

# University of Mumbai



AAMS\_UGS /ICC/2022-23/ 84

## CIRCULAR:-

Sub :- Certificate Course in Clinical Data Management.

Ref :- RB/MU-2022/CR-207/Edn-5/899, dated 18<sup>th</sup> August, 2022.

All the Principals of the Affiliated Colleges, the Head of the University Department and Directors of the recognized Institutions in Faculty of Science and Technology are hereby informed that the recommendations made by the Ad-hoc Board of Studies in **Pharmacy** at its online meeting held on 17<sup>th</sup> March, 2022 vide item No. 1 and subsequently passed in the faculty of Science and Technology and then by the Board of Deans at its online meeting held on 2<sup>nd</sup> May, 2022 vide item No. 6.3(N) have been accepted by the Academic Council at its meeting held on 17<sup>th</sup> May, 2022, vide item No. 6.6 (N) and subsequently approved by the Management Council at its meeting held on 25<sup>th</sup> May, 2022 vide item No. 4 and that in accordance therewith, in exercise of the powers conferred upon the Management Council under Section 74(4) of the Maharashtra Public Universities Act, 2016 (Mah. Act No. VI of 2017) the Ordinance 6795 & 6796 Regulations 9555 to 9557 and the syllabus of **Certificate Course in Clinical Data Management** has been introduced and the same have been brought into force with effect from the academic year **2022-23**, accordingly. (The same is available on the University's website [www.mu.ac.in](http://www.mu.ac.in)).

MUMBAI – 400 032

20<sup>th</sup> August, 2022

To,

(Dr. Vinod Patil)  
I/c. REGISTRAR

The Principals of the Affiliated Colleges, the Head of the University Department and Directors of the recognized Institutions in Faculty of Science and Technology.

A.C/6.6(N)/17/5/2022

M.C/4/25/5/2022

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20<sup>th</sup> August, 2022

Copy forwarded with Compliments for information to:-

- 1) The Chairman, Board of Deans
- 2) The Dean, Faculty of Science and Technology,
- 3) The Chairman, Ad-hoc Board of Studies in Pharmacy,
- 4) The Director, Board of Examinations and Evaluation,
- 5) The Director, Board of Students Development,
- 6) The Director, Department of Information & Communication Technology,
- 7) The Co-ordinator, MKCL.

(Dr. Vinod Patil)  
I/c. REGISTRAR

**Copy to :-**

- 1. The Deputy Registrar, Academic Authorities Meetings and Services (AAMS),**
- 2. The Deputy Registrar, College Affiliations & Development Department (CAD),**
- 3. The Deputy Registrar, (Admissions, Enrolment, Eligibility and Migration Department (AEM),**
- 4. The Deputy Registrar, Research Administration & Promotion Cell (RAPC),**
- 5. The Deputy Registrar, Executive Authorities Section (EA),**
- 6. The Deputy Registrar, PRO, Fort, (Publication Section),**
- 7. The Deputy Registrar, (Special Cell),**
- 8. The Deputy Registrar, Fort/ Vidyanagari Administration Department (FAD) (VAD), Record Section,**
- 9. The Director, Institute of Distance and Open Learning (IDOL Admin), Vidyanagari,**

**They are requested to treat this as action taken report on the concerned resolution adopted by the Academic Council referred to in the above circular and that on separate Action Taken Report will be sent in this connection.**

- 1. P.A to Hon'ble Vice-Chancellor,**
- 2. P.A Pro-Vice-Chancellor,**
- 3. P.A to Registrar,**
- 4. All Deans of all Faculties,**
- 5. P.A to Finance & Account Officers, (F.& A.O),**
- 6. P.A to Director, Board of Examinations and Evaluation,**
- 7. P.A to Director, Innovation, Incubation and Linkages,**
- 8. P.A to Director, Board of Lifelong Learning and Extension (BLLE),**
- 9. The Director, Dept. of Information and Communication Technology (DICT) (CCF & UCC), Vidyanagari,**
- 10. The Director of Board of Student Development,**
- 11. The Director, Department of Students Welfare (DSD),**
- 12. All Deputy Registrar, Examination House,**
- 13. The Deputy Registrars, Finance & Accounts Section,**
- 14. The Assistant Registrar, Administrative sub-Campus Thane,**
- 15. The Assistant Registrar, School of Engg. & Applied Sciences, Kalyan,**
- 16. The Assistant Registrar, Ratnagiri sub-centre, Ratnagiri,**
- 17. The Assistant Registrar, Constituent Colleges Unit,**
- 18. BUCTU,**
- 19. The Receptionist,**
- 20. The Telephone Operator,**
- 21. The Secretary MUASA**

