Hindi Vidya Prachar Samiti's

RamniranjanJhunjhunwala College

Of Arts, Science & Commerce

(Autonomous College)

Affiliated to

UNIVERSITY OF MUMBAI

Syllabus for the Post Graduate Diploma

Program: Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing

Program Code: **RJSPGDCSDMMW**

(Revised Syllabus Academic year 2020-2021)

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

Post Graduate Diploma in

Clinical Studies, Data Management and Medical Writing

Program Code: RJPGDCSDMMW

Preamble:

Clinical research has led to medical advances benefiting mankind. Clinical research is performed on human beings to evaluate safety and efficacy of a new treatment or a new drug. Clinical trial is aimed to evaluate if the medical intervention is more effective and less harmful than the standard treatment. Regulatory authorities approve or reject the marketing of the drug depending on the data obtained from clinical trial. Professional in the specialized industry of clinical research need to have good knowledge of International Conference on Harmonization Good Clinical Practices guidelines. Different level of training is needed at different functional levels of clinical research due to the complexity of overall drug development process. Clinical data management focuses on clinical trial data collection and data management. Methodical and scientific knowledge with good basic writing skills is essential for medical writing. In additional to technical skills, good interpersonal skills and excellent communication is essential for clinical research professional.

Post Graduate Diploma in Clinical Studies, data management and medical writing offers essentials of clinical research in a profound and concise manner to understand the overall process of drug development. The course emphasizes the theoretical and ethical clinical research and practical aspects of conducting clinical trials. The course is ideal for Graduates with the background of Life Science / Biotechnology / Chemistry / Statistics to build qualification and expertise to enter into the exciting world of clinical research. Real-world clinical trial case studies reinforce the knowledge of clinical studies that will help individuals accelerate their career in clinical research.

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Program Objectives and Outcomes:

This course is based on systematic teaching, learning and evaluation techniques. Quality based training, comprehensive coaching by experts from industry professionals and dynamic mentoring will fulfill following objectives.

- To understand the overall drug development process in compliance with ICH GCP, regulatory guidelines and ethics
- To identify and differentiate designs and phases of clinical trial and comprehend about the responsibilities of different stakeholders
- To consider the process of monitoring and managing a clinical trial conducted at the study site
- To understand the basics of clinical data management
- To contemplate the rationale of pharmacovigilance and medical writing

Title: Post Graduate Diploma in Clinical Studies, Data Management and Medical Writing

Eligibility: Bachelor's Degree in Life Science / Biotechnology / Chemistry / Statistics

Duration of the course: One Year (Part time) Blended teaching weekends

Fee Structure:

Tuition Fee	:	35,000.00
RFID	:	150.00
Examination Fees	:	500.00
Application form fees	:	Rs 100.00

Intake capacity: 40 students

Faculty: Industry and Academia Professional in area of Clinical research, Pharmacy, Clinical Data Management, Pharmacovigilance and Medical writing

Standard of Passing:

a. Candidate who secures minimum 50% marks in each paper be declared to have passed the examination in that subject.
b. A candidate who fails to secure 50% marks in a paper will be allowed to reappear in that paper.
c. 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.
d. 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.
e. 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

Scheme of Evaluation: There would be continuous evaluation

- Internal assessment: 40% weightage - multiple choice questions, quiz, assignments, case studies
- External assessment: 60% weightage - subjective questions

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SEMESTER I

PAPER	TITLE OF PAPER	INTERNAL		EXTERNAL		CREDITS	COURSE CODE
		Maximum	Minimum	Maximum	Minimum		
I	Clinical Pharmacology and Toxicology	40	16	60	24	8	RJSPGDCSDMMW101
II	Good Practices & Ethics	40	16	60	24	8	RJSPGDCSDMMW102
III	Clinical Trial Processes	40	16	60	24	8	RJSPGDCSDMMW103
	Total	**120**	**48**	**180**	**72**	**24**	

SEMESTER II

PAPER	TITLE OF PAPER	INTERNAL		EXTERNAL		CREDITS	COURSE CODE
		Maximum	Minimum	Maximum	Minimum		
I	Regulations	40	16	60	24	8	RJSPGDCSDMMW201
II	Pharmacovigilance	40	16	60	24	8	RJSPGDCSDMMW202
III	Clinical Data Management & Medical Writing	40	16	60	24	8	RJSPGDCSDMMW203
	Total	**120**	**48**	**180**	**72**	**24**	

Total (600) = Internal (240) + External (360)

Total Credits = 48

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SEMESTER I

Paper I: Clinical Pharmacology and Toxicology **8 Credits**

UNIT – 1:

Pharmaceutical Industry & globalization –Overview, Opportunities & Career options in Clinical Research

UNIT – 2:

Pharmacy - Physico-Chemical properties of drugs, different drug dosage forms, Formulation development and manufacture of drugs.

