Call us: 9980185087 / 8792590942
Mail: info@bcri.in

ONLINE | CLASS ROOM

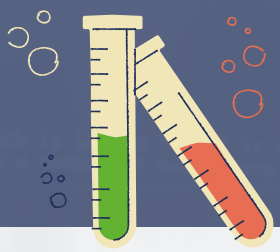
CLINICAL DATA MANAGEMENT

EXCLUSIVE COURSES FOR LIFE SCIENCE AND PHARMA GRADUATES

THE GLOBAL CLINICAL TRIALS MARKET SIZE IS EXPECTED TO REACH USD 69.8 BILLION BY 2027.

BANGALORE CLINICAL RESEARCH INSTITUTE

CERTIFICATION IN CLINICAL DATA MANAGEMENT



Process flow

- Data management plan
- Study set up
- Tracking CRF Data
- Entering data
- Managing lab data
- Identifying and Managing discrepancies
- Collecting adverse Event Data

Study Set-up

- Approved Protocol
- Project Plan
- eCRF Specification
- Visit Form Matrix
- DB design
- DVS
- UAT
- IxRS Integration
- Final Sign off – Go Live
- DMP

Clinical Trail Management

- Fundamentals of clinical trials
- Basic statistics for clinical trials
- Clinical trials in practice
- Reporting and reviewing clinical trials
- Protocol development
- Trial designs
- Project management and research co-ordination
- Regulatory affairs, good clinical practice and ethics
- Data management
- Data monitoring and interim analyses
- Data reconciliation
- DCMs and DCIs

CDM Systems

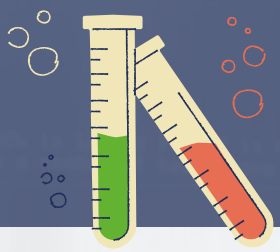
- Where systems come from?
- Choosing vendor products
- Implementing New Systems
- System Validation
- Test plans
- Migrating legacy Data
- Change control

Creating standards

- Creating hierarchies
- Sops and guidelines
- Working with CROS
- CRF Design Consideration
- Remote Data Entry
- Data entry in RDC and Discrepancy Management in RDC
- Auto coder Algorithms

Case Studies |100% Genuine placement Assistance | Industry Ready

CERTIFICATION IN PHARAMACOVIGILANCE



Study Conduct

- Tracking CRF, Data Creating Data Collection Modules and layouts corresponding to CRFs to allow for data entry
- Entering data, Generating and Testing data entry screens and validate the range, format, date, missing fields
- Data validation
- User acceptance testing (UAT)
- Managing lab data
- Identifying and Managing discrepancies
- Collecting AE Data
- SAE Reconciliation
- Reviewing clinical data as per SOP, protocol, and study specific guidelines
- Medical Coding
- IxRS Reconciliation
- Listing Reviews, consistency checks
- QC
- Status Reports
- All Subjects completed final visits/f-up visits
- Medical Coding data review completed and issues resolved
- Final SAE reconciliation
- All queries resolved and DB updated
- Final review completed
- All expected forms and visits are locked/frozen
- QC steps conducted and QC plan and report documented
- QA issues addressed if any
- All documentation completed as per DMP and stored according to SOP
- Data is archived/submitted

FULL TIME | ONLINE | PART TIME

TOP COMPANIES HIRING THE CLINICAL RESEARCH & MEDICAL CODING

ArisGlobal
We Bring the Future to Life™

Quanticate
The Clinical Data Experts

BIOCLINICA RESEARCH

COVANCE

MMS Holdings Inc.

IQVIA™

ah
accesshealthcare

accenture

Cognizant

novo nordisk

Omega Healthcare
Excellence in Business Outsourcing

BANGALORE CLINICAL RESEARCH INSTITUTE

TRAINING LOCATIONS

Marathahalli, Bangalore
Krishna Summit 3rd floor Service Rd, Aswath Nagar, Marathahalli, Bengaluru, Karnataka 560037.

Cunningham Road, Bangalore
Leeman's Complex, 30/1, 4th floor, Cunningham Rd, Vasanth Nagar, Bengaluru, Karnataka 560052.

Nagarbhavi, Bangalore
1st Floor, Opp KLE College, Kengeri Main Rd, above Raymond showroom, Naagarabhaavi, Bengaluru, Karnataka 560072

9980185087
8792592942
info@bcri.in
https://www.bcri.in