COMMUNITY CONFERENCE

WELCOME TO THE OSP CC 25

From the OSP Orga Team and MT

Dr Stephan Schaller

Chair OSP MT, CEO CLS Foundation, CEO ESQlabs

Acknowledgements

Acknowledgements: Sponsors

- Gold

- Silver

- Bronze

ASP 2025
COMMUNITY CONFERENCE

Acknowledgements: People

- Orga Team

Henrik Cordes
Sanofi

Donato Teutonico
Sanofi

Stephan Schaller
CLS Foundation, ESQlabs

Ibrahim Ince:
Boehringer Ingelheim

Wilbert De Witte
ESQlabs

Lars Küpfer
UK Aachen

André Dallmann
Bayer

Jan Schlender
Novartis

- Backoffice

Monique Fontana (LinkedIn, Marketing, Conference Operations)
ESQlabs

Robert McIntosh (Website)
ESQlabs

- Orga Team Supporters:
  - Salih Banamara (Sanofi)
  - Denise Feick (Sanofi)

COMPUTATIONAL LIFE SCIENCES FOUNDATION
Advancing Computational Life Sciences through Open Collaboration

AGAH
Arbeitsgemeinschaft für angewandte Humanpharmakologie e.V.
Association for Applied Human Pharmacology

ASP 2025
COMMUNITY CONFERENCE

Conference Program
- Outlook -

ASP 2025
COMMUNITY CONFERENCE

Conference Program

- Outlook -

- 106 Participants form 40 Institutions (From 105/40 last time)
- 6 PK-Sim and MoBi Workshops
  - Basics, PBBM, DDI, Pediatrics, MoBi, and OSP-R
- 4 Scientific Sessions (Broader Scope, less talks)
  - Session 1 & 2: Clinical Applications/ Development
    - DDI, PBBM, Special Pops, Regulatory Document
  - Session 3: Research & Discovery
    - AI/ML, ADMETox, HT-PBPK, IVIVE, Safety/Early tox
  - Session 4: Submission, Lifecycle & Approval
- 1 Software Session
  - OSP Software Roadmap and Collaborative SW Development

OSP 2025 COMMUNITY CONFERENCE

USP 2025 COMMUNITY CONFERENCE

Housekeeping

Housekeeping: Time

- Talks - Q&A
  - Packed Program: Stay on Time!!!
    - 20 min Talk (will be cut after 25 min), 10 min Q&A
    - All Session Chairs are expected to be strict on speking time!
  - Microphones will be circulated for Q&A

- Breaks
  - Coffee Breaks and Lunch
  - Directly here in the Building

Housekeeping: Social Event

Join us for an unforgettable evening at La Maison Sanofi Paris!

🗓️ Monday, September 29th , 2025

📍 46 Avenue de la Grande Armée, 75017 Paris Sanofi - Google Maps

⚠️ **Please make sure to bring the QR code you received with you. It will be required to access the site.** ⚠️

🚌 *Transportation to the DINNER venue*

🕕 Bus departure: 18:30 from Sanofi Vitry Main Entrance.

🌙 *Return Options*

Please note that the social event will wrap up around midnight. After our dinner at La Maison Sanofi Paris, you're on your own for the return journey, but don't panic! This is your chance to experience the City of Lights by night 🗼 ✨

ASP 2025 COMMUNITY CONFERENCE

OSP 2025
COMMUNITY CONFERENCE

THE OSP COMMUNITY

Fostering **Engagement** and **Collaboration**
for a thriving **Community**

Mindset for the OSP Community Conference

- Introduction to the OSP Community
  - Helping you understand Stakeholders and Dependencies
  - → Engage with people during coffee breaks and find connections for your topics/questions
- Current Engagement of the OSP Community
  - How and where do we interact: Finding your way
  - What is the OSP Growth Trajectory
  - → Engage at Posters during coffee breaks, find collaborators and get inspired to contribute to the growth
- Our Path Forward
  - How can we sustain and build relevance for the OSP in the future of MIDD and NGRA
  - Funding the OSP Community
  - → Engage with stakeholders during coffee breaks and discuss how you could contribute or share ideas for building a sustainable future for OSP

OSP 2025 COMMUNITY CONFERENCE

Vision and Mission of the OSP

OSP 2025
COMMUNITY CONFERENCE

Vision and Mission of the OSP

https://github.com/Open-Systems-Pharmacology/Roadmap

Robust and reliable, easy-to-use modeling & simulation tools, processes and models for pharmaceutical and other life-sciences applications qualified and accepted by a scientific community from academia, regulatory agencies and industry available and open to everyone.

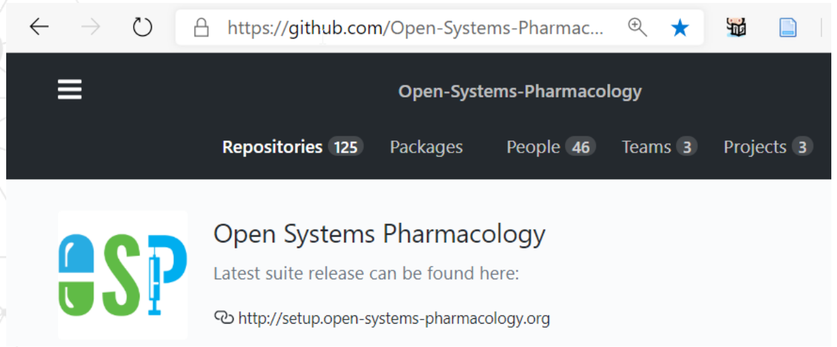
Provide a platform for joint development, review & qualification, and application of state-of-the-art tools for PBPK and Systems Pharmacology modeling and an open library of models for application as well as method & tool qualification purposes. Promote the idea of pre-competitive open collaboration for the advancement of modeling & simulation sciences in pharmaceutical and life science.

The OSP Management Team

- **The OSP management team** manages the community and its membership.
- It is responsible for regular review, endorsement and publication of the **OSP development roadmap** (“Executed” through Focus Groups).
- *The management team provides certification of the software platform, models and other systems pharmacology content such as qualifications and trainings.*
- It **releases** certified platform versions.
- The team organizes **contributions to the scientific and regulatory community** and publishes white papers.

The OSP Community Landscape

Stakeholders of the **Open Systems Pharmacology** community and **Management Team**



Open Source since 2017 on GitHub

MANAGEMENT TEAM

MICHAEL SEVESTRE
Design2Code Inc.

ROLF BURGHAUS
Systems Pharmacology & Medicine, Bayer AG

STEPHAN SCHALLER
CEO, esqLABS GmbH

ALEXANDER STAAB
Boehringer Ingelheim Pharma GmbH & Co. KG

esqlabs
we empower life sciences

SANOFI

Boehringer Ingelheim

BAYER

NOVARTIS

UF UNIVERSITY of FLORIDA

UNIVERSITÄT DES SAARLANDES

DESIGN{2}CODE

RWTH AACHEN UNIVERSITY

Pharmetheus
Pharmacometrics Consulting Services

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The OSP Community Focus Groups

Representing the “Executive Arm” of OSP Roadmap Implementation

Dedicated Focus Groups have been established to conceptualize, design and progress the individual areas, the Management Team will coordinate the interplay of focus areas and interfaces between them

Focus groups shall be the owner of the development in the respective focus area, they are expected to conceptualize and coordinate activities of the respective field.

EXISTING

- DDI
- Special Populations
- Absorption
- Automation
- PD
- Statistical modelling
- First in Human (IVIVE)
- Omics
- Suite Release Management
- Community Engagement (PR)
- Biologics

NEW

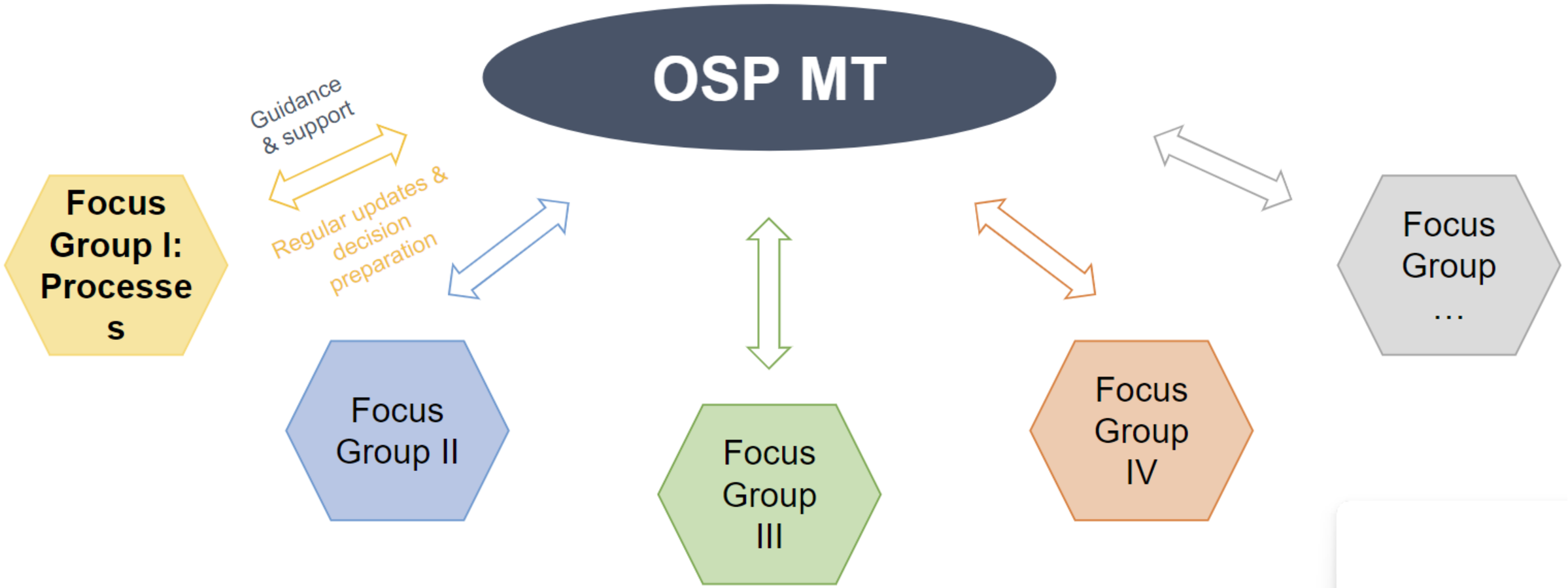
- Nonclinical PBPK
- PBBM
- HT PBPK
- Qualification
- Base PBPK Methodology

