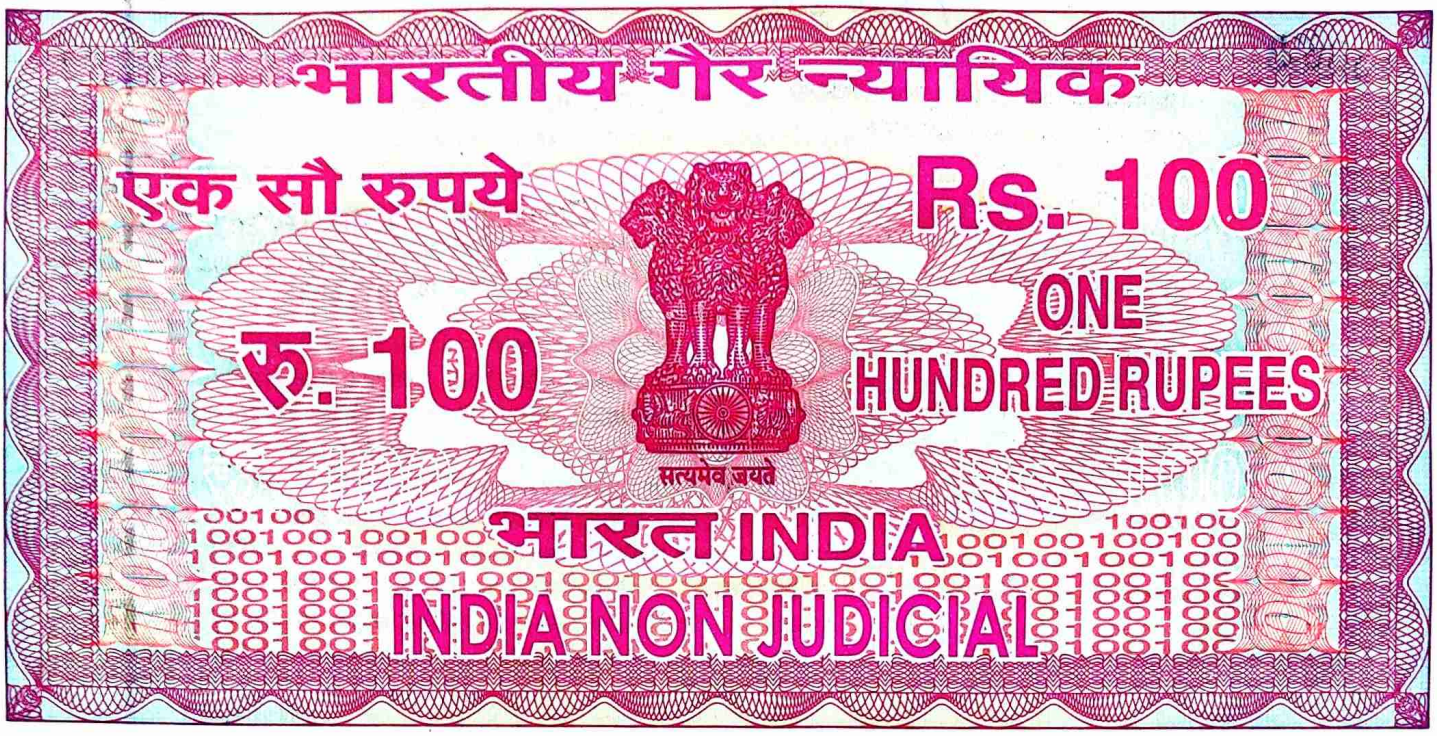

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 37AA 759775

प्रधान मुद्रांक कार्यालय, मुंबई.
प.मु.वि.क. 1000006
15 DEC 2022
सक्षम अधिकारी

CLINICAL STUDY INVESTIGATOR AGREEMENT

श्री. दि. फ. गावई

This Clinical Study Agreement with participating Investigator/Institution (Site) ("Agreement") will be effective post IEC/IRB approval and site initiation (refer section 9). This agreement is by and between, EVERSANA India Pvt Ltd located at Mundhwa, 7th Floor, Koregaon Park Annexe, AP81, Koregaon Park, Pune, Maharashtra, 411001 ("**Company**")

and

Dr Rajesh Venkataraman, Head, Clinical Trials, Adichunchanagiri Hospital & Research Centre, Adichunchanagiri University, B.G Nagara, Nagamangala Taluk, Mandya district, Karnataka –571448 ("**Site**").

and

Dr. Ravindra Pukale, Professor & Head, Department of OBG, Adichunchanagiri Hospital and Research Centre, B.G Nagara, Nagamangala Taluk, Mandya district, Karnataka – 571448 **("Principal Investigator")**

