

CLINICAL STUDY AGREEMENT

among

Syneos Health UK Limited
and

Dr Vijay Raghunath Kalrao
and

Bharati Vidyapeeth (Deemed To Be University) Medical College and Hospital

Pfizer Protocol # C3591025

This Clinical Study Agreement (“Agreement”) among

Syneos Health UK Limited, with a place of business at Farnborough Business Park, 1 Pinehurst Road, Farnborough, Hampshire GU14 7BF United Kingdom and its clinical affiliates including but not limited to **inVentiv International Pharma Services Private Ltd.** Located at 3rd Floor, Tower A, The Presidency Towers, 46/4, MG Road, Sector – 14, Gurgaon – 122001, India (“CRO”)

and

Dr Vijay Raghunath Kalrao, with a place of business at Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, Department of Pediatrics Pune-Satara Road, Dhankawadi, Katraj, Pune-411043, Maharashtra, India
(“Principal Investigator”),

Pfizer 1012152/18PFZ0017 C3591025 IND Tri Partite CSA
[**Dr Vijay Raghunath Kalrao**] [Bharati Vidyapeeth (Deemed to be University)
Medical College & Hospital Pune] [Site #1069]

Confidential

and

Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, with a place of business at Pune-Satara Road, Dhankawadi, Katraj, Pune-411043, Maharashtra, India ("**Institution**"),

when signed by all parties, is effective as of 01 Jun 2020.

Pfizer Inc. ("Pfizer") wishes to sponsor a clinical study trial/entitled "A PHASE 1, OPEN-LABEL, SINGLE-DOSE STUDY TO ASSESS THE PHARMACOKINETICS, SAFETY AND TOLERABILITY OF CEFTAZIDIME-AVIBACTAM (CAS-AVI) IN CHILDREN FROM 3 MONTHS TO LESS THAN 18 YEARS OF AGE WHO ARE HOSPITALIZED AND RECEIVING SYSTEMIC ANTIBIOTIC THERAPY FOR SUSPECTED OR CONFIRMED NOSOCOMIAL PNEUMONIA, INCLUDING VENTILATOR-ASSOCIATED PNEUMONIA" ("**Study**") to be conducted by Principal Investigator at Institution under the Pfizer protocol identified above ("**Protocol**"). Pfizer has delegated responsibility for management of this Study, including contracting and Study monitoring, to CRO, and has authorized CRO to bind Pfizer to all commitments within this Agreement identified as belonging to Pfizer.

The Principal Investigator as a signatory/confirming party to this Agreement acknowledges the liabilities and obligations as an 'investigator' under the provisions of the New Drugs and Clinical Trials Rules, 2019 ("**Rules**"). The parties agree as follows:

1. Responsibilities

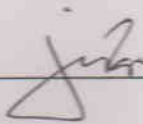
1.1 Investigators and Research Staff. The Study will be conducted by Principal Investigator, namely **Dr Vijay Raghunath Kalrao** ("**Principal Investigator**") at a facility that is identified as a 'clinical trial site' under the Rules. Principal Investigator is not an employee of Institution. Principal Investigator is authorized by Institution to conduct the Study at Institution under a separate agreement between Principal Investigator and Institution. Principal Investigator will ensure that only individuals who are appropriately trained, experienced and qualified assist in the conduct of the Study as investigators, sub-investigators or research staff. The Principal Investigator shall sign an undertaking in the form prescribed in **Table 4** of the **Third Schedule** of the Rules.


1.2 Compliance Obligations. Principal Investigator and Institution are responsible to CRO and Pfizer for compliance by all Study personnel with the terms of this Agreement, the Protocol, the applicable provisions of the Drugs and Cosmetics Act, 1940 ("**Act**"), the Rules, and International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research, as well as applicable law, regulations, and governmental guidance, including without limitation, the laws of the Republic of India. The Institution and CRO shall be jointly responsible for obtaining requisite permissions and approvals for the conduct of the Study in terms of applicable laws, including permission from the Central Licensing Authority. The Institution also undertakes to abide by and

Agreed to and Accepted by:

Syenos Health UK Limited

Dr Vijay Raghunath Kalrao






Date: 23 JUL 2020

Printed Name: John Michael Dominic Go

Title: Associate Director, Site Start Up & Regulatory

Date: 20 JUL 2020

Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital


PRINCIPAL
Bharati Vidyapeeth
(Deemed to be University)
Medical College
Printed Name : (Brng.) Dr Narayanan Subramanian Mani
Pune - 411 043.

Title: Principal, Bharati Vidyapeeth (DTU) Medical College & Hospital

Date: 28 July 2020

Attachments

Attachment A	Study Budget and Payment Terms
Attachment B	Indemnification and Research Injury Policy
Attachment C	Equipment and Materials
Attachment D	Pfizer International Anti-Bribery and Anti-Corruption Principles

Pfizer 1012858/18PFZ0017 C3591025 IND Tri Partite CSA
[Dr Vijay Raghunath Kalrao] [Bharati Vidyapeeth (Deemed to be University)
Medical College & Hospital Pune] [Site #1069]

Confidential

Exhibit 1 to Attachment A Study Budget

COMMITTEE		INVESTIGATOR									
STUDY NUMBER :	1012858/18PFZ0017	Dr. Vijay Raghunath Kalrao	Bharati Vidyapeeth Medical College and Hospital								
TITLE :	ANALYSIS OF CLINICAL, BIOLOGICAL, AND TOXICOLOGICAL DATA OF C3591025 IND TRI PARTITE CSA FROM 3 MONTHS TO LESS THAN 18 YEARS OF AGE WITH AND WITHOUT ADVERSE AND PRECIPITATING FACTORS ASSOCIATED WITH THE TREATMENT FOR SUBJECTS TO THE COMMITTEE	Dr. Vijay Raghunath Kalrao	Bharati Vidyapeeth Medical College and Hospital								
COUNTRY/CURRENCY :	INDIA - INR										
OVERHEAD	20.00%										
DESCRIPTION OF COST		Comments	COST	Frequency of Procedure	Total PSC	Total Vial	Screening Day -1 to 1	Baseline IV Infusion Day 1	48 Hour Assessment Day 2	48 Hour Assessment Day 3	Late Follow Up Day 28-35 Telephone Contact
Per Subject Cost	Informed Consent	Informed	3,741.48	1.0	3741.48	3741.48	1.00	0.00	0.00	0.00	0.00
	Physical Examination	Physical Examination	3,741.48	2.0	7482.96	7482.96	1.00	0.00	0.00	0.00	0.00
	Hematology	Hematology	584.82	1.0	584.82	584.82	0.00	0.00	0.00	0.00	0.00
	Blood Chemistry	Blood Chemistry	1,271.10	1.0	1271.10	1271.10	0.00	0.00	0.00	0.00	0.00
	Urine Analysis	Urine Analysis	276.16	1.0	276.16	276.16	0.00	0.00	0.00	0.00	0.00
	CAZ-AVI Administration	Administration should be via either an appropriately sized sterile syringe and calibrated syringe pump or IV infusion line and subcutaneous IV pump	4,562.00	1.0	4562.00	4562.00	0.00	1.00	4,562.00	0.00	0.00
CAZ-AVI preparation	Preparation of CAZ-AVI	1,630.02	1.0	1630.02	1630.02	0.00	1.00	1,630.02	0.00	0.00	
Study Coordinator (hourly)		Weight, BMI if applicable, Vital Signs, Oxygen Saturation (if available), Adverse Events and Serious Adverse Event, Adjunctive Therapeutic Intervention, Concomitant Medication Check, Prior/Concomitant Treatment, Obtain Results of Chest x-ray, CT Scan or other imaging Tests	1,777.26	0.5	11552.19	11552.19	3.00	5,331.78	1.00	1,777.26	0.50
	Admin Data Entry		1,609.42	4.0	6397.68	6397.68	2.00	3,198.84	0.50	799.71	0.50
		PSC Subtotal without Overhead	37,791.29				16,009.02	9,095.09	2,576.97	8,447.97	1,698.34
		PSC Subtotal with Overhead	45,340.56				19,210.82	10,892.79	3,092.36	10,137.56	2,026.01
Additional Treatment Related Costs	Additional Procedures that may not apply to all Patients				Total Potential PSC		Screening Day -1 to 1	Baseline IV Infusion Day 1	48 Hour Assessment Day 2	48 Hour Assessment Day 3	Late Follow Up Day 28-35 Telephone Contact
	Informed Consent	Informed Assent. Separate consent and assent must be obtained for collection of BAL fluid for CAZ-AVI analysis	2,269.74	1.0	2269.74	2269.74	0.00	1.00	2,269.74	0.00	0.00
	Hematology	Applicable at Screening if subject is not improving and lab assessments were performed and hours prior to screening	584.82	1.0	584.82	584.82	0.00	0.00	0.00	0.00	0.00
	Blood Chemistry	Applicable at Screening if subject is not improving and lab assessments were performed and hours prior to screening	1,271.10	1.0	1271.10	1271.10	0.00	0.00	0.00	0.00	0.00
	Urine Analysis	Applicable at Screening if subject is not improving and lab assessments were performed and hours prior to screening	276.16	1.0	276.16	276.16	0.00	0.00	0.00	0.00	0.00
	Sample Collection	At PK draws are applicable only 1 PK draw after CAZ-AVI infusion may be performed and hours prior to screening	737.58	1.0	737.58	737.58	0.00	1.00	737.58	0.00	0.00
	PK Samples Cohort 1	At PK draws are applicable only 1 PK draw after CAZ-AVI infusion may be performed and hours prior to screening	737.58	7.0	5163.06	5163.06	0.00	7.00	5,163.06	0.00	0.00
	PK Samples Cohort 2	At PK draws are applicable only 1 PK draw after CAZ-AVI infusion may be performed and hours prior to screening	737.58	6.0	4425.48	4425.48	0.00	6.00	4,425.48	0.00	0.00
	PK Samples Cohorts 3 and 4	At PK draws are applicable only 1 PK draw after CAZ-AVI infusion may be performed and hours prior to screening	737.58	4.0	2950.32	2950.32	0.00	4.00	2,950.32	0.00	0.00
	Processing BAL sample	Processing and shipping of BAL fluid subject to CAZ-AVI analysis	5,470.98	1.0	5470.98	5470.98	0.00	0.00	5,470.98	0.00	0.00
	Per Subject Cost Subtotal		37,791.29				16,009.02	9,095.09	2,576.97	8,447.97	1,698.34
	Additional Cost Subtotal		28,062.52				3,832.68	21,017.10	0.00	3,832.68	0.00
Summary Costs	Subtotal		66,473.81			30,095.15	19,841.70	2,576.97	12,280.65	1,698.34	0.00
	Overhead		13,234.70			3,198.84	0,017.23	915.39	2,406.13	237.97	0.00
	With Overhead		79,708.51			34,410.02	23,859.04	3,492.36	14,736.78	2,026.01	0.00

Pfizer 1012858/18PFZ0017 C3591025 IND Tri Partite CSA
[Dr Vijay Raghunath Kalrao] [Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital Pune] [Site #1069]

Confidential

Other Study Level Costs		Additional Procedures Not Included in the Per Subject Cost (Procedures not tied to a specific visit)	
Procedure	Comments	Cost	
Local IRB/EC Fee - Initial Review	To be paid directly		
Local IRB/EC Fee - Amendment	To be paid directly		
Local IRB/EC Fee - Annual Review	To be paid directly		
Pharmacy start-up fee		26,076.00	
Admin start-up fee		30,000.00	
Screen Fails	Applicable to subjects who BF at Visit 1. Max 4 SFs per site.	12,000.77	
Unscheduled visit	Reimbursed for actual procedures performed.	34,193.62	
Travel Allowance For Caregiver/Guardian	For Caregiver travel expenses for follow up visit. Budget 1 per 100% of subjects. Reimbursed for each site visit by paying the amount of INR 1000.00 OR amount of up to INR 3500.00 on submitting the actual receipt of the expenses.	Up to 3500.00	



BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)
MEDICAL COLLEGE & HOSPITAL, PUNE
Department of Pediatrics
Pediatric Research Cell

Pune-Satara Road, Dhankawadi, Pune - 411 043.
Phone : +91 20 24364308, Fax - +91 20 24375541
email - researchpedpune@gmail.com



Date: 8 June 2021

To,

The Chairman
Institutional Ethics Committee

Subject: Notification to Ethics Committee for Site Close-out for the E2007-G00-338 study

Protocol Number: E2007-G000-338

Protocol Title: "A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial with an Open-Label Extension Phase of Perampanel as Adjunctive Treatment in Subjects at Least 2 Years of Age with Inadequately Controlled Seizures Associated with Lennox-Gastaut Syndrome"

Dear Sir,

Please be informed that the "Site Close-out Visit" (SCV) for the above referenced study was performed on 07 June 2021 at Bharati Hospital, Pune.

We can confirm that there are no active screened or randomized patients pertaining to the study at our site.

We request you to acknowledge the receipt of the document and provide the acknowledgment copy of the same at the earliest.

Thanking you,


Principal Investigator

DR. KAVITA SRIVASTAVA





BHARATI VIDYAPEETH
(DEEMED TO BE UNIVERSITY)
MEDICAL COLLEGE & HOSPITAL, PUNE
Department of Pediatrics
Pediatric Research Cell

Pune-Satara Road, Dhankawadi, Pune - 411 043.
Phone : +91 20 24364308, Fax - +91 20 24375541
email - researchpedpune@gmail.com



Date: 09 April 2021

To,

The Chairman
Institutional Ethics Committee
Bharati Vidyapeeth (Deemed to be University) Medical College
Pune

Ref: **Protocol Title:** "A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial with an Open-Label Extension Phase of Perampanel as Adjunctive Treatment in Subjects at Least 2 Years of Age with Inadequately Controlled Seizures Associated with Lennox-Gastaut Syndrome"

Trial Code: E2007-G000-338

Subject: Notification to Ethics Committee for discontinuation of the E2007-G00-338 study

Dear Sir,

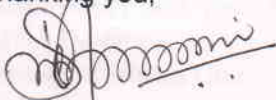
Please be informed that the Sponsor has taken decision to discontinue the E2007-G00-338 study. The Sponsor letter received for the study discontinuation has been enclosed herewith.

We had screened 1 patient on 01 Feb 2021 for this study, however, the patient was not randomized. Based on the sponsor decision, the patient has been termed as screened failure and discontinued from the study.

We can confirm that there are no active screened or randomized patients pertaining to the study at our site.

We request you to acknowledge the receipt of the document and provide the acknowledgment copy of the same at the earliest.

Thanking you,


Dr. Kavita Srivastava
Principal Investigator,
Bharati Hospital, Pune.



Received

12/04/2021

March 30, 2021

Dear Investigator,

Re: E2007-G000-338 Suspension of Recruitment Activities

Protocol Title: "A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial with an Open-Label Extension Phase of Perampanel as Adjunctive Treatment in Subjects at Least 2 Years of Age with Inadequately Controlled Seizures Associated with Lennox-Gastaut Syndrome"

We are writing to inform you that, regretfully, Eisai has taken the decision to discontinue the perampanel Phase 3 LGS study. Since study initiation in 2016, patient recruitment into this study has been challenging which is further impacted by the COVID-19 pandemic in the past year. This study discontinuation is not because of any safety concerns.

The last subject last visit date for the study is targeted to be 31 July 2021.

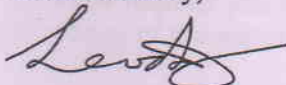
(Note: Please schedule the patient's study completion/early termination visit to take place by 23 July 2021 in order to allow for ~1 week of window shall unforeseen events require postponement of the last visit but no later than 31 July 2021.)

We understand that some of the study sites still have patients ongoing in the study. Please keep the following into consideration as you are making arrangements with the patients and their caregivers to schedule their remaining study visit(s):

- Patients currently in the Core Study can continue through the end of Core Study. If deemed by the investigator to be necessary, these patients will be allowed to enter Extension A (blinded conversion period only) provided the subject's last visit will be scheduled to take place by 23 July 2021 (and in any event no later than 31 July 2021 as detailed above).
- Patients currently in the Extension A or Extension B can continue in their respective extension phase; however, all patients should have their last study visit scheduled to take place by 23 July 2021 (and in any event no later than 31 July 2021 as detailed above).

In the coming days, your PPD CRA will be reaching to you with more detailed information about close out activities. Meanwhile, if you have any questions, please do not hesitate to contact your PPD CRA or Eisai's Study Director.

Yours Sincerely,



Stella Ngo, PhD
International Project Team Lead and Clinical
Lead for Fycompa
Neurology Business Unit
Eisai Inc.
Email: stella_ngo@eisai.com
Phone: +1-201-466-7398



Gleb Filippov, MD, PhD
Study Director and Medical Monitor for E2007-
G000-338
Neurology Business Unit
Eisai Inc.
Email: Gleb_Filippov@eisai.com
Phone: +1-551-264-6334

INSTITUTIONAL ETHICS COMMITTEE

BHARATI VIDYAPEETH DEEMED UNIVERSITY

Bharati Hospital & Research Centre, Pune-Satara Road, Dhankawadi, Pune 411043

Tel: 020 405555 55, Ext 265, Email: bvduiec@gmail.com

DCGI Regd. No. ECR/313/Inst/MH/2013/RR-19

NABH Accreditation No. EC-CT-2018-0016

IEC/2020/59

Date: 20 Jul 2020

To,

Dr. Kavita Srivastava,

Principal Investigator,

Professor, Pediatric Epilepsy & Neurology Unit,

Department of Pediatrics,

Bharati Vidyapeeth (Deemed to be University) Medical College,

Ref: **Protocol Title:** A Multicenter, Double-Blind, Randomized, Placebo-Controlled Trial With an Open-Label Extension Phase of Perampanel as Adjunctive Treatment in Subjects at Least 2 years of Age With Inadequately Controlled Seizures Associated With Lennox-Gastaut Syndrome

Trial Code: E2007-G000-338

Sub: Institutional Ethics Committee (IEC) **Approval** for conduct of the above referred study and study related documents.

Dear Dr. Srivastava,

The above referred study, submitted vide letter dated 05 Jun 2020 was reviewed and discussed in Institutional Ethics Committee meeting held on 08 Jul 2020, at 02:30 pm in the Conference Hall, ground floor, Bharati Vidyapeeth (Deemed To Be University) Medical College, Pune.

Following documents were submitted for review:

Sr. No.	Document/Language	Document Details/Versions
1.	Protocol No: E2007-G000-338	Version :11.0, Amendment 05, Version Date: 19 Nov 2018
2.	DCGI Submission Acknowledgment Letter	Dated 11 Mar 2020
3.	Investigator's Brochure	Investigator's Brochure Edition 19 Dated 26-Sep-2019
4.	Investigator's Brochure Addendum	Edition 19, Addendum 01, v1.0 dated 20 Jan 2020 Edition 19, Addendum 02, v1.0 dated 22 Apr 2020

5.	Insurance Certificate	Policy Period: Jan 28, 2020 to Jan 27, 2023 Policy No. 4067/192802706/00/000
6.	CRF Template	Dated March 5, 2019
7.	Draft CTA & Budget	NA
8.	English Adult ICF	India English Adult ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava
9.	Hindi Adult ICF	India Hindi Adult ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
10.	Hindi to English Adult ICF	India Hindi to English Adult ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
11.	Marathi Adult ICF	India Marathi Adult ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
12.	Marathi to English Adult ICF	India Marathi to English Adult ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
13.	English Parental ICF	India English Parental ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava
14.	Hindi Parental ICF	India Hindi Parental ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
15.	Hindi to English Parental ICF	India Hindi to English Parental ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
16.	Marathi Parental ICF	India Marathi Parental ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
17.	Marathi to English Parental ICF	India Marathi to English Parental ICF v6.1.0_11 Mar 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
18.	English Assent form Age 7-9 ICF	India English Assent 7-9 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava
19.	Hindi Assent form Age 7-9 ICF	India Hindi Assent 7-9 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
20.	Hindi to English Assent form Age 7-9 ICF	India Hindi to English Assent 7-9 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
21.	Marathi Assent form Age 7-9 ICF	India Marathi Assent 7-9 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020

22.	Marathi to English Assent form Age 7-9 ICF	India Marathi to English Assent 7-9 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
23.	English Assent form Age 10-11 ICF	India English Assent 10-11 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava
24.	Hindi Assent form Age 10-11 ICF	India Hindi Assent 10-11 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01Jun2020
25.	Hindi to English Assent form Age 10-11 ICF	India Hindi to English Assent 10-11 ICF v4.1.0_18 Feb2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
26.	Marathi Assent form Age 10-11 ICF	India Marathi Assent 10-11 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
27.	Marathi to English Assent form Age 10-11 ICF	India Marathi to English Assent 10-11 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
28.	English Assent form Age 12-15 ICF	India English Assent 12-15 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava
29.	Hindi Assent form Age 12-15 ICF	India Hindi Assent 12-15 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
30.	Hindi to English Assent form Age 12-15 ICF	India Hindi to English Assent 12-15 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
31.	Marathi Assent form Age 12-15 ICF	India Marathi Assent 12-15 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
32.	Marathi to English Assent form Age 12-15 ICF	India Marathi to English Assent 12-15 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
33.	English Assent form Age 16-17 ICF	India English Assent 16-17 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava
34.	Hindi Assent form Age 16-17 ICF	India Hindi Assent 16-17 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
35.	Hindi to English Assent form Age 16-17 ICF	India Hindi to English Assent 16-17 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
36.	Marathi Assent form Age 16-17 ICF	India Marathi Assent 16-17 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
37.	Marathi to English Assent form Age 16-17 ICF	India Marathi to English Assent 16-17 ICF v4.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020

38.	English Adult PG ICF	India English Adult PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava
39.	Hindi Adult PG ICF	India Hindi Adult PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
40.	Hindi to English Adult PG ICF	India Hindi to English Adult PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
41.	Marathi Adult PG ICF	India Marathi Adult PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
42.	Marathi to English Adult PG ICF	India Marathi to English Adult PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
43.	English Parental PG ICF	India English Parental PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava
44.	Hindi Parental PG ICF	India Hindi Parental PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
45.	Hindi to English Parental PG ICF	India Hindi to English Parental PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
46.	Marathi Parental PG ICF	India Marathi Parental PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
47.	Marathi to English Parental PG ICF	India Marathi to English Parental PG ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
48.	English Consent form for Audio Video Recording	India English AV ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava
49.	Hindi Consent form for Audio Video Recording	India Hindi AV ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
50.	Hindi to English Consent form for Audio Video Recording	India Hindi to English AV ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 01 Jun 2020
51.	Marathi Consent form for Audio Video Recording	India Marathi AV ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 12 May 2020
52.	Marathi to English Consent form for Audio Video Recording	India Marathi to English AV ICF v1.1.0_18 Feb 2020_Dr Kavita Srivastava Translation Certificate dated 02 Jun 2020
53.	English Patient Card	v1.0.0 dated 20 Nov 2019
54.	Hindi Patient Card	v1.0.0 dated 20 Nov 2019 Translation Certificate dated 29 Nov 2019

55.	Hindi to English Patient Card	v1.0.0 dated 20 Nov 2019 Translation Certificate dated 29 Nov 2019
56.	Marathi Patient Card	v1.0.0 dated 20 Nov 2019 Translation Certificate dated 29 Nov 2019
57.	Marathi to English Patient Card	v1.0.0 dated 20 Nov 2019 Translation Certificate dated 29 Nov 2019
58.	English Seizure Diary Book	Version 1.0_English-IN_Dated 20 Oct 2016
59.	Hindi Seizure Diary Book	Version 1.0_Hindi-IN_Dated 20 Oct 2016 Translation Certificate dated 19 Feb 2020
60.	Marathi Seizure Diary Book	Version 1.0_Marathi-IN_Dated 20 Oct 2016 Translation Certificate dated 19 Feb 2020
61.	English Patient Dosing Information	E2007-G00-338 Patient Dosing Information, v2.0, 07 Feb 2017
62.	Hindi Patient Dosing Information	E2007-G00-338 Patient Dosing Information_Hindi_v2.0, 07 Feb 2017 Translation Certificate dated 07Jan2020
63.	Hindi to English Patient Dosing Information	E2007-G00-338 Patient Dosing Information_Hindi to English_v2.0, 07 Feb 2017 Translation Certificate dated 07 Jan 2020
64.	Marathi Patient Dosing Information	E2007-G00-338 Patient Dosing Information_Marathi_v2.0, 07 Feb 2017 Translation Certificate dated 07 Jan 2020
65.	Marathi to English Patient Dosing Information	E2007-G00-338 Patient Dosing Information_ Marathi to English_v2.0, 07 Feb 2017 Translation Certificate dated 07 Jan 2020
66.	Investigator Undertaking Dr. Kavita Srivastava	Signed and dated on 04 Mar 2020
67.	CV & MRC for PI – Dr. Kavita Srivastava	CV dated 30 Dec 2019
68.	SRC approval letter	Dated 25 May 2020

Following members of the IEC attended the meeting to review and discuss the study proposal:

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/ Internal
1	Dr. Abhijeet Tilak	M.D. Pharmacology	Professor and Head, Department of Pharmacology, Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune - 18	Medical Scientist/ Pharmacologist (Acting Chairperson)	External

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/Internal
2	Dr. Priti Dave	MD Medicine	Professor Department of Medicine Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Clinician/ Physician	Internal
3	Dr. Sanjay Natu	MD DNB(Pediatrics) MNAMS FACEE (PEM)	Professor, Department of Pediatrics Smt. Kashibai Navale Medical College & General Hospital, Pune Consultant Pediatrician Shashwat Hospital, 22, Happy Colony, Kothrud, Pune	Clinician/ Pediatrician	External
4	Dr. Anand Deshpande	DNB (Pediatrics), DCH	Honorary Associate Professor, Department of Pediatrics, B. J. Medical College and Sassoon General Hospital, Pune Consultant Pediatrician, Deenanath Mangeshkar Hospital and Mai Mangeshkar Hospital, Pune	Clinician/ Pediatrician	External
5	Dr. Jayshree Dawane	MD Ph.D (Pharmacology)	Associate Professor, Department of Pharmacology Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Medical Scientist/ Pharmacologist	Internal
6	Adv. Ashwini Hogepatil	B.A., L.L.B.	Practicing Lawyer, Pune	Legal Expert	External
7	Mrs. Vidya Garkhedkar	M.A. (Philosophy) B. Ed	Assistant Teacher in Dept. of Philosophy & Logic at junior college, S.P. College, Pune 30	Philosopher	External
8	Mrs. Vijayalaxmi Bathe	B.A., B. Ed (Physical Education)	President of Jivhala Jesht Nagrik Sangh, Astoniya Royale, Ambegaon BK, Pune 411046 Yoga Teacher	Lay Person	External

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/ Internal
9	Mrs. Sarika Deshmukh	B. Com	Housewife	Lay Person	External
10	Dr. Prasad Pore	MD (P&SM) D.N.B. (SPM)	Professor Department of Community Medicine Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Member Secretary	Internal

Adv. Sangeeni Pol and Dr. Swati Shirwadkar were unable to attend the meeting and had intimated about the same.

