Advance Diploma in Clinical Research Management

Dysmech Clinical Services

ISO and Internationally Certified by

Power To Design The Desired

Elevate Your Career With Dysmech Clinical Services

Bridging the Gap Between Academia and the Clinical Research Industry

Dysmech Clinical Services (DCS) is a specialized educational and consultancy organization based in **Pune, India**, dedicated to bridging the critical gap between life science education and the dynamic demands of the professional clinical research industry. What makes DCS truly unique is our unwavering commitment to **job-oriented training and real-world consultancy**. Our programs, meticulously designed and delivered by seasoned industry experts, provide **hands-on skills and practical knowledge** that are immediately applicable in the workplace.

We empower aspiring and current professionals with the competencies needed to excel in roles across clinical trials, pharmacovigilance, regulatory affairs, and data management, significantly accelerating their career trajectories. Our expertise is rooted in a deep, current understanding of industry needs, ensuring our curriculum remains cutting-edge, relevant, and effective in developing competent and confident professionals ready for the global clinical research landscape.

Bridging the Gap Between Academia and the Clinical Research Industry

Mission, Vision, and Objectives

> “Tell me and I forget; teach me and I may remember; involve me and I learn.”

Our mentors adopted this mantra of impactful instruction years ago. At Dysmech Clinical Services, we remain steadfast in our commitment to evolving alongside the ever-shifting landscape of clinical exploration and healthcare technology.

1

Our Mission

Dysmech Clinical Services is dedicated to **bridging the critical gap** between academic theory and industry reality. We empower students with the specialized technical expertise required to thrive in clinical research and its allied fields. By leveraging an industry-leading faculty, we ensure every graduate is not just "certified," but truly **job-ready** and compliant with the highest global standards.

2

Our Vision

Our vision is to be a **global pillar of excellence**, shaping the workforce for tomorrow’s emerging industries. We don't just provide information; we nurture a dynamic generation of professionals through a "learning-by-doing" philosophy. By prioritizing hands-on experience and practical application, we cultivate a diverse skill set and the collaborative confidence necessary to lead in the healthcare sector.

3

Our Objectives

At Dysmech Clinical Services, we aim to provide **high-quality, innovative approaches** and methodologies for advanced learning in clinical research and other healthcare fields. Our goal is to enhance job prospects for our students in healthcare, pharmaceutical, and IT sectors, developing them into valuable resources for the industry and society.

Features That Make DCS Unique

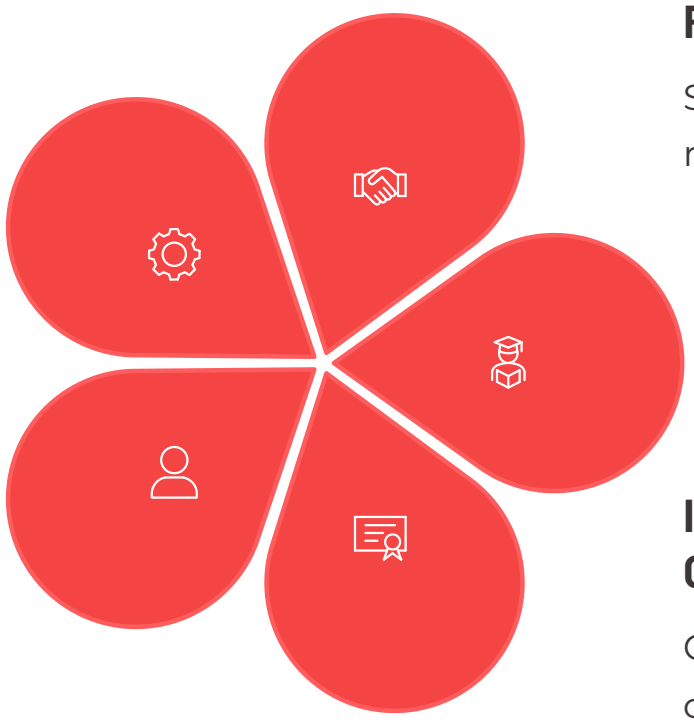
At Dysmech Clinical Services (DCS), we redefine clinical research education by blending industry-driven skills, real consultancy work, and next-gen technical learning. This integrated approach equips students with specialized expertise and real-world experience, making them job-ready leaders in healthcare.

Industry Skill–Driven Programs

Programs built for job-readiness, based on market needs.

1:1 Expert Guidance + 24/7 Support

Mentors from top tech companies and 24/7 assistance.



Real Consultancy Exposure

Solve actual client challenges for real-world expertise.

Faculty of Industry Leaders

Real-world insights from industry leaders.

International-Recognized Certification

Gain international-recognized certification with live projects.

