Clinical Monitoring and Site Management

I. Global Regulated Environment
- Introduction
- Regulations
- Events
- Code of Federal Regulations
- IND Regulations
- Assurance
- Establish Standards
- Compliance
- Organizational Chart
- Pre-IND Meeting
- Pre-IND Meeting
- End of Phase Two Meeting
- Pre-NDA Meeting (End of Phase III)
- Time Outline

II. HPB Regulated Environment
- Objectives
- Overall Structure
- Therapeutic Products Program
- Food & Drug Act
- Clarification
- Regulatory Submissions
- PreClinical
- Subsequent Stages of Development
- Review & Approval
- No Requirement Necessary
- IND Review & Approval Process
- Canadian “Unique” IND Components
- Biologics/Unique Requirements
- Future Initiatives
- Market Applications
- Cost Recovery
- Target Performance Standards
- Canadian Industry Performance
- Priority Review
- Early Access Reviews
- Key Messages

III. Informed Consent
- Objectives
- History
- Consent Form
- General Elements
- Basic Elements
- Additional Elements
- IRBs & ECs
- Primary Criterion
- Regulations

IV. Investigator Selection
- Objectives
- Identify Potential Investigators
- Criteria
- Medical Specialty
- Patient Population
- Clinical Research Experience
- Required Facilities/Equipment
- Required Research Staff
- Motivation
- Recording/Organization of Data
- Personality
- Cooperativeness
- Final Recommendation

V. Study Initiation/Inv. Selection
- Objectives
- Initial Visit Defined
- ICH Guidelines
- Documentation
- DocumentationII
- Attendees
- Planning Agenda
- Study Review
- Staff Involvement
- Understanding of Expectation
- Review Regulatory Responsibility
- Facility Reassessment
- Follow-up for Monitors
- Purposes
- Advantages
- Logistical Issues
- Tips/Follow-up

VI. DA (Drug Accountability)
- DA1-Objectives/Goals
- DA15-Record Keeping/Record Retention
- DA16-Unused Supply
- DA17-Sponsor’s Records and Reports
- DA18-Handling Controlled Substances
- DA2-CQA Audits
- DA21-Proper Dispensing of Drug
- DA22-Total Accountability
- DA25-Initial Visit
- DA 3-Routine Visit
- DA35-Final Visit
- DA4-Common Problems

VII. Sample Handling

VIII. Site Management / Visits

IX. Data Management

X. Quality Assurance
Definition of Quality
Typical CQA Group
CQA Group
GCP Audits
GCP Audits/Independent Assessment
Regulatory Expectations
Data Integrity & Compliance
Special Client Focus
Data Evaluation
Approaches
Selection of Sites
Selection of Patients
Conduct of Site Audit I
Conduct of Site Audit II
Conduct of Site Audit III
Site Audit Product
Objectives
Regulatory Responsibility
Corporate Responsibility
Personal Responsibility
Adverse Event Definition
Non adverse events
Treatment failure
Data collection requirements
Adverse event requirements

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