IEC composition was ICH - GCP and New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E) compliant. Required quorum was present for the meeting.

IEC reviewed the above mentioned documents and discussed the project in detail.

After reviewing all the study documents, IEC granted **Approval** for conduct of the study and study related documents for 1 year.

IEC suggested that after the 19 weeks of treatment period (Titration and Maintenance period), if the drug is beneficial, then those participants who are in control/ placebo arm, should also get the drug.

We approve the trial to be conducted in its presented form.

IEC expects to be informed about the progress of the study, any Serious Adverse Event (SAE) occurring in the course of the study, any changes in the protocol and patient information / informed consent, deviations, any new information that may affect adversely the safety of subjects or conduct of the study and asks to provide a copy of the final report.

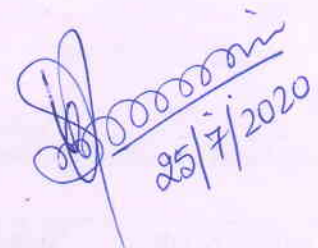
Kindly submit a report on the progress of the study every six months. Annual study status report needs to be submitted for approval for continuation of the study.

With best wishes,

Yours truly,



Dr. Prasad Pore
Member Secretary

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO AS OF THE 27th DAY OF
January 2021, 2020.

BETWEEN:

Indian Immunologicals Limited, a company duly incorporated under the Companies Act, and having its registered office at Road No. 44, Jubilee Hills, Hyderabad, Telangana- 500033 (hereinafter referred to as “IIL” or “Sponsor”) which expression shall be deemed to include its successors and administrators and assigns etc.

AND

Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital (BVDUMC), an institution incorporation under the laws of India, having its registered head office at Katraj-Dhankawadi, Pune-Satara Road, Pune-411043 India which expression shall be deemed to include its successors and administrators and assigns etc. (Hereinafter referred to as the ‘Institution’)

AND

Dr. Sonali Palkar, In-charge Pediatric Research, Department of Pediatrics and Associate Professor, Department of Community Medicine, Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, Katraj-Dhankawadi, Pune-Satara Road, Pune-411043 INDIA

(hereinafter referred to as the “Principal Investigator”) which expression shall be deemed to include its successors and administrators and assigns etc.

With each of the parties collectively or individually referred to as “Party” or “Parties”

AND RELATES TO THE CLINICAL TRIAL:

A Phase I Randomized Single Blind Placebo Controlled Study to Evaluate the Safety and Immunogenicity of Chikungunya Vaccine (Inactivated) of HBI when administered by two different dosage schedules to Healthy Subjects of 19 to 49 Years of age.

Code: HBI/CG/I/2020/001.02.00 Version 02

OR INDIAN IMMUNOLOGICALS LTD.

Signature: _____

Name: Dr K. Anand Kumar

Title: Managing Director

Signature: _____

Name: Dr. S. Sai Krishna

Title: DGM- Medical & Veterinary Services

FOR BHARATI VIDYAPEETH DEEMED
UNIVERSITY MEDICAL COLLEGE &
HOSPITAL, PUNE

Signature: _____

Name: (Brig.) Dr. Narayanan Subramanian Mani

Title: Principal

PRINCIPAL

Bharati Vidyapeeth

(Deemed to be University)

Medical College

Pune - 411 043.

PRINCIPAL INVESTIGATOR

Signature: _____

Name: Dr. Sonali Palkar

Title: Principal Investigator



SCHEDULE A
- FINANCIAL CONDITIONS -

1-Clinical Trial Costs:

For sake of clarity, the Parties hereby agree that:

- (i) "Estimated Budget" shall mean the estimated total amount to be paid by the Sponsor considering INR 25,080 (Twenty Five Thousand and Eighty Rupees only) per completed subject. Assuming 66 subjects will complete the study, the estimated budget will be INR 16,55,280 (Rupees Sixteen lakhs Fifty Five Thousand Two hundred and Eighty only).
- (ii) "Actual Budget" shall mean the real amount to be paid by the Sponsor to the Institution, i.e. the Estimated Budget reviewed according to actual number of subjects who have completed the study.
- (iii) Study Completion: Subjects who have completed all the required visits as per the protocol and have given the final blood sample.
- (iv) Drop out cases will not be considered for payment.

2- Payments:

- a) The breakdown of the payment of INR 25,080 per completed subject is as follows:

Particulars	Rs.
Study Coordinator	3400
Co-Investigator Charges	5500
Investigator charges	8500
Travel Expenses for Subjects	3500
Institutional overhead charges (20%)	4180
TOTAL per Subject	25,080
Total for minium of 66 Subjects	16,55,280

(Exclusive of Taxes applicable)

- b) The charges for each screen failure subject (Subject who has given the first blood sample and is found to be screen failure) is 2500 /- (Rupees Two thousand and five hundred only).
- c) The Payment for the Screen failures will be made based on the actuals as per the invoices received every month till the required total number of subjects for the site have been enrolled.
- d) If the subject drops-out from the study for any reason after enrollment, the sponsor will pay 50% of the per subject cost of the Investigator, Co-investigator and study coordinator.





INDIA NON JUDICIAL
Government of Gujarat
Certificate of Stamp Duty

Certificate No.

IN-GJ94955514007608T

Certificate Issued Date

12-Jan-2021 05:40 PM

Account Reference

IMPACC (AC)/ gj13023211/ GULBAI TEKRA/ GJ-AH

Unique Doc. Reference

SUBIN-GJGJ1302321126835903450718T

Purchased by

Cadila Healthcare Limited

Description of Document

Article 5(h) Agreement (not otherwise provided for)

Description

Agreement

Consideration Price (Rs.)

**0
(Zero)**

First Party

Cadila Healthcare Limited

Second Party

Dr Sanjay Lalwani

Stamp Duty Paid By

Cadila Healthcare Limited

Stamp Duty Amount(Rs.)

**300
(Three Hundred only)**

**Department of Pediatrics, Bharati Vidyapeeth
(Deemed To Be University)
Medical College & Hospital, Pune**



LB0012422180

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shgilestamp.com' or using e-Stamp Mobile App of Stamp Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The mode of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

CLINICAL STUDY AGREEMENT

Among

1. **CADILA HEALTHCARE LIMITED**, a multinational pharmaceutical company incorporated under the laws of India, having its Registered Office at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India (hereinafter referred to as **"the Sponsor"**)
2. **DR. SANJAY LALWANI**, (hereinafter referred to as **"Principal Investigator"**)
3. **BHARATI VIDYAPEETH (DEEMED TO BE UNIVERSITY) MEDICAL COLLEGE & HOSPITAL**, Pune-Satara Road, Dhankawadi, Katraj, Pune-411043 India (hereinafter referred to as **"the Institution"**)

CADILA PROJECT:

"A phase III, randomized, multi-centre, double blind, placebo controlled, study to evaluate efficacy, safety and immunogenicity of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited. (Project No. NCOV.20.002)"

This Clinical Study Agreement ("Agreement") is executed on **29th day of January, 2021** ("Effective Date") among Cadila Healthcare Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India (**"Sponsor"**) India; **Dr. Sanjay Lalwani, Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, Pune- Satara Road, Dhankawadi, Katraj, Pune-411043 India** for the study entitled **"A phase III, randomized, multi-center, double blind, placebo controlled, study to evaluate efficacy, safety and immunogenicity of Novel Corona Virus-2019-nCov vaccine candidate of M/s Cadila Healthcare Limited."** (Project No. NCOV.20.002)" (Hereinafter referred to as **"the study"**).

This Agreement also covers any companion protocol(s) later developed and approved by all the Parties that are conducted concurrently with the protocol identified herein (collectively **"Protocol"**) and that involve some or all the same subjects. The Sponsor and the Institution hereby declare that all the necessary permissions and licences required under the provisions of various acts and rules thereunder have been obtained for the performance of their respective obligations under this Agreement.

AND WHEREAS the Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study.

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:


THE PARTIES AGREE AS FOLLOWS:


1. The Sponsor would like to test the vaccine namely **ZyCOV D** which will be used for Prevention of Corona Virus Disease - 2019 in healthy subjects. The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules

CLINICAL STUDY AGREEMENT

Executed by the parties:

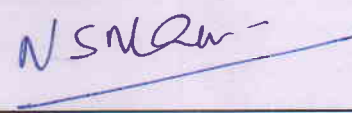
SPONSOR:


(Mr. Mukund Thakkar)
SVP, Legal




(Dr. Balaji More)
Sr. GM, Clinical R&D


INSTITUTION:


Sign: _____
Name: Brig. (Dr.) Narayanan Mani
Designation: Principal
Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital

PRINCIPAL
Bharati Vidyapeeth
(Deemed to be University)
Medical College
Pune - 411 043.

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

PRINCIPAL INVESTIGATOR:


Sign: _____
Dr. Sanjay Lalwani
Principal Investigator
Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital

Department of Pediatrics, Bharati Vidyapeeth
(Deemed To Be University)
Medical College & Hospital, Pune

CLINICAL STUDY AGREEMENT

Clinical Trial Budget- For Category 1			
S. No.	Visits	Particulars	Rate per Visit
A	Visit Expenses		₹ 10,000.00
1	W-0	Site and Investigator Charges	₹ 2,000.00
2	W-4	Site and Investigator Charges	₹ 1,000.00
3	W-8	Site and Investigator Charges	₹ 1,000.00
4	W-12	Site and Investigator Charges	₹ 1,000.00
5	W-52	Site and Investigator Charges	₹ 1,000.00
6	Telephonic follow-ups (days 70, 84, 98, 112, 126, 140, 154, 168, 182, 196, 210, 224, 238, 252, 266, 280, 294, 308, 322, 336 and 350 (± 3days) after 1st dose.)	Telephonic follow-ups (20 time, @200 per call)	₹ 4,000.00
B	Other Expenses		₹ 3,000.00
7	Patient Travel Reimbursement (@500 Per Visit for 6 visits)		₹ 3,000.00
C	Total (A+B) = C		₹ 13,000.00
D	Approx. Budget for 500 enrolled subjects (@13000)		₹ 65,00,000.00

Enrolled 8 = $8 \times 13000 = 1,04,000/-$
 4screened = $4 \times 2500 = 10,000/-$
1,14,000/-



Department of Pediatrics, Bharati Vidyapeeth
(Deemed To Be University)
Medical College & Hospital, Pune



सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 200

e-Stamp

Certificate No. : IN-KA83095631302573R
 Certificate Issued Date : 27-Mar-2019 03:38 PM
 Account Reference : NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
 Unique Doc. Reference : SUBIN-KAKAKSFCL0896108670151704R
 Purchased by : IQVIA RDS INDIA PRIVATE LIMITED
 Description of Document : Article 12 Bond
 Description : CLINICAL TRIAL AGREEMENT
 Consideration Price (Rs.) : 0
 (Zero)
 First Party : IQVIA RDS INDIA PRIVATE LIMITED
 Second Party : BVDU MEDICAL COLLEGE AND HOSPITAL
 Stamp Duty Paid By : IQVIA RDS INDIA PRIVATE LIMITED
 Stamp Duty Amount (Rs.) : 200
 (Two Hundred only)

सत्यमेव जयते



Please write or type below this line

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("Agreement") is made by and among:

- Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, having a place of business at Pune - Satara Road, Dhankawadi, Pune- 411043, Maharashtra, India (the "Institution"), and;
- Dr. Jitendra Shankarlal Oswal, having a place of business at Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, Pune - Satara Road, Dhankawadi, Pune- 411043, Maharashtra, India (the "Investigator"), and;

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

- **IQVIA RDS (India) Private Limited**, (formerly **Quintiles Research (India) Private Limited**) a Company incorporated under the Companies Act, 1956 and having its registered office at 2nd Floor, Etamin Block, Prestige Technology Park II, Sarjapur-Marathahalli Outer Ring Road, Bangalore – 560 103, India (hereinafter “**CRO**”), acting on behalf of **Serum Institute of India Pvt. Ltd.**, and;
- **Serum Institute of India Pvt. Ltd.** a company incorporated under Companies Act, 1956 having its registered office at 212/2, off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter “**Sponsor**”).

Each a “**Party**” and together the “**Parties**”.

Protocol Number:	SII-aPENTA/IN-02
Protocol Title:	A Phase II/III, Multicentre, Randomized, Open-Label, Active-Controlled Study to Assess the Immunogenicity and Safety of DTaP-IPV+Hib Vaccine Manufactured by Serum Institute of India Pvt. Ltd. in Comparison with Pentaxim® in Indian Toddlers and Infants
Protocol Date:	03 Oct 2018
Sponsor:	Serum Institute of India Pvt. Ltd.
Country where Site is Conducting Study	India
Investigator:	Dr. Jitendra Shankarlal Oswal
Key Enrollment Date:	30 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 “Key Enrollment Date” below)
IRB/IEC	Institutional Ethics Committee Bharati Vidyapeeth Deemed University 4th floor, Bharati Hospital & Research Centre Pune - Satara Road, Dhankawadi, Pune- 411043, Maharashtra, India Phone No - 020 40555555, Ext. 265 Email ID - bvduiec@gmail.com

The following additional definitions shall apply to this Agreement:

- Affiliate**: means any entity that controls, is controlled by, or is under common control with the party being referred to. “control” means the ability to vote more than fifty (50) per cent of the issued voting shares of that entity or the legal power to direct or cause the direction of the general management and policies of the company, partnership or other entity in question, and “controlled” shall be construed accordingly.
- Protocol**: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).
- Case Report Form or CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).
- Study**: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.
- Study Subject**: an individual who participates in the Study, as a recipient of the Investigational Product (defined below).



INITIALS:
Sponsor

CRO

Institution

Investigator

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

ACKNOWLEDGED AND AGREED BY SERUM INSTITUTE OF INDIA PVT. LTD.

Name: Dr. Hitt Sharma

Title : Study Director

Signature: _____

Date: _____



**ACKNOWLEDGED AND AGREED BY IQVIA RDS (India) PRIVATE LIMITED
(formerly Quintiles Research (India) Private Limited)**

Name: Shweta Pradhan

Title: Director & Head Site Management

Signature: _____

Date: _____

ACKNOWLEDGED AND AGREED BY INSTITUTION

Name: (Brig.) Dr. Narayanan Subramanian Mani

Title: Principal, Bharati Vidyapeeth (Deemed To Be University) Medical College

Signature: _____

Date: _____

PRINCIPAL
Bharati Vidyapeeth
(Deemed to be University)
Medical College
Pune - 42

ACKNOWLEDGED AND AGREED BY INVESTIGATOR

Name: Dr. Jitendra Shankarlal Oswal

Signature: _____

Date: _____

Q



INITIALS:
Sponsor

CRO

Institution

Investigator

5. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

6. SCREENING FAILURE

No payments is payable to for screen failures.

7. EC/IRB/IEC FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by CRO and Sponsor, will be reimbursed upon receipt of appropriate documentation.

8. Meeting Attendance:

Necessary travel and lodging expenses (including meals) incurred by the Site when attending Study start up meetings or other meetings necessary to provide information regarding the Study or Investigational Product will be reimbursed on a pass-through basis upon receipt of supporting invoices from a third party vendor.

9. BUDGET TABLE

SII-aPENTA_IN-02 (PART I)

Study visit	Grant	Institutional Overhead (20%)	Total
Visit 1	3600	720	11760
Visit 2	3100	620	
Visit 3	3100	620	
Budget	9800	1960	

SII-aPENTA_IN-02 (PART II)

Study visit	Grant	Institutional Overhead (20%)	Total
Visit 1	2000	400	15000
Visit 2	1500	300	
Visit 3	2000	400	
Visit 4	1500	300	
Visit 5	2000	400	
Visit 6	1500	300	
Visit 7	2000	400	
Budget	12500	2500	

Upon receipt of invoice, with adequate documentation, for the costs associated with a Study subject travel reimbursement up to a maximum amount of Rs 500/- per visit by will be reimbursed for the subject enrolled in the Study. This allowance per visit is intended to offset the Study subject's costs associated or incurred as a result of Study participation. This reimbursement shall be reflected in the Informed Consent Form as it will be provided to the Study subject.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED



INITIALS:
Sponsor

INITIALS:
CRO

INITIALS:
Institution

INITIALS:
Investigator



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

NIRT
NATIONAL INSTITUTE FOR
RESEARCH IN TUBERCULOSIS



आई सी एम आर - राष्ट्रीय खसमा अनुसंधान संस्थान
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार
ICMR - National Institute for Research in Tuberculosis
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No.DIR/NIRT/Covid-19/BVMC/2020-21/1398

Date: 31.08.2020

To

The Director,
Bharati Vidyapeeth Medical College and Hospital,
Pune-Satara Road,
Dhankawadi, Katraj, Pune - 411 043.

Sub: Sanction and budget allotment for the Scheme Entitled, "A Phase 2/3, Observer-blind, Randomized, Controlled Study to determine the Safety and Immunogenicity of COVISHIELD (COVID-19 vaccine) in Healthy Indian Adults"

Ref.: ICMR Lr.No.VIR/Covid-19/29/2020/ECD-I, dt.:25.08.2020

Sir,

With reference to ICMR letter under reference cited, the Director-in Charge, National Institute for Research in Tuberculosis, Chennai sanctions the above mentioned research scheme initially for a period of 8 months from 25.08.2020 to 24.04.2021 subject to extension upto the total duration specified in para 3(3) below:

The Director-in-Charge of NIRT also sanctions the Budget allotment of Rs.62,60,250/- (Rupees Sixty Two Lakhs Sixty Thousand Two Hundred and Fifty only) as detailed in the attached budget statement for the period from 25.08.2020 to 24.04.2021.

The grant in aid will be given subject to the following conditions:

1. The payment of the grant will be made in two instalments (1st instalment - 60%, 2nd & final instalment - 40% respectively) to the Head of the Institution. The first instalment of the grant will be paid as soon as a report regarding the commencement of the project is received by NIRT.
2. The staff appointed in the project should be paid as indicated in the Budget Statement attached.
3. The approved duration of the research scheme is 8 months. The extension will be given after review of the work done on the scheme during the previous months.

Cont..2..

नं. 1, मेयर सत्यमूर्ति रोड, चेटपुट, चेन्नई - 600 031, भारत
No.1, Mayor Sathiyamoorthy Road, Chetpet, Chennai - 600 031, India

Tel: +91-44-28369500
Fax: +91-44-28362528, 28262529
www.nirt.res.in



Sr.No	BUDGET HEAD	Quantity	AMOUNT	DURATION	Total
	Manpower <i>Dr. Vaishali</i>				
	Junior Medical officer (Medical) Rs. 60,000/-	1	60,000	8	4,80,000
	Staff Nurse @Rs. 31500/- p/m <i>Pragati Khan</i>		31,500	8	5,04,000
<i>Savita</i>	Lab technician @Rs. 18000/- p/m <i>Savita</i>	1	18,000	8	1,44,000
<i>Sampada</i>	Field Investigator / CRC @Rs. 31000/- p/m <i>Sampada</i>	1	31,000	8	2,48,000
<i>Krutika</i>	Research Assistant @Rs. 31000/- p/m <i>Krutika</i>	1	31,000	2	62,000
<i>Deepali</i>	Data entry operator (Grade C) @Rs. 31000/- <i>Deepali</i>	1	31,000	8	2,48,000
	Sub-Total-1				16,86,000
	Patient Management				
	Volunteer Reimbursement -I screening	320	500	1	160000
	Volunteer Reimbursement enrollemnt and follow up	250	500	4	5,00,000
	Communication & Stationery				6,60,000/-
	Communication	1	10000	6	60,000
	(Stationaries) Printing of forms, Registers, Protocol, SOPs	-	60000	1	60,000 →
	Archival charges	1	100000	1	1,00,000
	Laboratory Consumables				2,20,000/-
	CoVID swab testing	320	3000	1	960000
	Antibody Test (IgG)	320	600	1	192000 X
<i>42,000/-</i>	CoVID swab testing	100	3000	1	300000
	Additional Labs for symptomatics if needed	100	5000	1	500000
	Urine Pregnancy test	100	120	2	24000
	Vacutainer needles	400	15	1	6000
	Blood collection tubes	400	20	1	8000
	Disposable syringes	400	20	1	8000
	Urine containers	200	15	1	3000
	Test tub & Pipettes	400	10	3	12000
	Surgical mask	20	20	40	16000
	Hand sanitizer	20	250	10	50000
	N95 mask, Gloves, face shield	20	500	20	200000
	PPE suit	5	1500	100	750000
	Contingency/Miscellaneous				28,37,000
	Placing of recruitment advertise in Newspaper		10000	1	10000
	Conducting interviews		10000	1	10000
	Sub-total-2				39,29,000
	Overhead @5%				2,80,750
	Equipments				
	Pharmacy Grade Refrigerator	1	40,000	-	40,000
	Data logger	2	15,000	-	30,000
	Filing Cabinet	1	30,000	-	30,000
	Pen drive - 16GB	1	500	-	500
	Vaccine Carrier (Tropicool)	2	12,000	-	24,000
	Sub-Total-3				1,24,500
	Travel				
	Hiring of vehicles (1 no)	1	30000	8	240000
	Grand total = Rs. 62,60,250/-				

SRI T. ASHOK GOUD
S.V.L.NO.15-22-024/2000
RL.NO. 15-22-015/2012
H.NO.2-31/6/A
TARA NAGAR, SERTINGAMPALLY
RANGA REDDY DISTRICT
9/2/20
LICENSE NO. 39/2012



79587

136428

భారత్
JUN 18 2020

11:47

R.0000050 PB7142

NON-JUDICIAL
STAMP DUTY

TELANGANA

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO AS OF THE 27th DAY OF
October, 2020.

BETWEEN:

Indian Immunologicals Limited, a company duly incorporated under the Companies Act, and having its registered office at Road No. 44, Jubilee Hills, Hyderabad, Telangana- 500033 (hereinafter referred to as “**IIL**” or “**Sponsor**”) which expression shall be deemed to include its successors and administrators and assigns etc.