Eversana India Pvt. Ltd. CIN : U72200 PN2009 FTC142299 Pune

27 DEC 2022

3063

जोडपत्र-१/Annexure-I

फक्त प्रतिज्ञापत्रासाठी/Only for Affidavit

मुद्रांक विक्री नोंद वही अनु. क्रमांक/दिनांक
Sales Register Serial No/Date:

मुद्रांक विकत घेणाऱ्याचे नांव व रहिवाशी पत्ता व सही
Stamp Purchaser's Name/Place of Residence & Signature

27 DEC 2022

श्री राजन गणपत शिंदे परवानाधारक मुद्रांक विक्रेता
परवाना क्रमांक एल.एस.बी.-८०००००७
जी-३, हेमु वसाहिक इमारत, आझाद विहार हॉस्पिटलच्या बाजूला,
एल.आय.सी. कार्यालयाच्या मागे, एस.व्ही.रोड,
मालाड (पश्चिम), मुंबई-४०० ०६४
ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांचे नाव कारणासह
मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे
Tel.: 28807359 / Mob.: 9820141068

Deepak Bhatia (Adv.)
1-1, Raj Singh Nagar, Gamdevi Road
Ghatkopar (E), M-85.

Eversana India Pvt. Ltd.
CIN : U72200 PN2009 FTC142299
Pune

Conduct of the Study. Company is providing Contract Research Organisation services to P&G Health, Limited with registered address at Procter & Gamble Health Limited, Godrej One, 8th floor, Pirojshahnagar, Eastern Express Highway, Vikhroli East, Mumbai, 400079 India ("**Sponsor**") under a separate contract between Company and Sponsor. Company's services include Medical Writing, Monitoring and Data Management of the study entitled, "*Evaluation of the effectiveness of Livogen Z® (Ferrous Fumarate, Folic Acid and Zinc Sulphate) Fixed Dose Combination in Iron Deficiency Anemia – An Open Label, Single arm, Phase IV, Post-Marketing, Observational Study (LIBERTY)*" ("**Study**") and entering into this Agreement with Site. Site will ensure that the Investigator and all Study personnel will perform the Study in accordance with the Study protocol number CSD2021008 (including any subsequent amendments), attached hereto as Exhibit A ("**Protocol**") and incorporated herein by reference. Site and Investigator will ensure that all data provided is accurate and complete. The parties will comply with the principles contained in the Declaration of Helsinki and all other applicable laws and regulations relating to the conduct of the Study, including those related to the conduct of clinical research, data privacy, safety reporting, financial disclosure, conflict of interest, patient safety, anti-bribery and anti-corruption ("**Applicable Law**"). Site also will maintain any licenses, permits or registrations required to perform the Study.

1. Investigator. The Study will be conducted at Site's premises under the direction of its employee, Dr. Ravindra Pukale ("**Investigator**"). Investigator will supervise and conduct the Study according to this Agreement, the Protocol, ICH GCP and Applicable Law. Investigator is responsible for the conduct of the Study at Site and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. If the Investigator and Site retain the services of any individual or party to perform Study-related duties and functions, the Site and Investigator shall ensure this individual, or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator shall ensure strict adherence to Protocol and make no amendments without prior discussion with and written agreement by Company and Sponsor. Any amendment should be submitted by the Investigator to Ethics Committee for approval (if appropriate) and shall be deemed part of Protocol. Investigator and Site shall at no time jeopardize the health or well- being of the Study subject by unwarranted continuation of the subject in the Study.

The Study shall start, subject to the receipt of approvals from the responsible Independent Ethic Committee or Institutional Review Board (IEC/IRB) and /or relevant regulatory authorities. Investigator shall not commence the Study without first obtaining such approvals and will comply with any condition attached hereto.

Investigator shall do his/her utmost best to recruit at least **25** eligible subjects in the Study.

The Investigator shall meet with a representative of Company and/or Sponsor on a regular basis to discuss the progress of the Study or any problems associated with the Study. A reasonable amount of time should be set aside for these discussions.

The Investigator shall ensure that all clinical data is recorded in the relevant case report form (CRF) and that all Study records are kept up to date and maintained in accordance with Applicable Law.

The Investigator undertakes to operate and maintain a reliable and safe system for handling and storage of all source data held in connection with and generated under the Study.

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The Investigator shall ensure that CRFs are completed in real time not later than 48 hours from the subject visit date.

The Investigator shall agree to maintain all source data/documents/files, under the Study at the Site for a period of at least 5 years following either completion of Study or discontinuation of Study and shall seek Company/Sponsor permission before the record are destroyed at the Site.

