
OSP 2026
COMMUNITY CONFERENCE
OSP FG
< Community Engagement >

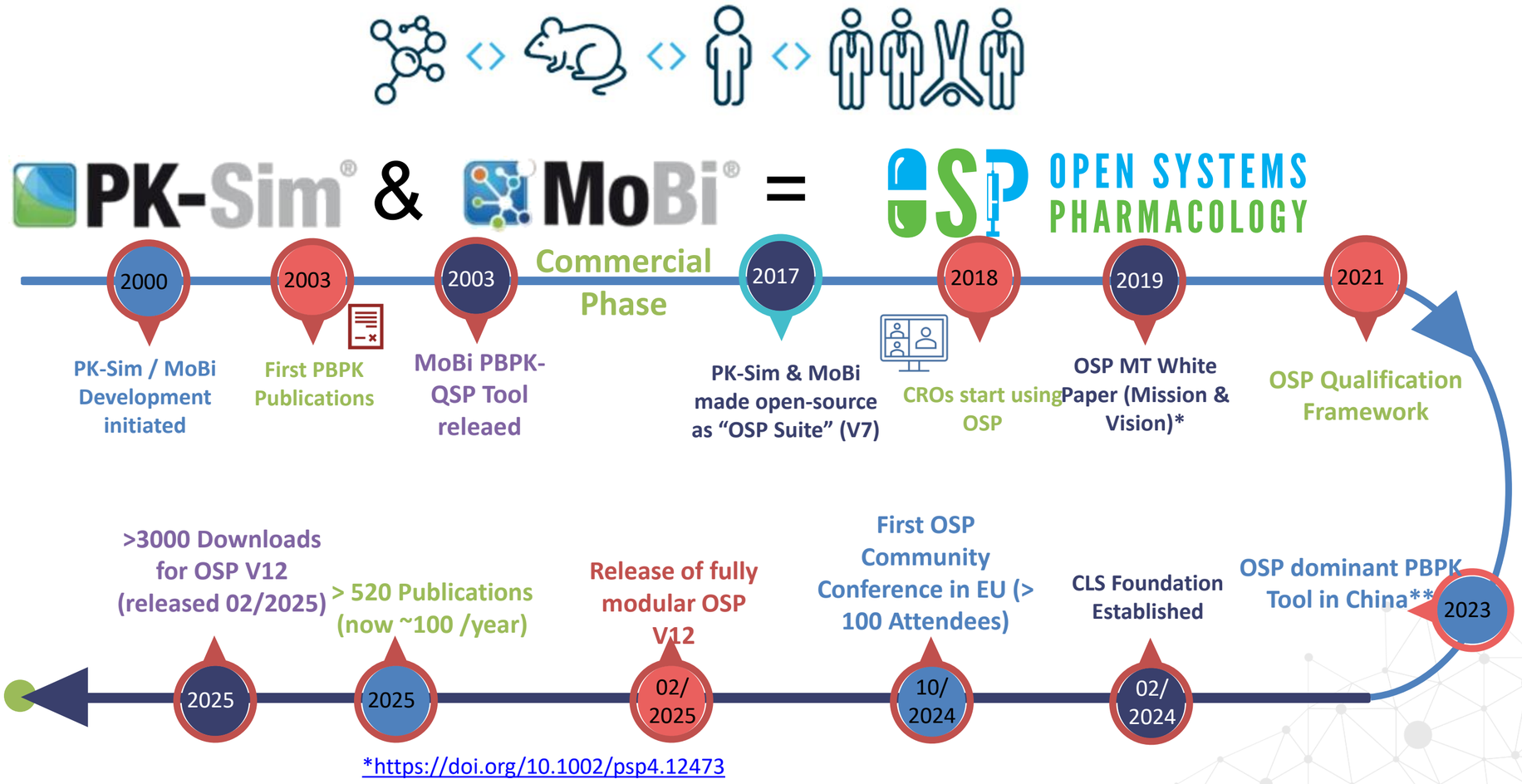
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History and Community Setup