Therapeutics - Principles of Management & Drug Therapy

UNIT – 3:

Pharmacokinetics - Absorption, bioavailability, distribution, metabolism protein binding, excretion, placental and blood brain barrier

Pharmacodynamics - Mechanism of drug action, receptors, agonists, antagonists, side effects and adverse events

UNIT – 4:

Toxicology - Acute, Sub-acute and Chronic Toxicity, Mutagenicity, Teratogenecity, Oncogenicity and effects on **fertility; pre-clinical studies**

Paper II: Good Practices & Ethics **8 Credits**

UNIT – 1:

Good Manufacturing Practices, Good Laboratory Practices

UNIT – 2:

International Conference on Harmonization, Good Clinical Practices

UNIT – 3:

History of Ethics in Clinical Research and Ethics Committee

UNIT – 4:

Belmont Report, Nuremberg Codes, Declaration of Helsinki

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Paper III: Clinical Trial Processes **8 Credits**

UNIT - 1:

Responsibilities of Stakeholders: Sponsors, Investigators, CROs, Monitors; Clinical Trial Designs

UNIT – 2:

Clinical Trial Phase I, Phase II, Phase III, Phase IV

UNIT – 3: Essential Documents in Clinical Trials:

SOP, Protocol, Investigator Brochure, Master Files, Informed Consent Forms, Case Record Form

UNIT – 4:

Managements of Clinical Trials - Investigator's Meeting, Project management, Patient Recruitment & Retention, Trial Monitoring, Drug Resource and supplies; Trial Budget, Audit and Inspection

SEMESTER II

Paper I: Regulations **8 Credits**

UNIT – 1:

BA/BE Studies - Bioavailability and Bioequivalence - Methods and Procedures, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability

UNIT – 2:

Regulation in India: Drugs and Cosmetics Act, Schedule 'Y', Quality in Regulatory Context, Patent laws; **ICMR**

UNIT – 3:

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

UNIT – 4:

EMEA: History, Structure & Function, Regulations;

JAPAN :History, Structure & Function

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Paper II: Pharmacovigilance **8 Credits**

UNIT – 1:

Overview of Pharmacovigilance: Importance; National & International Programs; Methods

UNIT – 2:

Principles of Pharmacovigilance: ADR; Assessment; Medication errors, Signal detection; Risk assessments

UNIT – 3:

Drug Dictionaries: Coding & Tools; **Drug Safety**: PSURs; Package inserts

UNIT – 4:

Regulatory Guidelines: ICH, EMEA, USFDA, Sch. 'Y'

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Paper III: Clinical Data Management & Medical Writing **8 Credits**

UNIT – 1:

Biostatistics: Descriptive Statistics - Data Types; Collection; Sampling, Compilation; Tables & Graphs, Measures of Central Tendency, Measures of variation

UNIT – 2:

Clinical Data Management: Overview, scope, terminologies; Principles of CDM

UNIT – 3:

Clinical Data Management: Data Entry, Queries & Data Clarification, Electronic Data Capture, Software in CDM

UNIT – 4:

Medical Writing: Literature Search & Medical Articles, Contract writing, Publication, Abstracts, Bibliography, Clinical Study Reports

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

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Contact

diliptripathi1@yahoo.co.in

www.linkedin.com/in/dilip-tripathi-56991523 (LinkedIn)
www.vintagepoint.in (Other)

Top Skills

Analytical Chemistry
Pharmaceutics
Microbiology

Dilip Tripathi

Senior Manager R&D at Johnson & Johnson

Experience

Johnson & Johnson
15 years 2 months

Senior Research Development Manager
August 2018 - Present (4 years 5 months)

Manager R&D
November 2007 - Present (15 years 2 months)

FDC Limited
Asst Manager Analytical Development
May 2005 - November 2007 (2 years 7 months)

Ivax Pharmaceuticals
Executive Analytical Services
January 2003 - May 2005 (2 years 5 months)

Sandoz India Pvt Ltd
Executive
2003 - 2004 (1 year)

Education

St. Joseph High School, Colaba
SSC

St. Joseph's High School, Colaba, Mumbai

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Contact

Sunnyvale California USA
naad_archana@yahoo.co.in

www.linkedin.com/in/archana-shirpurkar-5aa1a740 (LinkedIn)
www.hvpsinternationalschool.com (Company)

Top Skills

Clinical Research
Research
Teaching

Languages

English (Full Professional)
Hindi (Full Professional)
Marathi (Full Professional)
Kannada (Professional Working)

Certifications

Project Management Program
University Teaching
Foundation of Teaching for Learning: Curriculum, Assessments

Publications

'Selective Oxidation of alcohols to carbonyl compounds with homogenous reagent system'

'A new reagent for oxidation of alcohols to carbonyl compounds (a homogenous system)'

'Phase transfer catalyzed oxidation of alcohols to carbonyl compounds'

Archana Shirpurkar

Course Coordinator, Clinical Research at Ramniranjan Jhunjhunwala College

Experience

Ramniranjan Jhunjhunwala College
Course Coordinator, Clinical Research
June 2010 - Present (12 years 7 months)

HVPS International School
Campus Director
July 2010 - June 2012 (2 years)