The Investigator shall permit authorized representatives of Company, Sponsor, the ethics committee or appropriate authorities to conduct the monitor/audit/inspection of the Study at the Site.

Investigator declares that his/her curriculum vitae is accurate, and that Company has legitimate interests to process Investigator's personal data and may store such information for future research studies, and may share the curriculum vitae and personal data with its affiliates, Sponsor, Sponsor's affiliates and regulatory agencies worldwide, for the purpose of conducting this Study. Site declares that it has obtained the permission of Investigator and all Study personnel to share their personal data for purposes of this Study and possible future studies, including sharing their personal data with Company, Sponsor, and their agents, who may be located in countries that do not offer a comparable level of protection for such personal data, including the United States.

2. Compensation.

A. Payment Terms. Company will pay the party designated as Payee in accordance with Exhibit B, for satisfactory completion of all Study-related obligations hereunder. No costs or expenses related to any medical treatment of Study subjects (the "**Subjects**") will be paid. Neither Site nor Investigator will pay another physician to refer Subjects to the Study. Site and Investigator will comply with all applicable disclosure obligations relating to compensation as may be required by law, or by Company or any institution, medical committee or other medical or scientific organization affiliated with Site or Investigator.

B. Anti-Corruption/Anti-Fraud. Site and Investigator agree that the compensation provided (i) constitutes the fair market value and fair compensation for the services rendered in light of their expertise; (ii) is not an inducement to, or in return for, the past, present or future prescribing, purchasing, recommending, using, obtaining preferential formulary status, or dispensing any Sponsor product or in any way contingent or dependent upon any such activity; and, (iii) will not affect Site's or Investigator's judgment with respect to the advice and care of each Subject. Site and Investigator agree they will not directly or indirectly pay, induce, or offer items of value for the purpose of (i) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (ii) securing any improper advantage; or (iii) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

3. Institutional Review Board ("**IRB**") Approval. Site and/or Investigator will obtain the necessary approvals (or waivers of approval) from the applicable IRB(s) before starting the Study and will provide Company with copies of such approvals/waivers upon request. If Company is responsible for obtaining such approvals, then Site and Investigator will provide assistance to Company.

4. Informed Consent. Investigator will obtain an informed consent form ("**ICF**") from each Subject or Subjects legally acceptable representative prior to the Subject's participation in the Study. Investigator will ensure that the ICF was approved by the Company, Sponsor and IRB before use.

5. Inspections/Audits of Site. Company, Sponsor and their agents or affiliates may visit Site during normal business hours to monitor the Study and compliance with this Agreement and the Protocol. Site will be notified prior to any such visit and will provide assistance and cooperation. Investigator will authorize direct access to the Subject's original medical records by the monitor, auditor, IEC/IRB, and the regulatory authorities for verification of Study procedures and/or data, without violating the confidentiality and privacy of the Subject to the extent permitted by the Applicable Law. The monitor or auditor will maintain the confidentiality of all records viewed. Site also will cooperate with all regulatory audits or inspections and will notify Company promptly after receiving any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study.

6. Confidentiality. All materials, data, and reports generated in the conduct of the Study, as well as regarding Company and Sponsor business affairs, is confidential information ("**Confidential Information**") and is the property of Company or Sponsor, as applicable. All medical records and other source documents maintained by Site shall remain the property of Site.

The Site and Investigator undertake not to disclose the Confidential Information or permit it to be disclosed to any third party except for the purposes of and to the extent to which disclosure is necessary to enable the Investigator to carry out the obligations under this Agreement. The Site and Investigator further undertake not to use the Confidential Information for any other purpose than the purposes of this Agreement. The Site and Investigator shall ensure that the Confidential Information is maintained in a manner which assures its confidentiality and which permits immediate access and/or disposal upon the Sponsor's written request.

These confidentiality obligations will continue until fifteen (15) years after completion of the Study, but will not apply to information to the extent: (i) which can be shown through documentary records to have been known by Site and/or Investigator prior to receipt of such information from the Company and/or Sponsor and which has not been acquired from Company and/or Sponsor directly or indirectly; (ii) which is in the public domain or lawfully becomes generally available to the public through no fault of Site and/or Investigator; (iii) which is lawfully acquired from third parties, provided any such third party is not bound by an obligation of confidentiality with respect to such information at the time of disclosure; (iv) which by written agreement of the Company or Sponsor is released from confidential status; or, (v) which must be disclosed by Applicable Law.

Site will notify Company immediately in the event of a request for or disclosure of Confidential Information not permitted by this paragraph.

