INDIAN COUNCIL OF MEDICAL RESEARCH <u>Division of Epidemiology and Communicable Diseases</u> WALK-IN-INTERVIEW/ WRITTEN TEST (NOTIFICATION)

Date of Interview: 14 Februray 2019

Following posts is to be filled purely on contractual basis for working under the programme entitled 'India TB Research Consortium' (ITRC) under Division of Epidemiology and Communicable Diseases (ECD), ICMR Hqrs Office, New Delhi. Interested candidates for the positions mentioned below are invited to appear for the walk-in interview along with 5 copies of their applications in prescribed format (Annexure 1) with one photograph on 14th Februray 2019 between 9:00 am to 10:30 am at Indian Council of Medical research Ansari Nagar New Delhi 110029. The candidates can also submit their CV strictly the prescribed format attached before at teamtbconsortium@gmail.com;vadehra.icmr@gmail.com However the candidate should report for interview at 9.00AM for appearing for the interview on the date mentioned above in person for application/CV to be considered in interview.

Latecomers will not be entertained after 11:00 A.M. under any circumstances.

1. Post of Consultant (Data Management): One Post

S.	NO.	Details	Requirements/Information
1.	A	Name of Posts	Consultant (Data management)
	В	No. of Vacancies	One Post
	С	Essential Qualification Minimum Experience required	Professional with M.Sc (Bioinformatics)/ B.tech(Bioinformatics)/M.Tech (Bioinformatics) with strong Data Science background and 5-7 years of experience in data management in research/Bioinformatics. Working knowledge of Clinical Database Development tools will be preferred or Ph.D (Bio-Statistics) with 4-6 years of experience in data management in Clinical Research/clinical Trials with strong Data Science background/Bioinformatics. Working knowledge of Clinical Database Development tools will be preferred Or Retired government employee with above mentioned educational qualifications and experience and drawing pay in pay band of Rs.15,600-39100+grade pay of
			experience and drawing pay in pay band of Rs.15,600-39100+grade pay of Rs.6600/-at the time of retirement.
	D	Age	Limited as on date: up to 70 years
		1160	Emilited as on date. up to 70 years
	Е	Desirable	 Doctorate in Bioinformatics or relevant subject from a recognized University. Additional Post-Doctoral research/2YRS teaching experience in Bioinformatics in recognizedinstitute(s) after obtaining essential qualification. Strong Knowledge of use of Bioinformatics tools.
			Ability to work on a number of projects in parallel
			Ability to work independently and as a part of a team
			Close attention to detail, timelines and quality and Good planning and organization skills
			• Thorough knowledge of ICH, GCP and regulatory requirements Or Well-versed in regulatory requirements for validation of data management systems, GxP, Good Clinical Data Management Practices (GCDMP)
			• Excellent command of English, Good PC user knowledge, Proficient in Microsoft Office applications, internet, Email
			Sound understanding of the global drug development process
			Ability to develop/advise on training programs
			Familiarity with SAS programming
			 Additional Experience preferred in various phases of clinical trials with full project life cycle experience (CRF design to database lock and reporting); use of commercial and/ or proprietary clinical data management systems, coding dictionaries/ encoding systems (e.g. MedDRA, WHODRL), other software in support of data management activities (e.g SAS, Access, SQL, Oracle), programming skills and experience with electronic data capture a definite plus Knowledge of validating the system
		Nature of Duties	Work on research projects available with the centre.
		Nature of Duties	2. Providing data management and analysis services requested by the users of the Centre3. Work on collaborative research projects initiated by the Exploratory Team
			4. Providing technical support to the Exploratory Team (if required)5. Providing assistance to medical research groups on using different tools and
			techniques for their research.
			6. Data Validation and ongoing Quality Control
			7. Query Management: generate and reconcile queries
			8. Maintain study data and data management documents
			9. Training of data entry staff
			10. Participate in CRF development, CRF annotation, database design and screen design and Database testing