AND

Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital (BVDUMC), an institution incorporation under the laws of India, having its registered head office at Katraj, Dhankawadi, Pune-411043 India which expression shall be deemed to include its successors and administrators and assigns etc. (Hereinafter referred to as the ‘Institution’)

AND

Dr. Rahul Jahagirdar, Professor in Pediatrics, Department of Pediatrics, Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, Katraj, Dhankawadi, Pune-411043 INDIA

(hereinafter referred to as the “**Principal Investigator**”) which expression shall be deemed to include its successors and administrators and assigns etc.

With each of the parties collectively or individually referred to as “**Party**” or “**Parties**”

AND RELATES TO THE CLINICAL TRIAL:

A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of Measles and Rubella Vaccine (Live) of HBI with MR-VAC® Vaccine in Healthy Subjects

Code: HBI/MR/II/III/2019/001.02.00 Version 02



FOR INDIAN IMMUNOLOGICALS LTD.

FOR BHARATI VIDYAPEETH (DEEMED TO
BE UNIVERSITY) MEDICAL COLLEGE &
HOSPITAL (BVDUMC), PUNE

Signature: _____

Name: Dr. Prasanna Deshpande

Title: Deputy Managing Director



Signature: _____

Name: Dr. S. Sai Krishna

Title: DGM- Medical & Veterinary Services

Signature: _____

Name: (Brig.) Dr. Narayan Mani

Title: Principal

Bharati Vidyapeeth
(Deemed to be University)
Medical College
Pune-411 043.

PRINCIPAL INVESTIGATOR

Signature: _____

Name: Dr. Rahul Jahagirdar

Title: Principal Investigator



SCHEDULE A
- FINANCIAL CONDITIONS -

1-Clinical Trial Costs:

For sake of clarity, the Parties hereby agree that:

- (i) "Estimated Budget" shall mean the estimated total amount to be paid by the Sponsor considering INR 11,040 (Eleven thousand rupees only) per completed subject. Assuming 100 subjects will complete the study, the estimated budget will be INR 1104,000 (Rupees Eleven lakhs Four Thousand only).
- (ii) "Actual Budget" shall mean the real amount to be paid by the Sponsor to the Institution, i.e. the Estimated Budget reviewed according to actual number of subjects who have completed the study.
- (iii) Study Completion: Subjects who have completed all the required visits as per the protocol and have given the final blood sample.
- (iv) Drop out cases will not be considered for payment.

2- Payments:

- a) The breakdown of the payment of INR 11,040 per completed subject is as follows:

Particulars	Rs.
Study Coordinator	1200
Travel Expenses for Subjects	1000
Co-Investigator Charges	2000
Investigator charges	5000
Institutional overhead charges (20%)	1840
TOTAL per Subject	11,040
Total for minium of 100 Subjects	11,04,000

(Exclusive of Taxes applicable)

For NAAC 20 sub. \approx 2,20,800

Enrolled 31 \rightarrow $31 \times 11040 = 3,42,240/-$





महाराष्ट्र MAHARASHTRA

2018

AR 284800

5 MAR 2019

98203

500 L

प्रस्तावित प्रकार Agreement

दस्तावेज नोंदणी करणारा व्यक्तीचा नाव / मालकी

भिककलीचे वर्णन

मुद्रांक विकत घेणाऱ्याचे नाव

पत्ता

दुसऱ्या पक्षकाचे नाव

हस्ताक्षरकर्त्याचे नाव व पद

Handwritten signature

रजिनील काबळ

विक्रय देवराज खडकवत

कसबा नं. 22099224

मुद्रांक विकत घेणाऱ्याची सही जि.वा. कोडर प्रॉजिक्ट, कोल्हापूर येथे, पुणे - 41

या कारणासाठी जहाती मुद्रांक खोदी केला, त्याची खात्री करणारा मुद्रांक
खरेदी करणारासुद्धा ६ महिन्यांत यापुढे देयनकारण आहे.



5 MAR 2019

प्रथम मुद्रांक लिपीक
कोल्हापूर येथे करिता

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of _____ day of _____ (hereinafter "Effective Date") by and between:

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter "CRO"), acting on behalf of **Serum Institute of India Pvt. Ltd.** a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter "Sponsor");

Confidential

Page 1 of 41

PCV-10-003 SH-Bharati, Pune

Execution Version

Initial

Dr. Sanjay K Lalwani, Professor & Head, Department of Pediatrics, Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, Pune 411043; hereinafter referred to as Investigator; AND

Bharati Vidyapeeth (Deemed To Be University) Medical College & Hospital, Pune 411043 an institution functioning as per the provisions of the Societies Registration Act, 1860 having its Registered Office at - Katraj-Dhankwadi, Pune-Satara Road, Pune 411043, India; represented by its Principal, **Bharati Vidyapeeth (Deemed To Be University) Medical College, Brig. (Dr.) Narayanan Subramanian Mani** (which expression shall where the context so admits include its successors and permitted assigns) hereinafter referred to as Institution.

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled: **"Phase 3, Randomized, Double-Blind Study to Evaluate the Immunogenicity, Safety and Tolerability of Serum Institute of India's 10-valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) in Healthy Indian Infants."** Protocol no. – PCV-10-003, Version 4.0, dated 25-JAN-2019 ("the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **PCV-10-003**, Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator and Institution agree as follows.

CRO, Investigator and Institution are sometimes hereinafter individually referred to as a Party and collectively as Parties.

Article 1 – The Study

1.1 The Institution and the Investigator undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time. It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

Project: Protocol No. PCV-10-003

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR Principal Investigator:

By: [Signature] Date 01/04/2019
Name: Dr. Sanjay Lalwani
Title: Principal Investigator

full signature

FOR AND ON BEHALF OF:

Bharati Vidyapeeth (Deemed To Be University) Medical College, And Hospital Pune

By: NS N S Date 01 APR 2019
Name: Brig (Dr.) Narayanan Subramanian Mani
Title: Principal, Bharati Vidyapeeth (Deemed to Be University) Medical College, Pune
(Deemed to be University)
Medical College
Pune - 43

FOR AND ON BEHALF OF:

DiagnoSearch Life Sciences Pvt. Ltd.

By: [Signature] Date 20/MARCH/2019
Name: Mandar Vaidya
Title: Director-Operations

FOR AND ON BEHALF OF:

Serum Institute of India Pvt. Ltd.

By: [Signature] Date 11/3/2019
Name: Dr. Vistasp Sethna
Title: Head - Conjugate Vaccines and Monoclonals

SCHEDULE B DRAFT STUDY BUDGET

PNEUMOSIL Phase 3 Study - Site Budget							
Heading	Visit 1	Visit 2	Visit 3	Visit 4	Total	No. of Subjects randomized	Total per study
Informed Consent	1,200	-	-	-	1,200	30	36,000
Medical History, Reviews of AE/SAE/Concomitant Medications	700	700	700	700	2,800		84,000
Physical Examination	700	700	700	700	2,800		84,000
Physical Examination	700	700	700	700	2,800		84,000
Randomization	700	-	-	-	700		21,000
Study Vaccination	700	-	-	-	700		21,000
Review of Diary Cards	1,000	1,000	1,000	-	3,000		90,000
Blood Sample for Immunogenicity	-	700	700	700	2,100		63,000
Follow-up FRA Contact	-	-	-	1,000	1,000		30,000
Total (A)	5,000	3,900	3,900	3,900	16,700		72,000
Screen Failure (Assumption: 10% of randomized, hence 3)	-	-	-	-	-	-	-
Screening Process (B)	-	-	-	-	-	-	-
Total (A+B)	5,000	3,900	3,900	3,900	16,700	3	501,000
Institute Overhead 20% (C)	-	-	-	-	-	-	-
Patient Travel Cost (D)	500	500	500	500	2,000	30	102,000
Screen Failure travel Reimbursement (E)	500	-	-	-	500	30	60,000
Total (A+B+C+D+E)	6,000	4,400	4,400	4,400	19,200	3	1,500
Infrastructure set up cost* (F)	-	-	-	-	-	-	-
* One time payment	-	-	-	-	-	-	-
Heading	Unit Cost in INR	Quantity	Unit				
Operational and administrative cost (G)	15,000	8	month				
Archival Charges* (H)	10,000	-	-				
* One time charges	-	-	-				
Total Project Cost (A+B+C+D+E+F+G+H)							40,000.00
Per Subject Cost (Project cost/no. of subjects assumed to be randomized)							843,500.00
							28,116.67

Notes:

- Period of recruitment is assumed as 4-6 weeks.
- Maximum number of screen failures for which Investigator to be compensated shall not exceed 10% of total randomized subjects at the site.
- INR 500/- will be paid as a screening visit travel reimbursement for screen failures not exceeding 10% of the total randomized subjects at the site.
- The study recruitment will be a competitive, and there will be no upper limit to actual number of subjects enrolled. The final costs will be based on the actual number of subjects enrolled and actual number of visits completed. The final calculation will be done on prorated basis.
- Outpatient cost, if occur, would be reimbursed at actuals.

Inst. → Overhead charges will
given in final invoice
→ Pending
→ End of study

Confidential

PCV-10-003 SII-Bharati, Pune.

Execution Version

Page 28 of 41

Project: Protocol No. PCV-10-003

SCHEDULE E

FORM OF FINANCIAL REPORT TO SPONSOR

Investigator Name: Dr. Sanjay Lalwani Institutional Name: BVMURC, Pune		PAN number of Payee:	
Particulars	Rate / unit	Number of Units	Total
Investigator's subject Grant *			
Visit 1	5,000	-	-
Visit 2	3,900	-	-
Visit 3	3,900	-	-
Visit 4	3,900	-	-
Total (A)			-
Screen Failure (B)	3,000	-	-
Institute Overhead @ 20% (C)	*****	*****	-
Subject Grant Total (A+B+C)			-
Subject Travel Cost^			
Subject Travel Cost (D)	500	-	-
Screen Failure Travel Cost (E)	500	-	-
Other			
Infrastructure set up cost* (F) * One time payment	—	—	-
Operational and administrative cost (G)			
Month(s)	Unit Cost	Number of Units	
Mar-19	15,000.00	-	-
Archival (H)			
Archival Charges	10,000.00	-	-
Total Cost (A+B+C+D+E+F+G+H)			-
Notes			
• For timely release of payment please submit the Invoice monthly			
* Please attached an annexure to the Invoice with visit wise break-up for each subject			
^ Please provide visit-wise break-up of travel cost along with signed receipt for each subject			
• Institutional overheads are to be claimed in the final invoice over the actual cost of A+B.			



महाराष्ट्र MAHARASHTRA

2018

UM 650574

प्रधान मुद्रांक कार्यालय, मुंबई
प.म.वि.क्र. ८०००००९
20 FEB 2019
सक्षम अधिकारी

E-Track Number : 116566
Center Number : 203769
Reference for Payment : PO.....

श्री. प्र. ना. चिंचघरे

AGREEMENT FOR CLINICAL TRIALS

This Agreement for Clinical Trials (the "Agreement") is effective on 22-Mar-2019, (the "Effective Date") between

Bharati Vidyapeeth Deemed University and Medical College, Bharati Hospital and Research Centre, Department of Pediatrics, Katraj - Dhankawadi, Pune - 411043, Maharashtra, India (hereinafter referred to as "**Institution**")

And

Dr. Sanjay Lalwani, Bharati Vidyapeeth Deemed University and Medical College, Bharati Hospital and Research Centre, Department of Pediatrics, Katraj - Dhankawadi, Pune - 411043, Maharashtra, India (herein referred as the "**Principal Investigator**" or "**Investigator**")

And

GLAXOSMITHKLINE PHARMACEUTICALS LIMITED, a company registered under the Companies Act, 1956 and having its registered office at at Dr. Annie Besant Road, Worli, Mumbai 400030 (hereinafter referred to as "**GSK**").



NSNaw

WHEREAS GSK is a pharmaceutical company involved in the research, distribution and sale of vaccines for use in humans;

WHEREAS GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, B - 1330 Rixensart, Belgium (hereinafter referred to as "**GSK Bio**" or "**Sponsor**") is the sponsor of the Study (as defined below) and has subcontracted the conduct of the Study to its affiliated local company, GSK;

WHEREAS Institution is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

WHEREAS GSK is willing to contract with Institution to undertake the conduct of a sponsored study on the investigational Vaccine (as defined later) entitled "A phase **III**, randomized, open study to assess the immunogenicity, reactogenicity and safety of two different formulations of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine, *Rotarix*, when given as a two-dose primary vaccination, in healthy infants with no previous history of rotavirus illness or vaccination." (hereinafter referred to as the "**Study**"). Such Study will be conducted under the oversight and responsibility of Investigator at Institution; and

WHEREAS Investigator shall conduct the Study and Institution is willing to provide certain resources in furtherance thereof.

NOW, THEREFORE, in consideration of the promises and the mutual covenants and conditions hereinafter recited, the parties do hereby agree as follows:

I. INSTITUTION AND PRINCIPAL INVESTIGATOR

- a) Institution represents and warrants that it holds the necessary registrations and authorisations to perform the Study under this Agreement.
- b) Save as may be agreed from time to time by GSK and Institution, Principal Investigator shall take primary responsibility for the conduct of the Study at the Study site on behalf of Institution.
- c) The Institution represents that it is entitled to procure the services of Dr. Sanjay Lalwani to act as principal investigator for the Study ("**Principal Investigator**" or "**Investigator**") and shall be responsible for the performance of the obligations of the Principal Investigator and other Study staff set out in this Agreement. Institution represents that Investigator and other Study staff holds the necessary registration and has the necessary expertise, time and resources to perform the Study.
- d) Institution shall procure and shall ensure that Principal Investigator procures the performance of the obligations of the Study staff as set out in this Agreement with all due skill, care and diligence. Institution shall provide qualified personnel, facilities and resources, as required, to perform this Agreement.
- e) Where Institution is not the principal employer of Principal Investigator, Investigator represents that Principal Investigator has notified his/her principal employer of his/her proposed participation in the Study and, where relevant, his/her supervision of the Study staff and that his/her principal employer has



Handwritten signature and initials

Investigator's breach, negligence, gross negligence or wilful misconduct or a breach by Institution or any of its agents, contractors or subcontractors of this Agreement.

X. COMPENSATION

- a) GSK agrees to pay for up to a maximum of 90 subjects included in the screening sequence, (at a cost of 11400/- per screened subject).
- b) GSK also agrees to pay, for each subject enrolled and properly documented as detailed in the Protocol, the following fees, in INR and this up to a maximum of 90 subjects included in the Study:

Total study budget	Unit cost	No. of subjects	Amount
Study assessments	6300	90	567000
Investigator's fees	3600	90	324000
Study personnel's fees	1500	90	135000
Total			1026000
Overheads (to specify)	20%		205200
Travel reimbursement	1500	90	135000
Others (to specify)	100000		100000
Archival costs (for 25 years)			
Miscellaneous	20000		20000
Total study budget			1486200

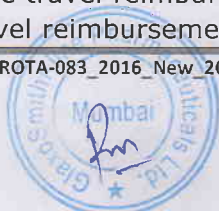
(hereinafter referred to as the "Study Budget")

Visit Activities	Cost in INR		
	Visit 1	2	3
Informed consent	800	0	0
Check Inclusion/Exclusion Criteria	700	0	0
Physical Examination - General	800	700	0
Vaccine/Treatment Administration	400	400	0
Record, Concomitant Medication/Vaccine	300	300	300
Blood Draw, Complex	800	0	800
Study Coordinator, Complex - per visit	500	500	500
Physician, Complex - per visit	1200	1200	1200

- c) The maximum Study Budget assigned to the Principal Investigator amounts to 1486200 (Study costs). The Principal Investigator shall be responsible for allocating and paying all costs of Study within the limit of the Study Budget to all co-investigators and sub-investigators working for the Study.

Payment of this Study Budget will be made upon achieving the following milestones:

Milestone payment	
I	First Payment: post site initiation visit: An amount of Rs.20000 will be released after site initiation visit.
II	Subsequent payments:
1	Towards subject visit: once in every two months based on subjects visits shown in eTRACK
2	Screen failure travel reimbursement payment: 10% of screen failures will be provided travel reimbursement.



NSN/Qu

3	Cost involved in medical management and additional costs: once in every two months; shall be made on the receipt of the invoice and supporting documents
III	Post query resolution: An amount of Rs.50000 will be put on hold from the second last invoice. The said payment will be made after post query resolution.
IV	Post close out: archival payment will be made.

- d) Payments shall be remitted by GSK in INR on a milestone-completion basis, within thirty (30) days after receipt of duly documented invoice or supporting documentation demonstrating completion of the milestone. If the number of the subjects is less than the then-current target number set forth in Section XI a), the Study Budget and the installments will be reduced accordingly.

The Study Budget shall cover all Study expenditure such as, but not limited to investigators fees, GE/IP surveillance fees, Study personnel's fees, laboratory costs, (including personal and material), travel costs linked to public disclosure activities (if and to the extent requested by GSK) such as Publication Steering Committee meetings, core writing team meetings and presentations of Study results at conferences or congresses, overheads and others (including but not limited to administrative costs, taxes, insurances, ERC submission costs, etc).

Such Study Budget has been agreed upon by the parties prior to start the Study, therefore GSK shall in no event accept any overspending and the Principal Investigator and the Institution undertakes to complete the Study within such Study Budget.

Payment instructions shall be specified in Schedule B attached hereto (please fill in the Schedule B – Payment Instructions Sheet).

Bank transfer costs shall be supported by GSK.

- e) The Institution will receive the fees mentioned in sub-paragraphs (a) and (b) above for every subject evaluable according to the Protocol. The fee mentioned under (b) above shall be paid only with respect to evaluable subject and when the vaccination's calendar as foreseen in the Protocol has been scrupulously respected. In the event of non-evaluable subject(s), only the screening costs specified in sub-paragraph (a) will be paid. The non-evaluable subject's criteria are defined in the Protocol and include, but are not limited to, the following events:
- i) subject or vaccine number not allocated;
 - ii) Study vaccine dose not administered but subject number allocated;
 - iii) administration of vaccine forbidden in the Protocol;
 - iv) wrong vaccine vial given;
 - v) deliberately breaking the randomization code at investigator site, violating the allowable reasons for breaking the code (i.e. SAE, etc.);




[Handwritten signature]

[Handwritten signature]

IN WITNESS WHEREOF, the parties caused this Agreement to be executed, as of the date first written above, in multiple counterparts (each of which will be deemed to be an original, and all of which together will constitute one and the same Agreement) by their duly authorized representatives who, by signing, confirm their authority to bind their respective party.

For and on behalf of
GLAXOSMITHKLINE PHARMACEUTICALS LIMITED

By : 
Name : Dr. Sanjay Gandhi
Title : Vice President – Vaccines Area Medical
Lead (Gavi, Asia) & Lead LML (Clinical
R&D, EM)

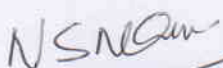
By :
Name :


Title :

For and on behalf of

By my signature I indicate my agreement to fulfill the role and obligations of Principal Investigator under this Agreement and consent to the disclosure of my name and Institution(s) with which I am affiliated as well as the details of any payment or benefit in kind made to me or for my benefit under this Agreement in publicly accessible worldwide registers.

Bharati Vidyapeeth (Deemed To be University) and Medical College, Pune

By : 
Name : **PRINCIPAL**
Title : **Bharati Vidyapeeth**
(Deemed to be University)
Medical College
Pune - 43

By : 
Name : Dr. Sanjay Lalwani
Title : **Dr S K. Lalwani**
Vice Principal

Professor and Head
Department of Pediatrics
Bharati Vidyapeeth Deemed University
Medical College
Pune-Satara Road, Pune-411 043

Attachments to the present Agreement :

Schedule A : Protocol

Schedule B : Payment instructions sheet

Schedule C : Statement of Investigator Financial Interest Form



Juhi Suhanda <juhi.x.suhanda@gsk.com>

Tue, Oct 13, 2020 at 5:09 PM

To: BVDUMC Pedresearch <researchpedpune@gmail.com>

Cc: "sampadaransubhe@gmail.com" <sampadaransubhe@gmail.com>, Hitesh Bharucha <hitesh.x.bharucha@gsk.com>, Jagdish Jamgade <jagdish.c.jamgade@gsk.com>, "sanjaylalwani2007@rediffmail.com" <sanjaylalwani2007@rediffmail.com>

Dear Dr Sonali,

Good Evening!

Please see below the Subject Visit Payments made so far. The payments marked in Green are already made to the site and those marked in yellow are pending.

<i>Upto 31st May 2019</i>	Subjects	Amount	Total
Visit 1	13	5500	71500
Visit 2	4	3100	12400
			83900
20 % Overhead			16780
			100680
Travel reimbursement	17	500	8500
			109180
<i>Upto 31st Jul 2019</i>	Subjects	Amount	Total
Visit 1	36	5500	198000
Visit 2	20	3100	62000
Visit 3	12	2800	33600
			293600
20 % Overhead			58720
			352320
Travel reimbursement	68	500	34000
			386320
<i>Upto 30th Sep 2019</i>	Subjects	Amount	Total
Visit 1	39	5500	214500
Visit 2	42	3100	130200
Visit 3	31	2800	86800
			431500
20 % Overhead			86300
			517800
Travel reimbursement	112	500	56000
			573800
<i>As of 26th Nov 2019</i>	Subjects	Amount	Total
Visit 1	9	5500	49500
Visit 2	27	3100	83700
Visit 3	20	2800	56000
			189200
20 % Overhead			37840
			227040
Travel reimbursement	56	500	28000
			255040

As of 13th Feb 2020	Subjects	Amount	Total
Visit 3	27	2800	75600
20 % Overhead			15120
			90720
Travel reimbursement	27	500	13500
Miscellaneous			20000
			124220
Retainage			50000
			74220
Last Payment			Amount (INR)
Archival Fees			100000
Retainage release			50000
			150000

Below is the calculation mentioning the payments deducted for subject withdrawals.

Subject Withdrawals(NOT PAID)			
Visit Type	No of subject withdrawn	Amount (INR)	Total
Visit 2	4	3100	12400
Visit 3	7	2800	19600
			32000
Overhead 20%			6400
Travel	11	500	5500
Total			43900

Also attached are the previous signed invoices for Subject Visit Payments received from site and cheques that were generated from GSK for your reference.

Do let me know in case of any further queries. Also kindly send the last invoice and online banking details so i can initiate the payment process.

Thank you! Stay Safe!

Best Regards

Juhi Suhanda

Clinical Trial Assistant

Clinical Operations

GSK Vaccines

252, Dr. Annie Besant Road, Worli,

Mumbai - 400030, India.

Email -juhi.x.suhanda@gsk.com

Mob - 9987810153

gsk.com | Twitter | YouTube | Facebook | Flickr



do more
feel better
live longer

31st may - 109,180

31 July - 386,320

30 Sep - 573,800

26 Nov - 255,040

~~132,434~~
132,434

Remaining
224,220 - Bal. awarded

19/04/2020



सत्यमेव जयते

Government of Karnataka

Rs. 100

e-Stamp

Certificate No. : IN-KA88909563250360T
Certificate Issued Date : 30-Aug-2021 11:41 AM
Account Reference : NONACC (FI)/ kagcsl08/ KORAMANGALA1/ KA-BA
Unique Doc. Reference : SUBIN-KAKAGCSL0837726249773340T
Purchased by : CBCI SOCIETY FOR MEDICAL EDUCATION CBCI
Description of Document : Article 12 Bond
Description : CLINICAL TRIAL AGREEMENT ACT
Consideration Price (Rs.) : 0
 (Zero)
First Party : HAMILTON HEALTH SCIENCES CORPORATION
Second Party : CBCI SOCIETY FOR MEDICAL EDUCATION CBCI
Stamp Duty Paid By : CBCI SOCIETY FOR MEDICAL EDUCATION CBCI
Stamp Duty Amount(Rs.) : 100
 (One Hundred only)

सत्यमेव जयते



Please write or type below this line

AMENDMENT 1 TO THE CLINICAL TRIAL AGREEMENT - ACT

This amendment ("Amendment 1") is effective as of August 16, 2021 (the "Amendment 1 Effective Date"), between:

Hamilton Health Sciences Corporation ("HHSC"), through its Population Health Research Institute ("PHRI"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada represented by Ms. Tanya Chow, Director of Contracts, PHRI (which expression shall, where the context so permits include his successors in office and assigns)

PD



DS

-and-

CBCI Society for Medical Education, ("CBCI") established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bengaluru -560034, Karnataka, India, represented by its Secretary (which expression shall, where the context so permits include his successors in office and assigns) hereafter referred as the "**Society**"

-and-

St. John's Research Institute, ("SJRI") a unit of the Society, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bengaluru-560034, Karnataka, India, represented by its Dean (which expression shall, where the context so permits include his successors in office and assigns) hereafter referred as "**Institute**"

-and-

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bengaluru-560 034 Karnataka; India, represented by, Dr. Denis Xavier, Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT and Dr Prem Pais, Adjunct Professor, Medicine Department, St. Johns Research Institute (hereafter called "**National Leaders**")

-and-

Bharati Vidyapeeth (Deemed to Be University) Medical College, at Pune - Satara Rd, Bharati Vidyapeeth Campus, Dhankawadi, Pune, Maharashtra, 411043, India ("**Institution**")

-and-

Dr. Purwa Doke, at Pune - Satara Rd, Bharati Vidyapeeth Campus, Dhankawadi, Pune, Maharashtra, 411043, India ("**Investigator**")

Capitalized terms used in this Amendment 1 but not defined herein shall have the meanings set forth in the Agreement, as hereinafter defined.

