The formula for a successful new-age career

For more information contact:
Manipal Universal Learning Pvt. Ltd., Manipal Towers, 14 Airport Road,
Bangalore – 560008 Call: 9731700774/9731700771
Email: cmeassist@manipalu.com Website: www.crra.manipal.edu

Diploma in Clinical Research and Regulatory Affairs
The formula for a successful new-age career
Clinical Research - An Overview

The healthcare industry is fast becoming one of the most sought after career avenues today. With the global population growing by leaps and bounds, quality healthcare is in great demand. Along with it, ancillary industries like medical and clinical research too are growing at an unheard of rate.

India, with its large patient population for most diseases with genetic diversity, is becoming one of the hotbeds for the clinical trials industry, which is set to scale the $1 billion mark by 2012 (McKinsey Report). These clinical trials are systemic studies of pharmaceutical products in human subject(s) in order to discover or verify the clinical, pharmacological, and/or adverse effects, with the objective of determining their safety and efficacy.

Today, with the implementation of international healthcare norms, results of clinical trials from India can be submitted in the USA, Europe and Japan amongst many other nations.

In such a scenario, there is a great need for qualified professionals who have an in-depth awareness of all facets of the clinical research world. To hone skills for clinical research and professional development in clinical data management, it is imperative that students are equipped with the knowledge to meet the requirements for Good Clinical Practices (GCP).

Manipal University’s Diploma in Clinical Research and Regulatory Affairs is one such course that can create such professionals who can carve out great careers for themselves while changing the face of this industry.
The Manipal Education and Medical Group (MEMG), as we know it today, was founded by the late Padmashri Dr TMA Pai in 1953 at Manipal. The Group has been at the forefront of education and healthcare for over 5 decades, attracting students from all over the world.

The Manipal Group has 4 universities, over 30 institutions, 10 global campuses, over 1,20,000 students from 53 countries and over 3,00,000 alumni. It has international academic collaborations for its ‘Twinning Programs’ with Universities in countries like the US, UK, Australia and Nepal. Manipal institutions are home to the largest international student population in India.

Manipal Healthcare manages 11 hospitals including 8 teaching hospitals with a total of 7,000 beds making it one of the largest providers of hospital management services in the country. These hospitals cover the entire spectrum from secondary to super-specialty care. Manipal Healthcare treats over 1.2 million patients each year.

Manipal University was one of the first institute to be recognized as a Deemed University by the Government of India in 1993. Manipal University offers programs in Medicine, Dentistry, Engineering, Nursing, Allied Health, Pharmacy, Life Sciences, Management, Mass Communication, Information Sciences, Hotel Management, Regenerative Medicine and many more.

Home to India’s top ranked institutions (in various surveys) such as Kasturba Medical College (KMC) and Manipal Institute of Technology (MIT), Manipal University has come to be recognized for its excellence in medical and engineering programs and continuing education in the areas of IT, management and healthcare for employed professionals.

The University has been placed in Category ‘A’ by a Task Force set up by the Ministry of Human Resource Development, New Delhi, in recognition of its high standards in professional education through cutting edge research, innovative pedagogy, state-of-the-art infrastructure, transparency and quality of governance.

Mission

To provide the entry level and mid career professionals with concrete building blocks to create a path for full employment and successful career.
Program Objective

The Program is expected to achieve the following objectives:

- Obtain a clear understanding of Good Clinical Practice and Standard Operating Procedure for Clinical Research and Clinical Data Management
- Provide trained skills to CROs in Bio-IT Life Science Institutions/Corporate, Academic Research Institutions and/or Clinical investigators at hospitals/medical sites conducting trials
- Provide an understanding of the use of the Electronic Data Capture (EDC) system and project monitoring in the clinical trial process
- Enable participation in design, conduct and management of global clinical trials, conducted at multi-centric sites in India and overseas
- Acquire an understanding of evolving regulatory processes, standards and practices of ICH GCP in the conduct of different therapeutic trials and in the preparation of submissions to be made to regulatory authorities in India and overseas
- Provide skill based professional training for career advancement

Program Details:

DURATION

- The program will be covered in various modules in 12 months
- Classes on Sundays and Saturdays (if required)

Program Structure:

The Program is divided into two semesters, each of 6 months duration. Program involves regular submission of assignments, internal assessment, end-semester examination and internship for one month.

Curriculum

Note: The Program does not include any practicals / experimentation on human or animal subjects.

