Scientific Programming Submission Application — SAMPLE (Symposium)

Submitter: Dr. Jane Smith

Organization: Modeling & Simulation Sciences, Inc.

Email of Submitter: jane.smith@modelsim.com

ISoP Membership: Member

Type: Symposium – 3 Speakers

Area: QSP/PBPK

Title of Submission: Integrating QSP and PBPK Modeling to Enhance Decision-Making in Oncology Drug Development

Session Description (250 words max):

Quantitative Systems Pharmacology (QSP) and Physiologically Based Pharmacokinetic (PBPK) modeling have emerged as powerful complementary tools to accelerate and refine decision-making in oncology drug development. This proposed symposium will explore innovative approaches for integrating QSP and PBPK methodologies across preclinical and clinical stages, highlighting real-world case studies and lessons learned from cross-disciplinary collaborations.

Speakers will discuss applications of mechanistic modeling to predict dose-response relationships, optimize combination therapies, and evaluate inter-patient variability in tumor response. Emphasis will be placed on the translational value of integrating systems-level insights with pharmacokinetic data to support regulatory submissions and clinical trial design. The session aims to promote cross-functional dialogue among pharmacometricians, clinical pharmacologists, and computational biologists, advancing best practices for model-informed oncology development.

Chair: Jane Smith, PhD, Pfizer, jsmith@pfizer.com

ISoP Membership: Member

Co-Chair: Alan Lee, PhD, Certara, alee@certara.org

ISoP Membership: Member

Budget Request: Travel support for one academic panelist.

Additional A/V Needs: Audio capability for video playback and Polling (ARS)

Speaker 1: Dr. Sarah Kim, OncoLogic Therapeutics, skim@abc.org

ISoP Membership: Member

Presentation: Bridging QSP and PBPK for Translational Oncology Modeling

Summary (background and scientific imp/ortance): Integration of mechanistic QSP models with PBPK simulations to guide dose selection and predict DDIs.

Learning Objectives: Upon completion, participant will be able to

- Understand the goals of automated structural model building and recognize the trade-offs involved in algorithmic model building approaches
- Identify which algorithms perform best in specific scenarios based on empirical comparisons,
- Learn how the new tool can navigate search spaces of different sizes to find optimal models,
- Evaluate how this approach can streamline workflows and enhance model-building outcomes.

Speaker 2: Dr. Michael Tan, University of Basel, tan@abc.org

ISoP Membership: Non-Member

Presentation: Applying PBPK Modeling to Predict Immunotherapy Pharmacokinetics

Summary: Examples of PBPK applications for checkpoint inhibitors with emphasis on model verification.

Learning Objectives: Upon completion, participant will be able to:

- Understand the fundamentals of Variational Inference Expectation Maximization (VIEM) and its application to nonlinear mixed effect (NLME) models.
- Learn the differences between VIEM and other algorithms such as Laplace, First Order Conditional Estimation (FOCE), and Stochastic Approximation Expectation Maximization (SAEM).
- Gain insights into the computational advantages of using VIEM over traditional methods

Speaker 3: Dr. Priya Natarajan, AstraZeneca, pnatarajan@az.org

ISoP Membership: Member

Presentation: Integrating Real-World Data into QSP Frameworks for Oncology

Summary: Strategies for leveraging RWD to calibrate and validate QSP models.

Learning Objectives: Upon completion, participant will be able to

- Understand the similarities and differences among existing PBPK guidelines, and how PBPK analyses were evaluated in NDAs and MAAs.

Includes Panel Discussion: Yes

Intent of Panel Discussion:

This panel will explore real-world challenges in implementing QSP and PBPK modeling strategies within global drug development programs. Pre-selected discussion topics will include:

How can QSP-PBPK integration improve confidence in first-in-human dose selection?

What are best practices for communicating mechanistic modeling insights to regulatory agencies?

How can cross-disciplinary collaboration accelerate model-informed decision-making?

Symposium Schedule:

1st Presentation – 15-minute presentation with 5-minute Q&A
Bridging QSP and PBPK for Translational Oncology Modeling - Dr. Sarah Kim

2nd Presentation - 15-minute presentation with 5-minute Q&A
Applying PBPK Modeling to Predict Immunotherapy Pharmacokinetics - Dr. Michael Tan

3rd Presentation - 15-minute presentation with 5-minute Q&A
Integrating Real-World Data into QSP Frameworks for Oncology - Dr. Priya Natarajan

Panel Discussion – The discussion will last 20 minutes, followed by 10 minutes for audience Q&A., Dr.'s Kim, Tan and Natarajan

Expected Attendance: 200–250 attendees

Scientific Programming Submission Application — SAMPLE (Tutorial)

Submitter: Dr. Alex Green

Organization: Pharmacometrics Learning Institute

Email of Submitter: alex.green@pli.org

ISoP Membership: Member

Type: Tutorial

Area: Stats/AI/ ML

Title of Submission: Building Reproducible Workflows for Pharmacometrics Using R and GitHub

Session Description (250 words max):

This hands-on tutorial introduces reproducible workflow management for pharmacometric analyses using R and GitHub. Attendees will learn how to structure modeling projects, version-control their code, and collaborate effectively across teams. The session emphasizes transparency, traceability, and reproducibility of pharmacometric modeling pipelines, promoting open science principles within the community.