Ramniranjan Jhunjhunwala College
Faculty in Chemistry
March 1993 - June 2007 (14 years 4 months)

Education

Institute Of Science Mumbai
B.SC, M.SC, Ph.D., Chemistry · (1988 - 1994)

Kriger Research Center, Toronto, Ontario
CRA Certification, Clinical Research Professional Development Program

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Contact

www.linkedin.com/in/dr-amey-mane-7b11566 (LinkedIn)

Top Skills

Pharmacovigilance

Clinical Trials

Neurology

Publications

Safety and immunogenicity of single dose live attenuated Varicella vaccine (VR 795 Oka strain) in healthy Indian children: A *randomized controlled study*

Long-term Immunogenicity of Single Dose of Live Attenuated Hepatitis A Vaccine in Indian Children

Conducting clinical trials in emerging markets of sub-Saharan Africa: review of guidelines and resources for foreign sponsors

Changing epidemiology of hepatitis A virus in Indian children

Cross-Sectional Study for Prevalence of Non-Steroidal Anti-Inflammatory Drug-Induced Gastrointestinal, Cardiac and Renal *Complications in India: Interim* Report

Dr.Amey Mane

Cluster Head-Medical Affairs at Sun Pharma India

Summary

I am a clinical pharmacologist with 16+ years of experience in multinational and Indian pharma.I have handled diverse responsibilities in medical affairs,clinical research,medical writing,ideation and pharmacovigilance.I have managed therapy shaping in different therapeutic areas like Neurology, Oncology, Cardiovascular, Diabetes,Dermatology,Vaccines,Rheumatology,Primary care and generic drugs.Stakeholder management including KOLs,regulatory authorities,internal & external customers and builiding up high performing teams have been the key activities of my profile.

Experience

SUN PHARMA
Cluster Head- Medical Affairs (India)
October 2022 - Present (3 months)

Lead and drive therapy shaping in cardiovascular,metabolics(diabetes),neurology,psychiatry,nephrology and dermatology ; Lead Real World Evidence(RWE) for diverse therapy areas ; Lead clinicoregulatory strategy for new drug approvals; Spearhead publication planning;Build and manage high performing teams; Collaboration with internal and external stakeholders including Thought Leaders,Key Opinion Leaders,physician associations and academic institutions

Dr. Reddy's Laboratories
Director Medical Affairs
January 2019 - October 2022 (3 years 10 months)

Head-Clinical Research,New product Ideation,Clinicoregulatory strategy & Publications for all therapeutic areas in India vertical

Accountable for the new product ideation process for NCEs/FTL, incremental innovation and differentiated products

•Clinical trial (phase I to Phase IV) documents (Protocol, IB, ICF, CSRs, Clinical summary, CTD etc.) preparation in coordination with scientist, regulatory, DM and investigators.
•Medical Monitoring, medical advisor during conduct of trial
•SAE processing, Narratives, MSMP and Risk Management plan Preparation

UCB India Ltd.
Medical Advisor-Neuropsychiatry
June 2009 - September 2011 (2 years 4 months)

• To be a leading scientific / medical / technical resource within UCB India by acquiring scientific knowledge of CNS & Psychiatry therapeutic area.
• To collaborate with all internal and external stake holders by proactive and need based provision of medical-scientific information.
• Be an active member of the brand planning team to provide medical steer to the strategies
• Scientific and Academic liaisons with.Key Opinion leaders in key therapeutic areas
• To provide medical and scientific support into the conduct of regional and national medical advisory board meetings, symposia and congresses by active participation.
• Conceptualization (wherever applicable), review and approval of promotional materials as per the local SOPs, UCB standards and local regulations.
• Identification and evaluation of new products in the area of UCB interest
• Medical training of field force, training and marketing group
• Regulatory affairs-Preparation of rationale for DCGI submissions for new products/indications, Prescribing and abbreviated prescribing information, liaison with regulatory manager for successful submissions
• Clinical research-To provide initial evaluation and continued support for clinical trials, investigator initiated studies(IIS),Non-interventional studies(NIS),Post-marketing surveillance (PMS)
• Adverse event reporting(Safety reporting) from the clinical trials & post-marketing experiences to concerned regulatory authorities in liaison with local safety officer

UCB India Ltd,
Clinical Pharmacologist
December 2008 - May 2009 (6 months)

• Overall responsibility for the Clinical Pharmacology aspects of any clinical program assigned to UCB India.

