# Department of Clinical Pharmacology Seth GSMC and KEMH, Parel, Mumbai – 400012

Date: 14<sup>th</sup> July 2021 DCP/II/ 685 / 2021

Subject: "Tender for engagement of Contract Research Organization (CRO) in respect of clinical study entitled to "(INCENTIVE) Indo-European Consortium for Next Generation Influenza Vaccine Innovation" to be undertaken by Department of Clinical Pharmacology (Diamond Jubilee Society Trust, Seth GSMC and KEMH, Parel, Mumbai- 400012)

The Department of Clinical Pharmacology, Seth GSMC and KEMH, Parel, Mumbai invites sealed quotations for engagement of Contract Research Organization (CRO) in respect of clinical study entitled to "(INCENTIVE) Indo-European Consortium for Next Generation Influenza Vaccine Innovation" to be undertaken by Department of Biotechnology, India preferably for a period 6 months to One year from the date of signing of CSA contract: -

#### 1. General information about the tender: -

a	Tender Reference No.	DCP/II/ 685 / 2021
b	Last date and time for receipt of	25 <sup>th</sup> July 2021
	Tenders	
С	Time and date of opening of Tenders	After receiving confirmation of date and time
		from DJST (Approx. after 1 Month)
d	Place of opening of Tenders	Diamond Jubilee Society Trust, College
		Building, 1 <sup>st</sup> floor, Seth GSMC and KEHM,
		Parel, Mumbai- 400012
e	Details of background activities to	Essential requirements for CRO
	be carried out as well as essential	
	requirements for CRO, technical	
	requirements & activities for	
	clinical trials etc	

#### 2. Disclaimer

- 1. This Request for Proposal (RFP) is not an agreement or offer by Department of Clinical Pharmacology, Seth G.S Medical College and K.E.M Hospital, Mumbai (hereinafter referred to as `DCP, KEMH') to the prospective bidder or party. The purpose of RFP is to provide interested parties with information to assist the formulation of their bid.
- 2. The RFP, along with its annexures, is not transferrable and will be issued only to persons who have obtained the same by payment of the requisite fees. The RFP and the information contained therein are to be used only by the person or party it is issued. It may not be copied or distributed by the recipient to third parties (other than in confidence to the recipient's professional advisors). If the recipient does not continue with its involvement in the project in accordance with the RFP, this RFP must be kept confidential.
- 3. While this RFP has been prepared in good faith, neither DCP, KEMH nor its employees or advisors/consultants make any representation or warranty express or implied as to the accuracy, reliability or completeness of the information contained in this RFP. The bidders shall satisfy themselves, on receipt of the RFP, that the RFP is complete in all respects.

- 4. Neither DCP, KEMH, its employees nor its advisors/consultants will have any liability to any bidder or any other person under the law of contract, tort, the principles of restitution or unjust enrichment or otherwise for any loss, expense or damage which may arise from or be incurred or suffered in connection with anything contained in this RFP, any matter deemed to form part of this RFP, the award of the project, the information supplied by or on behalf of DCP, KEMH or its employees, any advisors/consultants or otherwise arising in any way from the selection process for the said project.
- 5. By purchasing the RFP, the Bidder shall be deemed to have confirmed that the Bidder is fully satisfied with the process of evaluation of the responses to RFP and DCP, KEMH's decision regarding the qualification or disqualification or selection of the Contract research organization for project. The bidders hereby expressly waive any and all objections or claims in respect thereof.
- 6. The issues of this RFP does not imply that DCP, KEMH is bound to appoint the selected bidder, as the case may be, for the project and DCP, KEMH reserves the right to reject all or any of the Bids without assigning any reasons whatsoever.
- 7. DCP, KEMH may in its absolute discretion but without being under any obligation to do so, update, amend or supplement the information, assessment or assumptions contained in this RFP.
- 8. This RFP may be withdrawn or cancelled by the DCP, KEMH at any time without assigning any reasons thereof.. (already included in para 6)
- 9. The bidder shall bear all its cost associated with or relating to the preparation and submission of its bid including but not limited to preparation, copying, postage, delivery, fees, expenses associated with any demonstration of presentations which may be required by DCP, KEMH, or any other costs incurred in connection with or relating to its bid. All such costs and expenses will remain with the bidder and DCP, KEMH shall not be liable in any manner whatsoever for the same or for any other costs or so other expenses incurred by the bidder in preparation or submission of the bid, regardless of the conduct or outcome of the bidding process.

#### 3. Definitions

- 1. "Bid" shall be the bid submitted in respect of an element by a bidder in response to the RFP.
- 2. "Bid Due Date" shall mean the last date for the submission of the Bid.
- 3. "Bidder" shall mean a person/organization/company who has submitted a bid for the project in response to this RFP.
- 4. "Bidding Process" shall mean the process by which Diamond Jubilee Society Trust, Seth GSMC and KEMH, Parel, Mumbai- 400012 (DJST) and Department of Clinical Pharmacology, Seth GSMC and KEMH, Parel, Mumbai (DCP, KEMH) intend to select a bidder for the award of the project.
- 5. "RFP" shall mean this tender document of the project together with its Annexures, as amended, supplemented and modified from time to time.
- 6. "DJST" shall mean Diamond Jubilee Society Trust, Seth GSMC and KEMH, Parel, Mumbai- 400012.
- 7. "DCP, KEMH" shall mean Department of Clinical Pharmacology, Seth GSMC and KEMH, Parel, Mumbai.
- 8. "EU" shall mean European Union.
- 9. "DBT" shall mean Department of Biotechnology, Government of India
- 10. "Project" shall mean the services included in the scope of work to be performed by the successful bidder as contemplated under this RFP.
- 11. "Notification of Award" shall mean the letter to be issued by DCP, KEMH after the evaluation of Bids in accordance with the terms hereof awarding the Project to it.

#### 4. Procedure for award of the project

- 1. DCP, KEMH will receive Bids pursuant to this RFP in accordance with the terms set forth herein as modified, altered, amended and clarified from time to time by the DCP, KEMH and all Bids shall be prepared and submitted in accordance with such terms on or before the Bid due date. Each bid shall comply with the requirement under this RFP.
- 2. Generally, the selected bidder shall be the bidder who has quoted the lowest evaluated cost. The remaining bidders shall be kept in reserve and may, in accordance with the process specified in the RFP be invited to match the Bid submitted by the bidder with the lowest evaluated cost in case such highest bidder withdraws or not selected for any reason. In the event that none of the other bidder match the bid of bidder with the lowest evaluated cost, DCP, KEMH and/or DJST may, in its discretion, invite fresh bids from all bidders or annul the bidding process, as the case may be.
- 3. Prior to the bidding process, bidders are invited to examine the project in greater detail, and to carry out, at their cost, such studies as may be required for submitting their respective bids for award of contract.
- 4. DCP, KEMH and DJST together shall issue separate Notification of Award to the successful Bidders in respect of each element after the evaluation of the Bids received in accordance with the terms hereof
- 5. After the issue of the Notification of award, the successful bidder shall:
  - a. Within ten (10) days of the issue of the notification of award, furnish a Contract Performance Guarantee (CPG) in accordance with the technical specification
  - b. Within seven (7) days of submission of CPG, execute the contract agreement with DCP, KEMH and DJST
- 6. If the timelines mentioned in Point 5 are not followed, the Notification of Award to the successful bidder shall stand cancelled and thereafter shall be awarded to the next lowest bidder subject to his following time limits mentioned in point 5.

#### 5. Information and Instruction to Bidders

#### Scope of Work

The scope of work and the project profile is provided in the Technical specifications.

The Bidders shall submit their bids for the entire scope of work set out here in. The decision shall be taken by DCP, KEMH, at its sole discretion before the Notification of the Award. However, the bidders shall provide the overall performance guarantees of the facilities.

- a. Ethics Committee and regulatory submission, notification and approval
- b. Study Initiation
- c. Clinical monitoring
- d. Safety Recording
- e. Data Management
- f. Medical writing
- g. Project Management
- h. Site Management
- i. Vendor Management
- j. Others

The detailed scope of work is mentioned in the Technical Requirement of the CRO section.

- 1. All Bidders are required to ensure compliance with the standards and codes mentioned in Technical Specifications.
- 2. The Bidder shall provide:
  - a. Bid Proposal and qualifying requirement data mentioned under Essential requirements of CRO.
  - b. Advance bank guarantee five percent (5 %) of the bid amount
  - c. Contract Performance Guarantee Ten percent (10 %) of the bid amount
  - d. Deviation sheet
  - e. Special Conditions of Contract
  - f. General Conditions of Contract
  - g. Price bid schedule

#### 6. Cost of Bidding

All the costs and expenses in relation to preparation of the bid, discussions and conferences, if any, including pre-award discussions with the bidders, technical and other presentations including any demonstrations, etc, shall be to the account of the Bidder(s) and DCP, KEMH shall bear no liability whatsoever in relation to the same.

#### 7. Clarification and Pre-bid meeting

- 1. The bidders may seek clarification or suggest amendments to the RFP in writing, through a letter or by e-mail (in a PDF format under the letter head of the Bidder) to reach DCP, KEMH at the address indicated in the RFP within the date and time mentioned in critical date sheet.
- 2. The bidders or their authorized representatives are invited to attend the pre-bid meeting(s), which will take place on tentative date specified in critical date sheet of RFP, or any such other date as notified by DCP, KEMH. The time and address of this would be intimated later.
- 3. The purpose of the pre-bid meeting will be to clarify any issues regarding the RFP, including in particular, issues raised in writing by the bidders as per the provisions mentioned above.
- 4. Non-attendance at the pre-bid meeting will not be a cause of disqualification of a Bidder.
- 5. DCP, KEMH is not under any obligation to entertain/respond to suggestions made or to incorporate modifications sought for.
- 6. DCP, KEMH shall not respond to any clarification sought by the bidders after the date and time set out in critical date sheet or date notified by DCP, KEMH. There shall be no extension in bid due date on account of clarification sought.