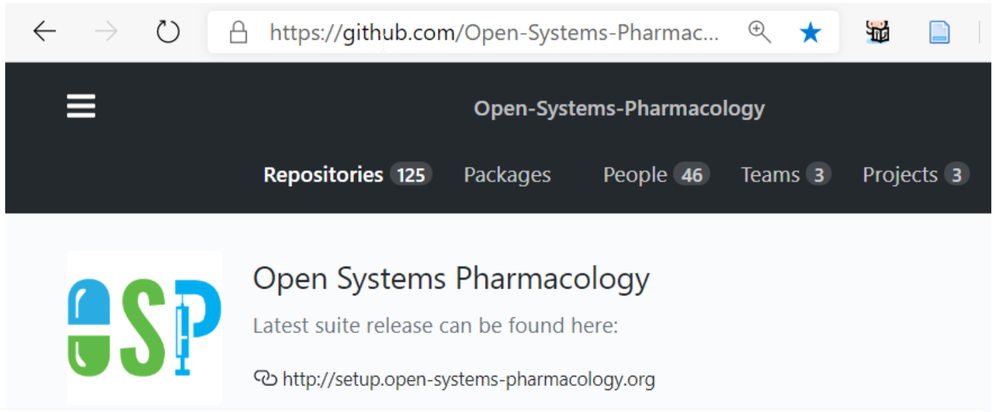
The OSP Journey so far

- 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

The OSP Community Landscape: Management Team



Open Source since 2017 on GitHub

MANAGEMENT TEAM



JURI SOLODENKO
Model-Informed Drug Development, Bayer AG

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Design2Code Inc.

ROLF BURGHAUS
Model-Informed Drug Development, Bayer AG

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Clinical Pharmacology | Pharmacometrics, Boehringer Ingelheim Pharma GmbH & Co. KG



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Modeling & Simulation, Novartis

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ERIK SJÖGREN
Pharmetheus and Uppsala University

IBRAHIM INCE
Translational Medicine & Clinical Pharmacology Data Science, Boehringer Ingelheim Pharma GmbH

esqlabs
we empower life sciences

SANOFI

NOVARTIS

Boehringer Ingelheim

BAYER

UF UNIVERSITY of FLORIDA

RWTH AACHEN UNIVERSITY

UNIVERSITÄT DES SAARLANDES

DESIGN{2}CODE

Pharmetheus
Pharmacometrics Consulting Services

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The OSP Community Landscape: Focus Groups

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)