**for information.**

AC - 17/05/2022

Item No. 6.6 (N)

# **UNIVERSITY OF MUMBAI**



## **Syllabus** **For** **Certificate Course in** **Clinical Data Management**

(To introduce with effect from the academic year 2022-23)



## UNIVERSITY OF MUMBAI



### Syllabus for Approval

Sr. No.	Heading	Particulars
1	Title of the Course 0.6795	Certificate Course in Clinical Data Management
2	Eligibility for Admission 0.6796	A candidate for being eligible at admission to the Certificate Course in 'Clinical Data Management' must be student pursuing UG/ PG / Ph.D. program in Pharmacy; preferably completed two years of a graduation program in Pharmacy.
3	Passing Marks R.9555	50%
4	Ordinances / Regulations ( if any)	----
5	No. of Years /Semesters / Duration of Course	30 Hours
6	Level	Certificate/Diploma/UG/PG ( Strike out which is not applicable)
7	Pattern	Not Applicable
8	Status	Revised/ New / Amended ( Strike out which is not applicable)
9	To be implemented from Academic Year	From Academic Year : 2022-2023

Date:

Signature:

*Supriya Shidhaye*

**Name: Prof. Supriya Shidhaye**  
Chairman of BoS of Pharmacy

Signature:

*Anuradha Majumdar*

**Dr. Anuradha Majumdar**  
Dean, Science and Technology

## PREAMBLE

**This is with reference to the AICTE Initiative & University of Mumbai guidelines, Clinical Data Management (CDM), thirty hours Value added certificate course** is introduced from the academic Year 2022-23. The students may take up this course as value-added certificate course offered by their institute while pursuing their education in pharmacy.

The Primary aim and scope of this 30 hours certificate course is to impart specific skills that students must acquire during their academic program with the aim of preparing well-rounded learners and to make the candidates employable as entry level resources in the domains of Clinical Data management, Pharmacovigilance/drug safety in BPOs, Pharmaceutical companies, Contract Research Organizations (CROs). The Program will serve as a sound introduction to the CDM domain for Pharmacy students even if they plan on not joining the domain in their industry career. The syllabus for the course shall be subjected to revision after every three years.

**O.6795: Title of Course**

"Certificate Course in Clinical Data Management"

**O.6796: Eligibility**

A candidate for being eligible at admission to the Certificate Course in 'Clinical Data Management' must be student pursuing UG/ PG / Ph.D. program in Pharmacy; preferably completed two years of a graduation program in Pharmacy.

**R.9556: Duration of Course**

30 Hours

**R.9557: Intake Capacity:**

Maximum 45 candidates in one batch

**Teachers:** Subject experts from HEIs and industry having the domain knowledge.

**Regulation: Fees**

It is an autonomous value-added paid course conducted at the Institution level. Examination will be conducted by the Institute and certificate will be issued by the Institute. However, the certificate will be jointly signed by the principal and Director, BOEE with logos of both organisation appearing on the certificate. All financial aspects will be taken care by the institution running the course. There won't be any provision for sharing of fees with University of Mumbai.

### EXAMINATION/ ASSESSMENT AND GRADING:

The certificate course shall be conducted at the Institute level. The institute shall conduct an examination and issue a certificate of completion of the course with credits assigned.

Performance assessment of every registered learner is to be carried out through various modes of examinations. These include Internal Assessment and Course Completion Exam.

**Table-1: Scheme for Assessment**

Nature of Assessment	Nomenclature	Maximum Marks
Internal Assessment/ Continuous Mode of Assessment: to be conducted intermittently during the course conduction	Quiz 1	10
	Quiz 2	10
	Quiz 3	10
	Quiz 4	10
Course Completion Exam: to be conducted upon completion of the course	Course Completion Exam	60
	Total	100

#### Paper pattern for Internal Assessment i.e. Quiz

##### Question paper pattern for Quiz:

I. Multiple Choice Questions (MCQs) [Duration: 20 Mins] = 10 x 1 = 10

(Answer all the questions)

Total = 10 marks

#### Paper pattern for Course Completion Exam

##### Question paper pattern for Course Completion Exam:

MCQs: (Answer all the questions) [Duration: 60 Mins] = 30 x 2 = 60

Total = 60 marks

### GRADING OF PERFORMANCES

- Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the completion of the course. The letter grades and their corresponding grade points are given in Table – 2.

