

## Frequently Asked Questions (FAQ's)

### **☞ Am I eligible to apply for the Integrated MSc & PhD in Clinical Research course?**

You are eligible to apply for integrated program in (Clinical Research) if you are:

A graduate in: medical and allied fields like dentistry, AYUSH (Ayurveda, Yoga, Unani, Siddha and Homeopathy), pharmacy, physiotherapy, nursing and veterinary science.

A graduate in: biological sciences (microbiology, biochemistry, biotechnology, botany, zoology), basic sciences (chemistry), occupational therapy and Biostatistics.

### **☞ Am I guaranteed entry into the PhD program if I get admission to this integrated program in Clinical Research?**

No, admission for the integrated program does not guarantee admission for the PhD program. The students who complete the Master's program under this program with a CGPA of 8 and above only will be eligible for the PhD program. A formal application needs to be submitted which will be screened & enrolment will be finalized by the PhD screening committee.

### **☞ Do I have a choice to exit after completion of the Master's program?**

After you pass the 2 years Master's program if you wish to exit from the integrated course you can do so and you will be awarded only the Master's degree.

### **☞ How important is it for me to have good working knowledge in English?**

The medium of teaching and evaluation is in English. All the prescribed test book will be also be in English. Proficiency in English is an added advantage.

### **☞ How computer savvy should I be?**

We expect students to have basic working knowledge in computing like using MS word, excel and power point along with internet browsing and emailing

### **☞ Should I be a medical doctor to apply?**

No, it is not necessary that you have to be medical doctor. This course is designed in such a way that comprehensive medical knowledge is not a compulsory requirement. We expect the candidate to have basic understanding about human body and diseases.

### **☞ Will choosing to do this course, mean that I change the course of my career?**

The answer could be Yes or No depending on your background experience/ qualification.

This program is relevant to those wishing to gain an in depth understanding of research methods & also keen to specialize in specific areas either laboratory based or hospital based or community based research in clinical research.

### **☞ What is the course fee for Masters?**

**For M.Sc in Clinical Research,**

**Indian and South Asian Applicants:**

The annual tuition fee for the students admitted in academic year 2018-20 is INR 1.80 Lakhs per student per academic year (The total tuition fee for the two year program is Rs. 3,60,000/- which includes Rs. 10,000/- admission fees and Rs. 10,000/- examination fees)

**International Applicants:**

The annual tuition fee for the students admitted in academic year 2018-20 is USD 5,500 per student per academic year.

The fee structure could be subject to change in the next academic year.

**❧ Should I have cleared the UGC -NET examination to be eligible for this integrated program?**

No, clearing NET examination is not mandatory. However, if a candidate has cleared the NET examination then they have an added advantage during the selection process of PhD or for applying for scholarships for PhD.

**❧ What is the course fee for PhD program?**

The student will have to pay the fees as fixed for the concerned programme from time to time by AcSIR and PHFI as per the terms and conditions notified. Tuition fees for the Integrated Ph.D programme will be charged directly by AcSIR following the approved guidelines of AcSIR. The current tuition fee is Rs. 1,000/- per month and the PhD thesis submission fee is Rs. 5,000/- payable to AcSIR. Additionally, a student needs to pay the registration fees and administration fees to PHFI directly. Currently, the one-time registration fee is Rs. 5,000/- and the administration fee is Rs. 10,000/- per semester payable to PHFI. They will also be encouraged to apply for research fellowships offered by various organizations including UGC-NET ([www.ugcnetonline.in](http://www.ugcnetonline.in)). The fellowship grant could be utilized for student's stipend and for project expenses.

**❧ Are scholarships available to the selected candidates?**

PHFI offers limited number of scholarships to the deserving students, depending on the availability of scholarships funds. For more details about scholarships please visit <https://www.phfi.org/our-activities/academic-programmes/scholarships>

**❧ Where are the classes conducted?**

The classes for MSc in Clinical Research will be held at *Indian Institute of Public Health –Delhi*, which is currently located at Plot-47, Sector-44, Gurgaon – 122002. If enrolled for PhD, the place of work/training would depend upon the nature of the project work (lab/field/hospital based).

**❧ When do the session start?**

Sessions would commence in the month of August every year.

**❧ What is the duration of the course?**

The MSc program in Clinical Research is an intensive 2 year, full time program. The PhD program is of minimum 3 year, full time and is project based.