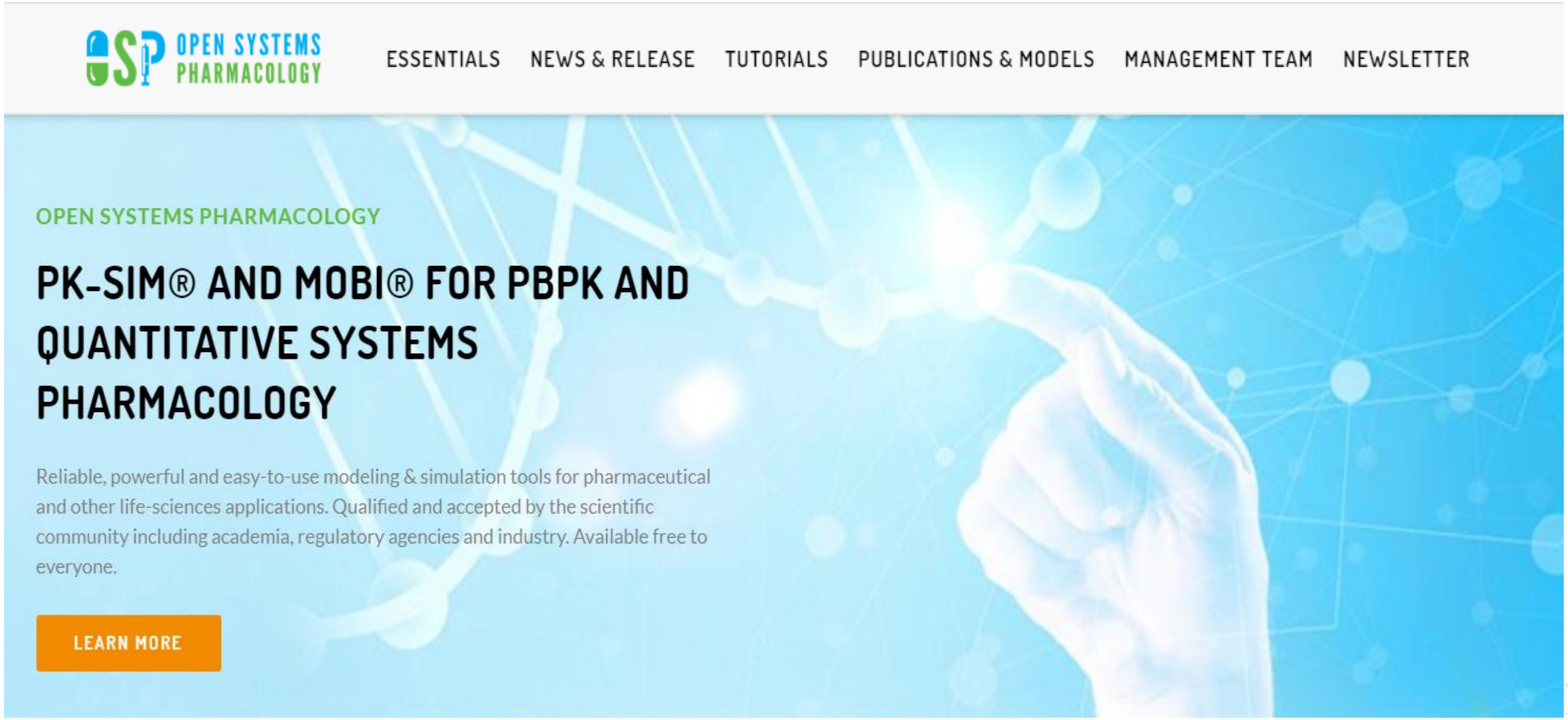

OPEN SYSTEMS PHARMACOLOGY
PK-Sim
MoBi
ΑΠΑΓΟΡΕΥΕΤΑΙ
ΤΟ ΚΑΠΝΙΣΜΑ
Available FREE to everyone at:
open-systems-pharmacology.org

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Community Channels



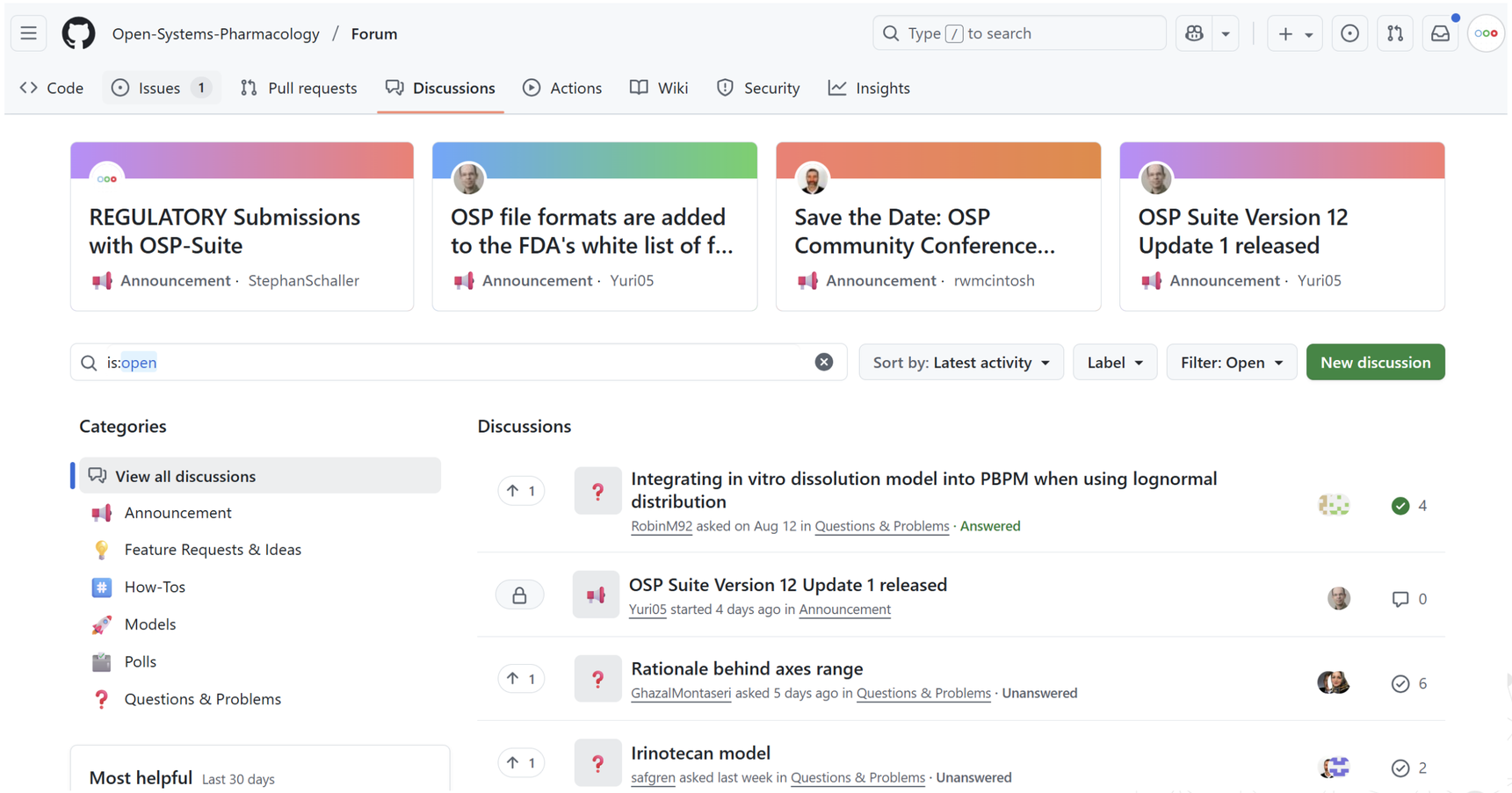
Website: www.open-systems-pharmacology.org