WHEREAS, the parties entered into an Agreement for the clinical trial entitled **Anti-Coronavirus Therapies to prevent progression of COVID-19 (ACT)** ("**Project**") on October 26, 2020 (hereinafter the "**Agreement**");

AND WHEREAS, the parties have agreed to amend the Agreement, subject to the terms and conditions outlined herein.

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein and other good and valuable consideration, the sufficiency of which is hereby recognized, the parties hereby agree as follows:

1. The following is deleted in the Agreement:

Hamilton Health Sciences Corporation ("HHSC"), through its **Population Health Research Institute** ("PHRI"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada represented by Ms. Tanya Chow, Director of Contracts, PHRI (which expression shall, where the context so permits include his successors in office and assigns)

and replaced with:

Hamilton Health Sciences Corporation ("HHSC"), through its **Population Health Research Institute** ("PHRI"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada represented by the Director of Contracts, PHRI (which expression shall, where the context so permits include such successors in office and assigns)

2. The following is deleted in the Agreement:

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bengaluru-

560 034 Karnataka; India, represented by, Dr. Denis Xavier, Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT Dr Prem Pais, Adjunct Professor, Medicine Department, St. Johns Research Institute (hereafter called "**National Leaders**")

and replaced with:

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bengaluru-560 034 Karnataka; India, represented by, Dr. Denis Xavier, Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT and Dr. Prem Pais, Adjunct Professor of Medicine, DCRT, St. Johns Research Institute (hereafter called "**National Leaders**")

3. The following Whereas: paragraph is deleted in the Agreement:

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Professor Dept. of Pharmacology, St. John's Medical College as its Head and Dr Prem Pais, Adjunct Professor, Medicine Department, St. Johns Research Institute.

and replaced with:

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Professor Dept. of Pharmacology, St. John's Medical College as its Head and Dr. Prem Pais, Adjunct Professor of Medicine, DCRT, St. Johns Research Institute.

4. The following Section 2.1 is deleted in the Agreement:

2.1 This Agreement shall commence on the Effective Date specified above, and continue until approximately August 31st 2021, or until PHRI receives all completed and corrected forms, reports and other documentation from the Institution as required by the Protocol and final payment is sent by PHRI or upon written notice from PHRI of early termination of the Project, whichever occurs first, unless otherwise terminated earlier in accordance with **ARTICLE 9 (Termination) ("Term")**.

and replaced with:

2.1 This Agreement shall commence on the Effective Date specified above, and continue until approximately August 31, 2023, or until PHRI receives all completed and corrected forms, reports and other documentation from the Institution as required by the Protocol and final payment is sent by PHRI or upon written notice from PHRI of early termination of the Project, whichever occurs first, unless otherwise terminated earlier in accordance with **ARTICLE 9 (Termination) ("Term")**.

5. The following in Section 10.1 is deleted in the Agreement:

And to:

Dr. Prem Pais
Adjunct Professor-Medicine Department
St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bengaluru -560 034, India
Tel: +91 80 49467005
Email: Prempais@sjri.res.in

and replaced with:

And to:

Dr. Prem Pais
Adjunct Professor of Medicine
DCRT, St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bengaluru -560 034, India
Tel: +91 80 49467005
Email: Prempais@sjri.res.in



6. The Payment Schedule, Exhibit 1, in the Agreement shall be replaced with the new and revised Exhibit 1-A appended to this Amendment 1. The new and revised Exhibit 1-A shall be retroactively effective as of the Effective Date of the Agreement.
7. The Payment Rule Form, Exhibit 2, in the Agreement shall be replaced with the new and revised Exhibit 2-A appended to this Amendment 1.
8. Except as set forth in this Amendment 1, the Agreement is unaffected and shall continue in full force and effect in accordance with its terms. If there is a conflict between this Amendment 1 and the Agreement, the terms of this Amendment 1 shall prevail to the extent of such conflict.
9. This Amendment 1 may be executed in two or more identical counterparts, facsimile counterparts or electronic counterparts, each of which when executed by a party shall be deemed to be an original and such counterparts shall together constitute one and the same Amendment 1. This Amendment 1 shall be binding and take full force and effect as of the Amendment 1 Effective Date.

- signature page to follow -

PD



Handwritten signature in blue ink.



ACT - INDIA - SITE # 459-0

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Amendment 1.

Hamilton Health Sciences Corporation

DocuSigned by:

Janette Panhuis

8F2C807FD562413

Signature

Name: Janette Panhuis

Position: Chief Operating Officer, Population Health Research Institute

Date: 2021-Aug-16 | 14:56 EDT

(YYYY-MMM-DD)

INSTITUTION: Bharati Vidyapeeth (Deemed to Be University) Medical College

Signature

Name:

Title:

Date:

(YYYY-MMM-DD)

INVESTIGATOR: Dr. Purwa D.

Signature

Date:

2021-Sept-15

(YYYY-MMM-DD)

CBCI Society for Medical Education

Signature

Name: Rev. Dr. Paul Parathazham

Title: Secretary

SECRETARY

C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, BANGALORE - 560 034

Date:

2021 Sept. 08

(YYYY-MMM-DD)

St. John's Research Institute

Signature

Name: Dr. Tony D.S. Raj

Title: Dean

DEAN

St. John's Research Institute
St. John's National Academy of Health Sciences
Koramangala, Bangalore - 560 034, INDIA

Date:


2021 Sept 01

(YYYY-MMM-DD)




ACT - INDIA - SITE # 459-0

National Leader Office


Signature
Name: Dr. Denis Xavier
Title: Head, Division of Clinical Research & Training

Date: 2021 Aug 28
(YYYY-MMM-DD)


Signature
Name: Dr. Prem Pais
Title: Adjunct Professor of Medicine, DCRT

Date: 2021 Aug 21
(YYYY-MMM-DD)



EXHIBIT 1-A – PAYMENT SCHEDULE

Payments will be processed on a **bi-monthly** basis with the payment run cut-offs February 28th, April 30th, June 30th, August 30th, October 31st and December 31st of each year. Payments will be issued within 25 days from the processing/run date (i.e., Payment for run date February 28th will be sent on or prior to March 25th). Payments shall be according to the following schedule, and will be made for all CRFs received and validated as clean prior to the applicable cut-off date.

Visit Type	Amount in CAD per Subject, per visit, including receipt by PHRI of the required CRF for such visit(s)
Baseline/Randomization	260
8 day follow up visit	162.50
45 day follow up visit	162.50
Final Visit	65
Total Per Subject Amount **	650

** Amount per completed Subject, including all costs (i.e., recruitment and follow-up including events reporting, overheads, coordinators time, investigators time, PPE, translation, pharmacists, drug storage costs, creatinine tests, monitoring visits, archiving, all applicable taxes, Subject expenses such as travel and parking, etc., if applicable). All relevant forms are to be completed at each visit, including all prior events and related documentation.

Additional payment:

Site coordinator insurance will be provided to each site as a one time payment of \$95 CAD with the first payment.

PD

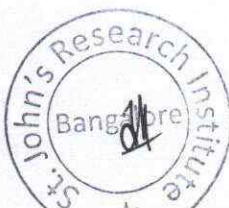


EXHIBIT 2-A - PAYMENT RULE FORM

COUNTRY:	INDIA
SITE #:	459-0
INSTITUTION:	Bharati Vidyapeeth (Deemed To Be University) Medical College Pune
INVESTIGATOR:	Dr. Purwa Doke

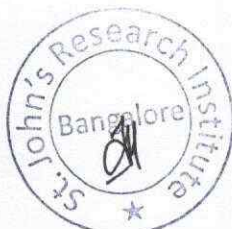
Payment will be in **CAD**. Payments will be processed on a **bi-monthly** basis with the payment run cut-offs on February 28th, April 30th, June 30th, August 30th, October 31st and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e., payment for run date February 28th will be sent on or prior to March 25th) provided that a minimum of **500CAD** has been earned within such payment period. Payments will be made for all CRFs received and validated to be clean prior to this date, according to the attached payment schedule.

Payments will be made to only one party.

(ALL INFORMATION BELOW MUST BE LEGIBLE)

The following information is required in order to generate payment by wire transfer. Incomplete information will result in no payment.

Bank Name:	State Bank of India, Katraj, Pune
Bank Address:	Sr No. 133/2 Near Bharati Vidyapeeth Satara Road Dist: Pune, Maharashtra, INDIA (411046) Tel No (020-24371861)
Bank SWIFT code:	-
Beneficiary (Account Holder) Name:	Principal, BVDU Medical College
Beneficiary Address:	Bharati Vidyapeeth (Deemed To Be University) Medical College Satara Road, Pune-411043
Beneficiary IBAN or Account number:	10277606023
IFSC Code (India only):	SBIN0008752
Reference (if applicable):	-
Contact name and email for payment notification:	Dr. Juilee Surve (icutritals@gmail.com)
Tax ID # / GST Registration # / VAT #:	-
PAN card #:	AAATB1836D
For HHSC use only - Vendor ID #:	



INSTITUTIONAL ETHICS COMMITTEE

BHARATI VIDYAPEETH DEEMED UNIVERSITY

Bharati Hospital & Research Centre, Pune-Satara Road, Dhankawadi, Pune 411043

Tel: 020 40555555, Ext 265, Email: bvduicc@gmail.com

DCGI Regd. No. ECR/313/Inst/MH/2013/RR-19

NABH Accreditation No. EC-CT-2018-0016

IEC/2020/129

Date: 06 Nov 2020

To,

Dr. Prachee Makashir

Principal Investigator,

Professor of Medicine,

Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital,
Pune.

Ref: **Protocol Title:** A phase 2 evaluation of the efficacy of homeopathic remedy Zincum Muriaticum as an adjuvant therapy to standard of care in adult subjects with moderate to severe COVID-19: Randomised, double blind, parallel group, placebo controlled, multicenter trial (ZIMCOV)

Sub: Institutional Ethics Committee (IEC) **Approval** for conduct of the above referred study and study related documents

Dear Dr. Makashir,

The above referred study was reviewed and discussed in Institutional Ethics Committee meeting held online, on Friday, 16 Oct 2020 and IEC had provided Conditional approval vide letter IEC/2020/119 dated 26 Oct 2020.

IEC has received responses to IEC queries vide letter dated 29 Oct 2020 as follows:

Q1. Only one formulation of medication (either tablet or liquid formulation) to be used for all patients.

Response:

1) Zincum muriaticum 200 C liquid potency is to be used in the trial. It's essentially a liquid potency drug as most of the homeopathic medicines are. The liquid potency drugs are impregnated on sucrose globules for ease of administration. The sucrose globules are just vehicle for the liquid drug. So essentially there is no change in the liquid formulation whether it is impregnated on sucrose globules or given in liquid form as such (for patients on ventilator). Then for ease of administration the liquid potency will be given per orally in diluted form as per details outlined in the protocol. This information is endorsed by Dr. Mrs. Anita Patil, Dean, Homeopathy Medical College, BVDU, a Co Investigator for the trial. So essentially it is the same formulation of drug.

2) Moderately severe Covid-19 is a medical condition that is known to deteriorate and some patients may need mechanical ventilation. As the patient may take time to show a response to the homeopathic medicine and since it is highly safe, the protocol proposes to continue the trial even if such an eventuality were to occur.

3) Submitted protocol has been approved by IEC Smt Kashibai Navale Medical College and General Hospital and the trial has been registered on CTRI and has recruited over 25 patients already at Navale hospital.

After reviewing responses to IEC queries, IEC found them satisfactory. CTRI number and Clinical Trial Agreement (CTA) need to be submitted.

IEC granted **Approval** for the conduct of the study and study related documents for 1 year.

We approve the trial to be conducted in its presented form.

IEC expects to be informed about the progress of the study, any Serious Adverse Event (SAE) occurring in the course of the study, any changes in the protocol and patient information / informed consent, deviations, any new information that may affect adversely the safety of subjects or conduct of the study and asks to provide a copy of the final report.

Kindly submit a report on the progress of the study every six months. Annual study status report needs to be submitted for approval for continuation of the study.

With best wishes,

Yours truly,



Dr. Prasad Pore
Member Secretary



INSTITUTIONAL ETHICS COMMITTEE

BHARATI VIDYAPEETH DEEMED UNIVERSITY

Bharati Hospital & Research Centre, Pune-Satara Road, Dhankawadi, Pune 411043

Tel: 020 40555555, Ext 265, Email: bvduiec@gmail.com

DCGI Regd. No. ECR/313/Inst/MH/2013/RR-19

NABH Accreditation No. EC-CT-2018-0016

IEC/2020/70

Date: 29 Jul 2020

To,

Dr. Vishwanath Patil

Principal Investigator,

Associate Professor,

Department of Critical Care Medicine,

Bharati Vidyapeeth (Deemed to be University) Medical College,
Pune

Ref: **Protocol Title:** An Open Label, Randomized, Multicenter, Controlled Clinical Study to Evaluate the Efficacy and Safety of Nafamostat Mesilate in the Treatment of Moderate COVID-19 disease
Protocol Version No. Version 2.0, Dated 30 May/2020

Sub: Institutional Ethics Committee (IEC) **Conditional Approval** for conduct of the above referred study and study related documents.

Dear Dr. Patil,

The above referred study, submitted for expedited review and approval vide letter dated 11 Jul 2020 was reviewed and discussed in Institutional Ethics Committee online meeting held on 22 Jul 2020, at 02:30 pm.
IEC has received SRC approval letter vide letter dated 24 Jul 2020.

Following documents were submitted for review:

Sr. No.	Details of document	Version No. and date
1	SRC approval letter	SRC/2020/25 dated 22 Jul 2020
2	Investigator's Brochure	Version 1.0, Dated 21/APR/2020
3	Clinical Study Protocol and Appendices (Appendix I, II, III, IV, V, VI) (Along with List of Changes)	Version 2.0, Dated 30/MAY/2020

4	Case Report Form (CRF)	Version Final 2.0, Dated 09/JUL/2020
5	Center Specific Patient Information Sheet and Informed Consent Form (PIS +ICF) in English	Version No. 2.0.1; Dated 02/JUN/2020
6	Translation & Back translation of Center Specific Patient Information Sheet and Informed Consent Form (PIS +ICF) in Hindi language	Version No. 2.0.1; Dated 02/JUN/2020
7	Translation & Back translation of Center Specific Patient Information Sheet and Informed Consent Form (PIS +ICF) in Marathi language	Version No. 2.0.1; Dated 02/JUN/2020
8	Translation & Back translation certificate for Center Specific PIS +ICF in Hindi language	06/JUN/2020
9	Translation & Back translation certificate for Center Specific PIS +ICF in Marathi language	06/JUN/2020
10	Draft Clinical Trial Agreement	-
11	CTRI	CTRI/2020/06/026220
12	Insurance (Policy No. 4067/119274809/04/000)	From 01 July 2020 to 30 June 2021
13	Investigator Undertaking & PSP	Dated 03/JUN/2020
14	CV and MRC certificate of PI	-
15	DCGI CT NOC (CT-ND/41/2020)	Dated 25/MAY/2020
16	DCGI notification letter	Dated 05/JUN/2020
17	DCGI notification letter	Dated 24/JUN/2020
18	DCGI notification letter	Dated 10/JUL/2020

Following members of the IEC attended the online meeting to review and discuss the study proposal:

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/ Internal
1	Dr. Abhijeet Tilak	M.D. Pharmacology	Professor and Head, Department of Pharmacology, Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune - 18	Medical Scientist/ Pharmacologist (Acting Chairperson)	External
2	Dr. Priti Dave	MD Medicine	Professor Department of Medicine Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Clinician/ Physician	Internal

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/Internal
3	Dr. Sanjay Natu	MD DNB(Pediatrics) MNAMS FACEE (PEM)	Professor, Department of Pediatrics Smt. Kashibai Navale Medical College & General Hospital, Pune Consultant Pediatrician Shashwat Hospital, 22, Happy Colony, Kothrud, Pune	Clinician/ Pediatrician	External
4	Dr. Anand Deshpande	DNB (Pediatrics), DCH	Honorary Associate Professor, Department of Pediatrics, B. J. Medical College and Sassoon General Hospital, Pune Consultant Pediatrician, Deenanath Mangeshkar Hospital and Mai Mangeshkar Hospital, Pune	Clinician/ Pediatrician	External
5	Dr. Jayshree Dawane	MD (Pharmacology) Ph.D (Pharmacology)	Associate Professor, Department of Pharmacology Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Medical Scientist/ Pharmacologist	Internal
6	Adv. Sangeeni Pol	L.L.B., B.S.L.	Practicing Lawyer, Pune	Legal Expert	External
7	Adv. Ashwini Hogeatil	B.A., L.L.B.	Practicing Lawyer, Pune	Legal Expert	External
8	Mrs. Vidya Garkhedkar	M.A. (Philosophy) B. Ed	Assistant Teacher in Dept. of Philosophy & Logic at junior college, S.P. College, Pune 30	Philosopher	External
9	Dr. Swati Shirwadkar	M.A., Ph.D (Sociology) D. Litt. (honoris causa)	Retired Professor from Savitribai Phule Pune University (SPPU)	Social Scientist	External
10	Mrs. Vijayalaxmi Bathe	B.A., B. Ed (Physical Education)	President of Jivhala Jeshth Nagrik Sangh, Astoniya Royale, Ambegaon BK, Pune 411046 Yoga Teacher	Lay Person	External

Sr. No.	Name	Qualification	Affiliation	Role in the IEC	External/ Internal
11	Mrs. Sarika Deshmukh	B. Com	Housewife	Lay Person	External
12	Dr. Prasad Pore	MD (P&SM) D.N.B. (SPM)	Professor Department of Community Medicine Bharati Vidyapeeth (Deemed to be University) Medical College, Pune	Member Secretary	Internal

IEC composition was ICH - GCP and New Drugs and Clinical Trials Rules 2019 G.S.R. 227 (E) compliant. Required quorum was present for the meeting.

IEC reviewed the above mentioned documents and discussed the project in detail.

IEC had following suggestions/ recommendations:

1. IEC seeks clarification for the continuous infusion of study drug for 10 days, as it is given for 5 days for other indications such as Pancreatitis and Disseminated Intravascular Coagulation (DIC). IEC suggested that as it is a first clinical trial, the study drug should be tried for 5 days first, if it is not successful, then it should be tried for further days.
2. IEC suggested that one more arm with the reduced time may be added in the study so that unnecessary exposure may be avoided.

After reviewing all the study documents, IEC granted **Conditional Approval** for the study related documents and conduct of the study and seeks clarifications to the above mentioned suggestions/ recommendations.

With best wishes,

Yours truly,



Dr. Prasad Pore
Member Secretary



3.1.6 Number of departments with UGC-SAP, CAS, DST-FIST, DBT, ICSSR and other recognitions by national and international agencies during the year						
Name of the Scheme/Project/ Endowments/ Chairs	Name of the Principal Investigator/ Co Investigator (if applicable)	Name of the Funding agency	Type (Government/Non-Government)	Department	Year of Award	Funds provided (INR in lakhs)
Fund for Improvement of Science and Technology	Dr K R Mahadik	DST-FIST	Government	Pharmaceutics	18 th Feb 2021	32

3.2.1 Extramural funding for Research (Grants sponsored by the non-government sources such as industry, corporate houses, international bodies for research projects)

Name of the Scheme/Project/ Endowments/ Chairs	Name of the Principal Investigator/ Co Investigator (if applicable)	Name of the Funding agency	Type (Government/Non-Government)	Department	Year of Award	Funds provided (INR in lakhs)
Effect of SAVA-1 on Cyclophosphamide induced neutropenia	Dr. Arulmozhi. S	SAVA Health Care Limited-R & D, Plot No. 17/6, Block DI, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	12/14/2020	0.7485
In-vivo Studies on the Antidiabetic activity and toxicity of Copper nanoparticles using Wistar Rats	Dr. Urmila M.Aswar	Dr Anirudh Vasant Pethkar, Department of Microbiology, Institute of Science, Aurangabad	Non-Government	Pharmacology	28-Jan-21	0.5
Investigation of immunomodulatory activity of SAVA3 in experimental animal models of immunity.	Dr. Arulmozhi. S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block DI, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	4/1/2021	0.5209
E.Tect of SAVA-4 and SAVA-5 on Cyclophosphamide induced neutropenia in mice.	Dr. Arulmozhi. S and Dr. Amol Muthal	SAVA Health Care Limited-R & D, Plot No. 17/6, Block DI, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	5/2/2021	0.60168

Effect of SAVA 3, SAVA 5 and SAVA 6 on Cyclophosphamide induced Neutropenia	Dr. Arulmozhi S and Dr. Amol Shinde	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	non-Government	Pharmacology	6/18/2021	0.75498
Effect of SAVA ED on Paroxetine-induced erectile dysfunction in rats	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	7/2/2021	1.57416
Ocular pharmacokinetics study of SAVA 7 in Wistar rats	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	7/2/2021	0.3649
Screening of Hepatic Profile of animals treated with SAVA 8	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	6/28/2021	0.70805
Effect of SAVA V0001979 on streptozotocin nicotinamide induced diabetes mellitus in rats.	Dr. Arulmozhi. S	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	3/20/2021	1.03984
Food and Drug Lab	Sangram Patil	Poona College of Pharmacy,	Non-Government	Insitute	4/3/2021	1.18 62.6927
PTL	Upendra Pendse	Poona College of Pharmacy,	Non-Government	Quality Assurance	28/11/20	0.984

3.2.2 Grants for research projects sponsored by the government agencies during the year (INR in Lakhs)

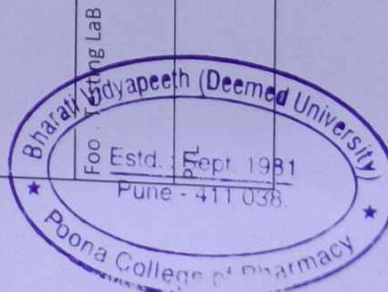
Name of the Scheme/Project/ Endowments/ Chairs	Name of the Principal Investigator/ Co Investigator (if applicable)	Name of the Funding agency	Type (Government/Non-Government)	Department	Year	Funds provided (INR in lakhs)
Nil	Nil	Nil	Nil	Nil	Nil	Nil

3.2.3 Number of research projects per teacher funded by government and non-government agencies during the year

Name of the Scheme/Project/ Endowments/ Chairs	Name of the Principal Investigator/ Co Investigator (if applicable)	Name of the Funding agency	Type (Government/Non-Government)	Department	Year	Funds provided (INR in lakhs)
Fund for Improvement of Science and Technology	Dr K R Mahadik	DST-FIST	Government	Pharmaceutics	18 th Feb 2021	32
Effect of SRV0001908 on Cyclophosphamide induced neutropenia.	Dr. Arulmozhi. S	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	12/14/2020	0.7485
In-vivo Studies on the Antidiabetic activity and toxicity of Copper oxide nanoparticles using Wistar Rats	Dr. Urmila M. Aswar	Dr Anirudh Vasant Pethkar, Department of Microbiology, Institute of Science, Aurangabad	Non-Government	Pharmacology	28-Jan-21	0.5
Investigation of immunomodulatory activity of SAVA3 in experimental animal models of immunity.	Dr. Arulmozhi. S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	4/1/2021	0.5209
Effect of SAVA-4 and SAVA-5 on Cyclophosphamide induced neutropenia in mice.	Dr. Arulmozhi. S and Dr. Anol Muthal	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	4/5/2021	0.60168

Effect of SAVA 3, SAVA 5 and SAVA 6 on Cyclophosphamide induced Neutropenia	Dr. Arulmozhi S and Dr. Amol Shinde	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	non-Government	Pharmacology	6/24/2021	0.75498
Effect of SAVA ED on Paroxetine-induced erectile dysfunction in rats	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	7/5/2021	1.57416
Ocular pharmacokinetics study of SAVA 7 in Wistar rats	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019.	Non-Government	Pharmacology	7/5/2021	0.3649
Screening of Hepatic Profile of animals treated with SAVA 8	Dr. Arulmozhi S and Dr. Deepa Mandlik	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	7/5/2021	0.70805
Effect of SRV0001979 on streptozotocin nicotinamide induced diabetes mellitus in rats.	Dr. Arulmozhi. S	SAVA Health Care Limited-R & D, Plot No. 17/6, Block D1, MIDC, Chinchwad, Pune 411019, Maharashtra.	Non-Government	Pharmacology	4/12/2021	1.03984
	Sangram Patil	Poona College of Pharmacy,	Non-Government	Insitute	4/3/2021	1.18 62.6927
	Upendra Pendse	Sahayadri Hospital Ltd 30C Erandwane Pune	Non-Government	Quality Assurance	28/11/20	0.984

Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.



