

## **CONTROLLING POLYMER CHANGE FOR EXTENDED RELEASE FORMULATION WITH PBPK**

An extended-release drug offers several potential advantages over other medicines. It reduces the frequency of the dose by modifying the rate of drug absorption. Thus, these types of extended-release drugs enable the higher doses to be given less frequently with less fluctuation in blood concentration. Extended-release drugs are commonly used when there is a challenge with patient compliance or coherence, often related to aging.

With a physiologically based pharmacokinetic model (PBPK), Certara was able to determine a bio-relevant dissolution testing method that successfully translated quantitatively or semi-quantitatively in vitro evaluations to in vivo, all based on the prior information about the drug and the formulation and the clinical data.

The model was able to identify the bio-relevant dissolution testing method so that it could be employed for this evaluation of the variants of the new formulation. With that, the model was able to identify what was the more likely outcome of the formulations that were developed, and then it helped expedite the decision making, and probably a number of trial and error formulations. When that formulation was staged in the clinic, the predictions from the model, based on the bio-relevant matter, were very comparable to the outcome that was observed in the clinical study.



**PBPK can guide development new and alternate formulations, increasing the number and type of patients that can benefit from therapeutics**