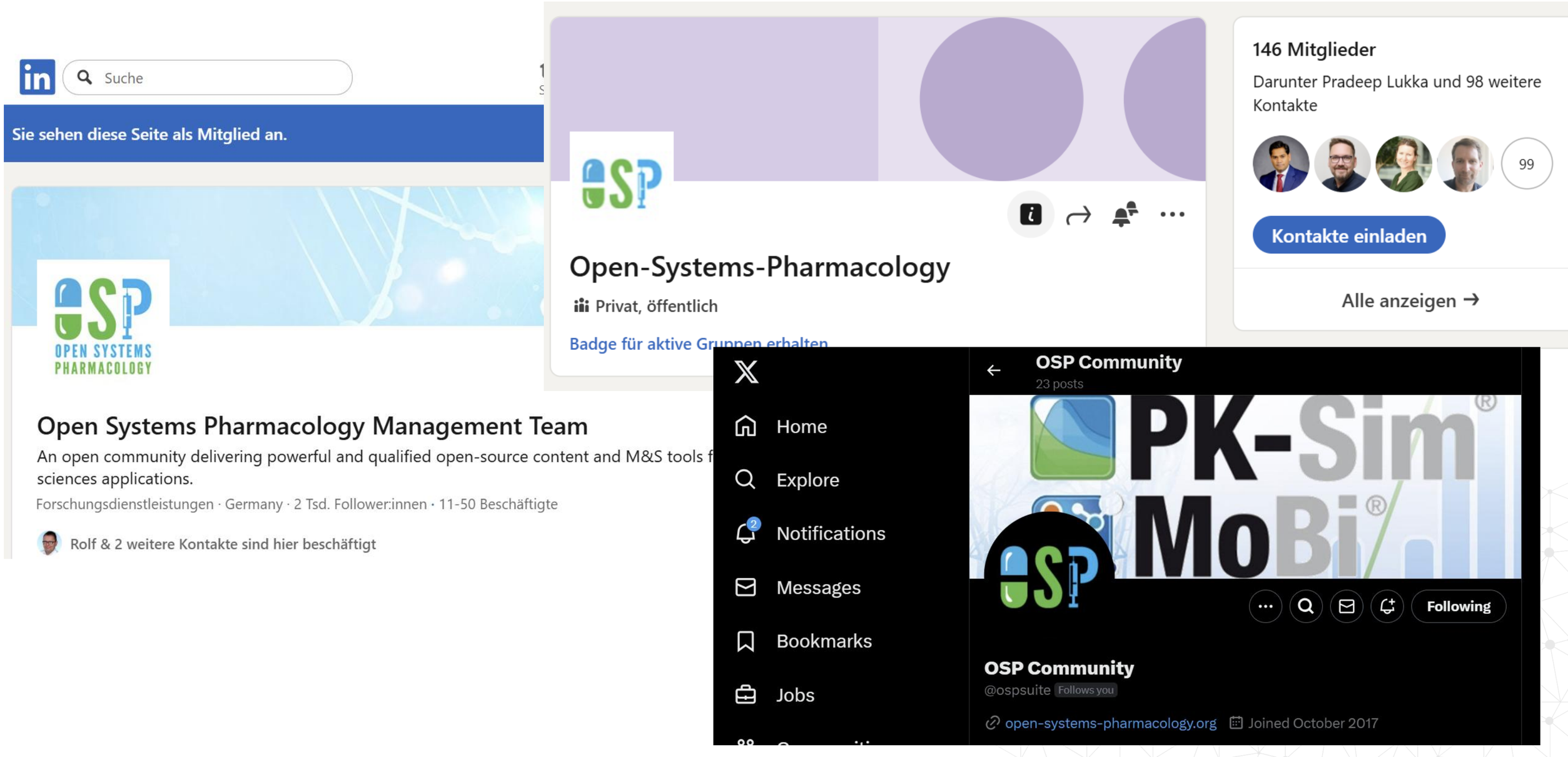
GitHub / Forum: github.com/Open-Systems-Pharmacology/Forum

