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ADVANCED DIPLOMA IN CLINICAL RESEARCH (ADCR)

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

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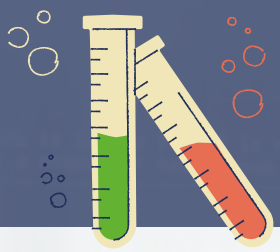
Clinical Research

ADVANCED DIPLOMA IN CLINICAL RESEARCH



Overview of Clinical Research

- Overview of clinical research
- Phases of clinical trials
- Phase 0 study and phase
- 5 clinical trial
- Clinical study and clinical trials

Conduction of clinical studies and observational studies

- Treatment trials
- Prevention trials
- Diagnostic trials
- Screening trials
- Quality of Life trials

Site and duration for clinical studies

- Clinical research vs.
- Medical care
- Phases of FDA approval
- Reasons for conducting clinical studies
- Micro dosing
- Dose Ranging
- Single ascending dose
- Multiple ascending dose
- Trial design
- Efficacy vs Effectiveness
- Investigational new drug and New drug application

Aggregation of safety data during clinical development

- Participants
- protection and considerations for participation
- Active control studies
- Percentage of drugs
- fail clinical trials
- Clinical research relationship to usual health care

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

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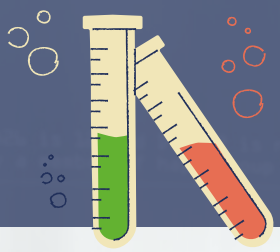
CERTIFICATION IN PHARAMACOVIGILANCE



Process flow

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

Study Set-up

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

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

Clinical Trail Management

- Fundamentals of clinical trials
- Basic statistics for clinical trials
- Clinical trials in practice
- Reporting and reviewing clinical trials
- Protocol development

Clinical Trail Management conti...

- 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

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

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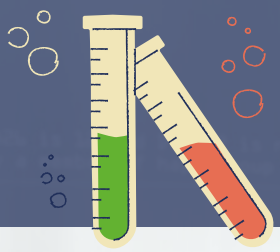

Study Conduct conti.....

- 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

Pharmacovigilance

Introduction of Drug Discovery and Development

- Discovery and Development
- Pre-clinical Research
- Clinical Research
- Drug Review
- Post Market Drug Safety Monitoring

Introduction to Pharmacovigilance

- Pharmacovigilance (WHO Definition)
- History of Pharmacovigilance
- Scope and purposes of Pharmacovigilance
- Basic Concepts: Terms and definitions
- General idea of PV and types of AE reporting
- Types and sources of data
- The process of Pharmacovigilance- Signal Detection and Drug recall
- What are safety signals?

Pharmacovigilance Reporting Database

- Risk Assessments & Evaluation
- Reporting Criteria to Health authorities and timelines
- Quality System In PV
- Expedited Reporting Criteria
- PSUR & PBRER

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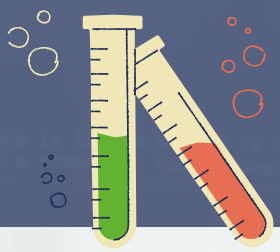

Pharmacovigilance Reporting Database conti....

- Different reporting formats used in PV
- PSUR and DSUR overview
- PV Database and Signal Detection
- Safety ignals
- Signal Management
- Risk Assessments & Managements

PV Database Index

- Case receipt
- Data verification and validity check
- Triage
- Duplicate search
- Book in and registration
- Data Entry
- Coding of AE and Drugs

Causality assessment

- Expectedness assessment
- Why causality assessment
- WHO – UMC causality assessment system
- Case Narrative
- Quality check
- Reporting or Submission
- Deletion and nullification
- Initial Receipt date and Day 0 Importance
- Case linking, Mother and Baby cases
- Special Case Scenarios: LOE, Off-Label use, Misuse, Overdose, Pregnancy &
- Medication Error
- Practicing Real Time cases scenarios

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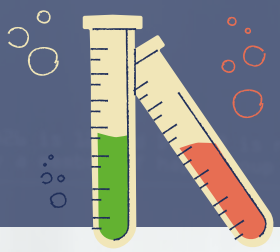

Drug Dictionaries, ADR dictionaries and Coding of the events

- WHO drug dictionary
- COSTART
- MedDRA
- ADR classification
- SAE and Seriousness criteria

Narrative Writing

- Overview and Characteristics Case Narrative
- Sections of Case Narrative
- Steps and Construction of a narrative

Regulatory Affairs

- Introduction to Global Regulatory Authorities for pharma and healthcare industries
- Regulatory affairs in clinical research
- WHO –UMC (Uppsala Monitoring Committee), CIOMS
- Drug Development Process, Clinical Trials and related norms and regulations
- European Pharmacovigilance System
- FDA Good Clinical Practice (GCP)
- ICH Good Clinical Practice (ICH-GCP) guidelines clinical trials
- International Council for Harmonisation
- GCP in pharma, Main GCP principles, GCP compliance
- GMP and other good practices.
- Institutional review board (IRB) / independent ethics committee (IEC)
- Quality Assurance and Drug Regulations, ICH and WHO guidelines
- Technical Requirements for Pharmaceuticals for Human Use
- Data monitoring committees
- European Forum for Good Clinical Practice (EFGCP),European Medicines Agency (EMEA)
- Dossier preparation in CTD format, eCTD submissions
- Healthcare Industry IPR, Patents, copyrights and Trademarks
- Pharma and Healthcare products- Marketing, Import and Export regulations
- Compliance guidelines, Govt. Audits (FDA, MHRA, PMDA, TGA, DCG, etc) and Breach reports
- Indian GMP Regulations

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