#### 8. Deviations

- 1. Deviations, if any from the bidding document shall be stipulated clearly in the form set out in the bid deviation schedule as contained in annexure, which shall be submitted with and construed to be the part of the bid. Any deviations mentioned elsewhere or any terms such as "See covering letter" or "See bidder's printed general terms and conditions" etc. shall be ignored. The bidder shall also provide the withdrawal price, if any, for withdrawal of each of the deviations.
- 2. Any deviations in any of the following will not be accepted under any circumstances
  - a. Terms of Payment
  - b. Liquidated damages

- c. Bests of contract price
- d. Bank guarantee requirements
- e. Defect's liability period and latent liability period
- f. Qualifying criteria
- g. Technical Specifications
- 3. Bidders may submit 'Alternative Bids' offering superior technical specifications. However, in order to submit an 'Alternative Bid', it will be essential for the bidder to submit a 'Main Bid' complying with the technical specifications as provided under RFP.
- 4. DCP, KEMH shall have the right to accept or reject the deviations proposed by the bidder and at the time of award of the contract, DCP, KEMH may require the bidder to withdraw the deviations or any of them proposed by the bidder that have not been accepted by DCP, KEMH. If the bidder refuses to withdraw such deviations or impose any conditions to such withdrawal, then the bid shall be liable to be rejected.
- 5. If the withdrawal of the deviation is because the deviation is not accepted by KEMH, the withdrawal price shall not be charged. The withdrawal price should only be for voluntary withdrawals by the bidders.
- 6. All decisions by DCP, KEMH shall be final and binding.

#### 9. Amendments to RFP

- 1. DCP, KEMH may, for any reason whatsoever, modify or amend the RFP, including the timelines specified in the critical timelines mentioned in the RFP
- 2. The amendments to the RFP shall be notified in writing to all the bidders and shall be binding on them.
- 3. DCP, KEMH may at its discretion, extend the Bid due date and all the bidders will be informed about the same.
- 4. A fresh date would be proposed where the bidder(s) can provide the fresh financial bid.
- 5. The documents required for re-bidding would be specified in the notification and would be communicated to all the bidder(s)

#### **10. The Bidding Process**

#### 1. Bid Formats

The Bids in response to the RFP will be submitted by the bidders in the manner and format provided in the annexure of RFP. The bids shall be accompanied by power of attorney as per the format mentioned in annexure , signed by a duly authorized officer of the bidder authorizing the signatory of the bid to submit the bid and do and execute all matters connected with the bid and the project on behalf of the bidder.

#### 2. Bidders to inform themselves fully

a. The bidders shall make independent enquiry and satisfy themselves with respect to all the required information, inputs, conditions and circumstances and factors that may have any effect on the bid. Once the Bidders have submitted their bid, the bidders shall be deemed to have inspected and examined the conditions (study site, recruitment strategy, expected screen failures, expected drop outs, sample collection, sample storage facilities, study team and facilities at the study site etc) and study site regulations as well laws and regulations in force in India. Accordingly, each bidder acknowledges that, on being selected as successful bidder and in execution

- of the contract, it shall not be relieved from any of its obligations under the bidding documents nor shall the successful bidder be entitled to any extension in the completion date mentioned in this RFP except when the recruitment of the study participants leads to delay in the study completion. In case of extension of the completion date apart from the reason mentioned in latter, financial compensation of 1.5% of the bidding amount will be payable by the bidder to DCP, KEMH for each month of extension.
- b. Bids are invited from all persons/parties/organizations in accordance with the procedures set out herein, which is in line with the guidelines for international competitive bidding.
- c. In their own interest, the bidders are requested to familiarize themselves with all relevant laws of India without limitation, New Drug and Clinical Trial Rules, 2019, the Income Tax Act 1961, the Companies Act 2013, Foreign Exchange Management Act 1999, the regulations/standards/guidelines framed by appropriate commissions/organizations/government bodies and all other related acts, laws, rules and regulations prevalent in India as amended from time to time.
- d. DCP, KEMH shall not entertain any requests for clarification from the bidders regarding the above laws/rules/regulations/standards/guidelines. Non-awareness of the same shall not be the reason for the bidders to request for extension in bid due date. The bidders undertake and agree that before the submission of their bids, all such factors as generally brought out above, have been fully investigated and considered while submitting their bids.

#### 11. Validity of Bid

- 1. The bidders shall submit the bid which shall remain valid upto 5 years, from the bid due date
- 2. DCP, KEMH reserves the right to reject any bid which does not meet the aforementioned validity requirement.
- 3. DCP, KEMH may solicit the bidder's consent for extension of the period of validity of the bid. The request and response, thereafter, shall be binding. A bidder accepting the DCP, KEMH's request for validity extension shall not be permitted to modify its bid.
- 4. The quoted prices cannot be raised till the completion of the contract. In case any other service is required by the purchaser, the bidder shall submit the additional bid for the same.

#### 12. Method of Submission of Bid

- 1. The bid and all related correspondences and documents in relation to bidding process shall be in English language. Supporting documents and printed literatures furnished by the bidder(s) in the bid should be in any other language provided that they are accompanied by appropriate translations of the pertinent passages in English language. Supporting materials, which are not translated in English shall not be considered.
- 2. For the purpose of interpretation and evaluation of the bid, the English language translation shall prevail.
- 3. The bidder shall provide all information sought under this RFP. DCP, KEMH and/or DJST will evaluate only those bids which are received in the required format and complete in all respects. Incomplete and/or conditional bids shall be liable to rejection.
- 4. For each element, the bidder shall prepare one original set of documents comprising the bid (together with original/copies of the documents required to be submitted along with /pursuant to this RFP) and clearly marked "ORIGINAL". In addition, the bidder(s) shall

- submit one (1) copy of bid marked "COPY" and one (1) CD of bid in a PDF format (separate techno-commercial and price bid) in a re-writable format. In the event of any discrepancy between the original and the copies of original, original shall prevail.
- 5. The bid and all the alterations, omissions, additions or any other amendments made to the bid shall be initiated by person(s) signing the bid together with the stamp of the bidder. The bid shall contain page numbers and shall be hard bound.
- 6. Each bidder shall submit each bid in the format specified in the annexure and seal it in an envelope and mark the envelope as "Bid". The bidder shall seal each copy of the bid together with the respective enclosures in separate envelopes duly marking the envelope as "ORIGINAL" and "COPIES". The envelopes shall together be sealed in an another outer envelope.
- 7. Each bid shall contain:
  - a. Envelope A: Bid form
  - b. Envelope B: Credentials
  - c. Envelope C
    - i. Power of Attorney
    - ii. Technical bid
    - iii. Price schedule duly filled (separate for each element)
    - iv. Deviations as per the format given
- 8. If the envelopes are not sealed and marked as instructed above, DCP, KEMH assumes no responsibility for the misplacement or premature opening of the bid submitted.
- 9. Unpriced techno-commercial bid may be sent through email.
- 10. Priced bids submitted by fax or email shall not be entertained and shall be rejected.
- 11. The following conditions shall be adhered to at the time of submitting the bid:
  - a. Bidders should attach clearly marked and referenced continuation sheets in the event that the space provided in the prescribed forms in the annexures is insufficient. Alternatively, bidders may format the prescribed form without editing the contents, thereof, making due provisions for incorporation of the requested information.
  - b. Information supplied by the bidder shall be that of the bidder only and not, unless specifically requested, of other associated companies/firms/organizations.

#### 13. Bid Due date

- 1. Bid(s) should be submitted on or before the bid due date, at the address provided in the subject of the application. Receipt thereof will be sent to the authorized personnel of the Bidder(s) on their specified email address.
- 2. DCP, KEMH and/or DJST may, in their sole discretion, extend the bid due date and all the bidders will be informed accordingly
- 3. Bid(s) received by DCP, KEMH after the specified time on the bid due date will be rejected.

#### 14. Withdrawals of bids

- 1. Bidder may withdraw its bid after submission, provided that written notice of the withdrawal is received by DCP, KEMH prior to bid due date.
- 2. No bids shall be modified, substituted, or withdrawn by the bidder on or after the bid due date.
- 3. Any alteration/modification in the bid or additional information supplied at any time unless the same has been expressly sought by the DCP, KEMH, shall be disregarded.

#### 15. Opening and Evaluation of Bids

- 1. DCP, KEMH with Diamond Jubilee Society Trust, Seth GSMC and KEMH, Parel, Mumbai- 400012 mentioned DJST hereafter will open the bids privately on its own convenient time and location for the purpose of evaluation. Bidders will not be invited at that juncture.
- 2. Bids for which notice of withdrawal has been submitted will not be opened.
- 3. Bidder(s) are advised that selection of the successful bidder will be entirely at the discretion of DCP, KEMH. Bidders will be deemed to have understood and agreed that no explanation or justification on any aspect of bidding process or selection will be given by DCP, KEMH.
- 4. Any information contained in the bid shall not in any way be construed as binding on DCP, KEMH its agents, successors, assignees but shall be binding against the bidder if any project is subsequently awarded to it under the bidding process, on the basis of such information.
- 5. DCP, KEMH reserves the right not to proceed with the bidding process at any time without notice and liability to reject any bid without assigning any reason(s).

