















# Master of Science (M.Sc.) in Clinical Research

Specialisation in Regulatory Clinical Trials

# Translational Health Science and Technology Institute

An autonomous institute of Department of Biotechnology, Ministry of Science and Technology, Government of India A WHO collaborating centre on clinical and translational research for innovation and access to medical products



# Partnering Institutions

- Center for Health Research and Development, Society for Applied Studies, New Delhi
- Christian Medical College, Vellore
- Employees' State Insurance Corporation Medical College and Hospital, Faridabad
- Jagadguru Sri Shivarathreeshwara University, Mysuru
- King Edward Memorial Hospital Research Center, Pune
- Medical Research Council Clinical Trials Unit at University College London, UK



# Career scope in India

With the tremendous growth in clinical research and health sciences, India has emerged as a prominent hub for talented and educated research professionals.

The constantly evolving research ecosystem demands conducting robust clinical trials and studies - opening up immense opportunities for career growth in this domain.

# Career opportunities

Various roles in academia/research organisations and industry depending on the educational background, and experience can be embarked upon after the successful completion of this programme. For students interested in academia and research organisations, this programme will help achieve their goals to become Principal Investigators.

In industry, there will be tremendous opportunities as experts in clinical project management, regulatory affairs, medical monitoring, quality assurance, compliance management, pharmacovigilance, clinical data management, biostatistics, etc.

#### Semester I:

Overview of clinical research

#### Semester II:

Design and planning of clinical trials (includes internship)

#### Semester III:

Conduct of clinical trials, closing and reporting of clinical trials

#### Semester IV:

Project dissertation

4 Semesters

# Why Ennol?

This course Is designed and developed by a collegium of expert institutions

Provides access to the best hands-on learning opportunities

Includes mentorship/ internship
(national / international) from
academic and research organisations and
industry, engagement with regulatory agency(ies)

Will provide opportunities in academia/ research organisations/ industry for career advancement



The two year post graduate degree will be awarded by the Regional Centre for Biotechnology (RCB), recognized as an institution of National Importance by the Parliament of India, established by the Department of Biotechnology, Government of India with regional and global partnerships synergizing with the programs of UNESCO as a Category II Centre.

# Apply online

https://thsti.in/application/jobs.php

The course will commence on July 31, 2023 Last date for online application is June 12, 2023.

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THSTI is a WHO Collaborating Centre on Clinical and Translational Research for Innovation and Access to Medical Products

# Master of Science (M.Sc.) in Clinical Research

Specialisation in Regulatory Clinical Trials

2023-25

# Apply online

https://thsti.in/application/jobs.php

Last date to apply: 12<sup>th</sup> June 2023







**WRITTEN TEST** 

INTERVIEW





TWO-YEAR, POST-GRADUATE DEGREE PROGRAMME



Bachelor's degree with a minimum of 50% marks

- MBBS/BHMS/BAMS/BDS
- BPharm/BSc Nursing/BVSc
- BSc/BTech (Life Sciences/Statistics/ Public Health)



# TUITION FEE

per semester

INR 25,000/-

INR 18,750/- (For OBC/EWS)

INR 12,500/- (for SC/ST/PWBD)



# IIII IMPORTANT DATES

Date of declaration of shortlisted candidates: 20th June 2023

> Date of written Test: 133h July 2023 Date of Interview: 14th July 2023

The course will commence on July 31, 2023



















# Master of Science (M.Sc.) in Clinical Research

Specialisation in Regulatory Clinical Trials

# Translational Health Science and Technology Institute

An autonomous institute of Department of Biotechnology, Ministry of Science and Technology, Government of India A WHO collaborating centre on clinical and translational research for innovation and access to medical products

# Partnering Institutions

- Center for Health Research and Development, Society for Applied Studies, New Delhi
- Christian Medical College, Vellore
- Employees' State Insurance Corporation Medical College and Hospital, Faridabad
- Jagadguru Sri Shivarathreeshwara University, Mysuru
- King Edward Memorial Hospital Research Center, Pune
- Medical Research Council Clinical Trials Unit at University College London, UK



