Pharmacokinetic insights in individual drug response

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Stellingen

Behorende bij het proefschrift

Pharmcokinetic insights in individual drug response

A model-based approach to quantify dose-exposure-response relationships in diabetic-kidney disease

1. Dose-finding studies should be conducted in the same population as the intended phase 3 population. (this thesis)

2. Since the dose-exposure-response relationship observed in early phase 2 trials could diverge from the dose-exposure-response relationship in late phase 3 trials, this relationship needs to be validated in phase 3 trials to confirm the adequacy of the used doses. (this thesis)

3. The dose of anti-diabetic drugs should not be solely based on glycaemic response parameters since anti-diabetic drugs have off-targets effects whose dose-exposure-response relationship does not follow the glycaemic dose-exposure-response relationship. (this thesis).

4. Insufficient attention is being put on off-target effects for dose justification of new anti-diabetic drugs to regulatory authorities. (this thesis)

5. The pharmacokinetic profile of the SGLT2 inhibitor dapagliflozin is similar in patients with and without type 2 diabetes. (this thesis)

6. Patient characteristics independent of plasma exposure contribute to variability in response to treatment with an endothelin receptor antagonist. (this thesis)

7. Drug development and patient care benefit from developing disease progression models that characterise the dynamic nature of disease.

8. Understanding variability in response alone is not sufficient to improve clinical practice, we also need to understand how to address this variability.

9. Geen enkel leven voegt zich naar de mediaan van een statistisch model. (Koning Willem-Alexander)

10. All generalizations are false, including this one. (Mark Twain)