Overview of Korean Pharmacometrics Modeling Library and web-based pharmacometrics platform

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Background and Objective

As an increasing number of pharmacometrics (PM) models have been developed based on data in Korea, which leads to the needs of archiving and further using developed models. In addition, a growing demand for prediction pharmacokinetic (PK) parameters in an easy way leads to motivation of developing an easy-to-use platform where one can easily estimate PK parameters in diverse methods. As those of trends, Korean Pharmacometrics Model Library (KPML) has been developed by collaboration of Ministry of Food and Drug Safety (MFDS) and Korean Society for Clinical Pharmacology and Therapeutics (KSCPT) as a web repository and platform to store the developed PM models in Korea and provides PM platform for estimate PK parameters using various methods such as non-compartment (NCA), compartment model (CA), allometric scaling (AS), or *in vitro in vivo* extrapolation (IVVIE).

Methods

KPML
- Collect and store model code and dataset pharmacometrics models in Korea (including of PK model, PKPD model, PBPK-PD model)

PM platform
- NCA: Develop based on some R packages, including bear (v2.8.7) [1], NonCompart (v0.4.5), and ncar (v0.4.2) [2]
- CA: Develop using nlmixr package in R [3]
- AS: Develop in R to extrapolate PK parameters from animal to human using single species scaling or simple allometric scaling equations
- IVIVE: Develop in R to estimate in vivo hepatic clearance (CL_h) from in vitro CL_h using three different methods (well-stirred, parallel and dispersion method)

PM training
- Provide materials related to PM works (lecture files, hands-on, including code files and data files, and result files)

Guidelines
- Update PM guideline from FDA, EMA, MFDS, ICH and other sources

Available link website: http://repository.kscpt.org/

Acknowledgement

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Results

- KPML provide developed models where one can refer when developing models for drugs

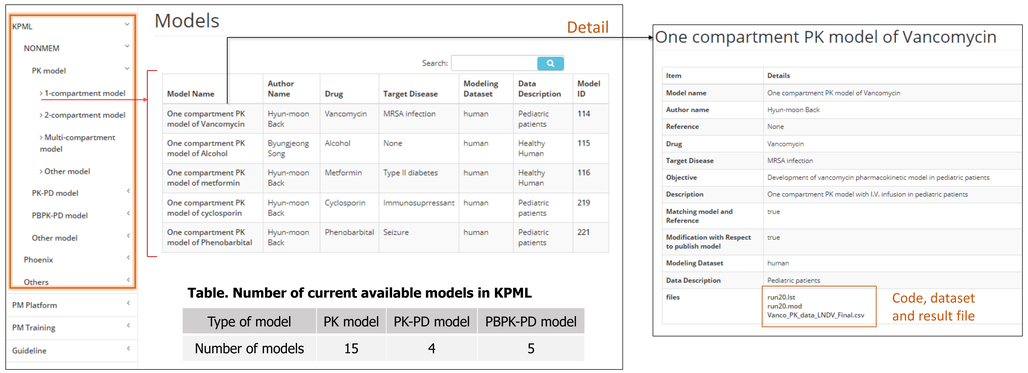
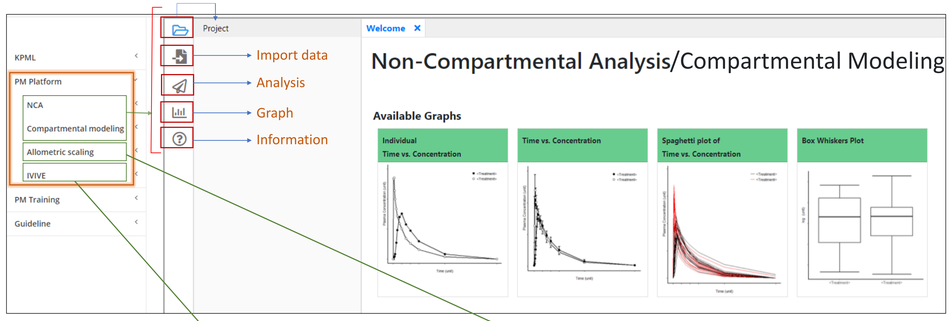
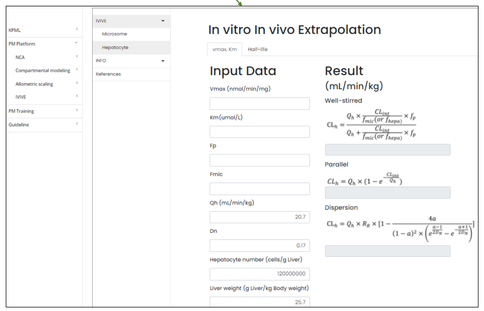