The Investigator shall assure that the identity of the Subjects participating in the Study will not be disclosed in any correspondence with Company, except in exceptional, unforeseeable circumstances, which may demand such disclosure, which will be at the discretion of the Investigator. The Investigator shall ensure that correct identification of the Subject will always be possible, within the framework of the medical-ethical confidentiality, for purposes of on-site monitors, audits or inspections by authorized representatives of Company, Sponsor, the ethics committee or the appropriate authorities, within reasonable time. Site will process personal data

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as necessary to perform the obligations hereunder, and such processing shall be in accordance with this Agreement and all applicable privacy and data protection laws and regulations. Site shall notify Company of any improper disclosures of personal data immediately.

7. Intellectual Property.

The Site and Investigator acknowledge the Sponsor's intellectual property rights and interest in all data, documentation and materials disclosed by the Company or Sponsor under this Agreement as well as in all materials, including but not limited to samples and specimens, used or obtained in the Study. The results of the Study and all documentation generated therein (including CRFs) and any or all intellectual property rights, including copyright, in such data documentation and materials, shall be handed to the Sponsor by the Site and/or Investigator.

The Investigator shall promptly disclose and assign any and all inventions, discoveries and improvements conceived or made by the Investigator relating to the Study and the services supplied under this Agreement or otherwise relating to the Study. The Site and/or Investigator shall ensure that all staff supporting the Investigator in this Study is made subject to the same conditions and obligations as the Investigator regarding intellectual property rights.

This clause 8 shall continue to apply after the expiry or termination of this agreement.

8. Publications. At least sixty (60) days prior to submitting or presenting a manuscript or other material relating to the Study to a publisher, reviewer or other outside person, Site will provide to Company and Sponsor a copy of all such material, and allow Company and Sponsor forty-five (45) days to review and comment on them. If requested, Site will remove any Confidential Information (excluding Study results) before submitting or presenting the manuscript. Neither party may use the other party's name, or Sponsor's name, in connection with any advertising, publication or promotion without the other party's, or Sponsor's, prior written permission.

As this Study is multi-centered, any publication based on the results obtained at the Site (or a group of sites) shall not be made before the first multi-centre primary publication. If a publication concerns the analyses of sub-sets of data from a multi-centred Study, the publication shall make reference to the relevant multi-centre primary publication(s).

In case of arising a publication out of a multi-centred Study, Sponsor will determine, depending on the tempo and number of included patients at Site in relation to global recruitment, if, and if so, what position the Investigator will have among the several (possible other) authors. In the event the Investigator wishes to publish the results of the Study, the Investigator shall supply a draft of any intended publication via Company to Sponsor not less than sixty (60) days before envisaged submission date of the publication in question and will supply a draft of any abstract or detailed paper or oral statement intended for public presentation not less than sixty (60) days before the earliest of the date of submission of the abstract or delivery of the public presentation. The Investigator agrees that in any such publication only data collected and analysed by Investigator him-/herself will be utilised, quoted and reported and that Investigator will not publish prior to the primary publication of the Study has appeared.

The Investigator agrees that all reasonable comments made by the Sponsor in relation to any proposed publication will be incorporated into the publication or that the publication will be amended accordingly. The Investigator further agrees to delay publication at the reasonable request of Sponsor where Sponsor considers such delay necessary for commercial reasons,

including for the protection of its intellectual property rights, and for such time as Sponsor indicates shall be required.

9. Term and Termination. This Agreement will become effective post IEC/IRB approval, and Site Initiation ("**Effective Date**") and will continue until completion (Site closeout and completion of all obligations of the parties under this Agreement) or termination of the study. Company may terminate this Agreement immediately upon written notice to Site if Sponsor cancels the Study. Company may terminate this Agreement without cause upon seven (7) days written notice to Site. Either party may terminate this Agreement for material breach, upon thirty (30) days written notice to the other party. In case of termination under this Section 9 upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and Company shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Exhibit B; provided, however, that final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein, Company shall pay the Site for all activities performed in accordance with this Agreement, and reasonable non-cancelable costs incurred until the effective date of such termination and the Site shall refund to Company any excess payments with respect to activities not performed or completed until the effective date of termination.

10. Mutual Exclusion for Consequential Damages. Neither party shall be responsible to the other party for any lost profits, lost business, lost opportunities, or any punitive, incidental, indirect or consequential damages.

11. Debarment. Site represents that neither Investigator nor its staff and personnel involved in the Study have ever been debarred, disqualified or suspended by the FDA or other regulatory body, nor have debarment, disqualification or suspension proceedings been commenced. During the term of this Agreement, Site will not employ or otherwise engage any individual to perform Study services who has been debarred, disqualified or suspended as described in this paragraph. Investigator represents that he/she is in good standing under all applicable medical associations.

