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EXECUTIVE CERTIFICATE COURSE IN

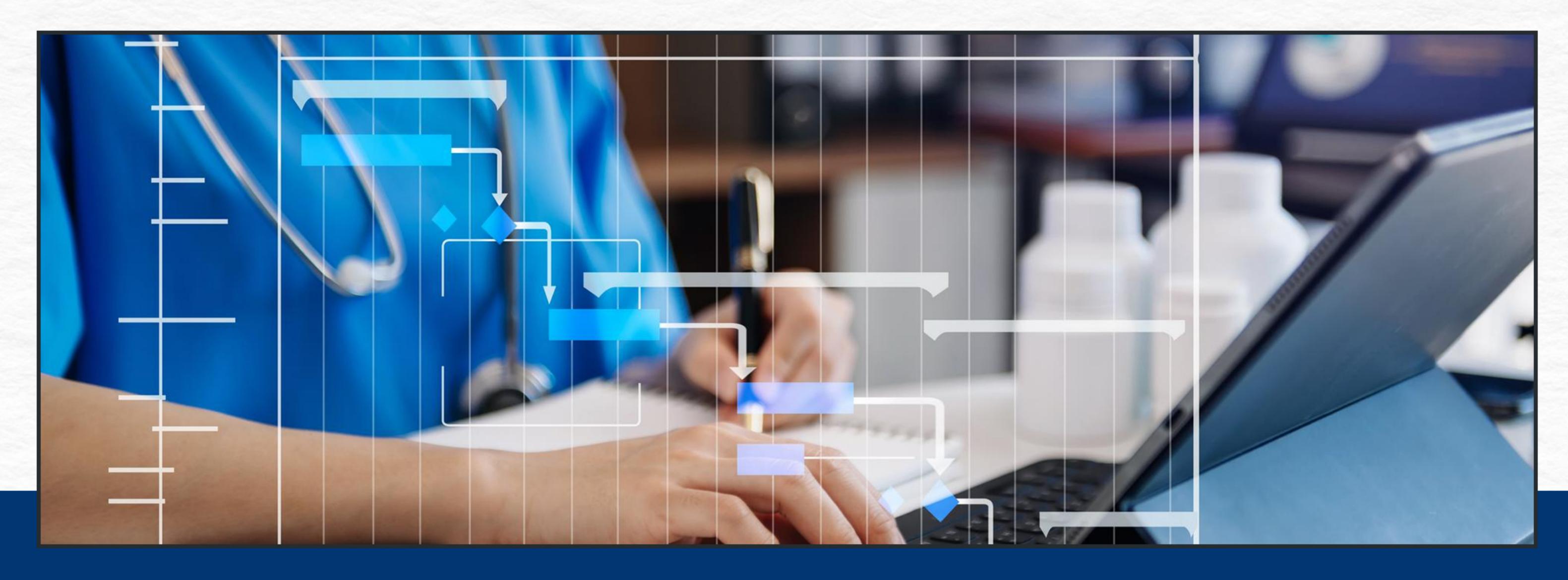
CLINICAL DATA MANAGEMENT



About the Curio

Curio Training and Research Institute (CTRI) is the Constituent Unit of CliMed Research Solutions India, dedicated to providing Pharma and Healthcare Industry Training. Curio is established to transform the pharma and healthcare landscape by nurturing talent, fostering innovation, and driving excellence in these critical sectors.

Curio commits to producing professionals well-versed in theory and equipped with practical skills to lead, innovate, and create positive change. Curio provides industryoriented value-added, skill development courses, corporate training, and career consultation to individuals and institutions/universities.



About the Course

Clinical Data Management (CDM) is a critical phase in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials. This helps to produce a drastic reduction in time from drug development to marketing. Team members of CDM are actively involved in all stages of clinical trial right from inception to completion. They should have adequate process knowledge that helps maintain the quality standards of CDM processes. Various procedures in CDM including Case Report Form (CRF) designing, CRF annotation, database designing, data-entry, data validation, discrepancy management, medical coding, data extraction, and database locking are assessed for quality at regular intervals during a trial. In the present scenario, there is an increased demand to improve the CDM standards to meet the regulatory requirements and stay ahead of the competition by means of faster commercialization of product



Syllabus

Module 1: CDM Process Overview

Module 2: Study Set up, Study Conduct and Close out Overview

Module 3: Protocol and CRF

Module 4: CRF design consideration

Module 5: Data Management plan

Module 6: Electronic data capture/Remote Data Entry

Module 7: Discrepancy management (Identifying and managing discrepancies)

Module 8: UAT and Tracking CRF data

Module 9: Data review/data validation, Query management

Module 10: eCRF Specification and Edit check specification

Module 11: Collective adverse event data

Module 12: Lab Data and SAE Reconciliation

Module 13: Database lock

Eligibility:

 This course is ideal for professionals working in clinical research, healthcare, and related fields, including project managers, clinical trial coordinators, research associates, and regulatory affairs professionals

 Any health science graduate (B. Pharm/Pharm D/Nursing/Medical/M Pharm/MSc/ Ph.D. inscience disciplines)

Certification

Upon successful completion of the program, participants will receive a recognized certificate, validating their expertise in project management in clinical research.



Course Commencement October 13, 2024



Last Date to Register September 29, 2024



Course Fee 2,499/- INR (50% Curio introductory discount on 4999/-)



Course Duration3-Months Live Classes



Classes
Weekend Evening
Classes Live



Registration Link https://rzp.io/l/cucdmoc



Course Convener

Dr. Ajit Singh

CEO and Founder, CliMed Research Solutions & Curio Research Scientist for ICMR, Department of Medicine, Kasturba Medical College & Hospital, MAHE

Dr. Ajit Singh, Founder, and chief Executive Officer at CliMed Research Solutions & Curio - India, a young entrepreneur & scientist, has completed his Ph.D. in Cardiology from the eminent Manipal Academy of Higher Education (MAHE), a leading organization in research and education in India. Recently, he was appointed as Research Scientist & RAIII for ICMR'' at the Department of Medicine, Kasturba Medical College, Manipal. He also serves as 'National Director for Research' at 'World Youth Heart Federation' (WYHF-India) & 'Principal Investigator for 'Manipal Heart Failure Registry (MHFR).' In July 2021, he was appointed as Vice president of the Medical Artificial Intelligence Wing at Indika AI, Mumbai.

He has published more than 40 papers in different streams of medicine, including Cardiology, Cardio-oncology, and Infectious Diseases. He is the investigator and site coordinator for many international clinical trials. Dr. Singh is an honorary reviewer in many reputed journals, including Oxford Group, BMJ Group, and The Springer Group of Journals. Dr. Singh has been appointed as Editor-in-chief for the Journal of Basic and Clinical Cardiovascular Research and an editorial board member for several medical journals. He has received several international research and travel grants from esteemed organizations, including the European Society of Cardiology, the Indian Council for Medical Research, DST-SERB, and the American College of Cardiology. He received the 'Young Achievers Award 2019' and 'The Young Scientist Award 2020' in Cardiology Research from reputed international organiztions. Dr. Singh has traveled to more than ten countries regarding his research presentations and invited lectures.