- **11**. Coding of medication, therapies and adverse events
- 12. Workflow development
- 13. Continual liaison with internal and external users
- **14**. Take responsibility for managing Clinical Data Management.
- **15**. Provide technical leadership, resource management and project management for the required technical aspects supporting CDM activities.
- 16. Ensure quality, timeline and productivity requirements are met or exceeded. Included in this are project planning and implementation, milestone tracking, organization and participation in team meetings, monitoring progress and providing updates as required
- **17**. Create, direct and maintain strategies in line with the Clinical Operations and/or Bioinformatic organization to help facilitate efficiencies within the department.
- **18.** Manage a team local to a site to provide work direction task prioritization, supervision, assistance and career development to assigned tasks.
- **19.** Manage all phases of data management activities from study start up to database close and not limited to database set-up, CRF design, data entry, validation/ edit checks, data transfer, and any ad-hoc programming required to support a clinical trial process
- **20**. Lead cross-functional meetings and drive initiatives to ensure the delivery of milestones and timelines for clinical studies.
- **21.** Identify and adequately resolve operational and technical problems. Manage process improvements.
- **22.** Communicate with the other operational groups regarding workflow, process, timelines, and resource planning to ensure transparency between the all functions as well as any external support groups.
- **23.** Define, develop and deploy appropriate operating procedures.
- **24.** Work closely with the Quality Management Groups (QMG) to ensure compliance with SOPs/ Guidelines, GCP and any other applicable local regulations.
- **25**. Provide relevant training/mentoring for staff to assist them in resolution of problems encountered in the conduct of their daily work or on application of Clinical Systems.
- **26.** Co-ordinate the improvement and implementation of tools, including, but not limited to standard project directories and subdirectories, document file names and status reports that result in improved efficiencies and quality.
- 27. Attend (as appropriate) client facing meetings to represent the CDM group on activities including, but not limited to, progress reviews, technical updates on key milestones, bid defences, technical requirements collection.
- **28.** Represent the CDM group at internal and external audits and regulatory inspections, as required.
- 29. Create and review case report forms as per protocol.
- 30. Creation of annotated CRFs
- 31. Development of data entry filling guidelines, data management plan, data validation plan/ edit checks documents and other DM related documentation
- 32. Database validation Ensures 100 % execution of Quality Control (QC) testing and User Acceptance Testing (UAT)
- 33. Develop, review and maintain clinical databases
- 34. Data quality check, Query management and data merging and Ensures 100% clean data for safety and efficacy for the study.
- 35. Data Cleaning for study close out and perform all database lock procedures
- 36. Report generation as and when required
- 37. Provide DM activities status to the team on daily basis
- 38. Overall responsible for all the activities of assigned project. Change Requests and takes approval from sponsor

		 39. Write and review DM SOPs in accordance with GCP and ICH guidelines and develop associated training and competency testing 40. Maintain CRF's and database standards work in conjunction with clinical operations, clinical research and other operations to ensure accurate, efficient and complete data collection 41. Responsible for performing all aspects of DM process as related to processing and Quality Check of the data. 42. Ensures all DM procedures executed with a high attention to detail, accuracy and timelines
F	Consolidated Emoluments	Maximum 100000/- per month consolidated depending upon experience and knowledge
G	Tenure	One Year
 Н	Place of Work	ICMR Hqrs.
I	Date & Time of Interview	14 th Februray 2019 at 11.00AM (Reporting time 9.00AM)