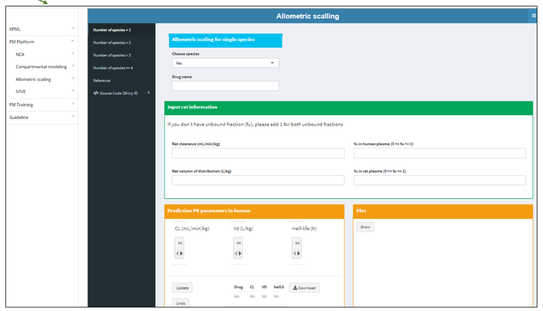
Table. Number of current available models in KPML

Type of model	PK model	PK-PD model	PBPK-PD model
Number of models	15	4	5

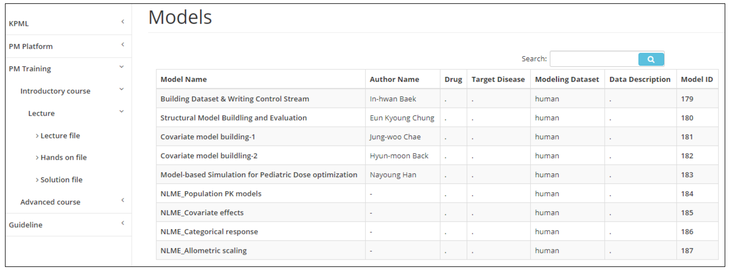
- PM platform provide environment where one can upload data and calculate PK parameters



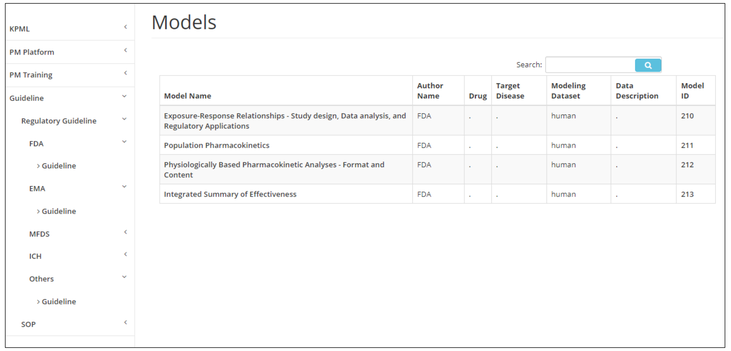




- PM training provide materials where one use it to learn and practice



- Guidelines provide update guidelines where one can easily find needed information



Conclusion

KPML with updated PM models is a precious repository which can be referred for developing new models or used in clinical practice. In addition, KPML with potential platforms would be an easy tool to predict precisely and reliably PK parameters. It can be widely applied to quickly predict and reduce time and unnecessary effort on prediction PK parameters.

Reference

[1]"The data analysis tool for average bioequivalence (ABE) and bioavailability (BA)." Available: http://pkpd.kmu.edu.tw/bear/.

[2]Kim et al. Translational and Clinical Pharmacology. 2018, 26(1), 10-15.

[3]Schoemaker et al. CPT Pharmacometrics Systems Pharmacology. 2019, 8(12), 923–930.