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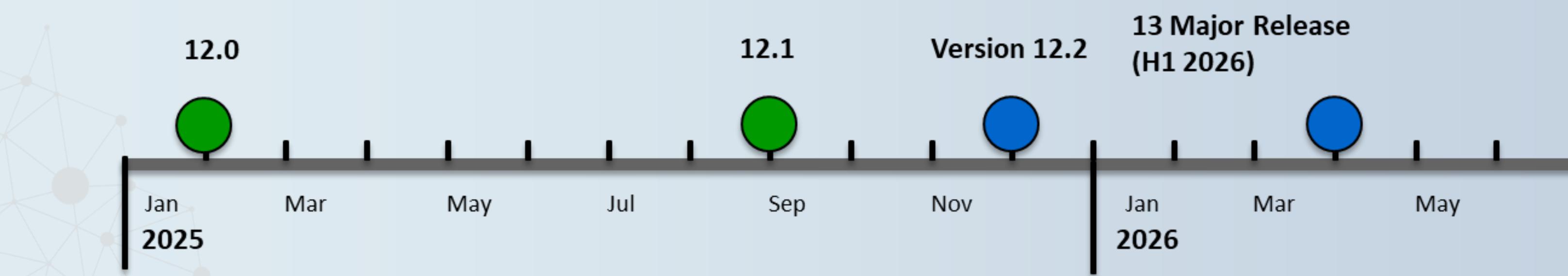
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# OSP Software Release Roadmap

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# 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

Type / to search

Add status update | Insights | Workflow

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 **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...
- MoBi #1426: "Extend" merge behavior for mc...
- MoBi #1978: Implement "Merge" behavior fo...
- MoBi #1572



V12.1

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# 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



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V13

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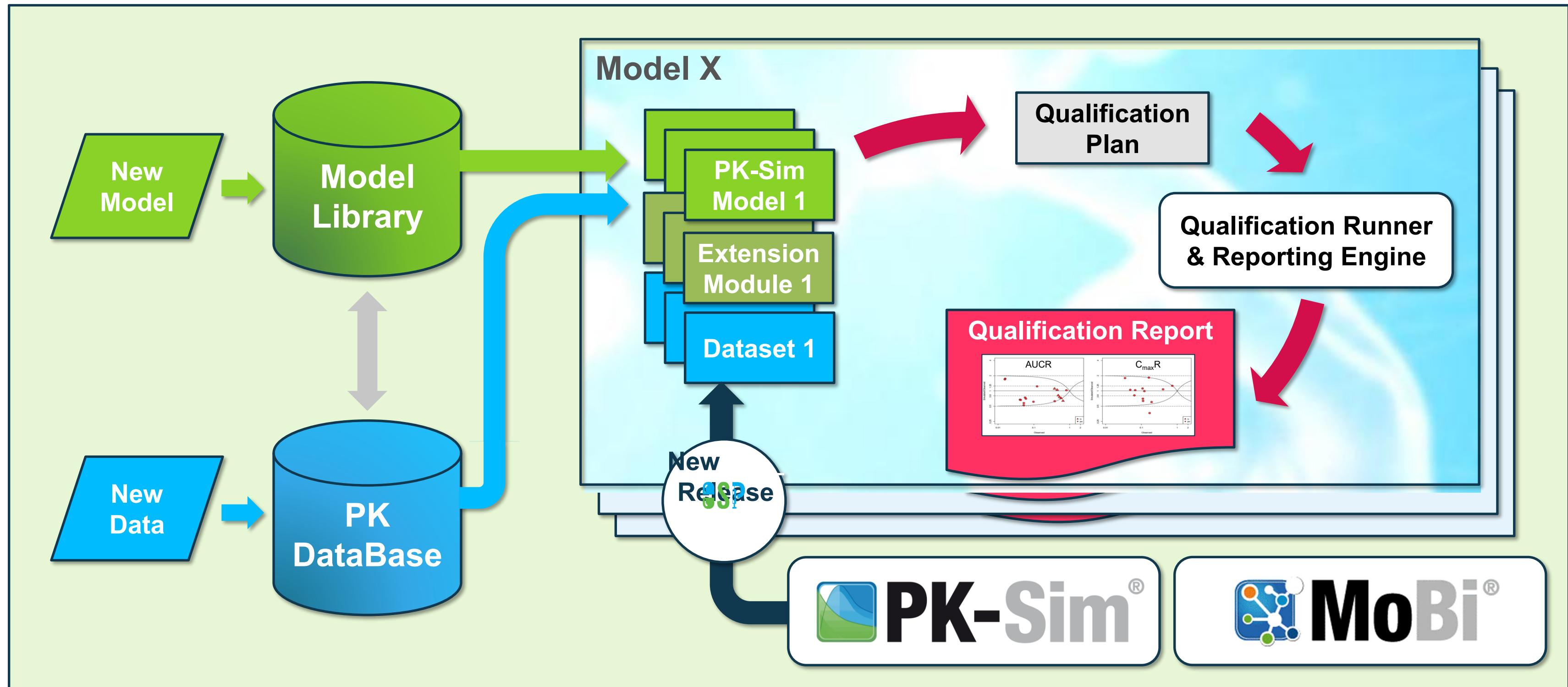
# V13

## 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

[{JSON}](#)

```

> Projects [5]
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  > PlotSettings [3]
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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



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V14+

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# 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

A large, semi-transparent network graph with grey nodes and white edges covers the left side of the slide. On the right side, there is a smaller, faint network graph.

Thank you!

