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QUESTION NO: 1

Which information should an auditee expect prior to an audit?

A. Auditor's credentials and certification number

B. Corrective action requests

C. Standard operating procedures

D. Audit plan or agenda

ANSWER: D

Explanation:

Audit plan or agenda is correct because pre-audit communication should give the auditee sufficient, practical information to prepare for an orderly and effective audit. The audit plan normally identifies the audit's objectives and scope, the planned dates and timing, areas or processes to be assessed, relevant locations or functions, and key logistical arrangements. Providing this information allows the auditee to identify appropriate personnel, make relevant records available, arrange system access or facilities where needed, and coordinate interviews without compromising the audit's independence.

This approach is consistent with audit-management principles in ISO 19011, which describe establishing and communicating an audit plan and adapting it as necessary during the audit. In the clinical-trial context, sponsor audit activity is part of the quality-assurance system required under ICH Good Clinical Practice. Clear advance planning supports a focused assessment of whether trial-related activities and data handling comply with the protocol, SOPs, GCP, and applicable requirements. The plan is therefore the appropriate pre-audit information for an auditee to expect, while also establishing a shared operational framework for the audit. See ISO 19011:2018—Guidelines for auditing management systems and ICH E6(R2) Good Clinical Practice.

QUESTION NO: 2

Which of the following processes is the most likely to remain in a study that utilizes electronic data capture?

A. Tracking case report forms

B. Updating the in-house database

C. Resolving queries

D. Retrieving case report forms

ANSWER: C

Explanation:

Resolving queries remains a core clinical data-management activity when electronic data capture is used. Electronic capture changes how data are entered, transmitted, tracked, and reviewed, but it does not remove the need to address data that are missing, inconsistent, implausible, or require clarification against source information or the protocol. Edit checks within the system can identify potential issues at the point of entry or during subsequent review, and data-management staff can also raise queries following central review. Investigators and delegated site staff then assess the issue and provide an appropriate electronic response or correction, with the system retaining an attributable audit trail.

This process supports data quality, completeness, and reliability throughout the study rather than only at database lock. Good Clinical Practice requires sponsors to implement systems that assure the quality of trial data and specifies that electronic trial-data handling systems should provide appropriate controls, including documented changes and safeguards for data integrity. Query review and resolution are practical components of those controls. SCDM's Good Clinical Data Management Practices also identifies data validation, discrepancy management, and query management as continuing responsibilities in modern clinical data workflows. See ICH E6(R2) Good Clinical Practice Addendum and SCDM Good Clinical Data Management Practices.

QUESTION NO: 3

The Medical Dictionary for Regulatory Activities (MedDRA) structure is in which of the following hierarchical orders, from most specific to least specific?

A. LLT, HLGT, PT, HLT, SOC

B. LLT, PT, HLGT, HLT, SOC

C. LLT, HLGT, HLT, PT, SOC

D. LLT, PT, HLT, HLGT, SOC

ANSWER: D

Explanation:

LLT, PT, HLT, HLGT, SOC is the correct hierarchy from the most specific MedDRA level to the broadest. Lowest Level Terms (LLTs) are the most granular terms and include lexical variants, synonyms, and quasi-synonyms used to support consistent verbatim-term coding. Each LLT is linked to one Preferred Term (PT), which represents a distinct medical concept used for analysis and reporting. Related PTs are grouped into High Level Terms (HLTs), and related HLTs are grouped into High Level Group Terms (HLGTs). At the highest level, System Organ Classes (SOCs) provide broad anatomical, physiological, etiological, or purpose-based groupings for regulatory medical information. This five-level structure enables clinical data managers to code reported adverse events consistently while allowing data to be summarized and analyzed at progressively broader levels. MedDRA is multiaxial, meaning that a PT can be associated with more than one SOC where medically appropriate; however, each PT has one designated primary SOC for cumulative reporting. The hierarchy itself remains LLT to PT to HLT to HLGT to SOC. See the MedDRA Introductory Guide and the MedDRA support documentation.

QUESTION NO: 4

An external organization has been hired to manage SAE follow-up for a large study. Which of the following would be used as guidance for exchange of the SAE data between the EDC system and the vendor's safety management system?

