

COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH

Anusandhan Bhawan, 2 Rafi Marg, New Delhi-110 001

CORRIGENDUM

OPEN TENDER NOTICE 1/2013 APPEARED ON 05/11/2013

Ref: Our Tender No. 13-2(08)/Insurance/2012-13/Pur regarding insurance for clinical trials to be conducted by CSIR-OSDD Unit at National Institute of Tuberculosis and Respiratory Diseases, New Delhi.

The detailed responses to the queries raised by participants during pre-bid conference held on 11th Nov. 2013 in CSIR, Anusandhan Bhawan , 2 Rafi Marg, New Delhi, are available on our website <http://www.csir.res.in> for information of all the prospective bidders. The last date for receipt of complete tender(s) is extended up to 31/01/2014 by 3.00PM. The technical bid(s) will be opened on the same day at 3.30PM onwards in the presence of bidders who wish to be present.

The other terms & conditions of the tender will remain the same.

STORES & PURCHASE OFFICER

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QUERY	RESPONCE
<p>1. Clinical trial phase II will be conducted at Lala Ram Sarup Institute, ND, - Exact date is required</p>	<p>The exact date of the start of the trial will be decided only after approval from DCGI and Ethics Committee. Lala Ram Sarup Institute is now known as National Institute of TB and Respiratory Diseases (NITRD).</p>
<p>2. Number of volunteers 240 and the trial will be for three years as follows-</p> <p>1st year : 80 patients 2nd year : 100 patients 3rd year : 60 patients</p> <p>Whether all of them shall be required to be insured in one go or year wise Depending upon their registration.</p>	<p>Please refer the brief of protocol.</p> <p>Rough estimate of the patients to be recruited year wise as given in the tender is the maximum number of the patients. Insurance is required for this number per year beginning from the month of registration of the first patient during that year.</p>
<p>3. Volunteers will be MDR patients - Details of MDR is required</p>	<p>Multi-drug-resistant tuberculosis is defined as tuberculosis that is resistant to at least isoniazid and rifampicin, the two most powerful first-line treatment anti-TB drugs.</p>
<p>4. Each year Study will be for 6 months and insurance cover is required for 7 months . Each volunteer will have to stay 8 weeks in hospital during trial- Study must be done in batch wise, if so number of patient/volunteer in each batch.</p>	<p>It is estimated that about 4-5 patients will be recruited each month. i.e. maximum of 60 patients a year. Taking a higher number than this estimation, the yearwise number of patients have been provided.</p>
<p>5. Sum Insured:- Liability limit for the policy Liability limit per patient/volunteer, if any.</p>	<p>As per DCGI guidelines on Compensation formula already provided to you. However based on our assumptions and as per the current DCGI guidelines a tentative calculation worked out at our end is as under: Total liability limit for the policy is Rs.12 Crores. Maximum liability limit per patient is Rs. 73.60 Lakhs.</p> <p>Please note that these values are purely tentative and may vary either way based on the nature of the subjects finally recruited for the study , number of SAE's and the DCGI guidelines in vogue on the date of execution.</p>
<p>6. Evaluation of Technical Bid:- It is not clear from the General Conditions, how the Technical Bids would be evaluated.</p>	<p>Technical Bids will be evaluated on the following grounds:</p> <ol style="list-style-type: none"> 1. Registration of the agency with IRDA. 2. Previous experience of providing similar insurance services to any organisation.

