Eligibility Criteria

The training programs provided by Clinnovo are suitable for Life science Graduates, Doctors, Medical Professionals, Pharmacists etc.

Anyone of the following minimum qualification is mandatory to eligible:

B. Sc / M. Sc in Biotechnology, Microbiology, Genetics, Biochemistry or Life Sciences

M.B.B.S / B.D.S / B.A.M.S / B.H.M.S

B. Pharmacy / M. Pharmacy

Graduates or Post Graduates in Nursing

B.E (BT) / B. Tech (BT)

Ph. D in Life Sciences / Biomedical Science

Contact Information

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CLINNOVO RESEARCH LABS

Clinnovo Research Labs Pvt Ltd is a clinical innovation company focused on conducting research on disease, promoting use of medical informatics in clinical practice and patient care, and development of indigenous medical technology.It has an exclusive Clinical Research Training centre that was established in 2005 and has successfully trained more than 3000 students till date The motive of this centre is to educate and guide individuals in the field of Clinical Research to meet industry needs. Clinnovo's alumini have been recruited world-wide in various Clinical Research Organizatons.

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COURSES OFFERED

- Certificate program in Clinical Research, CDM and SAS (3 months)
- Job Oriented Program in CR, CDM, SAS (6 months)
- Job Guaranteed Program in CR, CDM, SAS (1 Year)
- PG Diploma in Clinical Informatics

CLINICAL RESEARCH

Introduction to Clinical Research
Introduction to Drug Discovery & Development
Roles & responsibilities of study team
Regulatory Bodies
ICH and CDSCO guidelines
ICH-GCP
Informed Consent Form and Investigator's Brochure
Protocol Design
IRB/IEC
Preparations & Planning for Clinical Trials
Essential Documentation in Clinical Research
Clinical Trials Project Planning & Management
Study Start Up Process
Compliance, Auditing & Quality Control in Clinical Research
Standard Operating Procedures (SOP)

SAS & BIOSTATS

Introduction to SAS
Components of SAS
Different Data types
Base/SAS
SAS/GRAPH
SAS/STAT
SAS/ACCESS
SAS Procedures
SAS Macros
SAS (Working with SQL)
SAS Import and Export datasets
Basic Statistics for Clinical
Statistical Significance
Data visualization tools
Reporting Clinical trial analysis

CLINICAL DATA MANAGEMENT

Introduction to CDM
Data collection
CRF design elements
Paper based CRF design
Electronic Data Capture
Data Entry, Remote data Entry
Data Quality management plan
Data Validation and Edit checks
Query Management
Medical coding
MedDRA
Collecting Adverse Event data
Open Clinica (Comprehensive)
Open CDMS
Oracle Clinical (Overview)

PHARMACOVIGILANCE

Introduction to Pharmacovigilance
ADR, AE, SAE Criteria, PSUR & DSUR
PV in India, Reportable case criteria
PV database and signal detection
UMC, Causality assessment scales
MedDRA
Case Processing
Literature Case Narrative
Oracle Argus – Overview part I
Oracle Argus – Overview part II
Oracle Argus – Overview part III
Oracle Argus – Overview part IV
Regulatory guidelines and laws in PV
PV database and signal detection
PV auditing and Inspection
SOP's in PV

CDISC - SDTM

Understanding of SDTM Implementation Guide
Basic of SDTM Domains
CDISC Variable types and their importance
Fundamentals of CDISC SDTM
Special Purpose Domains
Creating Custom SDTM Domains
Timing variables in SDTM
CDISC SDTM core variables
Supplementary Qualifiers
Dealing with Non standard data
Controlled terminology and different types in it
SDTM Assumptions
Special Purpose Domains (DM,CO,SE,SV)
Interventions(CM,SU,EX,PR)
Events(AE,CE,DS,DV,HO,MH)
Findings(DA,PE,VS,LAB,IE,QS,RP,SS,ECG)
Annotation of Annotated CRF as per SDTM)
Creation of Mapping/Metadata Specification as per SDTM Guidelines
Creation of different SDTM Datasets(DM,AE etc)
Creation of Trial Design Domain datasets.
Programming of Various Standard SDTM Macros like study day,empty dataset etc.
SDTM datasets validation and resolution
FDA Submission standards of SDTM

ADaM

A) ADSL Subject level information basics
B) BDS basics
C) ADAM Implementation Rules
D) Creation of Adam Metadata Specification
E) Creation of ADAM datasets (ADSL and BDS dataset)
F) ADAM datasets validation and resolution
G) Creation of ADAM Define.XML
H) Creation of Analysis Data Reviewers Guide
I) FDA Submission standards of ADAM datasets
TABLES:Creation of Safety tables
Creation of Efficacy tables
Calculation of treatment variables, study day etc.
LISTINGS:Creation of Safety listings
Creation of Efficacy listing

MEDICAL IMAGING

Medical Imaging Trials
Site Qualification
Anatomy
Computed Tomography (CT)
Magnetic resonance imaging (MRI)
Positron emission tomography (PET)
Dual-energy X-Ray absorptiometry (DXA)
Quality Control in Medical Imaging
RECIST

JOB PROFILE

Clinical Research Associate
Clinical Data Associate
Clinical Coordinator
Clinical Specialists
Clinical Project Manager
Research Physician
Clinical Data Manager
Clinical Data Entry
Clinical Data Entry Analyst
Regulatory Affairs Associate,OTC
Safety Data Analyst (Pharmacovigilance)
Auditors/Compliance
Medical Writers
Safety/Pharmacovigilance Associate
Pharmacovigilance Director/VP roles
Pharmacovigilance Compliance
Pharmacovigilance Consultants
Quality Assurance
Auditing Assurance
Auditing (GCP,GMP,GLP)
Quality Control (Technician to Manager)
Quality Manager
SAS programmer/ Analyst