**❧ Can I retain my job and do the course?**

The class timings are 10 AM to 5 PM on weekdays. The Institute remains closed on weekends (Saturdays and Sundays). If you are working/ practicing in the evening/ night you are free to do so.as long this does not affect your attendance and attention in the classes. The course curriculum is comprehensive and so we would advise you against taking up any part time job during the course.

**❧ How much reading time will this course require?**

This course will require at least 8 hrs of reading per week (weekdays and weekends included). This includes time taken to cover day to day portions and time spent on completing assignments.

**❧ How will I be evaluated?**

The program will follow a credit system consistent with AcSIR norms. Credits are awarded for successful completion of each course (module) and thesis. A total of 64 credits need to be earned for awarding the degree. Student evaluation for each course (module) would be through a concurrent internal assessment during course work (that includes assignments, attendance and class room participation) and marks scored in the end of semester unseen written examination. The weighted average of both will contribute to the course (module) GPA. A detailed evaluation framework will be provided to the students before the beginning of the course.

**❧ What will happen if I am not able to pass in semester exams?**

You will have to re-sit for the courses you failed in the next semester. You are allowed to re-take twice. If you fail to clear the courses/modules after these attempts, you will be asked to discontinue the program.

**❧ What are the organizations where I might be placed for internship?**

The internship during the Master's program would provide the candidate with an opportunity to interact with potential researchers. The setting may be a hospital, CSIR laboratories, AcSIR or research organizations.

**❧ Do I have a choice to decide the place of internship of the Masters?**

Yes, the candidate is free to choose the place of Internship, as long as the course coordinator is consulted and acceptable to him/her.

**❧ Is there a provision for Lateral Entry?**

Currently there is no provision for lateral entry into the program.

**❧ What is my future job prospects?**

The placement cell will strive to arrange for campus interviews with companies in clinical research pursuits. The prospective job opportunities could be in research organizations, pharmaceutical industry, national and international NGOs, international organizations in public health, hospital with research units, government research bodies like ICMR, DBT, DHR. However, no formal guarantee will be provided to any candidate regarding future job selection after the completion of the program.

**❧ Is the degree recognized?**

Yes. The MSc & PhD (in clinical research) programme will be jointly conducted by PHFI and AcSIR and the degrees will be awarded by Academy of Scientific and Innovative Research (AcSIR). AcSIR was established by an Act of Parliament, the Academy of Scientific Innovative Research Act, 2011 vide The Gazette of India No.15 dated February 7, 2012 and notified on 3rd April 2012.

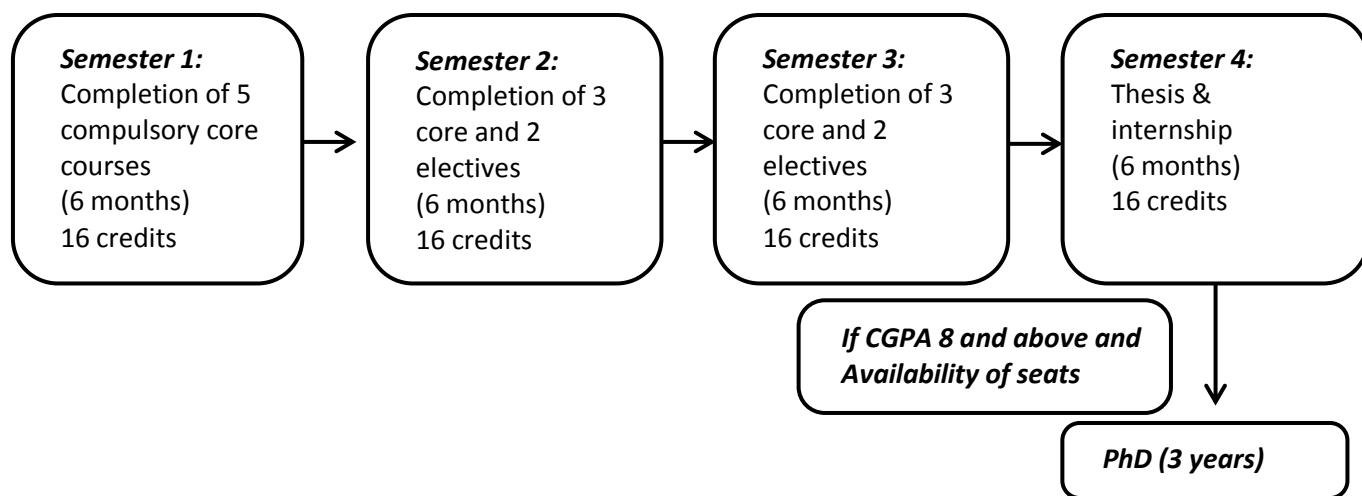
For more information, visit <http://acsir.res.in/>

**❧ What is the program structure and the course contents?**

Refer below for further details of program and the courses offered.

