

## CASE STUDY

# Using PBPK to Optimize Magnesium Concentrations in an Intravenous Formulation



## Background and Problem

A new intravenous formulation was developed and the client wanted to know if Allucent could help evaluate the proposed magnesium amount in the new formulation considering various populations of pregnant women, neonates, infants, pediatric patients, adults, and adults with renal impairments.

## Our Solution

A physiological-based pharmacokinetic (PBPK) model was established based on literature findings while taking into consideration biological parameters such as pregnancy-specific changes, neonates, body weight-based allometric scaling and renal impairment. The established PBPK model was then validated using a different set of literature data. The resulting PBPK model was used for simulations and predictions for pregnant women, neonates, infants, pediatric patients, adults, and adults with renal impairments.

## Outcome

The established PBPK model was used to simulate plasma magnesium concentrations in various populations to evaluate the client's proposed formulations. Additionally, an Rshiny app was established to allow the client to simulate a wide range of different formulation scenarios. The client used our modeling results to make a decision on the formulation.

### Physiologically Based Pharmacokinetic Modeling

PBPK modeling can be utilized in multiple stages of drug development. New guidance from regulatory agencies has highlighted key areas for the use of PBPK models, showing their ever-growing acceptance. Allucent scientists can help you untangle the complex data requirements of PBPK models, and bring these powerful modeling tools to bear on complex problems facing drug development.

