#### **NOTIFICATION FOR THE PROJECT POSTS**

Advertisement No. 1/2021

Date: 11/03/2021

The Indian Council of Medical Research (ICMR) has initiated its flagship program by establishing an "India TB Research Consortium" to advance technology and product development by harnessing interdisciplinary expertise and regional complementary strengths and focus on building and strengthening scientific capabilities and generating a better understanding to aid accelerating the development of new diagnostics, new & improved vaccines and immunotherapies, drugs for TB.

Following post is to be filled purely on contractual basis for working under various TB projects under Division of Epidemiology and Communicable Diseases (ECD) (Unit-Tuberculosis, Leprosy and Tribal Health), ICMR Hqrs Office, New Delhi. Interested candidates for the position mentioned below are requested to send the <u>application in the prescribed format only</u> along with updated Bio-Data and one passport size photograph up to 05:30 PM of 25<sup>th</sup> March 2021by email at <u>tbconsortium.hq@icmr.gov.in</u> <u>Candidates applying for more than one post should apply separately. Candidates are also requested to fill the details in the attached Excel sheet also. Late received applications will not be entertained. The list of eligible shortlisted candidates will be displayed on ICMR website and shortlisted candidates would be informed telephonically or via email (provided in CV) for the interview. A link to join for interview through Video Conference will be shared with shortlisted candidates through email.</u>

An interview would be held via webex/VC/ on 30<sup>th</sup> & 31<sup>st</sup> March. 2021 at 10.00 AM onwards. The Candidate will be asked to join the web link Web-Link for the interview about 30 minutes before the start of interview.

**NOTE:** All the posts are open to all caste categories

### Project: India TB Research Consortium - Project Management Unit

1. Name of Posts	Sr. Consultant (Scientific) (Medical/Non-Medical)
No. of Vacancies	One Post
Essential Qualification & Minimum Experience required	Professional with M.D. or Ph. D. (Medical Pharmacology/Medical Microbiology/Public health/Life Sciences) in relevant subject from recognized Institution and published papers with 20 years of experience in clinical research/clinical trial OR  Retired Government employees with requisite educational qualification Ph.D in Life Sciences with 20 years of experience in clinical research/clinical trial drawing pay in pay band of Rs.15,600/-39100+grade pay ofRs.6600/-at the time of retirement and having 20 years of relevant experience related to TB.
Desirable	<ul> <li>Experience in managing R&amp;D programme in biomedical area</li> <li>Experience in clinical trials/ vaccine trial specially TB Vaccine trial</li> <li>Experience in development and execution of multi-centric scientific programmes in biomedical area</li> </ul>
Age	Up to 70 years
Nature of Duties	<ul> <li>To provide vision and direction to the R&amp;D programmes relating to Tuberculosis control by identification of alternate technologies/products/ interventions in the area of therapeutics, diagnostics and vaccines for taking forward the ITRC mandate.</li> <li>Ensure that all processes contributing to the performance of a clinical trial are conducted properly as per the ITRC SOPs and consolidate the information pertaining to all the projects and activities undertaken for finishing the assigned tasks on time</li> <li>To review and initiate the clinical studies undertaken by ITRC for validation of identified vaccine candidates; therapeutic agents; diagnostics and implementation research</li> <li>Oversee file management of the projects and their administrative approvals in time</li> <li>To provide effective coordination and management of the implementing sites/institutions identified for clinical studies/validation by ITRC.</li> <li>To promote innovation through public private partnerships, capacity building for management of Intellectual Property and technology transfer; organize industry-academic interface.</li> <li>Travel to study sites may be required for site visit</li> <li>Any task assigned by the Head/Programme Officer</li> </ul>
Consolidated	Maximum upto Rs.1,50,000/- per month depending upon experience
Emoluments Tenure	and knowledge  Upto 31st March 2022. May continue for another year based on performance evaluation report
Place of Work	ICMR Hqrs.