Contact

www.linkedin.com/in/sagar-vaidya-76b8a9b (LinkedIn)

Top Skills

PCR
GCP
CTMS

Certifications

Planning an Effective Presentation
CEO Excellence Award 2020
Ensuring Successful Presentation Delivery
Building Your Presentation

Sagar VAIDYA

Project Manager at PPD

Experience

PPD
12 years 6 months

Project Manager
September 2021 - Present (1 year 4 months)

Sr. Clinical Trial Manager
April 2019 - September 2021 (2 years 6 months)

Clinical Trial Manager
April 2016 - March 2019 (3 years)

Principal CRA
April 2015 - March 2016 (1 year)

Senior Clinical Research Associate II
April 2012 - March 2015 (3 years)

-Lead CRA role for APAC region for Major Oncology Project of the client since Dec 2011.
-Successfully accomplished EMA inspection for Site recently in Sep 2013
•Perform and coordinate assigned aspects of the clinical monitoring process in accordance with GCPs and global SOPs to assess the safety and efficacy of investigational products and/or medical devices.
•Conduct site visits to determine protocol and regulatory compliance, and prepare required documentation.
•Develop collaborative relationships with investigative sites and client company personnel.
•Perform all duties of a CRA,serving as the primary contact with individual investigative sites that conduct clinical research for PPD

•Perform study-specific training with project team
•Develop study-specific monitoring tools and forms for use by monitoring team to assist in efficient review of study data
•Perform Serious Adverse Event reconciliation and worked with sponsor, study sites and CRAs to resolve discrepancies
•Review outstanding data reports and worked with CRAs to ensure data collection was met per contractual guidelines
•Assist sponsor, study sites, and CRAs with audit preparation/responses and quality issues
•Monitors investigator sites, with particular ability to manage complex studies and/or challenging sites, to ensure the accuracy and validity of CRF entries
•Provide mentoring and support to less experienced members of the project team and advice on training and quality issues.
•Perform and coordinate assigned aspects of the clinical monitoring process in accordance with GCPs and global SOPs to assess the safety and efficacy of investigational products.
•Conduct site visits to determine protocol and regulatory compliance, and prepared required documentation

Piramal LifeSciences Limited
Senior Executive
April 2008 - July 2010 (2 years 4 months)

•Was responsible for Initiations, Monitoring, Closures of Phase I, II trial in Ovarian Cancer, Pancreatic Cancer & Head-Neck Cancer.
•Was Responsible for Initiations, Monitoring of Phase IV trial in obesity.
•Handled 8 clinical sites of oncology across the country.
•Was involved in Investigational Product Management at site as well as clinical trial warehouse.
•Accomplished the recruitment target as per project plan at study start up level.
•Also worked as study start up champion for different projects. Conducted Site Feasibility and Site Assessments visits in various therapeutic areas like skin diseases, oncology, diabetes etc.
•Was responsible to maintain the Study files at Sponsor as well as Investigator's Site Level
•Achieved all requirements for Monitoring visit report, follow up letters finalization.
•Completed the co-monitoring/training visits to train new Clinical Research Associates/ Clinical Trial Assistants.
•Has participated in arranging the investigator's meet for various trials.

University of Mumbai

Master of Marketing Management - MMM · (2010 - 2013)

Welingkar Institute of Management

Diploma in Business Management, Basic Concepts of Management (Part Time) Weekend Course · (2006 - 2007)

Cranfield University

Master of Clinical Research, Clinical Research · (2005 - 2007)

Nagpur University

Bachelor of Pharmacy, Pharmaceutical Sciences · (2001 - 2005)

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Contact

drvishal.narang@gmail.com

www.linkedin.com/in/vishal-narang-ph-d-mba-0193245 (LinkedIn)

Top Skills

Microsoft Outlook

Clinical Research Organization functioning

Medical Writing

Certifications

Pharmacist

Publications

https://pubmed.ncbi.nlm.nih.gov/?term=narang+vs

Vishal Narang Ph.D., MBA

Sr.General Manager, Clinical Drug Development at Nivagen Pharmaceuticals, Inc.

Summary

Ongoing:

Nivagen, a virtual pharmaceutical company, has given me this terrific opportunity to learn and contribute in holistic areas of drug development including pharmaceutical formulation, tech-transfer, manufacturing and marketing.

Freshly working on:

1. Developing small animal models for proof-of-concept studies
2. Validating IVIVC data that serve as gatekeepers for bioequivalence/bioavailability studies in healthy/patient volunteers
3. Authoring and reviewing multiple Pre-investigational new drug (PIND) and new drug applications (NDA), prior to submission to either critique or initiate preparations for anticipated deficiencies.
4. Leading due-diligence activities to raise funds, and
5. Strategic-, Project-, Operational- and Vendor-mangement of global clinical trials with severely complex protocols for ongoing 505b2 projects

Earlier:

Completed first ever clinical trial with narcotics in India. Consequently, developed deep understanding of workings of regulatory bodies and bureaucracy of multiple states to manage disposition of narcotic investigational products.

Played a significant role in successful completion of the largest global clinical trial in the history of Quintiles. Briefly, managing a team of~ 30 colleagues spanning a battery of activities including clinical operations, data cleaning and queries resolution management, safety reporting to DSMB.

3. Development and validation of small animal models, and other in vitro techniques to improve the predictability of success during early clinical phase studies

4. Similar responsibilities mentioned below (whilst at Cipla). In addition, seek strategic inputs from thereapeutic-KOLs, regulatory bodies whilst developing clinical trial protocols, ePRO tools, study manuals and statistical analysis plans. Provide critical inputs and facilitate technical discussions while investors conduct their due diligence.