FORUM

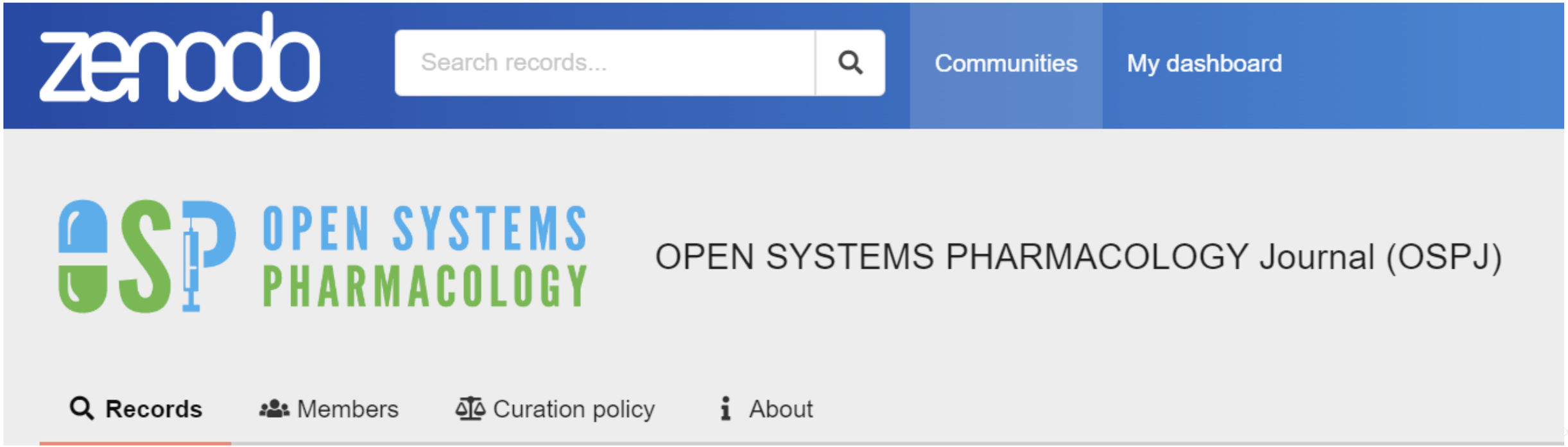
Have your questions answered or provide answers to others. The Forum is a great way to stay up-to-date on the community buzz around OSP.



LinkedIn (& TWITTER / X)



OSP Journal (Zenodo): https://zenodo.org/communities/ospj



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Sustain
Relevance of OSP



Sustain Relevance of the OSP Suite & Community

- Models & Software Ressources should be
  - Available
    - How many models are Published with Supplement or are on GitHub?
  - Accessibility
    - How easy are models to get and re-use?
  - Acceptance
    - How often is acceptance by regulators an issue?

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

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Sustain Relevance of OSP
- Funding OSP -

