SEMESTER-II

GANPAT UNIVERSITY									
FACULTY OF MANAGEMENT STUDIES									
Program	MBA		Branch/Spec.		MBA (Pharmaceuticals)				
Semester	II				Version	1.0.0.0			
Effective from Academic Year		2025-26			Effective for the batch Admitted in		June 2025		
Subject code	**IIA01CRD**		Subject Name		**Certificate Course in Clinical Research, Clinical Data Science and Pharmacovigilance**				
Teaching scheme									
(Per week)	Lecture(DT)		Practical(Lab.)		Total				
	L	TU	P	TW					
Credit	4	0	0		4				
Hours	4	0	0		4				

Objective:
To provide students with an integrated strategic framework for managing the lifecycle of a drug, from clinical development and data management to post-market safety surveillance, enabling them to lead effectively in the global biopharmaceutical industry.

Course Outcome:
CO 1: The students will be able to explain the end-to-end drug development lifecycle and the strategic interplay between clinical research, data science, and pharmacovigilance.
CO 2: The students will be able to analyze the operational, ethical, and regulatory components of managing clinical trials from a business and project management perspective.
CO 3: The students will be able to evaluate the strategic importance of clinical data management, including the role of data standards, technology platforms, and data integrity in regulatory submissions.
CO 4: The students will be able to formulate a high-level strategy for global pharmacovigilance and risk management, integrating emerging trends like AI and Real-World Evidence to ensure patient safety and business continuity.

Theory syllabus

Unit	Content	Hrs
1	Foundations of Drug Development & Regulatory Landscape, The Drug Development Lifecycle: From Discovery to Post-Market, The Business of R&D: Costs, Timelines & Success Rates, Introduction to Clinical Research (CR), Clinical Data Science (CDS) & Pharmacovigilance (PV), The International Council for Harmonisation (ICH) & its Strategic Importance, The Global Regulatory Ecosystem: FDA, EMA, PMDA, Introduction to GxP Principles (GCP, GLP, GMP) for Managers, Key Stakeholders: Sponsors, CROs, Investigative Sites, Patients, The Ethical Framework: Declaration of Helsinki & Informed Consent	12
2	Strategic Management of Clinical Research, Clinical Trial Phases (I-IV): Strategic Objectives & Business Implications, Good Clinical Practice (GCP): A Quality Framework for Trials, Essential Trial Documents: Protocol, Investigator's Brochure (IB), ICF, Clinical Trial Operations Management: - Site Selection & Feasibility Analysis - Patient Recruitment & Retention Strategies, The Role of Contract Research Organizations (CROs): Vendor Management, Budgeting & Financial Management of Clinical Trials, The Common Technical Document (CTD): Structure & Purpose.	12

3	Clinical Data Science for Business Leaders, The Strategic Value of High-Quality Clinical Data, The Clinical Data Management (CDM) Process Flow, Technology Platforms (Managerial View): EDC, CTMS, eTMF, The Importance of Data Standards: CDISC (SDTM, ADaM), Data Integrity & ALCOA+ Principles in a Business Context, The Role of Biostatistics & Statistical Analysis Plans (SAPs) (Conceptual), Database Lock: A Critical Business Milestone, Data Privacy in Clinical Research: GDPR & HIPAA.	12
4	Pharmacovigilance (PV) and Drug Safety Strategy, The Goal of Pharmacovigilance: Patient Safety & Public Health, Sources of Safety Data: Spontaneous Reports, Literature, Trials, Individual Case Safety Report (ICSR) Processing Lifecycle, Signal Detection & Management: Proactive Safety Analysis, Aggregate Reporting: PSURs, PBRERs, DSURs, Risk Management Plans (RMPs) & REMS Strategy, PV Audits & Inspections: Ensuring Compliance, The Role of the QPPV (Qualified Person for Pharmacovigilance).	12
5	Integrated Strategy, Technology, and the Future of Drug Development, The Data Lifecycle: From Patient to Submission to Post-Market, Real-World Evidence (RWE): Strategic Applications, The Impact of AI & Machine Learning (Conceptual): - AI in Trial Design & Patient Recruitment - AI in Data Cleaning & Signal Detection, Decentralized Clinical Trials (DCTs): Business Models & Challenges, Patient-Centricity: Integrating the Patient Voice in Development, The Future: Digital Biomarkers, SaMD, Personalized Medicine.	12
Practical content		

Reference Books	
1.	Pisano, Gary P. Science Business: The Promise, the Reality, and the Future of Biotech. Harvard Business Press, 2006.
2.	Weinberg, Sandy. The Pharmagellan Guide to Biotech Forecasting and Valuation. Routledge, 2020.
3.	Evens, Ronald G. The Development of Biopharmaceuticals: An Insider's Perspective. Wiley, 2010.
4.	Blecher, M. B., et al. Fundamentals of US Regulatory Affairs. 11th Edition, RAPS - Regulatory Affairs Professionals Society, 2019.
5.	Gazarian, M. The Essential Guide to Clinical Research. Wiley-Blackwell, 2011.
6.	Edwards, I. Ralph, and Biriell, C. (Eds.). Pharmacovigilance. 2nd Edition, Wiley-Blackwell, 2011.
7.	McFarlane, C., and De Tran, L. Clinical Data Management: A Practical Guide. SAS Institute, 2014.
8.	Gerrard, S., and Goldstein, L. H. Mastering the VC Game: A Venture Capital Insider's Guide to Fundraising and Dealmaking for Entrepreneurs. Portfolio, 2012. (For biotech startup context).
9.	Badings, I., and Dagher, R. (Eds.). Textbook of Pharmaceutical Medicine. 7th Edition, Wiley-Blackwell, 2014.
10.	Cramer, C. L. The Drug Development and Approval Process. 3rd Edition, Neoflora, 2020.
11.	Woodcock, J., and Marks, P. (Eds.). The FDA and Worldwide Drug Regulation. Wiley, 2017.
12.	Shapiro, Stan. Best Practices Are Stupid: 40 Ways to Out-Innovate the Competition. Portfolio, 2011. (For innovation mindset).
13.	Kaplan, Robert S., and Norton, David P. The Balanced Scorecard: Translating Strategy into Action. Harvard Business Review Press, 1996.