RAMNIRANJAN JHUNJHUNWALA COLLEGE
Visiting Faculty
July 2007 - Present (15 years 6 months)

Design and develop clinical-staff specific courses for various study personnel
Routinely conduct work-shops and corporate training for industry and clinical trial sites.
Deliver lectures on a spectrum of clinical trial related areas.

Cipla
Director, Clinical Project Leadership and Operations
April 2018 - August 2021 (3 years 5 months)

• Evaluate and recommend global and local strategic partner/s specifically in respiratory 'clinical' part of drug development
• Evaluate partners specializing in generating and analyzing data from varied sources including ePRO and eCOA.
• Manage and routinely report performance to CEO and Board of Directors for global clinical projects worth 60-75 mn USD
• Develop specific capabilities (human resources and technology) that promote better management of partners, collation of data and subsequent insights.
•Identify and establish specialized site-networks that can reduce the reliance on CRO and in-turn may provide a superior operating model.
•Inculcate a project management-driven culture, curate patient recruitment tools, and create robust processes while managing global resources that enhance sponsor's oversight during conduct of clinical trials.

IQVIA
Next Generation CLOPS Lead
March 2017 - April 2018 (1 year 2 months)

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Ensure acceptable engagement, motivation, utilization and realization amongst team members

Identify, and represent Quintiles for new business opportunities within the Northern Region

Support project delivery at various levels

Resource allocation and management

Vendor management

Quintiles Research Private Limited

Sr.Clinical Project Manager

October 2009 - November 2012 (3 years 2 months)

All duties and responsibilities mentioned below as Clinical Team Lead.

Identify quality risks and issues associated with execution of global clinical trials (involving at least 7 countries in Asia-Pacific and Australia-New Zealand). Consequently create and execute corrective action plans to prevent or correct deficiencies in performance of the study.

Ensure utilization of the personnel are above acceptable limits of 85% and that staff is meeting defined workload through regular review of deliverables

Ensure realization of the project are above acceptable limits of 85% and that execution of deliverables is within the contracted scope of work

Diligently track Out-of-scope activities and ensure remittance for the same is received by the organization.

Evaluate the training needs of personnel, and equip them with various study tools, systems access to enable them to complete job responsibilities.

Responsible for development and execution of plethora of plans mandatory for the execution of global clinical trials as per National and International regulatory guidance.

Quintiles Research Pvt. Limited

Clinical Team Leader/Project Manager

June 2008 - October 2009 (1 year 5 months)

Communicate and establish customer service relationship with clinical client representative.

Routinely participate in bid-defenses with a successful track record and decent 'win: participation' ratio.

Conduct feasibility for potential studies in various indications for various clients

Work collaboratively with various functional groups and third-party vendors to support achievement of milestones.

Preparation of submission documents, resolution of queries and procurement of eventual approval from ethics committee and regulatory agencies

Cipla Ltd
Clinical Research Scientist
October 2003 - January 2005 (1 year 4 months)

Responsibilities

Design, initiate, conduct, monitor and supervise bioequivalent and clinical studies for routine submissions to US-FDA:

Instrumental in developing and medical writing of pharmacokinetic section of the ANDA.

Protocol development for submissions to various regulatory authorities such as EMEA.

Initiated 'department of clinical trials' by incorporating basic elements of SOPs and personnel-development/training and electronic data capture systems.

To design and review documents such as protocols, statistical analysis, diary cards, IB, ICFs, CRFs. Facilitate translations into local languages.

To assist in site-selection and site-development endeavors: Impart training to PIs, and development of site-SOPs.

Management of the overall conduct and operational activities of one or more clinical studies (phase III) within a project.

Univ of Washington, Seattle
Clinical Research Associate
January 2003 - January 2005 (2 years 1 month)

Routinely present clinical data and experiences at project team meetings.

Provide operational updates, plans and recommendations to the site-staff to facilitate smooth conduct of the trial.

To draft and review protocols, statistical analysis, informed consent forms, case record forms and other relevant documents pertaining to clinical research. Ensure compliance with ICH and HIPAA guidelines with adequate supervision.

Periodically assist the site in facing numerous audits by external and internal funding agencies such as NIH. Audits were found to be satisfactory by the management with no significant finding.

Keep the senior management informed of significant issues such as changes in budget/spending, and timelines for the completion of trials.