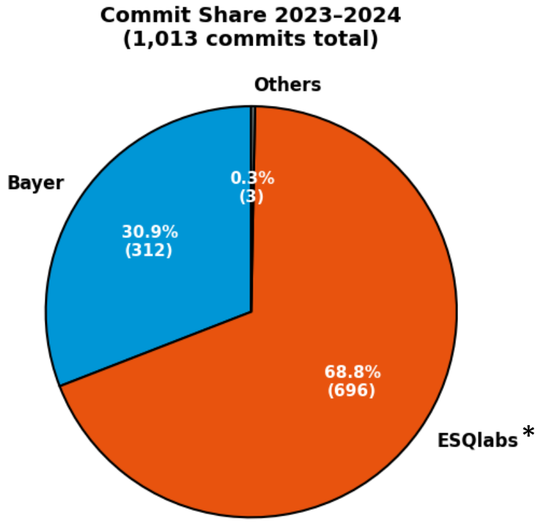


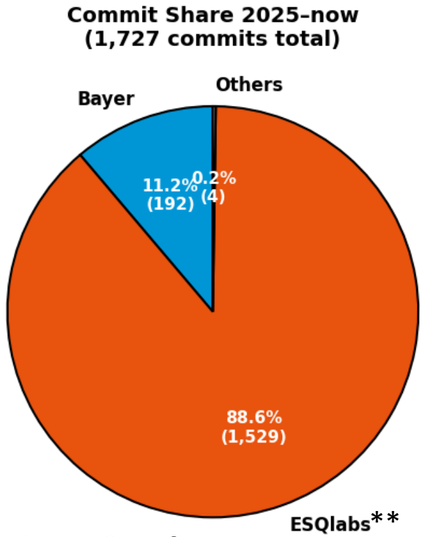
Funding Sources for OSP

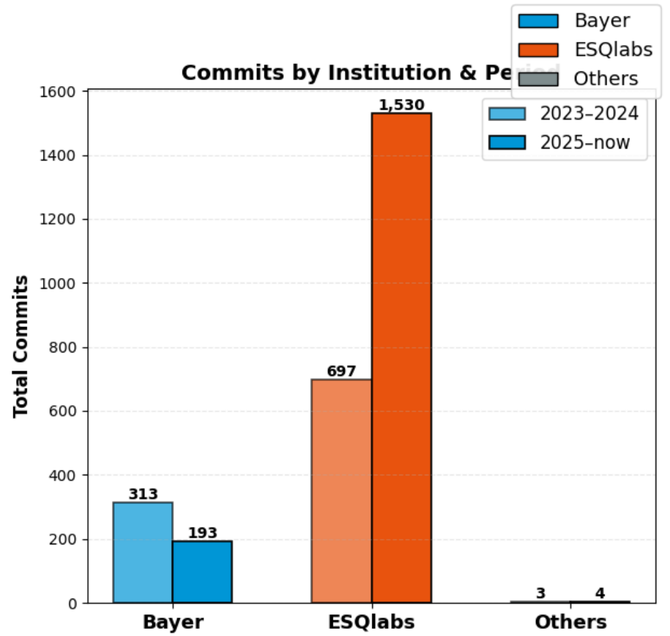
- Software
  - In-Kind Contributions (Bulk of “Ressources”)
    - Individual Stakeholders (Companies & Individuals)
  - Dedicated Industry Sponsoring for Feature Development
  - Grants
- Models & Qualified Content
  - In-Kind Contributions (Bulk of “Ressources”)
    - Individual Stakeholders (Companies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