A. Medical Document for Regulatory Activities

B. Biomedical Research Domain Model

C. Individual Case Safety Report

D. Submission Data Tabulation Model

ANSWER: C

Explanation:

Individual Case Safety Report is the appropriate guidance because a serious adverse event that requires safety processing is handled as an individual safety case, with information exchanged in a standardized structure between the clinical data-collection environment and the safety system. The ICH E2B standard defines the electronic transmission format and data elements for individual case safety reports, supporting consistent transfer of case details such as patient characteristics, adverse-event terms, seriousness criteria, suspect products, narratives, follow-up information, and reporter details. In an outsourced safety workflow, the study sponsor, EDC provider, and safety vendor should use this standard as the basis for interface specifications, data mapping, acknowledgements, reconciliation, error handling, and follow-up-case exchanges. This promotes timely pharmacovigilance processing and preserves the traceability needed for regulatory reporting. ICH E2B(R3) is the current internationally harmonized electronic standard for these transmissions and is implemented using HL7 messaging specifications. See the ICH efficacy guidelines and the FDA overview of Individual Case Safety Reports (ICSRs) E2B(R3).

QUESTION NO: 5

With the implementation of EDC, which company Standard Operating Procedure (SOP) would require updates for new procedures of handling data?

A. Handling External Data

B. Coding Medical and Clinical Terms

C. Data Backup, Recovery, and Contingency Plans

D. Data Review and Validation

ANSWER: D

Explanation:

Data Review and Validation is the SOP most directly affected by implementing an Electronic Data Capture system because EDC changes the operational workflow through which clinical data are checked, clarified, and accepted for analysis. The SOP should define the electronic processes for review of entered data, execution and documentation of edit checks, management and resolution of system-generated and manual queries, review of audit-trail information where applicable, and the respective responsibilities of site personnel, monitors, data managers, and medical reviewers. It should also establish how review status is documented in the system, what constitutes a resolved discrepancy, and how data-review activities support database lock.

These procedures must be controlled and consistently followed because EDC records are electronic clinical-trial records. Appropriate procedural controls help ensure that data remain attributable, legible, contemporaneous, original, accurate, complete, and traceable throughout the study. ICH GCP requires sponsors to maintain validated systems and documented procedures for handling trial data, including checks to ensure data are processed correctly. FDA requirements for electronic records likewise emphasize controls that support record reliability and integrity. See ICH E6(R2) Good Clinical Practice and the FDA's 21 CFR Part 11.

QUESTION NO: 6

Which of the following SOPs are required for management of an EDC system?

A. Management of vendors

B. Measurement of data quality

C. Maintenance of coding dictionaries

D. Change control

ANSWER: D

Explanation:

Change control is required because an EDC system is a computerized system used to create, modify, maintain, archive, retrieve, or transmit clinical-trial electronic records. Its configuration and operation must remain controlled throughout the system life cycle. A documented change-control SOP establishes how proposed changes—such as updates to edit checks, roles and permissions, database configuration, integrations, releases, or vendor-hosted software—are assessed for impact, authorized, tested, approved, implemented, and recorded. This preserves the validated state of the system and provides traceability from the reason for a change through evidence that it was appropriately verified before use in production.

This control directly supports data integrity because changes can affect how clinical data are entered, processed, reviewed, and retained. It also ensures that auditability, security, record protection, and applicable validation activities are considered whenever the system changes. FDA requirements for closed systems include validation, the ability to generate accurate and complete copies, protection of records, limited system access, and secure, computer-generated, time-stamped audit trails; a controlled change process is central to maintaining these controls over time. ICH GCP likewise requires documented procedures for computerized systems and that system changes are managed in a controlled manner. See 21 CFR Part 11 and ICH E6(R2) Good Clinical Practice.

QUESTION NO: 7

A Clinical Data Manager is drafting data element definitions for a new study. One of the definitions provided is:

"Baby's crown to heel length measured lying on back, measured physical quantity, precision of 0.1."

Which of the following is missing from the definition?

