

Apollo Research and Innovations Online Course Brochure 2022

Full AAHRPF

APOLLO RESEARCH & INNOVATIONS A DIVISION OF APOLLO HOSPITALS ENTERPRISE LTD.

INDEX

- 1) About ARI
- 2) Executive Program in Clinical Research (EPCR)
- 3) Executive Program in Clinical Data Management (EPCDM)
- 4) Executive Program in Pharmacovigilance (EPPVG)
- 5) Executive Program In Clinical research Internship (EPCRI)
- 6) Executive Program in Clinical Research Project(EPCRP)
- 7) Executive Program in Medical Writing (EPMW)
- 8) Professional Diploma in Clinical Research (PDCR)
- 9) Advanced Professional Diploma in Clinical Research (APDCR)
- 10) Advanced Post Graduate Diploma in Clinical Research (APGDCR)

FACULTY DIRECTORY

Dr. Jayanthi Swaminathan Director. ARI

Clinical Operations 26 years of experience

Ms. Chandana Pal Course Faculty, Hyderabad QA QC 21 years of experience

Mr. Alex Peter Course Faculty, Ahmedabad Clinical Trial Operations 21 years of experience Ms. Priyanka Kamdar Course Faculty, Hyderabad Ethics 18 years of experience

Dr. Sunita K Course Faculty, New Delhi Pharmacovigilance 18 years of experience Mr. Sathyanarayana K Course Faculty, Chennai Clinical Data Management 19 years of experience **Dr. Anitha Rani** Course Faculty, Chennai Medical Writing 10 years of experience

ABOUT ARI

Apollo

ARI is the first and largest Site Management/Solutions Organization of the Apollo Hospitals Group, functional from the year 2000. With 22 established site offices Pan India , ARI has the rich experience of having conducted/coordinated over 1250 clinical trials in the last 22 years. 80% of these are global, multi-centric trials, 10% domestic multi-centric and the remaining 10% are academic studies and investigator Initiated Studies

ARI has the track record of successfully completing 60+ batches of full/part time regular clinical research training programs in 5 ARI locations from the year 2007 onwards. The unique in built feature of the course was the theory classes imparted as a power point presentation, followed by six months on-site hospital based internship in clinical research and project work. This made the candidates ready from very first day of joining the job. ARI harnesses the strength of the students in counselling them for a suitable job opportunity.

The ethical conduct of clinical trial calls for a highly motivated and trained workforce, capable of meeting the challenges and increasing demand of the industry. With the present change in the mode of imparting education, the need to reach wider audience and the will to bridge the geographical distances, ARI has initiated virtual classrooms where online classes are rendered from 2020 onwards by a mix of ARI affiliated in house faculty of diverse specialties and external Non Affiliated Industry Experts. Starting with one basic online program - Executive Program in Clinical Research, today ARI offers at least 6 online courses and also bridging courses by combining EPCR with 1/2/3 other programs. A minimum number of four batchers of EPCR are conducted per annum. A number of webinars to cover GCP, NDCT rules and other topics related to clinical research.

There has been outstanding feedback from the employers, other stakeholders and the alumni on the course conduct and placement opportunities. The online course content is vetted by the industry leaders and domain experts.

COURSE CONTENT

EXECUTIVE PROGRAM IN CLINICAL RESEARCH (EPCR)

Clinical Research is a branch of healthcare science that evaluates the safety and efficacy of medications, devices, diagnostic products and treatment regimens intended for human use. Clinical research, through its activities of drug development traverses from ethics to the conduct to the 3M management of man, material and money, while collecting valid and credible data which is finally analyzed to generate a clinical study report. The continuous and dynamic research happening in the pharmaceutical industry have a great impact on the registration and/or marketing approvals by the relevant regulatory bodies before it reaches the doctor's prescription or the pharmacy outlets.

With the upsurge in disease burden and need for new technology/treatment modalities of drug, device or vaccine, there is a huge demand-supply gap for qualified and trained clinical research professionals. Looking at this, ARI started offering online virtual training programs in clinical research to train budding research professionals with latest knowledge and expertise in relevant areas. We firmly believe that with the vast experience gained by successful completion of 60+ batches of clinical research courses Pan India over the last 14 years, ARI is well poised to provide skilled clinical researchers to the pharmaceutical and biotechnology industry.

