

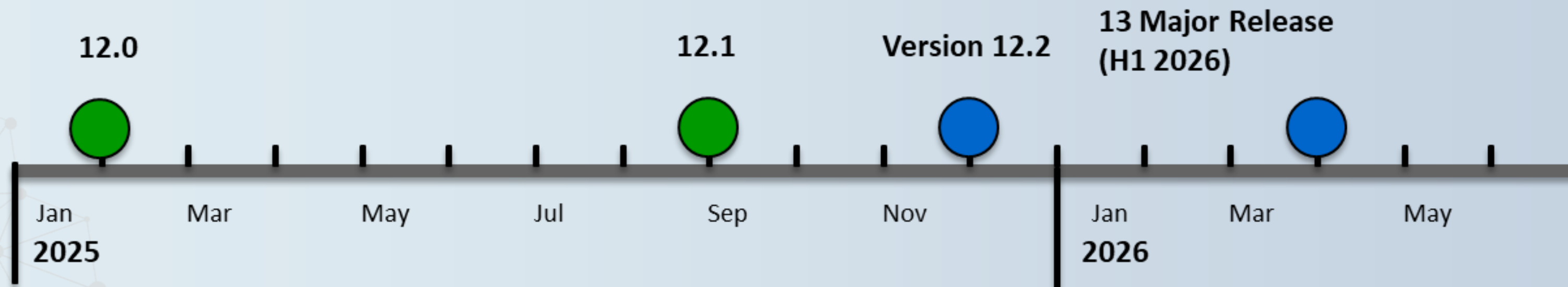


OSP Software Release Roadmap

Pavel Balazki /
Stephan Schaller

OSPS Roadmap

Current and planned releases



OSP Release strategy

One major release per year (H1)

- Major improvements
- New model features and components
- Structural model changes

Minor updates every 3-4 months

- Usability improvements
- Bug fixes
- No changes to **model behavior**

OSP Suite Software Roadmap: <https://tinyurl.com/OSP-Software-Roadmap>

Open-Systems-Pharmacology / Projects / OSP Suite Software Roadmap

Search: Type / to search

OSP Suite Software Roadmap

Board Table + New view

Filter by keyword or by field

Under discussion (technically feasible) ...

Contact the Release Management team if you would like to sponsor implementation of a feature

- PK-Sim #154
Sorting and graphing with population simulations
- PK-Sim #377
Animal Populations: Goettingen Minipig
up for grabs
- PK-Sim #4
Plotting Concentrations (C) at timepoint (t) = x, after population simulation
effort: medium (days) **prio: high**
- PK-Sim #6

Sponsored 25 ...

- PK-Sim #11
re-run/update all relevant existing simulations after changing drug or individual building block settings
prio: medium
- PK-Sim #2456
Run selected simulations with 1 click
- PK-Sim #1292
Feature request: Improving "Clone simulation" function
- PK-Sim #1582
Feature: PI: export PI setting in a convenient format to R

Version 12.1 (in development) 7 ...

- MoBi #527
Feature wish: Create Subfolders possible for modules
prio: high
- MoBi #1318
Save/load neighborhood
prio: high
- MoBi #1630
Folders for modules (v12, feature request)
prio: high
- MoBi #1820
It should be possible to trace back the source of a quantity in simulation

Version 13 13

- MoBi #2080
"Extend" merge behavior for Pa
- MoBi #1810
"Extend" merge behavior for Eve
prio: high
- MoBi #1426
"Extend" merge behavior for mc
prio: high
- MoBi #1978
Implement "Merge" behavior fo
- MoBi #1572



V12.1

V12.1

Minor usability update

Iteration of the Modularization concept introduced in v12

New Features:

- Trace Source of Parameters and Molecule Initial Values in Simulations
- Spatial Structure with Individual selection for preview
- Concurrent Execution of Simulations
- Batch edit mode for charts

