### Name of Institute: INDUS UNIVERSITY- IISHLS (Institute of science Humanities and liberal studies)

### Name of Faculty: Dr. Anokhi shah

Pharmacovigilance-II

Course code: **PCR0303**

Course name: **Msc clinical Research**

Pre-requisites: Basic understanding and knowledge of clinical research

Credit points: 4 credits

Offered Semester:

**Course Coordinator**

Full Name:Dr. Anokhi shah

Department with siting location: 4thfloor Bhawar building, class 11

Telephone: 9974702063

### Email:anokhishah.cr@indusuni.ac.in

Consultation times:Monday to Friday 3 to 4 pm

**Course Lecturer**

Full name:Dr.Anokhi shah

Department with siting location: 4thfloor Bhawar building, class 11

Telephone: 9974702063

Email:Anokhishah.cr@indusuni.ac.in

Consultation times: Monday to Friday 3 to 4 pm

Students will be contacted throughout the Session via Mail with important information relating to this Course.

# Course Objectives

By participating in and understanding all facets of this Course a student will:

 To learn about Advance inclinical data managementapplications.

Course Outcomes (CO)

After successful completion of course, student will able to understand,

* Pharmacovigilance and its work processes.
* Signal detection methods, case processing, safety data collection tools
* Medical Dictionaries used in Clinical Research.

Course Outline

(Key in topics to be dealt)

Course Content**:**

**UNIT 1: OVERVIEW ON PHARMACOVIGILANCE**

Introduction to Pharmacovigilance, Key Definitions in Pharmacovigilance, Pharmacovigilance Historical Perspective, Pharmacovigilance need and Objectives, Pharmacovigilance and Pharmacogenetics, Current methods in Pharmacovigilance. Adverse drug reactions and SAE criteria, Post Marketing Surveillance.

**UNIT 2: SIGNAL DETECTION IN PHARMACOVIGILANCE**

Signal generation, Signal Strengthening, Signal testing, Evaluation and Explanation, Sources and methods of signal detection, Spontaneous reporting system, Intensive Hospital- Based drug surveillance system, Prescription event monitoring, Case reports in literature, Epidemiology studies, Role of national pharmacovigilance centers in signal detection, automated quantitative signal detection, WHO adverse drug reaction database-VIGIBASE, application of quantitative methods for signal detection, Bayesian confidence propagation neural network (BCPNN), Measures of Disproportionality in technical terms, the UMC signalling process, WHO and UMC’s leadership in signal detection.

**UNIT 3: ADVERSE DRUG REACTIONS**

Adverse event, Adverse drug reaction, Importance of adverse drug reactions, Pharmacological Classification- Type A, B, C, D, E, F, Causality Classification (WHO-UMC Classification), Severity Classification, Seriousness Classification, Frequency Classification, Mechanism Classification, Statistical Classification, Mechanism of Adverse drug reactions- Type A reactions, Type B reactions. Adverse drug interactions, Classification of Adverse Drug interactions- Pharmacodynamic interactions, Pharmacokinetic Interactions and Pharmaceutical Interactions.

**UNIT 4: CASE PROCESSING**

Adverse event case processing- Introduction, Sources of individual case safety reports- Unsolicited sources, Solicited sources, Contractual Agreements, Regulatory authority as the sources, Criteria for reporting, Good adverse events Case processing practices- assessing patient and reporter identifiability, Consent and data privacy, efficient handling of adverse events data, Case processing principles, workflow in adverse events case processing operations.

**UNIT 5: PROCESSES AND REGULATIONS IN PHARMACOVIGILANCE**

Benefits risk assessment in Pharmacovigilance, MedDRA- overview, objectives of MedDRA, Applications of MedDRA, Regulatory status/Historical Overview, Medra structure, Lowest Level Term (LLT), High Level Term (HLT), Preferred Term (PT), System Organ Class (SOC), MedDRA rules, Criteria for term selection, Standardized MedDRA queries (SMQS), MedDRA and SMQ in signal detection. Pharmacovigilance regulations in various Countries-Europe, United Kingdom, France, Brazil, India, China, Japan, Australia, Canada, and USA, WHO Pharmacovigilance Programme for Global monitoring, Pharmacovigilance of Herbal drugs, Crisis management

# Method of delivery

1. Face to face lectures
2. PPT/Video presentation/
3. Class activities
4. Article presentation
5. Seminar presentation

# Study time

4 hours/week

# Blooms Taxonomy and Knowledge retention(For reference)

(Blooms taxonomy has been given for reference)



Figure 1: Blooms Taxonomy



Figure 2: Knowledge retention

# Graduate Qualities and Capabilities covered

(Qualities graduates harness crediting this Course)

|  |  |
| --- | --- |
| **General Graduate Qualities** | **Specific Department of \_\_\_\_\_\_Graduate Capabilities** |
| **Informed**Have a sound knowledge of an area of study or profession and understand its current issues, locally and internationally. Know how to apply this knowledge. Understand how an area of study has developed and how it relates to other areas. | **1 Professional knowledge, grounding & awareness:**Student will be able to learn regarding different application of clinical Data management, startup phase and process of data Management. |
| **Independent learners**Engage with new ideas and ways of thinking and critically analyze issues. Seek to extend knowledge through ongoing research, enquiry and reflection. Find and evaluate information, using a variety of sources and technologies. Acknowledge the work and ideas of others. | **2 Information literacy, gathering & processing**Student will be able to learn and createDifferent CRF designing and application could be done in different phases of trial. |
| **Problem solvers**Take on challenges and opportunities. Apply creative, logical and critical thinking skills to respond effectively. Make and implement decisions. Be flexible, thorough, innovative and aim for high standards. | **4 Problem solving skills**Student will be able to learn problem solving skill by solving queries in project and can use easy software Handling. |
| **Effective communicators**Articulate ideas and convey them effectively using a range of media. Work collaboratively and engage with people in different settings. Recognize how culture can shape communication. | **5 Written communication** |
| **6 Oral communication** |
| **7 Teamwork**Students can learn in industry with practical approach and in team work with user department and in collaboration with different stakeholders. |
| **Responsible**Understand how decisions can affect others and make ethically informed choices. Appreciate and respect diversity. Act with integrity as part of local, national, global and professional communities.  | **10 Sustainability, societal & environmental impact**Students can understand importance of data and application finally in drug research In the Pharmaceutical industry. |