12. Independent Contractors. Site is an independent contractor and will not be considered the partner, agent, employee or representative of Company or Sponsor, and neither Company nor Sponsor will be responsible for any employment-related taxes, benefits or insurance. Site will not have authority to make agreements with third parties that purport to bind Company or Sponsor.

13. Transparency. Investigator and Site acknowledge that the Sponsor or the Company, as applicable, may disclose the terms of this Agreement, and/or the total compensation (fees and expenses) payable or paid in accordance with this Agreement, as required by Applicable Law. The Site and Investigator agree to reasonably cooperate with the Sponsor or Company, as applicable, in providing required information to comply with disclosure requirements associated with this Agreement.

14. Third Party Beneficiary. Site expressly agrees that Sponsor is a third-party beneficiary to the Agreement and may enforce its rights under the Agreement. Each party to this Agreement acknowledges that except for the Sponsor, there are no third-party beneficiaries with any rights to enforce any of the provisions of this Agreement.

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15. Insurance.

Sponsor maintains a policy or program of insurance at levels sufficient to support its obligations assumed hereunder.

16. Miscellaneous. This Agreement, including its attachment(s), constitutes the complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement will be valid unless agreed to in writing by all parties. Failure to enforce any term of this Agreement will not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, it will be reformed to the extent possible, and the rest of this Agreement will remain in effect. This Agreement will be interpreted under the laws of India. Any dispute from this Agreement shall be settled by parties through negotiation. If no settlement can be made through negotiation, the dispute may be submitted to the courts of India. This Agreement will be binding upon the parties and their successors and assigns. Site will not assign or transfer any rights or obligations under this Agreement without the written consent of Company. Upon Sponsor's request, Company may assign this Agreement to Sponsor or to a third party, provided, that Site will be given prompt notice of such assignment. Sections 6 through 12, and 15-17 shall survive expiration or termination of this Agreement.

17. Force Majeure. 1. Force Majeure is an event or occurrence of war, rebellion, blockade, fire, sabotage, epidemics or natural disasters such as floods, earthquakes, strikes, failure of systems work or government policies that may directly affect either party in implement their obligations under this Agreement. 2. Delay or failure of one party to carry out one of its obligations under this Agreement does not constitute a breach of this Agreement if and as long as such things are caused by force majeure. In such case the party experiencing a force majeure must notify in writing to the other party at the latest 7 (seven) calendar days after the occurrence of force majeure. 3. When force majeure ended or have been resolved, the party experiencing a force majeure must immediately implement their obligations under this Agreement that were delayed due to force majeure. However, in the case of force majeure continues for more than 14 (fourteen) calendar days, the parties will resolve it under the mutual consensus.

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IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives as of the date set forth below.

EVERSANA India Pvt Ltd

Signature : _____

Print Name: Sohel Shameem

Title: Director

Date: 20/3/2023

SITE

Signature : _____

Print Name: Dr Rajesh Venkataraman

Title: Head, Clinical trials

Date: 1/2/2023

Read and Acknowledged:

INVESTIGATOR

Signature: _____

Print Name: Dr. Ravindra Pukale

Title: Principal Investigator

Date: 1-2-2023

PROF.DR.RAVINDRA.S.PUKALE.
MBBS,DGO,M.D (obg)
PROFESSOR & HOD.
DEPARTMENT OF OBSTETRICS & GYNAECOLOGY
A H & R C, A I M S, BG,NAGAR - 571448
K M C, REG. NO - 21460

EXHIBIT A

PROTOCOL

[To be appended.]

EXHIBIT B

BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

Site agrees that the payee designated below is the proper payee for this Agreement, and that payment under this Agreement to the payee designated below will not violate any rules or policies of the Site, will not violate applicable national, state, or local laws or regulations, and that payment under this Agreement will be made only to the following payee (the "**Payee**"):

PAYEE NAME:	**SACCP CLINICAL RESEARCH**
PAYEE ADDRESS:	**B.G Nagara, Nagamangala Taluk, Mandya District, Karnataka-571 448.**
PAYEE EMAIL ADDRESS	NA
VAT/GST/TAX ID NUMBER	**29AAAJA2708B1ZU**
Wire Transfer Details	Bank Name – **Canara Bank** A/c number - **8610101031980** IFSC Code – **CNRB0008610** PAN - **AAAJA2708B**

In case of changes in the Payee's bank details above, Payee is obliged to inform Company in writing. The parties agree that in case of any such changes, a formal amendment to this Agreement shall not be required, and that Payee shall inform Company of the change in bank details by written notice provided to the Company.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, shall be determined by a separate agreement between the Investigator and the Payee, which may involve different payment amounts and different payment intervals than the payments made by Company to the Payee. The Investigator acknowledges that if the Investigator is not the Payee, Company will not pay Investigator even if the Payee fails to reimburse the Investigator.