... and a list of bug fixes, smaller UX and performance improvements



V13

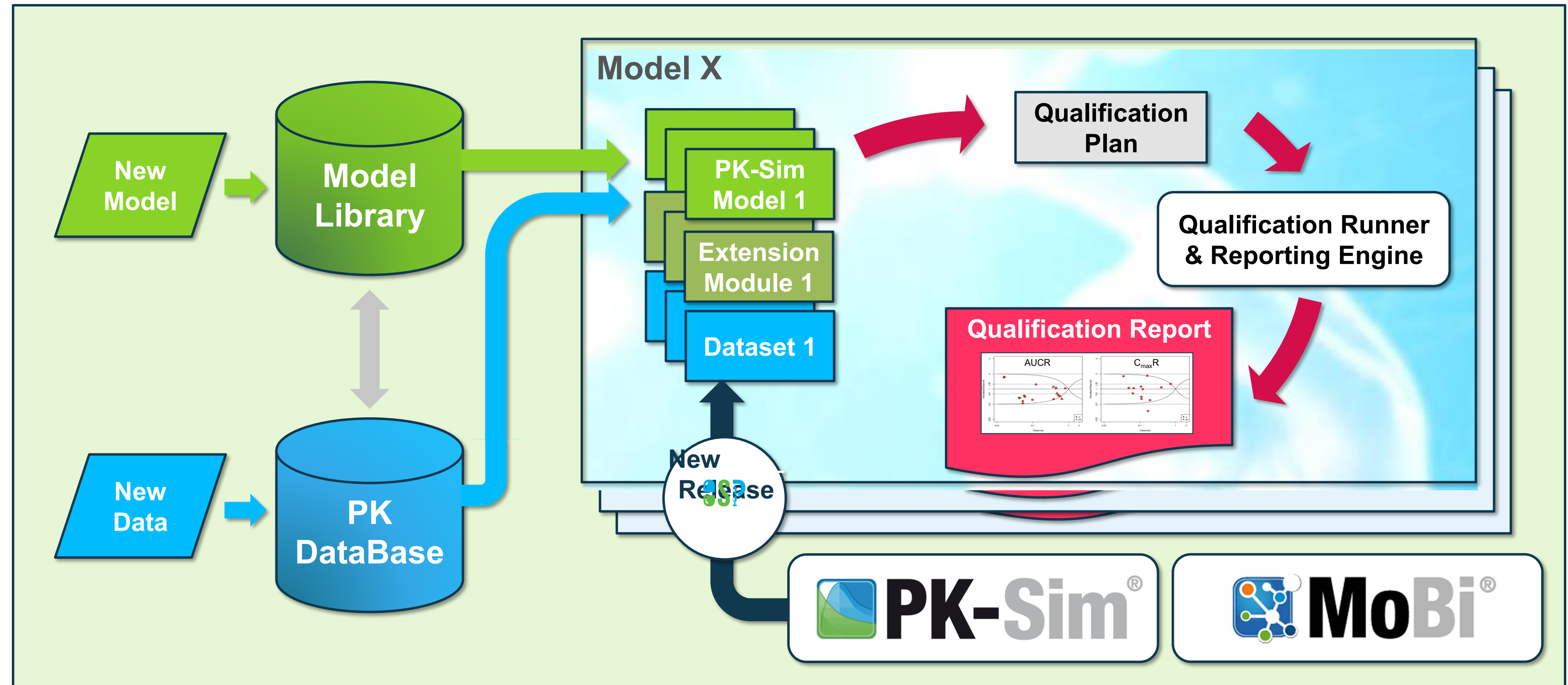
V13

Major update – focus on MoBi ReQualification and PBBM

- Automated ReQualification of MoBi Projects

Platform Qualification: Automatic (Re)-qualification Workflow

Sustainable and Agile (Re)-Qualification of Intended Use Scenarios for Regulatory Submissions