Participants will gain practical skills through guided exercises, including R project setup, GitHub repository management, and workflow automation using R Markdown and GitHub Actions. Example workflows for population PK/PD models will demonstrate integration of reproducibility principles into daily practice. The session is ideal for students, early-career pharmacometricians, and practitioners seeking to modernize their workflow management.

Lead Instructor: Dr. Alex Green, Pharmacometrics Learning Institute, alex.green@pli.org

ISoP Membership: Member

Budget Request: None.

Additional A/V Needs: projection capability for live coding demonstration

Instructor Summaries:

Instructor 1: Alex Green, PhD, Pharmacometrics Learning Institute, alex.green@pli.org

Presentation: Introduction to Reproducibility and Version Control

Summary: Overview of version control, project setup, and the foundations of reproducibility in pharmacometric modeling.

Learning Objectives: Upon completion, participant will be able to

•Understand the goals of automated structural model building and recognize the trade-offs involved in algorithmic model building approaches

•Identify which algorithms perform best in specific scenarios based on empirical comparisons,

•Learn how the new tool can navigate search spaces of different sizes to find optimal models,

•Evaluate how this approach can streamline workflows and enhance model-building outcomes.

Instructor 2: Lila Patel, PhD, ABC Company, lpatel@abc.org

Presentation: Structuring Pharmacometrics Projects for Collaboration

Summary: Demonstration of structured project design to improve collaboration across multi-site teams.

Learning Objectives: Upon completion, participant will be able to

•Understand the fundamentals of Variational Inference Expectation Maximization (VIEM) and its application to nonlinear mixed effect (NLME) models.

•Learn the differences between VIEM and other algorithms such as Laplace, First Order Conditional Estimation (FOCE), and Stochastic Approximation Expectation Maximization (SAEM).

•Gain insights into the computational advantages of using VIEM over traditional methods

Instructor 3: Tom Chen, XYZ Company, tchen@xyz.org

Presentation: Implementing Continuous Integration in Modeling Workflows

Summary: Application of R Markdown and GitHub Actions for automated reporting and workflow testing.

Learning Objectives: Upon completion, participant will be able to

•Understand the similarities and differences among existing PBPK guidelines, and how PBPK analyses were evaluated in NDAs and MAAs.

Instructor 4: Jane Doe, HIJ Company, jdoe@HIJ.com

Presentation: Implementing Continuous Integration in Modeling Workflows

Summary: Application of R Markdown and GitHub Actions for automated reporting and workflow testing.

Learning Objectives: Upon completion, participant will be able to

- Understand the fundamentals of Variational Inference Expectation Maximization (VIEM) and its application to nonlinear mixed effect (NLME) models.
- Learn the differences between VIEM and other algorithms such as Laplace, First Order Conditional Estimation (FOCE), and Stochastic Approximation Expectation Maximization (SAEM).

Tutorial Schedule:

1st Session – 40-minute lecture with 10-minute Q&A

Introduction to Reproducibility and Version Control – Dr. Alex Green

2nd Session – 40-minute interactive workshop with 10-minute Q&A

Structuring Pharmacometrics Projects for Collaboration – Dr. Lila Patel

3rd Session – 40-minute hands-on session with 10-minute Q&A

Implementing Continuous Integration in Modeling Workflows – Tom Chen

4th Session – 40-minute hands-on session with 10-minute Q&A

Implementing Continuous Integration in Modeling Workflows – Jane Doe

Expected Attendance: 75–100 attendees

Scientific Programming Submission Application — SAMPLE (Individual)

Submitter: Dr. Alex Green

Organization: Pharmacometrics Learning Institute

Email of Submitter: alex.green@pli.org

ISoP Membership: Member

Type: Individual

Area: Big Data/ AI/ ML/ Data Programming

Title of Submission: Building Reproducible Workflows for Pharmacometrics Using R and GitHub

Session Description (250 words max):

This hands-on tutorial introduces reproducible workflow management for pharmacometric analyses using R and GitHub. Attendees will learn how to structure modeling projects, version-control their code, and collaborate effectively across teams. The session emphasizes transparency, traceability, and reproducibility of pharmacometric modeling pipelines, promoting open science principles within the community.

Participants will gain practical skills through guided exercises, including R project setup, GitHub repository management, and workflow automation using R Markdown and GitHub Actions. Example workflows for population PK/PD models will demonstrate integration of reproducibility principles into daily practice. The session is ideal for students, early-career pharmacometricians, and practitioners seeking to modernize their workflow management.

Speaker: Dr. Alex Green, Director, Pharmacometrics Learning Institute, alex.green@pli.org

ISoP Membership: Member

Budget Request: None.

Additional A/V Needs: projection capability for live coding demonstration

Learning Objectives: Upon completion, participant will be able to

- Understand the goals of automated structural model building and recognize the trade-offs involved in algorithmic model building approaches
- Identify which algorithms perform best in specific scenarios based on empirical comparisons,
- Learn how the new tool can navigate search spaces of different sizes to find optimal models,