**Table – 2: Letter grades and grade points equivalent to Percentage of marks and performances**

Percentage of Marks Obtained	Letter Grade	Performance
90.00 – 100	O	Outstanding
80.00 – 89.99	A	Excellent
70.00 – 79.99	B	Good
60.00 – 69.99	C	Fair
50.00 – 59.99	D	Average
Less than 50	F	Fail
Absent	AB	Fail

A learner who remains absent for Course Completion Examination shall be assigned a letter grade of AB and a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

### CRITERIA FOR AWARD OF THE CERTIFICATE:

A student shall be declared **PASS** and eligible for getting the certificate of completion of the course if he/she secures at least **50%** marks in the course out of total 100 marks. There is no separate criteria for passing in individual head of assessment.

The list of the students successfully completing the certificate course will be submitted by the host institute to University of Mumbai along with the certificate signed by the head of the host institute. The certificate will be jointly signed by the head of the host institute and Director, Board of examination and evaluation and will bear logo of both- host institute and University of Mumbai.

The detailed syllabus of the **Clinical Data Management (CDM)** certificate course is given in the consequent section of this document.

Dr. Anuradha Majumdar (Dean, Science and Technology)

Prof. Shivram Garje (Associate Dean, Science)

Prof. Supriya Shidhaye (Chairperson BoS)

Dr. Shrirang Joshi (Member BoS)

Prof. K.G. Akamanchi (Member BoS)

Prof. Krishna Iyer (Member BoS)

Prof. Rajani Athawale (Member BoS)

Dr. Mohan Kale (Member BoS)

Dr. Meena Kanyalkar (Member BoS)

### **Clinical Data Management (CDM)**

(Total Hours- 30)

<b>Course Code</b>	<b>Course Name</b>	<b>Credits</b>
<b>PH-CDM</b>	<b>Clinical Data Management (CDM)</b>	<b>03</b>

- **Prerequisites:** Basic understanding of diseases (Pathology), Pharmacology and Clinical Research.
- **Course Outcomes: After completion of this course students should be able to:**
  - Demonstrate in depth understanding concepts of CDM and its importance, relevance and execution in the ambit of clinical development.
  - Demonstrate knowledge about the use of suitable data management tools for the generation of high-quality, reliable, and statistically sound data from clinical trials.

This will make them employable in the clinical research associated sponsor, CRO and BPO companies for jobs associated with CDM.

<b>Unit no.</b>	<b>Course content (topics and subtopics)</b>	<b>Hours</b>
<b>1</b>	<b>Introduction to Clinical Data Management (CDM):</b> <ul style="list-style-type: none"> <li>• Principles of CDM</li> <li>• Data and databases</li> <li>• Electronic data capture</li> <li>• Data Entry</li> <li>• Transcribing data</li> <li>• Queries &amp; Data Clarification</li> <li>• Software in CDM</li> </ul>	<b>4</b>
<b>2</b>	<b>Data management plan</b>	<b>2</b>
<b>3</b>	<b>Clinical Data Management System</b> (Preferably demonstrated using suitable Electronic Database Management System)	<b>2</b>
<b>4</b>	<b>Clinical data repositories</b>	<b>2</b>
<b>5</b>	<b>Loading of external data into CDM system</b>	<b>1</b>
<b>6</b>	<b>Query management</b>	<b>1</b>
<b>7</b>	<b>Data clarification form</b>	<b>1</b>
<b>8</b>	<b>Remote data entry</b>	<b>1</b>
<b>9</b>	<b>Clinical data entry – single, double, SAE reconciliation, coding of Adverse events</b>	<b>4</b>
<b>10</b>	<b>Data cleaning and data validation</b>	<b>1</b>
<b>11</b>	<b>Analysis Data model (ADaM) and STDM (Study Data Tabulation Model)</b>	<b>2</b>
<b>12</b>	<b>Working with missing values, outliers, start and end dates</b>	<b>1</b>
<b>13</b>	<b>Data base lock (DLP)</b>	<b>1</b>
<b>14</b>	<b>System validation</b>	<b>1</b>
<b>15</b>	<b>eCRF designing &amp; data tracking</b>	<b>2</b>
<b>16</b>	<b>Clinical data archiving</b>	<b>1</b>
<b>17</b>	<b>CDM Service Level Agreement (SLA)</b>	<b>1</b>
<b>18</b>	<b>Quality Assurance (QA) in CDM</b>	<b>2</b>
	<b>Total</b>	<b>30</b>