DDI	Quantitative DDI predictions (CYPs as well as transporters) are one of the key applications for PBPK and are a prerequisite for designing efficient clinical development programs and studies. A comprehensive library of well documented, qualified perpetrators and victims is a prerequisite for acceptance of DDI predictions from regulatory authorities.	Sebastian Frechen (@sfrechen)
IVIVE	• Improve and facilitate use of IVIVE in PK-Sim • Provide guidelines on how to conduct IVIVE in PK-Sim • Facilitate integration of in vitro data in prediction of DDI (e.g. integration of fraction metabolized) • Extrapolation of Caco-2 permeabilities to effective permeabilities	Donato Teutonico (@teutonicod)
Special populations	The addition of new or updated virtual populations is required to expand the application scope of the software in a consistent manner across users. The overall objectives are to define a process for 1. technical generation of populations destined for the OSP Suite and, 2. evaluation of those populations. This protocol will allow populations to be added more efficiently.	Andrea Edginton (@Aedginto)
Statistical Modelling	Statistical Modeling is a strategic theme of the OSP MT. Statistical modeling is a key enabler for PBPK and QSP M&S. Respective capabilities are required for all application areas to quantitatively assess population variability and uncertainty in prior knowledge and posterior results.	Christian Diedrich (@DiedrichC)

The OSP “Executive Body”: Focus Groups

Composition	- Everybody from OSP community can contribute to a focus group - At least one member from the OSP MT has to act as sponsor of a focus group (not necessarily participating in the work of the focus group)
Purpose	- Focus groups are the operating bodies of the OSP MT - They act on the mandate of the OSP MT and report directly into the MT (internal topic development) - Topics are not restricted and can range from Modell certification process to Marketing - Through a clear project structure small teams should be empowered to elaborate clearly defined topics for further decision in OSP MT
Requirements / Organization	- Clear and aligned Focus Group Charter - Self organizing units - Close tracking of all ongoing activities through regular updates in OSP MT - Transparent documentation (google drive) (further administrative harmonization to be discussed)

Focus Groups: Organization



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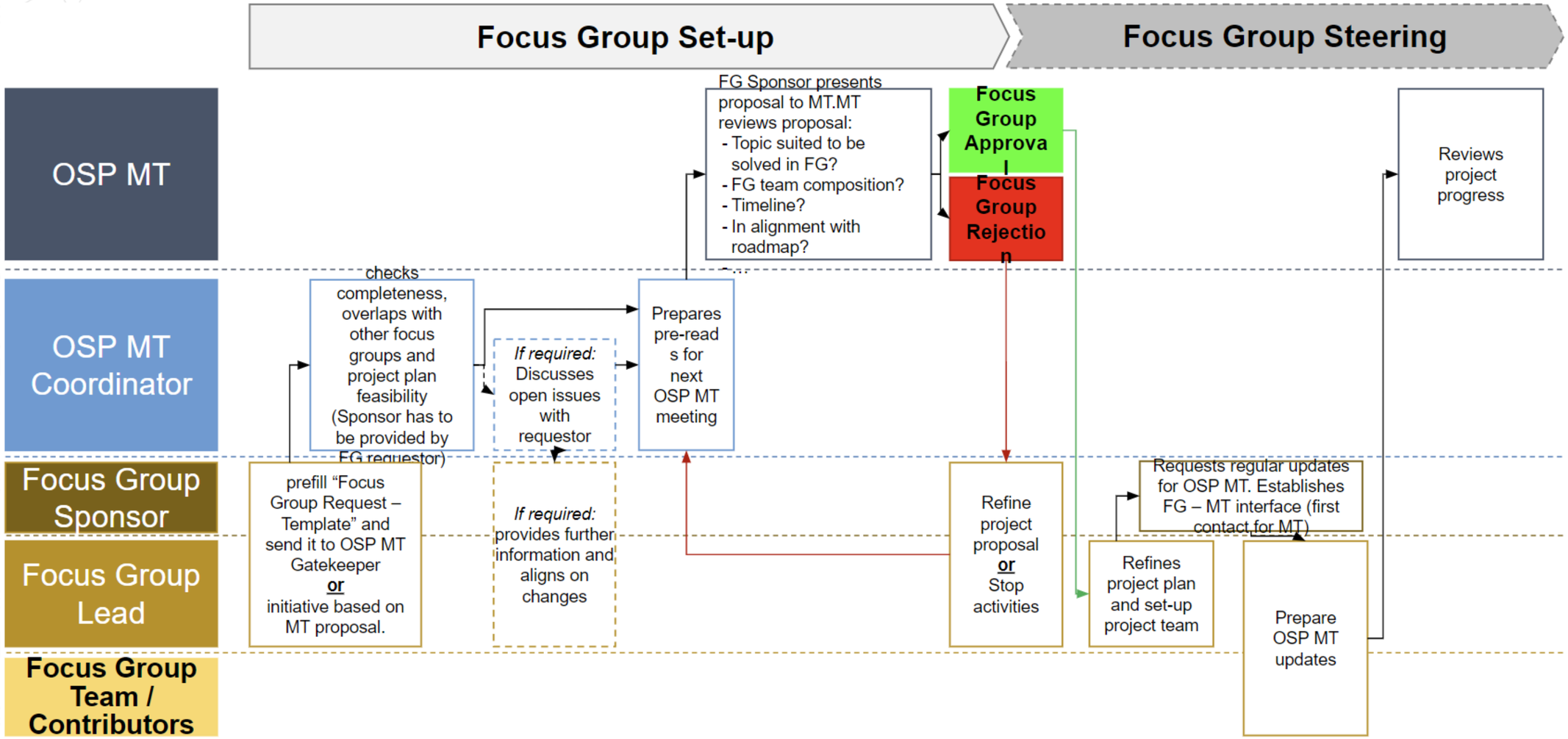
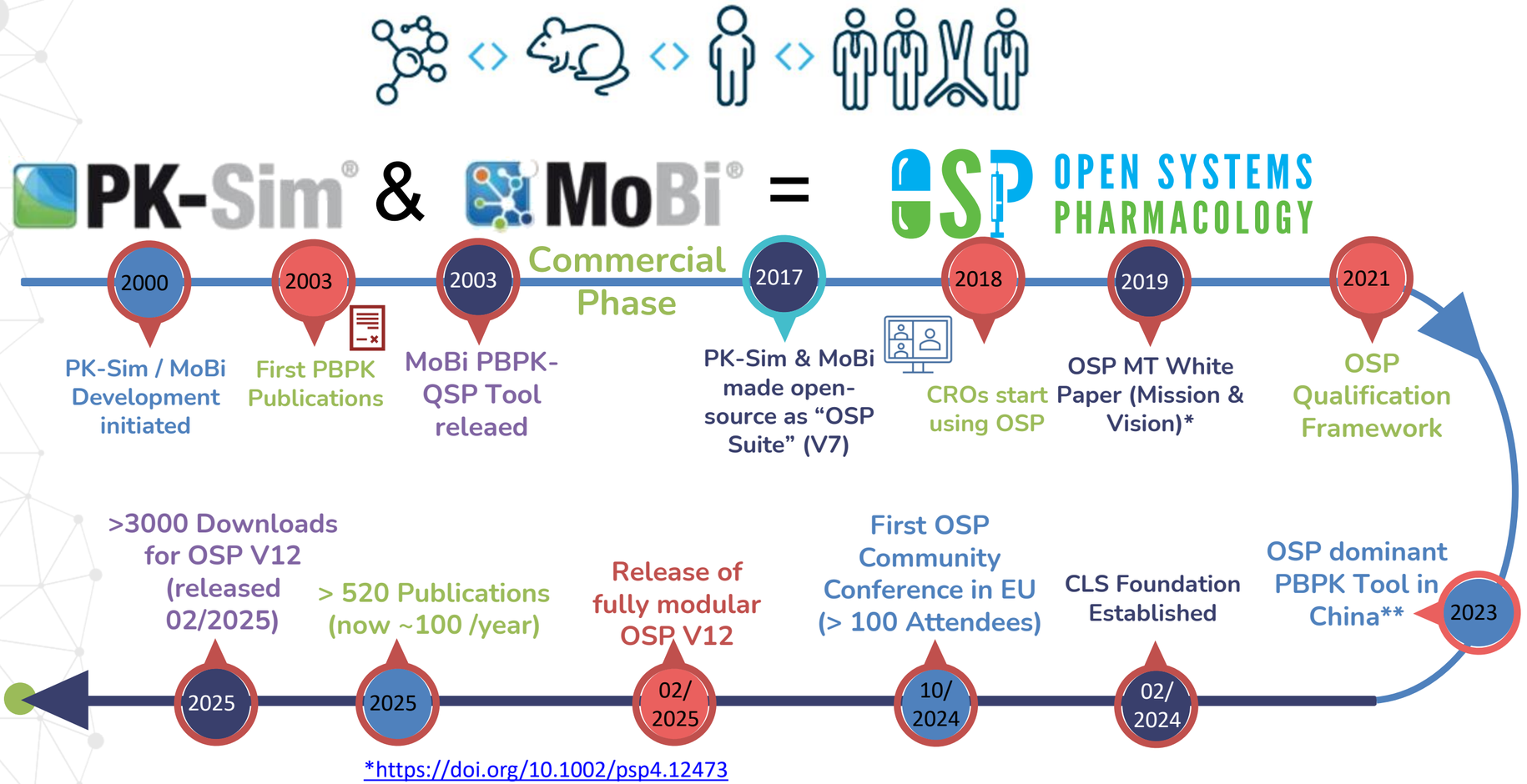
Focus Groups: Set-up and Steering Process



The OSP Journey so far

- An open-source Multiscale Physiologically-Based & Mechanistic Modeling platform which has been developed and refined for **20 years**!