2. Name of Post	Project Scientist Support-V (Bio-Statistician/Data Scientist)
No. of Vacancies	One Post
Essential Qualification& Minimum Experience required	Professional with 1 <sup>st</sup> class in M.Sc in Bio-statistics/ M. Tech (Data Scientist/ Computer Science) from recognized Institution with 4 years experience after M.Sc or 3 years after M.Tech published research papers OR  II class M.Sc in Bio-statistics/ M. Tech (Data Scientist/ Computer Science) with Ph.D (Statistics/Bio Statistics/Computer Science) with 4 yrs of relevant experience with published research papers
Desirable	<ul> <li>Experience of Data Management in multicentric clinical trials/studies specially drug trials/vaccine trials.</li> <li>Experience in handling clinical trial data-base</li> <li>Experience in data-cleaning, raising database queries, query resolution.</li> <li>Experience in handling and monitoring eCRF based studies</li> <li>Experience in statistical analysis and preparation of report</li> </ul>
Age	40 years. (Relaxable to OBC and SC/ST Candidate as per Govt. of India)
Nature of Duties	<ul> <li>To provide statistical support to all the studies/clinical trials Data management of all the clinical trials undertaken/coordinated by ITRC,ICMR</li> <li>Planning data analysis and overseeing data clinical management on site</li> <li>Preparation of Statistical Analysis Plan of various projects.</li> <li>Preparation of Clinical Study Report in consultation with implementing institutions.</li> <li>To provide statistical inputs on sample size calculation, data analysis etc. on development of protocols by ITRC.</li> <li>Any other related work assigned by the Head/Programme Officer</li> <li>Data Management in multicentric clinical trials/studies specially drug trials/vaccine trials.</li> <li>Data-cleaning, raising database queries, query resolution.</li> <li>Monitoring data of eCRF based studies</li> <li>Statistical analysis of the studies and preparation of report</li> <li>Support in Manuscript writing</li> <li>The site visit may require travel outside Delhi</li> </ul>
Consolidated Emoluments	Rs.57,660/- per month
Tenure Place of Work	Upto 31/03/2022. May continue for another year based on performance evaluation report  ICMR Hqrs.
Date of application submission	24 <sup>th</sup> March 2021 5:30 PM in the prescribed format only.
3. Name of the Post	Project Scientist Support-II (Medical Affairs and Clinical Development)
Number of positions	One
Essential Qualification:	Post Graduate Degree (MD/MS/DNB) after MBBS with one year experience OR Postgraduate diploma in medical subjects after MBBS with two years' experience OR MBBS degree with 4 years' experience in clinical research after MBBS.

Tenure	Upto 31 <sup>st</sup> March 2022. May continue for another year based on performance evaluation report.
Consolidated Emoluments	Rs. 72325/-per month
Age Limit	40 years. (Relaxable to OBC and SC/ST Candidate as per Govt. of India)
	xxi. Any other job assigned by PI or Program Officer.
	meetings.
	xx. The job may require travel to the trial sites and attending outstation
	planning xix. Develop site level risk plan for enrolment
	kviii. Manage Site enrolment performance, and assist sites in recruitment
	Operations
	xvii. Regulatory submissions, in affiliates which are managed by Clinical
	selection - Clinical studies and Observational Research
	<ul><li>xv. Able to prepare SOPs for trial conduct.</li><li>xvi. Study feasibility, site feasibility, site identification (with CRPs) and site</li></ul>
	xiv. Update the landscape documents in all thematic areas of TB.
	xiii. Preparation of the protocols and budget for studies.
	xii. Managing and maintaining databases for quality systems.
	research/bio-medical research projects
	when required with other ITRC staff.  xi. Initiate and Managenew/ongoing Vaccine/drug trial/clinical
	x. To work in team and undertake and share the responsibilities as and
	continuation
	ix. To review the progress reports of projects and take action for
	groups of ITRC, take follow-up actions till release of budget.
	viii. Process matters for sanction of the projects as recommended by expert
	vii. Keep up to date with all quality and compliance issues.
	financial approvals, draft letters for sending to various organizations and prepare the draft minutes of the meeting.
	vi. To organize meetings, take care of logistics and administrative and
	production activities.
	v. Report the status of the quality levels of the staff, systems and
	reports.
	iv. Prepare and assist in preparing annual reports and quality trending
	iii. Troubleshoot clinical trials and multi-centric projects.
	finishing the assigned tasks on time.
	trial are conducted properly as per the ITRC SOPs and consolidate the information pertaining to all the projects and activities undertaken for
	ii. Ensure that all processes contributing to the performance of a clinical
Nature of duties:	i. Co-ordinate the activities of the India TB Research Consortium
	v. /Data Management.
	iv. Knowledge of Computer Applications or Business Intelligence tools
	subjects in recognized institute(s).
	iii. Additional Post-doctoral research/teaching experience in relevant
	requirements for clinical trial conduct
	ii. Thorough knowledge of GCP, ICH guidelines and regulatory
	Administration/ Family Medicine/ Epidemiology/ Public Health) from a recognized university.
	Microbiology/Pharmacology/Community Health Administration/Health
and & Experience:	& Social Medicine/ Paediatrics/ Medicine/ Tropical Medicine/
Desirable Qualification	i. Master degree in the relevant subject (Community Medicine/ Preventive