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

OSP Suite — Contributions by Institution

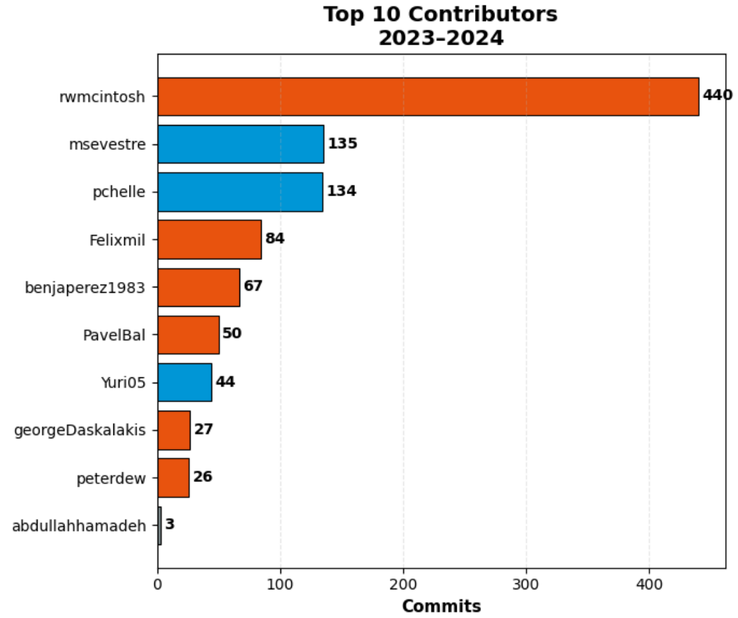


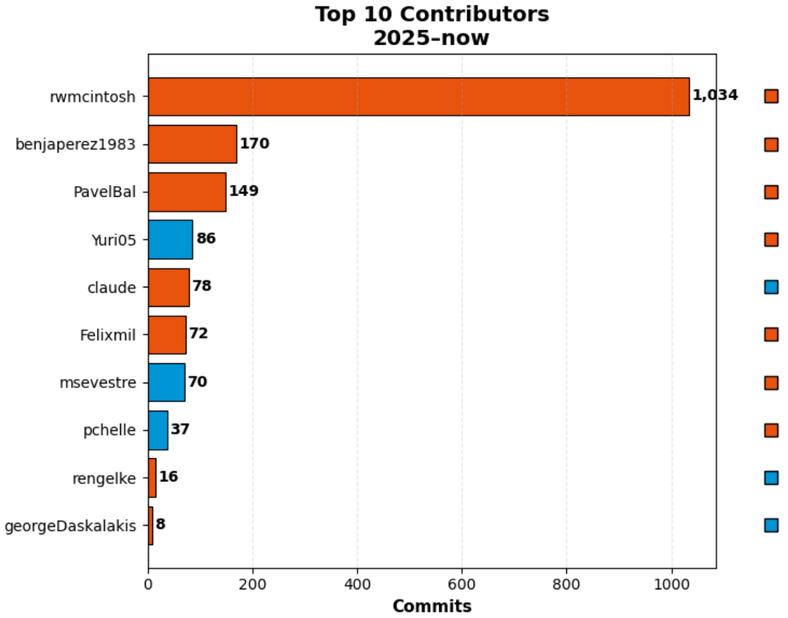


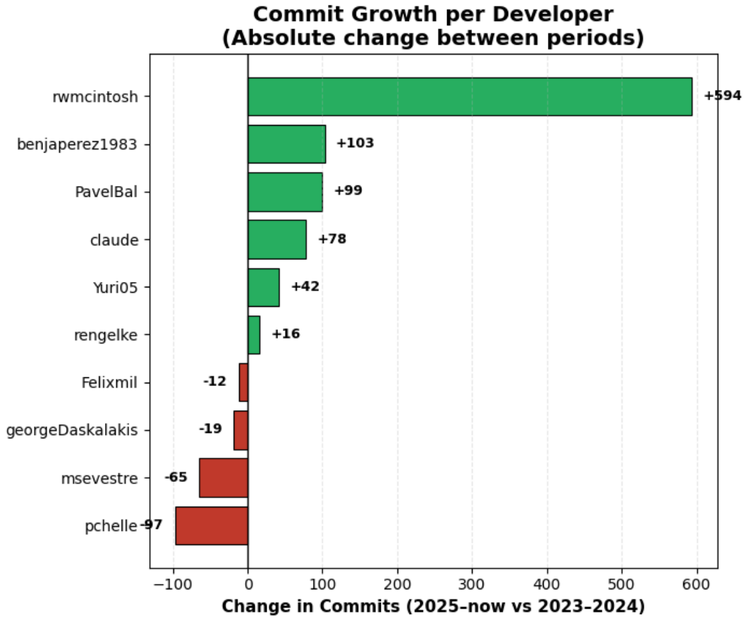


* Acknowledging ~15% funding by Bayer, Boehringer, Sanofi

** Acknowledging ~10% funding by Bayer







Implemented: CLS Foundation

(clsfoundation.org)



