**Experience with an European Medicines Agency related qualification advice of a PBPK model to simulate lactation related medicine exposure: a personal reflection.**

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**Introduction.** Lactation related medicine exposure is a relevant topic with increasing clinical research activities and increased regulatory interests, as e.g. reflected in the ongoing ICH efforts E21 on the inclusion of pregnant and breast-feeding individuals in clinical trials. PBPK models can be very instrumental to facilitate drug development, clinical trials or to provide clinical guidance in this specific field.

**Aims**. We intend to reflect on and share the preliminary experiences we had within the IMI Conception consortium (academia + industry) during the interactions with the European Medicines Agency on a qualification advice on the PBPK model to simulate lactation related medicine exposure.

**Methods**. Narrative reflection, based on a framework on processes of qualifying PBPK platforms.

**Results.** The steps taken for verification of the drug models, extension of the platform for various intended uses, and our example of the PBPK qualification effort, and needed next steps will be discussed.

**Discussion.** We perceived the qualification advice as a stepwise approach, with discussions that provide some more certainty on the additional work and efforts to be undertaken to attain qualification.