

SxP 

Statistics & Pharmacometrics

ISOP | **ASA** 

SPECIAL INTEREST GROUP

SxP SIG membership meeting

Co-chairs: Luke Fostvedt, Stacey Tannenbaum

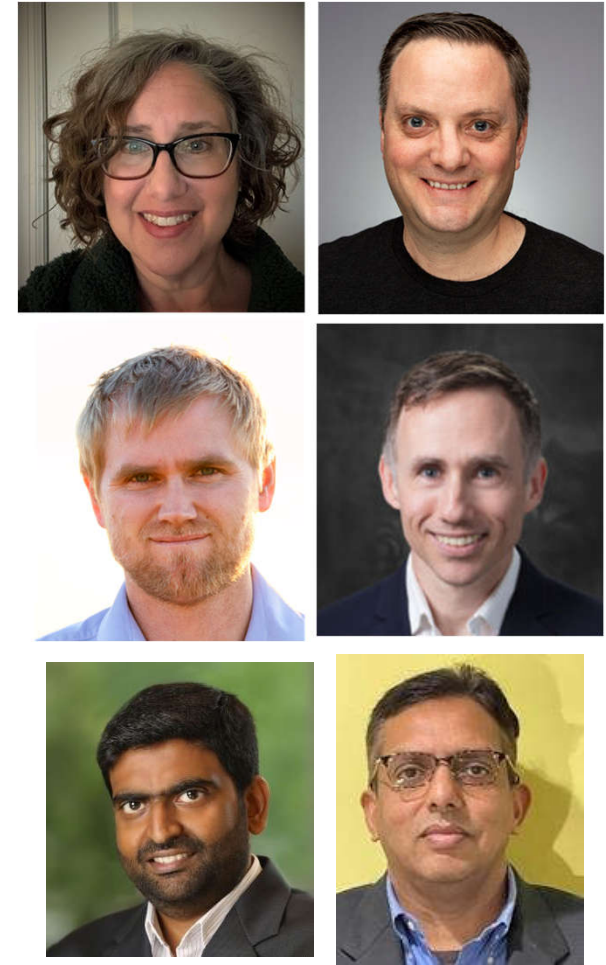


Agenda

- Welcome – Luke
- Leadership and Steering Committee – Stacey
- Communications Committee – Pavan Vaddady
- Education Committee – Ram Goteti
- MBMA SubSIG – Phyllis Chan
- PKPD Programming Forum- Stacey
- SxP SIG Trainee Award presentation – Lucie Fayette
- Open discussion – Luke and Stacey

SxP Leadership - for now!

- Luke Fostvedt – Statistics Co-chair
- Stacey Tannenbaum - PMX Co-chair
- Tim Waterhouse- PMX Co-chair Elect
- Mike Smith- Statistics past Co-chair
- Pavan Vaddady – Communications Committee chair
- Ram Goteti - Education Committee chair



SxP Leadership to be!

- Luke Fostvedt – Statistics Co-chair
- Tim Waterhouse- PMX Co-chair
- Stacey Tannenbaum - PMX past Co-chair
- ??? – Statistics Co-chair Elect
- Pavan Vaddady – Communications Committee chair
- Ram Goteti - Education Committee chair



Thank you, Mike!!

**Coming soon: Steering
Committee Refresh!**



SxP SIG Communication Committee

Pavan Vaddady



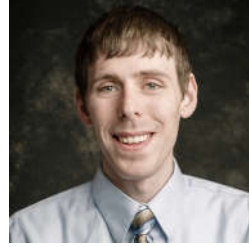
Team



Julie Bertrand



Erin Dombrowsky



Curtis Johnston



Siv Jonsson



Pavan Vaddady



Tim Waterhouse

Special thanks to
Teresa Belmont
from ISoP and **LT**
members for their
input and help!



Luke Fostvedt



Ram Goteti



Stacey Tannenbaum

New SxP Website!



<https://sxpsig.github.io>



A vertical screenshot of the website's navigation menu. At the top is the SxP logo with the text 'Statistics & Pharmacometrics' and 'ISOP | ASA | SPECIAL INTEREST GROUP'. Below the logo is a search bar. The navigation menu consists of the following items: 'Home' (highlighted in green), 'Join', 'About', 'Charter', 'Leadership' (with a right-pointing chevron), 'Subgroups' (with a right-pointing chevron), 'Events' (with a right-pointing chevron), 'Education' (with a right-pointing chevron), 'Links', and 'Contact Us'.

Home



Welcome!

The Statistics and Pharmacometrics Special Interest Group (SxP) was named in 2016 and is chartered by both the American Statistical Association and International Society of Pharmacometrics. This Special Interest Group promotes collaboration between Statisticians and Pharmacometricians, to enable each discipline to learn and grow from the other and to develop innovative approaches to model informed drug development.