## INTRODUCTION

The Master of Science (M.Sc.) in Clinical Research with a specialisation in Regulatory Clinical Trials is a postgraduate degree programme. The degree will be awarded by the Regional Centre for Biotechnology (RCB), recognised as an institution of National importance by the parliament of India, established by the Department of Biotechnology, Ministry of Science and Technology, Government of India with regional and global partnerships synergizing with the programs of UNESCO as a category II centre.

The course is conducted by the Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science and Technology, Government of India along with partnering institutions, which are, Center for Health Research and Development, Society for Applied Studies, New Delhi; Christian Medical College, Vellore; Employees' State Insurance Post Graduate Institute of Medical Sciences & Research and Employees' State Insurance Corporation Medical College and Hospital, Faridabad; Jagadguru Sri Shivarathreeshwara University, Mysuru; King Edward Memorial Hospital, Pune; Medical Research Council Clinical Trials Unit, at University College London, United Kingdom.

Domain experts from academia and industry (national and international), research organisations, and regulatory agencies will be the teachers and mentors.

The M.Sc. is a multidisciplinary course comprised of the principles and practice of clinical trials supported by foundational courses in research methods, ethical considerations, basic pharmacology, epidemiology, clinical trial design and planning, biostatistics, regulatory affairs, clinical data management, pharmacovigilance and safety reporting, bioavailability and bioequivalence studies, pharmacokinetic pharmacodynamic studies, and pharmacoeconomics, health technology assessment, quality management, and scientific communication.

This course will provide students with an in-depth theoretical and practical understanding of all aspects of the design, conduct, analysis, and interpretation of clinical trials.

The learning methods will include but are not limited to interactive lectures, online interactions, practical hands-on training, individual and group projects, case studies, clinical research/trial site visits, journal clubs, seminars, and workshops.

The students will be attached to clinical research studies or trials in academic or industry settings. An intensive internship programme and a mentored project dissertation are essential components. The students are expected to acquire a sound understanding of the design, conduct, and analysis of clinical trials, and have in-depth training in trial methodology through immersive learning.



### VISION

To create a skilled and efficient cadre of professionals who will meet the clinical research requirements of academia and industry.

The specific objectives are to provide:

- Knowledge required to design, and conduct a clinical research/trial
- Skills to evaluate, monitor, and implement a clinical research/trial
- Ability to analyze and present clinical research/trial data

## WHY ENROL?

- This course is designed and developed by a collegium of expert institutions
- Provides access to the best hands-on learning opportunities
- Includes mentorship/ internship (national / international) from academic and research organisations and industry, engagement with regulatory agency(ies)
- Will provide opportunities in academia/ research organisations/ industry for career advancement

### **ELIGIBILITY**

Graduation from a recognised university with a minimum aggregate of 50% marks in any of the following:

- Bachelor's degree in Allopathic Medicine (MBBS)
- Bachelor's degree in other fields of Medicine/Dentistry/Nursing/Veterinary Science (BHMS/ BAMS/ BDS/ BSc Nursing/BVSc)
- Bachelor's degree in Pharmacy / Life Sciences / Statistics / Public Health (B Pharm/BSc/ B Tech)

### DURATION

Two years (full-time)

#### MEDIUM OF INSTRUCTIONS

English

# **ADMISSION PROCESS**

Admissions will be made as follows:

- (a) The academic committee of THSTI shall decide the number of seats (starting with 15 and with a maximum of 25) each year for the M.Sc. degree programme.
- (b) Reservation of seats shall be as per the rules, guidelines, ordinances, and instructions of the Central Government. Currently, these are 27% seats for Other Backward Classes (OBC) (non-creamy layer), 15% seats for Scheduled Castes (SC), 7.5% seats for Scheduled Tribes (ST), 10% seats for Economically Weaker Sections (EWS), and 4% seats for differently-abled persons (Person with Benchmark Disability, PWBD). SC/ST/OBC/EWS candidates are required to submit certificates in respect of their claims from authorized officers as notified by the Government for the purpose from time to time. The differently abled, (with a minimum of 40% disability) candidates are required to submit a certificate from authorized Medical Doctors/Hospitals indicating the extent of physical disability.
- (c) The Academic Committee and the Programme Management Committee shall oversee the overall programme.
- (d) The notification for admission will be widely advertised in the national dailies, website, and the social media platforms of THSTI.
- (e) After the closing date, all applications shall be screened by the Admission Committee, a sub committee of the Programme Management Committee.
- (f) The eligible candidates shall apply online at the Institute's website https://thsti.in/application/jobs.php. Applications through any other mode will not be accepted.

- (g) A selection test will be conducted and this process shall include a written test followed by an interview.
- (h) Only the candidates who score above the 60th percentile in the written test shall be called for the interview, subject to the same being more than or equal to 40% marks. In case the 60th percentile is below 40% marks, only candidates scoring above 40% will be called for the interview.
- The minimum qualifying marks to be scored in the interview shall be 60%.
- Relaxation up to 5% for OBC and 10% for SC/ST shall be given if required.
- Written test and interview will be held at THSTI, NCR, Biotech Science Cluster, Faridabad, Haryana, India.
- An admission test comprising of a written examination with a total of 50 marks will be conducted followed by an interview of 50 marks: (admission test=100marks). 20 marks for questions on general knowledge; 20 marks for questions on general ability; 10 marks for comprehension-based questions.
- All instructions about date, time, venue, etc. shall be informed by email to the shortlisted candidates before the written test.
- The list of applicants selected for admission shall be hosted on the website. The selected applicant shall be informed by email.
- All results/ notifications will be published on our website. The candidates would be expected to visit the THSTI website regularly.
- All communications will only be made through email.



## PROGRAMME DETAILS

- (a) The Master of Science programme shall consist of the following two components, namely:
  - Course work, andProject dissertation
- (b) The M.Sc. course requires one hundred credits, where each credit comprises twelve teaching hours or six practical/hands-on training hours.
- (c) The M.Sc. course content is approved by the Academic Committee of THSTI. The course content was reviewed by the Expert Committee at RCB before its approval by the Board of Studies of the RCB.
- (d) Key features include:
  - National and international faculty/domain experts with experience in different aspects of clinical trials.
  - Interactive sessions.
  - Peal-life exposure to different aspects of clinical research/trials including designing, ethical considerations, regulatory approvals, site selection procedures, conduct, monitoring, analysis of data, reporting, data safety monitoring boards, etc.
  - Hands-on experience in engaging with activities related to protocol development, designing of case report forms, sample size calculations, quality management, etc.
  - Campus interviews Placement (academia/industry).

- (e) Based on interruptions or delays, students beyond two years may be continued on the recommendation of the Academic Committee, but the duration shall not be extended beyond a period of three years.
- (f) Work towards the dissertation shall be carried out at THSTI/assigned partnering institutes/other collaborating academic or research organisations or industry or a combination, as approved by the Programme Management Committee.
- (g) The dissertation report shall be graded by examiners appointed by the Academic Committee and presented to the Academic Committee for a viva voce examination. Relevant certificates will be issued by the Academic Committee based on this evaluation.
- (h) After the successful completion of the course work and the dissertation, the Registrar of RCB shall issue a grade card to each student.
- (i) Students who score grades equal to or above a minimum specified by the Board of Studies shall be declared as having completed the course requirements successfully and shall be awarded a Master of Science degree in Clinical Research with specialisation in Clinical Trials.
- (j) The decision on whether a student shall be allowed a second attempt, in the event of failing to secure the necessary grades on the first attempt, shall be taken by the Academic Committee.

