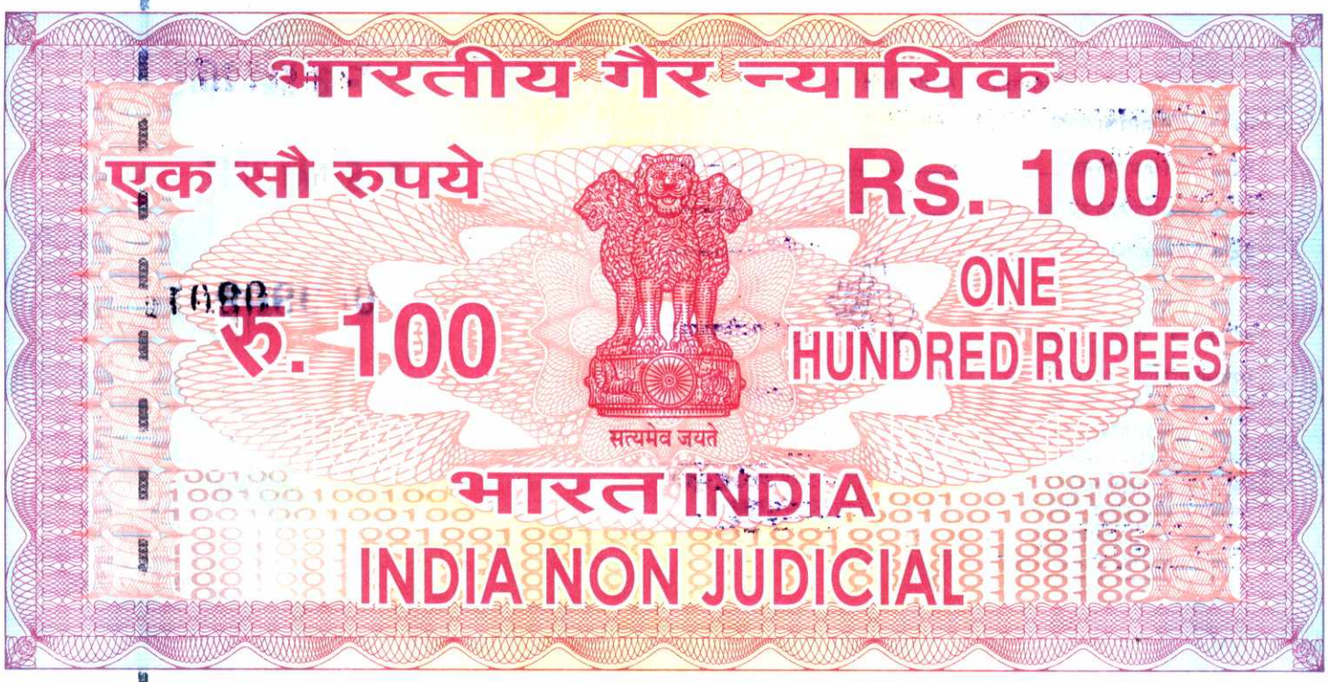

महाराष्ट्र MAHARASHTRA ◑ 2017 ◑ RW 447661

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००३
- 5 MAY 2017
सक्षम अधिकारी

AGREEMENT FOR FUNDING/ FACILITATING INVESTIGATOR INITIATED STUDY

प्र. ज. को. पाटील

This Funding / Facilitating Investigator Initiated Study agreement ("Agreement") is made as of this 05th day of May 2017(the "Effective Date") by and among

Wockhardt Limited a Company organized and existing under the Indian Companies Act, 1956 and having its registered office at D-4, MIDC, Chikalthana, Aurangabad-431006, and Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051, which expression shall unless repugnant to the context or to the contrary to the meaning thereof, be deemed to mean and/or include its successors in business and permitted assigns ("Wockhardt") and

Dr Nimain C Mohanty associated as Professor of Paediatrics with Mahatma Gandhi Medical College (MIHS) situated at Sector 1 Kamothe, Navi Mumbai 410209, Maharashtra India.

Wockhardt is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms.

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

Investigator is an individual from a health care institution engaged inter alia in the business of undertaking clinical studies including but not limited to Interventional clinical studies, Prospective observational clinical studies, Retrospective (records based) human subject research. Investigator has also represented that it has obtained all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement and that all such licenses, authorizations and permissions are in full force and effect, at present and during the term of this agreement.

For Investigator Initiated Study (IIS), Wockhardt would fund/ facilitate the Investigator Initiated Study in form of Grants, investigational products, resources, materials or support in developing study documents and/ or manuscript/ poster based on the study results IIS from time to time, to support the conduct of investigator-initiated study entitled "<<IIS project title>>" by the Investigator at the Institution.