## PROGRAM STRUCTURE (MSC)

The program curriculum for the Master's degree will be covered under core and elective courses (modules), with 18 months of contact session and 6 months of thesis work cum internship. On completion of 2 years the students earn 64 credits. During the 18 months period the students need to complete 11 core courses/modules and 4 electives.



### The Core courses

MD101 Basics in Epidemiology (3-1-0-4)

MD102 Basic Bio Statistics (3-0-2-4)

MD103 Clinical trials- design and analysis (2-1-0-3)

MD104 Clinical trials- conduct and operational issues (2-1-0-3)

MD105 Bio-ethics and regulatory affairs (1-1-0-2)

MD106 Basics in data management (2-1-2-4)

MD110 Project management and Communication (2-1-0-3)

MD201 Medical writing - Proposal development, Protocol and Report writing (1-1-2-3)

MD202 Pharmacovigilance and drug regulation (2-1-0-3)

MD205 Drug Development (2-2-0-4)

MD206 Systematic reviews and meta-analysis (1-1-2-3)

### The Elective Courses\*: (A four of the below electives can be chosen)

MD107 Laboratory sciences (2-0-2-3)

MD108 Drug Discovery (3-0-0-3)

MD203 Advanced data management (1-1-2-3)

MD204 Advanced statistics (1-1-2-3)

MD207 Advanced epidemiology (1-1-2-3)

MD208 Genetic Epidemiology (2-1-0-3)

MD209 Economic evaluation (1-1-2-3)

MD210 Pharmaceutical biotechnology (2-0-2-3)

MD211 Medical innovation (2-0-2-3)

MD212 Open elective\*\*

\* The student will be asked for the choice of elective courses towards the end of Semester 1. A chosen elective will be offered only if at least 5 students opt for that elective course

\*\*Open elective means the student can choose any course equivalent to 3 credits that is being offered at IIPHD or AcSIR)

**CORE Competencies gained** at the end of this MSc program:

- Reviewing existing evidence in literature
- Developing a grant application in bio-medical research
- Handling ethics and regulatory approvals of protocols
- Managing a research project
- Managing research data
- Planning and executing statistical analysis
- Communicating research results to a scientific community

### **Brief about the core and elective courses:**

#### **MD101 Basics in Epidemiology (4 credits)**

This course will introduce basic concepts, designs and methods in epidemiology and its application in clinical research. This course will help students to understand the relevance of research, tools and techniques to conduct observational study designs in clinical research, interpret and, communicate the study findings.

#### **MD102 Basic Bio-Statistics (4 credits)**

This course will introduce basic concepts of statistics and its application in clinical research. It will enable students to use and interpret key statistical tests and undertake basic data analysis independently using Stata software.

#### **MD103 Clinical trials- design and analysis (3 credits)**

This course will provide students with fundamental principles of comparative clinical trials in investigating effectiveness, efficacy and safety of interventions. Key design and analytical issues of parallel arm studies will be covered with introduction to alternate study designs.

#### **MD104 Clinical trials- conduct and operational issues (3 credits)**

This course will give an overview of the key steps in preparing, conducting and completing a clinical trial. Students will get to know the practical aspects of conducting trials, the roles and responsibilities of different stakeholders in a clinical trial, methods of recruitment, randomization and participant retention strategies in trials.

**MD105 Bio-ethics and regulatory affairs (2 credits)**

This course will give you an overview of history, general principles, dimensions and practice of research ethics. It will enable you to identify the key ethical issues that may arise in human research with special focus of Indian context. Students will also learn the processes involved in seeking ethical clearances and regulatory approvals.

**MD201 Medical writing - Proposal development, Protocol and Report writing (3 credits)**

This course aims provides a systematic approach and steps in developing right form developing a research question to getting a full proposal ready for grant application and further develop it into a full protocol. The students will also be given guidelines to follow, for developing study reports and be introduced to standard reporting guidelines for various study designs. This course will enable you to put into practice the concepts and techniques learnt so far to design a clinical research proposal.

