

HLL LIFECARE LIMITED
(A Government of India Enterprise)
CORPORATE R & D CENTRE,
AKKULAM, SREEKARIYAM P.O,
THIRUVANANTHAPURAM-695017
Email: materialscredc@lifecarehll.com
Website: www.lifecarehll.com
PH: +91 471 277 4700
FAX: +91 471 277 4707

EXPRESSION OF INTEREST (EOI)

FOR

EMPANELMENT OF CLINICAL RESEARCH ORGANIZATIONS (CRO) FOR CONDUCTING CLINICAL TRIALS



EOI No: HLL/CRD/PUR/TENDER/2015-16/15

HLL LIFECARE LIMITED
Corporate R & D Centre,
Akkulam, Thiruvananthapuram - 695017

Company background

HLL Lifecare Limited (formerly Hindustan Latex Limited) (HLL) is a Mini Ratna (Category-1 PSE) company under the Ministry of Health and Family Welfare. Our Corporate head office is at Thiruvananthapuram, Kerala. HLL has developed an impressive production infrastructure for a range of Contraceptives and Health Care Products.

HLL Lifecare Limited is the only company in the world manufacturing and marketing the widest range of Contraceptives. It is unique in providing a range of Condoms, including Female Condoms, Intra Uterine Devices, Oral Contraceptive Pills - steroidal, non-steroidal and Emergency contraceptive pills; and Tubal Rings

For HLL Innovation is a mission. The company introduces affordable new products to the market, positioning itself as a global leader in various realms of healthcare. HLL's Corporate R&D Centre (CRDC) has been established with the above objectives in mind and will focus on company's motto "Innovating for Healthy Generations".

HLL CRDC has several projects in hand, carried out in-house or on collaborative mode, with premier academic and research institutions in the country and abroad. These projects cover a wide area of research ranging from development of novel techniques for drug delivery to blood filters, novel contraceptives and cancer-care devices. Some of the institutions HLL has networked with are-Indian Institute of Technology (IIT), Kanpur; Central Drug Research Institute (CDRI), Lucknow; SreeChitraThirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram; Regional Cancer Centre (RCC), Thiruvananthapuram, and Population Council, USA.

The CRDC is self-contained and houses a number of facilities ie Medical Devices lab, Pharma lab, Diagnostics lab, Analytical lab and common incubation facility.

HLL LIFECARE LIMITED
Corporate R & D Centre,
Akkulam, Thiruvananthapuram - 695017

INSTRUCTION TO TENDERERS (ITT)

Empanelment of Clinical research organization for various clinical trials

1. It has been decided to invite Express of Interest (EOI) for empanelling Clinical Research Organizations (CRO) for conducting various clinical trials of HLL. The nature of services to be provided by the CRO will include, but not limited to study document development, selection of investigators, site identification and screening, ethics committee submission, study initiation, medical writing, data management and analysis, project management and vendor management. The scope of services would also include dossier preparation, getting all requisite regulatory approvals from the regulatory authorities and timely reporting of all safety data to EC and HLL. The CRO will be required to provide sufficient technically qualified and experienced staff for providing the required level of service.
2. **Eligibility Criteria:**
 - **The CRO should have an ample experience in conducting multicentric clinical trials.**
 - **Annual turnover of the company should be above Rs.50 lakh for last three financial years from clinical research services related activities (audited certificate should be attached)**
 - **Details of the major past inspection activities by Health Authorities/Regulatory Authorities for GCP activities. Past audit reports on the GCP compliance by the CRO is desirable.**
3. **Eligible interested parties are requested to complete Form A.**
4. **All interested parties are requested to submit their EOI for the empanelment process. The last date for submission of EOI is 30th March 2016, 05:30pm. The EOI will be opened on 31st March 2016, 10:00am. The Subsequent amendment / changes if any will be published only in our website.**
5. The notice, forms and annexures mentioned in the notice are available in our website www.lifecarehll.com.
6. Empanelment will be for a period of three years. (can be extended upto five years)
7. HLL may, at its discretion, extend this deadline for submission of EOI by amending the Bid Documents or any other reasons, in which case all rights and obligations of the HITES and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

8. Bid Submission method: Interested parties are requested to fill up all the forms enclosed and submit the bid with all the necessary documents. The sealed EOI shall be submitted to the following address on or before 30th March 2016, 05:30pm
- SVP (R&D) i/c**
HLL Corporate R&D Centre
HLL Lifecare Ltd,
Akkulam, Sreekariyam (P.O)
Thiruvananthapuram-695017, Kerala
9. EOI will be opened in the presence of bidders' representative(s) who choose to attend on the specified date and time, at the office of HLL at the address given in clause 8.0 above.
10. In the event of the date specified for bid receipt and opening being declared as a closed holiday for HLL, the due date for submission of EOI and opening of EOI will be the following working day at the specified times as given above.
11. HLL will not be held responsible for the postal delay, if any, in the delivery of the bidding document or the non-receipt of the same. EOI sent by Telex/Fax/Telegraph will not be accepted.
12. HLL reserves the right to club or split the items of works, change the qualifying criteria at their discretion and to reject or cancel the Invitation for EOI without assigning any reason thereof.
13. Evaluation: The evaluation will be carried out by a Technical committee of HLL based on the eligibility criterion. HLL shall reserve the right to reject the bid(s) on any grounds. Such decision by HLL shall bear no liability consequently and the decision of the committee shall be final
14. HLL rights: HLL reserves the right to accept or reject any bid in whole or in part, or to reject the EOI without assigning any reasons. HLL may decide not to continue with the empanelment and cancel the notice inviting EOI either full or in part at its discretion.
15. Arbitration: All disputes or differences whatsoever arising between the parties out of or relating to the consultancy services, meaning and operations or effect of this contract or the breach thereof shall be settled by arbitration. Matters to be arbitrated upon shall be referred to a sole Arbitrator, to be appointed jointly by the parties HLL and the award made in pursuance thereof shall be binding on the parties. Such arbitration shall be governed by the Indian Arbitration and Conciliation Act 1996. The jurisdiction of any disputes, suits and proceedings arising out of this tender shall be only in the courts of Thiruvananthapuram, Kerala State, India.

SVP (R&D) i/c

GENERAL INFORMATION

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 of clinical trials conducted in last four years:
.....
7. Details of Clinical trials associated with HLLs in - - for last three years, if any.
8. Details of certificates and accreditations (documents to be attached):
9. Details of major regulatory bodies inspection and audits (document to be attached):

Notes:

- (i) Attach an attested photocopy of Certificate of Registration.

Sign & seal of the tenderer

DETAILS OF CLINICAL TRIALS CONDUCTED IN LAST FIVE YEARS

Sl. No.	Study Title	Name and address of the Sponsor	Details of the study		Indication	Remarks
			Phase	Study Design		

Documents to be submitted

- Form A – General information
- Form B – Clinical trial details conducted in last 5 years
- CVs of key staffs
- Major certificates and accreditations
- Details of major audits and inspections with comments
- Attach audited balance sheets for last three financial year.