No SR/FST/College-2019-526 (C)
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF SCIENCE & TECHNOLOGY
R & D (Infrastructure) DIVISION

Technology Bhawan,
New Mehrauli Road,
New Delhi -110016

18th February, 2021

ORDER

Subject: Financial assistance (1st installment) to the **POONA COLLEGE OF PHARMACY, BHARATI VIDYAPEETH UNIVERSITY, PAUD ROAD, ERANDWANE PUNE, MAHARASHTRA - 411038** under FIST Program.

Sanction of the President is hereby accorded to the approval of the aforesaid project at a total cost of **Rs.72,00,000/- (Rupees Seventy two lakh only)** for 5 years. The detailed breakup of the grant for General as well as Capital Components are given below:

To strengthen the research facilities in the College (Being Govt. Aided College the amount would be shared on 50:50 ratio)
Capital Assets: Rs.69.0 L

E-Rs. 64.0 L [Flow Through cell apparatus - Rs 45.0 L, FT Raman Spectrometer - Rs. 19.0L]

NW-Rs. 5.0L Setting up computer lab (15 Desktop PCs, 1 server and UPS)]

General Components: Rs.3.0L

M- Rs.3.0 L

Total : Rs. 72.00 Lakh

[DST's contribution Rs.36.0 lakh & College's Share-Rs.36.0 lakh]

2 The total budget recommended for 5 years has been phased as below: (Rs. In lakh)

Budget Heads	1 st year	2 nd year	3 rd year	4 th year	5 th year	Total
Equipment	64.0					64.0 (DST- 32.0L, College- 32.0L)
NW	-	5.0				5.0 (DST- 2.5L, College- 2.5L)
Maintenance	-	0.75	0.75	0.75	0.75	3.0 (DST- 1.5L, College- 1.5L)
Total	64.0	15.75	0.75	0.75	0.75	72.0 (DST- 36.0L, College- 36.0L)

3 The sanction of the President is also accorded to the release of **Rs.32,00,000/- (Rupees Thirty two lakh only)** to the Principal, **POONA COLLEGE OF PHARMACY, BHARATI VIDYAPEETH UNIVERSITY, PAUD ROAD, ERANDWANE PUNE, MAHARASHTRA - 411038** under FIST Program as a 1st installment of the grant in 2020-2021 under 'creation of capital assets' head for the maximum cost of the aforesaid Equipment including (9.4%) Custom Duty & other duties under the 'Equipment'. The break-up of the 1st installment grant released now would be **Equipment: Rs. 32.0 lakh** for procurement of the equipments mentioned above [Equipments of Foreign Origin to be acquired on FE Terms only and should not include charges for any comprehensive Maintenance and training personnel from the vendors during procurement process].

4 The Department/Institute will appropriately limit the expenditure within the sanctioned amount in case of any expected excess expenditure. The Department is requested to utilize the released funds in first one year from the date of sanction order.

5 This sanction is subject to the condition that the grantee organisation will furnish to the Department of Science & Technology, financial year wise Utilization Certificate (UC) in the proforma prescribed as per GFR 2017 and audited statement of expenditure (SE) along with up to date progress report at the end of each financial year duly reflecting the interest earned / accrued on the grants received under the project. This is also subject to the condition of submission of the final statement of expenditure, utilization certificate and project completion report within one year from the scheduled date of completion of the project.

6 The aforesaid concurrence is subject to the stipulation that continuation beyond the first year will be subject to appraisal and approval of the continuation of the Schemes(FIST) under which this project is funded, as approved by DoE's vide their OM No 42(02)/PF-II/2014 dated 06.08.2020.

7 The grantee organisation will have to enter & upload the Utilization Certificate in the PFMS portal besides sending it in physical form to this Division with UC id generated in PFMS Portal. The subsequent/final installment will be released only after confirmation of the acceptance of the UC by the Division and entry of previous Utilization Certificate in the PFMS.

Bhattacharya

Incharge Principal

Bharati Vidyapeeth Deemed University

If the grant has been released under Capital head/General through separate sanction order(s) under the same project for purchase of equipment, separate SE/UC has to be furnished for the released Capital head/General grant.

9. There is no pending SE/UC on this Project as per details in the PFMS also. This is the first release of this project under FIST Program, which has been initiated, in this financial year so no previous UC is attached with this sanction order.

10. The grant-in-aid being released is subject to the condition that:

(a) a transparent procurement procedure in line with the provisions of General Financial Rules 2017 will be followed by the University/Institute under the appropriate rules of the grantee organisation while procuring capital assets sanctioned for the above mentioned project and a certificate to this effect will be submitted by the University/Institute immediately on receipt of the grant, and

(b) while submitting Utilization Certificate/Statement of Expenditure, the University/Institute has to ensure submission of supporting documentary evidences with regard to the purchase of equipment/capital assets as per the provisions of GFR 2017. Subsequent release of grants under the project shall be considered only on receipt of the said documents.

c) Grantee Institute may furnish copy of invoice in respect of equipments worth Rs. 5.0 L and above along with customs clearance certification (in case of imported equipments) after procurement of the equipments

d) Goods (consumables/equipment/Networking items) available in GeM portal may be procured through GeM (Government E-Market) platform only and the University/ Institute will also follow DOE's DoE's guidelines for incurring expenditure under the different sub-head.

e) The Grantee Institution is advised to start using EAT module and next release will be made only after mapping and following EAT modules by the grantee institutions.

f) Grantee Institute will furnish copy of bills showing expenditure incur on maintenance of the equipments after warranty period of respective equipments are over

11. In terms of Rule 230(8) of GFR 2017, the grantee organization will maintain separate audited account for the project and the entire amount of grant will be kept in an interest bearing bank account. For Grants released during F Y 2017-18 and onwards, all interests and other earnings, generated against released Grant shall be remitted to Consolidated Fund of India

12. DST reserves sole rights on the assets created out of grants. Assets acquired wholly or substantially out of government grants (except those declared as obsolete and unserviceable or condemned in accordance with the procedure laid down in GFR 2017), shall not be disposed of without obtaining the prior approval of DST. The ownership of the equipment/facilities created will vest with DST.

13. The account of the grantee organisation shall be open to inspection by the sanctioning authority and audit (both by C&AG of India and Internal Audit by the Principal Accounts Office of the DST), whenever the organisation is called upon to do so, as laid down under Rule 236(1) of General Financial Rules 2017.

14. Due acknowledgement of technical support / financial assistance resulting from this project grant should mandatorily be highlighted by the grantee organisation in bold letters in all publications / media releases as well as in the opening paragraphs of their Annual Reports during and after the completion of the project

15. Failure to comply with the terms and conditions of the scheme will entail full refund with interest in terms of Rule 231 (2) of GFR 2017.

16. The expenditure involved is to be debited to

Demand No -87 Department of Science & Technology

"3425" -Other Scientific Research (Major Head)

60-Others (Sub-Major Head)

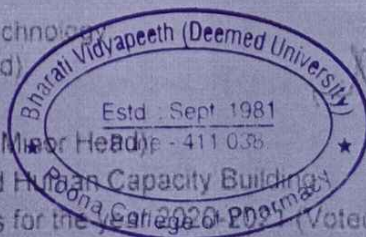
60 200-Assistance to other Scientific Bodies (Major Head)

68- Science and Technology Institutional and Human Capacity Building

68 04 35-Grants for creation of capital assets for the (Voted)

[Previous: R&D Support: 3425 60 200 68 00 35]

The above release is made under 'R&D' Scheme



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 036

The amount of Rs.20,00,000/- (Rupees Twenty lakh only) will be drawn by the Drawing and Disbursing Officer, DST and will be disbursed to the Principal, POONA COLLEGE OF PHARMACY, BHARATI VIDYAPEETH UNIVERSITY, PAUD ROAD, ERANDWANE PUNE, MAHARASHTRA - 411038. The bank details for electronic transfer of funds through RTGS are given below:-

1. Name of the Account Holder: Principal, POONA COLLEGE OF PHARMACY, BHARATI VIDYAPEETH UNIVERSITY
2. Name of the Bank: IDBI Bank
3. Bank Account Number: 0653104000125093
4. IFSC Code: IBKL0000653
5. MICR Code: 411259015

18. As per Rule 234 of GFR 2017, this sanction has been entered at S. No. 190 in the register of grants maintained in the Division for the scheme (R&D Support).

19. This issues with the concurrence of IFD Vide their Concurrence Dy.No.5123 dated the 17.02.2021.

(Arindam Bhattacharyya)
Scientist 'E'

Email: a.bhattacharyya@nic.in

To
The Pay and Accounts Officer,
Department of Science & Technology,
New Delhi.

Copy forwarded for information and necessary action to

1. Cash Section (with two spare copies)

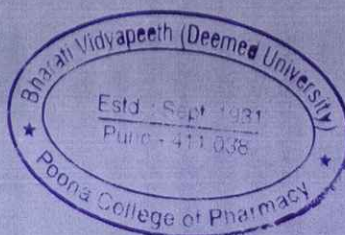
1. Principal,
POONA COLLEGE OF PHARMACY,
BHARATI VIDYAPEETH UNIVERSITY,
PAUD ROAD, ERANDWANE PUNE,
MAHARASHTRA - 411038

2. Office of the Director & Audit, Scientific Department, AGCR Bldg., 3rd Floor, IP Estate, New Delhi - 110002
3. Office of Account General, Maharashtra, Mumbai
4. FIST-Secretariat
5. CoA / IFD, DST, New Delhi.
6. Head, R & D (Infrastructure), DST New Delhi.
7. Sanction Folder

(Arindam Bhattacharyya)
Scientist 'E'




Email: a.bhattacharyya@nic.in

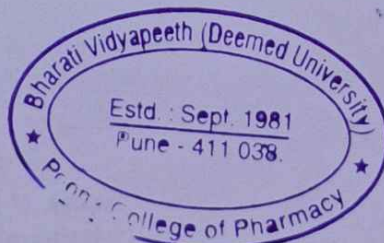
At




(Signature)
Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

1) Effect of SRV0001908 on Cyclophosphamide induced neutropenia.

SAVA HEALTHCARE LTD							
Billing Address Sava Healthcare Ltd - R & D, PLOT NO-176, BLOCK-D1, MIDC, CHURCHROAD PUNE - 411018 MAHARASHTRA, INDIA Tel No: Fax:	Insurance Policy No: 1 CIN No: 1011197/33959PLC074003 GSTIN: 17AAEC4345D12M PAN No: 1AAEC4345D Mfg Lic No: 1 Drug Lic No: 1						
PURCHASE ORDER							
Kind Attention: Mobile No: 1							
Vendor: Principal Poona College of Pharmacy Bharati Vidyapeeth Educational Complex Erandwane Pune-411038 MAHARASHTRA, INDIA Tel No: Email: GSTIN: 27AAAT1813D0572	Delivery Address: Sava Healthcare Ltd, Sava Healthcare Ltd - R & D, PLOT NO-176, BLOCK-D1, MIDC, CHURCHROAD PUNE - 411018 Tel No: 2018001241 Fax No: Email: H1.purchase@savaglobal.com						
P.O. No: 1SRD/2021/PO5WOC/00106 Date: 14/12/2020 PR No: 1SRD/2021/PR1QF/WOC/00113 Quotation Ref: Place of Supply: 27-MAHARASHTRA India State							
Kindly deliver material as per terms and conditions mentioned below in purchase order.							
Sr.	Item Code & Description	Quantity	UOM	Basic Rate (RS)	Basic Value (RS)	Tax/Charges	Total (RS)
1	SRV0001908 - Cyclophosphamide induced neutropenia SCOPE OF WORK: 1. SWISS ALBINO MICE, TOTAL 40 ANIMALS & TRANSPORTATION OF ANIMALS 2. COST OF CYCLOPHOSPHAMIDE, TOTAL AND DIFFERENTIAL WBC COUNT, NO. OF OBSERVATION - 3 (DAY 0, DAY 3 & DAY 10), ALSO COST OF GCSF INCLUDED 3. MISCELLANEOUS (ANAESTHETICS, BLOOD COLLECTION KIT'S AND VACUOTAINER, IACD STATIONERY ETC) 4. OVERHEAD CHARGES (20% OF TOTAL COST) 5. CONSULTANCY CHARGES (20% OF TOTAL COST) Manufacturer: HSN/SAC Code: 395346 Delivery: 14/12/2020	1.000	NOB	63432.00	63432.00	COST @ 500 - 5100.00 1.1 SGST @ 9.00 - 5100.00	74850.15
					63432.00	11417.15	74849.15
Amount in Words: (INR - Seventy Four Thousand Eight Hundred Fifty Only) Payment Terms: PAYMENT: 80% PAYMENT TO BE RELEASED BEFORE START OF THE PROJECT & REMAINING PAYMENT TO BE RELEASED AFTER APPROVAL OF DRAFT REPORT							Discount: 0.000 Round-Off: 0.24 Total Value: 74850.00
Prepared By: 							Checked By: 
Authorized By: 							




Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

2) In-vivo Studies on the Antidiabetic activity and toxicity of Copper oxide nanoparticles using Wistar Rats



Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor

DR. ATMARAM PAWAR
M.Pharm., Ph.D.
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor : Dr. Patangrao Kadam

- Accredited with 'A+' Grade (2017) by NAAC
- Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
- Category-I University Status by UGC

POONA COLLEGE OF PHARMACY

- Reaccredited by NBA & NAAC
- ISO-9001:2015 Certified Institute



Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 004 (M.S.) India
Tel : 020-25432251 Fax : 020-25432283
E-mail : pcp@bharativedu.com
Website : www.bharativedu.com

Date: 28th Jan 2021

Quotation for the study- 'Evaluation of anti-diabetic potential of Copper oxide nanoparticles in Wistar Rats'

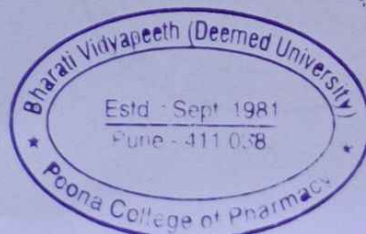
Budget parameters	Cost (Rs.)	Total
1. Cost of animals: Wistar rats @Rs. 300/- per animal Total 42 animals & Transportation of Animals	12,600/- 1000/-	13,600/-
2. IAC approval and Maintenance of animals during study: Rs. 2/- per day per rat with 42 rats for 60 days	2000/- 5040	7040
3. Drugs and Chemicals Streptozotocin, Metformin, miscellaneous for experiment- sample collection tubing's, eppendorf's, containers, markers etc.	30,000/-	30,000/-
4. Biochemical estimation kits- Biochemical kits- Blood glucose, SGOT, ALT, SOD, Cholesterol, Creatine, total protein, HbA1C.	25,000	25,000
4. Cost of histopathological studies of diabetic rats	3900	3900
Rs. 300 per sample		
Total		79540
4. Overhead Charges (15 % of the Total Cost)		11930
5. Consultancy Charges (15 % of the Total Cost)		11930
Grand Total		1,03,400

* At actual

Dr. Urmila M. Aswar
(Principal Investigator)

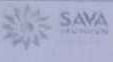

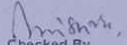
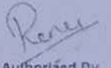
Incharge Principal

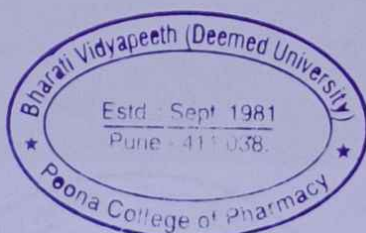
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

3) Investigation of immunomodulatory activity of SAVA3 in experimental animal models of immunity.

SAVA HEALTHCARE LTD							
 <p>PURCHASE ORDER</p> <p>Kind Attention : Mobile No :</p>	<p>Billing Address Sava Healthcare Ltd - R & D, PLOT NO-17/6, BLOCK-D1, MIDC, CHINCHWAD PUNE - 411019 MAHARASHTRA, INDIA Tel No : Fax :</p> <p>Insurance Policy No. : CIN No : U51397GJ2004PLC074963 GSTIN : 27AAECA9456D1ZM PAN No : AAECA9456D Mfg Lic No : Drug Lic No :</p>						
<p>Vendor Principal Ponna College of Pharmacy Bharati Vidyapeeth Educational Complex Erandwane Pune - 411038 MAHARASHTRA, INDIA Tel No : Email : GSTIN : 27AAATB18360522</p>	<p>Delivery Address Sava Healthcare Ltd., Sava Healthcare Ltd - R & D, PLOT NO-17/6, BLOCK-D1, MIDC, CHINCHWAD PUNE - 411019 Tel No : 2030601241 Fax No : Email id: purchase@savaglobal.com</p> <p>P.O. No. : SRD/2122/POS/WOC/00001 Date : 01/04/2021 PR No. : SRD/2122/PRQ/PWO/00001 Quotation Ref. : Place of Supply : 27 - MAHARASHTRA Intra State</p>						
Kindly deliver material as per terms and conditions mentioned below in purchase order.							
Sr.	Item Code & Description	Quantity	UOM	Basic Rate (RS)	Basic Value (RS)	Tax/Charges	Total (RS)
1	SRV0001979 - Testing Charges To investigate the immunomodulatory activity of SAVA-3 in experimental animal models of immunity. 1. Cost of animals: Swiss Albino mice @Rs. 140/-per animal. Total 60animals RS. 8400 & amp Transportation of Animals RS 1000 Feed and maintenance of animals (Rs. 2 per animal per day for 60 animals x 35 days) RS 4200 IAEC Approval Charges RS 10000 2. Cost of the experimentation: Cost of Cyclophosphamide RS 9352 Cost of SRBC's RS 9600 Miscellaneous (Anaesthetics, Blood collection kits and vacutainer, 96 well plates, Stationery) RS 10000 3. Contingency (5 % of Total expenditure) RS 2628 4. Consultancy Charges (20 % of Total expenditure) RS 10511 5. Overhead Charges (15 % of Total expenditure) RS 7883 Manufacturer : HSN/SAC Code 998346 Delivery 01/04/2021	1.000	NOS	73574.00	73574.00	CGST @ 9.00 6621.60 SGST @ 9.00 5621.60	86817.32
<p>Prepared By  Checked By  Authorised By </p> <p>Corporate office: SAVA House, Off New Airport Road, Viman Nagar, Pune - 411014 INDIA Tel: +91 20 30516100 Fax No: +91 20 30516161</p>							



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

4) Effect of SAVA-4 and SAVA-5 on Cyclophosphamide induced neutropenia in mice.



Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor
DR. ATMARAM PAWAR
M.Pharm., Ph.D.
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor : Dr. Patangrao Kadam

- Accredited with 'A+' Grade (2017) by NAAC
- Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
- Category-I University Status by UGC

POONA COLLEGE OF PHARMACY

- Reaccredited by NBA & NAAC
- ISO-9001:2015 Certified Institute



Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 038, (M.S.) INDIA
Tel: 020-25437737 Fax: 020-25439383
E-mail: pcp.bvu@gmail.com
Website: pcp.bharativedyapeeth.edu
www.bharativedyapeeth.edu

Date: 2/05/2021

To
SAVA Healthcare Ltd - R & D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune-411019.
GSTIN: 27AAECA9456D1ZM
Quotation for screening "Effect of SAVA 3 and SAVA 4 on cyclophosphamide induced neutropenia in mice"

1. Cost of animals - Swiss albino mice @ Rs. 140/- per animal Total 24 animals and Transportation charges Feed and maintenance of animals (Rs. 2 per animal per day for 17 days) IAEC Approval Charges	Rs. 3360/- Rs. 1000/- Rs. 816 /- Rs. 10,000/-	Rs. 15,176/-
2. Cost of Experimentation - i. Cost of cyclophosphamide ii. Total and Differential WBC count No. of observations - 3 (Day 0, Day 3 and Day 10) 3 x 24x 150 iii. Cost of C-GSF iv. Cost of AST,ALT v. Miscellaneous (Anaesthetics, Blood collection Kits, Vacoutainer, 96 well plates, stationery)	Rs. 9352/- Rs. 10,800/- Rs. 1800/- Rs. 3400/- Rs. 5000/-	Rs. 30,352/-
3. Contingency (5% of total Expenditure)		Rs. 2,276
4. Consultancy Charges (20% of total Expenditure)		Rs. 9,105
5. Overhead Charges (15% of total Expenditure)		Rs. 6,829
	Total	Rs. 63,738
	18% GST	Rs. 11,473
	Grand Total	Rs. 75,210

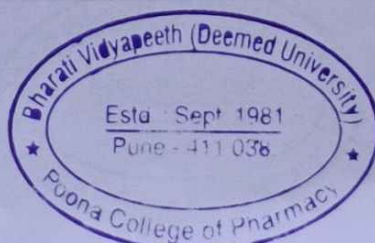
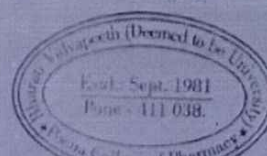
80 % of the cost to be released before the start of the project. Remaining 20 % of the cost to be released after approval of the draft report.

Payment mode: Cheque or NEFT in favour of Principal, Poona College of Pharmacy, Pune

Sava Health care Limited will provide with test substance 1 week prior to the start of the study.

Dr. Arulmozhi S.

Head,
Department of Pharmacology



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

5) Effect of SAVA 3, SAVA 5 and SAVA 6 on Cyclophosphamide induced Neutropenia



Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor

DR. ATMARAM PAWAR
M. Pharm., Ph.D.
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor: Dr. Patangrao Kadam

- Accredited with 'A+' Grade (2017) by NAAC
- Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
- Category-I University Status by UGC

POONA COLLEGE OF PHARMACY

- Reaccredited by NBA & NAAC
- ISO-9001:2015 Certified Institute



Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 038. (P.A.S.) 9804
Tel.: (020) 25437237 Fax: (020) 25439383
E-mail: pcph.bvu@gmail.com
Website: pcph.bharativedyapeeth.edu,
www.bvuuniversity.edu.in

18/06/2021

To
SAVA Healthcare Ltd - R & D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune 411019.
GSTIN: 27AAECA9456D1ZM

Quotation for Screening "Effect of SAVA 3, SAVA 5 and SAVA 6 on cyclophosphamide induced neutropenia in mice"

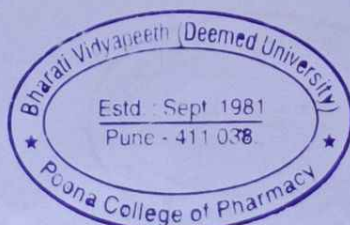
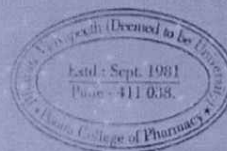
1. Cost of animals: Swiss Albino mice @Rs. 140/- per animal		Rs. 20,264
Total 36 animals & 1 Rabbit	Rs. 5040	
Transportation charges	Rs. 3000	
Feed and maintenance of animals (Rs. 2 per animal per day for 17 days)	Rs. 1000	
IAEC Approval Charges	Rs. 1224	
	Rs. 10000	
2. Cost of the experimentation:		Rs. 29,152
Cost of Cyclophosphamide	Rs. 9352	
Total and Differential WBC count, blood platelet counts	Rs. 16,200	
No. of observations - 3 (Day 0, Day 3 and Day 10) 3 x 36 x 150	Rs. 3600	
Cost of AST, ALT		
3. Miscellaneous (Anaesthetics, Blood collection kits and vacutainer, Stationery etc.)	Rs. 13000	Rs. 13000
4. Overhead Charges (20 % of the Total Cost)		Rs. 12,483
5. Consultancy Charges (20 % of the Total Cost)		Rs. 12,483
Total		Rs. 87382
18 % GST		Rs. 15729
Grand Total		Rs. 1,03,111

80 % of the cost to be released before the start of the project. Remaining 20 % of the cost to be released after approval of the draft report.