<p>7. Prices: Taxes i.e. Service Tax to be charged on Insurance Policies is notified by Government of India, normally prospectively, but some time, it is retrospectively also. Therefore, the taxes shall be applicable as may be notified by the appropriate authorities from time to time. You will appreciate, that it is not part of the premium and hence, cannot be fixed.</p>	<p>Taxes applicable as on date will be admitted for payment.</p>
<p>8. Arbitration:- All Insurance Policies are subject to Arbitration clause and since, our Insurance Policies are an agreement / contract enforceable at law, the Arbitration clause provided therein and approved by IRDA (Insurance Regulatory and Development Authority) shall be applicable.</p>	<p>The disputes would be resolved as per arbitration clause described in the last page.</p>
<p>9. Subjects:- As per the tender document, you have proposed to cover only the registered volunteers for a period of 7 months from the date of registration year wise. Please elaborate that the patients registered in the 1st year shall not be covered in the 2nd and 3rd year.</p>	<p>Each patient will be covered from the period of recruitment to the study for a period of 7 months.</p>
<p>10. Premium Payment:- How CSIR proposes to pay the premium, in one lump sum for 240 subjects or yearly depending upon registration.</p>	<p>Premium will be paid on yearly basis depending on registration of patients.</p>

<p>11. Clinical Trial Programme Phase II:- Please provide the following information related to Phase-I.</p> <p>a) Whether any subject of Phase I shall also be registered.</p> <p>b) Who was the Insurer for the Phase I Clinical Trial, their rates and terms of cover along with the Policy conditions.</p> <p>c) Claims (if any) reported and their status.</p>	<p>a) No</p> <p>b) Phase I was carried out outside India</p> <p>c) not available</p> <p>As Phase I studies were carried out mainly in South Africa and this was not carried out by us, we do not have this information.</p>
<p>12. Please provide the upto date guidelines issued by DCGI.</p>	<p>Already provided. Insurers should keep themselves abreast of DCGI guidelines in this regard.</p>
<p>13. Approval of Additional sites by Insurance Company shall be a pre-condition.</p>	<p>We intend to proceed with the current site only. In case another site is selected, this will be duly informed to you.</p>
<p>14. Exclusion Criteria:- In case of wrong declaration / falls declaration by the volunteer, How CSIR will verify the line of prior treatment.</p>	<p>The details of treatment taken by the patient will be verified by the Principle Investigator.</p>
<p>15. Any other clarification CSIR intends to provide.</p>	<p>Nil</p>

2.32. Settlement of Disputes

2.32.1 The Purchaser and the supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

2.32.2 If, after twenty-one (21) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the Purchaser or the Supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided, as to the matter in dispute, and no arbitration in respect of this matter may be commenced unless such notice is given. Any dispute or difference in respect of which a notice of intention to commence arbitration has been given in accordance with this Clause shall be finally settled by arbitration. Arbitration may be commenced prior to or after delivery of the Goods under the Contract. .

2.32.3 The dispute settlement mechanism/ arbitration proceedings shall be concluded as under:

(a) In case of Dispute or difference arising between the Purchaser and a domestic supplier relating to any matter arising out of or connected with this agreement, such disputes or difference shall be settled in accordance with the Indian Arbitration & Conciliation Act, 1996, the rules there under and any statutory modifications or re-enactments thereof shall apply to the arbitration proceedings. The dispute shall be referred to the Director General, Council of Scientific & Industrial Research and if he is unable or unwilling to act, to the sole arbitration of some other person appointed by him willing to act as such Arbitrator. The award of the arbitrator so appointed shall be final, conclusive and binding on all parties to this order.

(b) in the case of a dispute between the purchaser and a Foreign Supplier, the dispute shall be settled by arbitration In accordance with provision of sub-clause (a) above. But if this is not acceptable to the supplier then the dispute shall be settled in accordance with provisions of UNCITRAL (United Nations Commission on International Trade Law) Arbitration Rules.

2.32.4 The venue of the arbitration shall be the place from where the purchase_order or contract is issued.

2.32.5 Notwithstanding any reference to arbitration herein,

(a) the parties shall continue to perform their respective obligations under the Contract unless they otherwise agree; and

(b) the Purchaser shall pay the Supplier any monies due the Supplier.

2.33. Governing Language

2.33.1 The contract shall be written in English language which shall govern its interpretation. All correspondence and other documents pertaining to the Contract, which are exchanged by the parties, shall be written in the English language only.