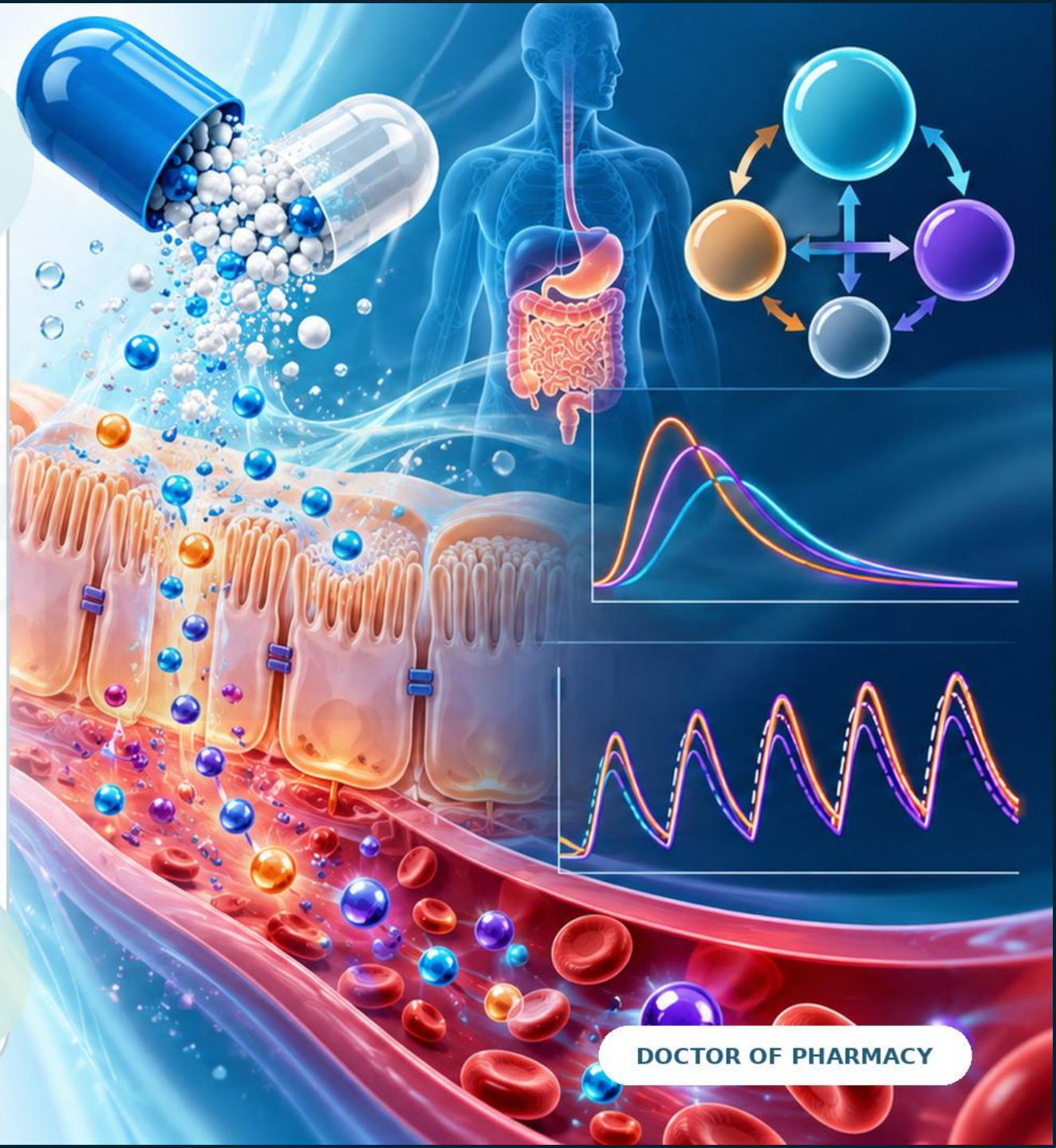
PHARM.D • YEAR 4

Biostatistics & Research Methodology

CHAPTER 1.1

Types of Clinical Study Designs

PPT CHAPTER COVER



DOCTOR OF PHARMACY

CLINICAL STUDY DESIGNS: THE MAP

DESCRIPTIVE



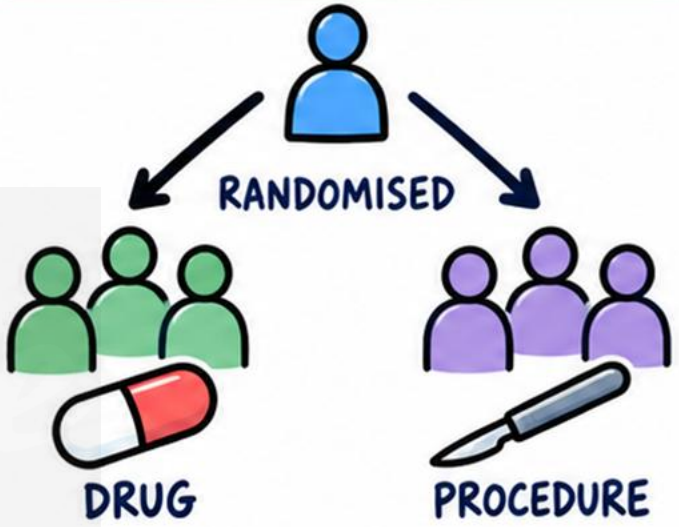
describes unusual patients or events.