Payment mode: Cheque or NEFT in favour of Principal, Poona College of Pharmacy, Pune

Sava Health care Limited will provide with test substance 1 week prior to the start of the study.

Dr. Arulmozhi S.
Head,
Department of Pharmacology



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

6) Effect of SAVA ED on Paroxetine-induced erectile dysfunction in rats



Prof. Dr. Shivejrao Kadam
M.Sc. Ph.D.

Chancellor
DR. ATMARAM PAWAR
M.Pharm, Ph.D.
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor : Dr. Patangrao Kadam

Accredited with 'A+' Grade (2017) by NMAC
Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
Category 1 University Status by UGC

POONA COLLEGE OF PHARMACY

Reaccredited by NMAC & NAAC • ISO 9001:2015 Certified Institute



Bharati Vidyapeeth Educational Complex
Erandwane, Pune - 411 008 • 28.51 NER
Tel: 020 25437327 Fax: 020 25438202
E-mail: pco@bharativedu.org
Website: www.bharativedu.org

Date: 2/9/2021

To
SAVA Healthcare Ltd - R&D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune 411019.
GSTIN: 27AAECA9456D1ZM

Effect of SAVA ED on Paroxetine-induced erectile dysfunction in rats

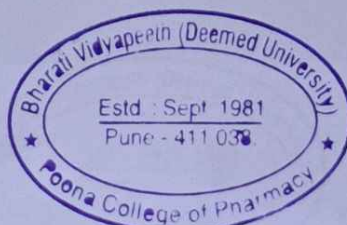
*1. Cost of animals: Wistar rats @Rs. 300/- per animal		
Total 30 animals &	Rs. 9000	Rs. 21,800
Transportation charges	Rs. 1000	
Feed and maintenance of animals (Rs. 2 per animal per day for 30 days)	Rs. 1800	
IAEC Approval Charges	Rs. 10000	
2. Cost of the experimentation:		Rs. 63,488
Sildenafil citrate, Paroxetine		
Vanadium chloride, Sulphanilamide		
Ethylendiaminedihydrochloride, Progesterone, estradiol benzoate	Rs. 63,488	
3. Miscellaneous (Anaesthetics, Blood collection kit, Travel, vacutainer, Stationery etc.)	Rs. 10000	Rs. 10,000
5. Manpower (10% of the Total Cost)		Rs. 9,529
4. Overhead Charges (15 % of the Total Cost)		Rs. 14,293
5. Consultancy Charges (15 % of the Total Cost)		Rs. 14,293
Total		Rs. 1,33,403
18 % GST		Rs. 24,013
Grand Total		Rs. 1,57,416

80 % of the cost to be released before the start of the project. Remaining 20 % of the cost to be released after approval of the draft report.

Payment mode: Cheque or NEFT in favour of Principal, Poona College of Pharmacy, Pune

Sava Health care Limited will provide with test substance 1 week prior to the start of the study

Dr. Arulmozhi S.
Head,
Department of Pharmacology



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

7) Ocular pharmacokinetics study of SAVA 7 in Wistar r) Ocular pharmacokinetics study of SAVA 7 in Wistar rat



Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.

Chancellor

DR. ATMARAM PAWAR
M.Pharm., Ph.D.,
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth (Deemed to be University)

Founder Chancellor : Dr. Patangrao Kadam

- Accredited with 'A+' Grade (2017) by NAAC
- Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
- Category-I University Status by UGC

POONA COLLEGE OF PHARMACY

- Reaccredited by NBA & NAAC
- ISO-9001-2015 Certified Institute

Celebrating



and Beyond

Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 038 (M.S.) INDIA
Tel : (020) 25437237 Fax : (020) 25439383
E-mail : pcp.bvu@gmail.com
Website : pcp.bharativedyapeeth.edu
www.bharativedyapeeth.edu

Date: 2/7/2021

To
SAVA Healthcare Ltd - R & D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune-411019.
GSTIN: 27AAECA9456D1ZM
Quotation for "Pharmacokinetics of SAVA 7 in wistar rats"

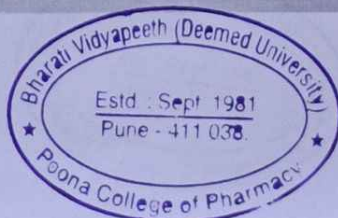
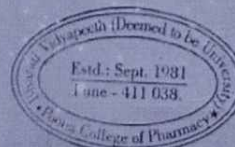
1. Cost of animals: Wistar rats @Rs. 300/-per animal		
Total 12 animals & Transportation charges	Rs. 3600 Rs.1000	Rs. 15,088
Feed and maintenance of animals (Rs. 2 per rat per day for 17 days and Rs. 4 per rabbit for 10 days)	Rs. 488	
IAEC Approval Charges	Rs.10000	
2. Miscellaneous (Anaesthetics, analgesics, Blood collection kit, solvent, vacutainer, Stationery etc.)	Rs. 7900	Rs. 7000
3. Manpower (10 % of the Total cost)		Rs. 2209
4. Overhead Charges (15 % of the Total Cost)		Rs. 3313
5. Consultancy Charges (15 % of the Total Cost)		Rs. 3313
Total		Rs. 30,923
18 % GST		Rs. 5,567
Grand Total		Rs. 36,490

80 % of the cost to be released before the start of the project. Remaining 20 % of the cost to be released after approval of the draft report.

Payment mode: Cheque or NEFT in favour of Principal, Poona College of Pharmacy, Pune


Sava Health care Limited will provide with test substance 1 week prior to the start of the study.

Dr. Arulmozhi. S
Head,
Department of Pharmacology




Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

8) Screening of Hepatic Profile of animals treated with SAVA



Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor : Dr. Patangrao Kadam

• Accredited with 'A+' Grade (2017) by NAAC
• Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
• Category-3 University Status by UGC



POONA COLLEGE OF PHARMACY
• Reaccredited by NBA & NAAC • ISO-9001:2015 Certified Institute

Source: Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 038, 06, 17, 18, 24
Tel: 020-25437234 Fax: 020-25428383
E-mail: pcpc@bharati.edu.in
Website: www.bharati.edu.in
www.poonacollege.edu.in

Prof. Dr. Shivajirao Kadam
M.Sc., Ph.D.
Chancellor
DR. ATMARAM PAWAR
M.Pharm., Ph.D.
IN-CHARGE PRINCIPAL

28/06/2023

To

SAVA Healthcare Ltd - R & D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune-411019.
GSTIN: 27AAECA94S6D1ZM

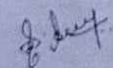
Quotation for "Screening of Hepatic Profile of animals treated with SAVA 8"

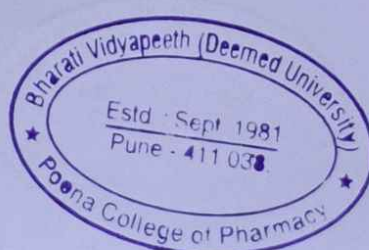
1. Cost of animals: Wistar rats @Rs. 300/- per animal		
Total 26 animals & Transportation charges	Rs. 7800	Rs. 20,360
Feed and maintenance of animals (Rs. 2 per animal per day for 30 days)	Rs. 1000	
IAEC Approval Charges	Rs. 1560	
	Rs. 10000	
2. Cost of the experimentation: SGPT, SGOT, ALP and Bilirubin kits	Rs. 7000	Rs. 14,500
Histopathology (15 Samples)	Rs. 7500	
3. Miscellaneous (Anaesthetics, Blood collection kit, Travel, vacoutainer, Stationery etc.)	Rs. 8000	Rs. 8000
4. Manpower (10 % of the total cost)		Rs. 4286
5. Overhead Charges (15 % of the Total Cost)		Rs. 6429
5. Consultancy Charges (15 % of the Total Cost)		Rs. 6429
Total		Rs. 60,004
18 % GST		Rs. 10,801
Grand Total		Rs. 70805


80 % of the cost to be released before the start of the project. Remaining 20 % of the cost to be released after approval of the draft report.

Payment mode: Cheque or NEFT in favour of Principal, Poona College of Pharmacy, Pune

Sava Health care Limited will provide with test substance 1 week prior to the start of the study.


Dr. Arulmozhi S
Head,
Department of Pharmacology




Incumbent Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

9) Effect of SRV0001979 on streptozotocin nicotinamide induced diabetes mellitus in



Prof. Dr. Shivajirao Kadam
Chancellor

DR. ATMARAM PAWAR
M.Pharm., Ph.D.,
IN-CHARGE PRINCIPAL

Bharati Vidyapeeth
(Deemed to be University)
Founder Chancellor : Dr. Patangrao Kadam

- Accredited with 'A+' Grade (2017) by NAAC
- Accredited (2004) & Reaccredited (2011) with 'A' Grade by NAAC
- Category-I University Status by UGC

POONA COLLEGE OF PHARMACY

- Reaccredited by NBA & NAAC
- ISO-9001-2015 Certified Institute



Bharati Vidyapeeth Educational Complex,
Erandwane, Pune - 411 038, (M.S.) INDIA
Tel. : (020) 25437237 Fax : (020) 25439383
E-mail : pcph.bvu@gmail.com
Website : pcph.bharativedyapeeth.edu
www.bharativedyapeeth.edu

TAX INVOICE

20/03/2021

PCP/M.Pharm/141/2020-21

Invoice No. 33/2020/21

To
SAVA Healthcare Ltd - R & D,
Plot No. 17/6, Block D1, MIDC,
Chinchwad Pune-411019.
GSTIN: 27AAECA9456D1ZM
PO Reference Number: SRD/2021/POS/WOC/00127

"Effect of SAVA1(SRV0001979) on Streptozotocin-Nicotinamide induced diabetes mellitus in rats"

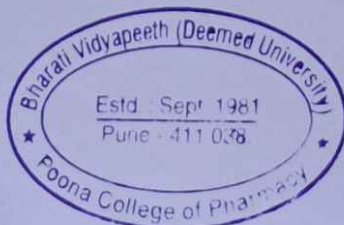
1. Cost of animals: Albino Wistar rats @Rs. 300/- per animal	Rs. 7200	Rs. 9544
Total 24 animals & Transportation of Animals	Rs. 1000	
Feed and maintenance of animals (Rs. 2 per animal per day for 24 animals x 28 days)	Rs. 1344	
2. Cost of the experimentation:		Rs. 41,400
Cost of Streptozotocin	Rs. 36500	
Cost of Nicotinamide	Rs. 3500	
Cost of Biochemistry		
Blood Glucose Kits	Rs. 1400	
3. Miscellaneous (Anaesthetics, Blood collection kits and vacutainer, 96 well plates, Histopathology containers IAEC Stationary etc.)	Rs. 12000	Rs. 12000
4. Overhead Charges (20 % of the Cost)		Rs. 12,589
5. Consultancy Charges (20 % of the Cost)		Rs. 12,589
Total		Rs. 88,122
18 % GST		Rs. 15,862
Grand Total		Rs. 1,03,984

GST No. 27AAATB1836D522
PAN No. AAATB1836D
TIN No. PNEB00400B

Signature of Study Director
Dr. Arulmozhi.S

Signature of Head of the Institution
Dr. A.P. Pawar
Incharge Principal

rats.



Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

10) Food Testing Laboratory (PTL)

11) PTL

Bharati Vidyapeeth (Deemed to be University), Pune (India)

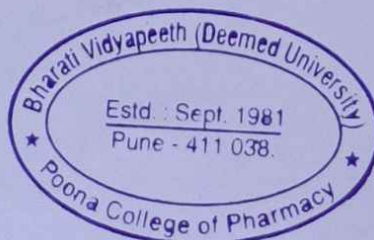
Name of College / Institute : - Poona College of Pharmacy, Pune - 411038 (PTL)

Receipt and Payment 2020-2021

Receipt	Amount	Payment	Amount
		Salary & Allowances	65,394
Chemical Testing Charges	1,77,206	Salary	
		Honorarium	14,979
		Administrative Expenditure	
		III) Educational Expenses	
		Labrotary/Chemical Exps	18,601
		Bank Charges	
		Telephone Exp	
		Miscellaneous	
Sub-Total	1,77,206	Sub-Total	98,974

Sanle
Mr. Upendra S. Pendke
22/09/2021
Head
Poona College Of Pharmacy
Public Testing Laboratory
Pune

fbhyst
ACCOUNTANT
Bharati Vidyapeeth (Deemed to be University)
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.



fbhyst
Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

BVDU Centre for Food Testing Laboratory, Pune 2021-22

LBS Road

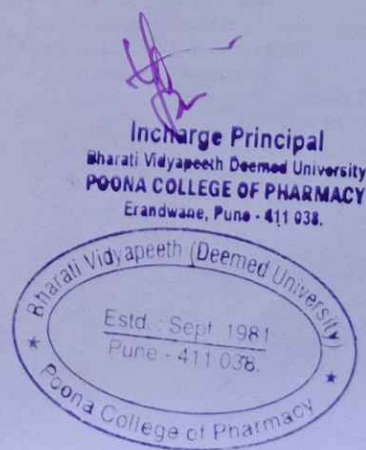
Pune

Income and Expenditure Statement

1-Apr-2020 to 31-Mar-2021

Particulars	1-Apr-2020 to 31-Mar-2021	Particulars	1-Apr-2020 to 31-Mar-2021
Purchase Accounts		Sales Accounts	41,88,536.92
Indirect Expenses		Sample Testing Fees	41,88,536.92
Administrative Expenditure	4,98,470.55	Bank Interest	16,163.00
Application/ Registration Fee Charge	34,000.00	Bank Interest	16,163.00
Audit Fee Charges	5,000.00	Other Receipts	
Bank Charges	820.40	Excess of expenditure over income	20,64,570.69
Cleaning & Maintenance Expenses	23,200.00		
Computer Repairs & Maintenance	23,196.57		
Conveyance Expenses	10,996.00		
Electrical Repairs & Maintenance	22,302.00		
Generator (Diesel) Expenses	4,000.00		
Insurance Charges (Machinery)	76,088.00		
Miscellaneous Expenses	30,720.58		
Postage & Courier Expenses	1,04,965.00		
Printing & Stationary	26,312.00		
Professional Fee Charges	60,760.00		
Repairs & Maintenance	48,987.00		
Telephone Expenses	2,406.00		
Transport Charges	2,400.00		
Travelling Expenses	22,317.00		
Depreciation	6,68,160.00		
Depreciation	6,68,160.00		
Laboratory Expenditure	26,24,440.06		
Equipments Repair & Maintenance	7,31,942.47		
GST Expenses (SGST & CGST)	30,076.00		
Internet /Website Expenses	2,497.00		
Journals & Reading Room Expenses	10,000.00		
Lab Consumable Material	14,04,879.59		
Laboratory Expenses	1,575.00		
Sample Collection Charges	1,80,370.00		
Sample Testing Charges	2,63,100.00		
Salaries & Allowance	24,78,200.00		
Provident Fund- Mangt Share	93,241.00		
Salary & Allowances	23,00,971.00		
Honorarium	83,988.00		
Total	62,69,270.61	Total	62,69,270.61

Handwritten signature



Bharati Vidyapeeth (Deemed to be University), Pune (India)

Name of College / Institute : - Poona College of Pharmacy, Pune - 411038 (PTL)

Receipt and Payment 2020-2021

Receipt	Amount	Payment	Amount
		Salary & Allowances	
Chemical Testing Charges	1,77,206	Salary	65,394
		Honorarium	
		Administrative Expenditure	14,979
		III) Educational Expenses	
		Labrotary/Chemical Exps	18,601
		Bank Charges	
		Telephone Exp	
		Miscellenous	
Sub-Total	1,77,206	Sub-Total	98,974

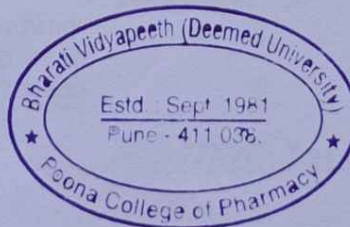
Janle

Dr. Upendra S. pendte

22/09/2021

Head

**Poona College Of Pharmacy
Public Testing Laboratory
Pune**



ABhyat
ACCOUNTANT
Bharati Vidyapeeth (Deemed to be University)
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

[Signature]
Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

BVDU Centre for Food Testing Laboratory, Pune 2021-22

LBS Road

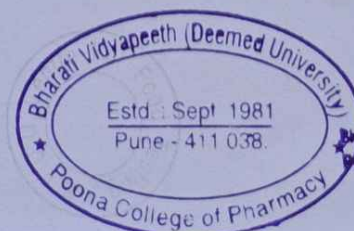
Pune

Income and Expenditure Statement

1-Apr-2020 to 31-Mar-2021

Particulars	1-Apr-2020 to 31-Mar-2021	Particulars	1-Apr-2020 to 31-Mar-2021
Purchase Accounts		Sales Accounts	41,88,536.92
Indirect Expenses		Sample Testing Fees	41,88,536.92
Administrative Expenditure	4,98,470.55	Bank Interest	16,163.00
Application/ Registration Fee Charge	34,000.00	Bank Interest	16,163.00
Audit Fee Charges	5,000.00	Other Receipts	
Bank Charges	820.40	Excess of expenditure over income	20,64,570.69
Cleaning & Maintenance Expenses	23,200.00		
Computer Repairs & Maintenance	23,196.57		
Conveyance Expenses	10,996.00		
Electrical Repairs & Maintenance	22,302.00		
Generator (Diesel) Expenses	4,000.00		
Insurance Charges (Machinery)	76,088.00		
Miscellaneous Expenses	30,720.58		
Postage & Courier Expenses	1,04,965.00		
Printing & Stationary	26,312.00		
Professional Fee Charges	60,760.00		
Repairs & Maintenance	48,987.00		
Telephone Expenses	2,406.00		
Transport Charges	2,400.00		
Travelling Expenses	22,317.00		
Depreciation	6,68,160.00		
Depreciation	6,68,160.00		
Laboratory Expenditure	26,24,440.06		
Equipments Repair & Maintenance	7,31,942.47		
GST Expenses (SGST & CGST)	30,076.00		
Internet /Website Expenses	2,497.00		
Journals & Reading Room Expenses	10,000.00		
Lab Consumable Material	14,04,879.59		
Laboratory Expenses	1,575.00		
Sample Collection Charges	1,80,370.00		
Sample Testing Charges	2,63,100.00		
Salaries & Allowance	24,78,200.00		
Provident Fund- Mangt Share	93,241.00		
Salary & Allowances	23,00,971.00		
Honorarium	83,988.00		
Total	62,69,270.61	Total	62,69,270.61

Signature




Signature
Incharge Principal
Bharati Vidyapeeth Deemed University
POONA COLLEGE OF PHARMACY
Erandwane, Pune - 411 038.

Envi.Edu.and Outreach Prog.(JRD TATA TRUST)

BHARATI SAH.BANK LTD A/C NO.27802 Book

1-Mar-2020 to 31-Mar-2020

					Page 1
Date	Particulars	Vch Type	Vch No.	Debit	Credit
31-3-2020	To B.V.D.U.Inst.of Environment Edu. & Research	Receipt	1	28,924.00	
	To Bank Interest	Receipt	2	744.00	
	By 3.3.1 Designing/Printing/stationary (73 % Trust)	Payment	1		36.00
	To ENVIRON.EDU.AND OUTREACH PROG.IN SCHOOLS	Receipt	3	15,00,000.00	
				15,29,668.00	36.00
By	Closing Balance				15,29,632.00
				15,29,668.00	15,29,668.00


Prof. Dr. Shamita Kumar
Vice Principal
Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road, Pune-411 043.

1-BVU Institute of Env. Edu. & Research[M.Sc]2018 to 2020

KATRAJ DHANKWADI

PUNE 411043

Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi

Ledger Account

1-Apr-2020 to 31-Mar-2021

Date	Particulars	Vch Type	Vch No.	Debit	Credit
1-4-2020 To	Opening Balance			3,39,153.00	
30-4-2020 To	(as per details)	Journal	4	38,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	45,000.00 Dr			
	Reshma Paradhi	22,000.00 Dr			
	Environment Garden Expenses	27,100.00 Dr			
	Envi.Edu.For Sustaibable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	1,53,300.00 Cr			
	<i>project staff salary for the month of April -2020</i>				
27-6-2020 To	(as per details)	Journal	8	62,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	85,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.For Sustaibable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	61,900.00 Dr			
	Profession Tax Payable	1,400.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	2,56,100.00 Cr			
	<i>project staff salary for the month of May -2020</i>				
6-7-2020 To	(as per details)	Journal	14	50,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Envi.Edu.For Sustaibable Dev. for SCHOOL IN MAVAL	22,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.For Sustaibable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Profession Tax Payable	1,200.00 Cr			
	Reshma Paradhi	2,000.00 Cr			
	Project Staff Salary Payable	2,03,600.00 Cr			
	<i>project staff salary for the month of June -2020</i>				
13-7-2020 By	(as per details)	Receipt	40		4,04,000.00
	TDS Receivable on Receipts	40,400.00 Dr			
	Bharati Saha.Bank A/c.5720	3,63,600.00 Dr			
	<i>ch.no.139482 dt.5.7.2020 as per receipt no. 15936</i>				
11-8-2020 By	Bharati Saha.Bank A/c.5720	Receipt	99		1,50,000.00
	<i>ch.no.478042 dt.10.8.2020 as per receipt no.15991 amount received JRD TATA TRUST SALARY TRANSFER AGAINST</i>				
30-9-2020 To	Bharati Saha.Bank A/c.5720	Payment	277	11,800.00	
	<i>ch.no.477704 dt.5.10.2020 as per day book as on dated 30.09.2020</i>				
Carried Over				5,00,953.00	5,54,000.00

continued ...

Shamita
Prof. Dr. Shamita Kumar
Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research,
Pune-Satara Road, Pune-411 043.

1-BVU Institute of Env. Edu. & Research[M.Sc]2018 to 2020

KATRAJ DHANKWADI

PUNE 411043

Edu.for Marine and Coastal Bio.in Schools at Mithap

Ledger Account

1-Apr-2020 to 31-Mar-2021

Date	Particulars	Vch Type	Vch No.	Debit	Credit
1-4-2020 To	Opening Balance			5,70,270.00	
30-4-2020 To	(as per details)	Journal	4	45,000.00	
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	38,000.00 Dr			
	Reshma Paradhi	22,000.00 Dr			
	Environment Garden Expenses	27,100.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	1,53,300.00 Cr			
	project staff salary for the month of April -2020				
27-6-2020 To	(as per details)	Journal	8	85,000.00	
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	62,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	61,900.00 Dr			
	Profession Tax Payable	1,400.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	2,56,100.00 Cr			
	project staff salary for the month of May -2020				
6-7-2020 To	(as per details)	Journal	14	65,000.00	
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	50,000.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	22,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	15,200.00 Dr			
	Profession Tax Payable	1,200.00 Cr			
	Reshma Paradhi	2,000.00 Cr			
	Project Staff Salary Payable	2,03,600.00 Cr			
	project staff salary for the month of June -2020				
11-8-2020 To	(as per details)	Journal	19	65,000.00	
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Profession Tax Payable	600.00 Cr			
	Project Staff Salary Payable	1,24,200.00 Cr			
	project staff salary for the month of July -2020				
3-9-2020 By	Bharati Saha.Bank A/c.5720	Receipt	176		12,00,000.00
	ch.no.139486 dt.5.9.2020 as per receipt no. 15670				

Carried Over

8,30,270.00

12,00,000.00

continued ...

Prof. Dr. Shamita Kumar
Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road. Pune-411 043.