DCS offers specialized programs with industry exposure in international standards with **Drug information Association (DIA), India** as a Knowldge Partner.

Advanced Diploma in Clinical Research Management

Behind every life-saving drug and medical breakthrough is a team of elite professionals who ensured it was safe, effective, and ready for the world. **Do you have the drive to be one of them?**

The **Advanced Diploma in Clinical Research Management** is your fast track into the heart of the global healthcare industry. This program bridges the gap between scientific passion and professional excellence, equipping you with the specialized skills to manage complex clinical trials, navigate global regulatory landscapes, and protect patient safety.

1

Clinical Research

ICH GCP E6 R1,R2 & R3, ICF, CRF, Protocol Writing, Global Regulations, Clinical Operations and AI & ML in Clinical Research.

2

Clinical Data Management (CDM)

CRF, e-CTD, CDM Documents, Rave EDC Workflow & Data Validation Specifications.

3

Pharmacovigilance (PV)

Adverse Event Reporting, Signal Detection, Oracle Argus Overview, MeDRA, PSUR & PADER.

4

Regulatory Affairs

IND & NDA Application, Intellectual Property Rights, Dossier preparation (CTD/eCTD).

5

Medical Writing

Medical Writing in BA/BE studies, Regulatory Guidelines, Biostatistics and Clinical Study Reports.

6

Soft Skills & Management

Business communication, interpersonal skills, and interview preparation.

DCS ADCRM Course Highlights

The Advanced Diploma in Clinical Research Management (ADCRM) is meticulously designed to equip you with specialized expertise across the most critical domains of clinical research. This comprehensive program delves into three core curriculum tracks, each offering in-depth knowledge and practical skills essential for a successful career in the global healthcare industry. Explore the foundational principles, cutting-edge methodologies, and regulatory landscapes that form the backbone of transforming scientific discovery into life-changing medical solutions.

Module 1: Clinical Research

1. Introduction to Life Science Industry & CR Overview
2. Drug Discovery & New Drug Development
3. Clinical Research (ICH-GCP E6) Guidelines
4. Clinical Research Regulation (RA)
5. Introduction to Medical Device CT
6. Regulatory Document & CT Protocol
7. Operational Aspects of Clinical Trials
8. Clinical Document Management
9. Clinical Trial Project Management

Module 2:Pharmacovigilance Module

1. Pharmacovigilance at Glance and Basic Concepts
2. Pharmacovigilance - Glossary and Related Terms
3. Regulatory Aspects of Pharmacovigilance
4. Different ICH & Other Requirements for Drug Safety
5. PV CDM & Case Processing
6. Medical Dictionary For Regulatory Activities (MedDRA)
7. Pharmacovigilance Reporting Database (Oracle Argus)
8. PV Signal Detection; PV-Management; PV-Risk Assessment
9. Medical Evaluation of Adverse Events in Pharmacovigilance

DCS ADCRM Course Highlights

Module 3: Clinical Data Management

1. Clinical Data Management Overview
2. Process of Collection and CRF Workflow
3. EDC System in Clinical Trial
4. Data Management Applications & Integration
5. Essential Characters of Database
6. CDM Coding
7. Query Generation, Verification & Validation
8. Database Lock (Soft Lock, Hard Lock)
9. Code of Ethics for CDM Professionals

Module 4:Medical Writing

1. Introduction to Medical Writing in CRO
2. Fundamentals of BA/BE Studies
3. International & National Guidelines
4. Regulatory Approvals in India (BENOC & Test License)
5. Ethics Committees & Informed Consent
6. Introduction to Biostatistics for BA/BE Studies
7. Protocol Writing
8. Clinical Study Report
9. Quality Control, Compliance, and Career Skills

Module 5 : Regulatory Affairs

1. Core Regulatory Submissions & Lifecycle Management.
2. Global Regulatory Standards & Harmonization
3. Quality, Safety & Compliance
4. Specialized Product Regulations
5. Emerging Trends & Skills
6. Regulatory Strategy Development
7. Global Market Access
8. Risk Assessment and Management
9. Quality Assurance and Auditing
10. Emerging Technologies & Trends

Module 6 : eTMF

1. Introduction to TMF and eTMF.
2. Wingspan Tab Overview
3. DIA Reference Model
4. Regulatory Compliance & Audit Readiness
5. Audit Trails & Traceability
6. Quality Control & Workflow Automation
7. Security & Access Control
8. AI and Intelligent Automation
9. Document Lifecycle Management
10. Vendor Selection Criteria

Key Career Roles & Salary Outlook in India

Clinical Research Coordinator (CRC)

– Manages trial operations, patient coordination, and documentation.

Clinical Research Associate (CRA)

– Monitors trial sites, ensures compliance, and verifies data.

