OSP Software Release Roadmap

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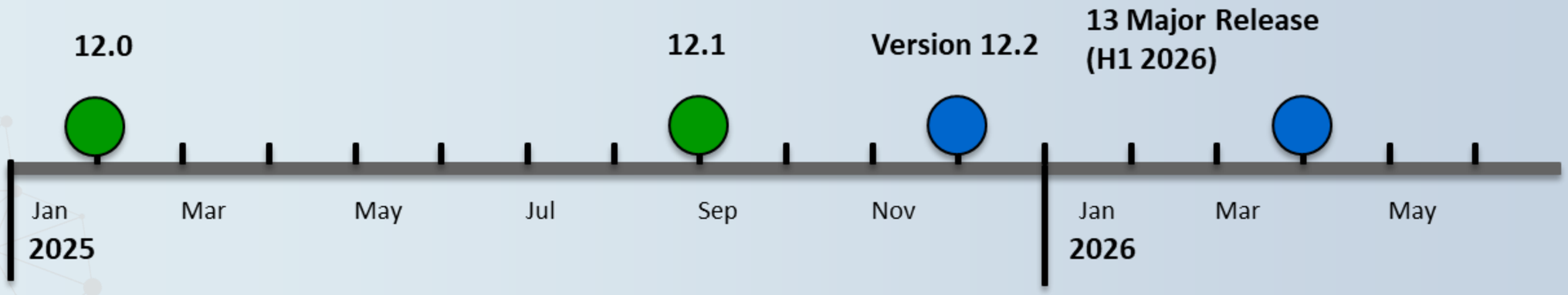
OSPS Roadmap

Current and planned releases



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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**

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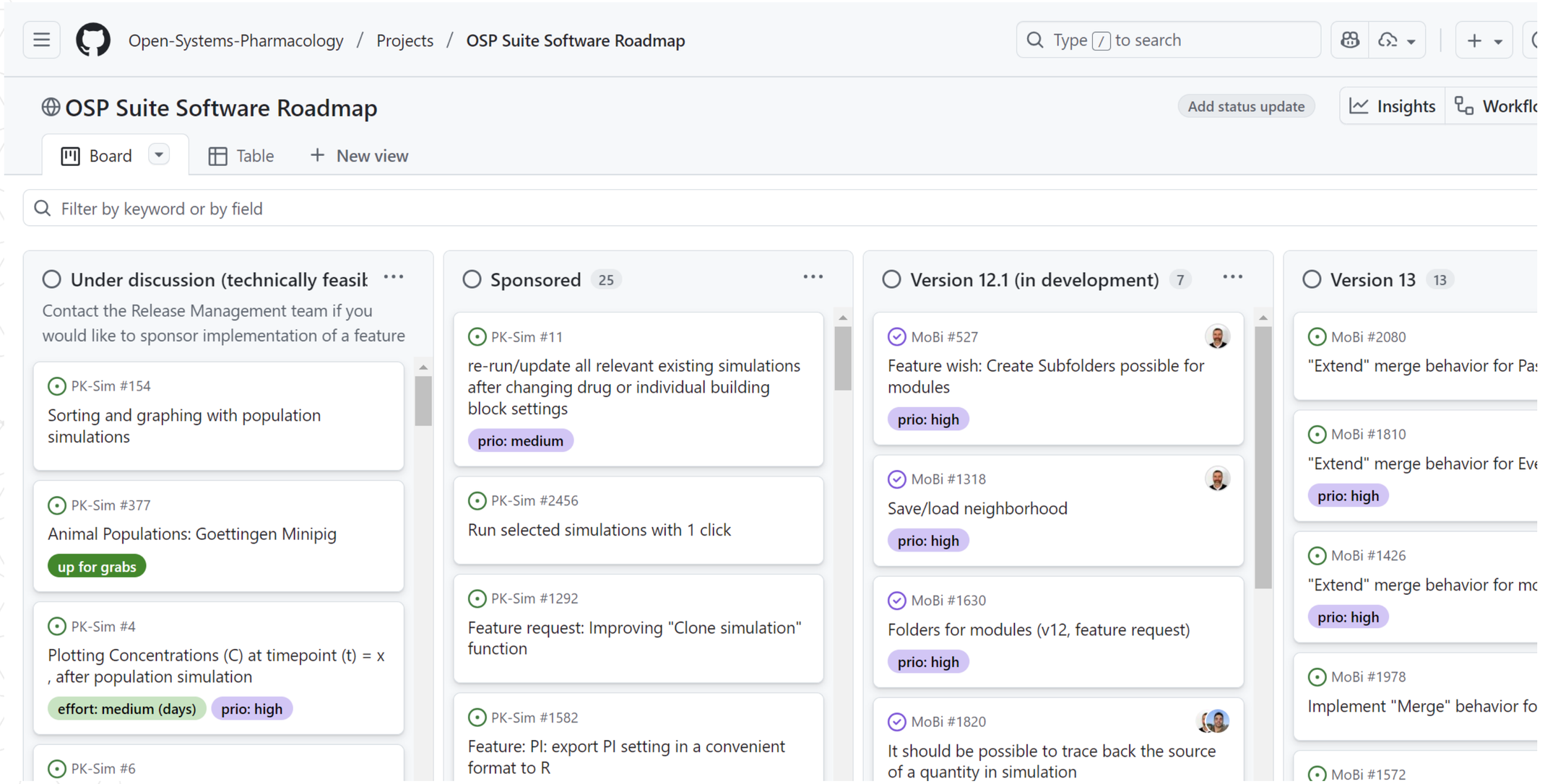
OSP Suite Software Roadmap: https://tinyurl.com/OSP-Software-Roadmap



