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Bioavailability and Bioequivalence Study Protocol

Practical 11 - Regulatory documentation practical

Aim

To prepare a fictional bioavailability/bioequivalence study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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. Define a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

BA/BE design additions

• Define product, comparator, strength, fasting/fed scope, analyte and the applicable current product-specific guidance.

• Justify parallel or crossover design, sequence allocation, washout, sampling, bioanalytical validation and the prespecified exposure endpoints and statistical model.

• Assess ethical suitability, participant safety, product accountability and the applicable bioequivalence rule; do not assume a standard two-period design suits every product.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.

• 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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