Wockhardt, Institution and Investigator agree as follows:

I) Responsibilities of Investigator and Institution

a. The Investigator shall conduct IIS (as defined below) at the Institution mutually agreed upon by Wockhardt and Investigator specified in writing from time to time, in accordance with this Agreement, IIS proposal, Protocol for the study, Good Clinical Practices (GCP) and all applicable laws, rules and regulations and with the standard of care customary in the area of clinical research.

b. Institution will ensure that the investigator complies with Institution's policies and procedures, including any applicable financial policies as well as applicable regulations. Institution will notify Wockhardt if there is any conflict between the terms of this agreement or any Investigator Initiated Study (IIS) Concept/ Proposal form and any such policy or procedure or applicable regulations and the parties will attempt to reach and appropriate accommodation.

c. IIS will be conducted by the investigator at the institution with the necessary prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the institution and all applicable laws and regulations.

d. Each IIS would be conducted in accordance with the protocol developed by the Investigator. If required, Investigator can also request Wockhardt to extend its support in protocol and other essential document preparation on submission of its idea or proposal in "Outline of Investigator Initiated Study (IIS) Concept/ Proposal" form.

e. Investigator agrees not to implement any deviation from or changes to the Protocol without prior ethics committee approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

f. Investigator shall promptly report to Wockhardt any significant developments that may occur during the Study, including but not limited to adverse events, serious adverse events related to Wockhardt's investigational product. In case of serious adverse events, Investigator shall address any further information request by Wockhardt's Pharmacovigilance department to meet applicable regulatory requirements.

g. Investigator and the institution agree to permit representatives of Wockhardt and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Wockhardt or other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. Investigator shall notify Wockhardt immediately if regulatory authority schedules or, without scheduling, begins such an inspection.

h. Investigator agrees to maintain records and data related to the IIS in compliance with all applicable laws and regulations.

i. An adverse event is considered to be an unintended and noxious clinical occurrence or laboratory test result observed in a Subject receiving a drug, which is related in time but not necessarily caused by the administration of the Study Material. It is considered as "serious" if the adverse event is life - threatening, requires or prolongs hospitalization, causes persistent relevant disability or incapacity, consists of congenital anomaly, results in death or requires intervention to avoid any of the mentioned serious medical outcomes. Furthermore, any event is to be evaluated if that event could affect the safety of the Subject or the conduct of the Study. The Institution and Investigator is obliged to inform Ethics committee and of any adverse events or serious adverse events occurring during IIS in accordance with the applicable rules and regulations.

j. The progress and results of the IIS will be collected, analyzed, and adequately reported to Wockhardt by the Investigator, including, at a minimum, submission of periodic progress, final study report and safety information.

k. The Investigator takes full responsibility for the design, initiation, management, data analysis and reporting of the study (including local regulatory obligations). Based on scientific merit and request by the IIS investigator, Wockhardt may consider providing on a case-by-case basis additional support (e.g., laboratory analysis, vendor for data management).

l. The provision of funding or facilitation by Wockhardt does not create any liability, explicit or implicit, on Wockhardt in respect of the manpower engaged in the Project by the Investigator or Institution.

m. In case of unilateral decision by any Investigator or Institution to abandon the project of any of the terms and conditions, the unutilized amount to be paid back to Wockhardt or for breach of any of the terms and conditions by any Investigator or Institution, the entire amount released by Wockhardt with interest to be paid back.

n. Cooperate with the Monitoring Committee / Wockhardt / its representative by providing it the requisite information and if requested, access to the premises where the project activity is being carried out;

o. Assist wherever necessary, the Monitoring Committee / Wockhardt / its representative with requisite technical inputs / facilities to help accomplish the objectives of the project;

p. Abide by the decision of the Monitoring Committee / Wockhardt / its representative on the assessment of the progress in the project and the modification in the objectives, outputs, milestones, targets, funding, as also the foreclosure of any activity or subproject;

q. In case of reorganization of Institution through merger, acquisition, termination, closure etc, the Institution undertakes to settle the Wockhardt's fund, even prior to initiating such measures.

II) Responsibilities of Wockhardt

a. Wockhardt agrees to provide funding or facilitation to the Investigator Initiated Study IIS as mutually agreed upon by the Investigator and Wockhardt and as mentioned in Outline of Investigator Initiated Study (IIS) Concept/ Proposal form. IIS Grants would be provided to the Institution and not directly to the Investigator. IIS Grants shall be solely used for the purpose as defined in this agreement.

b. Wockhardt will monitor the IIS investigators compliance and adherence to their contractual obligations related to disclosure of IIS findings, agreed upon milestones, and safety information reporting.

c. Wockhardt does not request any subject level data that could include protected health information as that termed defined in the privacy rule enacted pursuant to the health insurance portability and accountability ACT of 1996 from IIS supported with IISG from Wockhardt. However, Wockhardt shall gain access to the IIS data generated from IIS supported by Wockhardt that included protected health information for the purpose of ensuring that the funds/ facilitation is being utilized by the investigator and institution for the IIS as per the terms of this agreement. Wockhardt will take appropriate measures to protect the confidentiality and security of that protected health information during this process.