# SEMESTER PROFILE

The course consists of four semesters. Each semester will have seven to nine modules, with each module requiring twenty four or thirty six learning hours depending on whether it is a two or three credit module.

#### SEMESTER I:

Principles and practice of clinical research (described using a model disease), basic epidemiology, clinical pharmacology, foundation course – drug discovery and development, pre-clinical studies, clinical studies, introduction to biostatistics, clinical research methodology, ethical considerations, GxP (GMP, GLP, GCLP, GCP), Intellectual property rights and patenting.

#### **SEMESTER II:**

Regulatory aspects of clinical trials, clinical trial design, and planning – conventional & adaptive, application of biostatistics to clinical trial design, protocol development, clinical trial set up and conduct, and clinical data management. Internship programme (industry/academica/research organizations).

#### **SEMESTER III:**

Protecting patients and patient engagement, pharmacovigilance and safety reporting, quality management in clinical trials, financial management, statistical analysis in clinical studies, reporting and reviewing clinical trials, closing a trial, dissemination of trial results, pharmacoeconomics and health technology assessment, bioavailability and bioequivalence studies, pharmacokinetic and pharmacodynamic studies, scientific communication.

#### **SEMESTER IV:**

Project dissertation – A research project shall be chosen towards the end of Semester I with preparatory activities during subsequent semesters. The project will involve relevant research techniques in clinical research-related activities and may include the collection of data and analysis. This immersive learning activity shall conclude with the submission of a dissertation report and evaluation with viva-voce.

More specific details are provided below:

- (a) The project dissertation shall be carried out under the supervision of a mentor.
- (b) The project dissertation shall initiate from Semester I and continue till the end of the tenure (Semester IV)
- (c) At any point in time, the M.Sc. dissertation supervisor shall be allowed to guide a maximum of four students but under exceptional circumstances, the Academic Committee may waive this condition duly recording the reasons for such waiver.



## ASSESSMENT

Videos, reading materials, and practice exercises will be provided to prepare students for these assignments, which will form a part of formative and summative assessments. Formative and summative assessments will be conducted throughout the coursework. There will be:

- Semester wise examinations
- Project Dissertation and Viva-voce

Students will be graded separately on the course work (60 credits) and project dissertation (40 credits).

The Cumulative Grade Point Average (CGPA) is the ratio of the total credit points secured by a student in all semesters and the sum of total credits of all courses in all semesters (100 credits).

A passing grade shall be required on various peer-graded assignments.



## CAREER OPPORTUNITIES

Various roles in academia/research organisations and industry depending on the educational background, and experience can be embarked upon after the successful completion of this programme. For students interested in academia and research organisations, this programme will help achieve their goals to become Principal Investigators.

In industry, there will be tremendous opportunities as experts in clinical project management, regulatory affairs, medical monitoring, quality assurance, compliance management, pharmacovigilance, clinical data management, biostatistics, etc.

# FEE STRUCTURE

Tuition fee: INR 25,000 per semester (there will be four semesters) For OBC/EWS, the fees will be INR 18,750/- per semester and for SC/ST/PwBD candidates, the fees will be INR 12,500/- per semester.

	SEMESTER 1	SEMESTER 2	SEMESTER 3	SEMESTER 4
TUITION FEE				
General Category	25,000	25,000	25,000	25,000
OBC/EWS	18,750	18,750	18,750	18,750
SC/ST/PwBD	12,500	12,500	12,500	12,500
OTHER FEES				
One-time Admission Fee	7,500			-
Medical Insurance	3,500		3,500	-
University Application Fee	5,000	5,000	5,000	5,000
Exam Fee	1,000	1,000	1,000	1,000
Security deposit (refundable)	10,000			-
Hostel (if availed – 7,500 per month)	45,000	45,000	45,000	45,000

