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OVERVIEW OF CLINICAL RESEARCH

- Definition and Importance
- Role in medical advancements
- Impact on patient care and policy
- Historical Milestones in Clinical Research
- Key trials and their outcomes
- Evolution of regulations and guidelines

TYPES OF CLINICAL RESEARCH

- Interventional Studies
- Drug trials, device trials, and other interventions
- Observational Studies
- Cohort, case control, cross-sectional, and ecological studies
- Diagnostic and Screening Research
- Methods, validity, and reliability
- Prevention and Quality of Life Research
- Strategies for disease prevention and management of chronic conditions

ETHICS IN CLINICAL RESEARCH

- Principles of Bioethics
- Autonomy, beneficence, nonmaleficence, justice
- Informed Consent Process
- Detailed process, challenges, and legal implications
- Institutional Review Board (IRB)
- Role, function, and case studies

REGULATORY FRAMEWORK

- FDA Regulations
- Comprehensive review of drug and device approval processes
- ICH Guidelines
- Key guidelines and their impact on global research standards
- EMA Guidelines
- Specific regulations for conducting trials in the EU
- Other National and International Guidelines
- NDCT, ICMR, and other relevant guidelines

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- Industry-Relevant Training by Experienced Instructors
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DESIGNING CLINICAL TRIALS

- Types and Phases of Clinical Trials
- Detailed exploration of phases I to IV and their specific goals
- Randomization and Blinding
- Techniques and importance in trial design
- Protocol Development
- Elements, amendments, and practical exercises in drafting

PATIENT RECRUITMENT AND RETENTION

- Recruitment Strategies
- Effective methods, ethical considerations, and case studies
- Challenges in Patient Retention
- Common issues, strategies for improvement, and impact on research outcomes

CLINICAL DATA MANAGEMENT

- Data Collection and CRF Design
- Best practices in design and implementation
- Database Design and Management
- Security measures, data integrity, and regulatory compliance
- Quality Assurance in Data Management
- Standards, audits, and maintaining data quality throughout the trial

BIOSTATISTICS IN CLINICAL RESEARCH

- Statistical Concepts and Methods
- Descriptive and inferential statistics, hypothesis testing
- Sample Size Calculation
- Techniques, importance, and common errors
- Data Analysis Plan
- Development, statistical software tools, and interpretation of results

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GOOD CLINICAL PRACTICE (GCP)

- Principles of GCP
- Overview and importance in clinical trials
- Responsibilities of Investigators and Sponsors
- Detailed responsibilities and ethical considerations
- Regulatory Compliance in Clinical Trials
- Ensuring adherence to laws, guidelines, and ethical standards

ADAPTIVE CLINICAL TRIAL DESIGN

- Principles and Benefits
- Overview, advantages, and when to use adaptive designs
- Types of Adaptive Designs
- Description, applications, and case studies

PATIENT CENTERED AND REAL WORLD EVIDENCE STUDIES

- Patient Centered Outcomes Research (PCOR)
- Methods, importance, and impact on policy and practice
- Real World Evidence (RWE) Collection, analysis, and application in clinical settings

TECHNOLOGY IN CLINICAL RESEARCH

- Electronic Data Capture (EDC) Systems
- Features, benefits, and challenges
- Use of Mobile Health in Clinical Trials
- Innovations, case studies, and future directions

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CLINICAL TRIAL MANAGEMENT AND LEADERSHIP

- Project Management Principles
- Key concepts, tools, and strategies for effective management
- Leadership and Team Management Skills
- Developing skills for leading multidisciplinary research teams

GLOBAL CLINICAL TRIALS

- Conducting Multinational Clinical Trials
- Challenges, strategies, and regulatory considerations
- Cultural and Regulatory Considerations
- Adapting protocols for international and multicultural settings

FUTURE DIRECTIONS IN CLINICAL RESEARCH

- Personalized Medicine
- Role of genetics and biomarkers in developing personalized therapies
- Advanced Therapies
- Gene therapy, cell therapy, and regulatory challenges

CASE STUDIES IN CLINICAL RESEARCH

- Analysis of Successful and Failed Clinical Trials
- Lessons learned, best practices, and ethical considerations
- Ethical Dilemmas in Clinical Research
- Discussion of complex ethical issues and case studies

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WORKSHOPS AND SIMULATIONS

- Protocol Development Workshop
- Hands on training in protocol writing and review
- Data Management and Statistical Analysis Exercise
- Practical exercises in data handling and analysis

COMMON QUERIES AND QUESTIONS IN CLINICAL RESEARCH

- Scientific Terminologies in Clinical Research
- Understanding and using clinical research terminology effectively

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