OBSERVATIONAL



observes natural exposure and outcome; no assigned treatment.

INTERVENTIONAL



investigator assigns a drug, procedure or other intervention.

Design choice controls what can be concluded:

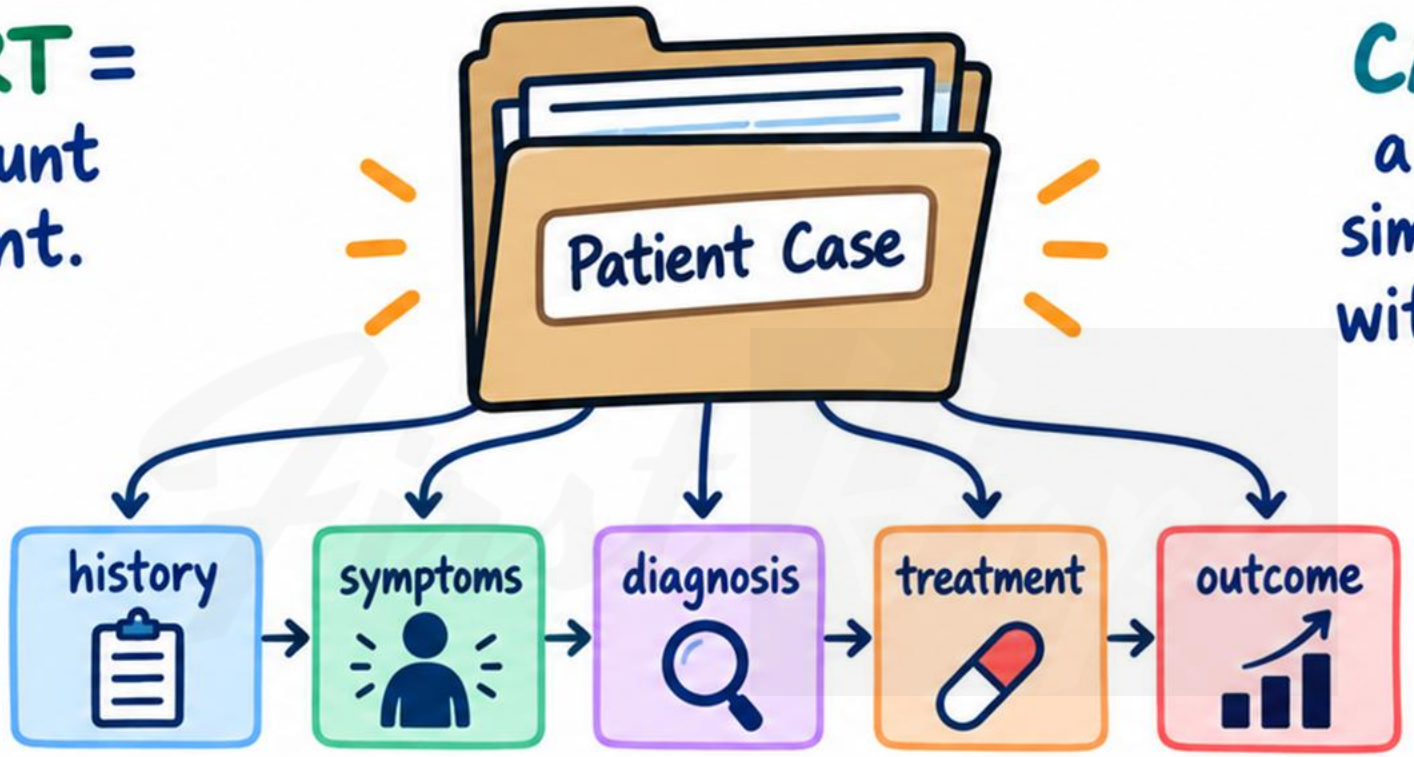
description → association → strongest test of causality.

