OSP 2026 COMMUNITY CONFERENCE

QUALIFICATION FOCUS GROUP

OSP Community Conference
24 September 2026





AGENDA

01. Background
02. Group members
03. Milestones & deliverables
04. Historical challenges & successes

1. Background and rationale of the focus group

Regulatory expectations are rising

- Increased validation standards
- New ICH guidelines

Growing demand for EMA qualification advice/opinion

- Balance regulatory-grade requirements with existing OSP processes (e.g., (re)qualification framework)

Alignment across OSP community & stakeholders

- Create a shared understanding of priorities, requirements, and expectations

1. Background: a word with two meanings

“Qualification” is used for two different things that should be separated

1 · OSP qualification of models

Harmonisation in qualification plans and the OSP library

- DDI: CYP1A2, CYP2C19, CYP3A4, P-gp, UGT1A1
- Paediatrics / ontogeny: GFR, CYP2C8, CYP3A4, UGT1A1 (in progress)

Where would we like additional qualifications? → obesity, PBBM, pregnancy

2 · Software-specific regulatory qualification

A qualification granted to the platform and specific context of use, not to a single model

- Simcyp: CYP3A4 qualification

Would we like the same for the OSP Suite?

2. Who is on board

A sponsor, a lead and 12 team members from industry, academia and CRO

SPONSOR

Stephan Schaller · OSP MT, ESQlabs

LEAD

Nina Nauwelaerts · ESQlabs
temporarily **Cleo Demeester** · ESQlabs

TEAM MEMBERS

Julia Macente · J&J

Juri Solodenko · Bayer

Donato Teutonico · Sanofi

Ingrid Michon · ESQlabs

Rodolfo Hernandes Bonan · UGhent

Thomas Wendl · Bayer

Ghazal Montaseri · BI

Mariana Guimaraes Sa Correia · ESQlabs

Ioannis Loisios-Konstantinidis · Novartis

Tobias Kanacher · Pharmetheus

Paul Malik · Ionis

Raphaëlle Lesage · ESQlabs

3. From milestones to deliverables

MILESTONES

1. Overview of regulatory pathways (EMA qualification advice/opinion, FDA, …) and requirements
2. Mapping historical challenges and successes with regulatory applications
3. Feasibility assessment on EMA qualification advice/opinion
4. Review of (re)qualification documents for regulatory compliance

DELIVERABLES

1. Documentation of regulatory pathways and requirements in view of OSP qualification
2. White paper on success stories of regulatory applications
3. Feasibility assessment on EMA qualification advice/opinion
4. Gap analysis of requalification documents

3. Where we focus today

MILESTONES

1. Overview of regulatory pathways (EMA qualification advice/opinion, FDA, …) and requirements
2. **Mapping historical challenges and successes with regulatory applications**
3. **Feasibility assessment on EMA qualification advice/opinion — talk by Ingrid Michon in Session 4**
4. Review of (re)qualification documents for regulatory compliance

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1. Documentation of regulatory pathways and requirements in view of OSP qualification
2. White paper on success stories of regulatory applications
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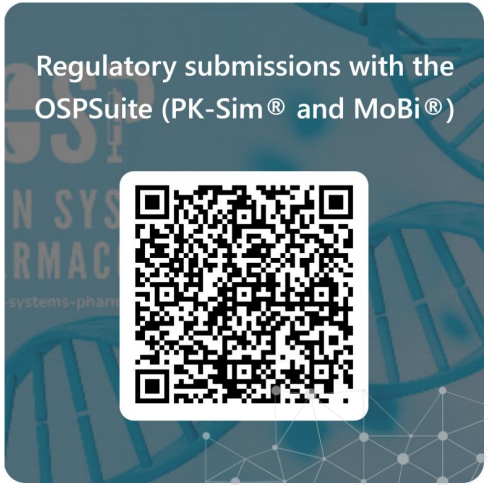
4. Mapping historical challenges and successes from applications