*https://doi.org/10.1002/psp4.12473

OSP 2025 COMMUNITY CONFERENCE

The OSP Journey so far

CPT: Pharmacometrics & Systems Pharmacology

Perspective | Open Access

Open Systems Pharmacology Community—An Open Access, Open Source, Open Science Approach to Modeling and Simulation in Pharmaceutical Sciences

Jörg Lippert, Rolf Burghaus, Andrea Edginton, Sebastian Frechen, Mats Karlsson, Andreas Kovar, Thorsten Lehr, Peter Milligan, Valerie Nock, Sergej Ramusovic, Matthew Riggs ... See all authors

First published: 31 October 2019 | https://doi.org/10.1002/psp4.12473 | Citations: 81

& Mechanistic Modeling
or **20 years**!

OPEN SYSTEMS PHARMACOLOGY

2018 2019 2021

PK-Sim / MoBi Development initiated

First PBPK Publications

MoBi PBPK-QSP Tool releaed

>3000 Downloads for OSP V12 (released 02/2025)

> 520 Publications (now ~100 /year)

Release of fully modular OSP V12

2025 2025 02/2025

*https://doi.org/10.1002/psp4.12473

CPT: Pharmacometrics & Systems Pharmacology

PERSPECTIVE | Open Access

Harnessing Open-Source Solutions: Insights From the First Open Systems Pharmacology (OSP) Community Conference

André Dallmann, Denise Feick, Pavel Balazki, Salih Benamara, Rolf Burghaus, Marylore Chenel, Siak-Leng Choi, Henrik Cordes, Mariana Guimarães, Abdullah Hamadeh ... See all authors

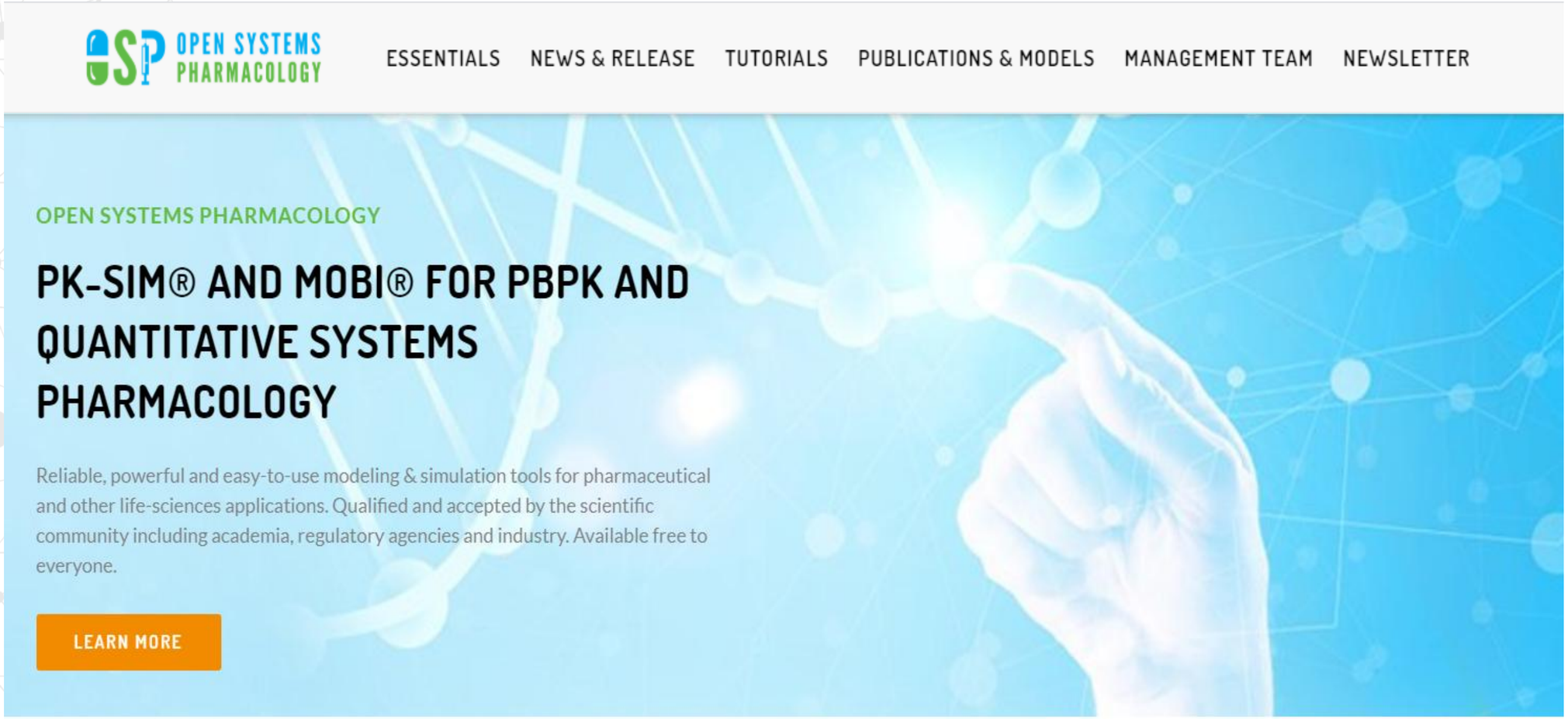
First published: 03 April 2025 | https://doi.org/10.1002/psp4.70028