The online based "Executive Program in Clinical Research" (EPCR) is designed for postgraduates, graduates and final year undergraduate students in life sciences including medicine, dentistry pharmacy, physiotherapy and alternative system of medicine graduates and existing clinical research professionals to understand and widen their scope and horizon of knowledge in this domain. The sessions have lectures on topics directly associated with clinical research and also have group discussions to build a team spirit mandatory for better job satisfaction. The expert interactive sessions with stakeholders of high repute has been planned to make the candidates understand the spirit of a clinical research professional from different perspectives. The course enriches the comprehension of the candidates and transforms them into a skilled clinical research professional.

The curriculum is reviewed and vetted by clinical research industry and academic experts to ensure complete exposure needed.

- Introduction to Clinical Research and 5. Drug Development 6.
- 2. Ethical guidelines and regulations
- 3. Study documents and development
- 4. Clinical Trial Management and quality assurance

- 5. Clinical Trial Finance
- 6. Research Methodology and Bio statistics
- 7. Clinical Data Management
- 8. Pharmacovigilance

DURATION

3 months weekend virtual classroom teaching Intake: 4 batches a year: Jan/Apr/Jul/Oct

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences and Pharmaceutical Sciences.

COURSE FEE

EXECUTIVE PROGRAM IN CLINICAL DATA MANAGEMENT (EPCDM)

The recent developments in biopharmaceutical arena signifies the importance of Clinical Data Management(CDM). It is at the forefront, leading the change, influencing direction and providing objective evidence. CDM is the development, execution and supervision of plans, policies, programs and practices that control, protect, deliver and enhance the value of data and information assets in the clinical trial arena.

With its diverse connectivity, cross functional features and a wide range of responsibilities, CDM globally continues to grow into a firmly established discipline in its own right. Its focus on managing clinical trial related data as a valuable resource is making it a career that requires multiple skill sets, such as background of sound clinical knowledge, scientific rigor, information technology, systems engineering and strong communications ability.

Executive Program in CDM is a comprehensive course offering candidate with knowledge on the clinical data management processes and tools. The candidates are taught critical concepts and practical methods of planning, supporting, collecting, cleaning, compiling, analyzing, disseminating and archival of data.

ARI, with the vast experience of successful completion of Clinical research courses covering CDM over the past 14 years, is instrumental in aiding the industry towards the requirement of skilled Researchers.. ARI now offers virtual Executive Program in CDM designed for working professionals/post-graduates/graduates and final year life science students including medics and paramedics to enrich their knowledge and skill set in data management principles and practices to increase their job prospects and productivity.



COURSE CONTENT

- 1. General Overview of clinical research & CDM
- 2. Basics of Clinical Data Management
- 3. Clinical Data Management Process
- 4. Clinical Data Management Standards

- 5. Clinical Data Management Systems
- 6. Introduction to Biostatistics
- 7. Training on EDC

DURATION

3 months weekend virtual classroom teaching Intake: 4 batches a year: Jan/Apr/Jul/Oct

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences and Pharmaceutical Sciences.

COURSE FEE

EXECUTIVE PROGRAM IN PHARMACOVIGILANCE (EPPVG)

Pharmacovigilance is one of the fastest growing streams of the clinical research industry. The World Health Organization (WHO) initiated a program for reporting all adverse reactions possessed by drugs. Further awareness about adverse drug reactions has resulted in the emergence of the practice and science of pharmacovigilance.

Pharmacovigilance (PV) is the pharmacological science related to the detection, assessment, understanding and prevention of adverse effects, both long term and short term side effects of medicines. It is also known as the monitoring and assessing of responses to pharmaceuticals to detect and prevent adverse effects. The continuous research happening in the pharmaceutical industry on the new molecules/products have a great impact on the registration and/or marketing approvals by the relevant regulatory bodies before it reaches the doctor's prescription or the pharmacy outlets. There is increased focus on streamlining post-marketing and risk management activities to proactively manage safety signals for both the Investigational New Drug and the marketed products. Although, India is participating in the Uppsala monitoring center program, its contribution to this database is relatively small. There is an emerging need of skilled professionals towards making PvPI (Pharmacovigilance program of India, a Central Drugs Standard Control Organization program coined in 2010) a success.

Executive Program in Pharmacovigilance is a comprehensive course offering the candidate relevant knowledge information about the modalities, methodology used, techniques of quality control during drug development precisely with the focus on Pharmacovigilance.

ARI, the research division of Apollo Hospitals Group with the vast experience of successful completion of Pharmacovigilance and Clinical research courses over the past 14 years, is instrumental in aiding the industry towards the requirement of skilled Researchers. ARI now offers online based virtual Executive Program in Pharmacovigilance designed for working professionals/post-graduates/graduates and final year life science students including medics and paramedics to enrich their knowledge in pharmacovigilance practice.