B. PAYMENT TERMS

Company, or a Company affiliate on behalf of Company, will reimburse the Payee in accordance with this Agreement and attached budget. Compensation will be upon verification of completed subject visit data in electronic Case Report Forms ("**eCRFs**").

Services performed that result in disqualified data due to major, disqualifying Protocol violations are not payable under this Agreement.

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Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Company or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Subject to the provisions of the following paragraph, neither Company nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site.

Company is obligated to, and will withhold expanded withholding tax, as applicable, in accordance with Indian tax laws, as amended from time to time.

C. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. DISCONTINUED OR EARLY TERMINATION PAYMENTS

Reimbursement for discontinued or early termination of Subjects will be prorated based on the number of completed visits for those Subjects in accordance with the Protocol.

E. INVOICES

Original invoices pertaining to this Study of the following items must be issued to:

EVERSANA INDIA PVT LTD.
Mundhwa, 7th Floor, Koregaon Park Annexe,
AP81, Koregaon Park, Pune - 411001
MAHARASHTRA

Code: 27 | GSTIN: 27AAHCA5575C1ZP

Invoices will not be processed unless they reference the Sponsor name, Study name, Protocol number and Investigator name. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for Study activity.
Invoice Payment will be processed within 30 days of the Invoices raised from the site.

F. INSTITUTIONAL REVIEW BOARDS ("IRB")/ETHICS COMMITTEE ("EC") PAYMENTS

IRB/EC costs will be reimbursed on a pass-through basis and are not included in the budget. Any subsequent re-submissions or renewals, upon approval by Company and Sponsor, will be reimbursed upon receipt of appropriate documentation.

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G. SUBJECT TRAVEL EXPENSES

Each subject will receive a reimbursement for the travel costs as set forth in the informed consent form, at a rate of **500 Indian Rupees** (Rupees Five Hundred) per patient per visit, this will be made payable to Payee 1. Patient travel expenses will be reimbursed on an actual basis upon receipt of original supporting invoices or supporting document of the expense incurred (e.g., subject reimbursement tracking log) and will be payable to Payee 1. Invoices or supporting document must contain the subject number, amount paid, and visit number and visit date in which subject travel is being requested.

H. SUBJECT STUDY TREATMENT (Livogen Z®)

Study Subject Treatment (Livogen Z®) costs will be reimbursed to Payee 1 on a pass-through basis upon receipt of supporting invoices for enrolled subjects. Site requires to bill this cost for each subject for consecutive 3 months (90 days) of study duration as defined in the Protocol. Study Subject ID (SSID) must be included on the invoice. The maximum for one subject study drug cost for the entire duration of the study (90 days) will be approximately **INR 960.**

I. Laboratory Assessment

As described in the protocol for the patients screened and enrolled in the study, a total of four (4) - CBC and two (2) - Serum Ferritin laboratory tests will be reimbursed upon receipt of the actual invoices

J. RECORD STORAGE FEE

A one-time non-refundable record storage payment of **INR 25000 (Rs Twenty-five Thousand) with applicable GST tax**, will be made upon study closeout and receipt of original supporting invoices from a third-party vendor. In accordance with Sponsor's Protocol requirements, Investigator shall maintain all Site Study records (including study site files and source documents) and Institution shall keep the hospital medical records in a safe and secure location for a period of Five (5) years to allow easy and timely retrieval, when needed. Any costs for archiving outside the above amounts and period will be subject to prior approval by Sponsor.

No other additional funding requests will be considered.

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K. BUDGET

- A research fee calculated based on the visits performed by the eligible patients will be provided as mentioned in below table. The research fee would include the investigator/sub-investigator fees, lab profiling of CBC and Serum ferritin as per defined in the protocol, fees for research staff assisting investigator on this study and administrative cost: -
- GST shall be as applicable (IGST outside the state) and (CGST & CGST within the state) by the norms of Good and Sales Tax India.

