ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान

TRANSLATIONAL HEALTH SCIENCE
AND TECHNOLOGY INSTITUTE

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

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

Azadi Ka Amrit Mahotsav

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 and pharmacodynamic studies, 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.

(i) For securing admission, selected applicants shall be required to pay the admission fee as per THSTI policy and will be expected to join the academic programme by the scheduled date advertised for that academic year. Requests for extensions for joining the academic programme after the scheduled date shall be granted by the Academic Committee only if they are consistent with the admission policy. Waitlisted candidates shall be admitted against vacancies as per the policy approved by the Admission Committee.

(j) The rules and regulations of RCB, the degree awarding institutions will apply, as appropriate.

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TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE

United Nations Educational, Scientific and Cultural Organization

क्षेत्रीय जैव प्रौद्योगिकी केन्द्र Regional Centre for Biotechnology

PROGRAMME DETAILS

(a) The Master of Science programme shall consist of the following two components, namely:

- Course work, and
- Project 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.
- Real-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:

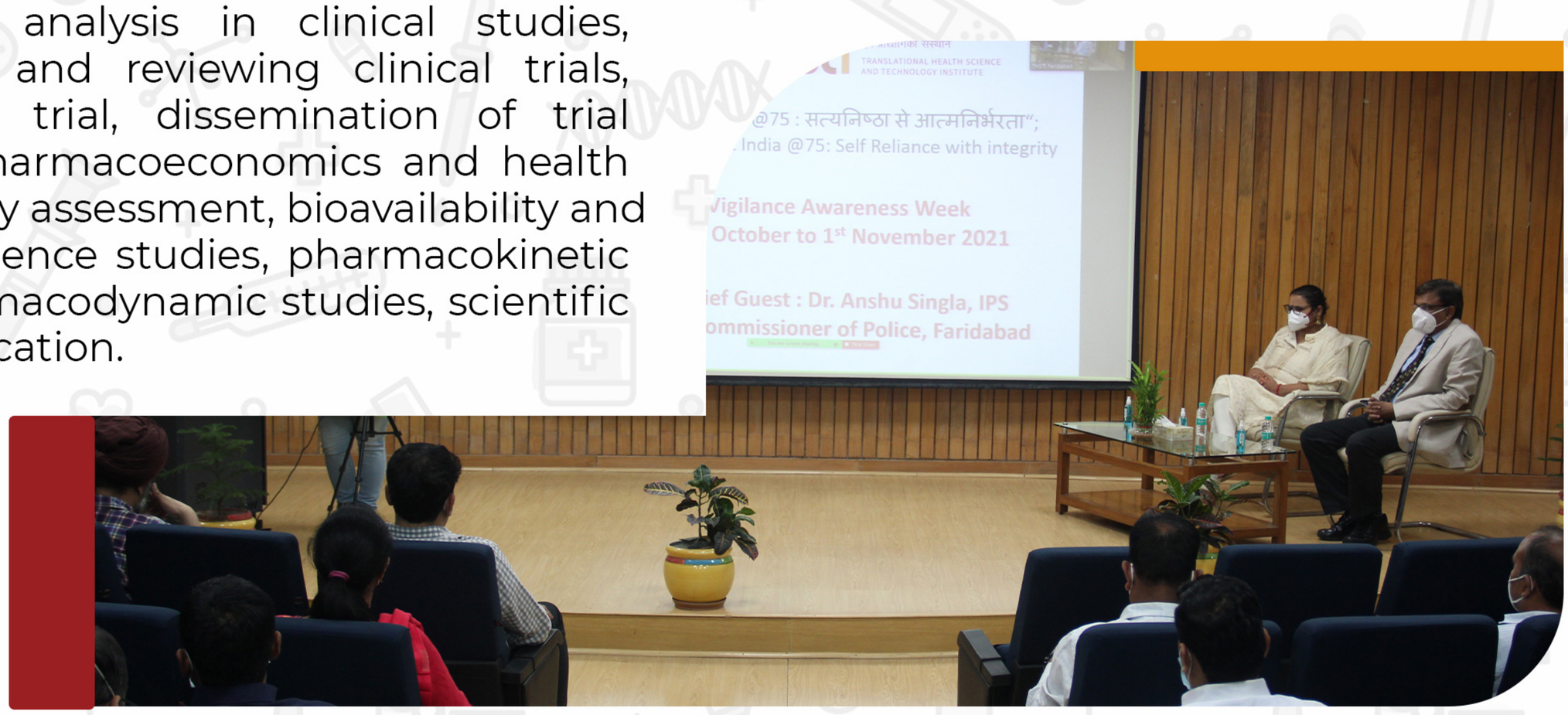
Project dissertation – A research project shall be chosen towards the end of Semester I with preparatory activities during subsequent semesters. The project will involve relevant research techniques in clinical research-related activities and may include the collection of data and analysis. This immersive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