Education

University of Cincinnati

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Admission Procedure Booklet

admission21-ppt-PG-FY

STEP 1: Filling of the Online admission Form

Online Registration on the portal

https://admission.rjcollege.edu.in//firstyear/#/login
https://admission.rjcollege.edu.in//firstyear/#/first-register
*Students who have passed TY in 2021-22 can use their login id and password of TY for Login **https://admission.rjcollege.edu.in//firstyear/#/login** and students of other college and previous years should register fresh on portal **https://admission.rjcollege.edu.in//firstyear/#/first-register***

1. If there are any changes in dates, the revised schedule will be notified on the website, and students are requested to abide by this and keep looking into this page for notification
2. Portal will open on 10 June 2022.
3. **Admission to for PGD Programs will be based on Sem V Marks. Hence, Students applying are required to enter the Sem V marks obtained and total marks in the Educational Details Tab. If you don't have marks obtained and total marks in the marksheet get a conversion certificate from your parent college.**
4. Students are required to enter the correct mobile no (WhatsApp no) and email id while filling the online form since all communication will be sent on the same email id and WhatsApp no.
5. Students have to fill all the details correctly.
6. Students of Hindi Linguistic Minority should tick on Hindi Minority Option as Yes and if you have marked Yes then only you will be considered under Hindi Linguistic Minority Quota.

STEP 2: Admission

1. Admission will be on First cum First basis for Postgraduate Diploma Courses. Once you subit your form wait for 24 hours. The fee payment tab will get activated. Once the seats are full the admission will close. No Merit List.
2. All Admission are provisional, subject to verification of documents and fulfilling the eligibility criteria for the course applied. If the documents and eligibility criteria is not fulfilled, the admission will be cancelled.
3. Your admission will be cancelled if any false information is provided for eg. Wrong entry of Sem V marks, not falling under Hindi Minority Quota, Failed or have pending ATKT in any of the semester.
4. The admission is based on merit and the College does not accept any donation for any admission.
5. **The Principal decision will be final and principal reserves the right to refuse admission for non-fulfilment of eligibility criteria of UGC and University of Mumbai**
6. First preference will be given to students of 2021-22 batch
7. Refund rules are available on the website for reference.

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

PGD in Clinical Studies Data Management and Medical Writing

Eligibility	:	Graduates in Botany,Zoology,life Science, Microbiology,Biotechnology, Biochemistry, Forensic Science, B Pharm, Medical and all allied medical graduates.
Duration	:	1 Year
Class Time	:	Saturday & Sunday (10.00 am to 1.00.00 pm)
Fees	:	Rs. 36200/-
Syllabus	:	Link

Ramniranjan Jhunjhunwala College of Arts, Science & Commerce ★ Ghatkopar (W), Mumbai-400 086, INDIA ★ Est. 1963 AUTONOMOUS NAAC Re-accredited 'A' Grade

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

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LIST OF STUDENTS WHO ENROLLED FOR THE COURSE ?? ?2?22?2?2?

Sr No	Full Name	Roll No
1	JANITA JOHN PETER JACINTHA MARY	2078
2	SHAHID SAMIULLAH SALIMUNNISA	2014
3	ANSARI NAGHMAKHATOON RAMZAN SABIRAN	2017
4	BANSODE SIDDHANT SAHEBRAO NANDA	2071
5	BHANUSHALI MEGHA ALPESH BHAGAWATI	2045
6	BOLBANDA SHRUSTI RAMESH SARITA	2093
7	CHAVAN AJAY ASHOK ARCHANA	2029
8	DALVI RITU RAJENDRAKUMAR REENA	2009
9	DEOLEKAR TRUPTI VILAS AMITA	2018
10	DEORUKHKAR SANTOSHI SUDHAKAR KALPANA	2060
11	DEVKAR JANAVI RAJENDRA SULBHA	2057
12	DHANGE SADIQUA MOIN TAHSEEN	2095
13	DHOKA MOKSHA JITENDRA SARIKA	2021
14	DHURI POOJA LAXMAN SULAKSHANA	2056
15	DINGANE CHARUSHILA SUBHASH RAJANI	2066
16	DUBEY AAYUSHI PRADEEP SANGEETA	2085
17	DUBEY NEHA GIRISHCHAND SUMAN	2032
18	GADA VIRAG GANGJI DAKSHA	2006
19	GAIN IMRAN ABDUL REHMAN ZAITOON	2040
20	GILL KARAN HARDEEP SINGH LALITA	2010
21	GUPTA MANGESHKUMAR DINESHCHANDRA GEETA	2063
22	HASHIM ABU MD MAHBOOB NIKHAT KHATOON	2092
23	HOTKAR POOJA RAMESH JAYSHREE	2049
24	HUSNA KM MOHAMMAD SULEMAN NAJMA BEGUM	2088
25	JADHAV ANKITA DILIP SANGEETA	2067
26	JADHAV ANKITA JAYWANT SADHANA	2098
27	JADHAV APURVA ASHOK MANISHA	2011
28	JADHAV SACHIN SUNIL SMITA	2005
29	JAISWAL POONAM MOTILAL DHARMAVATI	2041