COURSE CONTENT

- 1. Overview of drug discovery & development
- 2. Introduction to PVG
- 3. PVG Terminologies (Glossary)
- 4. Regulatory guidelines & laws

- 5. PVG Methodology
- 6. Safety reporting process
- 7. PVG work flow & database
- 8. Introduction to PVG software

DURATION

3 months weekend virtual classroom teaching Intake: 4 batches a year: Jan/Apr/Jul/Oct

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences and Pharmaceutical Sciences.

COURSE FEE

COURSE CONTENT

1. Overview of Medical Writing

- 2. Types of Medical Writing
- 3. Medical Writing Norms
- 4. Regulatory Writing
- 5. Medico Marketing

- 6. Scientific Writing
- 7. Plagiarism and Ethics in Medical Writing

DURATION

3 months weekend virtual classroom teaching Intake: 4 batches a year: Jan/Apr/Jul/Oct

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences and Pharmaceutical Sciences.

COURSE FEE

Application Fee: Rs.1000/- payable at the time of submission of the application form. Course Fee: Rs. 35,000/-(Rupees Thirty Five thousand) plus taxes.

Medical Writing is a specialized area which has gained importance in the last two decades. For those who have a flair for writing with the scientific background, it is a creative and rewarding career option. Medical writing involves manuscript writing and regulatory writing which are essential in the medical fraternity and also in the pharma industry including clinical research. The two major domains where the medical writer is in demand are regulatory writing and medico marketing writing. A medical writer's primary responsibility is to create well-written communicable documents and manuscripts in compliance with regulatory standards and for the approval of new clinical trials, drugs, medical devices, and biologics. Thus, Medical writers play an important role in drug discovery and development sector in preparing the critical documents which are mandatory for regulatory approvals.

EXECUTIVE PROGRAM IN

MEDICAL WRITING (EPMW)

With the exponential growth in pharmaceutical industry and in research and development, many business models are started providing an importance to the specialized field such as medical writing. Executive Program in Medical Writing is a comprehensive course offering the candidate with insights and the relevant knowledge on the requirement of Medical Writing, Scientific Acumen and Accuracy, Regulatory and Medico Marketing focused on Medical Writing.

ARI, the research division of Apollo Hospitals Group, with the vast experience of successful completion of Clinical research courses over the past 15 years, is instrumental in aiding the industry towards filling in the gap for the requirement of skilled Researchers. ARI now offers online based virtual Executive Program in Medical Writing designed for working professionals/post-graduates/graduates and final year life science students including medics and paramedics to enrich their knowledge in Medical Writing.

EXECUTIVE PROGRAM IN CLINICAL RESEARCH INTERNSHIP (EPCRI)

ARI has initiated a stand-alone internship program at many of its locations to provide by hands-on training after a basic theoretical knowledge in clinical Research. This augments skills in the practice domain. It gives opportunity to the candidate to get a peek into live trial conduct and enables them to understand the practical domain in a better way.

"Not Documented is Not Done" is the Clinical research saying. Learning is incomplete without practicing.

In internship, it is the hands-on practice approach under the shadow of an experienced research team that helps the candidate develop right approach and learn the right attitude in taking research protocols forward as a team. The delegation is done based on the basic qualification of the candidate. Monthly reviews and feedback collected by the senior mentor helps to plan the future delegation of the candidate. Every aspect of the internship calendar is based on a personalized ability, need and focus. Internship is a focused training in relevant aspects of clinical trial conduct from its initiation to completion, close out and beyond.

Candidates passing out after the basic course in clinical research with an internship are well versed with the requirements of clinical research from the site, EC, Sponsor and regulatory perspective. While at ARI, they learn to manage the documents that get generated during the lifetime of a clinical trial, understand the importance of each one of them. They also learn and practise timeline compliance as is the need of this industry

ARI takes the pride to announce that there are 4 locations with 50 GCP certified trained researchers to hand hold the interns

COURSE CONTENT

1. GCP revision

pollo

- 2. Current regulations
- 3. From Site and EC perspective
 - Pre-Trial activities
 - During trial activities
 - Post-Trial activities
- 4. Monitoring & audits

*an elaborate checklist of activities shared with the interested candidate after enrolment

DURATION

3* months on-site (extendable) Intake: 12 months a year (every 1st Saturday)

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences and Pharmaceutical Sciences.