#### 16. Confidentiality

Information relating to the examination, clarification, evaluation and recommendation from the bidder(s) shall not be disclosed to any other person who is not officially concerned with the process or is not a retained professional advisor advising DCP, KEMH in relation to or matters arising out of, or concerning the bidding process. DCP, KEMH will treat all information, submitted as part of the Bids, in confidence and would require all those who have access to such material to treat the same in confidence. DCP, KEMH will not divulge any such information unless it is directed to do so by any statutory authority that has the power under law to require its disclosure or is to enforce or assert any right or privilege of the statutory authority DCP, KEMH.

A confidentiality disclosure document need to be furnished by the bidder as mentioned in Annexure II and the terms and conditions of Confidentiality Disclosure Agreement and Pre-contract Integrity Pact mentioned in Annexure V would be binding on the bidder.

#### 17. Tests of Responsiveness

- 1. DCP, KEMH reserves the right to reject any bid which is non-responsive, and no request for alteration, modification, substitution or withdrawal shall be entertained by DCP, KEMH in respect of such bid.
- 2. DCP, KEMH shall not entertain any correspondence with any bidder in relation to the acceptance or rejection of any bid.

#### 18. Clarification

- 1. To facilitate evaluation of bids, DCP, KEMH may, at its sole discretion, seek clarification or additional information from any bidder regarding its bid. Such clarification(s) or additional information shall be provided within the time specified by DCP, KEMH for this purpose. Any such request and all clarification(s) and additional information submitted pursuant thereto shall be in writing.
- 2. If the bidder does not provide clarification(s) or additional information sought within

the prescribed time, its bid shall be liable to be rejected. In case the bid is not rejected, DCP, KEMH may proceed to evaluate the bid by construing particulars requiring clarifications to the best of its understanding and the bidder shall be barred from the subsequently questioning such interpretations of DCP, KEMH.

#### 19. Proprietary Data

All documents and other information supplied by DCP, KEMH or submitted by a bidder to DCP, KEMH shall remain or become the property of DCP, KEMH. Bidders are to treat all information as strictly confidential and shall not use it for any purpose other than for preparation and submission of their bid. DCP, KEMH will not return any bid or any information provided along therewith.

#### 20. Contract Performance Guarantee

In accordance with the general conditions of contract, the successful bidder will provide to DCP, KEMH the contract performance guarantee equivalent to ten percent (10 %) of the total contract price at the time specified. The contract performance guarantee shall be valid for the period specified in general conditions of the contract.

#### 21. Bid Price

The bidder shall quote in each of its bid the rates, quantities related to the entire scope of work in respect of such element covered under the bidding documents as per the format of price schedules as per Annexure III hereto. Bidders are advised not to edit the same. In case they wish to add so, they are advised to do so on a separate page using the same format.

Each of the bidder has been provided with the bid forms, price schedules, etc. in soft form along with the RFP. Bidders are advised to use the same for the preparation of their bid.

The bidders shall quote firm prices for the entire scope of work.

In case of any arithmetical errors in the price schedules, the unit prices shall prevail.

If the bidder fails to quote the prices in respect of any part of scope of works under the bidding document, then the price quoted shall be deemed to be applicable in respect to the entire scope of work envisaged under the bidding document.

#### 22. Bid currencies

Prices shall be quoted in the following currencies

- 1. The services offered by the bidder shall be in Indian Rupees (INR).
- 2. The bidder shall be paid in currencies (i.e INR /or internationally acceptable currencies) as quoted in the bid

#### 23. Award of Contract

DCP, KEMH shall award the contract to the successful bidder whose bid has been determined to be substantially responsible. DCP, KEMH reserves the right to award

works relating to each element or any service thereof to more than one bidder. DCP, KEMH shall not incur any liability in respect of any determination by DCP, KEMH under this RFP.

#### 24. DCP, KEMH's right to reject any or all bids

- 1. DCP, KEMH reserve the right to reject one or all bids without assigning any reason.
- 2. DCP, KEMH reserves the right to reject any bid if:
  - a. At any time, a service misrepresentation is made or
  - b. The bidder does not provide, within the time specified by the DCP, KEMH any clarification or any supplemental information sought by DCP, KEMH for evaluation of the bid. Such misinterpretation / improper response would lead to disqualification of the bidder. If such disqualification/rejection occurs after the bid has been opened and the lowest bidder gets disqualified/rejected then DCP, KEMH reserves the right to
    - i. Invite the remaining bidders to submit their bids in accordance with the RFP or.
    - ii. Take any such measure as may be deemed fit in the sole discretion of DCP, KEMH, including annulling of the bidding process; or
  - c. If DCP, KEMH determines in its sole discretion that such bid does not comply with the requirement of the project.
- 3. In case it is found during the evaluation or any time before signing the contract or after its execution and period of subsistence thereof that one or more of the criteria of evaluation have not been met by the bidder or the bidder has made material misrepresentation or has given any materially incorrect or false information, the bidder shall be disqualified forthwith if not yet appointed as the contractor either by the issue of notification of award or has entered into a contract agreement as the case may be, and the same shall, notwithstanding anything to the contrary contained therein or in this RFP, be liable to be terminated, by a communication in writing by DCP, KEMH to the bidder, without DCP, KEMH being liable in any manner whatsoever to the bidder.
- 4. DCP, KEMH reserves the right to verify all statements, information and documents submitted by the bidder in response to the RFP. DCP, KMH to undertake such verification which shall not relieve the bidder of its obligations or liabilities here under nor will it affect any rights of DCP, KEMH thereunder.

#### 25. Extension of Time

- 1. If the CRO requires extension of time, they shall intimate in writing to DCP, KEMH within seven (7) days of the occurrence of such hindrance/delay.
- 2. Extension of time would only be entertained in case of slow recruitment of participant due to Act of God or pandemic extending the project timelines.
- 3. No extension of time would be considered if the provided services by the bidder require corrections and/or not satisfactory in the eyes of DCP, KEMH and/or DBT and/or European Union and/or DJST.
- 4. The DCP, KEMH after satisfying himself about the reasonableness of grounds, may grant extension of time as in its opinion be justified and communicate the same in writing to the bidder. (The decision of DCP, KEMH shall be final and binding). Whenever such extension of time is granted, it would be without prejudice to the rights of DCP, KEMH. Any extension of time granted as stated above shall neither entitle the CRO to any claim for increase in their fees nor shall it release him from any of the obligations under the said agreement.

#### 26. Payment Terms

Without prejudice to DCP, KEMH right to damage under the terms of the contract, payment less agency commission, if any, shall be made through an irrevocable Letter of Credit or credit notes. The Letter of Credit (L/C) shall not be transferable, divisible and assignable.

The charges for establishing L/C and bank charges in India shall be borne by DCP, KEMH and/or the selected tender committee. The L/C extension and amendment charges will be to the account of the party responsible for occasioning the extension/amendments.

#### 27. Payment Schedule

- a. An advance of 5% of the bidding amount will be given as credit note which will be reimbursed later.
- b. The payment will be done in the form of credit notes as per milestone basis.

SI No	Project Progress	Payment to be given of
		the bidding amount
1.	Signing of the Agreement	5%
2.	Enrollment of the first participant	20%
3.	Enrollment of the 50% of the participant	25%
4.	Completion of the study enrollment	20%
5.	Submission of the final close out report	20%
6.	Submission of manuscript	10%

- c. No payment for reimbursement shall be entertained over and above the bidding price quoted by the bidder.
- d. The bidder shall quote the fix total price of each service and no variable cost will be provided by the DCP, KEMH to the bidder.
- e. DCP, KEMH reserves the right and as per its discretion it may decide the amount to be paid to the bidder in case of extension of the project timelines or pre-decided deviations mentioned above.
- f. The payments would be made only after the reports and assigned service are to the satisfaction of the DCP, KEMH and/or DBT and/or EU and/or DJST. No payments shall be made for any revision made to the projects.
- g. DCP, KEMH will not be liable to pay for extension of timelines if the delay happens due to reviewing and correction processes of the report/documents provided by the bidder.
- h. The payment would be done as per the price quoted for each study mentioned in the scope of work.

#### 28. Guarantees

- a. Advance guarantee: 5% of the bid amount shall be given by the bidder as bank guarantee as per the form attached below.
- b. Contract performance guarantee: 10 % of the bid amount shall be given by the

bidder as bank guarantee.

- c. The advance bank guarantee will be returned to the bidder within 6 months after awarding of the contract by DCP, KEMH to the bidder.
- d. Contract performance guarantee shall be given back after completion of the study by DCP, KEMH to the bidder.

#### 29. Liquidated damage

1. The applicable rate is 0.5% per week and maximum deduction is 10% of the contract price.

#### 30. Arbitration

Any dispute arising out of the terms of this REP shall first attempted to be resolved by mediation amicably by the good offices of both parties within a period of thirty (30) days – failing which the same shall be referred to an arbitrator jointly agreed by the successful bidder and DCP, KEMH. Further, unresolved disputes, if any, shall be resolved by arbitration by Dean KEMH and Appointed person/team by the successful bidder as arbitrators which is to be conducted under the Indian Arbitration and Conciliation Act 1996 in the English language at Mumbai and under jurisdiction of Mumbai.