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Gold

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Pharmetheus

sanofi

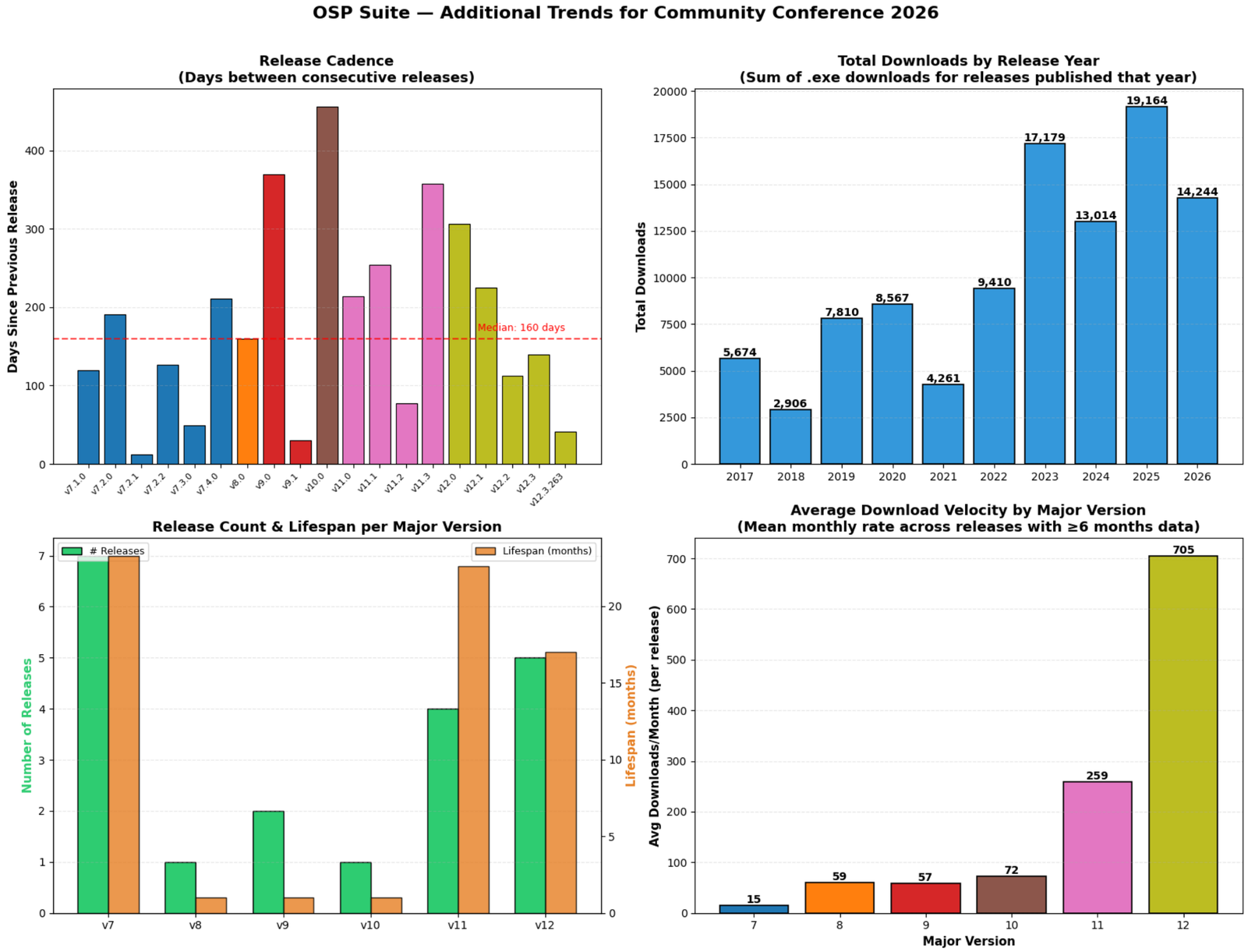
Boehringer Ingelheim



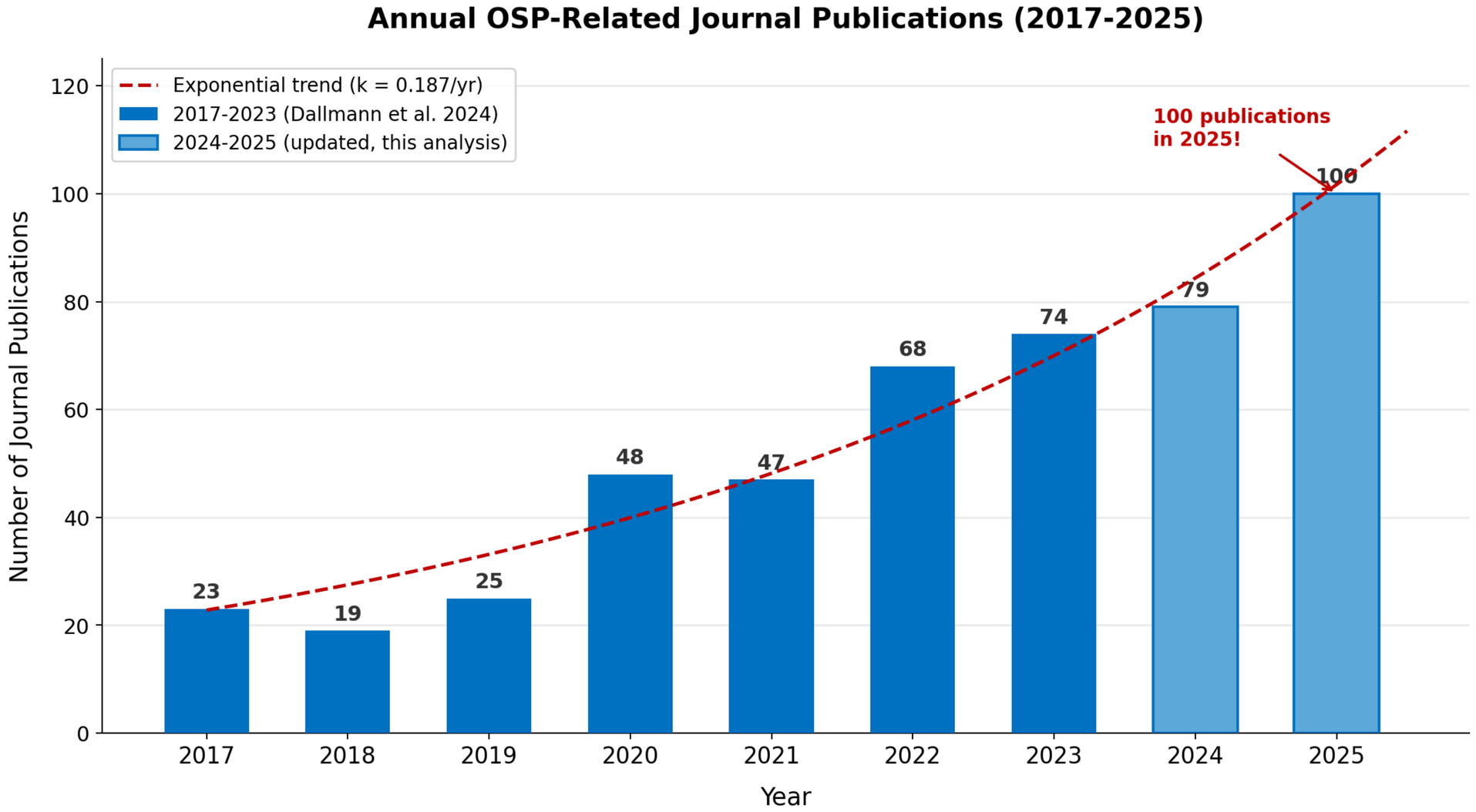
Bronze

METRUM
RESEARCH GROUP

Growth Metrics by OSP Suite Downloads



Growth Metrics by Publications



2017-2023 counts from Dallmann et al. (2024), J Clin Pharmacol. 2024-2025 counts from GitHub OSP database + PubMed search (Sep 2026).