COURSE FEE

EXECUTIVE PROGRAM IN CLINICAL RESEARCH PROJECT (EPCRP)

The course content trains the students to gain leadership qualities and make them to manage the clinical trials independently. With exposure to the entire clinical trial process, the interns/students are able to independently plan a project, implement the plan, identify potential risks & plan to mitigate them, keep track on the study activities including budget and monitor status with periodic analysis throughout the duration of the study. Hence EPCRP gives a momentum to learn the complete conduct of clinical trials.

After learning the basic lessons needed for the ethical conduct of a trial, EPCRP hand holds the students to designing and conducting a research study. It gives a practical exposure on the designing of the essential documents which includes the project specifying the target population, study design, Ethics Committee review process, screening and recruitment, data variables, data collection and final analysis for the report generation. In EPCRP, the candidate gets to design a protocol right from the scratch, design tools for data collection, clean and analyze the data to compile the report.

This executive program helps designing the needful scientific documents based on existing literature, identifying the right research project and conduct. Student batches from ARI have successfully completed projects as part of their curriculum and gained not only the experience of doing a study but also how to bring it to fruition by seeing it in print.

EPCRP helps students to enhance their management skills, by leveraging their individual strength, trains them to handle a clinical trial process independently (under direct supervision) while ensuring ethical practices throughout

COURSE CONTENT

- 1. Plan and identify research project
- 2. Preparation of study documents

pollo

- 3. Ethics Committee Review Process
- 4. Study Methodology & conduct of the study
- 5. Data collection, entry, compilation, cleaning
- 6. Data Analysis and preparation of TLG's
- 7. Clinical Study Report & Manuscript Preparation

DURATION

3* months on-site and off site Hybrid Program (extendable) Intake: 12 months a year (every 1st Saturday)

ELIGIBILITY

Graduates and final year graduate students of Life Sciences, Medical Sciences & Allied Health Sciences, and Pharmaceutical Sciences.

COURSE FEE



PROFESSIONAL DIPLOMA IN CLINICAL RESEARCH (PDCR)

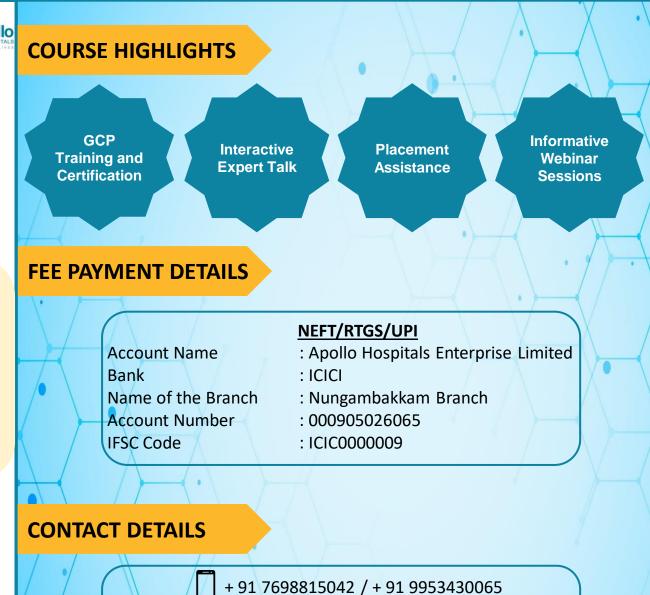
Executive program in clinical research (EPCR) + Any one course from executive programs list **Duration:** 6 months **Application Fee:** Rs 1000/- payable at the time of submission of the application form. **Course fees:** Rs. 70,000/-(Rupees Seventy Thousand)

ADVANCED PROFESSIONAL DIPLOMA IN CLINICAL RESEARCH (APDCR)

Executive program in clinical research (EPCR) + Any two courses from executive programs list **Duration:** 9 months **Application Fee:** Rs 1000/- payable at the time of submission of the application form. **Course fees:** Rs. 1,05,000/-(Rupees One Lakh and Five Thousand)

ADVANCED POST GRADUATE DIPLOMA IN CLINICAL RESEARCH (APGDCR)

Executive program in clinical research (EPCR) + Any three courses from executive programs list **Duration:** 12 months **Application Fee:** Rs 1000/- payable at the time of submission of the application form. **Course fees:** Rs. 1,40,000/-(Rupees One Lakh and Forty Thousand)



aricrcourse@apolloari.com

www.apolloari.com