



# R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

20/06/2018

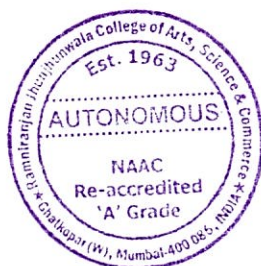
## ADMISSION NOTICE FOR POST GRADUATE DIPLOMA PROGRAMS 2018-2019

### DEGREE COLLEGE

The admissions of Post Graduate Diploma programs in-

1. Dietetics and Applied Nutrition
2. Regulatory Affairs
3. Clinical Studies Data Management and Medical Writing
4. Horticulture and Landscape Designing

will commence from 1<sup>st</sup> July 2018. Students must fill the form. The eligibility criteria and fee structure is available on the college website. Admission will be on fulfilment of criteria. Students must pay the fees.



*Ushra*  
Principal

PRINCIPAL  
RAMNIRANJAN JHUNJHUNWALA COLLEGE  
OF ARTS, SCIENCE & COMMERCE (AUTONOMOUS)  
Ghatkopar (W), Mumbai-400 086, Maharashtra, INDIA

2019: Star College Status by DBT

2008: Best College by University of Mumbai 2010: IMC RBNQ Award 'Performance Excellence' for the year 2009

2011: 'Best Teacher Award' by Government of Maharashtra 2013: DST-FIST 2014: DBT STAR College

2013 & 2014: 'Jagar Jaanivancha Award' by Govt, of Maharashtra 2016: ISO 14001:2015 2016: ISO 9001:2015 2017: ISO 27001:2013

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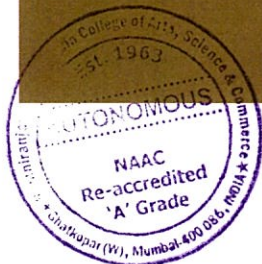
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## BROCHURE



# Postgraduate Diploma in

## Clinical Studies, Data Management & Medical Writing



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Academic Council 25/05/2011

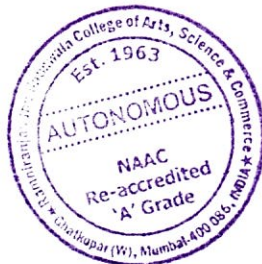
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## UNIVERSITY OF MUMBAI



**Syllabus for Clinical Studies  
Program: Diploma  
Course: Post Graduate Diploma  
in  
Clinical Studies, Data Management & Medical  
Writing**

(Introduced as per Credit Based Semester and  
Grading System with effect from the academic  
year 2011–2012)



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- O Title** : Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing
- O Eligibility** : Bachelor Degree in Life Science or Biotechnology or Chemistry or Statistics
- R Duration of the Course** : One Year (Full Time/)
- R Fee Structure** : Rs. 30000/-
- R Intake Capacity** : 40 Students
- R Teacher Qualifications** : Completed Course in Clinical Studies and Experts from Clinical Research or Pharma industry
- R Standard of Passing** :
- Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
  - A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
  - Candidate can carry forward at his/her option the marks in the paper in which he/she has passed, in such a case student is entitled for award of class.
  - Candidate who secures a minimum of 50% marks in each paper and an aggregate of 60% and above marks on the whole shall be declared to have passed the examination in the First Class.
  - Candidate who secures a minimum of 50% marks in each paper and an aggregate of 70% and above marks on the whole shall be declared to have passed the examination in First Class with Distinction.
- Medium of Instruction** : English
- Field Visit** : Clinical Research Organizations



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## Syllabus for Post Graduate Diploma

in

### Clinical Studies, Data Management and Medical Writing Scheme of Examination

PAPER	TITLE OF PAPER	MAXIMUM MARKS	MINIMUM MARKS	Credits	PAPER CODE
I	Clinical Pharmacology	100	50	8 Credits	PGDCS001
II	Good Practices & Regulations	100	50	8 Credits	PGDCS002
III	Clinical Trial Process	100	50	8 Credits	PGDCS003
IV	Drug Safety & Pharmacovigilance	100	50	8 Credits	PGDCS004
V	Data Management & Medical Writing	100	50	8 Credits	PGDCS005
VI	Management Skills	100	50	8 Credits	PGDCS006
	TOTAL	600	300	48 Credits	