III) Financial Conditionalities

a. The Institution shall ensure that the Wockhardt's funds of the project are utilized only for the project as per this Agreement. Without the approval of Wockhardt, the institution will not affect re-appropriation of funds from one budget head to other.
b. The institution shall immediately refund to Wockhardt any funds released by Wockhardt remaining with it unutilized on foreclosure or completion of the project.
c. Wockhardt shall retain the right to transfer the capital assets acquired (with Wockhardt funds) during the tenure of the project or after completion of the project.
d. The provision of the loan/grant to the institution does not create any liability explicit / implicit on Wockhardt of the manpower engaged by the industry for the project.

IV) IIS Review Committee

a. IIS Review Committee shall monitor the project for achieving the defined objectives in the time and costs projected. The terms of reference to the IIS Review Committee are:

    i. To review and examine the progress of the project in conformance with the deliverables/milestones, targets and objectives set as contained in the agreement;
    ii. revising the funding support to any / or all implementing parties;
    iii. To advise on issues related to publications and securing of IPR individually or severally by the implementing parties; and
    iv. Any other matter as referred to by Wockhardt

V) Completion

The project envisaged shall be deemed to have been successfully completed, as assessed by IIS Review Committee. In case, during the tenure of the project, it is found that the project or any project component is not likely to lead to successful completion, the IIS Review Committee may decide to foreclose the project or the project component as warranted. The decision of the IIS Review Committee is fully binding on all the participants.

VI) Term and Termination

a. The term of this Agreement shall begin on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol or upon expiry of two (2) years, whichever is later, unless sooner terminated as provided herein. The validity period of this Agreement may be extended or amended or renewed by express mutual consent of the parties conveyed in writing.

b. The Agreement may be terminated by the Wockhardt at any time upon thirty (30) days prior written notice, except that the Investigator may terminate the Study immediately upon written notice to the other parties if necessary to protect the health, welfare or safety of any research subject.

c. That Wockhardt will terminate this Agreement if there is a material breach of this Agreement and also there is violation of clauses VII, VIII, X, XI of this Agreement.

d. In the event that Wockhardt receives notice from Investigator or otherwise becomes aware that a debarment action has been brought against or threatened against Investigator, Wockhardt may terminate this Agreement immediately. In the event of termination hereunder, Investigator shall without undue delay deliver to Wockhardt all data required under this Agreement.

e. Total grant payable by Wockhardt pursuant to this Agreement shall be equitably prorated for actual work performed to the date of termination with any unexpended funds previously paid by Wockhardt to Investigator being refunded to Wockhardt.

f. Upon termination or expiration of this Agreement, neither Investigator/Institution nor Wockhardt shall have any further obligations under this Agreement, or in the case of termination or expiration of a IIS proposal, under such Proposal, except that (a) Investigator/Institution shall terminate all Services in progress in an orderly manner as soon as practical and in accordance with a schedule agreed to by Wockhardt , unless Wockhardt specifies in the notice of termination that Services in progress should be completed, (b) Investigator/Institution shall deliver to Wockhardt any Materials in its possession or control that was supplied by Wockhardt for the IIS, (c) Wockhardt shall pay Investigator/Institution any monies due and owing Investigator/Institution, up to the time of termination or expiration, for Services actually performed, all authorized expenses actually incurred (as specified in the applicable IIS proposal) and any additional fees associated which were duly approved by Wockhardt with the termination, (d) Investigator / Institution will refund or adjusted /reduced invoice of any payment made by Wockhardt for which Investigator/Institution is not able to provide the Services and e) Investigator/Institution shall immediately return to Wockhardt all Wockhardt's Confidential Information and copies thereof provided to Investigator/Institution under this Agreement or under any IIS proposal which has been terminated or has expired.

