D Y Patil University Kolhapur

Syllabus

Fellowship Course in Advanced Clinical Research

Course Details

1. **Curriculum**

    I.   Title of the Course – **Fellowship Course in Advanced Clinical Research**
    II. **Aims/Objective & Desirability** –

    Obtain a clear understanding of Good Clinical Practice and Standard Operating Procedure for Clinical Research and Clinical Data Management.

    Provide Individuals / Students / Professionals from Pharmacy, Medical, Nursing, Life Sciences, Research & Development, Clinical Research, Allied areas and Academic fields, a basic to advanced level understanding of various clinical trial processes.

    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.

    Support overall clinical trial process electronically by implementing Electronic Data Capture (EDC) system and Project Monitoring. Course

    To accomplish these goals, fellows are supported for 1 year.

    III. Duration – 1 year

    IV. Eligibility Criteria for admission –
         Graduates in Life Sciences, Pharmacy, Biotechnology, MBBS, BHMS, BAMS, BDS and BPT, Paramedical and Allied Health Sciences.

         Entrance Test : Theory- MCQ of 50 marks without negative marking,
                         Shortlisting - 3 times of the number of seats.
                         Final selection by interview.

    V.   Intake capacity – 1 per Teacher

Selection Criteria for candidates:

Fellows should be selected in a fair and non-discriminatory manner in accordance with the Equal Opportunities. The selection process will be according to DYPU guidelines.

The candidate is expected to appear for the multichoice(MCQ) written examination of 100 marks. Selected candidates will be called for the interview. Ultimately, selection of a candidate for a fellowship will be done by an interview with panel of faculties constituted by the DYPU.

Examination paper for selection of candidates for Fellowship:

Three sets of MCQ paper will be set by the committee of the faculties approved by DYPU & only one paper will be selected by random process on the day of examination.

Evaluation of the examination conducted will be done by a committee of faculties

Merit list & Successful candidates name will appear on the WEB site of DYPU

Syllabus / Course contents –

- **Module-I: Introduction to Clinical Trials**
    1. Introduction to Clinical Research
    2. Definition, History
    3. Drug Discovery and Drug Development
    4. Pharmacology- PK, PD
    5. ICH, GCP
    6. Schedule-Y
- **Module-II: Clinical Trials**

    1. Clinical Trial Designs and Phases
    2. Informed Consent [Main, Children, Geriatric, Special Population]
    3. Source Documentation
    4. CRF Design, CRF Entry, CRF Types
    5. Protocol Design and Development
    6. Source data verification, monitoring, Inspection, Audit
    7. Data Management
    8. Pharmacovigilance - AE, SAE, ADR

- **Module-III: Pretrial and Trial Related Discussions**
    1. Pre-trial activities
    2. Essential Documents
    3. Standard Operating Procedures
    4. Quality Control and Quality assurance, Monitoring role & responsibility, monitoring plan and implementation
    5. Monitoring visit type, monitoring activities
    6. Scientific paper writing, publishing a research paper

- **Module-IV: Regulatory**
    1. Drug Regulatory Authorities- US-FDA, EU, DCGI, ICMR, ICH-GCP, SCHEDULE-Y, IPR, HIPPA, Patent
    2. IND,NDA- Submission forms, submission process
    3. Pre and post drug approval
    4. Inspection and Audits-Regulatory Overview
    5. Ethics Committee, IRB, DSMB

- **Module-V: Miscellaneous**
    1. Biostatistics
    2. GMP & GLP
    3. BA/BE Studies
    4. Role of Central lab
    5. IMP handling
    6. Communication skills
    7. Collaborative research-National/International
    8. Funding agencies

        I. Teaching Scheme
            i. Lectures
            ii. Surgical
            iii. Practical
            iv. Presentations

     v.   Publications

     vi.   Other – As per speciality

II.   Mentorship required -- yes

III.   <u>Evaluation/Examination Scheme</u>

     i.   Attendance

     ii.   Log book

     iii.   Publications

     iv.   <u>Credit hour system</u>

         i.   Didactic lectures

         ii.   Surgical work

         iii.   Clinical work

         iv.   Practical

         v.   Research work/publications

         vi.   Assignment

         vii.   Portfolio

         viii.   Presentations

         ix.   Lab rotation

         x.   Seminar

         xi.   Log book

         xii.   Any other – As per speciality

         xiii.   Conferences/Workshop of that speciality attended

1. No. of teaching / non teaching staff required

   A. Teaching

   i.   Professor

   ii.   Associate Professor

   iii.   Lecturer

   iv.   Tutor

   B. Non Teaching

   i.   Nurses

   ii.   Technicians

   iii.   Clerical :

   iv.   Counselor

   v.   Social worker :

   vi.   Attendant

2.   Eligibility criteria for teaching staff at each level

   i.   Minimum 10 years teaching experience and minimum including at least 3 years of postgraduate teachership.

   ii.   Minimum experience of teacher in the speciality of course applied for : Research experience 3 years.

The entire course is Credit System based. For each Module, the candidates will be assigned credits for their work by respective Faculty/Institute.

Total Credits: 300

Minimum Number of Credits for successful completion of programme:-240 credits

Breakup of credits
- **For each Module (or week) 20 credit points (Total of 100 credits)**

  Throughout the course student will be evaluated through questions, observing the understanding, etc. Credits will be allotted at the end of each module.
- **Research Project work (100 credit point)**
  Fellow has to design and conduct a research/study project on a research question under faculty guidance and present/publish and submit it to MUHS.
- **Theory: (50 Credit points) MCQs**
- **Practicals (50 credit points)**

  1. Exam on Biostatistics. (**25 credit points)**
  2. Discussion on journal article (**10 credit points)**
  3. Viva (**15 credit points)**
  15. **Announcement of results**

     Results will be announced on the website and notice board within one week of the conclusion of the examination.

  16. **Award of Fellowship**

     Certificates will be awarded by the DYPU