A. Discrete values for a drop-down list

B. Enumeration

C. Data type of the data element

D. Unit or dimensionality of measure

ANSWER: D

Explanation:

Unit or dimensionality of measure is missing. The definition identifies the clinical concept being captured—an infant's crown-to-heel length in the lying position—and conveys that the value is a measured physical quantity with a precision of 0.1. However, a numeric measurement is not fully interpretable unless its unit is explicitly specified, such as centimetres or inches. A value of 52.0, for example, has very different clinical and analytical meaning depending on the unit attached to it.

In clinical-study metadata, the unit is an essential attribute because it ensures that collection, storage, validation, conversion, and analysis use the same dimensional basis. Explicitly defining the unit also supports unambiguous CRF completion and traceable transformation into standardized submission variables. CDISC CDASH guidance describes recording test results together with their units and supports controlled, consistently represented measurement metadata; see the CDISC CDASH standard. Likewise, CDISC's CDASH implementation resources describe standardized data-collection conventions that promote consistent capture of measurements: CDASH Implementation Guide. Therefore, the measurement definition needs its unit or dimensionality of measure to be complete.

QUESTION NO: 8

In the transfer of obligations for a double-blind, multi-center trial, a sponsor has maintained the task of creating the randomization schedule. Who at the sponsor company should create the randomization schedule?

A. The sponsor's project statistical programmer

B. The CRO biostatistician

C. A sponsor's biostatistician not on the project

D. The sponsor's project biostatistician

ANSWER: C

Explanation:

A sponsor's biostatistician not on the project should create the randomization schedule. In a double-blind trial, the schedule is a controlled, potentially unblinding document: it specifies the treatment allocation sequence and may also include stratification or blocking details. Its generation and confidential handling must therefore be separated from personnel who conduct the trial, manage operational decisions, assess outcomes, or otherwise need to remain blinded. A qualified sponsor biostatistician who is not part of the project team provides the required statistical expertise while preserving that operational independence.

Retaining this activity at the sponsor does not alter the core blinding requirement when other obligations are transferred to a CRO. The sponsor remains accountable for ensuring that access to the allocation sequence is restricted, that the schedule is securely controlled, and that processes for treatment assignment and emergency unblinding are documented. ICH E9 states that randomization is a fundamental design feature for minimizing bias and addresses the need to protect the treatment code

and blinding arrangements. ICH E6 also requires appropriate systems and procedures to assure trial quality and the reliability of trial data. See ICH E9: Statistical Principles for Clinical Trials and ICH E6(R2) Good Clinical Practice Addendum.

QUESTION NO: 9

Which information is most useful in working with sites to catch up a backlog of unresolved queries at sites?

A. Graph and summary table of clean cases by site

B. Table of outstanding queries counts by site

C. Graph of expected versus actual enrollment

D. List of late queries by site and summary table

ANSWER: D

Explanation:

“List of late queries by site and summary table” is the most useful information because it combines actionable, query-level detail with a concise view of the scale and urgency of the issue at each site. To reduce a backlog, the clinical data management team and site need to identify precisely which queries require attention, how long they have remained unresolved, and where follow-up should be prioritized. A site-specific late-query list supports direct, efficient communication and permits focused action on individual data discrepancies. The accompanying summary table lets the team assess overall workload, compare sites, monitor whether remediation is effective, and escalate persistent delays in a proportionate manner.

This approach aligns with good clinical data management practice: query management should facilitate timely clarification of data while maintaining traceability of communications and resolution. It also supports the ICH GCP expectation that investigators and trial personnel provide trial-related data and respond to monitoring or data-review activities appropriately. Used regularly, the report can guide targeted site support, monitoring follow-up, and practical recovery plans without losing sight of study-level query trends. See the SCDM Good Clinical Data Management Practices resources and ICH E6(R2) Good Clinical Practice addendum.

QUESTION NO: 10

If database auditing is used for data quality control during a study, which is the optimal timing of the audits?