Credit Details

- Minimum 16 credits to be earned in each semester
- Mandatory 14 credits from Core subjects in each semester
- Minimum 2 credits to be derived from Optional subjects in each semester

<table>
<thead>
<tr>
<th>SEMESTER-I</th>
<th>Credits</th>
<th>Optional Subjects*</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fundamentals of Clinical Operations</td>
<td>4</td>
<td>Human Biology I</td>
<td>2</td>
</tr>
<tr>
<td>Regulatory Affairs - I</td>
<td>2</td>
<td>Human Biology II</td>
<td>2</td>
</tr>
<tr>
<td>Basics of Pharmacy, Drug Discovery And Development</td>
<td>2</td>
<td>Basics of Molecular Biology &amp; Biotechnology</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Data Management - I</td>
<td>2</td>
<td>Basics of Health and Nutrition</td>
<td>2</td>
</tr>
<tr>
<td>Audit and Inspections</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statistics for Clinical Research</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Credits</td>
<td>14</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SEMESTER-II</th>
<th>Credits</th>
<th>Optional Subjects*</th>
<th>Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPR &amp; Data Exclusivity, Bioethics &amp; Clinical Research</td>
<td>2</td>
<td>Basics of Epidemiology</td>
<td>2</td>
</tr>
<tr>
<td>Regulatory Affairs-II</td>
<td>4</td>
<td>Pharmacology</td>
<td>2</td>
</tr>
<tr>
<td>Preclinical Studies: Safety &amp; Efficacy</td>
<td>2</td>
<td>Review &amp; Seminar</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Data Management-II</td>
<td>4</td>
<td>SAS Programming**</td>
<td>2</td>
</tr>
<tr>
<td>Clinical Studies: PK, BA, BE</td>
<td>2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Total Credits</td>
<td>14</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

* Respective modules to be offered if there is an acceptable minimum number of students.
** 2 credits awarded to students who have independently undergone SAS training and have obtained Sylvan Prometric - SAS certification.

1. Exempted for Medical / Paramedical / Nursing / Pharmacy Graduates.
2. Exempted for Medical / Paramedical / Nursing / Pharmacy Graduates.
3. Exempted for Biotech Graduates.
4. Exempted for Medical / Paramedical / Nursing / Pharmacy Graduates.
5. Exempted for Medical / Paramedical / Nursing / Pharmacy Graduates.
Teaching Methodology:
The Program will have regular classroom lectures, seminars, tutorials, group discussions, case presentations by participants and an internship program for students. Homework assignments are given and extra reading is recommended. In addition:

- Students will be required to complete assignments, tutorials and a project to familiarize with the real life clinical research situation.
- Additional guest lectures by renowned faculty.

Eligibility criteria:

- Graduate / final year graduation* students in Life Science, Pharmacy, Medicine, Dentistry, Paramedical Science, Allied Health Sciences and Biotechnology.
- A minimum of 50% aggregate in the qualifying exam. In case of final year students, a minimum of 50% aggregate in the previous year’s examination.
- Post Graduate Diploma will be awarded to final year graduation students after successful completion of the program and graduation degree.

Application Process:
Interested candidates can collect the Application Form from Manipal Universal Learning’s office by paying Rs. 500/- in cash. Those who wish to submit the application form through post/courier can download the application form from the website (www.crra.manipal.edu) and submit the filled-in application along with a DD of Rs. 500/- drawn in favour of “Manipal Universal Learning Pvt. Ltd.” payable at Bangalore.

The application form complete in all respects should be accompanied by:

1. Attested copies of the qualifying exam mark sheets of all years/semesters.
2. Attested copy of the degree certificate.
3. 3 passport size photos.

Selection Process:
Entrance Test & Personal Interview

Admission Process:
Candidates selected after the Entrance Test and Personal Interview need to confirm their admission by submitting the Demand Draft of Rs.40,000/- (the 1st Installment of the Program fee) drawn in favour of “Manipal University” payable at Udupi or Manipal.

Fee Structure & Payment Schedule

<table>
<thead>
<tr>
<th>Fee (Rs)</th>
<th>Installment Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Installment</td>
</tr>
<tr>
<td>1,20,000</td>
<td>First</td>
</tr>
<tr>
<td></td>
<td>Second</td>
</tr>
<tr>
<td></td>
<td>Third</td>
</tr>
<tr>
<td></td>
<td>Fourth</td>
</tr>
</tbody>
</table>

The fee includes Registration fee, Tuition fee, Certificate fee & Study material.

1. Additional Rs. 8,750/- per subject to be paid at the time of selecting optional subject (if any).
2. Amount is payable in the form of DD drawn in favour of “Manipal University” payable at Udupi or Manipal.
3. In case of lumpsum payment one would be eligible for a 10% discount in the total fee. The total fee in such a case will be Rs.1,08,000/-.
4. Examination fee Rs.500/- per subject is extra.
5. Fee paid is not refundable.
Faculty:
The faculty pool comprises of professionals from reputed Clinical Research Organizations such as Ecron Acunova and Stempeutics for core Clinical Research subjects. The faculty is well experienced in the industry. Overall Manipal has a large pool of experienced faculty members in various functional areas. We believe in a good blend of theory and practice and accordingly the faculty members chosen have both academic and industry experience. Their qualification ranges from PhD, MPhil, MSc, MBBS and BE (for Clinical Data Management subjects).

Courseware:
The comprehensive courseware pertaining to the Program will be provided to individual student. In addition to the courseware provided, students are advised to refer to additional material as suggested by individual faculty members as per the requirement of the subject.