4. Name of the Post	Project Scientist Support-V (Clinical Operations)
Number of positions	One
Essential Qualification:	Candidates should possess 1st Class Master Degree in Biotechnology/clinical Pharmacology or 1st Class M. Pharm or any equivalent post from a recognized university with 4 years' experience in CRO industry/Pharma/Biotech/ Public Health/clinical research OR 2nd Class M. Sc. or 2nd Class M. Pharm or any equivalent post + PhD degree in relevant subjects from a recognized university with 4 years' experience in experience in Pharma/Biotech/CRO industry/ Public Health/ clinical research
Desirable Qualification and & Experience:	<ul> <li>i. At least 2 year post Doc experience in biomedical subject particularly in health research related areas. Working experience in scholarly publications</li> <li>ii. Knowledge of computer applications or business intelligence tools/data management/data synthesis/Report writing, data mining, writing popular articles/working on databases.</li> <li>iii. Thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial conduct</li> </ul>
Nature of duties:	<ol> <li>To manage all clinical aspects of study including assessing operational feasibility and recommending study execution plan; developing and managing comprehensive study timelines and metrics</li> <li>To participate in Selection and management/Oversight of CRO/vendors, develops vendor specifications; review vendor reports, budgets and metrics</li> <li>To provide study specific training and leadership to Clinical Research Staff, including CRO, CRAs, Sites and other contract personnel</li> <li>To plan, Execute and Lead study specific meetings</li> <li>To participate in Site monitoring visits and oversee clinical monitoring activities ensuring compliance with Good Clinical Practices</li> <li>To prepare and/or review study related Standard Operating procedures and Documents</li> <li>To develop and manage study budget and maintain it within financial goals</li> <li>To manage study files and process or administrative approvals</li> <li>Any other work assigned by the team leader pertaining to ITRC</li> <li>The job may require travel to the trial sites and attending outstation meetings</li> </ol>
Age Limit	40 years. (Relaxable to OBC and SC/ST Candidate as per Govt. of
Consolidated Emoluments	India) Rs. 57660/- per month
Tenure	Upto 31 <sup>st</sup> March 2022. May continue for another year based on performance evaluation report.
5 Name of the next	Project Scientist Support-V (Clinical Coordinator/QC)
5. Name of the post Number of positions	One Continuation (Clinical Coordinator/QC)
Essential Qualification:	Candidates should possess 1st Class Master Degree in Biochemistry/Chemistry/Pharmacology/Biotechnology or 1 <sup>st</sup> Class M. Pharm or any equivalent post from a recognized university with 4 years' experience in CRO industry/Pharma/Biotech/ Public Health/clinical research related to clinical research /trials  OR  2 <sup>nd</sup> Class M. Sc. In Biochemistry/Chemistry/Pharmacology/Biotechnologyor 2 <sup>nd</sup> Class M. Pharm or any equivalent post + PhD degree in relevant subjects from a