Year	Compound	Brandname	Company	Agency	Tool	Application	Status
2011	Nomegestrol	Zoely	MSD	TGA	PK-Sim	Exposure in adolescent girls	approved
2012	Levonorgestrel IUD	Skyla	Bayer	FDA	PK-Sim® and MoBi® (v4.1 and 2.1)	Exposure in adolescent girls	approved
2013		Skyla		FDA			
2014		Jaydess		TGA			
2014	Riociguat	Adempas	Bayer	TGA	PK-Sim	Pediatric exposure	approved
2014	Vaniprevir	Vanihep	MSD	PMDA	PK-Sim	Exposure in Japanese HCV patients	approved
2018	Levoketoconazole	Recorlev	Strongbridge Dublin Limited	FDA	PK-Sim	BCRP and OATP1B DDI liability	approved; modeling not approved
2018	Amifampridine (3,4-DAP)	RUZURGI	Jacobus Pharmaceutical Company, Inc.	FDA	PK-Sim	Pediatric population	approved
2019	Solifenacin	Vesicare LS	Astellas	FDA	PK-Sim® v5.1	Dosing regimen in pediatrics	approved
2020	Iclepertin	na	Boehringer Ingelheim Pharmaceuticals, Inc.	FDA-EMA-PMDA	PK-Sim version 9	CYP3A4 DDI	partially accepted
2021	Finerenone	Kerendia	Bayer	FDA	PK-Sim V7.4 and 9.1	CYP3A4 DDI liability	approved
2021	Vericiguat	Verquvo	MSD / Bayer	FDA	PK-Sim V7.1 and MoBi V7.1	UGT1A1 DDI liability	approved
2022	Rivaroxaban	Xarelto	Janssen Pharmaceuticals	FDA	PK-Sim Version 4.2	Pediatric exposure	approved
2022	Aponvie	Aprepitant injectable emulsion	Heron Therapeutics, Inc	FDA	PK-Sim (version 9.1)	DDI CYP3A4 liability	approved
2024	Deltamethrin	Deltagard SC Insecticide		Pest Management Regulatory Agency Canada	PK-Sim (version 9)	BBB penetration and absorption, NGRA	approved ("acceptable with limitations")
2024	Zongertinib	HERNEXEOS	Boehringer Ingelheim Pharmaceuticals, Inc.	FDA, PMDA	PK-Sim version 11	CYP3A DDI	partially accepted
2025	Elinzanetant	Lynkuet	Bayer	MHRA / EMA, FDA	PK-Sim	CYP3A4 victim liability	approved
2025	Treosulfan	Grafapex	Medexus Pharmaceuticals	FDA	PK-Sim V8.0	DDI CYP3A4, P-gp and CYP2C19	approved; modeling not approved
2021 & 2026	Survodutide	na	Boehringer Ingelheim Pharmaceuticals, Inc.	FDA-EMA-PMDA	PK-Sim version 11	DDI	partially accepted
na	Sonlicromanol	na	Khondrion	EMA	PK-Sim version 9.1	First in pediatric dosing	ongoing (POC trial ongoing)

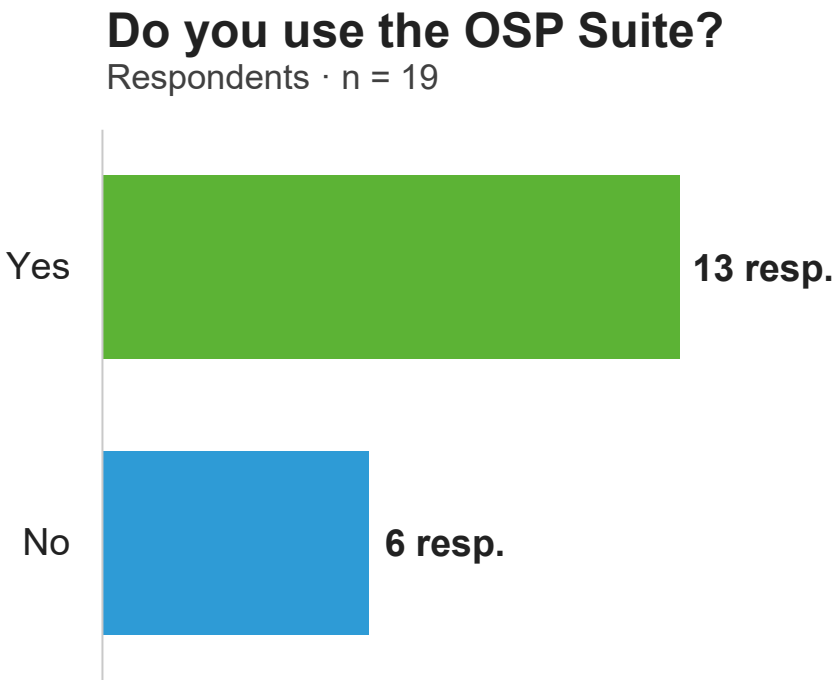
4. Mapping historical challenges and successes with regulatory applications

- Survey for submission stories from the community
- Gather opinions on the software and qualification