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30	JAISWAR SWATI HANSRAJ POONAM	2036
31	JUWATKAR SAMRUDDHI BHARGAV REVATI	2019
32	KAGALARAM YUGANDHARA SHANKAR APARNA	2094
33	KATARIA MEGNA NIELKANT SONIA	2089
34	KATE VINIT ARUN POOJA	2024
35	KATHE SIDDHI UMESH CHHAYA	2030
36	KHANVILKAR MADHAVI DILIP SUJATA	2079
37	KHARAT ABHISHEK BHAGWAN VIJAYA	2025
38	KOKITAKAR ASHWINI MAHADEV VANDANA	2081
39	KOLTE PRADNYA RAVINDRA VRUSHALI	2054
40	KONAR SADISH ESSAKIAPPAN MAHALAKSHMI	2034
41	KSHETRE SUVARNA ANIL LALITA	2083
42	KUMBHAR SAKSHI SURESH VIJAYMALA	2022
43	LINGAYAT VIGHNESH VISHWANATH VARSHA	2073
44	MADDILI SARASWATI NARASIHMA DHARTI	2050
45	MALI SWATI SUDHAKAR PRATIMA	2077
46	MASTER ZAINA ADAM SHABNAM	2052
47	MISHRA LAXMI CHANDRABHUSHAN RUKMINI	2002
48	MOMIN ZOYA AFZAL AHMAD ZAHEDA	2076
49	MORE GAYATRI SACHHIDANAND PRATIBHA	2042
50	MORE SWAPNALI GAJANAN JAYASHRI	2027
51	MUKADAM TANVI VILAS MANISHA	2058
52	MULIK SUPRIYA SURESH CHHAYA	2003
53	NADAR JEHU JAMES ESTHER	2023
54	NANGLE SAKSHI VIJAY TEJAL	2001
55	PAL PRIYA SHYAMNARAYAN URMILA	2035
56	PANDEY POONAM RAMKISHUN GAYATRI	2053
57	PANDEY PRIYA ASHOK MAYA	2031
58	PANDEY RUPAM GAURISHANKAR MANJUDEVI	2037
59	PARAB PRANJALI SHAMKUMAR SHARMILA	2069
60	PATEL ABHISHEK AMRITLAL KAMLAWATI	2028
61	PATIL SWARA GAJANAN PRATIBHA	2039

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62	PAWAR VINIT VIJAY SUDHA	2072
63	PENDSE GAYATREE UPENDRA PENDSE JAYASHREE PENDSE	2016
64	PRAJAPATI MIHIR VINOD KUMAR MADHURI	2007
65	RANE NETRA SUDHAKAR SUVIDHA	2004
66	RANE SANIKA PRABHAKAR PRAVINA	2008
67	SAWANT LEENA MILIND MANISHA	2064
68	SAWANT SAURABHI DEEPAK UJWALA	2026
69	SAWANT SAYALI UMESH SUPRIYA	2065
70	SHAHANEDIWAN UDAA MOINUDDIN SAIRABANU	2075
71	SHAIKH SHABINA KAUSAR MOHD SAQIB AFSANA KHATOON	2012
72	SHAIKH MARYAM NAZIR AHMED ZEHNAB	2074
73	SHAIKH MUSKAAN ABDUL REHMAN DILSHAD	2013
74	SHAIKH SHABNAM MUKIM AHMED TABASSUM	2051
75	SHAIKH SOLEHA SAMREEN AHMED KHALIDA	2097
76	SHAIKH URMA AFAQUE ALAM IBRAT JAHAN	2070
77	SHELAR SAYALI VINOD VANITA	2086
78	SHUKLA KRISHNA TIRTHRAJ VANDANA	2033
79	SIDDIQUE WASIUDDIN FASIUDDIN SHAHEEN	2087
80	SINGH GARIMA OMPRAKASH SHAKUNTALA	2090
81	SINGH HARSH RAJESH ARCHANA	2062
82	SINGH LAKKI PRADEEP REENA	2020
83	SINGH MAHENDRA LOKENDRA ROHINI	2080
84	SINGH SEJAL NILESH KUMKUM	2044
85	SURYAWANSHI PRATHAMESH KAILASH HEMA	2061
86	TARFE YASH ANIL SHRIDHAR TARFE RAJNI ANIL TARFE	2068
87	THAKUR SAMEEKSHA PRAKASH SUPRIYA	2091
88	THEVAR ARUN SHAKTHI YOGESH RAJA SHANKARA PANDIAN THEVAR MEENATCHI	2038
89	THORAT AKSHATA VIJAY JAYSHREE	2048
90	WAGH LALIT ANIL SUNITA	2046
91	YADAV ANKITA RAMDHARI PUSHPA	2059
92	YADAV DEEPA RAJKUMAR MANBHAVATI	2096

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93	YADAV LAKSHMINA AMARJEET CHANDRAKALA	2047
94	YADAV NEHA RAJBAHADUR KAMLA	2043
95	YADAV NIKITA GURUNATH GIRIJA	2084
96	YADAV PRITI SURENDRANATH BHANMATI	2015
97	YADAV SUNITA SURAJ BIMLA	2082

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List of Students who Completed the Program in 2021-2022