Clinical Research Scientist

– Analyzes data and supports research conclusions.

Clinical Investigator

– Leads trials and ensures patient safety.

Medical Writer

– Prepares clinical and regulatory documents.

Data Analyst / Biostatistician

– Applies statistics to interpret trial data.

Drug Safety Associate

– Monitors drug safety and adverse events.

Clinical Data Associate

– Maintains accurate clinical databases.

Medical Coder/Biller

– Handles medical coding and records.

Pharmacologist

– Studies drug effects and development.

CLINICAL & PHARMA CAREER SALARY MAP – INDIA

— From Fresher to Industry Leader —

ENTRY LEVEL (0–3 YEARS)

Focus: Learning | *Certifications* *Software Skills*

- Medical Coder / Biller ₹2–4 LPA
- Drug Safety Associate ₹3–5 LPA
- CRC / CRA ₹3–5.5 LPA
- Regulatory Affairs Exec ₹5.5–5 LPA
- Clinical Research Scientist ₹4–6 LPA
- Data Analyst / Biostatistician ₹4–6 LPA
- Pharmacologist (PhD) ₹5–8 LPA

Key Skills: GCP, EDC, PV Tools, Regulatory Basics, Data Handling

MID LEVEL (4–8 YEARS)

Focus: Specialization | Project Handling Client Interaction

- Clinical Data Manager ₹5–8 LPA
- Drug Safety Officer ₹5–8 LPA
- CRC (Lead) ₹5.5–8.5 LPA
- Regulatory Affairs Officer ₹5–8 LPA
- Medical Writer (Scientific) ₹5–8 LPA
- Clinical Research Scientist ₹6–10 LPA
- Biostatistician / Data Analyst ₹6–10 LPA
- Pharmacologist ₹8–12 LPA

Key Skills: *Global Trials, Submissions, Protocols, Advanced Analytics*

SENIOR LEVEL (9+ YEARS)

Focus: *Leadership | Strategy* *Global Exposure*

- CDM Lead ₹8–12 LPA
- Drug Safety Manager ₹8–12 LPA
- CRA / Project Manager ₹8–14 LPA
- Regulatory Affairs Manager ₹8–14 LPA
- Senior Clinical Scientist ₹10–18 LPA
- Senior Biostatistician ₹10–18 LPA
- Pharmacology Specialist ₹12–20 LPA

Key Skills: *Strategy, Regulatory Approvals, Global Audits, AI Tools*

CAREER GROWTH LADDER

- **Clinical Research:** CRC → CRA → *Project Manager*
- **Pharmacovigilance:** → Drug Safety Assoc. → PV Manager
- **Clinical Data:** → Data Assoc. → CDM Lead
- **Medical Writing:** → *Medical Writer* → *Lead Writer*
- **Regulatory Affairs:** → RA Exec → RA Manager
- **Biostatistics / Data Science:** → Data Analyst → *Data Science Lead*

Course Details & Admission

Eligibility

B. Pharmacy, M. Pharmacy, Pharm D, Medicine (MBBS, BDS, BAMS, BHMS), Nursing, Biotechnology, Biochemistry, Microbiology, Graduates in Life & other allied health sciences.

Course Fees (Offline Mode)

Rs. 60,000 + GST

Duration & Hours

Duration - 6 Months **||** Total Hrs - 108 Hrs
No. of Hours Monthly: 18 Hours
(6 Session / Month)

Course Fees (Online Mode)

Rs. 30,000 + GST

Admission Process

Application submission, Profile Screening, followed by a interview, get Enrolled

Documents Required

ID Proof, Educational Certificate, Resume, 2 Photos

Don’t just get a certificate—get a career. DCS provides **100% Placement Support** through a robust network of industry partners and a proactive Corporate Interface Cell.

How We Prepare You for Day One:

- **Mock Interviews:** Master the art of the interview with expert-led simulations.
- **Resume Excellence:** Build a high-impact portfolio that stands out in the stack.
- **Skill Alignment:** We bridge the gap between your training and current market needs.
- **Industry Access:** Connect directly with recruiters and top-tier hiring managers

