Clinical-trial Phases - Assignment

Experiment 9 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To complete the clinical-trial phases - assignment activity and document a justified outcome.

Principle

Clinical development phases have different primary objectives. A study phase does not by itself establish that a result is reliable or applicable.

Requirements

- Institution-assigned hospital scenario, approved policy documents or coded records.
- Activity form, calculator where required and supervising pharmacist.

Procedure

1. Classify supplied studies

Identify the study objective and phase from the assigned synopsis.

2. Compare objectives

Describe early safety/pharmacology, exploratory efficacy, confirmatory benefit-risk and post-approval questions.

3. Inspect design

Record population, comparator, endpoint, duration and major eligibility considerations.

4. Review oversight

Identify the documented protocol, ethical review, consent, monitoring and reporting requirements in the assigned setting.

5. Conclude

Explain what each supplied study can support and what remains uncertain.

Observations and Record

Record component	Entry
Study / phase	_____
Main objective	_____
Population / comparator	_____
Endpoint and limitations	_____
Oversight / reporting record	_____

Result

Activity / case code: ____. Finding: ____. Proposed action: ____. Review outcome: ____.

Precautions

- Use supplied records or the authorised local workflow; do not invent approvals or completed work.
- Protect patient and institutional confidential information.
- Keep a proposed student action distinct from an approved operational decision.

Viva Questions and Answers

1. Why document the basis of a decision?

It permits review of the evidence, responsibility and outcome.

2. What does the supervisor review?

The suitability of the proposed action and whether the record supports the conclusion.

Phase Comparison

Phase	Typical emphasis
I	Initial human safety, tolerability and pharmacology; the population depends on the product.
II	Exploratory efficacy and dose-related benefit-risk in the target condition.
III	Confirmatory evidence of benefit-risk for the intended use.
IV	Post-approval questions and longer-term or broader-use evidence.

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