VII) Intellectual Property / Ownership and Use of Data .

a. All clinical data, case report forms, documents, information, clinical specimens and results prepared and developed by the Investigator in connection with the IIS or this Agreement whether in written or electronic form (collectively the "Information") shall remain the property of Investigator or Institution. However, Investigator shall provide brief summary of results of the IIS to Wockhardt and permit Wockhardt to use the same any way it deems legally appropriate. Further, investigator and institution agrees to provide Wockhardt a copy of any article/ abstract/ poster published or presented based on the resulted on this IIS for their internal use.

b. All Materials provided to Investigator/ Institution by Wockhardt for the performance of Services and all associated intellectual property rights shall remain the exclusive property of Wockhardt. Investigator/ Institution shall use materials provided by Wockhardt under any IIS proposal solely for rendering the Services under the applicable IIS proposal. Wockhardt will provide Investigator/ Institution with any relevant occupational safety information known by Wockhardt, including a Material Safety Data Sheet (MSDS). Any Materials remaining upon completion of the Services under IIS proposal shall be, at Wockhardt's direction, either returned to Wockhardt or destroyed.

c. In the event that Investigator/ Institution conceives, produces and/or reduces to practice inventions relating to any Material transferred to Investigator/ Institution in the course of or in connection with the Services, including without limitation any new uses or formulations of or improvements to such Material, the parties hereto acknowledge and agree that Wockhardt shall share, title and interest in such improvements and shall share all related documents to the Wockhardt without any cost.

d. Investigator/Institution hereby assigns and agrees to share with Wockhardt title to the Results, including any intellectual property rights embodied in or derived from such Results (whether or not protectable under patent, copyright, trade secret or similar laws).

e. Investigator/Institution shall maintain all materials and all other data and documentation obtained or generated by Investigator/ Institution in the course of IIS duration hereunder, including all computerized records and files (the "Records") in a secure area reasonably protected from fire, theft and destruction and shall make them available for review by Wockhardt as and when requested.

f. All Records shall be (i) retained by Investigator/ Institution for a period of five (5) years, or as a matter of law or regulation or (ii) disposed of, at their discretion, unless such Records are otherwise required to be stored or maintained by Investigator/ Institution as a matter of law or regulation. In no event shall Investigator/ Institution dispose of any such Records without first giving Wockhardt sixty (60) days' prior written notice of its intent to do so for the purpose of any verification or review prior to disposal as it deems appropriate. Notwithstanding the foregoing, Investigator/ Institution may retain copies of any such Records as are reasonably necessary for regulatory or insurance purposes, subject to Investigator/ Institution's obligation of confidentiality.

VIII) Confidential Information

a. The Investigator/ Institution ("Receiving Party") acknowledges that certain confidential information and data relating to the Wockhardt ("Disclosing Party") and its activities shall be furnished in connection with the purpose. Such information and data shall hereinafter be referred to as "Confidential Information" and shall include collectively and individually all or any proprietary and confidential information and data in any form whether oral, written or in electronic form relating to plans, products, intellectual property (including but not limited to information related NCE, patents, patent applications, trademarks, copyrights, know-how, rights on software and rights on databases), analyses, projects, processes, testing methods, technical data, formulations, techniques, trade secrets, know-how, data, reports, methodology, equipment, systems, marketing, information regarding sources of supply, business plans and the existence or scope of activities of any research, development, manufacturing, marketing or other projects of Wockhardt (including negative developments), research or development activities, non public corporate information and all technical or scientific information or know-how of Wockhardt relating to the purpose. Information disclosed by Disclosing Party to Receiving Party in the course of the discussions between the Parties shall constitute "Confidential Information".

b. The Receiving Party agrees that the Confidential Information disclosed by the Disclosing Party under this Agreement shall remain confidential and it shall not without the Disclosing Party's prior written consent disclose the same to any third party nor shall use the same for any purpose other than the fulfilment of its obligations under the terms of this Agreement.

c. Confidential Information will not include information that:

(i) is known to the Receiving Party, as evidenced by the Receiving Party's written records, before receipt of it under this Agreement

(ii) is disclosed to the Receiving Party by a third party having a right to make such disclosure; or

(iii) is or becomes part of the public domain through no fault of the Receiving Party; or

(iv) is independently developed by or for the Receiving Party, without recourse to such Confidential Information disclosed under this Agreement as evidenced by the Receiving Party's written records.

d. The Receiving Party agrees that:

(i) It will not use any Confidential Information received from a Disclosing Party except for the purposes of performing this Agreement.

(ii) It shall maintain Confidential Information of the Disclosing Party in strict confidence and follow the procedures to prevent unauthorized disclosure or use of the Disclosing Party Confidential Information and prevent it from becoming disclosed or being accessed by unauthorized persons.

