Preclinical Experimental Study

Definition:
A **preclinical experimental study** is a type of biomedical research conducted **before** clinical trials in humans. It involves **in vitro (cell-based)** or **in vivo (animal)** models to investigate biological mechanisms, drug efficacy, toxicity, or disease processes.

Key Features

- **Subjects**: Non-human (e.g., rats, mice, pigs, or cell lines)
- **Purpose**: To test hypotheses about disease mechanisms or potential treatments under controlled laboratory conditions.
- **Interventions**: May involve drugs, gene therapy, surgical techniques, or physical devices.
- **Endpoints**: Usually surrogate markers (e.g., protein expression, tumor volume, histological changes), **not clinical outcomes**.
- **Level of evidence**: **Very low** for clinical decision-making; designed to support or generate hypotheses, not guide patient care.

Relevance in Neurosurgery

- Used to model neurological diseases (e.g., glioblastoma, spinal cord injury, intracranial aneurysms).
- Common in vascular neurosurgery to study angiogenesis, venous hypertension, or response to new embolic agents.
- Enables mechanistic insights prior to translation into human studies.

⚠ Limitations

- **Species differences**: Animal physiology may not reflect human responses.
- **Lack of external validity**: Artificially induced disease may not replicate human pathology.
- **No clinical outcomes**: Cannot inform directly on therapeutic efficacy or safety in patients.
- **Ethical considerations**: Must follow strict animal welfare protocols.