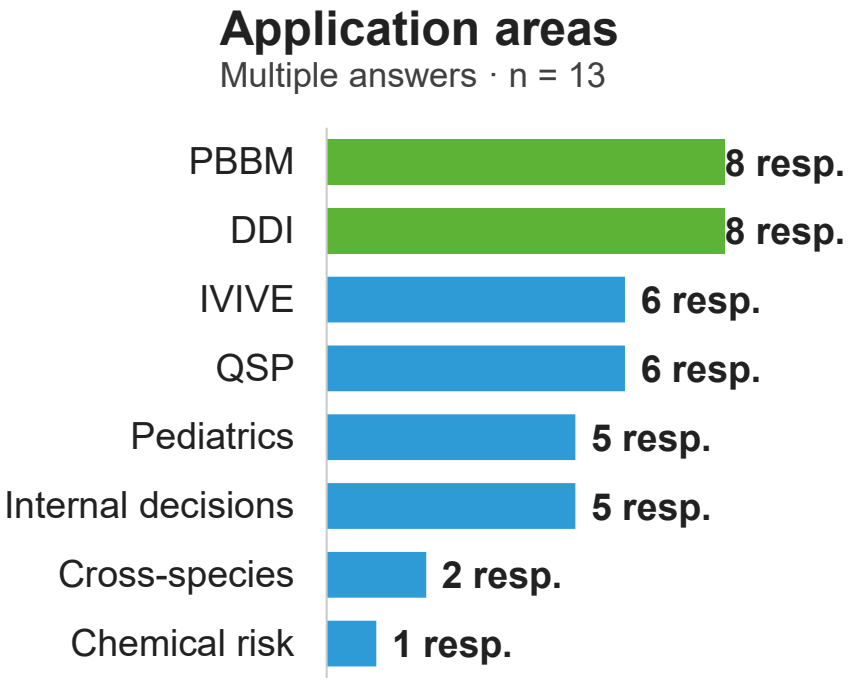
4. Preliminary Survey Results: Who responded and who uses OSP

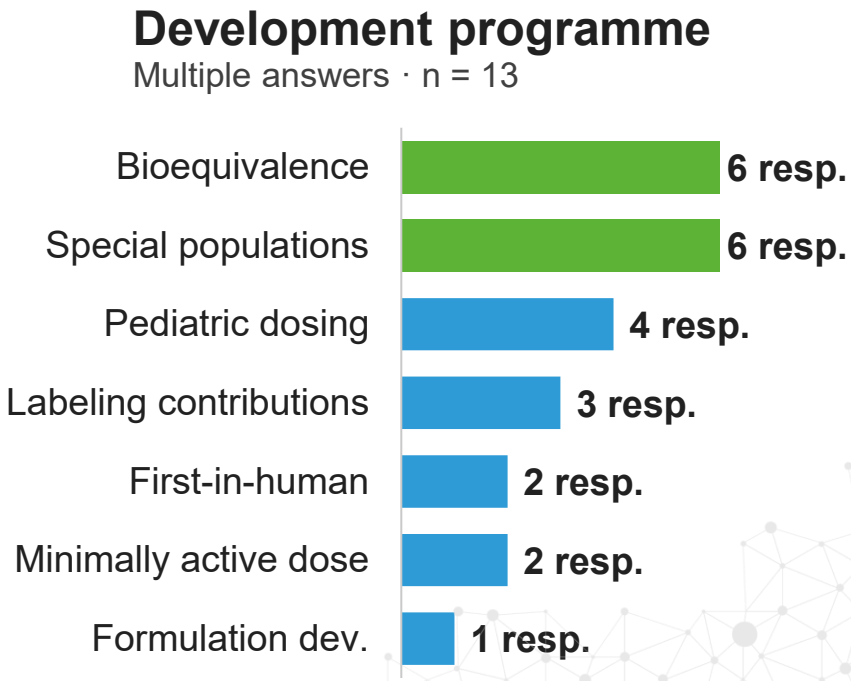


Main reasons for not using OSP (n = 6)

- **Not started yet** — intends to try it this year (UCL)
- **No PBPK work yet** — Singapore
- **No use case so far** — Leiden University
- **Never heard of it** — Uppsala University
- **Outside my domain** — J&J
- **Established on other software** — Univ. of Cape Town, Pharmacometrics