**MD106 Basics in data management (4 credits)**

The aim of this course is to understand the principles and practices required to ensure that the participant data collected as part of clinical research are of high quality. The key skills and resource requirements necessary to manage a successful data management project will be discussed. We will introduce the student the key clinical trial regulations directly relevant to data management

**MD202 Pharmacovigilance and drug regulation (3 credits)**

This course will describe the pharmacological science relating to detection, assessment and reporting of adverse effects of drugs. Key tools for pharmacovigilance and methods to generate plan for the prevention of adverse drug effects will also be covered.

**MD206 Systematic reviews and meta-analysis (3 credits)**

Systematic reviews seek to collate all the evidence that fits pre-specified eligibility criteria to address a specific research question. These methods minimize bias by the use of explicit and systematic methods for informing health care decisions. This course will familiarize students with the concepts of systematic reviews in health care, impart skills to conduct and critically appraise systematic reviews.

**MD205 Drug Development (4 credits)**

This course will help understand the roadmap of the process of new drug development, particularly oriented to researchers and individuals entering the pharmaceutical field. Key concepts and design of pre-clinical studies along with ethical and regulatory requirements of pre-clinical and early phase trials will be covered.

**MD110 Project management and communication (3 credits)**

Effective management of resources is the key to successful implementation of any project. Apart from managing physical resources such as money and materials, it is also important to manage people who are the most important resources. This course will introduce students with key tools for project planning, in identifying their own leadership style and practice effective communication

**MD203 Advanced data management (3 credits)**

This course will build on the skills gained in the basics of data management course. Specific issues related to Clinical Data Management (CDM) and associated international standards for the conduct of clinical trial research will be covered. Students will also be exposed to hands on practice in developing a database, cleaning and managing data using software programs.

**MD204 Advanced statistics (3 credits)**

This course will deal with various statistical techniques commonly used in a variety of epidemiological study designs. It will build on the concepts and skills learnt in basic biostatistics course. Multivariable analysis using various regression (linear, logistic, poisson, cox) techniques will be introduced. The students will get hands on experience in Stata statistical software.

**MD107 Laboratory sciences (3 credits)**

This course will introduce students to basic laboratory techniques in biotechnology along with knowledge in good lab practices. This course will be a mix of theory, demonstrations and hands on practice

**MD108 Drug Discovery (3 credits)**

This course will enable the students to understand the steps involved in drug discovery process.

**MD208 Genetic Epidemiology (3 credits)**

The aim of this course is to provide an introduction to the main concepts and applications of human genetic epidemiology. The course explores how genotyping methods and statistical techniques can be used in epidemiological studies to facilitate human disease research, including the ability to comprehend the role of genetic inheritance in disease.

**MD207 Advanced epidemiology (3 credits)**

This course will build on knowledge and skills gained through basic epidemiology and biostatistics course. It will enable the student to have an in-depth understanding of the design, conduct and analytical issues arising from observational studies with focus on cohort and case-control designs.

**MD209 Economic evaluation (3 credits)**

This course will provide a broad understanding of the concepts, application and analytical techniques in economic evaluation of health care interventions. The module will introduce the underlying concepts of comparison between costs and outcomes in clinical research. The students will carry forward the learning to the types of economic evaluation commonly employed in health research.

**MD210 Pharmaceutical biotechnology (3 credits)**

This course will introduce students to the basics of this topic and introduce them to various processes involved in biotechnology and unique input of this discipline in the drug discovery process.

**MD211 Medical Innovation (3 credits)**

The aim of this course is to attain practical knowledge of design development, deployment and evaluation in medical innovations.

**Thesis and Internship**

The student will undertake a project work as a compulsory component of the MSc program and is equivalent to 16 credits. Though the dedicated time for project work is six months, the work on developing the proposal for the project and obtaining clearances will start early during the MSc program. The primary guide and a co-guide will be identified for each student for this activity. The student will be placed as an intern in a research organization/ hospital/ CSIR laboratory or will continue as a student at IIPH-D for completion of the project work. During this period of 6 months they will be involved with the day to day activities as decided by the organization for a stipulated percentage of time. A project report needs to be submitted towards the end of semester 4, in accordance to the standard requirements developed by the institute for earning the 16 credits. The submitted final report will be also reviewed by an external committee.