# Practical work:

Document preparation

Case studies in clinical trials

# Lecture/tutorial times

(Give lecture times in the format below)

4 Lectures/week

# Attendance Requirements

The University norms states that it is the responsibility of students to attend all lectures, tutorials, seminars and practical work as stipulated in the Course outline. Minimum attendance requirement as per university norms is compulsory for being eligible for mid and end semester examinations.

# Details of referencing system to be used in written work

Mind maps of Pharmacovigilance Basics- Amrita Akhouri, 2015 edition.

# Text books

Highlights of Pharmacovigilance – P.G Yeolo ,DhanalakshmiIyer, 2013 edition.

**Additional Materials**

Notes and PPT assessment guidelines

Your final course mark will be calculated from the following:

**Assessment guidelines**

|  |
| --- |
| Subject : Pharmacovigilance – II |
| Program : M.Sc. Clinical Research  | Subject Code :PCR0303 | Semester : III |
|  |
| Teaching Scheme | Examination Evaluation Scheme |  |
| Lecture | Tutorial | Practical | Credits | University Theory Examination | University Practical Examination | Continuous Internal Evaluation (CIE)- Theory | Continuous Internal Evaluation (CIE) - Practical | Total |
| 4 | 0 | 0 | 4 | 40 |  | 60 |  | 100 |

# Mid sem exam 40 marks Attendance 05 marks Presentation 05 marks Assignment 1 05 marks Assigment 2 05 marks Final exam 40 marks

# SUPPLEMENTARY ASSESSMENT

Students who receive an overall mark less than 40% in mid semester or end semester will be considered for supplementary assessment in the respective components (i.e mid semester or end semester) of semester concerned. Students must make themselves available during the supplementary examination period to take up the respective components (mid semester or end semester) and need to obtain the required minimum 50% marks to clear the concerned components.

# Practical Work Report/Laboratory Report:

A report on the practical work is due the subsequent week after completion of the class by each group.

# Late Work

Late assignments will not be accepted without supporting documentation. Late submission of the reports will result in a deduction of -% of the maximum mark per calendar day

# Format

All assignments must be presented in a neat, legible format with all information sources correctly referenced. **Assignment material handed in throughout the session that is not neat and legible will not be marked and will be returned to the student.**

# Retention of Written Work

Written assessment work will be retained by the Course coordinator/lecturer for two weeks after marking to be collected by the students.

# University and Faculty Policies

Students should make themselves aware of the University and/or Faculty Policies regarding plagiarism, special consideration, supplementary examinations and other educational issues and student matters.

**Plagi**a**rism** - Plagiarism is not acceptable and may result in the imposition of severe penalties. Plagiarism is the use of another person’s work, or idea, as if it is his or her own - if you have any doubts at all on what constitutes plagiarism, please consult your Course coordinator or lecturer. Plagiarism will be penalized severely.

***Do not copy the work of other students.***

***Do not share your work with other students (except where required for a group activity or assessment)***

***.***

# Course schedule(subject to change)

**(Mention quiz, assignment submission, breaksetc.as well in the table under the Teaching Learning Activity Column)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Week #**  | **Topic & contents**  | **CO Addressed** | **Teaching Learning Activity (TLA)** |
|  | Weeks 1 | Introduction to Pharmacovigilance | Presentation material | PPT/Notes |
| Weeks 2 | Key Definitions in Pharmacovigilance, Pharmacovigilance Historical Perspective, | Presentation material | PPT/Notes |
| Week 3 | Current methods in Pharmacovigilance. Adverse drug reactions and SAE criteria, Post Marketing Surveillance.  | Presentation material | PPT/Notes |
| Week 4 | centers in signal detection, automated quantitative signal detection | Presentation material | PPT/Notes |
| Week 5 | WHO adverse drug reaction database-VIGIBASE, application of quantitative methods for signal detection | Presentation material | PPT/Notes |
|  |  |
|  | Week 6 | Adverse event, Adverse drug reaction, Importance of adverse drug reactions, Pharmacological Classification- Type A, B, C, D, E, F | Presentation material | PPT/Notes |
| Week 7 | Adverse event case processing- Introduction, Sources of individual case safety reports-  | Presentation material | PPT/Notes |
| Week 8 | Consent and data privacy, | Presentation material | PPT/Notes |
| Week 9 | Benefits risk assessment in Pharmacovigilance | Presentation material | PPT/Notes |
|  | Week 10 | Regulatory status/Historical Overview, Medra structure, Lowest Level Term (LLT), High Level Term (HLT), Preferred Term (PT), System Organ Class (SOC | Presentation material | PPT/Notes |
| Week 11 | Pharmacovigilance regulations in various Countries-Europe, United Kingdom, France, Brazil, India, China, Japan, Australia, Canada, and USA,  | Presentation material | PPT/Notes |
|  | Week 12 |  WHO Pharmacovigilance Programme for Global monitoring, Pharmacovigilance of Herbal drugs, Crisis management | Presentation material | PPT/Notes |