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COMMUNITY CONFERENCE 2025

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

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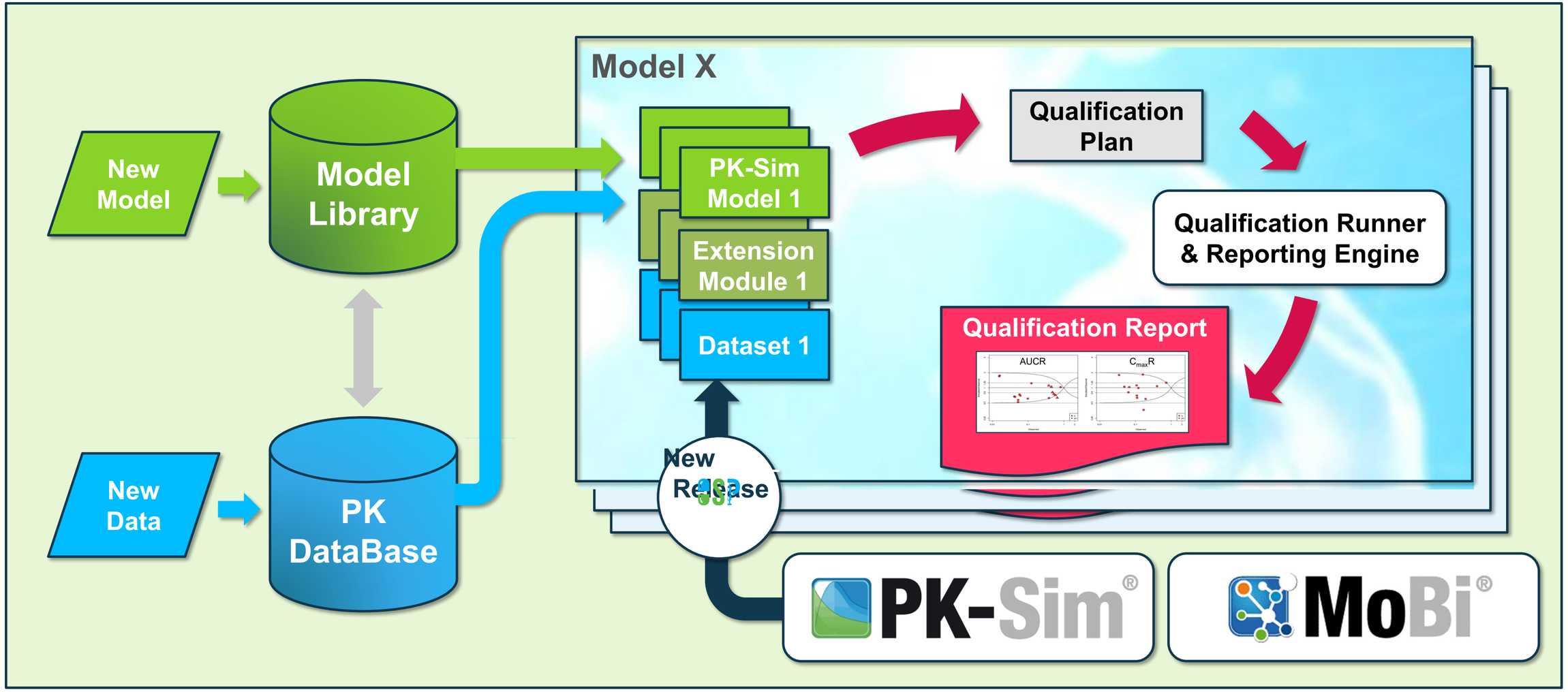
Platform Qualification: Automatic (Re)-qualification Workflow

