

Kidney function considerations are critical when assessing drugs in clinical trials

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Kidney function can affect the potency and metabolism of drugs that are eliminated by the kidneys or other pathways, but little information is available on how to interpret the effects of kidney function on the benefits and risks of drugs in development.

A new review highlights important considerations when designing clinical studies in individuals with kidney disease, and it highlights techniques such as mathematical modeling tools that will help provide optimal dosing recommendations in these patients.

"During [clinical development](#), a stand-alone clinical study that assesses the pharmacokinetics of drugs in subjects with [kidney disease](#) is typically conducted, and dosing recommendations for this population are usually derived from this study," said Dr. Michael Tortorici, lead author of the *Journal of Clinical Pharmacology* review. "Our review article provides considerations for drug developers that go beyond that single clinical study, focusing on analyses that leverage clinical program level data."

More information: Tortorici, M. A., Cutler, D. L., Hazra, A., Nolin, T. D., Rowland-Yeo, K. and Venkatakrishnan, K. (2015), Emerging areas of research in the assessment of pharmacokinetics in patients with chronic kidney disease. *Journal of Clinical Pharma*. [DOI: 10.1002/jcph.444](#)

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