(iii) It shall immediately advise the Disclosing Party of any unauthorized disclosure, loss, or use of Confidential Information

The Receiving Party may disclose the Confidential Information if required by law or by any court, tribunal, regulator or other authority with competent jurisdiction, provided to the extent practically possible and permissible under the law, gives notice to the Disclosing Party of such disclosure and shall disclose only that portion of Confidential Information which is required to be disclosed under the law. The Receiving Party agrees not to disclose any Confidential Information received from the Disclosing Party to any third party without the prior written consent of the Disclosing Party, except to its Affiliates, employees, agents, consultants, subcontractors, directors and officers on a need to know basis to effectuate the purpose of this Agreement (a "Representative"); provided, that in every Representative of the Consultant shall be informed of the confidentiality provisions of this Agreement.

e. The Receiving Party shall within fifteen (15) days of written request either before or after termination of this Agreement (for whatever reason), return to the Disclosing Party all materials, Confidential information (in whatever form) incorporating, embodying or recording any such Confidential Information in its possession or control and, if requested by the Disclosing Party, certify in writing that it has done so.

f. The confidentiality and non-use obligation under this Agreement shall survive for period of this Agreement and for a period of [10 (ten)] years following its expiration or termination.

IX) Investigator Initiated Study Grants (IISG)

a. Wockhardt agrees to provide funds/ facilitation to the investigator, Investigator Initiated Study (IIS) in accordance with IIS proposal and as amended from time to time upon mutual agreement and in writing.

b. No component of the IIS funds/ facilitation will be provided to the investigator until Wockhardt has received the necessary documents identified in IIS proposal form.

c. Investigator will use IIS funds solely for the purpose of the Investigator Initiated study specified in this agreement. IIS funds will not be used to pay physician referring potential subjects for enrolment in the study. At the completion of the study, investigator will confirm in writing that Wockhardt IIS funds have been used only to support the Investigator Initiated study.

d. If a particular IIS proposal calls for Wockhardt to provide a Wockhardt Product/ other medicines/ equipment/ materials, Wockhardt will provide, free of charge, sufficient supplies of the same to conduct the Study as per mutual agreement documented in proposal.

e. Investigator will maintain appropriate control of the Wockhardt Product/ other medicines/ equipment/ materials and will not provide it to anyone else except research staff who are directly involved in investigator initiated study conduct.
f. Except for, and limited to, the use specified in the Protocol &/or proposal form for the applicable Study, Wockhardt grants Investigator no express or implied intellectual property rights in the Wockhardt Product or in any methods of making or using the Wockhardt Product. Investigator will use Wockhardt Product/ other medicines/ equipment/ materials only as specified in the Protocol &/or proposal form for the applicable Study. Any other use of the Wockhardt Product/ other medicines/ equipment/ materials constitutes a material breach of this.
g. Investigator will not charge study subjects for Wockhardt Products/ other medicines/ equipment/ materials.

X) Investigator/ Institutions Representations, Warranties & obligations.

a. The Investigator/ Institution confirms having obtained the written approval of the appropriate authority/authorities for the study Protocol prior to conduct of such study.
b. The Investigator/ Institution shall not at any time during or after the expiration of the term divulge or allow to be divulged to any person any confidential information relating to the business or affairs of Wockhardt or any of the Material/ Product or the trials or studies conducted pursuant to this Agreement without the prior written consent of the Wockhardt. Further, if any confidential information was disclosed to the Investigator/ Institution prior to the date of this Agreement in anticipation of the parties entering into this Agreement, such confidential information shall be subject to the terms and conditions of this Agreement.
c. Investigator/ Institution shall take all reasonable precautions in dealing with the Material/Product and with any information documents and papers provided to it by Wockhardt so as to prevent any unauthorized person from having access to such Product, information, documents or papers or to any report on or records of any non-clinical/ Clinical Studies carried out.
d. Investigator/ Institution shall conduct the clinical studies in compliance with rules/ guidances issued by the competent authority and to the Protocol agreed to by Wockhardt and given approval by such competent authority.
e. Investigator/ Institution agrees to apply quality control to each of data handling and ensure that all data provided by it to Wockhardt is reliable.
f. Investigator/ Institution agrees that time is the essence of the contract and undertakes to complete the studies within the term as specified in each IIS proposal.
g. Investigator/ Institution undertakes not to terminate the trials prematurely without the consent of Wockhardt.
h. Investigator/ Institution warrants that it has qualified and experienced personnel to assume responsibility for the proper conduct of the studies/ trial and shall maintain a list of such qualified persons to whom it has delegated significant trial related duties.
i. Investigator/ Institution warrants that it is thoroughly familiar with the appropriate use of the Material/ Product.
j. Investigator/ Institution warrants that it is aware of and shall comply with the Guideline for Good Clinical Practice and other regulatory requirements.
k. Investigator/ Institution warrants that it shall submit the protocol to appropriate authority/authorities for approval and start the study only after the approval from appropriate authority/authorities is obtained.

l. Investigator/ Institution warrants that it is aware that the Wockhardt has agreed to provide its services/ funds/ products based upon the aforesaid declarations and warranties.