Attendance:
Attendance for the lectures is a critical part of the Program. Students need to maintain a minimum of 75% attendance in each subject to be eligible for appearing for the end semester University Examination. Absence due to illness should be supported by a valid Medical certificate, which should be endorsed by HOD. No extension of time shall be provided for submission of assignments beyond the designated date.

Evaluation Criteria
Internal assessment:
It comprises of two internal tests (Internal Assessment - IA) and an assignment in each subject. The maximum weightage of internal assessment will be 40% of the total marks in each subject.
1. The marks allotted to assignments and internal examinations (best of 2) will be averaged and reduced to 80 for 4 credit subjects and 40 for 2 credit subjects, and sent to Manipal University for all subjects.
2. The students have to score a minimum of 40% marks in internal assessment (IA Exam + Assignment) to be eligible to take up University exam.

Final University Exam:
Final University Examination evaluation will be by Optical Mark Reader (OMR). The maximum weightage for the same will be 60% of the total marks allocated for each subject.

a. Internship will not be assessed on any marks basis. However, each student has to submit the successful completion certificate from the Head of the institution offering the internship, before the University issues the Diploma.

b. * In case of Exempted subjects students will be given the credits.

Certification
A Diploma is awarded to the student at the end of the Program based on the following:
• Completion of all assignments
• All internal assessments
• Final University Examination
• Viva Voce for presentation subjects, if any
• 50% aggregate marks
• Internship
• Completion of degree for students who enroll during their final year of graduation

The Grading System followed by the University is as under:

<table>
<thead>
<tr>
<th>Letter Grade</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>80% and above</td>
</tr>
<tr>
<td>B</td>
<td>70 to 79%</td>
</tr>
<tr>
<td>C</td>
<td>60 to 69%</td>
</tr>
<tr>
<td>D</td>
<td>50 to 59%</td>
</tr>
<tr>
<td>F</td>
<td>Below 50%</td>
</tr>
</tbody>
</table>

* Refer curriculum
Career Prospects

Segment wise opportunities:

Doctors: Principal Investigator, Co-investigator, Medical Advisor, Drug Developers, Regulatory Affairs Manager and Clinical Research Physician.


Management Professionals (with Life Sciences/Health Sciences Background): Business Development Manager, Clinical Project Manager, Clinical Research Manager and Regulatory Affairs Manager.

Placement

As an institute that understands the crucial role of placement in every student’s life, we provide a great platform and valuable career guidance to students and help them with career opportunities in renowned organizations with improved roles and responsibilities.

The Placement Cell at Manipal assists students right from the commencement of the Program. For every batch, quite early, the dedicated placement team identifies suitable openings in leading companies for each student based on their academic background, experience and interest, and prepares them accordingly. No wonder, more than 90% of the previous batch has been successfully placed in leading Clinical Research Organizations.

Student Speak

“After completing my graduation when I was looking for some Program which could give me a promising career, I came across this Program of Diploma in Clinical Research from Manipal University. I joined it and now I know I had taken a right decision of joining this Program. The faculty who came to teach us were invited from the industry which helped us to gain a good practical and real life insight. The materials provided to us for reference were too good covering all important aspects. Presently I am working in Ecron Acunova as Clinical Data Coordinator. I heartily thank the faculty, the entire team of Manipal.

Srimati kini”

“After completing the Clinical Research Program from Manipal University, I am currently working for one of the leading CROs in India, Clinigene International Ltd., Bangalore. I owe all my success to Manipal University’s Clinical Research Team and thank the entire team for their wholehearted support and cooperation which in turn helped me achieve my dream career. I really consider myself fortunate to be a part of this esteemed institution with the help of which I could start my career in a very good CRO. It’s only because of Manipal that I was able to boost up my confidence and accomplish my dream which would not have been possible without the support of the people associated with this institution.

Gaurav Verma”

“I got placed in BIOCON even before I completed the Clinical Research Program from Manipal. I am very happy about the way the teaching faculty guided me throughout my Program, and placement cell gave me an excellent platform to enter into the industry. Each and every step taken either during the Program or in the interview was streamlined. I sincerely thank the teaching faculty and Manipal Placement Cell for all this good that happened.

Dr. Pavithra K”
The decision to join Manipal University’s Clinical Research Program proved to be a real fruitful one for me. As a result of the excellent teaching from the Industry experts and the experienced faculty members from Manipal, and the additional support from the entire Clinical Research team, I got placed in Novartis. I would recommend this Program from Manipal to all students looking for a career in the Clinical Research Industry.

Dr. Deepak Chaturvedi

It was a great experience to be a part of the Clinical Research Program from Manipal University. I thank the team of Manipal for providing complete support - be it related to academics, operational support, extra activities or placement. I got an excellent learning opportunity as a result of which I got placed in Quintiles, the number one CRO in the world. Thank you once again.

Ashaqullah M

I will always be indebted to Manipal University for the world class training provided during the Diploma in Clinical Research program. The facilities were state-of-the-art and imparting of knowledge was impeccable. This has put my career on the fast track and has enabled me to earn my dream job in a premier company.

Anoop Sankar