Community Channels

ESP 2025
COMMUNITY CONFERENCE

Website

www.open-systems-pharmacology.org

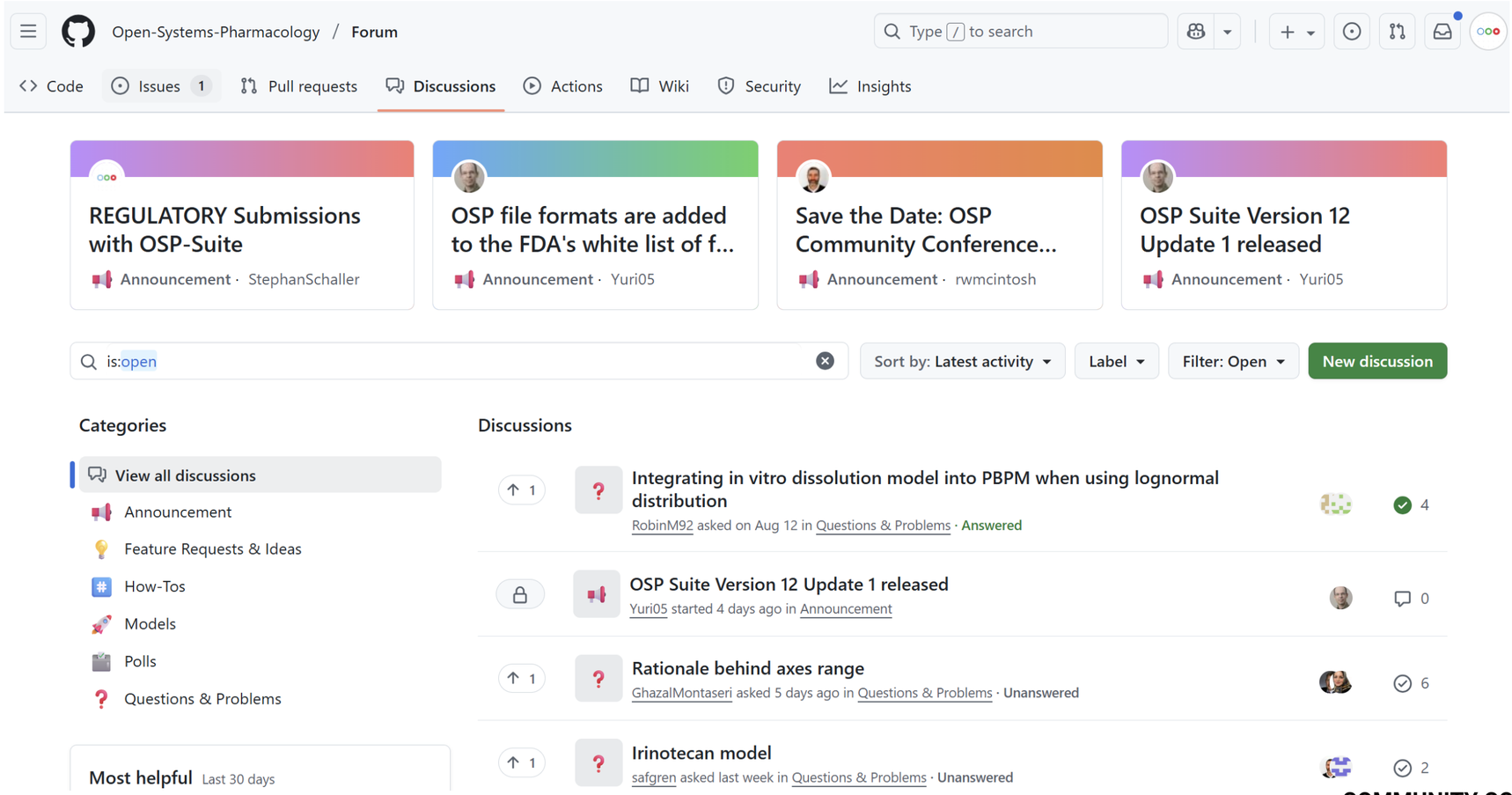


GitHub / Forum

User Community: Forum: github.com/Open-Systems-Pharmacology/Forum

FORUM

Have your questions answered or provide answers to others. The Forum is a great way to stay up-to-date on the community buzz around OSP.



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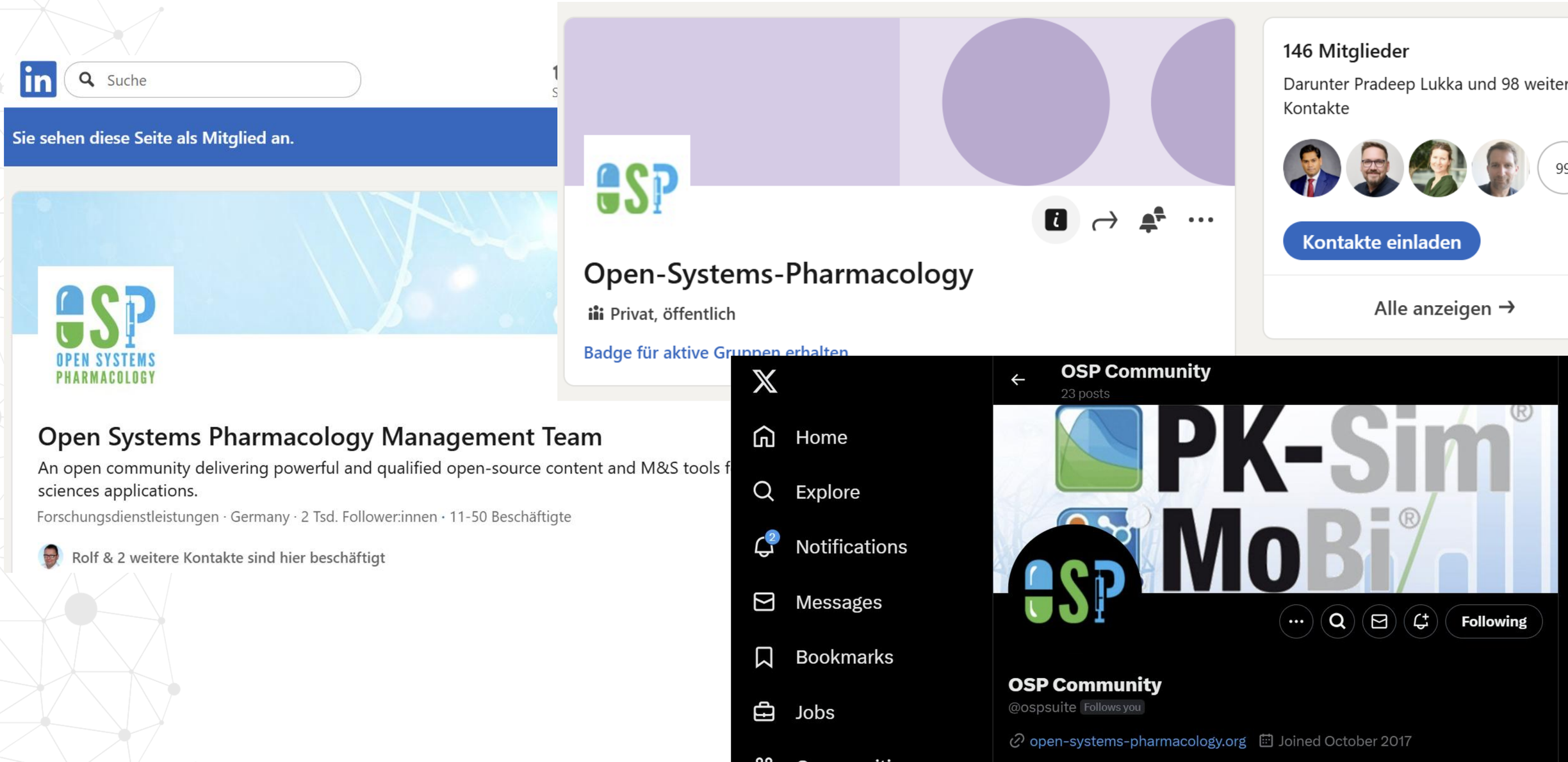
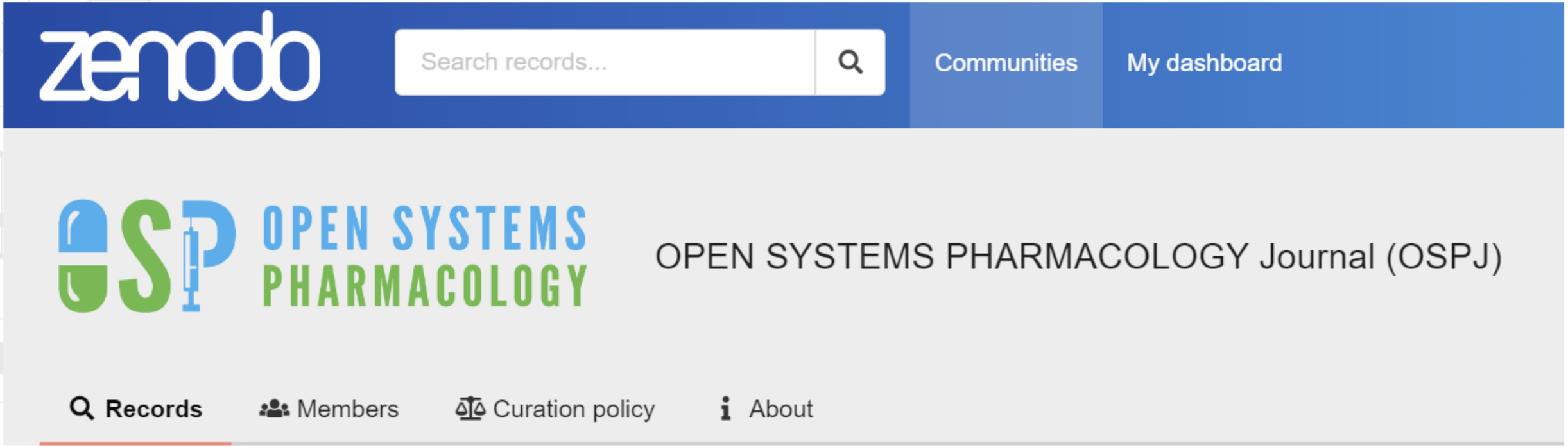
LinkedIn (& TWITTER / X)



OSP Journal (Zenodo)

https://zenodo.org/communities/ospj



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A Growing OSP Community

OSP 2025 COMMUNITY CONFERENCE

Growth Metrics by Publications

Source 1: Global Bibliometric Analyses

The Journal of Clinical Pharmacology
Official Publication of the American College of Clinical Pharmacology

Editor's Choice: Original Article | Open Access

In-Depth Analysis of the Selection of PBPK Modeling Tools: Bibliometric and Social Network Analysis of the Open Systems Pharmacology Community

André Dallmann PhD, Donato Teutonico PhD, Stephan Schaller PhD, Rolf Burghaus PhD, Sebastian Frechen MD