XI) Investigator initiated Study Data and Publication Rights

a. Investigator shall share the data generated from investigator initiated study with Wockhardt for but not limited to support data management, clinical study report preparation, manuscript publication/ abstract or poster presentation.

b. Investigator can publish the results of the investigator initiated Study ("Study Data"), and use study data generated from the investigator initiated study for their own research and educational purposes and programs after obtaining written consent from Wockhardt. Any third party other than the investigator and Wockhardt, will not use or permit others to use non-public or unpublished raw Study Data from any Study that involves the use of a Wockhardt Product for the commercial benefit of any third party.

c. Investigator shall have the right, consistent with academic standards, to publish or present the results of the Study provided that the manuscript, abstract or other material proposed to be published or presented ("Proposed Publication") shall be submitted to Wockhardt at least sixty (60) days prior to submission for publication or presentation to permit Wockhardt to request removal of any Confidential Information contained therein and to protect its rights to any patentable Invention. Wockhardt shall complete its review within thirty (30) days after receipt of the Proposed Publication. If Wockhardt believes that any Proposed Publication contains any information relating to any patentable Invention, the disclosure of such Proposed Publication shall be delayed for up to two (2) years from the date of receipt of the Proposed Publication to permit the filing of a patent application. If Wockhardt believes that any Proposed Publication contains Confidential Information, Wockhardt shall so notify Investigator, and they shall remove any such Confidential Information prior to publication or presentation.

d. Investigator will comply with recognized ethical standards concerning publications and authorship.

e. Investigator will disclose Wockhardt's support of the Study in any publication of Study results

f. If Wockhardt wishes to disclose results or other study information, Study Data or parts or all of the Study Report earlier than indicated above, Wockhardt may submit a request to Investigator in writing. Investigator will consider any such request in good faith. Any such request must identify the results or other Study information, Study Data or parts of the Study Report that Wockhardt wishes to disclose and how and where it would be disclosed. In any publication by Wockhardt of the results of the Study, Wockhardt will acknowledge the roles and efforts of Investigator in the Study.

XII) Indemnification

a. Wockhardt shall take the full responsibility of any issues/ events related to the Wockhardt product, when it is used within limits of recommendations of product's latest package insert/ leaflet and indemnify investigator against all losses, claims, or damages arising from such usage of the Wockhardt product within the investigator initiated study or otherwise, except that the foregoing indemnity shall not apply to any liability arising from investigator's intentional deviation or omission or negligence in the performance of its obligation under this agreement or any use of the product beyond recommendations of product's latest package insert/ leaflet.

b. Wockhardt shall guarantee that no Wockhardt product/ other medicines/ equipment/ materials shipped to investigator in connection with the Study covered by this Agreement will be adulterated or mislabelled.

c. Investigator agrees to keep all accountability of all Wockhardt product/ other medicines/ equipment/ materials

d. Investigator and Institution agrees at their own cost and expense to indemnify, defend and hold harmless Wockhardt and its Affiliates, employees, officers, and directors (Wockhardt Indemnities) from and against any and all losses, costs, expenses and damages, including but not limited to reasonable attorney's fees, based on a personal injury and/or for damage to or loss of property incurred as a result of Investigator/ Institution its officers', directors', agents', or employees'(including Principal Investigator's, and Sub-Investigators') (i) breach of its obligations including violation of clause VII, VIII, X, XI of this Agreement under this Agreement, including, but not limited to the Protocol; (ii) negligence or malfeasance or nonfeasance; and (iii) breach of any applicable local, state or federal law(s), rule(s), or regulation(s), including, but not limited to, applicable Regulatory Authority regulations, ICH-GCPs and other governmental requirements or any other governmental authority or agency (iii) from all actions, suits, claims, or demands brought by any third party based on or arising under this Agreement to the extent that such loss is caused by the negligence or willful misconduct or any use of the Wockhardt product beyond recommendations of product's latest package insert/ leaflet by the Investigator, Institution, their employees or agents.

e. Neither party will be liable for any loss or damage, including loss of profits, loss of goodwill or any other special, incidental, indirect or consequential damages whatsoever (and whether caused by the negligence of either party or its employees or agents or otherwise) arising out of or in connection with any act or omission of either party whether for breach of contract, tort (including negligence and strict liability), or otherwise relating this Agreement.

XIII) Insurance.

a. Investigator shall maintain such professional liability and other insurance as shall be reasonably necessary to insure himself against any claim or claims for damages, whether arising by reason of personal injury or death occasioned directly or indirectly in connection with the Study or services provided under this Agreement. Investigator shall provide evidence of such coverage to Wockhardt upon request.

XIV) Force Majeure.

a. A party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, government action, or power failure (a "Force Majeure Event") provided the affected party gives the other party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected party will be unable to perform its obligations under this Agreement. The affected party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that the Wockhardt may terminate this Agreement if such Force Majeure Event continues for a period of ninety (90) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event

XV) Agreement Modification.

a. This Agreement may not be altered, amended or modified except by a written document signed by all the parties.