2. Post of (Technical Assistant- Biostatistics) –One post (OBC)

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-	NO.	Details	Requirements/Information
1.	A	Name of Posts	Consultant (Technical Assistant- Biostatistics)
	В	No. of Vacancies	One Post (OBC)
	С	Essential Qualification Minimum Experience required	Graduate in Statistics with Biostatistics/Medical statistics as one of the subject from a recognized University with minimum 3 years of Demonstrated experience in clinical development program Biostatistics and analyzing statistical software's like SPSS;R and STATA. OR Master's degree in Biostatistics/Medical statistics from a recognized University OR Master's degree in Statistics from a recognized University with 2 years experience in Biostatistics from a recognized University
	D	Desirable	 PhD in Biostatistics/Statistic/Medical statistic, familiarity with modern database systems and Knowledge of MS Office (Word, Power Point, Excel) along with latest version . Knowledge of programming is desirable. Updated knowledge in statistical concepts, methods, and techniques
	Е	Age	Limited as on date: up to 60 years
		Nature of Duties	 Provide statistical expertise to the clinical development program for assigned projects to ensure scientifically valid conclusions. Develop project analysis plan, including computer-generated table specifications, statistical analysis plan, and research report Format and co-operate in further development of internal guidelines and SOPs Prepare project summaries for weekly/monthly status meetings Maintain state of the art statistical applications in clinical research Responsible for data processing for accurate relocation, formatting, generating Transmitting required data as per requirements of programme officer Local travel in India to study sites for data Monitoring and compilation.
	F	Consolidated Emoluments	Rs.31,000/- per month fixed without any other allowances
	Г	Consolidated Emoraments	1 10.51,000/ per month fixed without any other unowances
	G	Tenure Tenure	Two Years
		Tenure Syllabus for Written Examination	
	G	Tenure Syllabus for Written	Two Years Degree level statistics/ computers/ Generalknowledge/ test of reasoning, if written

Selection Procedure: Interview will be conducted for the eligible candidates. However, if more number of candidates are found eligible for the post advertised, Written Test/ Skill Test may also be conducted on the same day before final round of Interview.

The candidates should bring 5 copies of Biodata and application forms along with all original certificates of educational qualifications (from SSC onwards), experience, Aadhaar Card, caste certificate (if applicable for the post) with one set of photocopies of the same duly attested (can be self attested) along with a passport size photograph for attending the Written Test/Interview. No TA/DA will be paid for attending the Written Test/ Interview. The recruited project staff is eligible for leave as per rules and will have to give an undertaking before joining.

GENERAL CONDITIONS: The conditions for 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. The appointing authority has the right to accept/reject any application without assigning any reason(s) and no correspondence in this matter will be entertained. Age, Qualification, experience etc., will be reckoned as on the date of walk-in written test/ Interview.

Note: No electronic device including Calculator and Mobile phones would be allowed in the examination Hall.

INDIAN	COUNCIL	OF MEDICAL	RESEARCH
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Photo	

ANSARI NAGAR, NEW DELHI-110029

APPLICATION FORM

1. 2.	Name of the Project	:	"India 1B	Research Consortium"
<u>3</u> .	Applying for the Post of		:	
4.	Name of the Candidate	:		
5.	Father's Name	:		
6.	Sex (Male/Female)	:		
7.	a) Date of Birth (Date/Month/Year)	:		
Da	Present Age (as on last date of : ys eipt of Application)		Years	Months
8.	Postal Address (Present)	:		
				_
				

9.	Permanent Address	:		
			_	
			_	
10.	Email ID (Mandatory)	:	_	
11.	Mobile No. (Mandatory)	:	_	

12. Educational Qualification

a) Essential Qualification:

Examination passed	Year of passing	Name of the Board/ University	Class/ Percentage obtained	Subject Studied
10 th				
12 th				
Graduation				
Post- Graduation				
Other Qualification, if any				
Other				

b) Desirable qualification as per advertisement:

13. V	Work Experience (Total Nu	mber of Years)) :				
	Name of the Employer	Period (Date	/month/year)	Post held and			
S. No	(Name of the office/Institution)	From	То	responsibilities			
14. Any other Research Experience / Information							
15. (Check List						
S. No.	Title (Please tick)						
1	Documentary proof of date of birth (PDF/JPG)						
2	All Educational Qualification Certificates (PDF/JPG)						
3	Experience certificate from previous and current employer						

	(PDF/JPG)	
4	Caste Certificate (if applicable)	
5	Scan copy of Signature (JPG)	
6	Scan copy of Passport Size photograph (JPG)	

DECLARATION

I hereby declare that the information furnished above is true, complete and correct to the best of my knowledge and belief. I understand that in the event of any of the information provided by me are found false or incorrect at any stage, my candidature / appointment shall be liable for cancellation / termination without notice or any compensation in lieu thereof.

Place:	
Date:	(Signature of the Candidate)