<sup>\*</sup>INR-Indian Rupees

Online application fee (General, OBC & EWS candidates) - INR 590 /- (inclusive of 18% GST)
Note: SC/ST/Women/PwBD candidates are exempted from payment of application fees

## IMPORTANT DATES

Last date of online application	12 <sup>th</sup> June 2023
Date of declaration of shortlisted candidates	20 <sup>th</sup> June 2023
Date of written test/Interview	13 <sup>3h</sup> July 2023/ 14 <sup>th</sup> July 2023

# **FACILITIES**

THSTI shares a lush green campus with RCB and other institutes of the National Capital Region Biotech Science Cluster at Faridabad, Haryana, India.

- Hostel accommodation with mess, transport facility (payment, at actuals)
- State-of-the-art campus with many recreational facilities, subsidised canteen
- Visit to hospitals, industry, and clinical research/trials sites for hands-on training
- Internship with an academic institution, industry, regulatory agency, research organization, etc.
- Engagement with ongoing clinical research/trials of the institution or partnering institutions (dissertation)
- Support for placements (industry/academia/research organizations)
- Possibility of continuing with Ph.D. subject to fulfillment of the THSTI Ph.D. policy
- Student welfare, anti-ragging provisions
- Bank on the campus.





















# COURSE CURRICULUM

No.	Course Title	Code	Credits
0	SEMESTER I		20
1.1	Principles and practice of clinical research	251	3
1.2	Drug discovery, drug development, and pre-clinical studies	252	2
1.3	Basics of epidemiology	253	2
1.4	Basics of Clinical pharmacology	254	2
1.5	Introduction to biostatistics	255	o 2
1.6	Clinical research methodology	256	2
1.70	Ethical Considerations	257	3
1.8	GXP (GMP, GLP,GCLP, GCP)	258	2
1.9	Intellectual property rights and patenting	259	2
	SEMESTER II		20
2.1	Regulatory aspects of clinical trials	351	3
2.2	Clinical trial design and planning - Conventional and adaptive	352	3
2.3	Application of biostatistics to clinical trial design	353	3
2.4	Protocol development	354	3
2.5	Clinical trial set up and conduct	355	3
2.6	Clinical data management	356	3
2.7	Internship programme	357	2
	SEMESTER III		20
3.1	Protecting patients and patient engagement	358	2
3.2	Pharmacovigilance and safety reporting	359	2
3.3	Quality management in clinical trials	360	O 2
3.4	Financial management	361	2
3.5	Statistical analysis in clinical studies	362	3
3.6	Reporting and reviewing clinical traials, closing a trial,	363	3
	dissemination of trial results	0/10	
3.7	Pharmacoeconomica and health technology assessment	364	2
3.8	Bioavailability and bioequivalence studies.	365	2
	pharmacokinetic and pharmacodynamic studies		(CAPE)
3.9	Scientific communication	366	2
	SEMESTER IV		40
4.1	Project dissertation (spread over four semesters)	367	40
	Total cre	dits	100

<sup>\*</sup>one credit = 12 teaching hours; one credit = 6 hands-on sessions (sessions of 2 hours each)

# CONTACT US

Clinical Development Services Agency, Translational Health Science & Technology Institute