Milestone	Inclusion	Amount (INR)
Agreement Signed	Investigator fee for 5 completed subjects (01-05)	**75000**
After 10 completed subjects visit	Payment for 10 subjects completed visit (subject no 01-10) post adjustment for earlier payment, discontinuation/ withdrawal	**150000**
After 20 completed subjects visit & Site Closeout	Payment for 10 subjects completed visit (subject no 11-20) post adjustment for discontinuation/ withdrawal	**150000**
	Total per completed 25* subjects	**3,75,000**

<u>* Recruitment for this study is competitive and minimum subject enrollment per site expected is 25 subjects.</u>

- If the site exceeds or fails to meet the number of subjects allocated in this agreement, Investigator fees will be paid on a pro-rata basis per subject per visit.
- Screen failures will not be accounted for payments
- Payments will be disbursed once the data has been entered in the eCRF based on visit(s) of the patients and the data is clean, and source verified

Type of Visits	Investigator and Study coordinator Fees
Screening - Baseline Visit - V1; Day 0	3,000
During Treatment Period - Visit 2; Day 21	3,000
During Treatment Period - Visit 3; Day 60	3,000
During Treatment Period - Visit 4; Day 90	3,000
Close Out	3,000

- All payments made as per agreement are subject to tax deduction at source.

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Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:15:12 GMT)

CTRI Number	CTRI/2023/04/051785 [Registered on: 19/04/2023] - **Trial Registered Prospectively**
Last Modified On	04/05/2023
Post Graduate Thesis	No
Type of Trial	PMS
Type of Study	Drug
Study Design	Single Arm Study
Public Title of Study	An observational study of Livogen Z tablet in patients with iron deficiency anemia
Scientific Title of Study	Evaluation of the effectiveness of Livogen Z® (Ferrous Fumarate, Folic Acid and Zinc Sulphate) Fixed Dose Combination in Iron Deficiency Anemia – An Open Label, Single arm, Phase IV, Post Marketing, Observational Study (LIBERTY)

Secondary IDs if Any

Secondary ID	Identifier
CSD2021008, Version 1.0 dated 02-Dec-2022	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Poonam Sule
Designation	Senior Clinical Manager
Affiliation	Procter & Gamble Health Limited
Address	Ground floor and First Floor P&G Plaza Cardinal Gracious Road Chakala Andheri (East) Mumbai (Suburban) MAHARASHTRA 400099 India
Phone	09619207436
Fax	
Email	sule.p@pg.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Poonam Sule
Designation	Senior Clinical Manager
Affiliation	Procter & Gamble Health Limited
Address	Ground floor and First Floor P&G Plaza Cardinal Gracious Road Chakala Andheri (East) Mumbai (Suburban) MAHARASHTRA 400099 India
Phone	09619207436
Fax	
Email	sule.p@pg.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Poonam Sule
Designation	Senior Clinical Manager
Affiliation	Procter & Gamble Health Limited
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Procter & Gamble Health Ltd.

Primary Sponsor

Primary Sponsor Details	
Name	Procter and Gamble Health Limited
Address	Ground floor and First Floor Procter and Gamble Plaza Cardinal Gracious Road Chakala Andheri Mumbai 400099 Maharashtra
Type of Sponsor	Pharmaceutical industry-Global

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Ravindra Pukale	Adichunchanagiri Hospital & Research Centre	BG Nagar, Mandya, Bangalore, Karnataka - 571418 Bangalore KARNATAKA	09449751733 ravindrapukale@yahoo.com
Dr Parag Biniwale	Biniwale Womens Clinic	Flat no: 8, Second floor, 1202/2A/4, Apte Road, Dream Residency, Shivaji Nagar, Pune, Maharastra - 411005. Pune MAHARASHTRA	8600973116 parag.biniwale@gmail.com
Dr Lakshmi Swetha Karlapudi	Sanjeevani Hospital	DP Road, Parijat Colony, Gadital, Hadapsar, Pune, Maharastra - 411028. Pune MAHARASHTRA	08975068940 drlakshmikarlapudi.pi@gmail.com
Dr Nimisha Pagare	Srushti Hospital and Maternity Home	27 A Nandigram Colony, Pundalik Nagar Road, Near Essar Petrol bunk, Garkheda, Aurangabad - 431001. Aurangabad MAHARASHTRA	07028931524 drnimishapagare.pi@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee of AH and RC	Approved	28/04/2023	No
Royal Pune Independent Ethics committee	Approved	10/03/2023	Yes
Royal Pune Independent Ethics committee	Approved	10/03/2023	Yes
Royal Pune	Approved	10/03/2023	Yes

Independent Ethics committee			

Regulatory Clearance Status from DCGI

Status	Date
Notified	10/03/2023

Health Condition / Problems Studied

Health Type	Condition
Patients	Iron deficiency anemia

Intervention / Comparator Agent

Type	Name	Details
Intervention	Livogen Z® tablets	Dose: 1 Tablet twice daily, Duration - 90 days (3 months) Route: Oral, Fixed Dose Combination consist of: Ferrous Fumarate IP - 152 mg Equivalent to 50 mg elemental iron Folic acid IP - 750 mcg Zinc sulphate Monohydrate USP - 61.8 mg (Equivalent to elemental Zinc - 22.5 mg)