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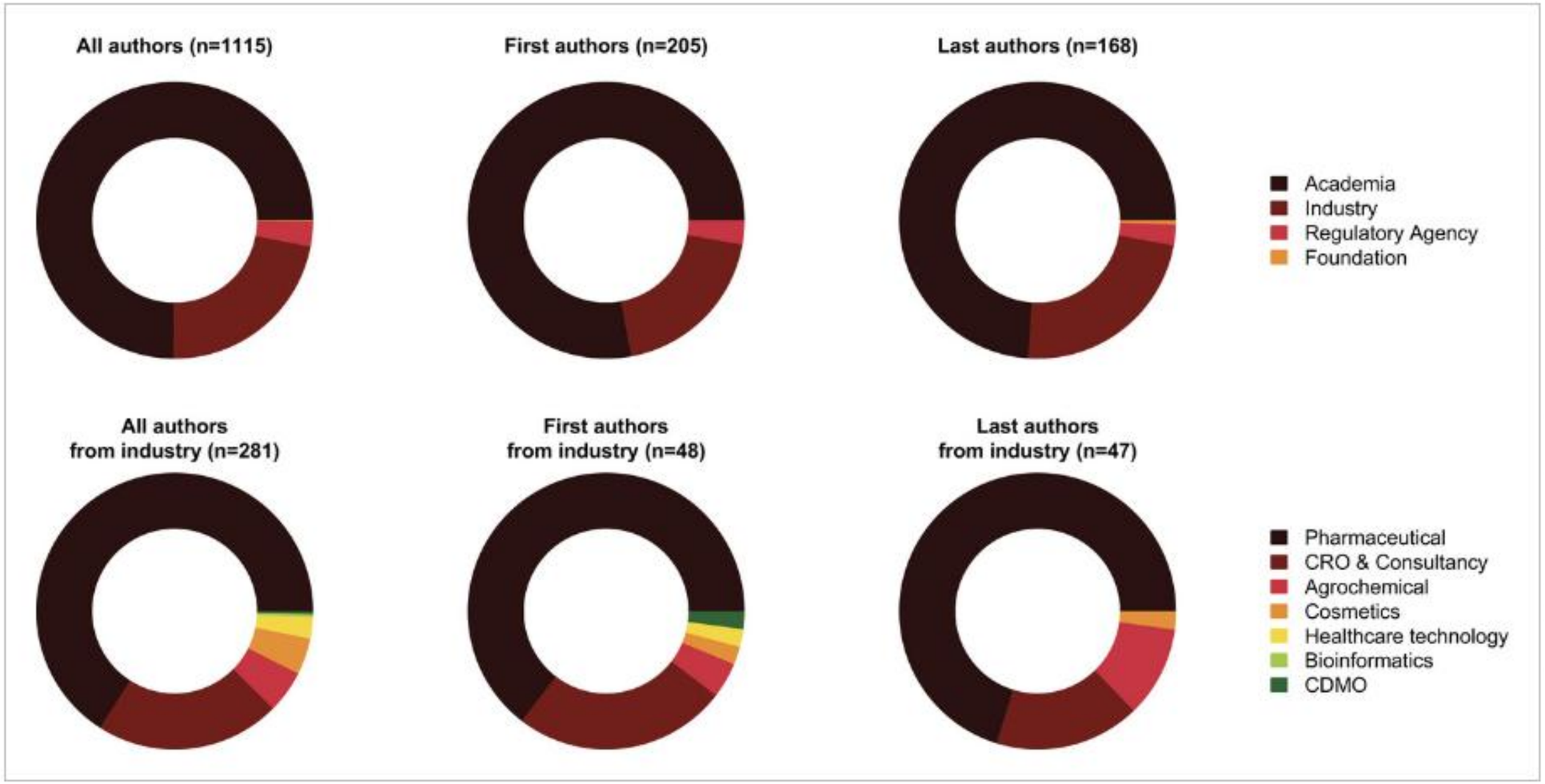
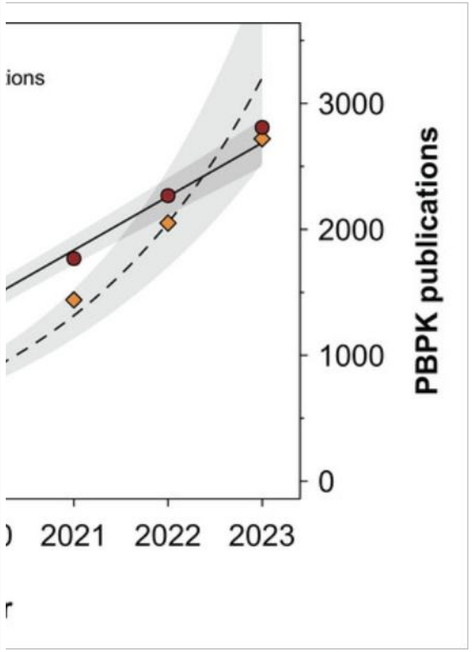
Growth Metrics by Publications

Source 1: Global Bibliometric Analyses (up to 2023)

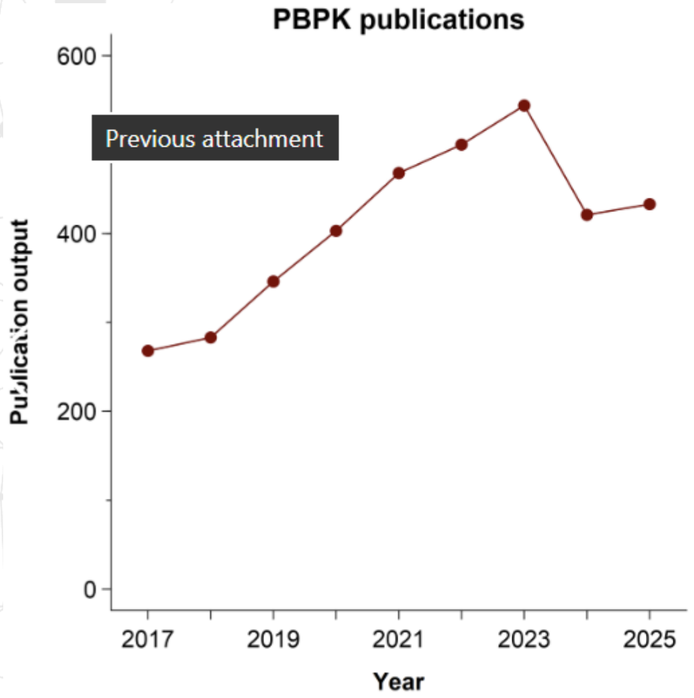


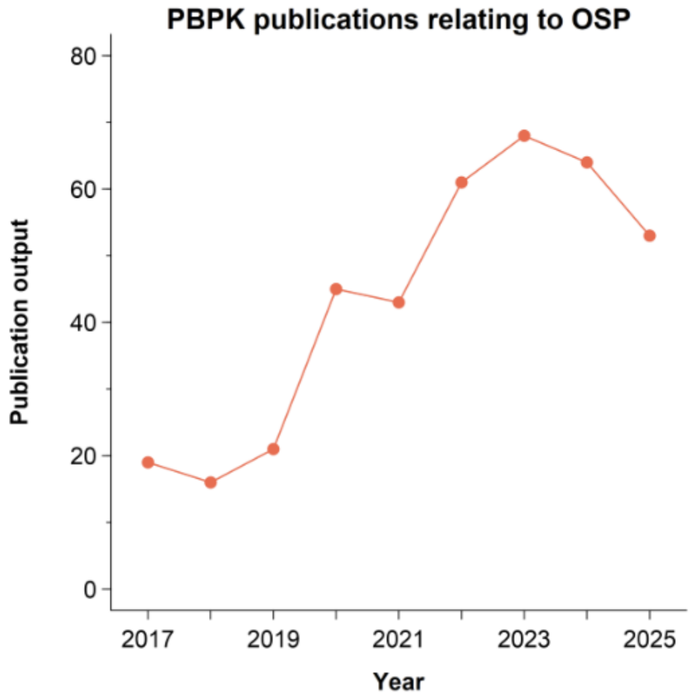


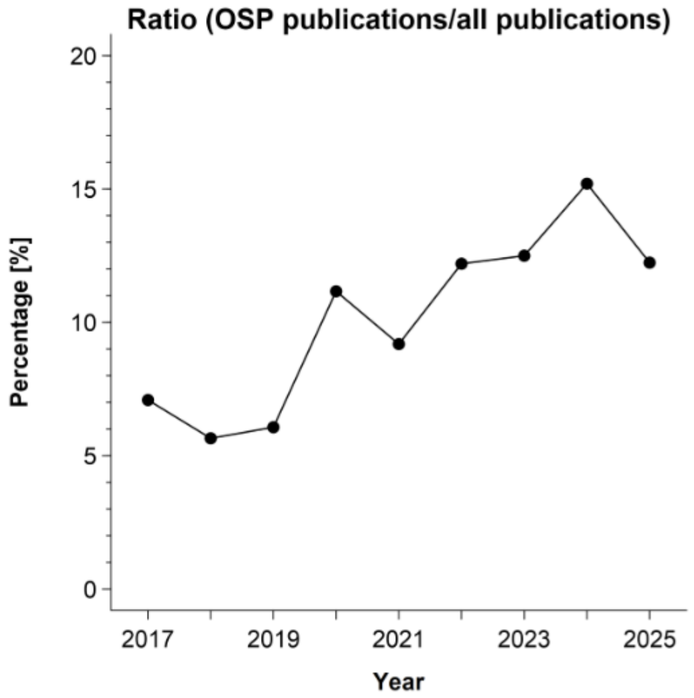
COMMUNITY CONFERENCE

Growth Metrics by Publications

Source 1: Global Bibliometric Analyses (EXPANDED to 2025)







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Growth Metrics by Publications

