

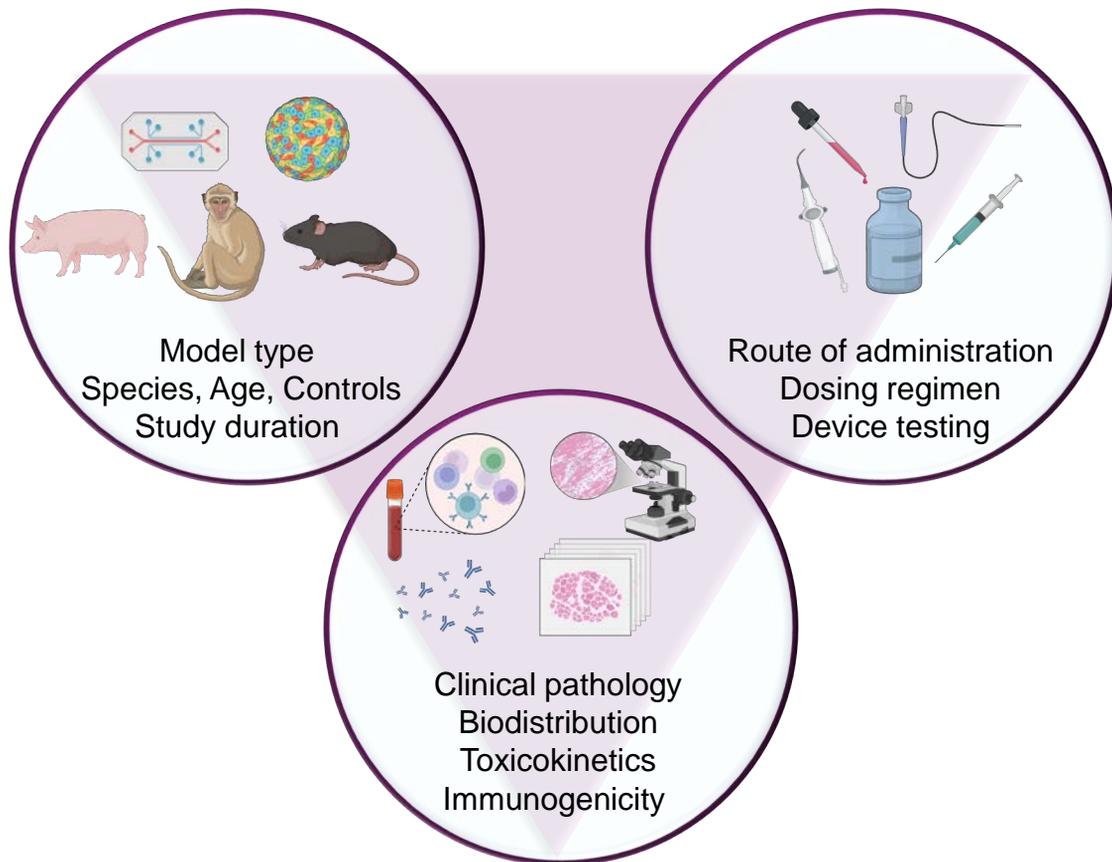
TOXICOLOGY



How to ensure the drug is safe for testing in humans?

Prior to clinical testing, determine the safety of the intended drug product in vitro and in vivo in a toxicology study

Key considerations in designing a toxicology study



Information gathered from a toxicology study



- ✓ Safe clinical doses
- ✓ Product related toxicities
- ✓ Route of administration related toxicities



Toxicology studies must align with the clinical study plan and gather essential safety data for evaluating treatment risks vs therapeutic benefits

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PaVe-GT relevant resources: PCCA pre-IND package (coming soon)