			$ Rate		No.		
Supplies - stock/nonstock:							
	Office Supplies Stock/Non Stock						5,000
	Specimen collection supplies	Bulk					-
	Lab reagents and supplies	Bulk					10,000
	Liquid Nitrogen Supplies	Bulk					-
	Dry ice for specimen transport	Bulk					-
	Office maintenance, cleaning and general supplies	bulk					-
Supplies capital:							
	Name of the items	unit	rate	Qty.	Total		
	Laptop/Docking Computer with all Accessories		2,000	1	2,000		
	Refrigerator		2,000	1	2,000		
	Air Conditioner		2,000	2	4,000		
			Capital supplies:				8,000
	Subtotal						23,000
Others			$ Rate		No.		
	Staff Development Training (Int. and local)						5,000
	Workshop / Seminar (Int. and local)						10,000
	CCD Admin staff development, training and workshop						-
	Other services, Stipend / Labor charge						-
	Communication(Fax, Phone bill, Courier, postage etc.)						8,000
	Shipment and Int. Courier						8,000
	Office set up, Rent, Utilities, Repairs & Maintenance		1200		-		12,000
	RSC (RA, OC, Grant contracts, Library, comms. And others)				1		2,000
	Printing and photocopy	Bulk					4,000
	Lab test/Interdepartmental Cost						8,300
	Miscellaneous						7,765
	Infrastructure Services, security in support to CCD	bulk					-
	Subtotal						65,265
Total direct cost							473,476
Total Indirect cost							140,523
	PEI Admin Cost						52,082
	Icddr,b support cost: (15%+4%)						88,440
Total Budget:							613,999

16. SOP of different activities: N/A

17. Reference documents: Submitted.

Observations:

1. The sponsor/PI has mentioned that this is a phase IV study and a non-inferiority, open label, randomized clinical trial. But it should be a phase III clinical trial.
2. The sponsor/PI does not submit any abstract.
3. The sponsor/PI does not submit any Investigator's Brochure (IB).
4. The sponsor/PI does not submit any certificate of analysis of investigational product.
5. The sponsor/PI does not submit any GMP certificate of investigational product.

31.01.2022

S.M. SABRINA YESMIN
Asssitant Director
Directorate General of Drug Administration
of the People's Republic of Bangladesh
Dhaka