Source 2: China Bibliometric Analyses

REVIEW OPEN ACCESS

PBPK
Precis

Dongsheng Y
Xiaoqiang Xi

[1]Department of
National Medic
Formulations f

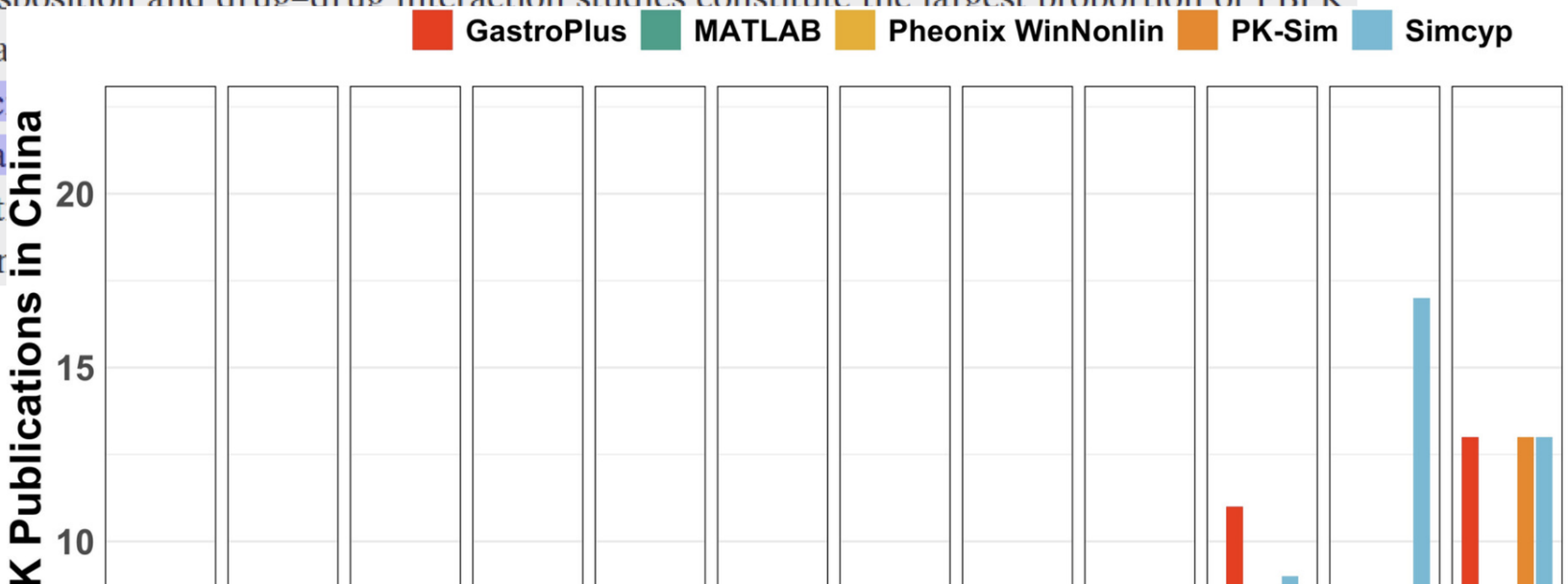
Correspondent

Received: 15 C

Funding: This

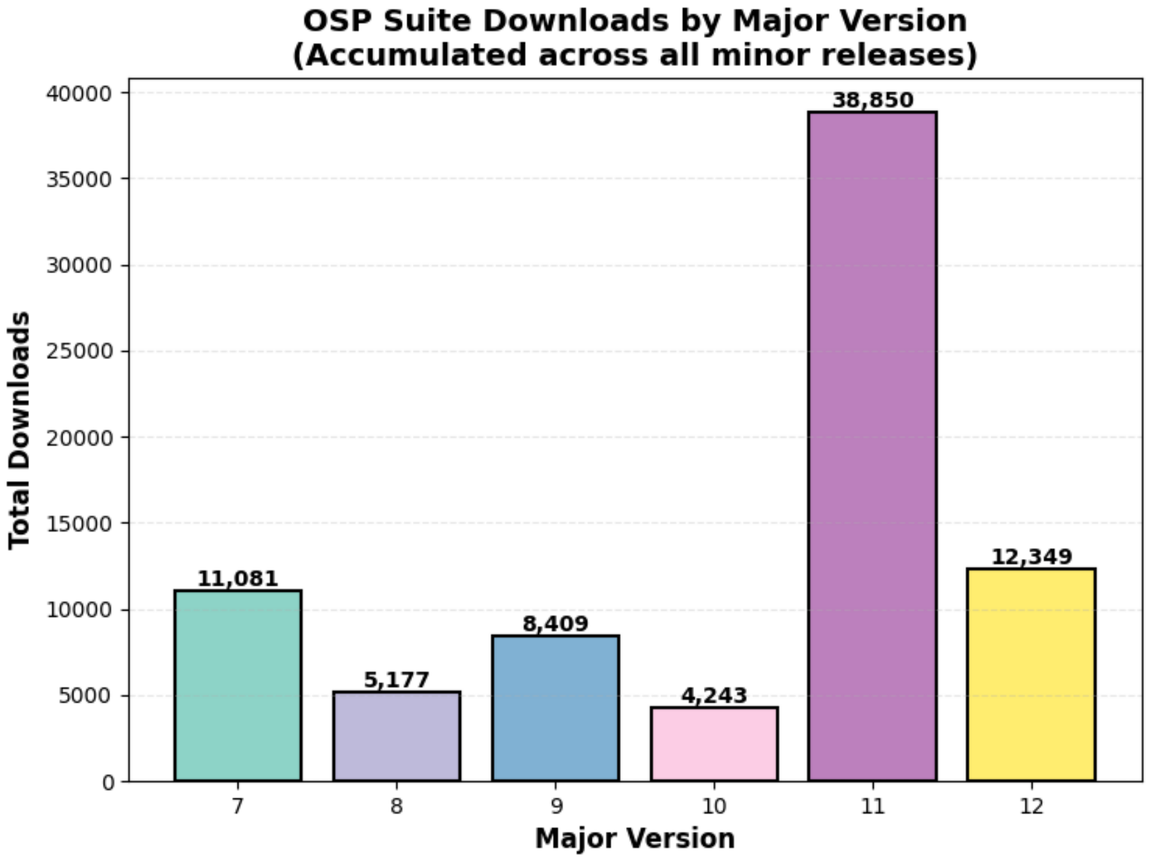
ABSTRACT

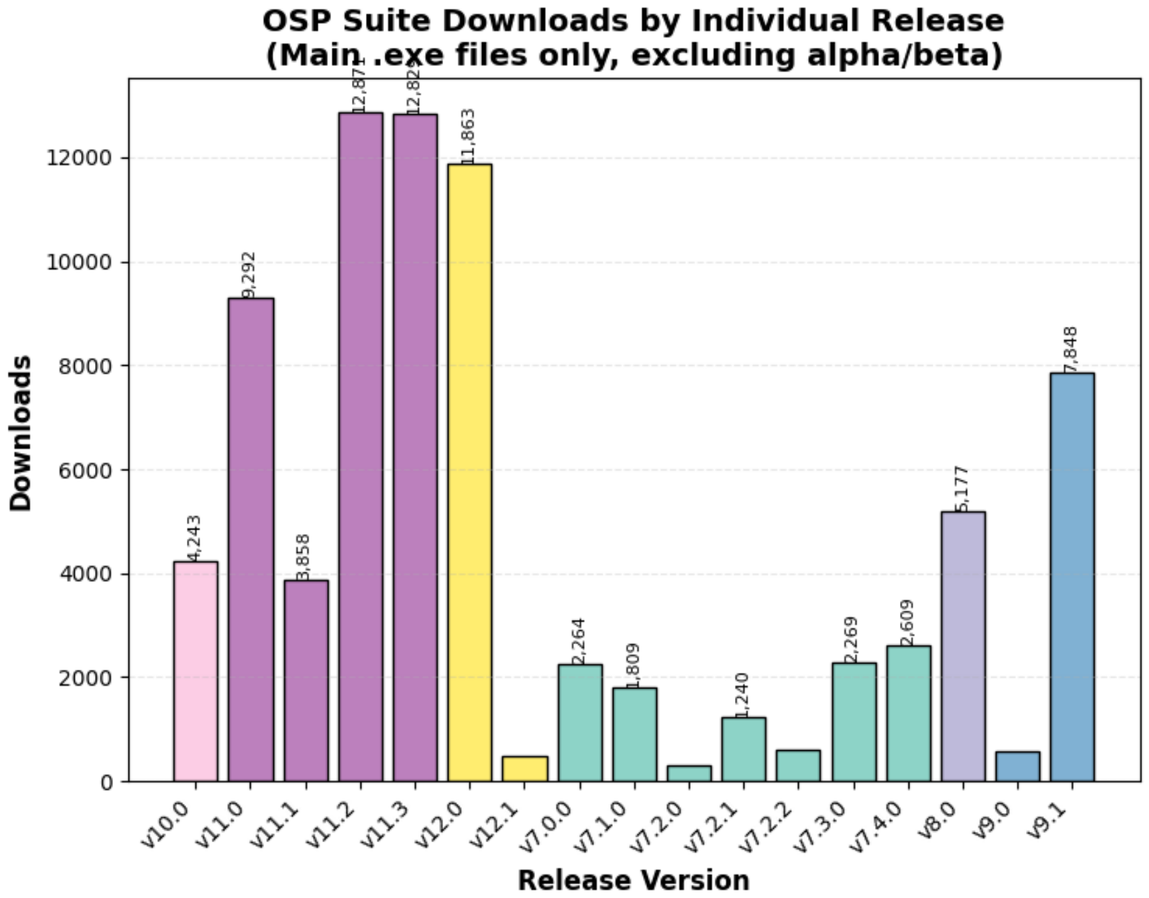
Physiologically based pharmacokinetic (PBPK) modeling, a cornerstone of model-informed drug development and model-informed precision dosing, simulates drug disposition in the human body by integrating physiological, biochemical, and physicochemical parameters. While PBPK modeling has advanced globally since the 1970s, China's adoption of this technology has followed a distinctive path, characterized by accelerated growth over the past 2 decades. This review provides a comprehensive analysis of China's contributions to PBPK modeling, addressing knowledge gaps in publication trends, application domains, and platform preferences. A systematic literature search yielded 266 original PBPK research articles from PubMed up to August 08, 2024. The analysis revealed that drug disposition and drug–drug interaction studies constitute the largest proportion of PBPK analyses in China. Chinese universities a
in China. Although established commerc
pharmaceutical industry, open-source pla
This review underscores the transformat
insights into future directions and challer