Date	Particulars	Vch Type	Vch No.	Debit	Credit
	Brought Forward			8,30,270.00	12,00,000.00
10-9-2020	To (as per details)	Journal	24	65,000.00	
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	5,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	600.00 Cr			
	Project Staff Salary Payable	1,36,200.00 Cr			
	project staff salary for the month of August -2020				
30-9-2020	To (as per details)	Journal	28	65,000.00	
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	5,200.00 Dr			
	Profession Tax Payable	400.00 Cr			
	Project Staff Salary Payable	1,08,200.00 Cr			
	project staff salary for the month of September-2020				
5-11-2020	To (as per details)	Journal	36	65,000.00	
	Biodiver.& Biores.Potential of Solat Plants at Neem	80,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Profession Tax Payable	1,400.00 Cr			
	Project Staff Salary Payable	2,07,200.00 Cr			
	project staff salary for the month of October-2020				
3-12-2020	To (as per details)	Journal	42	65,000.00	
	Biodiver.& Biores.Potential of Solat Plants at Neem	40,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	5,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Project Staff Salary Payable	1,67,600.00 Cr			
	project staff salary for the month of Novem, ber-2020				
31-12-2020	To (as per details)	Journal	50	65,000.00	
	Biodiver.& Biores.Potential of Solat Plants at Neem	40,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Project Staff Salary Payable	1,67,600.00 Cr			
	project staff salary for the month of December-2020				
8-1-2021	By Bharati Saha.Bank A/c.5720	Receipt	420		1,52,568.00
	ch.no.139502 dt.08.01.2021 as per receipt no.16304				

Carried Over

11,55,270.00

13,52,568.00

continued ..


Prof. Dr. Shamita Kumar
Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road, Pune-411 043.

National Act.for the Internat.Menot.for Esd Leaders


Bharati Sah.Bank Ltd. A/c No.31368

Monthly Summary

1-Apr-2020 to 31-Mar-2021

Page 1

Particulars	Transactions		Closing Balance
	Debit	Credit	
Opening Balance			
April			
May			
June			
July			
August			
September			
October			
November	3,742.00	5.00	3,737.00 Dr
December	8,48,866.00	3,88,001.40	4,64,601.60 Dr
January		3,82,015.00	82,586.60 Dr
February			82,586.60 Dr
March	3,207.00	123.00	85,670.60 Dr
Grand Total	8,55,815.00	7,70,144.40	85,670.60 Dr


Prof. Dr. Shamita Kumar
Vice Principal
Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road, Pune-411 043.

1-BVU Institute of Env. Edu. & Research[M.Sc]2018 to 2020

KATRAJ DHANKWADI

PUNE 411043

Biodiver.& Biores.Potential of Solat Plants at Neem

Ledger Account

1-Apr-2020 to 31-Mar-2021

Date	Particulars	Vch Type	Vch No.	Debit	Page 1 Credit
5-11-2020	To (as per details)	Journal	36	80,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Profession Tax Payable	1,400.00 Cr			
	Project Staff Salary Payable	2,07,200.00 Cr			
	project staff salary for the month of October-2020				
	To Bharati Saha.Bank A/c.5720	Payment	383	17,476.00	
	ch.no.492120 dt.04.11.2020 as per day book as on dated 05.11.2020				
	To Bharati Saha.Bank A/c.5720	Payment	384	752.00	
	ch.no.492121 dt.04.11.2020 as per day book as on dated 05.11.2020				
3-12-2020	To (as per details)	Journal	42	40,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	5,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Project Staff Salary Payable	1,67,600.00 Cr			
	project staff salary for the month of Novem, ber-2020				
31-12-2020	To (as per details)	Journal	50	40,000.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Project Staff Salary Payable	1,67,600.00 Cr			
	project staff salary for the month of December-2020				
28-1-2021	To Bharati Saha.Bank A/c.5720	Payment	545	8,133.00	
	ch.no.492211 dt.01.02.2021 as per day book as on dated 28.01.2021				

Carried Over

1,86,361.00

continued ...

Prof. Dr. Shamita Kumar
Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road, Pune-411 043.

Date	Particulars	Vch Type	Vch No.	Debit	Credit
	Brought Forward			1,86,361.00	
30-1-2021	To (as per details)	Journal	57	27,742.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	13,548.00 Dr			
	Environment Garden Expenses	17,719.00 Dr			
	Envi.Edu.For Sustainable Dev. for SCHOOL IN MAVAL	5,200.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	975.00 Cr			
	Project Staff Salary Payable	1,40,234.00 Cr			
	project staff salary for the month of January -2021				
2-2-2021	By Bharati Saha.Bank A/c.5720	Receipt	438		2,40,500.00
	ch.no.139505 dt.01.02.2021 as per receipt no. 16318				
26-2-2021	To Cash in Hand	Payment	603	9,892.00	
	as per day book as on dated 26.2.2021				
	To Bharati Saha.Bank A/c.5720	Payment	604	12,992.00	
	ch.no.492228 dt.19.2.2021 as per day book as on dated 26.2.2021.				
	To Bharati Saha.Bank A/c.5720	Payment	605	8,870.00	
	ch.no.492232 dt.19.2.2021 as per day book as on dated 26.2.2021				
	To Bharati Saha.Bank A/c.5720	Payment	606	4,868.00	
	ch.no.492264 dt.1.3.2021 as per day book as on dated 26.2.2021				
	To Bharati Saha.Bank A/c.5720	Payment	607	9,000.00	
	ch.no.492263 dt.1.3.2021 as per day book as on dated 26.2.2021				
	To Bharati Saha.Bank A/c.5720	Payment	608	7,600.00	
	ch.no.492269 dt.1.3.2021 as per day book as on dated 26.2.2021				
27-2-2021	To (as per details)	Journal	63	43,871.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	H20-T-T2s in Urban Fringe Areas Koln University	40,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	20,000.00 Dr			
	Profession Tax Payable	2,100.00 Cr			
	Project Staff Salary Payable	1,66,771.00 Cr			
	project staff salary for the month of february -2021				
12-3-2021	To Bharati Saha.Bank A/c.5720	Payment	669	9,022.00	
	ch.no.492274 dt.12.3.2021 as per day book as on dated 12.3.2021				
	To Bharati Saha.Bank A/c.5720	Payment	670	5,000.00	
	ch.no.492277 dt.12.3.2021 as per day book as on dated 12.3.2021				
	To Bharati Saha.Bank A/c.5720	Payment	671	5,000.00	
	ch.no.492276 dt.12.3.2021 as per day book as on dated 12.3.2021				
	To Bharati Saha.Bank A/c.5720	Payment	672	10,000.00	
	ch.no.492275 dt.12.3.2021 as per day book as on dated 12.3.2021				
	Carried Over			3,40,218.00	2,40,500.00

continued ...


Prof. Dr. Shamita Kumar
Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research
Pune-Satara Road, Pune-411 043.

1-BVU Institute of Env. Edu. & Research[M.Sc]2018 to 2020

KATRAJ DHANKWADI

PUNE 411043

Envi.Edu.For Sustaible Dev. for SCHOOL IN MAVAL

Ledger Account

1-Apr-2020 to 31-Mar-2021

Date	Particulars	Vch Type	Vch No.	Debit	Credit
1-4-2020	To Opening Balance			1,94,165.00	
30-4-2020	To (as per details)	Journal	4	15,200.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	45,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	38,000.00 Dr			
	Reshma Paradhi	22,000.00 Dr			
	Environment Garden Expenses	27,100.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Profession Tax Payable	1,000.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	1,53,300.00 Cr			
	project staff salary for the month of April -2020				
1-6-2020	By Bharati Saha.Bank A/c.5720	Receipt	4		3,75,000.00
	ch.no.139481 dt.1.6.2020 as per receipt no. 15902				
27-6-2020	To (as per details)	Journal	8	15,200.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	85,000.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Building Maintenance	12,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	62,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	61,900.00 Dr			
	Profession Tax Payable	1,400.00 Cr			
	Reshma Paradhi	5,000.00 Cr			
	Project Staff Salary Payable	2,56,100.00 Cr			
	project staff salary for the month of May -2020				
	To Cash in Hand	Payment	67	5,000.00	
	as per day book as on dated 27.6.2020				
6-7-2020	To (as per details)	Journal	14	37,200.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Edu.for Sust.Dev.Prog.in Schools at Kirloskarwadi	50,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Profession Tax Payable	1,200.00 Cr			
	Reshma Paradhi	2,000.00 Cr			
	Project Staff Salary Payable	2,03,600.00 Cr			
	project staff salary for the month of June -2020				
11-8-2020	To (as per details)	Journal	19	5,200.00	
	Edu.for Marine and Coastal Bio.in Schools at Mithap	65,000.00 Dr			
	Envi.Edu.for Sustainable Dev. for School in Mulshi	28,200.00 Dr			
	Environment Garden Expenses	26,400.00 Dr			
	Profession Tax Payable	600.00 Cr			
	Project Staff Salary Payable	1,24,200.00 Cr			
	project staff salary for the month of July -2020				
	Carried Over			2,71,965.00	3,75,000.00

continued ...

Prof. Dr. Shamita Kumar

Vice Principal

Bharati Vidyapeeth Deemed to be University
Institute of Environment Education & Research

Pune-Satara Road, Pune-411 043.



Grant-in-Aid Agreement

This **Grant-in-Aid Agreement ("GIA Agreement")** is made and entered into on this **15** day of **June**, 2020 ("**Effective Date**"),

BETWEEN

Tata Power Community Development Trust, a Trust duly registered under the Bombay Public Trusts Act 1950, vide Registration number E - 25632 with its registered office at Bombay House, 24, Homi Mody Street, Mumbai 400001(hereinafter referred to as **TPCDT** which expression shall unless repugnant to the context thereof be deemed to mean and include its successors and assigns), of the ONE PART;

AND

Bharati Vidyapeeth (Pune), a non-profit organization registered as **Registered with Charities Commissioner**, registration number **90186** under the **Societies Registration Act 1860** with its registered office **BVDU Social Sciences Centre, New Law College Building, Erandwane Campus, Pune 411 038** India, represented by its Trustee/Authorised Signatory **Dr. Ganesh R Rathod** having current and valid Income tax 12AA registration certificate for tax exemption and 80G tax Deduction certificate, hereinafter referred to as **Bharati Vidyapeeth (Pune)** which expression shall unless repugnant to the context thereof be deemed to mean and include its successors and permitted assigns), of the OTHER PART.

(Hereinafter **TPCDT** and **Bharati Vidyapeeth (Pune)** shall be individually referred to as "**the Party**" and collectively as "**the Parties**")

WHEREAS:

- a) TPCDT is, inter alia, engaged in non-profit & community development initiatives **under 5 thrust areas namely Education, Health & Sanitation, Livelihood & Employability, Water and Financial Inclusion**, and is a key facilitator that supports developmental projects across identified locations to create and offer sustainable solutions to the diverse challenges faced by local communities.
- b) **Bharati Vidyapeeth (Pune)** is a non-profit organization based out of **Pune** working in the field of **Health & Sanitation**. The NGO works in the states of **Maharashtra**. The mission is to **To be world class university for social transmission through dynamic education linkages with employability on entrepreneurship especially women and adolescent girls**. The average annual gross contribution received by the NGO for last three years amount Rs5Cr. The NGO operates at locations such as

Pune, Solapur, Sangli District of Maharashtra. in the thrust areas of Education, Health, Livelihood, Women Empowerment and Employability.

- c) ***Bharati Vidyapeeth(Pune)*** has submitted a proposal dated 15-May-2020 to TPCDT for conducting ***Integrated Community Health Care : Promote and sensitize preventive health care – Anemia, Malnutrition, Breast Feeding, Health Behavior Change Communication*** and same forms part of GIA Agreement and is marked as **Annex- 3**
- d) TPCDT is desirous of being partner in the Intervention to be implemented by Bharati Vidyapeeth (Pune)The scope of the intervention and funding are as detailed and forms part of this GIA Agreement
- e) ***Bharati Vidyapeeth (Pune)***would not sublet or delegate any of the project activities as part of this GIA Agreement.
- f) Believing the aforesaid to be true, and in furtherance of its Mission & Objectives, TPCDT has agreed to engage ***Bharati Vidyapeeth (Pune)***, **through this GIA Agreement**, as the implementing agency to ***Integrated Community Health Care : Promote and sensitize preventive health care – Anemia, Malnutrition, Breast Feeding, Health Behavior Change Communication***

NOW THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, agree as follows:

1. INTERVENTION & ADMINISTRATION

- a) **Intervention Title:** ***Integrated Community Health Care : Promote and sensitize preventive health care – Anemia, Malnutrition, Breast Feeding, Health Behavior Change Communication***
- b) **Scope:** ***To improve technical knowledge and counseling skill on Nutrition and Health from AWW & ANM/ASHA and Peer Educators from Mulshi and Mangaon Taluka of Pune and Raigad Districts.***
- c) **Project Objectives:** ***To create awareness about COVID-19 virus, Anemia , Malnutrition and Health as well as Nutrition among 8500 villagers and Govt. Service providers. (Refer Annex-3, Sec-B,4)***
- d) **Project Timelines:** ***From 01-Jun-2020 to 31-Mar-2021***
- e) **Name of Collaborating Organizations:**
- f) ***Bharati Vidyapeeth (Pune)*** is the implementing organization for this Project.
- g) TPCDT is the non-profit organization, which would be funding this Project, by way of Grant-in-Aid in furtherance of developmental objects.

2. PROJECT LOCATION:

- a) State & District ***Maharashtra & Pune***
- b) Revenue Block ***Mulshi***
- c) Gram Panchayat or Ward ***Mulshi (Kh)***
- d) No of Villages or Ward Mohallas ***20*** covered
- e) Beneficiaries potentially covered through this project ***8500 (Refer Annex-3,Sec-B-6)***
- f) SC & ST Beneficiaries as ***20*** % of above (No.), covered through this intervention.

3. THE WORKING RELATIONSHIP:

The bipartite collaboration would be guided by the following mutually agreed principles:

- a) All the parties shall ensure transparency and accountability in all activities undertaken as a part of the intervention.

- b) The parties shall encourage adoption of a scientific, rational, democratic, bottoms-up, community needs-based approach to the issues addressed.
- c) The parties shall encourage the use of technology-based interventions for higher impacts, outreach and outcomes.
- d) Each stakeholder to designate Single Point of Contact (SPoC) for effective coordination during the project execution.

4. **INTERVENTION TERM AND WORKPLAN**

- a) The intervention shall be implemented in accordance with GIA Agreement and the intervention proposal set out in Annexure-3.
- b) **Bharati Vidyapeeth (Pune)** shall forthwith notify TPCDT in writing in the event of the occurrence of any event that may cause delay in achieving the intervention delivery milestone.
- c) The terms of the intervention under this GIA Agreement of FY-19.
- d) The work plan in terms of (NGO name) deliverables with timelines mentioned in (Annexure-3, Sec B-8)

5. **INTERVENTION BUDGET/PARTNERS NAME & PAYMENT TERMS:**

- a) TPCDT has sanction to **Bharati Vidyapeeth (Pune)** a Grant-in-Aid of **600000.0** (Indian Rupees **Six Lakhs** for the Project to be undertaken by **Bharati Vidyapeeth (Pune)** in relation to Integrated Community Health Care : Promote and sensitize preventive health care – Anemia, Malnutrition, Breast Feeding, Health Behavior Change Communication as "Authorized/Approved Activities")
- b) TPCDT shall deploy financial resources for the Term of this GIA Agreement up to a total cost of INR **600000.0** (Indian Rupees **Six Lakhs** only). (Annex-3 Sec-B-8) The **Bharati Vidyapeeth (Pune)** agrees that the project management charges shall not exceed 10% of the total Grant-in-Aid (INR) Amount, and to that effect satisfies TPCDT.
- c) It is understood and agreed between the Parties that TPCDT's Grant-in-Aid to **Bharati Vidyapeeth (Pune)** , is with respect to the intervention as per KPIs mentioned in (Annex-2)
- d) Compliances & Schedule of Payments for Total Grant Amount of Rs: **600000.0**

Installment number	Installment payment (in %)	Installment Amount	Key Milestone (Annex-1)
1	25%	150000.0	On signing of GIA Agreement
2	30%	180000.0	On completion of agreed key deliverables mentioned in Annexure-1 and 80% utilization of 1st installment.
3	35%	210000.0	On Completion of 50% of Key performance indicators [Midline study] (Refer KPIs annex-2) and 80% utilization of 2nd installment.
4	10%	60000.0	Completion of all initiatives, 80% utilization of 3rd installment, achieving 100% KPIs and submission of end line report.

- a) **Bharati Vidyapeeth (Pune)** shall submit expenditure statements, indicating usage of 80% of first and consequent Grant installments, during course of the project based on actuals.
- b) Any cost escalation of the Project beyond the Grant in Aid Amount, committed hereinabove shall be borne by **Bharati Vidyapeeth (Pune)**
- c) The pre-commissioning process shall start immediately after accepting and signing of the GIA Agreement between the Parties. Work shall be completed as per milestones and timelines defined in "Scope" part of this document jointly planned and agreed by both parties.
- d) **Bharati Vidyapeeth (Pune)** shall submit program report for the immediate previous month in the reporting cycle by 5th of the month, along with relevant supporting documents to TPCDT.
- e) **Bharati Vidyapeeth (Pune)** shall submit financial report including expenses incurred for the immediate previous month in the reporting cycle of 1st to 31st calendar month, along with relevant supporting documents to TPCDT
- f) If TPCDT does not receive two consecutive progress reports (both programmatic and financial) it shall be at liberty to hold the project or hold further release of Grant-in-Aid Assistance agreed by TPCDT
- g) **Bharati Vidyapeeth (Pune)** shall refund any unutilized Grant, to TPCDT at the end of a Project. Both Parties may discuss possibility of, and TPCDT may approve appropriate utilization of unutilized grants in a manner agreed by both Parties, with set timelines
- h) TPCDT has the sole authority to hold, stop or extend the Project timeline and Grant-in-Aid Amount.
- i) TPCDT provides Grants based on funding received annually from its Funders. In cases of multiyear programs, where the payments cross a financial year (31 March), the Grant Amounts made post this period may vary, depending on changes in funds and program directions/focus.

6. **REPRESENTATIONS & WARRANTIES:**

- a) **Mutual Representations and Warranties** - Each Party represents and warrants to the other Party that:
 - i. It has the full right, power and authority to enter into this GIA Agreement, to Grant-in-Aid the rights Grant-in-Aided hereunder and to perform its obligations hereunder;
 - ii. The execution of this GIA Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary action of the Party; and
 - iii. When executed and delivered by such Party, this GIA Agreement will constitute the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.
 - iv. For hardware and software, **Bharati Vidyapeeth (Pune)** is solely responsible and accountable owner of the same.
 - v. The product warranties, any maintenance, repair or damage will be tracked by **Bharati Vidyapeeth (Pune)**
- b) **Representations and Warranties of Bharati Vidyapeeth (Pune)**

Bharati Vidyapeeth (Pune) represents and warrants to TPCDT that: The execution, delivery and performance of this GIA Agreement do not and shall not be inconsistent and violate any agreed obligation of **Bharati Vidyapeeth (Pune)**;

 - i. The Grant-in-Aid shall be directed only towards Authorized/ Approved Activities as set out;

- ii. From time to time, Mr./Ms. ***Dilip Kawade*** or any other nominee of TPCDT shall be invited to respective field locations or project locations, to undertake field visits, along with employees/representative of ***Bharati Vidyapeeth (Pune)*** engaged in the Project
- iii. It shall furnish to TPCDT, copies of all necessary permissions and other necessary documents received from relevant government authorities and departments, conveying permission/ no-objection for covering the selected Project;
- iv. The resources received for this project shall be used for the Project objectives only and not for any commercial use. The resources shall be used, maintained and treated as a value to the respective projects;

7. **USE OF TATA POWER LOGO FOR BRANDING:**

- g) This Intervention is being deployed under Tata Power Health & Sanitation CSR Intervention. The logo of Tata Power and brand name of intervention can be used appropriately by ***Bharati Vidyapeeth (Pune)*** within the scope of this intervention with mutual consent of both parties.

8. **NO LIABILITY**

- a) ***Bharati Vidyapeeth (Pune)*** shall comply with all laws, regulations and also arrange to provide all the necessary approvals for carrying out all the plans agreed between the parties, for ensuring compliance of all applicable law, statutes for deployment as mentioned in this GIA Agreement. TPCDT shall not be liable in any manner whatsoever for any non-compliance in respect of the applicable laws, regulations and in the event of any adverse claim of whatsoever nature arising thereof, the entire burden shall be strictly borne by ***Bharati Vidyapeeth (Pune)***.
- b) Nothing in this GIA Agreement is intended or shall be construed to authorize either Party to create or assume any liability or indebtedness of any kind in the name of, or on behalf of the other Party or to act for or be responsible for the performance of the other Party in any manner except and to the extent expressly provided in this GIA Agreement. Notwithstanding anything contrary contained herein the parties shall not be obliged to incur any liability in case of any of the parties shall without prior specific approval/ consent of the other parties' credit or accept any contract binding upon the parties other than as envisaged in this GIAA.

9. **CONFIDENTIALITY**

The parties agree that all data which is transmitted or communicated by either party to the other party shall in all cases be held in confidence by the Receiving Party and not disclosed to any third party unless written consent of Disclosing Party is first obtained, except that, Receiving Party has the right to disclose such information to its own employees, consultants and representatives who are bound by an obligation of confidentiality and who need to know such information for the purposes specified hereinabove. The Receiving Party agrees that it shall not use the confidential data for any purpose(s) other than the ones specified herein. However, the Receiving Party shall not be required to maintain confidential or be restricted in its use of any data which,

- i. Was in public domain at the date of disclosure to Receiving Party
- ii. Becomes public knowledge during the term of this GIA Agreement without breach of this GIA Agreement
- iii. Receiving Party can show that it was in its possession prior to disclosure by Disclosing Party, and

- iv. Disclosure of which is required by law or by order of a court of competent jurisdiction. The obligation as to confidentiality shall survive for 5 years post termination/ expiry of this GIA Agreement.

10. INTELLECTUAL PROPERTY RIGHTS (IPR)

With respect to the services rendered under this GIA Agreement, the Parties agree that:

- a) All IPR arising out of this GIA Agreement and the data, information or activities therein shall solely vest with **TPCDT**. Usage of any such data or information that involves the IPR for **TPCDT** shall amount to an infringement if such usage is not authorized in writing.
- b) **Bharati Vidyapeeth (Pune)** agrees that it shall comply with all the relevant laws and shall not infringe in any IPR in the course of performing its obligations under this GIA Agreement.
- c) **Bharati Vidyapeeth (Pune)** agreed to indemnify/ keep indemnified **TPCDT** from all claims, suits, actions, losses, penalties or liabilities arising out of a breach of the clauses above.

11. ETHICAL BEHAVIOUR:

- a) **Bharati Vidyapeeth (Pune)** represent and warrant that it has conducted and shall conduct its business in accordance with the highest ethical standards and it shall comply with all applicable laws in the performance of its obligations under this **GIA Agreement**, including but not limited to, laws dealing with ethical business practices.
- b) If, at any time during the term of this **GIA Agreement**, **Bharati Vidyapeeth (Pune)** is informed or information comes to its attention that it or any of its affiliates is or may be in violation of any applicable law (or if it is so determined by any court, tribunal or governmental agency or authority), **Bharati Vidyapeeth (Pune)** shall immediately take all appropriate steps (including any reasonable requests by **TPCDT**) to remedy such violation and comply with such a law in all respects. Where such violation occurs and is not remedied **TPCDT** may terminate this GIA Agreement with immediate effect.
- c) **Bharati Vidyapeeth (Pune)** shall establish and maintain all proper records (including accounting records) required by applicable law and shall make such records available to **TPCDT**, if requested to do so. A certified utilization certificate shall be issued at the end of any project.
- d) **Bharati Vidyapeeth (Pune)** acknowledges of having read Tata Code of Conduct, accessed from Tata Power company website URL: <https://www.tatapower.com/pdf/aboutus/Tata-Code-Power-of-Conduct.pdf>
Bharati Vidyapeeth (Pune), as CSR Partner of Tata Power, acknowledges to comply with the guidelines given therein as part of upholding highest ethical standards during the deployment of this Project.

12. TERM, EXTENSION&TERMINATION/EXPIRY:

- a) This GIA Agreement shall commence as of the Effective date and shall remain in force until **31-Mar-2021**. Unless terminated earlier in accordance with the terms of this GIA Agreement. The Parties may renew this GIA Agreement on 'no cost to **TPCDT**' basis for a mutually agreed period if the situation so warrants, and the extension of period of agreement envisaged herein occasioned for the reasons not attributable to **Bharati Vidyapeeth (Pune)**, for its non-performance or delay in performance.
- b) **TPCDT** shall have the right to terminate this GIA Agreement immediately, for any reason whatsoever without assigning any reason thereof.

