

Selection of preclinical disease model

Does the model express the target or targeted pathway?

Does the model reflect the clinical phenotype of human disease?

Is the model standardized?

Does the age of the animal impact results?

Does the sex of the animal impact results?

Interventions in late-stage preclinical studies

Can the compound be tested in a model with already established kidney dysfunction?

Can more than one study be performed (i.e., different strain, model, species, injury point)?

Can the compound's toxicity be evaluated in more than one species?

Is the PK, PD and safety profile of the compound established?

Choice of animals

Rodent animal models are preferred over model organisms in the late stage phase

Are inbred animals matched for strain and substrain?

Are animals housed under the same conditions?

Can experiment involving animals be performed using organoids or organs-on-chip?

Controls and analysis in preclinical models of kidney disease

Is the calculated sample size accurate with desired statistical power?

Can appropriate randomization and blinding be ensured?

Do reports follow required preclinical reporting guidelines?

Can appropriate control groups (i.e., negative, positive, vehicle, comparators) be included?

Evaluation of kidney disease models

Can target engagement be demonstrated?

Can relevant kidney function endpoints such as GFR be measured?

Can assessment of circulating factors be performed?

Can histologic, fluid-phase and tissue-phase biomarkers be evaluated?