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

### Name of Faculty: Dr. Anokhi shah

### Clinical Data Management

Course code: UCR0502

Course name: **B.SC CLINICAL RESEARCH AND HEALTHCARE MANAGEMENT**

Pre-requisites: Basic understanding and knowledge of clinical research

Credit points: 3 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:

1 To learn about Advance inclinical data managementapplications.

Course Outcomes (CO)

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

* Creating data repository for reference, compliance & retrieval.
* To learn about different types of coding dictionaries
* To learn about types and queries and management

Course Outline

(Key in topics to be dealt)

**Course Content:**

**Unit 1 Introduction to Clinical Data Management and SOPs**

Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management, review and authorization. CRF design , Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs. Database design and build ,Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen validation, data entry process, symbols, data entering. Guidelines and regulations in Clinical Trial data.

**Unit 2 Medical Coding, Query Management**

Introduction, Types of dictionaries, types of Coding

Types of queries, Management of queries, SAE reconciliation.

**Unit 3 Quality control of clinical data**

Terminology and definitions, quality control process, data errors and quality measurement, responsibilities, operational QC, data management matrix, QA in Clinical data management.

**Unit 4 Electronic data management and Database lock**

Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices.

Electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives, Lab data loading -Roles and responsibilities of lab loader technician, helpdesk, study coordinator, -loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously.

# Method of delivery

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

# Study time

3 hours/week

# Blooms Taxonomyand 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 create  Different 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)

3 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

* Fundamentals of Database Systems. By Ramez Elmasri, Shamkant B. Navathe, T. Benjamin. 2nd edition, 2002.
* Database System Concepts By Henry F. Korth, Abrabam Silberchatz, Mc Graw Hill. 4th edition, 2002.

An Introduction to Database Systems. By C.J. Date, Addison Wesley. 7th edition, 2003.

# Text books

# Database Management and Design. By Gary W. Hansen, James V. Hansen, Prentice Hall, 2nd edition

**Additional Materials**

Notes and PPT assessment guidelines

Your final course mark will be calculated from the following:

**Assessment guidelines**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject : Clinical Data Management** | | | | | | | | | |
| **Program : B.Sc-Clinical Research and Healthcare Management** | | | **Subject Code : UCR0502** | | | **Semester : V** | | | |
|  | | | | | | | | | |
| **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** | |
| 3 | 0 | 0 | 3 | 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 CDM, Basic terminologies | | | Presentation material | | PPT/Notes |
| Weeks 2 | definitions and Glossary, Importance of CDM | | | Presentation material | | PPT/Notes |
| Week 3 | Data privacy, Data Management standards in clinical research | | | Presentation material | | PPT/Notes |
| Week 4 | Design and development of data collection instruments | | | Presentation material | | PPT/Notes |
| Week 5 | Electronic data capture. | | | Presentation material | | PPT/Notes |
|  | | |  | | | | |
|  | Week 6 | Start Up: Protocol review, CRF design, Annotation of CRF, Data base build process- eCRF validation | | Presentation material | | PPT/Notes | |
| Week 7 | Home page, System Settings, Authorized User List, Report data Extract/Source Data Extract, Edit check specifications, Edit Check Validation, | | Presentation material | | PPT/Notes | |
| Week 8 | Test case creation. Database GoLive, preparation of DMP documents. | | Presentation material | | PPT/Notes | |
| Week 9 | Conduct: Dataset Validation process, Manual query writing | | Presentation material | | PPT/Notes | |
|  | Week 10 | Discrepancy management, Lab data reconciliation, SAE reconciliation, Non-eCRF validation process | | Presentation material | | PPT/Notes | |
| Week 11 | Close-out: Close out Checklist, Burning of trial data, Archiving process. | | Presentation material | | PPT/Notes | |
|  | Week 12 | Training, assurance data quality, measuring data quality, DMP, Designing CRF, eCRF Completion Guidelines, SAE Reconciliation, Lab Reconciliation, Query Management, Edit Check Specification Logic, | | Presentation material | | PPT/Notes | |