(All papers include theory, viva, project and case studies)

## Syllabus for Post Graduate Diploma

in

### Clinical Studies, Data Management and Medical Writing

Paper I	: Clinical Pharmacology
Paper II	: Good Practices & Regulations
Paper III	: Clinical Trial Process
Paper IV	: Drug Safety & Pharmacovigilance
Paper V	: Data Management & Medical Writing
Paper VI	: Management Skills



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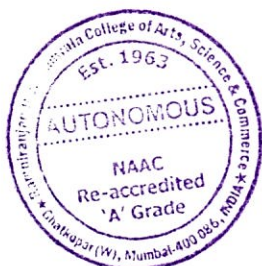
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## Paper I : Clinical Pharmacology

8 Credits

1. **Pharmaceutical Industry & globalization** –Overview, Opportunities & Career options in Clinical Research
2. **Pharmacy** - Physico-Chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs.
3. **Therapeutics** - Principles of Management & Drug Therapy
4. **Pharmacokinetics** - Absorption, bioavailability, distribution, metabolism protein binding, excretion, placental and blood brain barrier
5. **Pharmacodynamics** - Mechanism of drug action, receptors, agonists, antagonists, side effects and adverse events
6. **Toxicology** - Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenicity, Oncogenicity and effects on fertility
7. **BA/BE Studies** - Bioavailability and Bioequivalence - Methods and Procedures, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability



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## Paper II : Good Practices & Regulations

8 Credits

GMP

GLP

ICH GCP

Ethics in Clinical Research

Regulation in India : Drugs and Cosmetics Act, Schedule 'Y'. Quality in Regulatory

Context, Patent laws

USFDA : History, Structure & Function, Code of Federal Regulation

EMA : History, Structure & Function, Regulations

JAPAN : History, Structure & Function

ICMR : Overview

## Paper III : Clinical Trial Process

8 Credits

1. Responsibilities of Stakeholders : Sponsors, Investigators, CROs, Monitors
2. Clinical Trial Design
3. Clinical Trial Phase I
4. Clinical Trial Phase II
5. Clinical Trial Phase III
6. Clinical Trial Phase IV
7. Essential Documents in Clinical Trials : SOP, Protocol, Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form
8. Managements of Clinical Trials - Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies
9. Trial Budget, Audit and Inspection



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## Paper IV : Drug Safety & Pharmacovigilance

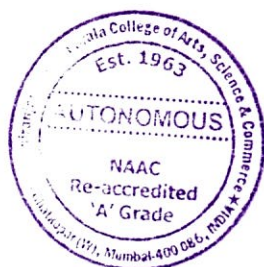
8 Credits

1. **Principles of Pharmacovigilance** : Importance; National & International Programs; Methods
2. **Principles of Pharmacovigilance** : ADR; Assessment; Medication errors, Signal detection; Risk assessments
3. **Drug Dictionaries**: Coding & Tools
4. **Regulatory Guidelines** : ICH, EMEA, USFDA, Sch. 'Y'
5. **Drug Safety** : PSURs; Package inserts

## Paper V : Data Management & Medical Writing

8 Credits

1. **Bio-Statistics : Descriptive Statistics** : Data Types; Collection; Sampling, Compilation; Tables & Graphs. Measures of Central Tendency, Measures of variation
2. **Bio-Statistics : Analytical Statistics** : Overview, hypothesis testing in CR
3. **Clinical Data Management** : Principles of CDM, Data Entry, Queries & Data Clarification, Softwares in CDM
4. **Medical Writing** : Literature Search & Medical Articles, Contract writing, Publication, Abstracts, Bibliography, Clinical Study Reports





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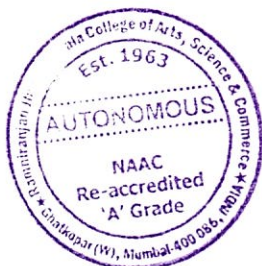
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## Paper VI Management Skills