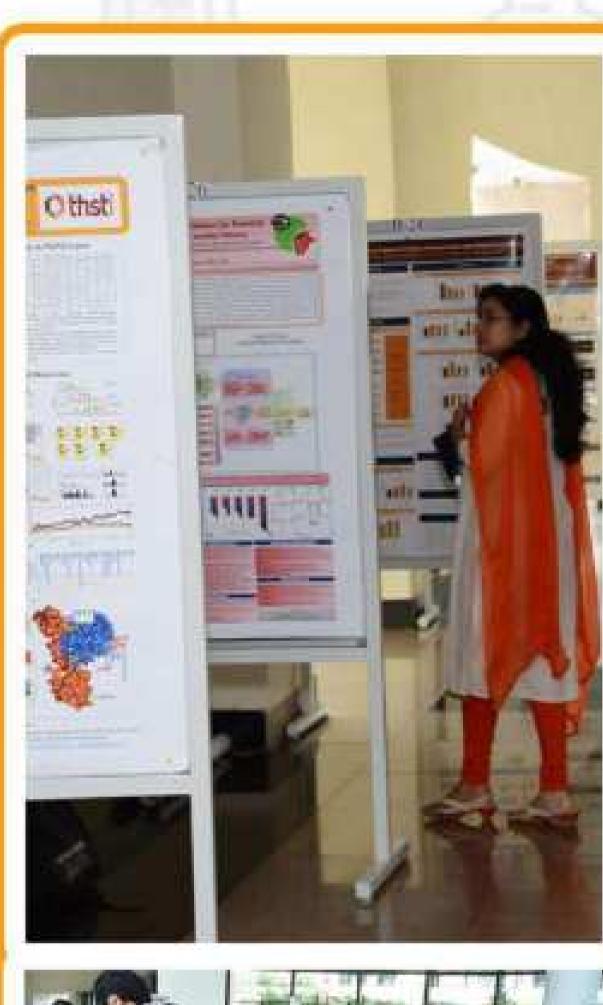
(An autonomous institute of Department of Biotechnology, Ministry of Science & Technology, Government. of India),

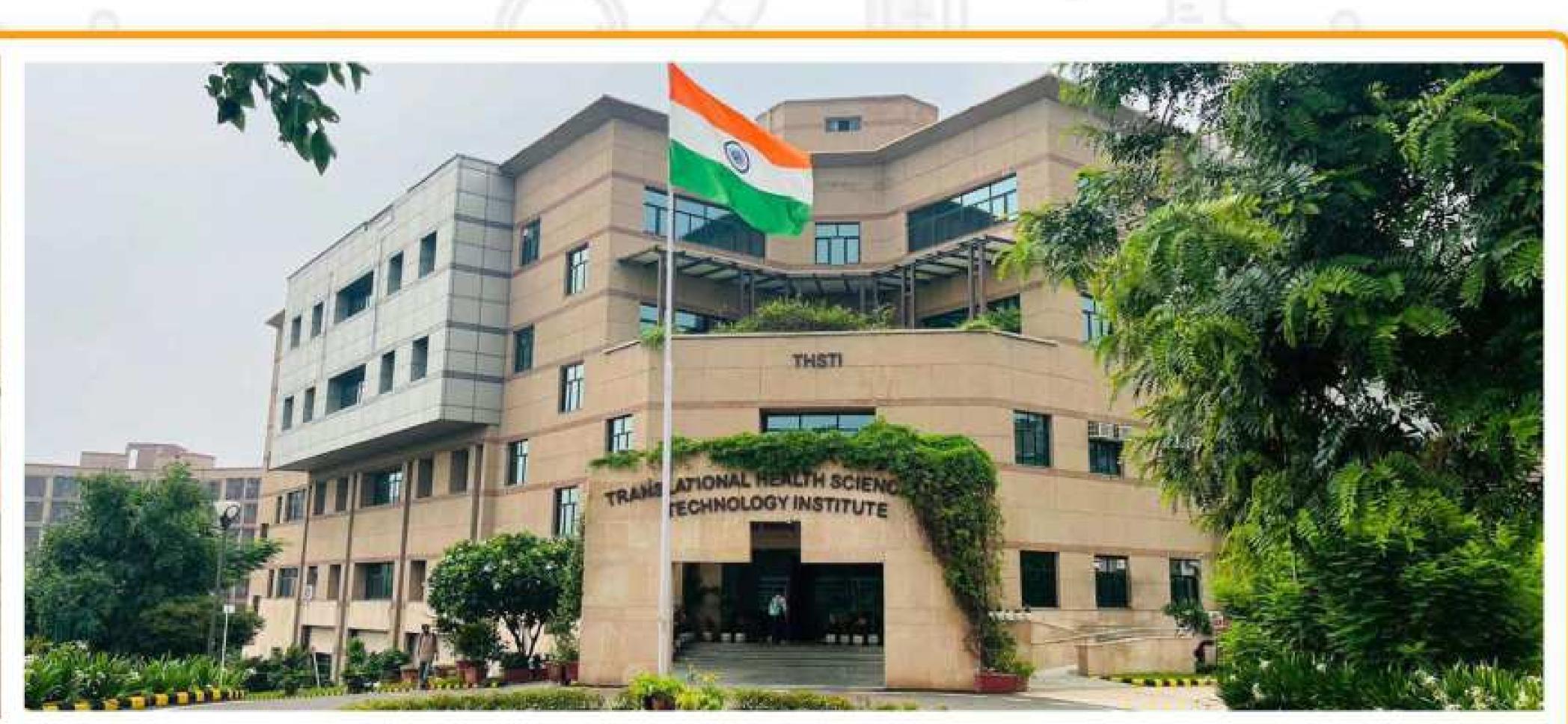
NCR Biotech Science Cluster, 3rd Milestone, Gurgaon- Faridabad Expressway,