XVI) Assignment.

a. This Agreement may not be assigned by the Investigator without the prior written consent of Wockhardt.

XVII) Successors and Assigns.

a. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

XVIII) Notice

a. Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to Wockhardt:	Attn: Dr. Hanmant Barkate Wockhardt Limited Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India Facsimile:022 -26534242
If to Institution:	Attn: Dr . G.S. Narshetti MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093
If to Investigator	Attn: Dr. Nimain C Mohanty MGM MEDICAL COLLEGE (MIHS), Sector 01 Kamothe, Navi Mumbai 410209, Maharshtra India. Facsimile: 022-27431093

XIX) Severability.

a. If any provision of this Agreement shall be declared invalid for any reason whatsoever, that decision shall not affect any other provision of this Agreement, which shall remain in full force and effect; and to this end the provisions of this Agreement are hereby declared severable.

XX) APPLICABLE LAW AND COMPETENT COURTS

This Agreement shall be governed by Laws of India, under exclusive jurisdiction of courts of Mumbai.

If any question of dispute shall at any time during the term or thereafter arise between the Parties with respect to the validity, interpretation, implementation or alleged material breach of any provision of this Agreement or the rights or obligations of the Parties hereunder, or regarding any question including the question as to whether the termination of this Agreement by either Party has been legitimate, then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within sixty (60) days, then such a question or dispute shall be referred to and finally resolved by arbitration under the Arbitration and Conciliation Act 1996, (as amended from time to time). The seat of the

arbitration shall be Mumbai. All proceedings of such arbitration, including without limitation, any agreements or awards, shall be in the English language.

XXI) Entire Agreement.

a. This Agreement constitutes the entire agreement between the parties and supersedes all prior agreements and understandings whether written or oral relating to the subject matter of this Agreement.

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed by its duly authorized representative as of the date written above.

[WOCKHARDT LIMITED]

By:

09/05/2017

Name: Dr. Hanmant Barkate

Its: Vice President – Medical Affairs

[INSTITUTION]

By:

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Name: Dr . G.S. Narshetti

Its: Dean – MGM Medical College, Kamothe.

[INVESTIGATOR]

By:

9/5

Name: Dr. Nimain C Mohanty

Its: Principal Investigator

Professor
Dept. of Paediatrics
MGM Medical College & Hospital,
Navi Mumbai

Exhibit A

Accepted Investigator Initiated Study (IIS) Proposal

(Attached)

Department of Pediatrics
MGM Medical College, Sector-1, Kamothe, Navi Mumbai 410209
MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s of 3 UGC Act, 1956)
Accredited by NAAC with 'A' Grade

Date: 02.05.2017

To,
VP- Medical Affairs & Clinical Research
Wockhardt Limited

Subject: Proposal for Investigator Initiated Study on Zeebon R

Dear Sir,

I hereby propose a study on Wockhardt product Zeebon R entitled " A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children"

The study will be conducted to recruiting 60 evaluable subjects (age Group 06 months to 06 years) suffering from acute viral diarrhea.

The objective of the study is to evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care(Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of :

- Time to resolution of diarrhea
- Time to normalization of stool consistency (Passage first well-formed stool)
- Time to normalization of stool frequency (Passage of stool < 3 times/ day)

I look forward to Wockhardt's support for the conduct and execution of this study in terms of (delete the not applicable)

- Funding (Tentatively Rs. 11,16000)
- Supplying Wockhardt product Zeebon R (Tentatively 900 bottles no.)
- Facilitating study activities, contracting vendors or documentation

Find enclosed the duly filled & signed IIS proposal for your consideration.

Regards, Nimain Mohanty

Name: Dr. NIMAIN C. MOHANTY
Title: Professor, Emeritus Paediatrics
Institute: MGM INSTITUTE OF HEALTH SCIENCE, KAMOTHE,
NAVI MUMBAI-410209

Proposer	Name Dr Nimain C. Mohanty Title PROF OF PEDIATRICS MGM Institute of Health Sciences, Kamothe, Navi Mumbai Address MGM MEDICAL COLLEGE HOSPITAL NAVI MUMBAI 410209 Contact No. 09920410522_; Emailnimain.mohanty@gmail.com
Study type	Clinical☐ check ☐ obervational; ☐ interventional Animal☐ check ☐ disease model; ☐ toxicity; ☐ other In-vitro ☐
Request for*(Break-up of requirements for funds, medicine/ product/ material shall be enclosed)*	☐Funding specify tentative amount __11,16,000_____ ☐ Wockhardt product specify in the next section ☐ Other medicine specify in the next section ☐ Equipment specify function _____, Make _____& Model _____. ☐ Materials specify _____. ☐ Facilitate check the appropriate activities requiring support ☐ Protocol & study document development ☐ Study insurance (vendor search and qoutation validation) ☐ EC submission & approval ☐ Training of study team e.g. GCP, product use ☐ Clinical Data Management & Statistics(vendor search and qoutation validation) ☐ Study Report Writing(vendor search and qoutation validation) ☐ Preparation of manuscript/ abstract/ poster
Wockhardt product under study	Name: Zeebon R
	Formulation : Probiotic suspension
	Strength :Bacillus clausiiSpores IHS 2 x 109 Spores
	Quantity required : 900 bottles of 5 ml each
Other medicineto be	Name