Specifically, the goals of the SxP SIG are to:

- Provide educational opportunities to learn about Statistics and Pharmacometrics
- Encourage career growth and mentoring for people new in the field
- Promote cross-disciplinary methodology research and publications, and to encourage cross participation at conferences
- Create best practices leveraging both disciplines
- Provide opportunities to discuss computing platforms and share code

Join →

Join us!

Join the SxP mailing list by signing up on the website - even if you are already a member

Questions or comments about SxP?

Contact us at our new email address: sxp.sig@gmail.com



A screenshot of the SxP website's navigation menu. At the top is the SxP logo with the text 'Statistics & Pharmacometrics' and 'ISOP | ASA | SPECIAL INTEREST GROUP'. Below the logo is a search bar. The navigation menu includes links for Home, Join (highlighted in green), About, Charter, Leadership, Subgroups, Events, Education, Links, and Contact Us. Each link has a right-pointing chevron symbol.

Join

Join SxP SIG

Sign up as an SxP member for educational content, learning about upcoming events and networking!

I work as a

By subscribing to SxP SIG, you agree that your information will be held by the SxP SIG in its member directory unless otherwise specified and will be utilized to keep you informed. This information will not be provided in any form to any third parties. You can unsubscribe any time, if you wish so.

 I'm not a robot reCAPTCHA
Privacy - Terms

Subscribe

SxP SIG Education Committee

Ram Goteti



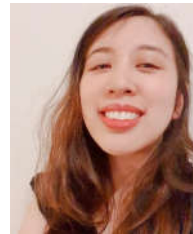
Membership



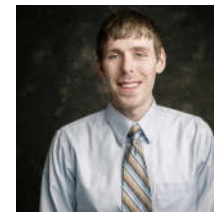
Kosalaram (Ram) Goteti
(Education Committee Chair)



Alice Zong



Camille Vong



Curtis Johnston
Also communication committee member



Jessica Barry
(Student Representative)



Julie Bertrand
Also communication committee member



Marion Bouillon-Pichault



Susan Willavize



Luke Fostvedt
(Stats Co-Chair)



Pavan Vaddady
(Communications Chair)



Stacey Tannenbaum
(PMx Co-Chair)

Website & Content

Website: <https://sxpsig.github.io/>

← → ↻ 🏠 🔒 <https://sxpsig.github.io/leadership/educationcommittee.html>

Charter
Leadership >
 Steering Committee
 Sub-Committees <
 Communications
 Education
Subgroups >
Events >
 Education
 Stats for PMx
 PMx for Stats
 Regulatory
 Guidances
 Conference Content
 Student Resources
Links
Contact Us

Chair:

- Kosalaram (Ram) Goteti

Members:

- Alice Zong
- Camille Vong
- Curtis Johnston
- Jessica Barry
- Julie Bertrand
- Marion Bouillon-Pichault
- Susan Willavize

← Communications

Content

Education >

Stats for PMx

Logistic Regression, Time to Event, Bayesian Statistics, etc

PMx for Stats

Compartmental modeling, PBPK, QSP, NONMEM, etc

Regulatory

Guidances

FDA, EMEA guidances

Conference Content

ACOP, PAGE, WCOP, etc

Student Resources

Academic websites, educational content for students, etc

Next Year Remit & Upcoming Events

- Continue to build the Educational content sub-section
- Webinar's
 - PMx & Estimands
 - PMx & Causality
- Variability and Uncertainty



Please send your questions, comments and feedback to: webinar@rosaandco.com

How To Join The Webinar

Wed, Nov 16, 2022 12:00 PM - 1:00 PM EST

Thank you for registering for "Variability and uncertainty: interpretation and usage of pharmacometric simulations and intervals".

Chuanpu Hu, PhD. Senior Scientific Director and Fellow
Janssen R&D, LLC

MBMA SubSIG

Phyllis Chan



Phyllis Chan
MBMA subSIG Co-Chair



Monica Simeoni
MBMA subSIG Co-Chair

Our Mission and Goals

To promote model-based meta-analysis and its application in drug development, to raise awareness and interest, and to support the education of others in MBMA.

1. Raising awareness and building a community of practice
2. Identifying training opportunities for MBMA
3. Establishing best practices in MBMA
4. Broadening the scope of MBMA beyond PMx/Statistics

The Team

The SubSIG is composed of:

- **a core team:** eleven members from pharmaceutical companies, consulting companies, and regulatory agencies - responsible for the achievement of the SubSIG workstream goals.
- **an advisory team:** senior members from pharmaceutical and consulting companies - provides strategic support and leadership.