Growth Metrics by OSP Suite Downloads

Source: GitHub





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Growth?-Metrics by PAGE attendance ;-)

Source: PAGE OSP Booth Picture Time (we didn’t coordinate well in 2025)

OSP COMMUNITY:
ONWARD

Sustaining **Engagement** and **Collaboration**
for a continuing thriving **Community**

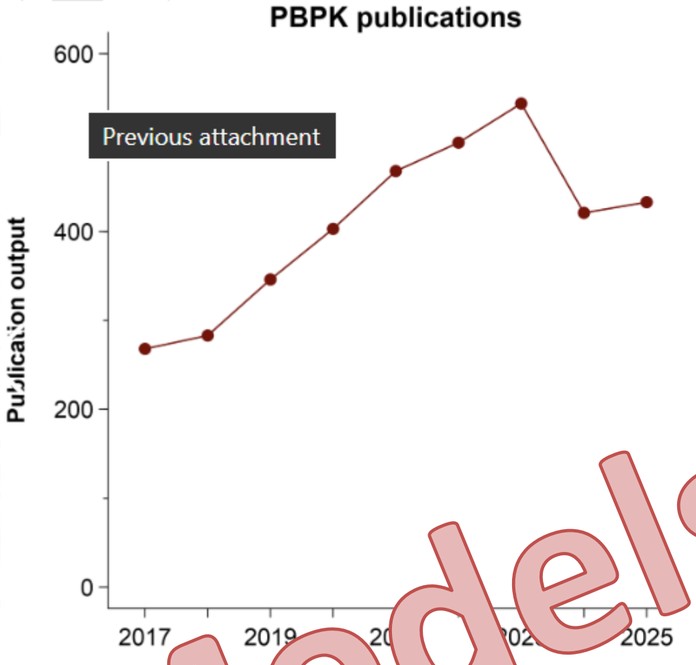
Sustain
Relevance of OSP

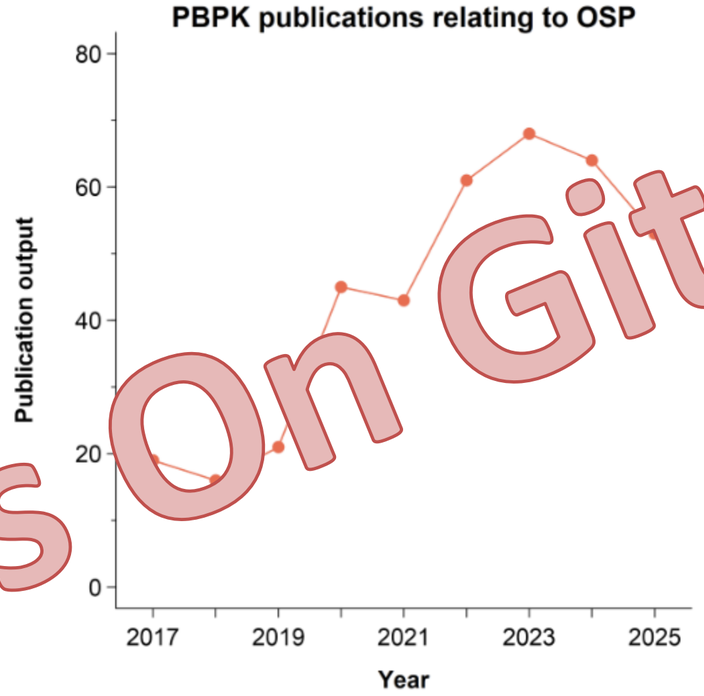
OSP 2025
COMMUNITY CONFERENCE

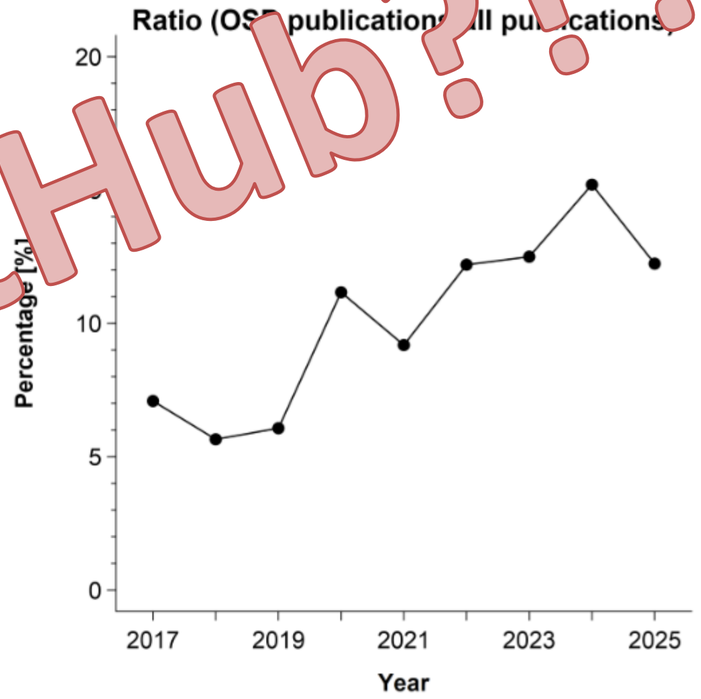
Sustain Relevance of the OSP Suite & Community

- Models & Software Ressources…
  - …Availability
  - …Accessibility
  - …Acceptance

Model Availability?







Models On GitHub???

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Model Accessability?

OSP Suite Version 12 Update 1 released

Latest suite release can be found here	Check our documentation	Need help? Visit the discussion forum
ospuite-R	Tutorials	Journal publications
How do I upload a model?	OSP Roadmap	Documentation for develope

Pinned

MoBi Public

MoBi® is a software tool for multiscale physiological modeling and simulation

C# 36 13

Forum ic

cussion forum for the Open Systems Pharmacology Project

67 18

Suite ubl

Ope arm y Suite Setup

Rich xt Format 120 28

PK-Sim Public

PK-Sim® is a comprehensive software tool for whole-body physiologically based pharmacokinetic modeling

C# 129 56

OSP-Qualification-Reports Public

Qualification Reports recreated with every new OSP Release

3 8

OSP-PBPK-Model-Library Public

Library of released PBPK substance models and evaluation reports

31 24

GitHub easy to use???

OSP 2025 COMMUNITY CONFERENCE

- **OSP Suite Essentials**
  - Releases & Set-up
  - PK-Sim
    - Platform-Qualifications
    - PBPK Model Library
  - MoBi
    - Systems Model Library
  - Manual
  - Forum
- Qualification Framework
- Reporting Engine
- R-Toolbox

DDI Enzymes

Pediatrics

Obesity

DDI Transporters

Covid-19

Depression

Model Acceptance

Certification | Validation | Qualification

Certification

- Independent peer review by ≥ 2 reviewers
- FORMALIZATION: Accepted by OSP MT (statement → “OSP MT certified”)

Qualification (only qualified content can be implemented in PKSim)

- Applicability (useful for others, predictability → provide use cases)
- Reasonable results (might not be acceptable for high impact results (poor data availability, …))
- [Note: Relation to PBPK best practice document(s)]