Case Report or Case Series?

CASE REPORT =
in-depth account of one patient.

CASE SERIES =
a small group with similar unusual findings, without a control group.







Typical content: history → symptoms → diagnosis → treatment → outcome.

Main purposes:

- recognize a rare disease or unusual presentation
- document an unexpected adverse effect or outcome
- generate a hypothesis for later research

Case Study: Design & Strengths



DESIGN

- usually 1–10 patients
- retrospective or prospective clinical records
- qualitative details may include laboratory or imaging values
- no comparison group and usually no statistical comparison

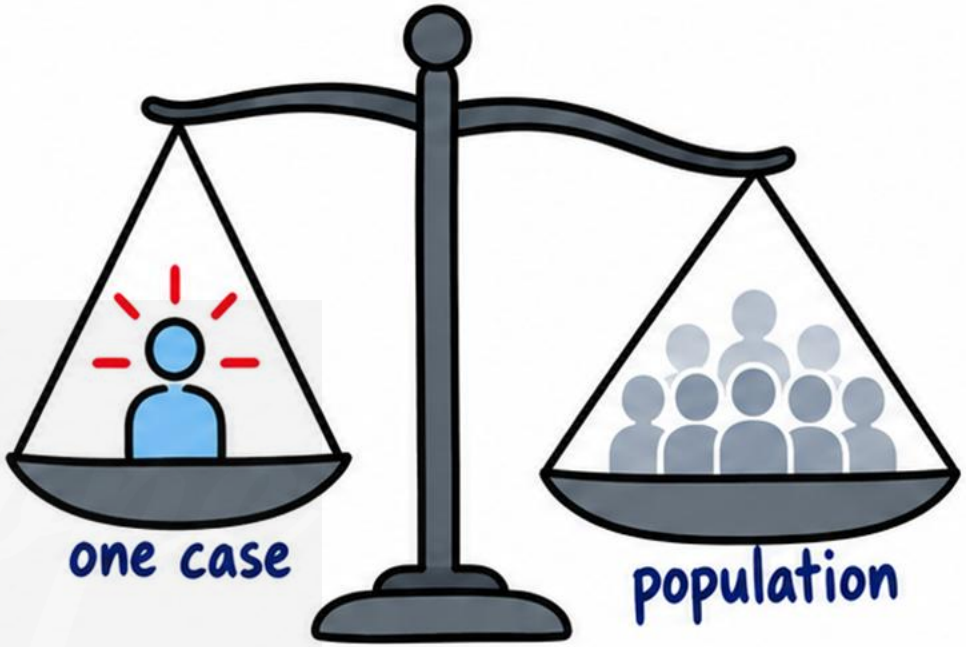
STRENGTHS

- quick and relatively inexpensive
- detects novel diseases, presentations or side effects early
- useful for hypothesis generation

Case Study: What It Cannot Prove

LIMITATIONS

- no control group → cannot infer causality
- small, selected sample → poor generalizability
- vulnerable to selection and reporting bias
- cannot estimate incidence or prevalence



event followed exposure --X--> exposure caused event

Example: one rare neurological event after vaccination may signal a possible association, but it requires systematic follow-up before any causal conclusion.

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