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Clinical Data Collection Manual

Practical 17 - Regulatory documentation practical

Aim

To compile a clinical data-collection and management manual.

Principle

A data manual defines how protocol observations become attributable, traceable and analysable records. Good data management preserves source provenance and corrections rather than replacing inconvenient values.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Create a schedule-linked case-report form and dictionary with variable names, units, permitted values and missingness codes.
4. Define source transcription, access controls, query generation/resolution, audit trail and coding conventions.
5. Specify adverse-event capture, reconciliation with safety records, confidentiality and secure transfer.
6. Define review, cleaning, database freeze/lock, exports and retention with roles and documented approvals.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Illustrative weight is entered as 700 kg for a case whose source says 70.0 kg. Issue a traceable query and preserve the correction history; do not overwrite the record without attribution.

Result and Interpretation

- Deliver a manual, example CRF, data dictionary and a completed query-resolution example.
- A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

- Distinguish scientific content requirements from electronic-publishing rules.
- Recheck current forms, amendments, scope and local requirements at actual filing.
- Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

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