#### 31. The tender should consist of the following terms and conditions:

- i. The technical Bid must contain information/documents signed by the authorized signatory of the bidding firm/agency and should be kept in Technical Bid envelope along with other documents/information prescribed in this tender notice.
- ii. The firm should not handover execution of order to any other/sister firm(s) and in such a case it will amount to violation of contract and may entail cancelation of contract and forfeiture of Performance Security
- iii. The tenders will be opened on stipulated date and time in the presence of the member secretory, members of DJST and representative from Department of Clinical Pharmacology.
- iv. The tenderers should quote their rates excluding taxes (Taxes should be mentioned separately).
- v. Communication of acceptance of the tender constitutes concluded contract.
- vi. In case where a successful tenderer, does not provide the service in time or seeks time to provide the services, DCP, KEMH at its discretion may obtain such services from the next higher tenderer and the loss, if any, caused to DCP, KEMH due to increased rates shall be borne by the defaulting tenderer.
- vii. The performance security shall be returned to the bidder within two months after the expiry of the contract period, but in the event of any dispute arising between DCP, KEMH and the bidder, DCP, KEMH shall be entitled to deduct such sums which in the opinion DCP, KEMH 1 are due from/not payable to the bidder.
- viii. No enhancement of rates will be considered during the period of contract.
- ix. The Bidder firm should not have been black listed by any Govt. /Semi Govt. /Semi Govt. Dept. Therefore, bidder should furnish an Undertaking to this effect that any Govt. /Semi Govt., Dept. /Office has not black listed their firm/agency.
- x. The bidder must submit the copy of last 03 years Income Tax Return (ITR).

- xi. The bidder shall quote/indicate the rates for all items (in Indian Rupees) offered by it in the 'Proforma for Financial Bid' attached with this tender notice (Annexure attached)
- xii. The Member Secretary, Diamond Jubilee Society Trust and Head of Department of Clinical Pharmacology, Seth G.S Medical College and KEM Hospital, Mumbai has every right to reject/accept any bid without assigning any reasons
- xiii. The bids received after due date and time will not be accepted while incomplete bids are liable to be ignored.
- xiv. The TDS will be deductible u/s 194C of the Income Tax Act, 1961.
- xv. The period of contract shall be for five years. If performance of the bidder is not found satisfactory, the contract may be cancelled at any point of time without assigning any reason.
- xvi. The bidder should have a minimum "FIVE years' experience in the field of clinical studies and population studies
- xvii. The information arising out of the research will be the intellectual property of DCP, KEMH and bidder will not have any right on the result/information

	Critical Date sheet					
Sr. no.	Stage	Date				
1.	Published date	15 <sup>th</sup> July 2021				
2.	Date to download the details of tender	$15^{th} - 25^{th}$ July 2021				
3.	Pre-bid conference date	26-28 <sup>th</sup> July 2021				
4.	Last date of submission of technical bid	30 <sup>th</sup> July 2021				
5.	Technical bid opening date	2nd August 2021				
6.	Financial bid opening date	5 <sup>th</sup> August 2021				
7.	Financial bid closing date	10 <sup>th</sup> August 2021				
8.	Notification of award	14 <sup>th</sup> August 2021				

#### xviii. Amendment of tender documents if required

- a. At any time prior to the deadline for submission of bids, DCP, KEMH may, for any reason, whether at its own initiative or in response to a clarification requested by a prospective bidder, modify the tender documents by amendment. The same would also be hosted on the website of the DCP, KEMH and all prospective bidders are expected to surf the website before submitting their bids to take cognizance of the amendments. But nonetheless the copies of the amendments would be sent by registered post/speed post/courier/e-mail to all the bidders who have purchased the tender documents.
- b. In order to allow prospective bidders' reasonable time in which to take the amendment into account in preparing their bids, the DCP, KEMH , at its discretion, may extend the deadline for the submission of" bids and host the changes on the website of the DCP, KEMH

#### xix. Code of Integrity

- a. The bidders/ should sign a declaration about abiding by the Code of Integrity for Public Procurement in bid documents. In case of any transgression of this code, the bidder is not only liable to be removed from the list of registered suppliers, but it would be liable for other punitive actions such as cancellation of contracts, banning and blacklisting or action in Competition Commission of India, and so on.
- b. Code of integrity for Public Procurement: The Purchaser as well as bidders, suppliers, contractors and consultants should observe the highest standard of

ethics and should not indulge in the following prohibited practices, either directly or indirectly, at any stage during the procurement process or during execution of resultant contracts:

- i. "corrupt practice": making offers, solicitation or acceptance of bribe, rewards or gifts or any material benefit, in exchange for an unfair advantage in the procurement process or to otherwise influence the procurement process or contract execution;
- ii. "Fraudulent practice": any omission or misrepresentation that may mislead or attempt to mislead so that financial or other benefits may be obtained or an obligation avoided. This includes making false declaration or providing false information for participation in a tender process or to secure a contract or in execution of the contract;
- iii. "anti-competitive practice": any collusion, bid rigging or anti-competitive arrangement, or any other practice coming under the purview of the Competition Act, 2002, between two or more bidders, with or without the knowledge of the purchaser, that may impair the transparency, fairness and the progress of the procurement process or to establish bid prices at artificial, non-competitive levels;
- iv. "coercive practice": harming or threatening to harm, persons or their property to influence their participation in the procurement process or affect the execution of a contract;
- v. "conflict of interest": participation by a bidding firm or any of its affiliates that are either involved in the consultancy contract to which this procurement is linked; or if they are part of more than one bid in the procurement; or if the bidding firm or their personnel have relationships or financial or business transactions with any official of DCP, KEMH who are directly or indirectly related to tender or execution process of contract; or improper use of information obtained by the (prospective) bidder from the DCP, KEMH with an intent to gain unfair advantage in the procurement process or for personal gain; and
- vi. "Obstructive practice": materially impede the DCP, KEMH investigation into allegations of one or more of the above mentioned prohibited practices either by deliberately destroying, falsifying, altering; or by concealing of evidence material to the investigation; or by making false statements to investigators and/or by threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or by impeding the DCP, KEMH Entity's rights of audit or access to information

#### c. Obligation for Proactive disclosures

 The DCP, KEMH as well as bidders, are obliged under Code of Integrity for Public Procurement to sue-moto proactively declare any conflicts of interest (coming under the definition mentioned above pre-existing or as and as soon as these arise at any stage) in any procurement process or execution of contract.

- Failure to do so would amount to violation of this code of integrity; and
- ii. The bidder must declare, whether asked or not in a bid document, any previous transgressions of such a code of integrity with any entity in any country during the last three years or of being debarred by any other Procuring Entity. Failure to do so would amount to violation of this code of integrity;
- iii. To encourage voluntary disclosures, such declarations would not mean automatic disqualification for the bidder making such declarations. The declared conflict of interest would be evaluated and mitigation steps, if possible, taken by the DCP, KEMH

#### d. Punitive provisions

Without prejudice to and in addition to the rights of the DCP, KEMH to other penal provisions as per the bid documents or contract, if the DCP, KEMH concludes that a (prospective) bidder/, directly or through an agent, has violated this code of integrity in competing for the contract or in executing a contract, the DCP, KEMH may take appropriate measures including one or more of the following:

- i. If his bids are under consideration in any procurement:
  - a. Forfeiture or encashment of bid security
  - b. Calling off of any pre-contract negotiations; and
  - c. Rejection and exclusion of the bidder from the procurement process

#### i. If a contract has already been awarded

- a. Cancellation of the relevant contract and recovery of compensation for loss incurred by the DCP, KEMH
- b. Forfeiture or encashment of any other security or bond relating to the procurement.
- c. Recovery of payments including advance payments, if any, made by the DCP, KEMH along with interest thereon at the prevailing rate.

#### ii. Provisions in addition to above:

- a. Removal from the list of registered suppliers and banning/debarment of the bidder from participation in future procurements of the purchaser for a period not less than one year;
- b. In case of anti-competitive practices, information for further processing may be filed under a signature of the Joint Secretary level officer, with the Competition Commission of India.

c. Initiation of suitable disciplinary or criminal proceedings against any individual or staff found responsible.

#### iii.The Bidding Documents

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Tec	nnı	cal	Kı	n
100		Lai	וע	u

M/s

111/10	_
(Name, address Landli	ine and Mobile Nos.
of the bidding firm/age	ency firm/ agency): -

Sr.No Document kept in technical bid Whether enclosed (The firm would write Yes OR No the respective columns) Copy of Registration/License and other documents as 1 proof. 2 Self-certificate in respect of not being blacklisted by any Govt. /Semi. Govt. Office Details & copy of GST registration of firm 3. 4. Copy of PAN of firm 5. Copy of rate contract for providing the similar services in for last ten years Documentary proof that the CRO should have ten years 6. working experience in the field. 7. Documentary proof that the CRO have an Clinical Research expert as a member of core team for better understanding of the implementation of clinical trials. Documentary proof that the perspective bidders 8. have capability to cater service throughout the Country across states and UT's with adequate Human Resources and Infrastructure. 9. Acceptance of the condition that Confidentiality of the study data will be maintained with utmost care. Acceptance to sign Memorandum of Understanding 10. (MoU) to be executed between Department of Clinical Pharmacology, Seth G.S Medical College and KEM Hospital, Mumbai and CRO. 11. Along with all the necessary documents/certificates required as per the tender conditions, the bidder should furnish a brief write-up, backed with adequate data, explaining his available capacity (both technical and financial), for the specified work and its timeline of completion, after meeting all their current commitments 12. Supporting documents submitted by the bidder must be certified as follows: i. All copy of research done; respective completion

certificate and contact details of clients:

	documents issued by the relevant Industries;	
	annual report, etc., in support of experience, past	
	performance and capacity /capability should be	
	authenticated by the by the person authorized to	
	sign the tender on behalf of the bidder.	
	Original Documents must be submitted for inspection, if	
	so demanded.	
	ii) All financial standing data should be certified by	
	certified accountants, for example, Chartered	
	Accountants/Cost Accountants or equivalent in relevant	
	countries; and Indian bidder or Indian counterparts of	
	foreign bidders should furnish	
	their Permanent Account Number, PAN and GST number.	
13	Proof for Others terms of reference as in Annex-	
	I (if any)	
14	Proof of five or more clinical trials conducted within	
14	timelines	
15		
13	Proof of fifty (50) or more employees working since last	
1.5	three (3) years	
16	Proof of number of studies done in accordance to	
	European Union	
17	Proof of study done with collaboration of Government of	
	India and European Union	

The details to be attached with Annexure 1.