Chairs

Phyllis Chan [Genentech] and Monica Simeoni [GSK]

Core Team

Marion Bouillon-Pichault [BMS]

Matt Zierhut [Certara]

Chandni R. Valiathan [Janssen]

Clemence Rigaux [Sanofi]

Jian Zhou [BMS]

Junshan Qiu [FDA]

Li Qin [Certara]

Rana Jreich [Sanofi]

Yaming Hang [Takeda]

Advisory Team

Jonathan French [Metrum]

Jaap Mandema [Certara]

Jose Pinheiro [Janssen]

Jeff Sachs [Merck]

Bernard Sebastien [Sanofi]

Kevin Sweeney [Pfizer]

Recent Activities

- **Advance on the various workstream activities**
 - regular team meetings to plan for upcoming activities
 - creation of LinkedIn groups to advertise the group more broadly
 - design of a template for LinkedIn posts to illustrate case studies
 - collate material for a repository of impactful MBMA examples
- **Raise awareness and promote MBMA**
 - organizing educational sessions – e.g. “Introduction to MBMA” 26 January 2021, “How to deal with missing values in MBMA” 18 May 2022
 - advocate for MBMA approaches at conferences (PAGE, ASCPT, ACoP) – e.g. a [poster about the SubSIG activities](#) was presented at PAGE 2022.

PKPD Programming Forum

Overview

The PK/PD Programming Forum promotes discussions related to the handling of data and supportive programming for Pharmacokinetic (PK) and Pharmacokinetic/Pharmacodynamic (PK/PD) or Pharmacometric analyses

. **Objectives:**

- Establish a community for pharmacometric and pharmacokinetic programmers across industry and academics
- Collect and share best practices, challenges and examples for programmers to support pharmacometric and PK analysis

Membership and Contact

Current members:

- Li, Xiaobin
- Patel, Samarth
- Radtke, David B
- Su, Jing (co-founder & co-chair)
- Thanneer, Neelima (co-founder & co-chair)
- Vadhavkar, Shweta
- Zong, Alice

pkpd0pgm0forum@gmail.com

jing_su@merck.com

neelima.thanneer@bms.com

CDISC ADaM Population PK Data Standard Working Group

- Working group goal: make the [ISoP PPK Data Standard](#) CDISC ADaM compliant
 - Consists of members from across the industry: CDISC experts, Programmers and Pharmacometricians
 - Co-led by Neelima Thanneer and Luke Reinbolt
- CDISC ADaM compliance:
 - Brings much-needed standards for PPK datasets
 - Recognizes ADPPK globally as a standard ADaM dataset.
 - Minimizes the variations of how PPK datasets are prepared across the industry
 - Improves quality and efficiency
- [ADaM popPK Implementation Guide v1.0](#) is now open for public review
 - **Please review and comment!!**
 - The working group will address comments from public review and gear for publishing ADPPK standard next year

<https://link.springer.com/article/10.1007/s10928-018-9595-8>

You Tube playlist for webinars

<https://youtube.com/playlist?list=PLJEUID4Y7xnn5T4mCCCKXv1ofIY8D2G6v>

The screenshot shows a YouTube playlist page for the 'PKPD Programming Forum'. The page features a search bar at the top, a navigation menu on the left, and a main content area with video thumbnails and titles. The first video, 'Update on CDISC ADaM Population PK Data Standard ADPPK', is highlighted with a red border. The second video is 'Review of proposed NCA ADAM standard', and the third is 'ADA/Immunogenicity Data Handling'. The channel name 'International Society of Pharmacometrics (ISOP)' is visible at the bottom left, along with a 'SUBSCRIBE' button.

YouTube

Search

Home

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Library

ASAP, Statistics and Pharmacometrics Interest Group (SxP) ISOP

Analysis Data for Population Pharmacokinetic Analysis

ADPPK

PLAY ALL

PKPD Programming Forum

3 videos • 9 views • Last updated on Jun 10, 2022

International Society of Pharmacometrics (ISOP)

SUBSCRIBE

- 1 Update on CDISC ADaM Population PK Data Standard ADPPK
International Society of Pharmacometrics (ISOP)
48:46
- 2 Review of proposed NCA ADAM standard
International Society of Pharmacometrics (ISOP)
49:37
- 3 ADA/Immunogenicity Data Handling
International Society of Pharmacometrics (ISOP)
51:52



SxP Trainee Award Presentation

*Pharmacometrics Enhanced
Bayesian Borrowing
Lucie Fayette*



Let's talk!

Opportunities to get involved – volunteer for the SIG!

- Join the Steering Committee
- Join a subSIG (MBMA, PKPD programming)
- Join a committee (Communications, Education)
- Host a webinar or help to identify speakers and topics

Interactions with ASA, other SIGs

How can we support trainees?

What do you want from SxP?

THANKS FOR COMING!

sxp.sig@gmail.com

<https://sxpsig.github.io/>



SxP LT will be at the ISoP booth in the exhibit hall today from 3:30-4:30. Stop by to chat with us about your ideas for SxP!