Faridabad, Haryana, India 121001

+91-129 287 6468

m training.cdsa@thsti.res.in



























(An Autonomous Institute of the Department of Biotechnology, Govt. of India)

NCR Biotech Science Cluster, 3<sup>rd</sup> Milestone, Faridabad – Gurugram Expressway, P.O. Box No. 04, Faridabad - 121001

No.: THS/AN/02/2023

### <u>ADMISSION TO MASTER OF SCIENCE IN CLINICAL RESEARCH</u>

- 1. Translational Health Science and Technology Institute is designed to be a dynamic and interactive organization with a mission to conduct innovative translational research across disciplines and professions to accelerate the development of concepts into products to improve human health.
- 2. Applications are invited for admission to the <u>Master of Science (M.Sc.) in Clinical Research</u> (<u>Specialisation in Regulatory Clinical Trials</u>) for the academic session 2023-2025. The details of the course are as under:
  - a. This is a two-year, post-graduate degree course. The degree will be awarded by the Regional Centre for Biotechnology (RCB), recognized as an institution of National Importance by an Act of the Parliament of India.
  - b. The course curriculum is enclosed as Annexure-A
  - c. The course will commence on July 31, 2023
  - d. Tuition fee: INR 25,000 per semester (there will be four semesters) For OBC/EWS, the fees will be Rs.18,750/- per semester, and for SC/ST/PwBD candidates, the fees will be Rs.12,500/- per semester.

#### 3. Education Eligibility:

A degree as mentioned below with a minimum of 50% marks in aggregate:

- a. Bachelor's degree in Allopathic Medicine (MBBS)
- b. Bachelor's degree in other fields of Medicine/Dentistry/Nursing/Veterinary Science (BHMS/BAMS/BDS/BSc Nursing/BVSc)
- c. Bachelor's degree in Pharmacy/Life Sciences/Statistics/Public Health (B Pharm/BSc/ B Tech)

Note: Candidates awaiting their graduation results can also apply. They will be considered subject to submission of their graduation result (mark list and at least the provisional degree certificate) on the day of the interview.

### 4. Selection Procedure

- a. Written test will be followed by an interview.
- b. Those candidates who score 60 percentile and above in the written test will only be called for the interview subject to the same being more than or equal to 40% marks.
- c. The minimum qualifying marks to be scored in the interview will be 60% marks.
- d. Relaxation up to 5% for OBC and 10% for SC/ST will be given if required.
- e. Written test and interview will be held at THSTI, Faridabad, Haryana, India.
- f. All instructions pertaining to the syllabus, date, time, venue, etc. will be sent separately before the written test to the shortlisted candidates.

