EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Questions to panel on reporting and evaluation of predictive performance

PBPK workshop 21 November 2016

Questions to panel on predictive performance

1. How can we demonstrate adequacy of the predictive performance of a drug model? What is adequate?
2. Can a general workflow be followed for each application?
3. Can essential parameters be determined/agreed upon for a given application (e.g., fm for predicting drug as CYP substrate; Ki for predicting drug as CYP inhibitor)
4. Can essential parameters be determined/agreed for system parameters?
5. When and how to assess impact of uncertainty in the parameters important for the intended purpose?
6. For lower impact purposes (e.g. supporting design of a PK study in paediatrics), what should be focused on when presenting simulation results to encompass model uncertainty?