It is hereby declared that the Terms & Conditions of the Department of Clinical pharmacology, Seth G.S Medical College and KEM Hospital, Mumbai are fully acceptable to our firm/agency.

(To be signed by the Authorized Signatory) of the Firm/Agency with Name and Stamp

# Financial Bid (Overall)

Sr. No	Study	Estimated sample size and Centre's	Price quoted (Excluding GST)
1	Immunogenicity and safety of a commercialized quadrivalent influenza vaccine administered by the intramuscular route in subjects 60 years of age and older in Europe (Belgium) and India.	100 in KEM	
2	A phase IV study to assess immunogenicity of QIV in healthy children and infants in Europe and India.	3-8 years – 100 in KEM 6-12 months- 100 in KEM	
4	INCENTIVE- A phase II, double blind, placebo controlled trial.	60 (India-KEM)	
6.	INCENTIVE-QIV DCE:	100 (India – KEM)	

The financial bid shall also be attached with detailed quoted prices of the each study mentioned in the Technical Requirement of CRO of each scope of work mentioned.

Member Secretary
Diamond Jubilee Society Trust
Department of Clinical Pharmacology
Seth G.S Medical College and KEM Hospital, Mumbai – 400012

Respecte	ed Sir,							
research work No	institute and hereby	d organizat offer	ion invo	lved in the vari quotation and accep ent duly signed	ious clinical s against ot the terms	tudies un the & conditi	dertaken / R tender ons of the te	& D ref.
Yours fa	iithfully,							

Note: This letter of authority should be on the letterhead of the concern and should be signed

#### **Details of CRO as under**

(Name) for and on behalf of M/s

(Name of Contract Research Organization)

by an authorized signatory.

- ii. Essential requirements for CRO are:
- 1. The CRO should have ten years working experience
- 2. The CRO should have a Clinical Research expert as a member of core team for better understanding of the implementation of clinical trials.
- 3. The CRO must have a prior experience of efficiently working and handling projects related to the European Union.
- 4. Proof of at least 5 or more successfully executed clinical trials, within specified timelines.
- 5. Proof of manpower with at least fifty (50) or more employees since last 3 years.
- B. Technical requirements for CRO (List of activities proposed to be carried out by CRO for clinical trials on INCENTIVE Project)

	Technical Reproject	equirement for	studies unde	er INCENTIVE
	QIV – 1	QIV - 2 & 3	Double Blind Placebo controlled study	DCE
Requirements	Sample – 100	Sample – 200 (100 + 100)	Sample – 60	Online Questionnaire
	Tentative starting – June 2021	Tentative starting – September 2021	Tentative starting – October 2023	Tentative starting – As soon as possible
Ethics Committee and regulatory submission, notification and approval  1. EC/IRB submission assistance  2. HMSC approval	Yes	Yes	Yes	Yes
Study Initiation  1. Preparation  2. Set-up study master file  3. Collect and compliance prestudy document  4. Site initiation meeting  5. SIV report	Yes	Yes	Yes	NA
Clinical Monitoring  1. Routine and non-routine on site monitoring  2. Source Document verification  3. Verify site compliance to protocol and GCP requirements.  4. Review of CRF  5. Review drug records  6. Monitoring reports  7. Audit by any other	Yes	Yes	Yes	NA
regulatory agency Safety recording 1. Adverse event reporting to IEC,	Yes	Yes	Yes	NA

	<u> </u>			<u> </u>	
	Sponsor and				
	European				
	regulators				
2.	Serious adverse				
	event reporting and				
	analysis to IEC,				
	Sponsor, Indian and				
	European				
	regulators				
Data M	Ianagement	Yes	Yes	Yes	Yes
	Data management	105	105	105	105
1.	using eCRF				
2	Database designing				
	Data management				
٥.	plan (DMP)/ Data				
	validation plan				
	-				
4	(DVP) Database validation				
5.	CRF and Data				
	clarification form				
	(DCF)/Tracking				
	DCF Resolution				
	Database lock				
	al Writing	Yes	Yes	Yes	Yes
1.	Development of				
	clinical study report				
	in DCGI/DBT/EU				
2.	Study report				
	finalization				
Project	Management	Yes	Yes	Yes	Yes
1.	Set up of project				
	management plan				
2.	Generate study				
	progress reports				
3.	Develop study				
	monitoring and				
	report system				
4.	Communications				
	with DBT/EU				
5.	Development and				
]	source document				
	template				
6	Translations of				
0.	PIS/ICD/Participant				
	diary/recruitment				
	fliers				
Cita M		Yes	Yes	Yes	NA
	anagement	168	168	168	INA
1.	Study file update				
	and management				
2.	IP assistance				

<ul> <li>3. Regulatory approval for IP if any</li> <li>4. IP shipping, accountability and archival</li> <li>5. Subject enrollment log</li> </ul>				
Vendor Management  1. Shipment of the samples to India and Abroad in liquid nitrogen tanks  2. Coordination with labs	Yes	Yes	Yes	NA
Others  1. Reporting of study progress report on timely manner to DBT/EU/Indian Regulators	Yes	Yes	Yes	Yes

# Annexure I

### **Technical Bid Details**

# GENERAL INFORMATION

Notes:
(i) Attach an attested photocopy of Certificate of Registration.
1. Names of the firm:
2. Legal Status of the Firm: Individual/Association/Joint Venture/Consortium
3. Registered Address, telephone, Tele-fax.
4. Contact Person, Designation and address including email id
5. Number of years in Clinical Research
6. Number projects for the last five years, if any
7. Details of Clinical trials associated with Bidder in for last five years, if any.
8. State the Quality System followed in the Company. Does the company have an ISC
certificate or it follows an internal quality system

# NUMBER OF CLINICAL TRIALS CONDUCTED IN VACCINE STUDIES AND/OR COLLABORATION WITH EU

SI No	Study Title	Name and Address of	Details of the Study			Year of Comple	Remarks
		Sponsor	Phase	Study Design	Cost	tion of Study	
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

<sup>\*</sup>If more studies need to be mentioned then to be added in the continuation sheet as per the above mentioned format.

#### **KEY PERSONNEL DETAILS**

SI No.	Technical Team	Education	Designation	Total Years of Experience	Relevant Experience in Years	Details as per annexures
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						

#### Note

- 1. A summary of the qualification and work experience of each key staff to be part of the project to be attached.
- 2. **CVs** to be submitted for all the proposed personnel in the format provided
- 3. If more personnel will be allocated then the names and experience to be added in the continuation sheet as per the above mentioned format.

# **CVs OF KEY STAFF**

Name of the Sta	ff		
Designation			
Name of the CRO present	y employed		
Years with the presen	at CRO		
Proposed Position	on		
Details of Task Assi	gned		
Man-months budgeted for t	ask assigned		
<b>Key Qualifications:</b>		<u> </u>	
<b>Education:</b>			
	Employme	ent Record	
Name of the			
CRO/Pharmaceutical Industry/Other Company	Positio	n Held	Years of Employment

# FINANCIAL AND TECHNICAL DATA OF THE BIDDER

SI	Description	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
No		- 16	<b>– 17</b>	<b>- 18</b>	- 19	- 20	- 21
1.	Annual Turnover						
2.	Net Profit						
3.	Fixed Assets						
4.	<b>Current Assets</b>						
5.	Inventories						
6.	Cash and Bank Balance						
7.	Advances						
8.	Liabilities						
9.	Creditors						
10.	EBIDTA						
11.	Number of Employees*						
12.	Rating from the reputed rating agency (viz. CRISIL/CARE/Brickwork etc.)						
13.	Number of CCRC Employees* (Passed the ACRP certification exam)						

- 1. Attach Audited balance sheets in support of the data clearly marking the relevant portion.
- 2. Attach the copies of Income Tax Returns Filed
- 3. \* Number of Employees to be given by the Bidder
- 4. Rating agency certificate in support of financial data

#### **Annexure II**

#### **Confidential Disclosure Agreement**

This agreement ("Agreement") is made and entered into this date of 2021

by and between

Department of Clinical Pharmacology, Seth G.S Medical College and K.E.M Hospital, Mumbai, (here in after referred to as "DCP, KEMH" which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns)

And
(DCP, KEMH andare hereinafter individually referred to as a "Party"
and collectively referred to as the "Parties".)
Whereas the Parties wish to discuss business opportunities in connection with Clinical Trial Studies (the "Purpose");
Whereas in connection with the Purpose, each Party (the "Discloser") will disclose certain commercial, scientific, technical and other type of information to other Party (the "Recipient") which must remain confidential, including without limitation, any formulations, techniques, equipment, pre-clinical, clinical and other data, methods, results, patent, patent application, trademark, copyright or other intellectual property right, manufacturing information, technical, financial or business information, partners, and the existence, scope and activities of any research, development, manufacturing, marketing, or other projects of DCP, KEMH AND/OR Department of Biotechnology, Government of India AND/OR European Union and
its Affiliates or business partners respectively, in whatever form and using whicheve media, whether marked as confidential or not (hereinafter referred to as the "Confidential Information").

"Affiliate" means, for the purpose of this Agreement and with respect to a Party, any entity that is a subsidiary of such Party or is directly or indirectly controlling, controlled by or under common control with such Party.

