CITI Training

Conducting Investigator-Initiated Studies According to FDA Regulations and GCP

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| What is a sponsor investigator? | individual who both initiates and conducts the clinical investigation and under whose immediate direction the investigational drug or device is being administered, used, or dispensed |
| What is an IND? | Investigational New Drug Application |
| What is an IDE? | Investigational New Device Application |
| When is an IND not needed? |  |
| What is the content of an IND? |  |
| What are the sponsor investigator responsibilities with an IND? |  |
| What are the reports needed for an IND? |  |
| What is the content of an IDE? |  |
| What are the sponsor investigator responsibilities with an IDE? |  |
| What are the reports needed for an IDE? |  |

Investigator Obligations in FDA-Regulated Research

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| What should an investigator consider when participating in a clinical trial? |  |
| What are sponsor site assessments? | Sponsor representative will review the study requirements and answer any questions that the investigator or staff might have about the execution of the study and check for… |
| What is the initial investigator reports and approvals? | Sponsor will enter into a clinical trial agreement (CTA) with the investigator. This agreement is a contract that defines both the terms of study conduct and the financial agreements. Other documents include…      Which must be sent for |
| What are some study conduct themes? | matinence |
| What are things the sponsor should keep in mind? |  |
| What are things IRB IEC should keep in mind? |  |
| What are the things the research subjects should keep in mind? |  |
| What are the things the FDA should keep in mind? |  |

Managing Investigational Agents According to GCP Requirements

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| All investigational products should be what? | Regulated and controlled |
| What is the product accountability list? |  |
| How should investigational products be packaged? |  |
| How should investigational products be labeled? |  |
| How should investigational products be stored? |  |
| How are investigational products dispensed? |  |
| When a drug is dispensed to a subject, what information should be recorded? |  |

Overview of U.S. FDA Regulations for Medical Devices

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| What are some definitions regarding medical devices? |  |
| What are the regulations for device trials? |  |
| What are the classifications of medical devices based on medical control? |  |
| What is a drug-device combination product? | Medicinal component is coupled with the device. An example of such a combination product is a bandage (device) impregnated with an antibacterial agent (medicinal agent), or a drug-eluting stent. |
| What are the documents needed to market a medical device? |  |
| What is the exemption criteria for an IDE? |  |
| What is the exemption criteria for an abbreviated IDE? |  |
| What are the types of IDEs? |  |
| How does the FDA handle IDE applications? |  |
| What are the contents of an IDE application? |  |
| What are the investigator responsibilities? |  |
| What are the IRB/IEC responsibilities? |  |
| What is expanded early access? |  |

Informed Consent in Clinical Trials of Drugs, Biologics, and Devices

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| What are some definitions regarding informed consent? |  |
| What are the investigator requirements for informed consent? |  |
| What are the required elements for informed consent? | In addtion… |
| How should consent forms be documented? | When the subject (or the subject's LAR) agrees to the subject's participation in the trial, consent is documented by having the subject (or the subject's LAR) personally sign and date the consent form. |
| What does obtaining informed consent involve? |  |
| What does improving understanding involve? |  |
| What are some issues that may arise when obtaining consent? |  |
| What are some vulnerable populations? | Additional safeguards must be put in place |
| What sort of consent process must be followed when working with subjects who cannot personally sign? | When a clinical trial includes subjects who can only be enrolled in the trial with the consent of the subject's LAR (for example, minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should assent, or agree, by signing and personally dating the written informed consent (ICH [2016] E6 Section 4.8.12). |
| When can consent be waived? |  |
| What is electronic informed consent? |  |

Detecting and Evaluating Adverse Events

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| What are some definitions regarding adverse events? |  |
| What is the difference between subjective and objective adverse events? |  |
| What are the two forms of adverse events? |  |
| What are the sources for adverse events? |  |
| How should adverse events be treated? |  |

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| How should adverse events be recorded? |  |
| How should causality be approached? |  |
| What are the categories of causality? |  |

Reporting Serious Adverse Events

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| What are some definitions regarding reporting serious adverse events? |  |
| What are the types of adverse events? |  |
| What should the principal investigator report? |  |
| When should the principal investigator report? |  |
| What are the sponsor monitoring requirements? |  |
| What are the sponsor reporting requirements? |  |
| What is the difference in reporting adverse events to sponsors and IRB/IRC? |  |
| What are blinded studies? |  |

Monitoring of Clinical Trials by Industry Sponsors

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| What are some definitions regarding monitoring trials by industry sponsors? |  |
| What is the sponsors role? |  |
| What are the key sponsor site visits? |  |
| What happens when a sponsors identified noncompliance? |  |
| What are some of the required documents for drug or device studies? |  |
| What is the record retention requirement? | Both the FDA and ICH E6 require that sites maintain study-related records for at least two (2) years after the drug has been granted marketing approval in the U.S. for the indication tested in the study or, if no application will be filed or if the application is not approved for the indication, for at least two (2) years after the investigation is terminated and the FDA is notified. |

Audits and Inspections of Clinical Trials

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| What are some definitions regarding audits and inspections of clinical trials? |  |
| What is the difference between an audit, monitoring, and inspections? |  |
| What is the FDA Bioresearch program? |  |
| What are the types of investigator FDA inspections? |  |
| What sorts of trials does the FDA inspect? |  |
| What is the FDA inspection process? |  |
| What are the regulatory documents that are reviewed during inspections? |  |
| What are common deficiencies during FDA inspections? |  |

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| How does the FDA respond to inspections? |  |
| What are the office for human research protections compliance visits? |  |
| What is the office for human research protections compliance process and outcome? |  |
| What is a sponsor audit? |  |
| What do auditors look for? |  |