#### **Reference books:**

1. Practical Guide to Clinical Data Management, Third Edition by Susanne Prokscha
2. Data Management for Researchers: Organize, maintain and share your data for research success (Research Skills) Paperback – September 1, 2015 by Kristin Briney
3. <https://www.scdm.org/publications/gcdmp/> (several publications are available on SCDM website for free or for nominal fee if you join as a member)
4. Research Data Management: Practical Strategies for Information Professionals (Charleston Insights in Library, Information, and Archival Sciences) by Joyce M. Ray
5. Latest Regulatory Guidelines related to CDM and Clinical Data Reporting.



**(Appendix 'B')**

**New ordinances 6795 & 6796 relating to the  
Certificate Course in Clinical Data Management**

<b>1</b>	<b>Necessity of starting these courses</b>
	<p>The primary aim and scope of suggesting value-added course under mentioned are to boost the employability of the B. Pharm students and to help them to be at par with global trends and global technology.</p> <p>‘Clinical data Management Course (CDM)’ for Pharmacy students is to make the candidates employable as entry-level resources in the domains of Clinical Data management, Pharmacovigilance/drug safety in BPOs, Pharmaceutical companies, Contract Research Organizations (CROs). The Program will serve as a sound introduction to the CDM domain for Pharmacy students even if they plan on not joining the domain in their industry career.</p>
<b>2</b>	<b>Whether UGC has recommended to start the said courses?</b>
	<p>UGC Quality mandate states that to ensure holistic development of the students at the university/college level, efforts need to be made to reorient the teaching pattern with a focus on all types of courses including Elective courses — chosen by students from other departments as per their aptitude. UGC Quality mandate mentions Learning Outcome-based Curriculum Framework (LOCF) — revision of curriculum in regular intervals. Under this objective, UGC suggests that HEIs should boost the employability of graduates through curriculum reform.</p> <p>National Education Policy (chapter 20.5) mentions –“India must also take the lead in preparing professionals in cutting-edge areas that are fast gaining prominence, such as Artificial Intelligence (AI), 3-D machining, big data analysis, and machine learning, in addition to genomic studies, biotechnology, nanotechnology, neuroscience, with important applications to health, environment, and sustainable living that will be woven into undergraduate education for enhancing the employability of the youth”</p>
<b>3</b>	<b>Whether all the courses have commenced from the academic year 2022-23?</b>
	<p>It is proposed to be introduced from academic year 2022-23. Since it is a value-added course, not confined within the framework of syllabus of B. Pharm/ M. Pharm / Ph.D. for award of degree or credit transfer, any affiliated Pharmacy college can conduct the course based on the availability of the resource persons and interest of the students. Students may take up the course as per their interests. Any student pursuing UG/ PG / Ph.D. program in Pharmacy is eligible for admission to this course. The course can be taken anytime, preferably upon completion of the second year B. Pharm</p>
<b>4</b>	<b>The courses started by the University are self-financed, whether adequate number of eligible permanent faculties are available?</b>

	It is a paid course. It is optional for the UOM-affiliated colleges to conduct the course at their respective institutions. It is an autonomous value-added course independent of the student-teacher ratio and may be delivered by guest faculty from HEIs and Industry.
<b>5</b>	<b>To give details regarding duration of the Course and is it possible to compress the course?</b>
	<ul style="list-style-type: none"> <li>• Duration: 30 Hours</li> <li>• This is the minimum duration required and not recommended for further compression.</li> </ul>
<b>6</b>	<b>The intake capacity of each course and number of admissions given in the current academic year 2022-23?</b>
	Batch size should be ideally restricted to maximum 45 to increase the effectiveness of the course. The course is proposed to be introduced from academic year 2022-23
<b>7</b>	<b>Opportunities of employability / employment available after undertaking these courses.</b>
	Clinical Data management, Pharmacovigilance/drug safety in BPOs, Pharmaceutical companies, Contract Research Organizations (CROs), etc.

  
**Signature –**  
**Dr. Supriya Shidhaye,**  
**Chairman, Ad-hoc Board of Studies in Pharmacy**  
**Under the faculty of Science and Technology**