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	55.00 Year(s)
Gender	Female
Details	1. Female subjects with known IDA as per WHO criteria to whom Livogen Z® will be prescribed per routine clinical practice of the investigator. IDA as per WHO criteria 1. Non-Anemia (g. dL) a. Non-pregnant women (age > 15 years or above) ? 12 or higher b. Pregnant women (age > 15 years or above) ? 11 or higher 2. Anemia (g. dL) A. Non-pregnant women (age > 15 years or above) a. Mild (Non-pregnant women) 11 to 11.9 b. Moderate (Non-pregnant women) 8 to 10.9 c. Severe (Non-pregnant women) Lower than 8 B. Pregnant women (age > 15 years or above) a. Mild (Pregnant women) 10 to 10.9 b. Moderate (Pregnant women) 7 to 9.9 c. Severe (Pregnant women) < 7 2. Subjects willing to provide written informed consent 3. Subject aged > 18 to ? 55 years 4. Subjects willing to comply with the prescribed treatment regimen for the duration of study participation.

Exclusion Criteria

Exclusion Criteria	
Details	Subjects will be excluded if they meet any of the following criteria: 1. Subjects with a severe case of anemia requiring blood transfusions. 2. Subjects with anemia, which in the opinion of the investigator is caused by known conditions other than dietary deficiency including: a. Pernicious anemia b. Thalassemia c. Sickle cell or aplastic anemia d. Active peptic ulcer e. Regional enteritis f. Ulcerative Colitis g. Hemorrhoids h. Esophageal varices i. Helminthiasis j. Megaloblastic anemia k. Porphyria cutanea tarda 3. Subjects with folate dependent tumours. 4. Subjects with serious gastrointestinal disorders,(e.g., inflammatory bowel disease,

	intestinal strictures and diverticulae), who cannot take iron therapy by mouth. 5. Subjects with any known autoimmune disease. 6. Malnourished subjects who also have a known underlying infection that interferes with iron absorption. 7. Subjects with primary or secondary hemochromatosis or who are known to have a risk for iron overload. 8. Subjects with IDA in whom oral therapy has failed in clinical practice. 9. Subjects with an acute bleeding condition. 10. Subjects who have become pregnant with assisted reproduction technology (like In-vitro Fertilization (IVF), etc.) 11. Pregnant subjects in their third trimester gestation week 27 onwards. 12. Pregnant subjects with gestational diabetes or hypertension. 13. Subjects with bleeding disorders. (e.g. blood dyscrasia, subjects with hemophilia, thrombocytopenia, low platelets, coagulopathy, etc.) 14. Subjects suffering from severe or uncontrolled systemic or metabolic diseases. 15. Pregnant subjects with multifetal pregnancy. 16. Subjects who have taken hematinic agents (except Livogen Z®) /supplements continuously for two weeks with a daily dose of elemental iron ?27 mg in pregnant subjects, ?18mg in non-pregnant subjects and within 4 weeks prior to study start. 17. Subjects with severe concurrent illness (cardiovascular, renal, hepatic), and with any other condition that in the opinion of the investigator does not justify the inclusion of the subject in the study. 18. Subject whose lifestyle (including diet and food intake) would, in the Investigator's judgment, affect the subject's participation in the study. 19. Subjects who have participated in any other clinical trial in the past 30 days from the study start.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Change in hemoglobin concentration from baseline visit (Visit 1)	90 Days

Secondary Outcome

Outcome	Timepoints
Change in hemoglobin concentration from baseline visit (Visit 1)	Days 21±7, and 60 ± 3 days
Change from baseline (Visit 1) in serum ferritin concentration at EOS.	EOS
Assessment of adverse events, GI tolerability and product acceptability.	EOS

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Post Marketing Surveillance
Date of First	24/04/2023

Enrollment (India)	
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**11 **Days=**30
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	none yet
Brief Summary	This is a single-arm, open-label, multicenter, prospective observational study. A total of 100 patients with Iron Deficiency Anaemia (IDA) will be enrolled in the study. The duration of the study for each participant will be up to 3 months (90 Days). During a routine consultation, subjects will be recruited as per the protocol eligibility criteria. The aim of this study is to evaluate the changes in hemoglobin among subjects with IDA after 90 days of treatment with Livogen Z® or the last post-baseline hemoglobin assessment.