Signature of Proposer

supplied	Formulation
	Strength
	Quantity required
Research sites*(for multiple sites, add details of all sites. CV & MRC of investigator shall be enclosed)*	Single ☐ Name of Investigator: Dr Nimain Mohanty Institute: MGM hospital , Navimumbai. Name of EC: MGM Institute of Health Sciences, Kamothe, Navi Mumbai EC Reg. No. ECR/Inst.457/INST/MH/2013dated 05_/ 09_/2013
Study Title*(Synopsis of the study shall be enclosed)*	A prospective, randomised, parallel group, single centre study to evaluate efficacy & safety of Bacillus clausii (2 Billion Spores per 5 mL) suspension as an add on therapy to standard of care in acute viral diarrhea in children
Study Rationale	There are variable reports on usefulness of probiotics in viral diarrhoea. Role of B. clausii needs ~~further~~ eva
Objectives	To evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care (Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of • Time to resolution of diarrhea* * Resolution of diarrhea is defined as normalization of consistency (well-formed stool for child aged ≥ 1 year; return to the consistency existing prior to onset of diarrhea for infants) and frequency (<3 times/ day for child aged ≥ 1 year; return to the frequency existing prior to onset of diarrhea for infants) of passing stools. **Secondary Objective** To evaluate impact of co-administering Bacillus clausii (2 Billion Spores per 5mL) suspension as add on to standard of care (Oral Rehydration Salt and Zinc) in treatment of acute viral diarrhoea in terms of • Time to normalization of stool consistency (passage first well-formed stool) • Time to normalization of stool frequency (passage stool < 3 times/ day) Additionally, investigator also intends to undertake a subgroup analysis of the study patients to compare patients with • rota-virusdiarrhea vs. non-rota-virus diarrhea

Signature of Proposer

	• Reduction in stool Volume
Endpoints	**Primary Endpoints** • Time to resolution of diarrhea. **Secondary endpoints.** • Time to normalization of stool consistency • Time to normalization of stool frequency. • Reduction in stool Volume ***Safety endpoints.*** Adverse Events
Sample size	60 Evaluable subjects
Dosing regimen	SOC as per WHO guideline. Dosing of B. clausii - 10 ml twice daily for children > one year and 5 ml twice da < one year.
Duration of study	01 year including last patient last visit.
Planned study dates	01 June, 2017
Publication plans	

Signature of Proposer

Exhibit B

Outline of Investigator Initiated Study (IIS) Funding/ Facilitation Terms

Professional cost				
	Unit cost	# of visits	# of patients	total cost
Investigator grant (Enrolled cases)	2500	3	60	450000
Investigator grant (screen failure cases)	800	1	20	16000
Visit travel cost for subjects	100	3	60	18000
total professional cost				484000
Pass through cost				
Insurance	1	NA		250000
Lab assessments (Stool test & ELISA)	500	1	60	30000
EC fees				50000
Data Management	1		250000	250000
IP procurement				70000
total pass though cost				665000

Total budget value – 11, 49,000

Instalment terms for payment to Investigator			
Milestone Payments	**Milestones**	**Percentage of amount paid to Investigator**	**Actual Amount (Rs.)**
1st Milestone	Project Start up fees	-	**5,00,000**
2nd Milestone	Project Initiation (Recruitment of 1st patient)	20 % of 649000	**1,29,800**
3rd Milestone	Recruitment of 66 subjects	20 % of 649000	**1,29,800**
4th Milestone	Transfer of complete/ accurate data for data management (66 subjects)	20 % of 649000	**1,29,800**
5th Milestone	Signing of final CSR	40 % of 649000	**2,59,600**
Total Amount			**11,49,000**

Payment terms.

1. Payments will be released on Milestone basis.
2. Project Start-up payment will be released once the IIS agreement is signed and executed.
3. Investigational product Zeebon R will be provided to the investigator.
4. Tax deduction at source will be done.

Payments to be released in following account		
Payee account name	MGM Medical college Navi Mumbai Research society.	
PAN details of the Payee	AAATM4256E	
Bank account number	0183104000166669	IDBI bank Belapur IFSC : IBKL0000183