8 Credits

1. Principles of Management
2. Management & relevance to CR
3. Introduction to Organization behavior
4. Introduction to Marketing
5. Introduction to Business environment
6. Aptitude Tests
  - Language & Vocabulary
  - Spelling
  - Comprehension
  - Numerical
  - Reading
7. Effective communication skills
  - Process
  - Types/Barriers
  - Business Language writing
  - E-mail writing
  - Report writing
8. Public speaking
9. Presentation skills
10. Self Management & People Skills
  - SWOT, Self Motivation
  - Emotional Intelligence



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- Being Assertive
- Working together- team member
- Time management
- Managing conflicts
- Developing Leadership skills
- Creativity & Innovation
- Cross cultural skills

11. Corporate etiquettes & workplace behavior
12. Developing Personal Impact
13. Interviews Skills and etiquettes & mock sessions through FAQs.
14. Group Discussions
15. Writing compelling CV and covering letter

## List of Reference Books :

1. Research in education by J W Best and J V Khan Prentice Hall of India, New Delhi (1995).
2. Pharmaceutical Statistics by Sanford Bolton, Marcel Dekker, New York, USA, Informa Healthcare; 4 edition (October 17, 2003).
3. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
4. Managing the clinical drug development process, C. Nardi, Marcel Dekker, New York, USA (1991).
5. Basic managerial skills for all by E H Mcgrath, Prentice Hall of India, N.Delhi (2002).
6. Organizational Behavior, John W Newstrom, Keith Davis, Tata McGraw Hill, New Delhi (2002)



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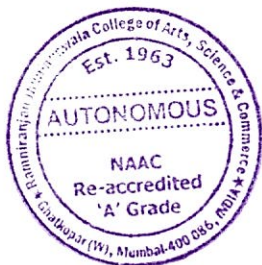
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7. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press (2008).
8. Clinical Trials. Lelia Duley and Barbara Farrell (eds), BMJ Books, London, 2002.
9. Handbook for good clinical research practice WHO Library Catalogue.
10. Artciles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
11. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M, CBS publishers and distributors(2006).
12. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA (1974).
13. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer (2007)



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## PG Diploma in Clinical Studies, Data Management and Medical Writing

### REPORT

The PG Diploma in Clinical Studies, Data Management and Medical Writing commenced on 10th August 2018 with an orientation about the course by Dr. Archana Shirpurkar the course coordinator. 49 students successful completed the program. The program was conducted in two semesters semester I and Semester II. Eminent invited faculty trained the students in different aspects of Clinical studies. The eminent faculty from the industry were Dr. Vishal Narang, Dr. Amey Mane, Mr. Sagar Vaidya. All students had to attend all the continuous evaluation, and semester end examinations for qualifying for the PG Diploma Program.



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# R. J. COLLEGE of Arts, Science & Commerce (AUTONOMOUS)

(Hindi Vidya Prachar Samiti's RAMNIRANJAN JHUNJHUNWALA COLLEGE of Arts, Science & Commerce)

Opposite Ghatkopar Railway Station, Ghatkopar (West), Mumbai 400086, Maharashtra, INDIA.

Website: www.rjcollege.edu.in Email: rjcollege@rjcollege.edu.in Tel No: +91 22 25151763 Fax No: +91 22 25150957

College is recognized under Section 2(f) & 12(B) of the UGC Act, 1956

Affiliated to UNIVERSITY OF MUMBAI || NAAC Re-Accredited 'A' Grade (CGPA: 3.50)

## PHOTOGRAPHS OF THE CONVOCAATION PROGRAMME OF 2018-2019 BATCH OF POST GRADUATE DIPLOMA IN CLINICAL STUDIES, DATA MANAGEMENT AND MEDICAL WRITING



SHRI. B. G. BARVEM JT. MANAGING DIRECTOR, BLUE CROSS LABORATORIES PVT LTD AND PRINCIPAL  
DR. USHA MUKUNDAN



SHRI. B. G. BARVEM INTERACTING WITH THE STUDENTS OF POST GRADUATE DIPLOMA IN CLINICAL STUDIES, DATA MANAGEMENT AND MEDICAL WRITING



*Usha*  
PRINCIPAL  
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## PG DIPLOMA IN CLINICAL STUDIES, DATA MANAGEMENT AND MEDICAL WRITING