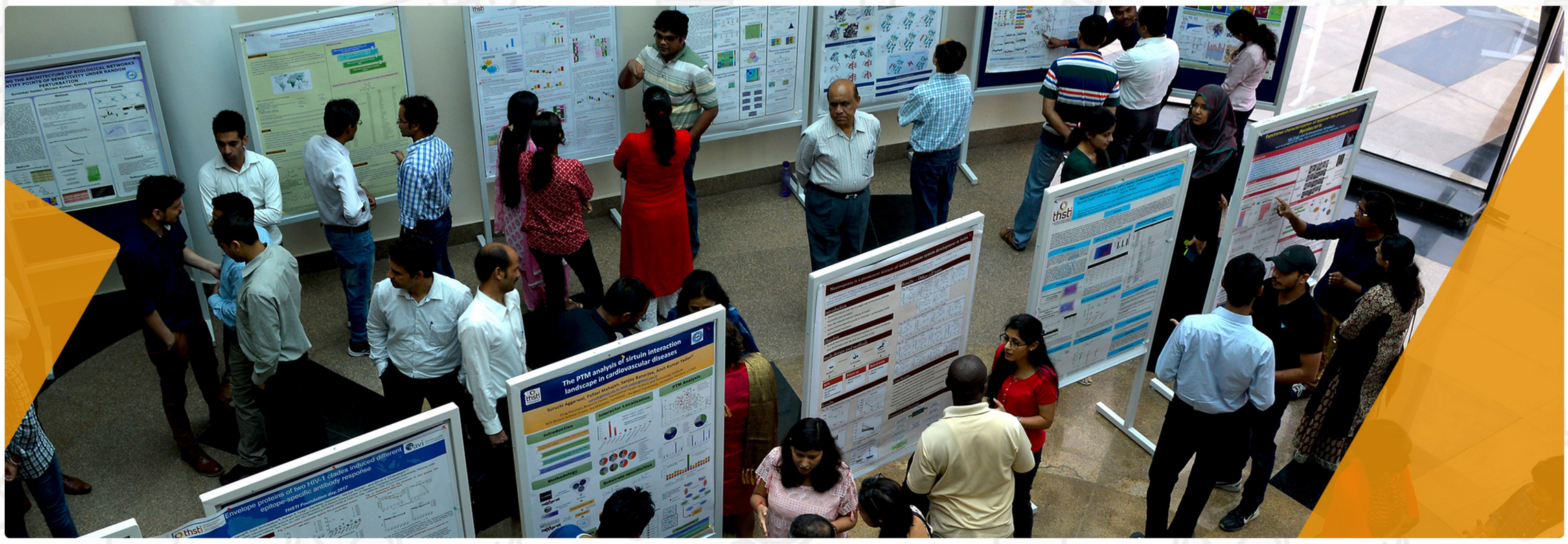
Videos, reading materials, and practice exercises will be provided to prepare students for these assignments, which will form a part of formative and summative assessments. Formative and summative assessments will be conducted throughout the coursework. There will be:

- **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

**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

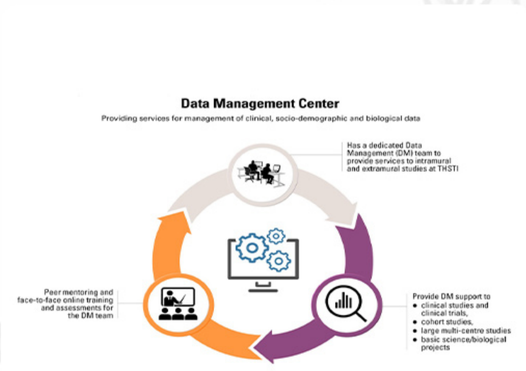
IMPORTANT DATES

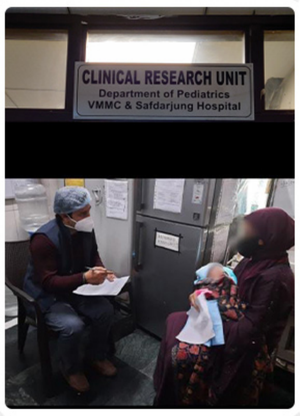
Last date of online application	16th July 2023
Date of declaration of shortlisted candidates	21st July 2023
Date of written test/ Interview	173h August 2023/ 18th August 2023

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.





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COURSE CURRICULUM

No.	Course Title	Code	Credits*
	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	2
1.6	Clinical research methodology	256	2
1.7	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	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, dissemination of trial results	363	3
3.7	Pharmacoeconomica and health technology assessment	364	2
3.8	Bioavailability and bioequivalence studies. pharmacokinetic and pharmacodynamic studies	365	2
3.9	Scientific communication	366	2
	SEMESTER IV		40
4.1	Project dissertation (spread over four semesters)	367	40
		Total credits	100

*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,
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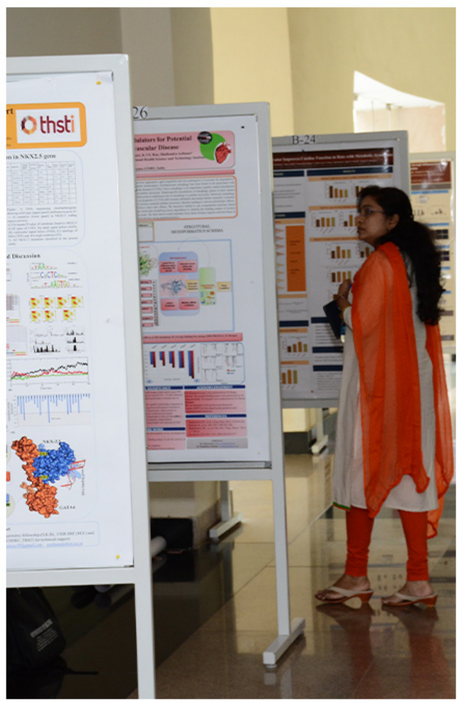

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