#### 5. Other terms and conditions:

- a. No. Seats 15
- b. Reservations: 27% seats for Other Backward Classes (OBC) (non-creamy layer), 15% seats for Scheduled Castes (SC), 7.5% seats for Scheduled Tribes (ST), 10% seats for Economically Weaker Sections (EWS), and 4% seats for the differently abled person (Person with Benchmark Disability, PwBD) are reserved for candidates belonging to these categories. SC/ ST/ OBC /EWS candidates are required to submit certificates in respect of their claims from authorized officers as notified by the Government for the purpose from time to time. The differently abled, (with a minimum of 40% disability) candidates are required to submit a certificate from authorized Medical Doctors/ Hospitals indicating the extent of their physical disability.
- c. During the course, the student will not apply for any other course/post-graduate program/ scholarship or appear for any examination or interview outside. If the student has applied for any of the above before applying for this program, she/he must give proper information to this institution.
- d. Candidate must ensure that he/she fulfils all the eligibility criteria as stipulated in the advertisement. If it is found that he/she does not fulfil the stipulated criteria by misinterpretation or any other reason during the selection process, the candidature of the candidate will be cancelled. If the same is noticed after the admission, the candidate will be terminated following due process.
- e. All future communications will only be through email.
- f. All results/notifications will be published on our website; therefore, the candidates must visit the THSTI website regularly till the completion of the admission process.

#### 6. Facilities Provided by the institute during the course:

- a. Hostel accommodation with mess (payment, at actuals)
- b. State-of-the-art campus with many recreational facilities
- c. Visit hospitals, industry, and clinical research/trials sites for hands-on training.
- d. Internship with academic institutions, industry, regulatory agencies, research organizations, etc.
- e. Engagement in actual ongoing clinical trials of the institution during the dissertation period for hands-on training
- f. Support for placements
- g. Possibility of continuing with Ph.D. subject to fulfillment of the THSTI Ph.D. policy
- 7. **Application process:** The eligible and interested candidates are required to apply online at the Institute's website <a href="https://thsti.in/application/jobs.php">https://thsti.in/application/jobs.php</a>. Applications through any other mode will not be accepted.

#### a. Procedure for filling up online application:

Step 1: Details of the applicant

Step 2: Uploading documents

Step 3: Payment of application fee

- > The payment can be made by using a Debit Card / Credit Card / Internet Banking / UPI.
- Once payment is made, no correction/modification is possible.
- > Candidates are requested to keep a copy of the provisional receipt for future reference.
- > The fee once paid shall not be refunded under any circumstances.

> Details of fees to be paid are as shown below:

General, OBC & EWS candidates	Rs 590/- (Inclusive of 18% GST)
	1

#### Note: SC/ST/Women/PwBD candidates are exempted from payment of application fees

- b. Documents to be kept handy before filling up the online application: (all the documents except (a) should be in pdf format):
  - i. A soft copy of your recent passport-size photo and signature (jpeg/jpg/png format).
  - ii. Matriculation certificate (equivalent to 10th Standard) / Mark sheet.
  - iii. Intermediate certificate (equivalent to 12th Standard) / Mark sheet.
  - iv. Graduation degree certificate and Mark sheet.
  - v. Caste / Disability certificate (if applicable) in the format prescribed by the Govt. of India.
- Note:
- i). Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference
- ii) Providing false/ incorrect information in the application form or non-possession of essential qualifications detected at any stage of the selection process will lead to the disqualification of the candidate.
- iii) Incomplete applications will be rejected and no correspondence in this regard will be entertained.
- iv) In case of difficulty filling up the online form, please e-mail training.cdsa@thsti.res.in along with the screenshot of the error displayed (if any).

#### 8. Important dates:

Last date of online application	12th June 2023
Date of declaration of shortlisted candidates	20th June 2023
Date of written test/Interview	13th July 2023/14th July 2023

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