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

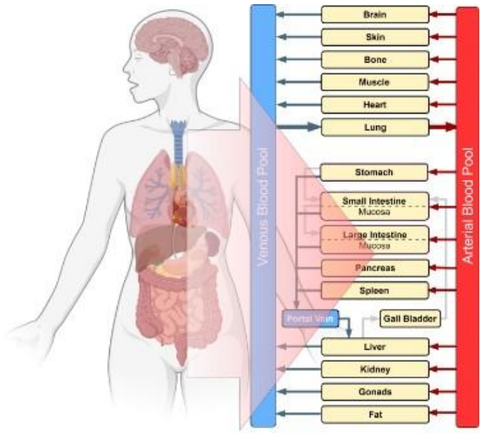


QSP Platform Qualification

MoBi Project Snapshot

a) {JSON} **Project snapshot**

PK-Sim® PBPK models



Expression Profiles

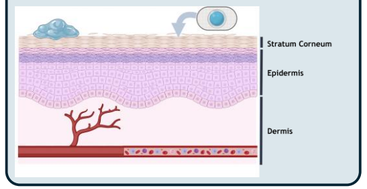
- ✓ CYP3A4
- ❑ CYP2D6 PM
- ✓ CYP2D6 UM

Individuals

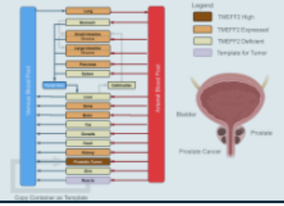
- ❑ Male 35yrs 85 kg
- ✓ Female 30yrs 60 kg
- ❑ Preterm male

MoBi® Extension modules

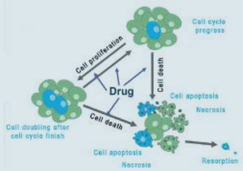
Skin permeation



Tumor



Drug PD



Disease state

- ❑ Healthy
- ✓ T2DM
- ✓ Renal impairment
- ❑ Hepatic impairment

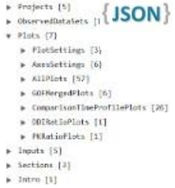
b) **Qualification workflow**

Simulation scenarios

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

Qualification plan

- Markdown text
- Figure definition
- Scenario definition



PDF report

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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

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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

MoBi®

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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

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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

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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

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Thank you!

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