A. Immediately following database lock

B. A week or two before database lock

C. After the first few cases have been entered

D. Periodically throughout the study

ANSWER: D

Explanation:

“Periodically throughout the study” is the optimal timing because database auditing is most valuable as an ongoing quality-control activity, integrated into study conduct rather than reserved for a single milestone. Recurrent audits allow the clinical data management team to assess whether the database continues to support accurate, complete, attributable, and reviewable data as sites enroll participants, enter data, respond to queries, and implement approved changes. The findings can be trended to identify recurring errors, training needs, configuration concerns, or process weaknesses early enough for meaningful corrective and preventive action. Periodic review also supports a risk-based approach: the frequency and scope can be tailored to factors such as study complexity, data criticality, enrollment rate, known quality signals, and protocol amendments. This makes audit activity both proactive and proportionate, while preserving adequate time to resolve issues before final data review and database lock. ICH Good Clinical Practice requires quality management throughout the trial lifecycle and emphasizes identifying and controlling risks that could affect participant protection or reliability of trial results. FDA guidance likewise describes controls and procedures for ensuring the reliability and integrity of electronic clinical-

investigation data. See ICH E6(R2) Good Clinical Practice Addendum and FDA Guidance: Electronic Source Data in Clinical Investigations.

QUESTION NO: 11

A Clinical Data Manager reads a protocol for a clinical trial to test the efficacy and safety of a new blood thinner for prevention of secondary cardiac events. The stated endpoint is all-cause mortality at 1 year. Which data element would be required for the efficacy endpoint?

A. Drug level

B. Coagulation time

C. Cause of death

D. Date of death

ANSWER: D

Explanation:

Date of death is required because all-cause mortality at one year is an event-based efficacy endpoint: each participant must be classified according to whether death occurred during the defined one-year follow-up period. The date establishes whether the event falls within that endpoint window and, where the statistical analysis plan uses survival methods, provides the event time for calculation from the protocol-defined time origin, such as randomization. Complete and reliable ascertainment of death dates also supports appropriate censoring of participants who have not died by the analysis cutoff or whose follow-up ends earlier. Because the endpoint is *all-cause* mortality, the essential efficacy outcome is occurrence and timing of death irrespective of its attributed cause. During protocol review and data-management planning, the Clinical Data Manager should ensure that the eCRF, external data transfers, reconciliation processes, and query procedures can capture and verify this endpoint-critical date, including its source and any applicable partial-date conventions. ICH E9 describes time-to-event variables as requiring both a defined origin and a relevant event time, while the ICH E9 addendum emphasizes precise endpoint definitions and estimands. See ICH Efficacy Guidelines (including E9) and the SCDM Good Clinical Data Management Practices.

QUESTION NO: 12

QA is conducting an audit on a study for ophthalmology which is ready for lock. Inconsistencies are found between the database and the source. Of the identified fields containing potential data errors, which fields are considered critical for this particular study?

A. Subject Identifier

B. Concomitant Medications

C. Weight

D. Medical History

ANSWER: B

Explanation:

Concomitant Medications is the best answer because medication exposure can materially affect both the safety profile and the interpretability of ophthalmology-study outcomes. Systemic and topical medicines may alter ocular findings, including visual function, intraocular pressure, inflammation, healing, or retinal outcomes. They may also introduce clinically relevant interactions with the investigational product. Accurate concomitant-medication information therefore supports assessment of adverse events, attribution of potential causes, identification of prohibited or restricted treatments, and interpretation of efficacy endpoints without avoidable confounding.

Before database lock, discrepancies in this information should be assessed and resolved according to the protocol-defined critical-data and critical-process strategy. ICH E6(R3) describes critical data as data that are important to reliable trial results and participant protection, and it calls for risk-proportionate quality management focused on factors that matter to those objectives. FDA risk-based monitoring guidance likewise identifies information needed to evaluate participant safety and the reliability of trial results as a central focus for oversight. In an ophthalmology trial, concomitant treatments commonly meet this threshold because of their potential direct effect on ocular safety and endpoint interpretation. See ICH E6(R3) Good Clinical Practice and the FDA risk-based monitoring guidance.

QUESTION NO: 13

In a study, data are key entered by one person after which a second person enters the data without knowledge of or seeing the values entered by the first. The second person is notified during entry if an entered value differs from first entry and the second person's decision is retained as the correct value. Which type of entry is being used?