In consideration of these premises and in order to induce the Discloser to disclose the Confidential Information to the Recipient, the Parties hereby agree as follows:

1. The Recipient agrees to retain the Confidential Information in strict confidentiality, not to use it for any purposes OTHER than for the Purpose and not to disclose it to others except to those of their respective authorized representatives that need to

access the Confidential Information for the Purpose and only if such authorized representatives have previously undertaken to not disclose the Confidential Information to others or are bound by similar duties of confidentiality to the Recipient with respect to the Confidential Information. For the purpose of this Agreement, any disclosure of Confidential Information made by or on behalf of the Discloser, including by employees, agents or consultants of the Discloser and its Affiliates, shall be deemed a disclosure by the Discloser.

- 2. The Recipient acknowledges and agrees that all communications and information relating to the Purpose received from the Discloser or on its behalf prior to the date of this Agreement shall be deemed to have been received under an obligation of confidentiality from the time of receipt under the terms set out in this Agreement and forms a part of Confidential Information.
- 3. The obligation of confidentiality and non-use of Confidential Information shall not apply to the Confidential Information which:
  - a. was in possession of the Recipient prior to disclosure by the Discloser;
  - b. is or becomes generally available or known to the public, through no fault of or breach of its obligations hereunder by the Recipient, its Affiliates or any of its authorized representatives or consultants;
  - c. is lawfully disclosed to the Recipient by a third party not bound by nondisclosure obligations with regard to such information or to the Discloser or its Affiliates or business partners to which the Confidential Information relates;
  - d. was already known by the Recipient prior to its disclosure by or on behalf of the Discloser, otherwise than by unlawful disclosure, as evidenced by written dated records; or
  - e. was independently developed by the Recipient without the benefit of the Confidential Information supplied.

The onus is on the Recipient who to prove that any of the above mentioned exceptions apply.

- 1. The Recipient agrees to maintain the Confidential Information as confidential taking the same caution level as it would take with its own confidential information with a similar sensitivity but in any event follow reasonable procedures to prevent unauthorised disclosure or use of the Confidential Information and to prevent it from falling into the public domain or the possession of unauthorised persons.
- 2. Any inventions or improvements whether patentable or unpatentable which are conceived of, discovered, or developed the Receiver, its Affiliates or any person claiming through them any way derived from, related to, based on, or resulting from the use of Confidential Information shall be promptly disclosed to the Discloser.
- 3. The Recipient is liable for any breach of this Agreement by any of its employees, officers, directors, representatives, agents and consultants, and agrees to take any and all necessary actions (including legal proceedings), at its own cost and expense, in order to prevent and remedy to such breach.
- 4. The Confidential Information and any right, title and interest therein shall remain the exclusive property of the Discloser, its Affiliates or partners, as the case may be, and

- nothing contained in this Agreement shall be construed as creating an express or implied license to practice or use the Confidential Information for the Recipient's or third parties' benefit.
- 5. If the Recipient is required by applicable law or court order to disclose any Confidential Information, it shall first notify the Discloser in writing, sufficiently in advance so as to provide the Discloser with reasonable opportunity to seek to prevent such disclosure or to seek to obtain a protective order for such Confidential Information and shall disclose only that portion of the Confidential Information that Recipient is legally required to disclose.
- 6. The Recipient acknowledges and agrees that the Discloser is not making and shall not be deemed to have made any representations or warranties regarding the accuracy or completeness of the Confidential Information or any other type of information furnished in accordance with this Agreement.
- 7. Upon expiration or termination of this Agreement upon receipt of a written request from the Discloser, the Recipient shall cease all use of the Confidential Information and promptly return to the Discloser all documents and materials of the Discloser which relate to or contain any of the Confidential Information without retaining any copy thereof. The Recipient or its Affiliates shall not use or exploit the Confidential Information retained in intangible form in the unaided memory of its directors, employees, contractors, advisors or of any person to whom such Confidential Information is shared.
- 8. Because the Discloser may not be adequately compensated in damages in the event of a breach of this Agreement by the Recipient, the Discloser shall be entitled, in addition to any other rights or remedies available to it (including damages), to an injunction restraining such breach or any threatened breach and to specific performance of any obligation thereof.
- 9. This Agreement shall become effective on the date first above written and shall remain in full effect for 5 (five) Year(s) from the date of signing or until at any earlier time, the Discloser expresses its intention to terminate this Agreement by giving written notice of termination to Recipient, whichever comes earlier, provided that such termination or expiration of this Agreement shall not affect the Recipient's obligations hereunder with respect to the Confidential Information that has been disclosed or delivered prior to termination or expiration.
- 10. Any notice, direction or other instrument required or permitted to be given under this Agreement shall be in writing and given by delivering it by hand or sending it by registered mail with receipt requested, by recognized courier service with acknowledgement of receipt requested, by facsimile or other similar form of recorded communication addressed:

Date:
Place.

To,

Department of Clinical Pharmacology,
Seth G.S Medical College and K.E.M Hospital,
Acharya Donde Marg, Parel
Mumbai, Maharashtra
India – 400012

Any such communication shall be deemed to have been validly and effectively given (i) if personally delivered or sent by registered mail (with receipt requested), by internationally recognized courier service with acknowledgement of receipt requested, on the date of such delivery or receipt if such date is on a business day prior to 4:00 p.m. (local time at the place of delivery) and otherwise on the next business day, or (ii) if transmitted by facsimile or similar means of recorded communication on the business day following the date of transmission.

Any Party may change its address for service from time to time by notice given in accordance with the foregoing.

Neither of the Parties hereto may assign this Agreement or any of its rights and obligations hereunder.

- 1. No failure or delay on the part of the Discloser in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or a future exercise thereof or the exercise of any other right or remedy granted hereby or by law.
- 2. If any provision of this Agreement is held to be invalid or unenforceable for any reason, it shall be adjusted rather than voided, if possible, in order to achieve the intent of the Parties to the fullest extent possible. In any event, all other provisions of this Agreement shall be deemed valid and enforceable to the fullest extent possible.
- 3. This Agreement constitutes the entire agreement and understanding between the Parties concerning the subject matter hereof and supersedes all prior discussions, agreements and negotiations between them as to the subject matter

hereof. The recitals form an integral part of the Agreement.

- 4. Nothing in this Agreement shall be deemed to create any obligation on the Discloser to enter into any further agreement.
- 5. No amendment of this Agreement shall be effective unless made in writing and signed by a duly authorized representative of each Party.
- 6. This Agreement shall be governed and interpreted according to the laws of Govt. of India (without reference to conflicts of laws provisions).
- 7. The place of the arbitration shall be Mumbai, Maharashtra, India. The language of the arbitration proceedings shall be English.
- 8. The Parties may apply at all times to any competent judicial authority for interim or conservatory measures. The application of a Party to a judicial authority for such measures or the implementation of any such measures ordered by the arbitrator shall not be deemed to be an infringement or a waiver of the arbitration agreement.

In witness whereof, the Parties have, by duly authorized persons, executed this Agreement.

Department of Clinical Pharmacology Seth G.S Medical College and K.E.M Hospital, Mumbai By its duly authorized representative, As s/he so declares

By its duly authorized representative, As s/he so declares

# **Annexure III**

# Format for Financial Bid (On letter head of the Company)

Date:

To,
Professor and Head
Department of Clinical Pharmacology,
1st Floor, New Building
Seth G.S Medical College and K.E.M Hospital,
Acharya Donde Marg, Parel
Mumbai, India – 400012
SUB: Offer for conducting the studies under INCENTIVE Project
Dear Madam,
Being duly authorized to represent and act on behalf of, and
having reviewed and fully understood all the requirements of bid submission provided
vide the bid document dated Pertaining to the above mentioned work,
we hereby provide our financial proposal for conducting studies under INCENTIVE
Project.

SI.	Studies	Total Basic	Taxes	Others (If	Total (Rs)
No		Price		Any)	
1.	QIV – 1				
2.	QIV – 2				
3.	QIV – 3				
4.	A double-blind				
	placebo-controlled				
	trial				
5.	DCE				
Gran	d Total Price of All th	e Studies			

	(Should be given in a sealed envelope)
PLACE: DATE:	ADDRESS AND SIGNATURE OF THE TENDERER (WITH OFFICE SEAL)
NAME OF	F TENDERER:
	that the rate quoted will hold good for six months during which apward revision will be asked for.
•	Levies if any: Remark(s):
Validity: S	six months from the date of opening of financial bid
*Detailed	Split Up Rates Should Be Attached Separately

#### Annexure - IV

#### Format of Bank Guarantee

#### NOTE

- 1. This guarantee should be furnished by a Nationalised Bank/ Scheduled Bank authorised by RBI to issue a Bank Guarantee. NLC reserves its rights to reject the Bank Guarantee if the same is not in the specified format.
- 2. This bank guarantee should be furnished on stamp paper of value not less than Rs.100.00
- 3. The stamp paper should have been purchased in the name of the Bank executing the Guarantee.
- 4. In the case of foreign bidder the B.G may be furnished by an international reputed bank acceptable to the DCP, KEMH / RBI.
- 5. The advance Bank Guarantee shall be valid till the completion of Study with a grace period of 3 (Three) months thereafter.
- 6. Any deviation in this format will not be acceptable.

	ADVANCE PAYMENT GUARANTEE NO:
PLACE:	
DATE:	
TO	

1. Pursuant to the Contract, herein after referred to as "The CONTRACT" which M/S ...... herein after referred to as the "CRO" (which expression shall,

unless repugnant to the context or meaning thereof, include its successors,

administrators, representatives and assignees), have concluded with M/s Department of Clinical Pharmacology, Seth G. S Medical College and K.E.M Hospital, Mumbai

herein after referred to as "DCP, KEMH" (which expression shall unless repugnant to

the context or meaning thereof, include its successors, administrators, representatives

and assignees), on ....... 2015 ...... vide. Work order No: ...... ...... Dated: ...... (scope of work)

for ..... Contract price.