	recognized university with 4 years' experience in experience in Pharma/Biotech/CRO industry/ Public Health related to clinical research /
	trials
Desirable Qualification and & Experience:	<ul> <li>a. At least 2 year post Doc experience in biomedical subject particularly in health research related areas. Working experience in Quality Control/Assurance</li> <li>b. Knowledge of computer applications or business intelligence tools/data management/data synthesis/Report writing, data mining, writing popular articles/working ondatabases.</li> <li>c. Thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trialconduct</li> </ul>
Nature of duties:	<ul> <li>i. To manage all clinical aspects of study including assessing operational feasibility and recommending study execution plan; developing and managing comprehensive study timelines andmetrics</li> <li>ii. Job requires frequent All India travel to sites for monitoring, quality assurance and quality management for at least 15 days a month.</li> <li>iii. To prepare QA/QC Plan for the sites for all studies and participate in Selection and management/Oversight of sites, CRO/vendors, develops vendor specifications; review vendor reports, budgets andmetrics</li> <li>iv. To provide study specific training and leadership to Clinical Research Staff, including CRO, CRAs, Sites and other contractpersonnel</li> <li>v. To plan, Execute and Lead study specificmeetings</li> <li>vi. To participate in Site monitoring visits and oversee clinical monitoring activities ensuring compliance with Good ClinicalPractices</li> <li>vii. To prepare and/or review study related Standard Operating procedures and Documents</li> <li>iii. To develop and manage study budget and maintain it within financialgoals</li> <li>ix. To manage study files and process or administrativeapprovals</li> <li>x. Any other work assigned by the team leader pertaining toITRC</li> <li>xi. The job may require travel to the trial sites and attending</li> </ul>
A T	outstationmeetings
Age Limit	40 years. (Relaxable to OBC and SC/ST Candidate as per Govt. of India)
<b>Consolidated Emoluments</b>	Rs. 57660/- per month
Tenure	Upto 31 <sup>st</sup> March 2022. May continue for another year based on performance
	evaluation report.

# B. For Project Management Unit for 'TB Vaccine trial'

1.	Name of the Post	Project Scientist Support-II (Clinical Services)
	Number of posts	Two
	<b>Essential Qualification:</b>	Post Graduate Degree (MD/MS/DNB) after MBBS with one year experience OR
		Postgraduate diploma in medical subjects after MBBS with two years' experience
		OR MBBS degree with 4 years experience preferably in clinical research/trial after MBBS Degree
	Desirable Qualification and & Experience:	i. Experience in conducting Vaccine/drug trial/clinical research /Clinical Management.
	-	ii. Able to prepare safety reports and ensure the timely management and reporting of AEs an SAEs by sites by supporting them
		iii. Experience in managing and maintaining databases for quality systems. iv. Able to prepare SOPs for trial conduct and write safety reports and SAE narratives.
		v. Thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial conduct.
		vi. Good communication skills
	Nature of duties:	<ul> <li>a. Monitor the clinical trial and Prepare strategy for site monitoring and timely completion of recruitment targets and follow -up visits</li> <li>b. Checking of resources and Site initiation</li> </ul>
		c. Monitor vaccine trial, check all the source documents and completeness of data CRFs and ensuring timely completion of data entry in compliance with study protocol.
		<ul> <li>d. Review SAE tracker and SAE document repository every 15 days</li> <li>e. Prepare a patient tracker and discuss with site PI to ensure compliance and minimize missing visits of subjects</li> </ul>
		f. To match the tracker every week against recruitment target for each site and take necessary actions accordingly
		<ul><li>g. Discussion with PI's and project staff for patient compliance</li><li>h. Review of Ensure that all processes contributing to the performance of a</li></ul>
		clinical trial are conducted properly.  i. Prepare and assist in preparing annual reports and quality trending
		j. Prepare the site wise and consolidated site report regarding enrollment
		<ul> <li>data vs. targets and share with Team lead/PO every week.</li> <li>k. Keep upto date with all quality and compliance issues and Report the status of the quality levels of the staff, systems and production activities.</li> <li>1. Any other job assigned by the PI or Programme officer</li> </ul>
		m. Job requires frequent All India travel to sites for monitoring, quality assurance and quality management for at least 15 days a month.
	Age Limit	40 years. (Relaxable to OBC and SC/ST Candidate as per Govt. of India)
	Emoluments	Rs. 72325/-
	Tenure	Upto 31 <sup>st</sup> March 2022. May continue for another year based on performance evaluation report.