Your Gateway to Top Recruiters


DCS®
Power To Design The Desired

Dysmech Clinical Services
ISO and Internationally Certified by

Sr. No.	Student Name	Company Name	Designation
1	Ashwini Choudhari	IQVIA	Safety Associate Trainee
2	Pradnesh Deshmukh	IQVIA	Safety Associate Trainee
3	Neelam Mulik	IQVIA	Safety Associate Trainee
4	Milonee Yagnik	TCS	Senior Process Associate
5	Amruta Shende	TCS	Clinical Data Associate
6	Prashant Bhaskare	TCS	Patients safety specialist
7	Shrikant Gunale	Indian Council of Medical Research	Clinical Data Management
8	Rutuja Bokare	Fedora Advantage Solution	Billing Executive
9	Kushavarta Karhale	Cognizant	Safety Data Analyst
10	Rupali Rokade	Cognizant	Trainee Junior Data Analyst
11	Ishant Dhobale	ISS Research	CRC Intern
12	Yash Dakale	ISS Research	CRC
13	Sonali Wagh	KEM	Ethics Committee Co-ordinator Intern
14	Kshitija Bhagangare	KEM	CRC Intern
15	Vibhavari Jawale	Vedant Multispeciality Hospital	CRC
16	Ashwini Mali	Wipro	Drug Safety Associate
17	Payal Shelke	KEM	CRC Intern
18	Aarti Shinde	Kem's Hospital	Lab Assistance
19	Meghana pandhare	Clinithink Services Pune	Trainee Clinical Research Coordinator
20	Chaitrali Koli	Clinithink Services Pune	Trainee
21	Vaishnavi Bind	Covance Scientific services and Solutions	Jr. Regulatory Affairs Specialist
22	Shraddha Kekare	Covance India Pharma Services Pvt Ltd	Safety Science Analyst
23	Rupali Gholap	Hikal Analytical R & D	Scientist 1
24	Rekha Kumari	Clinithink Services Pune	Trainee-Clinical Research Coordinator
25	Anjali Patil	Clinithink Services Pune	Trainee-Clinical Research Coordinator
26	Shivani Sontakke	Ascentrik Research Pvt Ltd Wakad	Clinical Research Associate
27	Pallavi Jagtap	Clinithink Services Pune	Trainee-Clinical Research Coordinator
28	Aditi Ambekar	Unique Clinical Research Services Pune	Trainee-Clinical Research Coordinator
29	Yugandhara Patil	Technosoft Global Solut's LLP (IQVIA Project)	Research Associate
30	Dr Shweta Magar	Mitcon Biopharma	Medical Reviewer
31	Amruta Shinde	TCS	Clinical Data Associate
32	Pratiksha Dhumal	Lupin biotech	Desktop Support Engineer
33	Sanket Patil	King Edward Memorial Hospital	CRC Intern
34	Reshma Dhage	Lambda Therapeutic Research	Research Associate
35	Rushikesh Ambore	King Edward Memorial Hospital	CRC Intern
36	Anjali Bargal	King Edward Memorial Hospital	Ethics Committee Co-ordinator Intern
37	Aafreen Qureshi	Truhealthy LLP	Training Executive
38	Divya mali	Wipro	Data Associate
39	Tejashree jndre	Dysmech Clinical Services	CR Buisness Analyst
40	Kausthubh Harde	King Edward Memorial Hospital	CRC
41	Shraddha Kapadnis	Bion Clinicals	CRA Intern
42	Nikhil Shirsat	King Edward Memorial Hospital	CRC Intern
43	Trupti Bargal	King Edward Memorial Hospital	CRC Intern
44	Abhilasha Alure	King Edward Memorial Hospital	CRC Intern
45	Shraddha Pawar	Aihana College of pharmacy	Assistance Professor
46	Jishan Shaikh	Kamla Nehru hospital, Krsna diagnostic	Microbiology Technician
47	Padmesh Kulkarni	Dysmech Clinical Services	CR Buisness Analyst
48	Anupa Wagh	Bion Clinicals	CRA Intern
49	Janhvi Pagare	Bion Clinicals	CRA Intern
50	Pawan Satav	Bion Clinicals	CRA Intern
51	Adesh Chavhan	Bion Clinicals	CRA Intern
52	Aboli Maloka	Bion Clinicals	CRA Intern
53	Kumar Giri	Bion Clinicals	CRA Intern
54	Purvaja baldav	Bion Clinicals	CRA Intern
55	Akshada More	MYLAN LABORATORIES LIMITED	Quality Assurance Incharge

Power To Design The Desired

Our Recruiter Network

Unlock Your Future: In a High-Demand Career

Invest in your career with our specialized programs, designed to equip you with critical, in-demand skills for the pharmaceutical and biotechnology industries, fostering significant growth and unparalleled opportunities.

Begin Your Journey: Connect With Us

Our team at Dysmech Clinical Services Pvt. Ltd. is ready to guide your enrollment and answer questions about our programs, start dates, and application deadlines.

Dysmech Clinical Services Pvt. Ltd.

Address: Office No. 502, 5th Floor, Royal Avenue, BRS Road, Shivar Chowk, Rahatani, Pimple Saudagar, Pune 411027. MH

Website: www.dcsplm.com

Phone: 8698181853 / 8956895738

Take the Next Step! Contact us today to secure your spot and transform your career.