- c) In the event of termination, the ***Bharati Vidyapeeth (Pune)*** shall refund the unspent residual amount to TPCDT.

13. WAIVER:

No failure or delay by a party to exercise any right or remedy provided under this GIA Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.

14. VARIATION:

Both the Parties agree and confirm that the terms and conditions contained in this GIA Agreement may be changed / altered through written mutual consent; at any point, during course of the Agreement.

No variation of this GIA Agreement shall be effective unless it is in writing and signed by the Parties (or their authorised representatives).

15. SEVERANCE:

If any court or competent authority finds that any provision of this GIA Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this GIA Agreement shall not be affected.

16. THIRD PARTY RIGHTS:

No person other than a Party to this GIA Agreements shall have any rights to enforce any term of this GIA Agreement.

17. NO PARTNERSHIP OR AGENCY:

Nothing in this GIA Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute either Party the agent of the other Party, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.

18. NOTICES:

All notices related to this GIA Agreement which are permitted hereunder shall be in writing and deemed to have been duly given/served if delivered personally or sent by facsimile transmission (with answerback received) or overnight express or by registered mail or certified mail, postage prepaid. All notices shall be sent to the addresses mentioned in the title clause or to such other address as the Parties may designate from time to time in writing.

19. FORCEMAJURE:

- a) Neither Party shall be liable to the other for any delay or failure in the performance by it of any obligation under this GIA Agreement to the extent affected, delayed or prevented by an event of Force Majeure, provided that the Party that is affected by the Force Majeure shall provide notice thereof to the other Party as soon as practicable, but in any event not later than 7 [seven] days from the time which the affected Party knew or should reasonably have known of the commencement of the event of Force Majeure.
- b) The affected Party shall use its reasonable endeavours to mitigate the adverse effects of the Force Majeure event affecting it and shall seek reasonable alternative means to resume the Services, to the extent not affected by the event of Force Majeure. The affected Party shall provide to the other Party reasonable details as requested by the other Party regarding the nature of the Force Majeure event.

Neither Party shall be entitled to make any claim on the other for any fees, costs, expenses, losses or damages incurred or suffered as a result of an event of Force Majeure.

- c) If any event of Force Majeure continues beyond a period of one month, either Party may terminate this GIA Agreement.

20. ASSIGNMENT AND OTHER DEALINGS PROHIBITED:

This GIA Agreement is personal to the Parties and no Party shall, without the prior written consent of the other Party (such consent not to be unreasonably conditioned, withheld or delayed), assign, transfer, or deal in any other manner with this GIA Agreement or any of its rights and obligations under or arising out of this GIA Agreement, or purport to do any of the same. No Party shall sub-contract or delegate in any manner any or all of its obligations under this GIA Agreement to any third party or agent. Each Party that has rights under this GIA Agreement is acting on its own behalf and not for the benefit of another person.

21. ARBITRATION:

Any dispute or differences arising out of or in connection with this GIA Agreement (including the validity or interpretation hereof) shall be referred to the sole arbitrator to be nominated by Parties and the arbitration shall be governed by the provisions of the Indian Arbitration & Conciliation Act, 1996 or any law relating to arbitration in force at the time of such reference. The venue of the arbitration shall be Mumbai. The parties submit to the exclusive jurisdiction of the Courts of Mumbai.

22. GOVERNING LAW AND JURISDICTION:

This GIA Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of India. The parties irrevocably agree that the courts of Mumbai shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this GIA Agreement or its subject matter or formation (including non-contractual disputes or claims).

23. COUNTERPARTS:

This GIA Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this GIA Agreement, but all the counterparts shall together constitute the same GIA Agreement. No counterpart shall be effective until each party has executed at least one counterpart.

24. ENTIRE AGREEMENT:

This GIA Agreement constitutes the entire agreement between the parties and supersedes all previous agreements between the parties relating to its subject matter.

IN WITNESS WHEREOF the Parties hereto have caused this GIA Agreement to be executed, in duplicate, by their duly authorized representatives on the date first written above.

<p>For TPCDT</p> <p>Approved On: 25-Jun-2020 07:34:43 PM</p> <p>Name: <i>Nagori Forum</i></p> <p>Designation: <i>Head - Corporate Social Responsibility</i></p>	<p>For Bharati Vidyapeeth (Pune)</p> <p>Signature: <i>[Signature]</i></p> <p>Name: Dr. G. R. Rathod</p> <p>Designation: DIRECTOR</p> <p>Bharati Vidyapeeth (Deemed to be University) Social Science Centre (M.S.W) Erandwane, Pune - 411 038.</p>
--	--



Grant-in-Aid Agreement

This **Grant-in-Aid Agreement ("GIA Agreement")** is made and entered into on this **30** day of **June**, 2020 ("**Effective Date**"),

BETWEEN

Tata Power Community Development Trust, a Trust duly registered under the Bombay Public Trusts Act 1950, vide Registration number E - 25632 with its registered office at Bombay House, 24, Homi Mody Street, Mumbai 400001(hereinafter referred to as **TPCDT** which expression shall unless repugnant to the context thereof be deemed to mean and include its successors and assigns), of the ONE PART;

AND

Bharati Vidyapeeth(Pune), a non-profit organization registered as **Registered with Charities Commissioner**, registration number **90186** under the **Societies Registration Act 1860** with its registered office **Social Sciences Centre, FIED8 Dr. G. R. Rathod** having current and valid Income tax 12AA registration certificate for tax exemption and 80G tax Deduction certificate, hereinafter referred to as **Bharati Vidyapeeth(Pune)** which expression shall unless repugnant to the context thereof be deemed to mean and include its successors and permitted assigns), of the OTHER PART.

(Hereinafter **TPCDT** and **Bharati Vidyapeeth(Pune)** shall be individually referred to as "**the Party**" and collectively as "**the Parties**")

WHEREAS:

- a) TPCDT is, inter alia, engaged in non-profit & community development initiatives under **5 thrust areas namely Education, Health & Sanitation, Livelihood & Employability, Water and Financial Inclusion**, and is a key facilitator that supports developmental projects across identified locations to create and offer sustainable solutions to the diverse challenges faced by local communities.
- b) **Bharati Vidyapeeth(Pune)** is a non-profit organization based out of **Pune (Maharashtra)** working in the field of **Livelihood & Skill Building**. The NGO works in the states of **Maharashtra**. The mission is to **Social transmission through dynamic education**. The average annual gross contribution received by the NGO for last three years amount Rs 5Cr. The NGO operates at locations such as Social Sciences Centre, BharatiVidyapeeth Deemed University, Erandawane, Pune-411038 in the thrust areas of Education, Health and livelihood and employability.

GNT202100000023

- c) ***Bharati Vidyapeth(Pune)*** has submitted a proposal dated 14-May-2020 to TPCDT for conducting ***Micro Enterprises for Women (DHAAGA)*** and same forms part of GIA Agreement and is marked as **Annex - 3**
- d) TPCDT is desirous of being partner in the Intervention to be implemented by ***Bharati Vidyapeth(Pune)*** The scope of the intervention and funding are as detailed and forms part of this GIA Agreement
- e) ***Bharati Vidyapeth(Pune)*** would not sublet or delegate any of the project activities as part of this GIA Agreement.
- f) Believing the aforesaid to be true, and in furtherance of its Mission & Objectives, TPCDT has agreed to engage ***Bharati Vidyapeth(Pune)***, **through this GIA Agreement**, as the implementing agency to ***Micro Enterprises for Women (DHAAGA)***

NOW THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, agree as follows:

1. INTERVENTION & ADMINISTRATION

- a) **Intervention Title:** ***Micro Enterprises for Women (DHAAGA)***
- b) **Scope:** ***Women will be linkages for financial resources with Government scheme.***
- c) **Project Objectives:** ***400 women from Mulshi block will be financially independent FIELD 15 , Sec-B,4)***
- d) **Project Timelines:** ***From 01-Apr-2020 to 31-Mar-2021***
- e) **Name of Collaborating Organizations:**
- f) ***Bharati Vidyapeth(Pune)*** is the implementing organization for this Project.
- g) TPCDT is the non-profit organization, which would be funding this Project, by way of Grant-in-Aid in furtherance of developmental objects.

2. PROJECT LOCATION:

- a) State & District ***Maharashtra & Pune***
- b) Revenue Block ***Mulshi***
- c) Gram Panchayat or Ward ***Maley***
- d) No of Villages or Ward Mohallas ***15*** covered
- e) Beneficiaries potentially covered through this project ***400 (Refer Annex-3,Sec-B-6)***
- f) SC & ST Beneficiaries as ***20 %*** of above (No.), covered through this intervention.

3. THE WORKING RELATIONSHIP:

The bipartite collaboration would be guided by the following mutually agreed principles:

- a) All the parties shall ensure transparency and accountability in all activities undertaken as a part of the intervention.
- b) The parties shall encourage adoption of a scientific, rational, democratic, bottoms-up, community needs-based approach to the issues addressed.
- c) The parties shall encourage the use of technology-based interventions for higher impacts, outreach and outcomes.
- d) Each stakeholder to designate Single Point of Contact (SPoC) for effective coordination during the project execution.

4. **INTERVENTION TERM AND WORKPLAN**

- The intervention shall be implemented in accordance with GIA Agreement and the intervention proposal set out in Annexure-3.
- Bharati Vidyapeth(Pune)** shall forthwith notify TPCDT in writing in the event of the occurrence of any event that may cause delay in achieving the intervention delivery milestone.
- The terms of the intervention under this GIA Agreement of FY-19.
- The work plan in terms of (NGO name) deliverables with timelines mentioned in (Annexure-3, Sec B-8)

5. **INTERVENTION BUDGET/PARTNERS NAME & PAYMENT TERMS:**

- TPCDT has sanction to **Bharati Vidyapeth(Pune)** a Grant-in-Aid of **1300000.0** (Indian Rupees **Thirteen Lakhs only** for the Project to be undertaken by **Bharati Vidyapeth(Pune)** in relation to Micro Enterprises for Women (DHAAGA) as "Authorized/Approved Activities")
- TPCDT shall deploy financial resources for the Term of this GIA Agreement up to a total cost of INR **1300000.0** (Indian Rupees **Thirteen Lakhs only** only). (Annex-3 Sec-B-8) The **Bharati Vidyapeth(Pune)** agrees that the project management charges shall not exceed 10% of the total Grant-in-Aid (INR) Amount, and to that effect satisfies TPCDT.
- It is understood and agreed between the Parties that TPCDT's Grant-in-Aid to **Bharati Vidyapeth(Pune)**, is with respect to the intervention as per KPIs mentioned in (Annex-2)
- Compliances & Schedule of Payments for Total Grant Amount of Rs: **1300000.0**

Installment number	Installment payment (in %)	Installment Amount	Key Milestone (Annex-1)
1	25%	325000.0	On signing of GIA Agreement
2	30%	390000.0	On completion of agreed key deliverables mentioned in Annexure-1 and 80% utilization of 1st installment.
3	35%	455000.0	On Completion of 50% of Key performance indicators [Midline study] (Refer KPIs annex-2) and 80% utilization of 2nd installment.
4	10%	130000.0	Completion of all initiatives, 80% utilization of 3rd installment, achieving 100% KPIs and submission of end line report.

- Bharati Vidyapeth(Pune)** shall submit expenditure statements, indicating usage of 80% of first and consequent Grant installments, during course of the project based on actuals.
- Any cost escalation of the Project beyond the Grant in Aid Amount, committed hereinabove shall be borne by **Bharati Vidyapeth(Pune)**
- The pre-commissioning process shall start immediately after accepting and signing of the GIA Agreement between the Parties. Work shall be completed as per milestones and timelines defined in "Scope" part of this document jointly planned and agreed by both parties.
- Bharati Vidyapeth(Pune)** shall submit program report for the immediate previous month in the reporting cycle by 5th of the month, along with relevant supporting documents to TPCDT.

GNT202100000023

- e) **Bharati Vidyapeth(Pune)** shall submit financial report including expenses incurred for the immediate previous month in the reporting cycle of 1st to 31st calendar month, along with relevant supporting documents to TPCDT
- f) If TPCDT does not receive two consecutive progress reports (both programmatic and financial) it shall be at liberty to hold the project or hold further release of Grant-in-Aid Assistance agreed by TPCDT
- g) **Bharati Vidyapeth(Pune)** shall refund any unutilized Grant, to TPCDT at the end of a Project. Both Parties may discuss possibility of, and TPCDT may approve appropriate utilization of unutilized grants in a manner agreed by both Parties, with set timelines
- h) TPCDT has the sole authority to hold, stop or extend the Project timeline and Grant-in-Aid Amount.
- i) TPCDT provides Grants based on funding received annually from its Funders. In cases of multiyear programs, where the payments cross a financial year (31 March), the Grant Amounts made post this period may vary, depending on changes in funds and program directions/focus.

6. **REPRESENTATIONS & WARRANTIES:**

- a) **Mutual Representations and Warranties** - Each Party represents and warrants to the other Party that:
 - i. It has the full right, power and authority to enter into this GIA Agreement, to Grant-in-Aid the rights Grant-in-Aided hereunder and to perform its obligations hereunder;
 - ii. The execution of this GIA Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary action of the Party; and
 - iii. When executed and delivered by such Party, this GIA Agreement will constitute the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.
 - iv. For hardware and software, **Bharati Vidyapeth(Pune)** is solely responsible and accountable owner of the same.
 - v. The product warranties, any maintenance, repair or damage will be tracked by **Bharati Vidyapeth(Pune)**
- b) **Representations and Warranties of Bharati Vidyapeth(Pune)**

Bharati Vidyapeth(Pune) represents and warrants to TPCDT that: The execution, delivery and performance of this GIA Agreement do not and shall not be inconsistent and violate any agreed obligation of **Bharati Vidyapeth(Pune)** ;

- i. The Grant-in-Aid shall be directed only towards Authorized/ Approved Activities as set out;
- ii. From time to time, Mr./Ms. **Dilip Kawade** or any other nominee of TPCDT shall be invited to respective field locations or project locations, to undertake field visits, along with employees/representative of **Bharati Vidyapeth(Pune)** engaged in the Project
- iii. It shall furnish to TPCDT, copies of all necessary permissions and other necessary documents received from relevant government authorities and departments, conveying permission/ no-objection for covering the selected Project;
- iv. The resources received for this project shall be used for the Project objectives only and not for any commercial use. The resources shall be used, maintained and treated as a value to the respective projects;

7. **USE OF TATA POWER LOGO FOR BRANDING:**

- g) This Intervention is being deployed under Tata Power Livelihood & Skill Building

GNT202100000023

CSR Intervention. The logo of Tata Power and brand name of intervention can be used appropriately by **Bharati Vidyapeth(Pune)** within the scope of this intervention with mutual consent of both parties.

8. **NO LIABILITY**

- a) **Bharati Vidyapeth(Pune)** shall comply with all laws, regulations and also arrange to provide all the necessary approvals for carrying out all the plans agreed between the parties, for ensuring compliance of all applicable law, statutes for deployment as mentioned in this GIA Agreement. TPCDT shall not be liable in any manner whatsoever for any non-compliance in respect of the applicable laws, regulations and in the event of any adverse claim of whatsoever nature arising thereof, the entire burden shall be strictly borne by **Bharati Vidyapeth(Pune)**.
- b) Nothing in this GIA Agreement is intended or shall be construed to authorize either Party to create or assume any liability or indebtedness of any kind in the name of, or on behalf of the other Party or to act for or be responsible for the performance of the other Party in any manner except and to the extent expressly provided in this GIA Agreement. Notwithstanding anything contrary contained herein the parties shall not be obliged to incur any liability in case of any of the parties shall without prior specific approval/ consent of the other parties' credit or accept any contract binding upon the parties other than as envisaged in this GIAA.

9. **CONFIDENTIALITY**

The parties agree that all data which is transmitted or communicated by either party to the other party shall in all cases be held in confidence by the Receiving Party and not disclosed to any third party unless written consent of Disclosing Party is first obtained, except that, Receiving Party has the right to disclose such information to its own employees, consultants and representatives who are bound by an obligation of confidentiality and who need to know such information for the purposes specified hereinabove. The Receiving Party agrees that it shall not use the confidential data for any purpose(s) other than the ones specified herein. However, the Receiving Party shall not be required to maintain confidential or be restricted in its use of any data which,

- i. Was in public domain at the date of disclosure to Receiving Party
- ii. Becomes public knowledge during the term of this GIA Agreement without breach of this GIA Agreement
- iii. Receiving Party can show that it was in its possession prior to disclosure by Disclosing Party, and
- iv. Disclosure of which is required by law or by order of a court of competent jurisdiction. The obligation as to confidentiality shall survive for 5 years post termination/ expiry of this GIA Agreement.

10. **INTELLECTUAL PROPERTY RIGHTS (IPR)**

With respect to the services rendered under this GIA Agreement, the Parties agree that:

- a) All IPR arising out of this GIA Agreement and the data, information or activities therein shall solely vest with TPCDT. Usage of any such data or information that involves the IPR for TPCDT shall amount to an infringement if such usage is not authorized in writing.
- b) **Bharati Vidyapeth(Pune)** agrees that it shall comply with all the relevant laws and shall not infringe in any IPR in the course of performing its obligations under this GIA Agreement.

GNT202100000023

- c) **Bharati Vidyapeth(Pune)** agreed to indemnify/ keep indemnified **TPCDT** from all claims, suits, actions, losses, penalties or liabilities arising out of a breach of the clauses above.

11. ETHICAL BEHAVIOUR:

- a) **Bharati Vidyapeth(Pune)** represent and warrant that it has conducted and shall conduct its business in accordance with the highest ethical standards and it shall comply with all applicable laws in the performance of its obligations under this **GIA Agreement**, including but not limited to, laws dealing with ethical business practices.
- b) If, at any time during the term of this **GIA Agreement**, **Bharati Vidyapeth(Pune)** is informed or information comes to its attention that it or any of its affiliates is or may be in violation of any applicable law (or if it is so determined by any court, tribunal or governmental agency or authority), **Bharati Vidyapeth(Pune)** shall immediately take all appropriate steps (including any reasonable requests by **TPCDT**) to remedy such violation and comply with such a law in all respects. Where such violation occurs and is not remedied **TPCDT** may terminate this **GIA Agreement** with immediate effect.
- c) **Bharati Vidyapeth(Pune)** shall establish and maintain all proper records (including accounting records) required by applicable law and shall make such records available to **TPCDT**, if requested to do so. A certified utilization certificate shall be issued at the end of any project.
- d) **Bharati Vidyapeth(Pune)** acknowledges of having read Tata Code of Conduct, accessed from Tata Power company website URL: <https://www.tatapower.com/pdf/aboutus/Tata-Code-Power-of-Conduct.pdf> **Bharati Vidyapeth(Pune)**, as CSR Partner of Tata Power, acknowledges to comply with the guidelines given therein as part of upholding highest ethical standards during the deployment of this Project.

12. TERM, EXTENSION&TERMINATION/EXPIRY:

- a) This **GIA Agreement** shall commence as of the Effective date and shall remain in force until **31-Mar-2021**. Unless terminated earlier in accordance with the terms of this **GIA Agreement**. The Parties may renew this **GIA Agreement** on 'no cost to **TPCDT**' basis for a mutually agreed period if the situation so warrants, and the extension of period of agreement envisaged herein occasioned for the reasons not attributable to **Bharati Vidyapeth(Pune)**, for its non-performance or delay in performance.
- b) **TPCDT** shall have the right to terminate this **GIA Agreement** immediately, for any reason whatsoever without assigning any reason thereof.
- c) In the event of termination, the **Bharati Vidyapeth(Pune)** shall refund the unspent residual amount to **TPCDT**.

13. WAIVER:

No failure or delay by a party to exercise any right or remedy provided under this **GIA Agreement** or by law shall constitute a waiver of that or any other right or remedy, nor shall it preclude or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.

14. VARIATION:

Both the Parties agree and confirm that the terms and conditions contained in this **GIA Agreement** may be changed / altered through written mutual consent; at any point, during course of the Agreement.

No variation of this **GIA Agreement** shall be effective unless it is in writing and signed by the Parties (or their

authorised representatives).

Page 6 of 10

GNT202100000023

15. SEVERANCE:

If any court or competent authority finds that any provision of this GIA Agreement (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this GIA Agreement shall not be affected.

16. THIRD PARTY RIGHTS:

No person other than a Party to this GIA Agreements shall have any rights to enforce any term of this GIA Agreement.

17. NO PARTNERSHIP OR AGENCY:

Nothing in this GIA Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute either Party the agent of the other Party, nor authorise either Party to make or enter into any commitments for or on behalf of the other Party.

18. NOTICES:

All notices related to this GIA Agreement which are permitted hereunder shall be in writing and deemed to have been duly given/served if delivered personally or sent by facsimile transmission (with answerback received) or overnight express or by registered mail or certified mail, postage prepaid. All notices shall be sent to the addresses mentioned in the title clause or to such other address as the Parties may designate from time to time in writing.

19. FORCE MAJEURE:

- a) Neither Party shall be liable to the other for any delay or failure in the performance by it of any obligation under this GIA Agreement to the extent affected, delayed or prevented by an event of Force Majeure, provided that the Party that is affected by the Force Majeure shall provide notice thereof to the other Party as soon as practicable, but in any event not later than 7 [seven] days from the time which the affected Party knew or should reasonably have known of the commencement of the event of Force Majeure.
- b) The affected Party shall use its reasonable endeavours to mitigate the adverse effects of the Force Majeure event affecting it and shall seek reasonable alternative means to resume the Services, to the extent not affected by the event of Force Majeure. The affected Party shall provide to the other Party reasonable details as requested by the other Party regarding the nature of the Force Majeure event. Neither Party shall be entitled to make any claim on the other for any fees, costs, expenses, losses or damages incurred or suffered as a result of an event of Force Majeure.
- c) If any event of Force Majeure continues beyond a period of one month, either Party may terminate this GIA Agreement.

20. ASSIGNMENT AND OTHER DEALINGS PROHIBITED:

This GIA Agreement is personal to the Parties and no Party shall, without the prior written consent of the other Party (such consent not to be unreasonably conditioned, withheld or delayed), assign, transfer, or deal in any other manner with this GIA Agreement or any of its rights and obligations under or arising out of this GIA Agreement, or purport to do any of the same. No Party shall sub-contract or delegate in any manner any

or all of its obligations under this GIA Agreement to any third party or agent. Each Party that has rights under this GIA Agreement is acting on its own behalf and not for the benefit of another person.

21. ARBITRATION:

Page 7 of 10

GNT202100000023

Any dispute or differences arising out of or in connection with this GIA Agreement (including the validity or interpretation hereof) shall be referred to the sole arbitrator to be nominated by Parties and the arbitration shall be governed by the provisions of the Indian Arbitration & Conciliation Act, 1996 or any law relating to arbitration in force at the time of such reference. The venue of the arbitration shall be Mumbai. The parties submit to the exclusive jurisdiction of the Courts of Mumbai.

22. GOVERNING LAW AND JURISDICTION:

This GIA Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of India. The parties irrevocably agree that the courts of Mumbai shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this GIA Agreement or its subject matter or formation (including non-contractual disputes or claims).

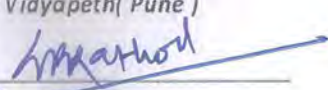
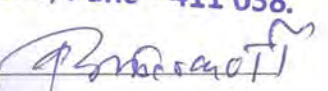
23. COUNTERPARTS:

This GIA Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this GIA Agreement, but all the counterparts shall together constitute the same GIA Agreement. No counterpart shall be effective until each party has executed at least one counterpart.

24. ENTIRE AGREEMENT:

This GIA Agreement constitutes the entire agreement between the parties and supersedes all previous agreements between the parties relating to its subject matter.

IN WITNESS WHEREOF the Parties hereto have caused this GIA Agreement to be executed, in duplicate, by their duly authorized representatives on the date first written above.

For TPCDT Approved On: 14-Jul-2020 02:09:08 AM Name: Nagori Forum Designation:	For Bharati Vidyapeeth(Pune) Signature:  Name: Dr. G. R. Rathod Designation: DIRECTOR Bharati Vidyapeeth (Deemed to be University) Social Science Centre(M.S.W) Erandwane, Pune - 411 038.
Approved On: Name: Designation:	Witness: Signature:  Name: Dr. Vijay Kulkarni Designation: (Associate Professor)