### LIST OF STUDENTS WHO COMPLETED THE COURSE

Sr No	Name	Roll No
1	BARVE VINAYA VILAS USHA	1
2	CHAVAN BHAKTI MANGESH MANASI	2
3	DEVKAR RUPALI RAJENDRA SULBHA	4
4	GUPTA SONAM SANTOSH SANJU	5
5	JADHAV MANISHA LAXMAN INDU	6
6	JANNELA JAYKUMAR VIJAY VIJAYA	7
7	JAWALE SHRIYA MANGESH SMITA	8
8	KAMBLE ATUL BALIRAM MANGAL	9
9	KAMBLE PARAG VISHWANATH ASHWINI	10
10	KANNOUJIYA SNEHA NANDLAL PRABHA	11
11	KAWLE AKSHATA THAKSEN MANALI	12
12	KHAN SHIREEN MOHAMMED HUSSAIN RESHMA	13
13	KHAN AAZMA SHAMSHULLAH SHAHEDA	14
14	MALKAR AISHWARYA ULHAS VEENA	15
15	MASURKAR SAMPADA BHARAT BHAGYASHREE	16
16	MISHRA SHIVAMKUMAR BECHAI PREMA	17
17	MOMIN AYMEN MOHAMMAD ASLAM SALMA	18
18	MULIK USHA MUKUND SUPRIYA	19
19	NAGPURWALA HUZEFA ABID SHAKERA	20
20	NAVALE VISHAL VALMIK BABY	21
21	PARKAR ARBAAZ SHABBIR SHAHENAZ	22
22	PATEL RENUKA MUNIRAJ PRABHA	23
23	PATIL SNEHAL TANAJI SHEVANTA	24
24	PATIL PRIYANKA PANDIT SANGEETA	25
25	PATIL PRANALI GANPAT POOJA	26
26	PIWAL POOJA ASHOKKUMAR SANYOGITA	27
27	PRASAD SUDHA RAJENDRA PRABHAVATI	29
28	RANE DEEPAK HARISHCHANDRA ANITA	30
29	RAORANE SAMIR ANIL ANJALI	31
30	RAUT RUCHIKA RAVINDRA ADVETA	32
31	RAVALE MAITREY LAXMIKANT SANGEETA	33
32	RAWOOL AKSHADA SUBHASH	34
33	RAWOOL SWAPNIL SUBASH USHA	35
34	RODRIGUES PREEMA MICHAEL FLAVY	36
35	SAWANT PRIYANKA SITARAM VIDYA	37
36	SHAIKH MOHAMMAD SOHAIL SALIM RUKSANA	38



  
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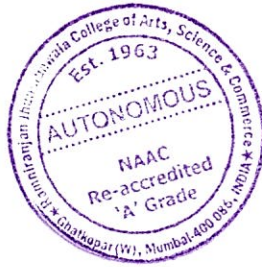
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37	SHUKLA PRIYANKA RAKESHKUMAR SUDHA	40
38	THATIPAMULA PRATHYUSHA SRINIVAS RATHNAMALA	41
39	TIWARI NISHANT JAYPRAKASH NEELAM	42
40	VALMIKI AKSHAWENI AMBRESH YASHODA	44
41	YADAV ANKITKUMAR ANILKUMAR KUSSUM	45
42	YADAV PREETI RAMPRAKASH RENU	46
43	RAJU SUNILA LALCHAND SANTOSH	47
44	SINGH NIDHI SANJAY SINGH VIMLA SINGH	48
45	YADAV NISHANT JAGANNATH RESHMAVATI	49
46	PAWAR PURVA MANOHAR ANUJA	50
47	PATIL MRUDULA AJAY AMRUTA	51
48	DEVARE ROSHAN SURESH SUHASINI	52
49	KHAN DILSHAD ANIS RIZWANA	53



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# **CERTIFICATE OF MERIT**



This is to certify that

**BARVE VINAYA VILAS USHA**

has secured

**'A' Grade**

in Postgraduate Diploma in Clinical Studies, Data Management  
& Medical Writing in the examination held in May, 2019.

Controller of Examination

**Certified as  
TRUE COPY**

**Principal**

Ramniranjan Jhunjhunwala College,  
Ghatkopar (W), Mumbai-400086.

Principal