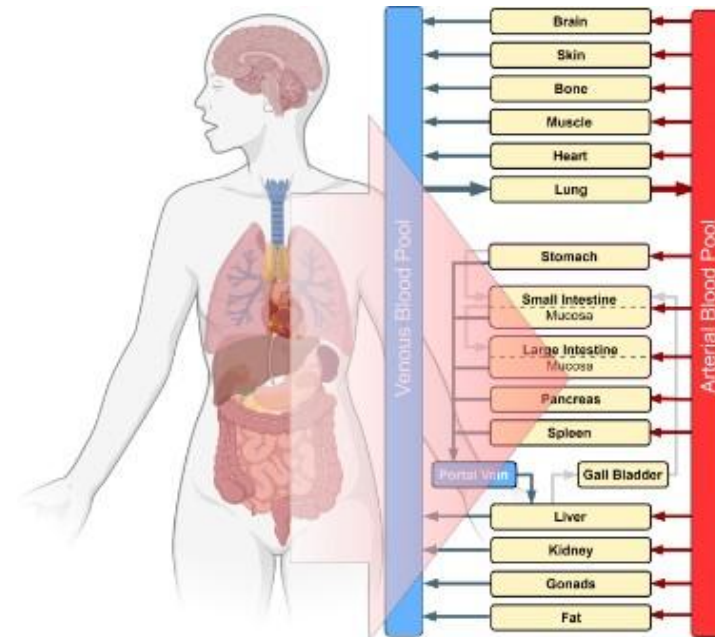


QSP Platform Qualification

MoBi Project Snapshot

a) {JSON} Project snapshot

PK-Sim® PBPK models



Expression Profiles

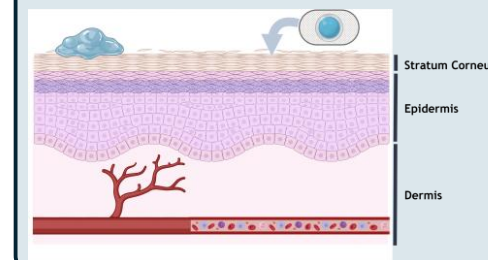
- ☒ CYP3A4
- ☐ CYP2D6 PM
- ☒ CYP2D6 UM

Individuals

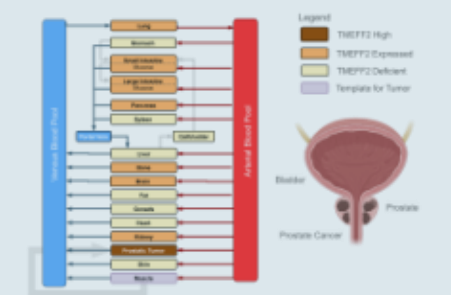
- ☐ Male 35yrs 85 kg
- ☒ Female 30yrs 60 kg
- ☐ Preterm male

MoBi® Extension modules

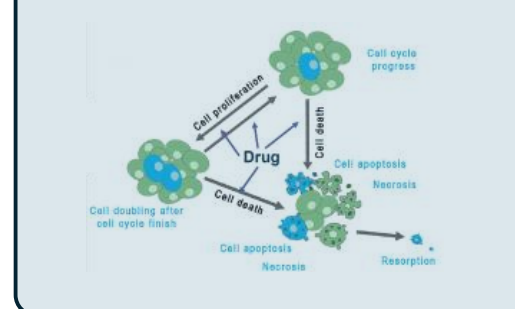
Skin permeation



Tumor



Drug PD



Disease state

- ☐ Healthy
- ☒ T2DM
- ☒ Renal impairment
- ☐ Hepatic impairment

b) Qualification workflow

Simulation scenarios

- Healthy
- Tumor non-treated
- Tumor treatment (f)
- Tumor treatment (m)

Qualification plan

- Markdown text
- Figure definition
- Scenario definition

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PDF report



V13

Major update – focus on MoBi ReQualification and PBBM

- Automated ReQualification of MoBi Projects
- MoBi.R – an extension of the {ospsuite} R Package for interaction with MoBi projects and modules

MoBi.R

{ospsuite} R package will support MoBi projects in v13

R workflows will support:

- Loading of MoBi Projects
- Creating simulations from available modules
- Creating new individuals, expression profiles
- Loading modules from PKML
- Adjusting parameter values, adding new parameters, setting initial conditions



V13

Major update – focus on MoBi ReQualification and PBBM

- Automated ReQualification of MoBi Projects
- MoBi.R – an extension of the {ospsuite} R Package for interaction with MoBi projects and modules
- Improvement of oral absorption model

Oral PBBM Workflow

OSP Solubility Toolbox



– Interactive tool designed to derive key parameters that influence drug solubilization from in vitro data –

This toolbox offers the estimation of parameters critical for drug solubilization, including:

- Impact of medium pH on aqueous drug solubility
- Effect of surfactants (e.g., bile salts) on drug solubility
- Calculation of surface pH for monoprotic acids and bases
- Visual performance metrics for fitted parameters

Dissolution Model (in vitro)



– Novel and versatile model for drug release kinetics that enables bridging between various in vitro test conditions –

This new dissolution model implemented in MoBi[®] incorporates a mechanistic framework that features:

- Integration of micellar solubilization
- Differentiation between the release kinetics of free and micelle-bound drug
- Mechanistic description of the effect of medium agitation rate on the diffusion layer thickness
- Refined kinetics for particle regrowth and precipitation

PBPK Model Upgrade



– PK-Sim[®] upgrade featuring an updated human GI tract and the new dissolution model for enhanced PBBM capabilities –

This update introduces new features in PK-Sim[®] to enhance PBBM applications, including:

- Integration of the novel model for drug release kinetics
- Incorporation of physiological bile salt concentrations in the intestinal lumen
- Addition of population variability in luminal pH across all GI tract segments
- Description of stomach pH as a function of hydrogen dilution due to water intake

V13

Major update – focus on MoBi ReQualification and PBBM

Additionally:

- Extension of the Modularization Concept (“Extend” for all Building Blocks)
- Redesign of events and applications in MoBi
- PK-Sim: Simulation Parameters Building Block



V14+

V14+

Outlook into the future

- New populations (obese, Chinese, pospratum)
- Further improvements of Oral Absorption model
- Extension of the Qualification Framework
- R Interface to C++ compiled models
- Solver performance optimizations
- Support of Linux and MacOS (R packages experimentally support MacOS)

V14+

Outlook into the future

YOUR INPUT CAN DRIVE THE ROADMAP

Thank you!

