Checklist of Information to be Included When Reporting a Clinical Pharmacokinetic Study[a]

	Checklist Item	
	Title/Abstract	**Reported on Page Number**
1	The title identifies the drug(s) and patient population(s) studied.	
2	The abstract includes the name of the drug(s) studied, the route of administration, the population in whom it was studied, and the results of the primary objective and major clinical pharmacokinetic findings.	
	Background	
3	Pharmacokinetic data (i.e., absorption, distribution, metabolism, excretion) that is known and relevant to the drugs being studied is described	
4	An explanation of the study rationale is provided	
5	Specific objectives or hypotheses is provided	
	Methods	
6	Eligibility criteria of study participants is described	
7	Information about ethical approval of the study and subjects' consent is provided.	
8	Co-administration (or lack thereof) of study drug(s) with other potentially interacting drugs or food within this study is described.	
9	Drug preparation and administration characteristics including dose, route, formulation, infusion duration (if applicable) and frequency are described.	
10	Body fluid or tissue sampling (timing, frequency and storage) for quantitative drug measurement is described.	
11	Validation of quantitative bioanalytical methods used in the study is described in detail or described briefly and referenced.	
12	Pharmacokinetic modeling methods, observed and derived parameters along with the formulas, and software used are described.	
13	Formulas for calculated variables (such as creatinine clearance, body surface area, AUC, and adjusted body weight) are provided or referenced.	
14	The specific body weight used in drug dosing and pharmacokinetic calculations are reported (i.e., ideal body weight vs. actual body weight vs. adjusted body weight)	
15	Statistical methods including software used are described	
	Results	
16	Study withdrawals or subjects lost-to-follow up (or lack thereof) are reported.	
17	Quantification of missing or excluded data is provided if applicable.	
18	All relevant variables that may explain inter- and intra-patient pharmacokinetic variability (including: age, sex, end-organ function, ethnicity, weight or BMI, health status or severity of illness, and pertinent co-morbidities) are provided with appropriate measures of variability.	

19	Results of pharmacokinetic analyses are reported with appropriate measures of variability and precision (such as range, standard deviation, 95% confidence interval, etc.)	
20	Studies in patients receiving extracorporeal drug removal (i.e., dialysis) should report the mode of drug removal, type of filters used, duration of therapy and relevant flow rates.	
21	In studies of drug bioavailability comparing two formulations of the same drug, F (bioavailability), AUC, C_{max} (maximum concentration) and t_{max} (time to maximum concentration) should be reported.	
	Discussion/Conclusion	
22	Study limitations describing potential sources of bias and imprecision where relevant should be described	
23	The relevance of study findings (applicability, external validity) is described	
	Other Information	
24	Funding sources and conflicts of interest for the authors are disclosed.	

[a] Adapted from: Kanji S, Hayes M, Ling A, et al. Reporting Guidelines for Clinical Pharmacokinetic Studies: The ClinPK Statement. Clin Pharmacokinet. 2015. DOI 10.1007/s40262-015-0236-8.