Dear Sir,

2. According to the said Contract, the DCP, KEMH, has undertaken to make an advance

	payment of Rs (Rupees only) being the payment of
	% for against issuance of an advance payment guarantee by a
	Bank.
3.	For this advance payment, We, the undersigned (Name)
	(Address), herein after referred to as the bank, which expression shall unless
	repugnant to the context or meaning thereof include its successors, administrators,
	representatives and assignees, hereby guarantee to the effect that we irrevocably
	under-take to pay the DCP, KEMH merely on demand without any previous
	notice and without any demur and without recourse to the CRO and without
	referring to any other source, any and all monies payable by the CRO towards the
	advance or part thereof paid by the DCP, KEMH, but not exceeding Rs
	(Rupees only) provided the DCP, KEMHadvice us that
	the CRO has failed to fulfil his contractual obligations stipulated in the said Contract.
	Any such demand made by DCP, KEMH on the bank shall be conclusive and binding,
	absolute and unequivocal notwithstanding any difference between the DCP,
	KEMH and the CRO or any dispute or disputes raised /pending before any
	court, Tribunal Arbitrator or any other authority.
4.	This guarantee will not be discharged due to the change in the constitution of the
	Bank or the CRO.
5.	This guarantee will become invalid three months after the completion of the
	(scope of work) by the CRO under the said Contract or as soon as this Letter
	of Guarantee has been returned to us at the latest, however, on unless a claim has
	been lodged with us under this guarantee before that date.
6.	We (Bank) further agree that if the said CRO fails to adhere to the total or
	individual time schedule stipulated in the said Contract and if there be delay in the
	to reimburse to the DCP, KEMH interest at the prevailing rate as applicable
	for cash/ credit facilities on the amount of advance payment made by the DCP,
	KEMH.

- 7. The DCP, KEMH shall have the fullest liberty without affecting in any way the liability of the bank under this guarantee from time to time to extend the time of performance by the CRO. The Bank shall not be released from its liability under these presents by any exercise of the DCP, KEMH of the liberty with reference to the matter aforesaid.
- 8. The Bank also agrees that the DCP, KEMH shall be entitled at his option to

enforce this guarantee against the Bank as a Principal Debtor, in the first instance notwithstanding any other Security or Guarantee that it may have in relation to the CRO's liabilities.

- 9. The Bank further agrees that the decision of the DCP, KEMH as to the failure on the part of the CRO to fulfil the Contractual obligations stipulated in the said Contract and/or to the amount payable by the Bank to the DCP, KEMH shall be final conclusive and binding.
- 10. This guarantee is revocable only with the written consent of the DCP, KEMH.

11.	This guarantee shall remain in force upto and including and shall be		
	extended from time to time for such period as may be desired by M/S		
	on whose behalf this guarantee has been given.		
12.	In any case, our liability under this advance payment guarantee does not		
	exceed Rs(		

13. Notwithstanding anything contained herein:

Dated this ...... day of ......2021

- a. Our liability under this bank guarantee shall not exceed ...... (in words)
- b. this bank guarantee shall be valid upto .....; and
- c. we are liable to pay the guaranteed amount or any part thereof under this bank guarantee only and only if you serve upon us a written claim or demand on or before ......

Return of this document to us by any person before the aforesaid date will, however, extinguish our liability as on the date of return.

FOR AND ON BEHALF OF		
THE	BANK.	
SIGNATURE OF AUTHORIZED BANK OFFICIAL		
NAME:		
DESIGNATION:		
STAMP/SEAL OF THE BANK: .		
SIGNED, SEALED AND DELIVE	ERED	

FOR AND ON BEHALF OF THE				
BANK BY THE ABOVE				
NAMED	_INTHE PRESENCE OF:			
WITNESS 1.				
SIGNATURE	•••••			
NAME				
ADDRESS				
WITNESS 2.				
SIGNATURE				
NAME				
ADDRESS	DATED			

### Annexure V

## PRE-CONTRACT INTEGRITY PACT

This pre-contract integrity pact (herein after called the integrity pact) is made on		
day of the month of		
Between		
Department of clinical pharmacology, Seth G.S Medical College And K.E.M		
Hospital, Acharya Donde Marg, Parel, Mumbai – 400012 (herein called DCP, KEM	Η	
which expression shall mean and include, unless the context otherwise requires	,	
his successors in office and assigns) of the first party.		
And		
M/s with office at represented by		
shri, (hereinafter called the "bidder/s which expression shall		
mean and include, unless the context otherwise requires, his successors and		
permitted assigns) of the second party.		
Preamble		
[both DCP, KEMH and bidder referred above are jointly referred to as the parties]		
DCP, KEMH intends to award, under laid down organizational procedure purchase orders / contract/s against tender /work order /purchase order number of the contract of the con	io. WS	
therefore,		
void all forms of corruption by following a system that is fair, transparent and free		
any influence/prejudiced dealings prior to, during and subsequent to the currency of the	e	
ract to be entered into with a view to:-		

- 1. Enable DCP, KEMH to obtain the desired materials/ work/ project/services done at a competitive price in conformity with the defined specifications by avoiding the high cost and the distortionary impact of corruption on public procurement; and
- 2. Enable the bidder to abstain from bribing or indulging in any corrupt practice in order to secure the contract by providing assurance to them that their competitors will also abstain from bribing and other corrupt practices and DCP, KEMH will commit to prevent corruption, in any form, by its

  Officials by following transparent procedures.

The parties hereto hereby agree to enter into this integrity pact and agree as follows:

### Clause.1. Commitments of DCP, KEMH

- a. DCP, KEMH undertakes that DCP, KEMH and/or its associates (i.e. Employees, agents, consultants, advisors, etc.) Will not demand, take a promise for or accept, directly or through intermediaries, any bribe, consideration, gift, reward, favour or any material or immaterial benefit or any other advantage from the bidder, either for themselves or for any person, organization or third party related to the contract in exchange for an advantage in the bidding process, bid evaluation, contracting or implementation process related to the contract.
- b. DCP, KEMH will, during the tender process / pre-contract stage, treat all bidders with equity and reason, and will provide to all bidders the same information and will not provide any such information or additional information, which is confidential in any manner, to any particular bidder which could afford an advantage to that particular bidder in comparison to other bidders in relation to tendering process or during the contract execution.

- c. all the officials of DCP, KEMH will report to chief vigilance officer of DCP, KEMH (cvo), any attempted or completed breaches of the above commitments as well as any substantial suspicion of such a breach.
- d. DCP, KEMH will exclude from the process all known prejudiced persons and persons who would be known to have a connection or nexus with the prospective bidder.
- e. if the bidder reports to DCP, KEMH with full and verifiable facts any misconduct on the part of DCP, KEMH's associates (i.e. Employees, agents, consultants, advisors, etc.) And the same is prima facie found to be correct by DCP, KEMH, necessary disciplinary proceedings, or any other action as deemed fit, including criminal proceedings may be initiated by DCP, KEMH. Further, such an associate may be debarred from further dealings related to the contract process. In such a case, while an enquiry is being conducted by DCP, KEMH the proceedings under the contract would not be stalled.

### Clause 2. Commitments of bidders/ contractors

The bidder commits itself to take all measures necessary to prevent corrupt practices, unfair means and illegal activities during any stage of its bid or during any pre-contract or post-contract stage in order to secure the contract or in furtherance to secure it and in particular commit itself to the following:-

a. the bidder will not offer, directly or indirectly (i.e. Employees, agents, consultants, advisors, etc.) Any bribe, gift, consideration, reward, favour, any material or immaterial benefit or other advantage, commission, fees, brokerage or inducement to any official of DCP, KEMH, connected directly or indirectly with the bidding process, or to any person, organization or third party related to the contract in exchange for any advantage in the bidding, evaluation, contracting and implementation of

the contract.

- b. The bidder further undertakes that it has not given, offered or promised to give, directly or indirectly any bribe, gift, consideration, reward, favour, any material or immaterial benefit or other advantage, commission, fees, brokerage or inducement to any official of DCP, KEMH or otherwise in procuring the contract or forbearing to do or having done any act in relation to obtaining or execution of the contract or any other contract with the government for showing or forbearing to show favour or disfavor to any person in relation to the contract or any other contract with the government.
- c. The bidder will not engage in collusion, price fixing, cartelization, etc. With other counterparty(s).
- d. the counterparty will not pass to any third party any confidential information entrusted to it, unless duly authorized by DCP, KEMH.
- e. The counterparty will promote and observe ethical practices within its organization and its affiliates.
- f. Bidder shall disclose the name and address of agents and representatives and Indian bidders shall disclose their foreign principals or associates.
- g. The counterparty will not make any false or misleading allegations against DCP, KEMH or its associates.
- h. bidders shall disclose the payments to be made by them to agents/brokers or any other intermediary, in connection with this bid/contract.
- i. The bidder further confirms and declares to DCP, KEMH that it has not engaged any individual or firm or company whether Indian or foreign to intercede, facilitate or in any way to recommend to DCP, KEMH or any of its functionaries, whether officially or unofficially to award the contract to the bidder, nor has any amount been paid, promised or intended to be

paid to any such individual, firm or company in respect of any such intercession, facilitation or recommendation.