A. Blind verification

B. Manual review

C. Third-party compare

D. Single entry

ANSWER: A

Explanation:

Blind verification is the correct term for this workflow. It is a form of double data entry in which the initial and verification entries are made independently: the verification operator cannot see the value entered initially. This blinding reduces the risk that the verification operator will simply reproduce, consciously or unconsciously, the original transcription rather than independently interpreting the source record. The data-entry system compares the two values as the verification entry is made and alerts the operator when they differ. The operator can then check the source document and make a documented decision, with the verified value retained according to the study's configured verification procedure.

This process is an important quality-control approach for transcribing paper case report form data, particularly where direct electronic capture and its built-in edit checks are not used. Procedures should define the fields subject to verification, how discrepancies are handled, the authorized roles, and audit-trail expectations. These controls support the broader regulatory expectation that computerized clinical-investigation systems ensure the accuracy, reliability, and integrity of entered data. See the SCDM Good Clinical Data Management Practices resource and the FDA's Computerized Systems Used in Clinical Investigations guidance.

QUESTION NO: 14

Which list should be provided to support communication with sites regarding late data and queries?

A. List of entered and clean data by site

B. List of subjects screened and enrolled by site

C. List of user account activity by site

D. List of outstanding data and queries by site

ANSWER: D

Explanation:

The **List of outstanding data and queries by site** is the appropriate communication tool because it provides each investigational site with an actionable view of the information that requires attention. For late data, the list can identify expected but unentered or incomplete CRF data; for queries, it can show the affected participant, form or data item, query status, date issued, and aging. This focused reporting enables site personnel, clinical research associates, and the data-

management team to prioritize follow-up, assign responsibility, and monitor timely resolution before data-cleaning milestones or database lock.

Site-level query and missing-data listings also support a documented, consistent communication process. They help teams recognize recurring operational barriers, track whether follow-up has resulted in action, and escalate aged items through the appropriate study-management channels. Good Clinical Practice requires investigators and institutions to permit monitoring and to maintain accurate case-report-form data, while electronic clinical-data systems should support traceable review and correction workflows. A current outstanding-items listing turns those responsibilities into a practical routine for ongoing data review. See ICH E6(R2) Good Clinical Practice Addendum and the SCDM Good Clinical Data Management Practices resource.

QUESTION NO: 15

A sponsor plans to upgrade the medical dictionary used for coding adverse events before the final coding run. The new version includes updated terminology that may change some coded terms. What is the most appropriate approach?

A. Update only newly entered adverse events and leave all prior coded events unchanged

B. Assess the impact, document the dictionary version, and apply a controlled recoding strategy

C. Change coded terms without recording which dictionary version was used

D. Stop all adverse-event coding until after database lock

ANSWER: B

Explanation:

Assess the impact, document the dictionary version, and apply a controlled recoding strategy is correct. Dictionary versions can affect coded terms, groupings, and analysis outputs. Before implementation, the study team should assess the impact on previously coded records, define whether and how recoding will occur, test the process as appropriate, and maintain traceability to the dictionary version used.

Updating only newly entered events would create inconsistent coding within the study unless a documented convention specifically supports it. Changing codes without retaining version information prevents reproducibility. Deferring all coding until after database lock can delay required safety review and does not address the controlled handling of the version change.

QUESTION NO: 16

A protocol amendment adds a required assessment at Week 12 and changes the allowable visit window. Which activity should occur before the revised EDC database is released to sites?

A. Perform an impact assessment and test all affected forms, visit rules, edit checks, reports, and existing-data implications

B. Add the new assessment form and defer testing until after the first subject completes Week 12

C. Revise only the study schedule because the existing visit forms are already validated

D. Instruct sites to record the new assessment in a free-text comments field

ANSWER: A

Explanation:

Perform an impact assessment and test all affected forms, visit rules, edit checks, reports, and existing-data implications is correct. A protocol amendment can affect more than the new eCRF field or visit itself. The new assessment and revised window may require changes to visit schedules, conditional form display, missing-data checks, protocol-deviation reports, data-review listings, completion guidelines, and downstream data mappings.

A documented impact assessment identifies these dependencies and establishes the scope of configuration and validation. Testing should demonstrate that the revised functionality operates as specified and does not adversely affect unchanged functions. Releasing only the new form without assessing associated edit checks and existing-data handling risks inconsistent data collection and unnecessary queries.