# C. For Project Management Unit of RATION Studies

1. Name of the Post	Consultant Scientific (Project Coordinator)
Number of posts	One
Essential Qualification:	Professional with M.D. or Ph. D. (Medical Pharmacology/Medical Microbiology/Public health/Life Sciences) in relevant subject from recognized Institution and published papers with 20 years of experience in clinical research/clinical trial OR  Retired Government employees with requisite educational qualification Ph.D in Life Sciences with 20 years of experience in clinical research/clinical trial drawing pay in pay band of Rs.15,600/-39100+grade pay ofRs.6600/-at the time of retirement and having 20 years of relevant experience in clinical Research
Desirable Qualification and & Experience:	i. Experience in conducting nutritional studies /clinical research/ National Task Force project in Clinical nutrition.
	ii. Experience in managing and maintaining data base of research projects.
	iii. Able to prepare & review SOPs and logs relevant requirement for trial sites.
	iv. Thorough knowledge of Schedule Y, GCP, GCLP, ICH guidelines and regulatory requirements for conduct of clinical trial.
Nature of duties:	<ol> <li>i. Ensure that the all process of a clinical studies / filed based multi-centric studies are conducted properly.</li> <li>ii. Troubleshoot of clinical trial or multi-centric studies</li> <li>iii. Prepare and assist in preparing Annual Reports and quality tranding reports</li> <li>iv. Keep upto date all quality and compliances issues</li> <li>v. Any other job assigned by the PI or Programme officer</li> <li>vi. Job requires frequent All India travel to sites for monitoring, quality assurance and quality management for at least 15 days a month.</li> </ol>
Age Limit	Upper age limit for up to 70 years
<b>Consolidated Emoluments</b>	Maximum Up to Rs. 1,00,000/- per month depending upon work experience and knowledge
Tenure	Upto 31 <sup>st</sup> March 2022. May continue for another year based on performance evaluation report.

#### **Terms and Conditions:**

- 1. Departmental candidates or candidates working/have worked on projects of ICMR Institutes/Centre's shall be given age relaxation to a minimum of five (5) years or a completed months/year based on earlier project service, whichever is less, they meet the essential qualification and experience prescribed for the post, with a view to provide them opportunity to compare with other candidates.
- 2. Age relaxation against post earmarked for reserved candidates will be as per Govt. of India Norms. No relaxation will be allowed in unreserved posts.
- 3. Qualification and experience should be in relevant discipline/field and from a reputed institution/organization recognized by relevant authority. Experience shall count from the date of completion of minimum educational qualification.
- 4. Submission of incorrect or false information daring the process of personal discussion and/or video conferencing shall disqualify the candidature at any stage.
- 5. Mere fulfilling the essential qualification / experience does not guarantee selection.
- 6. Candidates employed in Govt. Service / Semi Govt. Autonomous Bodies of State / Central Govt. should submit a "No Objection Certificate" from their employer.
- 7. Above post is contractual for the duration offered may or may not be renewed subject to satisfactory performance and requirement.
- 8. Age will be reckoned from last date of receipt of application.
- 9. This post is purely temporary and co-terminable with the project. Employees will be on consolidated pay basis.
- 10. The appointment will be made on the basis of results of personal discussions and / or video conferencing mode.
- 11. Selected candidate will not have any right to claim for regular appointment in the council on the basis of contract appointment.
- 12. Candidates willing to apply for the post with hard copy may download application from the ICMR website (<a href="www.main.icmr.nic.in">www.main.icmr.nic.in</a>). Duly filled application with <a href="Recent Photograph">Recent Photograph</a> along with self-attested copies of all relevant certificates and experience should be sent to Room No 311, Division of ECD, Indian Council of Medical Research, V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110029 before the end of last date as per advertisement.
- 13. Late received applications will not be considered. Only short-listed will be informed via Phone/email and called for interview/video-conferencing, no correspondence will be entertained in this regard.
- 14. Incomplete application, without photograph or without copies of relevant certificates and application not in prescribed format including Xcel sheet will not be entertained. The Director ICMR reserves the right to increase/decrease the no. of posts or reject the applications or cancel the applications or cancel the notification without assigning any reason thereof.
- 15. No TA/DA will be paid for appearing in interview /video conferencing.
- 16. Any canvassing by or on behalf of the candidates or to bring political or outside influence with regard to selection/recruitment shall be disqualification.
- 17. Shortlisted candidates will be called for personal discussion and / or video conferencing after verification of essential qualification and experience.
- 18. The selection Committee reserves the right to reduce the experience in case of deserving candidates.

**GENERAL CONDITIONS:** The conditions of employment will be the same as that of the project staff on contract basis. The candidates have no right to claim for any regular employment at this institute.

For any query please contact Mrs. Harjeet Kaur Bajaj, Administrative Officer, Division of ECD or Mr. Ramesh Chand, Section Officer, Division of ECD, ICMR HQ., New Delhi @ extension number 259 /284 or at 011-26589699