- j. The bidder while presenting the bid or during pre-contract negotiations or before signing the contract, shall disclose any payments he has made, is committed to or intends to make to officials of DCP, KEMH or their family members, agents, brokers or any other intermediaries in connection with the contract and the details of services agreed upon for such payments.
- k. The bidder will not accept any advantage in exchange for any corrupt practice, unfair means and illegal activities.
- 1. The bidder commits to refrain from giving any complaint directly or through any other manner without supporting it with full and verifiable facts.
- m. If the bidder or any employee of the bidder or any person acting on behalf of the bidder, either directly or indirectly, is a relative of any of the officers of DCP, KEMH, or alternatively, if any relative of an officer of DCP, KEMH has financial interest/stake in the bidder's firm, the same shall be disclosed by the bidder at the time of filing of tender. The term 'relative' for this purpose would be as defined in section 6 of the companies act 1956.
- n. The bidder shall not lend to or borrow any money from or enter into any monetary dealings or transactions, directly or indirectly, with any employee of DCP, KEMH.
- o. the bidder will not collude with other parties interested in the contract to impair the transparency, fairness and progress of the bidding process, bid evaluation, contracting and implementation of the contract, and will not enter into any undisclosed agreement or understanding with other bidders, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to

introduce cartelization in the bidding process.

- p. The bidder will not commit any offence under the relevant Indian penal code, 1860 or prevention of corruption act, 1988; further the bidder(s)/contractor(s) will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the DCP, KEMH as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically. The bidder also undertakes to exercise due and adequate care lest any such information is divulged.
- q. The bidder will not instigate third persons to commit offences outlined above or be an accessory to such offences.
- r. The bidder(s)/contractors(s) of foreign origin shall disclose the name and address of the agents/representatives in india, if any. Similarly the bidder(s)/contractors(s) of Indian nationality shall furnish the name and address of the foreign principal(s), if any.

# Clause.3. Previous contravention and disqualification from tender process and exclusion from future contracts

- a. the bidder declares that no previous contravention occurred in the last three years immediately before signing of this integrity pact, with any other company in any country in respect of any corrupt practices envisaged hereunder or with any public sector enterprise in india or any government department in india that could justify bidder's exclusion from the tender process
- b. The bidder agrees that if it makes incorrect statement on this subject, bidder can be disqualified from the tender process or the contract, if already awarded, can be terminated for such reason.

If bidder before award or during execution has committed a contravention through a violation of clause 2, above or in any other form such as to put his reliability or credibility in question, t DCP, KEMH is entitled to disqualify the bidder from the tender process.

### Clause .4. Equal treatment of all bidders

4.1

The bidder(s)/ undertake(s) to demand from

His subcontractors a commitment in conformity with this integrity pact.

4.2

DCP, KEMH will enter into agreements with identical conditions as this one with all bidders.

4.3

DCP, KEMH will disqualify from the tender process all bidders who do not sign this pact or violate its provisions.

### Clause .5. Consequences of violation / breach

- 5.1 any breach of the aforesaid provision by the bidder or any one employed by it or acting on its behalf (whether with or without the knowledge of the bidder) shall entitle DCP, KEMH to take all or any one of the following action, wherever required:-
- a. to immediately call off the pre-contract negotiations without assigning any reason or giving any compensation to the bidder. However, the proceedings with the other bidder(s) would continue.
- b. If bidder commits violation of integrity pact policy during bidding process, he shall be liable to compensate DCP, KEMH by way of liquidated damages amounting to a sum equivalent to 5% to the value of the offer or the amount equivalent to bid security, whichever is higher.
- c. In case of violation of the integrity pact after award of the contract, DCP,

KEMH will be entitled to terminate the contract. DCP, KEMH shall also be entitled to recover from the contractor liquidated damages equivalent to 10% of the contract value or the amount equivalent to performance guarantee, whichever is higher.

- d. To immediately cancel the contract, if already signed, without giving any compensation to the bidder.
- e. To recover all sums already paid by DCP, KEMH, and in case of an Indian bidder with interest thereon at 2% higher than the prevailing prime lending rate of state bank of India, while in case of a bidder from a country other than India with interest thereon at 2% higher than the libor. If any outstanding payment is due to the bidder from DCP, KEMH in connection with any other contract such outstanding payment could also be utilized to recover the aforesaid amount.
- f. To encash the advance bank guarantee and performance guarantee /warranty bond, if furnished by the bidder, in order to recover the payments already made by DCP, KEMH, along with interest.
- g. to cancel all or any other contract with the bidder. The bidder shall be liable to pay compensation for any loss or damage to DCP, KEMH resulting from such cancellation / recession and DCP, KEMH shall be entitled to deduct the amount so payable from the money(s) due to the bidder.
- h. To debar the bidder from participating in future bidding processes of DCP, KEMH for a minimum period of five (5) years, which may be further extended at the discretion of DCP, KEMH or until independent external monitors is satisfied that the counterparty will not commit any future violation.
- i. To recover all sums paid in violation of this pact by bidder(s) to any middleman or agent or broker with a view to securing the contract.
- j. in cases where irrevocable letters of crejdit have been received in respect of any

contract signed by DCP, KEMH with the bidder, the same shall not be opened.

5.2 DCP, KEMH will be entitled to all or any of the actions mentioned in para 5.1(i) to (x) of this pact also on the commission by the bidder or any one employed by it or acting on its behalf (whether with or without the knowledge of the bidder), of an offence as defined in chapter ix of the Indian penal code, 1860 or prevention of corruption act, 1988 or any other statute enacted for prevention of corruption.

5.3 the decision of DCP, KEMH to the effect that a breach of the provisions of this pact has been committed by the bidder shall be final and conclusive on the bidder. Howjever, the bidder can approach the independent external monitor(s) appointed for the purposes of this pact.

#### Clause.6. Fall clause

The bidder undertakes that it has not supplied/is not providing similar services at a price / charge lower than that offered in the present bid in respect of any other ministry/department of the government of India or psu and if it is found any stage that similar service was provided by the bidder to any to the ministry/department of the government of India or a psu at a lower price, then that very price, with due allowance for elapsed time will be applicable to the present case and the difference in the cost would be refunded by the bidder to DCP, KEMH, if the contract has already been concluded.

### Clause .7. Independent external monitor(s)

- a. DCP, KEMH has appointed independent external monitor(s) (hereinafter referred to as monitor(s)) for this pact in consultation with the central vigilance commission (name and addresses of the monitor(s) to be given).
- b. The responsibility of the monitor(s) shall be to review independently and objectively, whether and to what extent the parties comply with the obligations under this pact.
- c. The monitor(s) shall not be subject to instructions by the representatives of the parties and perform their functions neutrally and independently.

- d. Both the parties accept that the monitor(s) have the right to access all the documents relating to the project/ procurement, including minutes of meetings.
- e. As soon as the monitor(s) notices, or has reason to believe, a violation of this pact, he will so inform the cvo.
- f. The bidder(s) accepts that the monitor(s) have the right to access without restriction to all project documentation of DCP, KEMH including that provided by the bidder. The bidder will also grant the monitor(s), upon his request and demonstration of a valid interest, unrestricted and unconditional access to his project documentation. The same is applicable to subcontractors engaged by the bidder. The monitor(s) shall be under contractual obligation to treat the information and documents of the bidder/ subcontractor(s) with confidentiality.
- g. DCP, KEMH will provide to the monitor(s) sufficient information about all meetings among the parties related to the project provided such meeting could have an impact on the contractual relation between the parties. The parties will offer to the monitor(s) option to participate in such meetings.
- h. The monitor(s) will submit a written report to the cvo of DCP, KEMH within 8 to 10 weeks from the date of reference or intimation to him by DCP, KEMH/bidder and, should consent arise, submit proposals for correcting problematic situations.

Clause.8. criminal charges against violating bidder(s)/

If DCP, KEMH obtains knowledge of conduct of a bidder, or of an employee or a representative or an associate of a bidder, which constitutes corruption, or if DCP, KEMH has substantive suspicion

In this regard, DCP, KEMH will inform the same to the chief vigilance officer.

Clause.9. Facilitation of investigation

In case of any allegation of violation of any provisions of this pact or payment of commission,

DCP, KEMH or its agencies shall be entitled to examine all the documents, including the books of accounts of the bidder and the bidder shall provide

Necessary information and documents in English and shall extend all possible help for the purpose of such examination.

Clause. 10. Law and place of jurisdiction

Both the parties agree that this pact is subject to Indian law. The place of performance and hence this pact shall be subject to Mumbai jurisdiction.

Clause.11. Other legal actions

The actions stipulated in the integrity pact are without prejudice to any other legal action that may follow in accordance with the provisions of the extant law in force relating to any civil or criminal proceedings.

Clause.12. Validity and duration of the agreement

This pact begins when both parties have legally signed it. It expires for the contractor/successful bidder 12 months after the last payment under the contract or the complete execution of the contract to the satisfaction of the both DCP, KEMH and the bidder /seller, including warranty period, whichever is later, and for all other bidders/unsuccessful bidders 6 months after the contract has been awarded.

If any claim is made / lodged during this time, the same shall be binding and continue to be valid despite the lapse of this pact as specified above, unless it is discharged / determined by chairman and managing director of DCP, KEMH.

Clause. 13. Other provisions

- a. changes and supplements as well as termination notices need to be made in writing.Both the parties declare that no side agreements have been made to this integrity pact.
- b. if the contractor is a partnership or a consortium, this agreement must be signed by

all partners or consortium members.

c. should one or several provisions of this agreement turn out to be invalid, the remainder of this agreement remains valid. In this case, the parties will strive to come to an agreement to their original intentions

In witness thereof the parties have signed and executed this pact at the place and date first above mentioned in the presents of following witnesses:

DCP, KEMH	BIDDER	
NAME: DESIGNATION:	NAME: DESIGNATION:	
SIGNATURE:	SIGNATURE:	
WITNESS	WITNESS	
1	1	
2	2	

<sup>\*</sup> PROVISIONS OF THESE CLAUSES WOULD BE AMENDED /DELETED IN LINE WITH THE POLICY OF THE DCP, KEMH IN REGARD TO INVOLVEMENT OF INDIAN AGENTS OF FOREIGN SUPPLIERS.