Validation

- Technical robustness

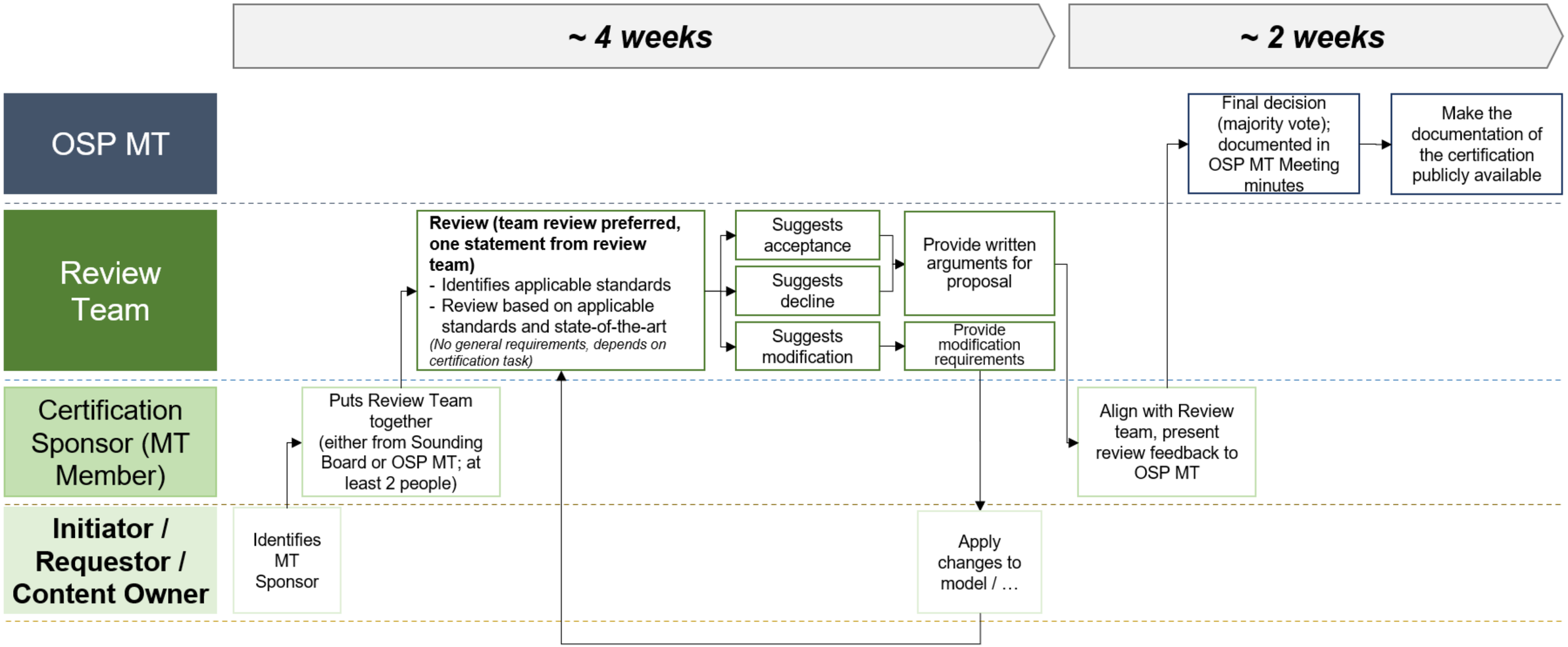
OSP 2025 COMMUNITY CONFERENCE

Certification: Models, Tools & More

Goal: Provide review and **certification as a learned society** applying fully transparent processes

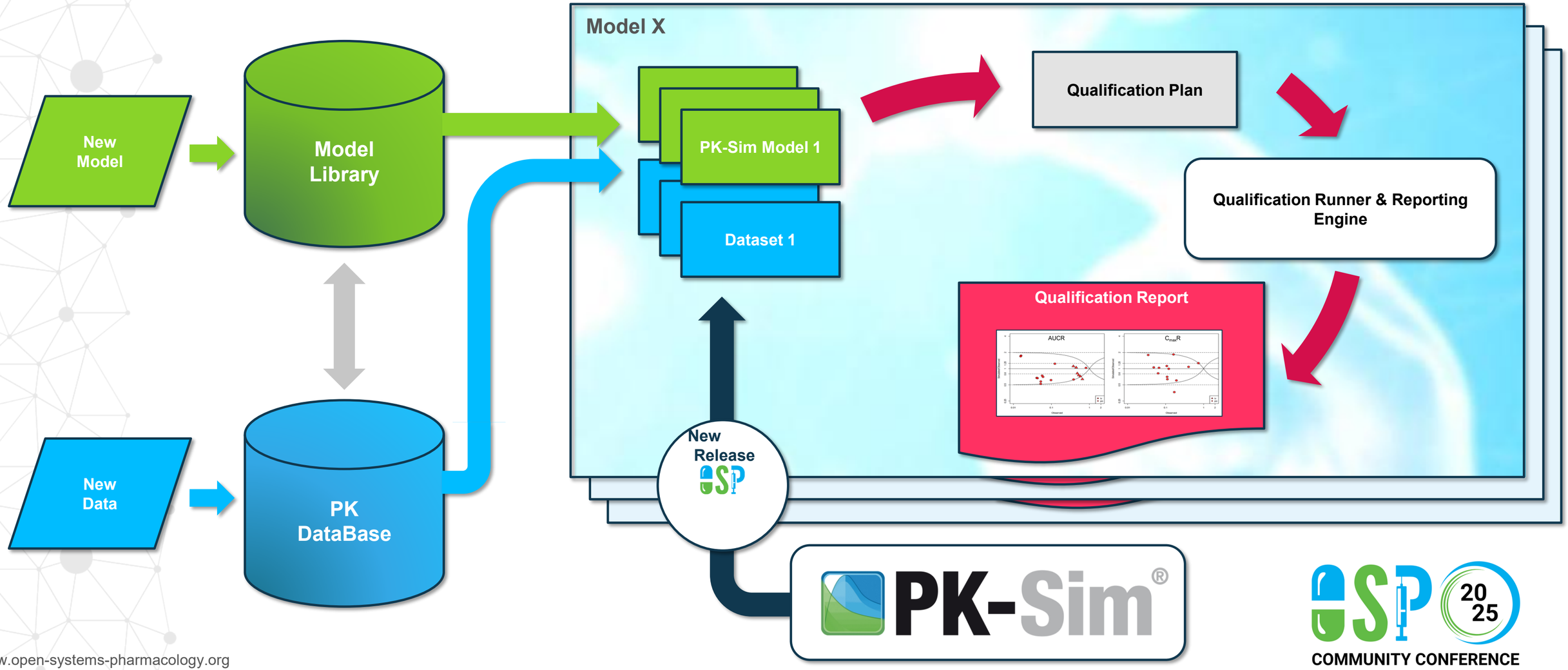
- Provide PBPK and systems pharmacology based approaches, best practices, systems and tools that are **evaluated regarding their compliance with (regulatory) guidelines** and state-of-the art modelling / software **qualification approaches**
- Ensure that the **certification** can be done **in a sustainable way** that allows for (re-)qualification with each software version release **supported by automated processes**

Certification Process



Community-Driven CoU Qualification Framework

Automatic (Re)-qualification Workflow



Regulatory Submissions with PK-Sim

Just to be sure:

"OSP file formats are added to FDA's white list of file formats for electronic submissions"

- The following OSP file formats are included:
- **.pksim5** (PK-Sim project file)
- **.mbp3** (MoBi project file)
- **.pkml** (OSP model exchange format)
- **.json** (PK-Sim project snapshots file)

Specifications for File Format Types Using eCTD Specifications

Revision History

Date	Version	Summary of Changes
2023-12-01	9.0	Updated .docx permissible uses Updated .xml accepted locations and permissible uses Removed "CDER Only" from permissible uses for: .csv, .cas, .dat, .rmd, .r Updated file format added: Modeling & Simulation file types: .pksim5, .mbp3, .pkml, .json, .mlxtran, .mlxproperties, .pkx, .pkxproperties, smlx, .smlxproperties, .syc, .datxplore

Further Increasing Acceptance

- FDA Model Master File (MMF)
  - Master File for **standardized** model documentation and validation data that FDA can reference across multiple submissions
  - Focuses on regulatory **efficiency and consistency** through standardization (models can be proprietary OR open-source)
- EMA Qualification Opinion
  - Public scientific opinion **confirming a model/method is suitable** for specific Context(s) of Use in regulatory decision-making
  - Once qualified, sponsors can **use without re-establishing platform credibility,** with all qualification data becoming publicly available

- …all requires effort = budget = funding

Funding OSP

OSP 2025 COMMUNITY CONFERENCE

Funding Sources for OSP

- Software
  - In-Kind Contributions (Bulk of “Ressources”)
    - Individual Stakeholders (Companies & Individuals)
  - Dedicated Industry Sponsoring for Feature Development
  - Grants
- Models & Qualified Content
  - In-Kind Contributions (Bulk of “Ressources”)
    - Individual Stakeholders (Companies & Individuals)
  - Dedicated Industry Sponsoring for CoU Qualification
  - Grants

  - → No steady and continuous stream of “funding”, especially for software “maintenance”

COMMUNITY CONFERENCE

Initial Idea: OSP Foundation

- Institutionalization of the project “open system pharmacology” in a non-profit organization (NPO) to promote the public health care system (§ 52 Abs . 2 Nr. 3 AO) and / or to promote science and research (§ 52 Abs . 2 Nr. 1 AO).

- <u>General conditions:</u>
  - NPO must be able to participate in legal transactions
  - participation opportunities for non-profits and for-profits
    - donors, companies (all sizes), individuals, academic partners like universities or other research institutions
    - Contributions can be financial, cooperational, ideational

Implemented: CLS Foundation

(clsfoundation.org)

COMPUTATIONAL LIFE SCIENCES FOUNDATION

Advancing Computational Life Sciences through Open Collaboration

NGOsource
Equivalency Determination on File

CLS FOUNDATION ACHIEVES US PUBLIC CHARITY CERTIFICATION!

We are now officially certified as a US Public Charity through NGOsource's Equivalency Determination.
Read more about this milestone and what it means for global open science collaboration.

Read the News

the R&D landscape through open cooperation and innovation.

ABOUT OUR FOUNDATION

SUPPORT OUR MISSION

SUPPORT OUR MISSION

Help us drive innovation in life sciences through open source software

SUPPORT SPONSOR DONATE

Interested in other ways to support our mission? Contact us to discuss corporate giving, matching programs, or planned donations.

SUPPORT

Support is directed towards specific projects or initiatives. By supporting our projects, you help ensure their continued development and maintenance.

OSP SUITE WEB UI (FOR MAC)

Support the development of our OSP Suite Web UI

SUPPORT SPECIFIC FEATURE IMPLEMENTATION

What can the CLS Foundation stand for?

- A means to empower the Community with the funding received from Foundation/Consortium Member Organizations
- Funding of:
  - Integrative Efforts for the Software/Models Ecosystem,
    - Enabling 3A: Availability, Accessibility, and Acceptance
  - Qualification and Regulatory Acceptance
  - Organize Events (Connect to Collaborate),
  - Synergy-Driving activities, and
  - (seed-fund?) Focus Group Initiatives

THANK YOU!

- Feedback Form
  - Use throughout for any feedback

- Questionnaire
  - For structured post-conference feedback

ASP 2025 COMMUNITY CONFERENCE