4. Preliminary Survey Results: Where and for what OSP is used



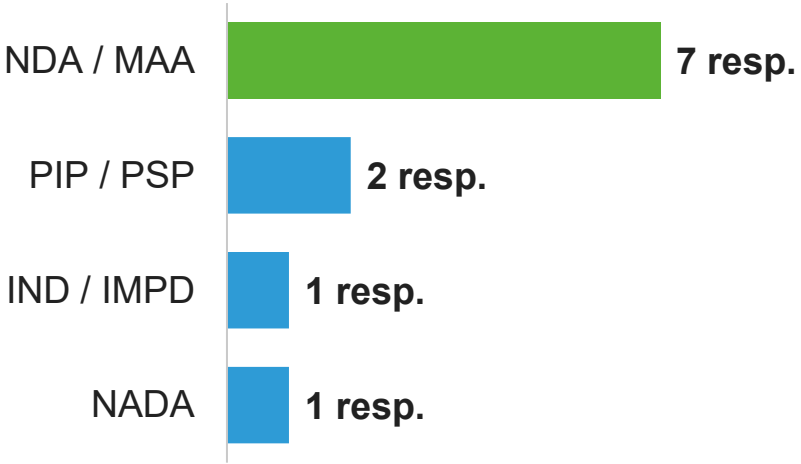


4. Preliminary Survey Results: Submission experience and feedback

7 of 13 OSP users included the work in a regulatory submission

Submission types

Multiple answers · n = 7 submissions



Feedback received

- Positive - study waivers accepted in all three cases (Finerenone, Vericiguat, Elinzanetant)
- Positive, but did not replace a clinical study
- One submission still under review

→ OSP is acceptable for regulatory use!

→ How did you experience submissions with OSP?

4. Preliminary Survey Results: Challenges reported

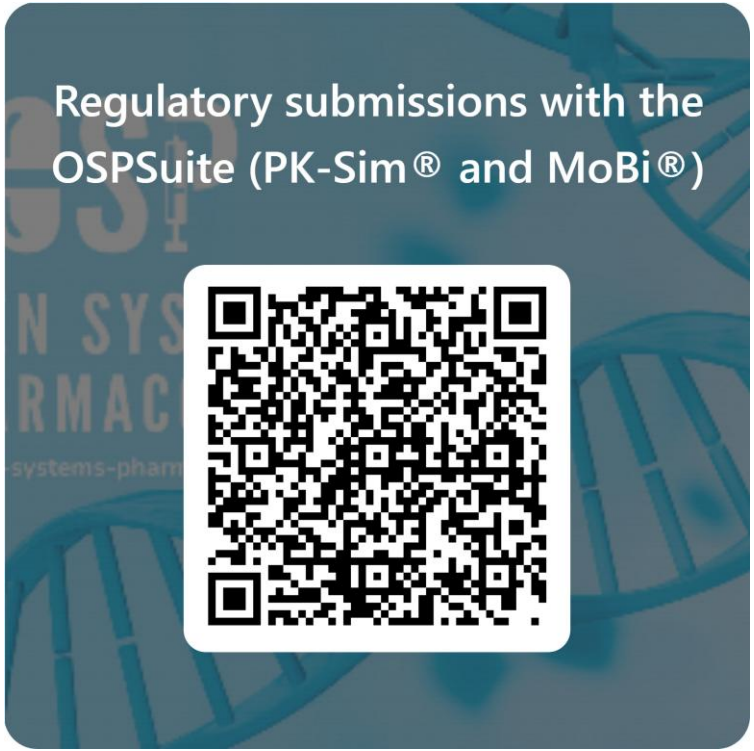
Challenges reported

- Proving qualification / validation of the platform (2 respondents)
  → Would EMA qualification help? And is this feasible? → Presentation tomorrow Session 4
- Justifying parameters used in parameter identification and default values
  → General science challenge
- Regulator questions framed from a Simcyp perspective — hard to answer given OSP's different model structure and parameterisation
  → Gather examples

4. Survey will be extended with questions

- What comments or questions have you received on the modelling part of your submissions (e.g. verification, sensitivity analysis)?
- Did those comments mainly concern:
    - Multiple choice: CoU definition, model risk assessment, model development and structure, verification, validation and applicability, uncertainty quantification, reporting and documentation
- Would qualification of the platform by a regulatory body such as the EMA help your submission?
- If so, for which context of use (CoU) should it be qualified?
    - Multiple choice across the different CoUs
- Would you place more value on formal regulatory qualification of the software for a specific context of use, or do you consider scientific qualification/validation for that context of use by the community to be sufficient on its own?

Help gather the stories and opinions!



THANK YOU



Photo: Grote Markt, Antwerp, Belgium

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