Sr No.	Name	Division	Roll No
1	MAYUGHA MANILAL SINDHU	A	1
2	SHIVANI NARESH SUVARNA	A	2
3	AHIR JAYSHRI SHANKAR REKHA	A	3
4	ANSARI NAZIA MOHAMMED AMIN MUMTAZ	A	4
5	ANSARI AAYSHA MEHFUZ AKBARI	A	5
6	CHAUDHARI PRIYANKA PRITHVIPAL GUNINDER	A	6
7	DESAI HINDAVI RAVINDRA GEETA	A	7
8	DUBEY SONALI ASHOK KIRAN	A	8
9	GAVANDE JUHI SANJAY MANSI	A	9
10	GUPTA NIDHI SHANKARLAL SAVITADEVI	A	10
11	JAISWAL PANKAJ RAMRATHI NEELAM	A	11
12	KAMBLE CHARUSHILA MAHESH MANISHA	A	12
13	KESARKAR NISHA SHAMRAO KANCHANA	A	13
14	KHOND NEHA RAJENDRA SAVITA	A	14
15	MAHAJAN AKSHAYA DHANANJAY APARNA	A	15
16	MENON VAISHNAVI VIKRAM HEMA	A	17
17	MULLA JUVERIA FEROZ NUZHAT	A	18
18	NAIK AISHWARYA PRASAD SAMRUDHI	A	19
19	NARVEKAR JAGRUTI TUSHAR TEJASWI	A	20
20	PASI HITESH KAMLESH SAVITRI	A	22
21	PATIL GAURAV MANISH MITALI	A	23
22	PATIL MANASI KRISHNAKANT NEELAM	A	24
23	PILLAI DIVYA ALAGESAN SHANTI	A	25
24	PRAJAPATI KAJAL CHOTELAL SANGEETA	A	26
25	RAJANI IRAM MUNIR DILSHAD	A	27
26	REDEKAR SAURABH MARUTI SUNITA	A	28
27	SAGVEKAR ANIKET SHASHIKANT SHYAMAL	A	29
28	SAIYYAD SHAHZADI PARVEEN MOHD ASLAM SULTANA BEGUM	A	30
29	SANTOSH SHUBHAM SAWANT CHHAYA	A	31
30	SAWANT GOVIND YASHWANT YOGITA	A	32
31	SHAIKH SOPHIYA MUNAWAR RABIA	A	33
32	SHAIKH UZMA ATIQUE MUMTAZ	A	34

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33	SHELAR ULKA PRAKASH JYOTI	A	35
34	SINGH HARSHITA PRAMOD VANDANA	A	36
35	SINGH MAHEE CHANDRABAHADUR NEELAM	A	37
36	SINGH PRIYA HARISHCHAND SUMAN	A	38
37	THAKUR POOJA PRADEEP PRAJAKTA	A	39
38	TUNGE SHREYA JITENDRA SHAILA	A	41
39	TURBADKAR SANJANA MANOJ PAWAR SHOBHA PAWAR	A	42
40	VISHWAKARMA KIRAN SHIVKUMAR BINDU	A	43
41	PATEL TITHI HASMUKH BINDUBEN	A	44
42	DIXIT PRIYANKA RAMAKANT SAROJINI	A	45
43	YADAV ANKITA JAIGOVIND SEETADEVI	A	46
44	VISHWAKARMA RIDDHI BHARAT JAYANTI	A	47
45	KAMBLE KUSUM DAULU SAGUNA	A	48
46	KAMBLE PRANALI ARUN UJWALA	A	49
47	YADAV ABHINAV GHANSHYAM UMA	A	50
48	MORE SHRIYA MOHAN SAMIKSHA	A	51
49	PISAL UTKARSH NANDKUMAR MANGALA	A	52
50	MORAJKAR SHITAL MAHADEV SHUBBHANGI	A	53
51	JONDHALE MAYURI RAVI RAJARAM JONDHALE AARTI RAVI JONDHALE	A	54

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RAMNIRANJAN JHUNJHUNWALA COLLEGE
of Arts, Science & Commerce
(Autonomous)

Affiliated to UNIVERSITY OF MUMBAI

CERTIFICATE OF MERIT

विद्यया अमृतं अश्नुते
ESTD. 1963
RJC

This is to certify that

MAYUGHA MANILAL SINDHU

has secured

'A+' Grade

in Postgraduate Diploma in Clinical Studies Data Management and Medical Writing

in the examination held in Aug 2022.

Controller of Examination

Certified as
TRUE COPY

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

Principal

Certificate ID: *PGDCSDMMW-2021-22-01*

Date of Declaration: 30th Aug, 2022

Hindi Vidya Prachar Samiti's

RAMNIRANJAN JHUNJHUNWALA COLLEGE
of Arts, Science & Commerce
(Autonomous)

Affiliated to UNIVERSITY OF MUMBAI

CERTIFICATE OF MERIT

This is to certify that

WALUNJ SHIVANI NARESH SUVARNA

has secured

'A' Grade

in Postgraduate Diploma in Clinical Studies Data Management and Medical Writing

in the examination held in Aug 2022.

Controller of Examination

Certified as
TRUE COPY

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

Principal

Certificate ID: *PGDCSDMMW-2021-22-02*

Date of Declaration: 30th Aug, 2022