Statistics & Pharmacometrics

ISoP | ASA

SPECIAL INTEREST GROUP

SxP SIG membership meeting

Co-chairs: Luke Fostvedt, Stacey Tannenbaum

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ACoP 13
AMERICAN CONFERENCE ON PHARMACOMETRICS

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

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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

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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!

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SxP SIG Communication Committee

Pavan Vaddady

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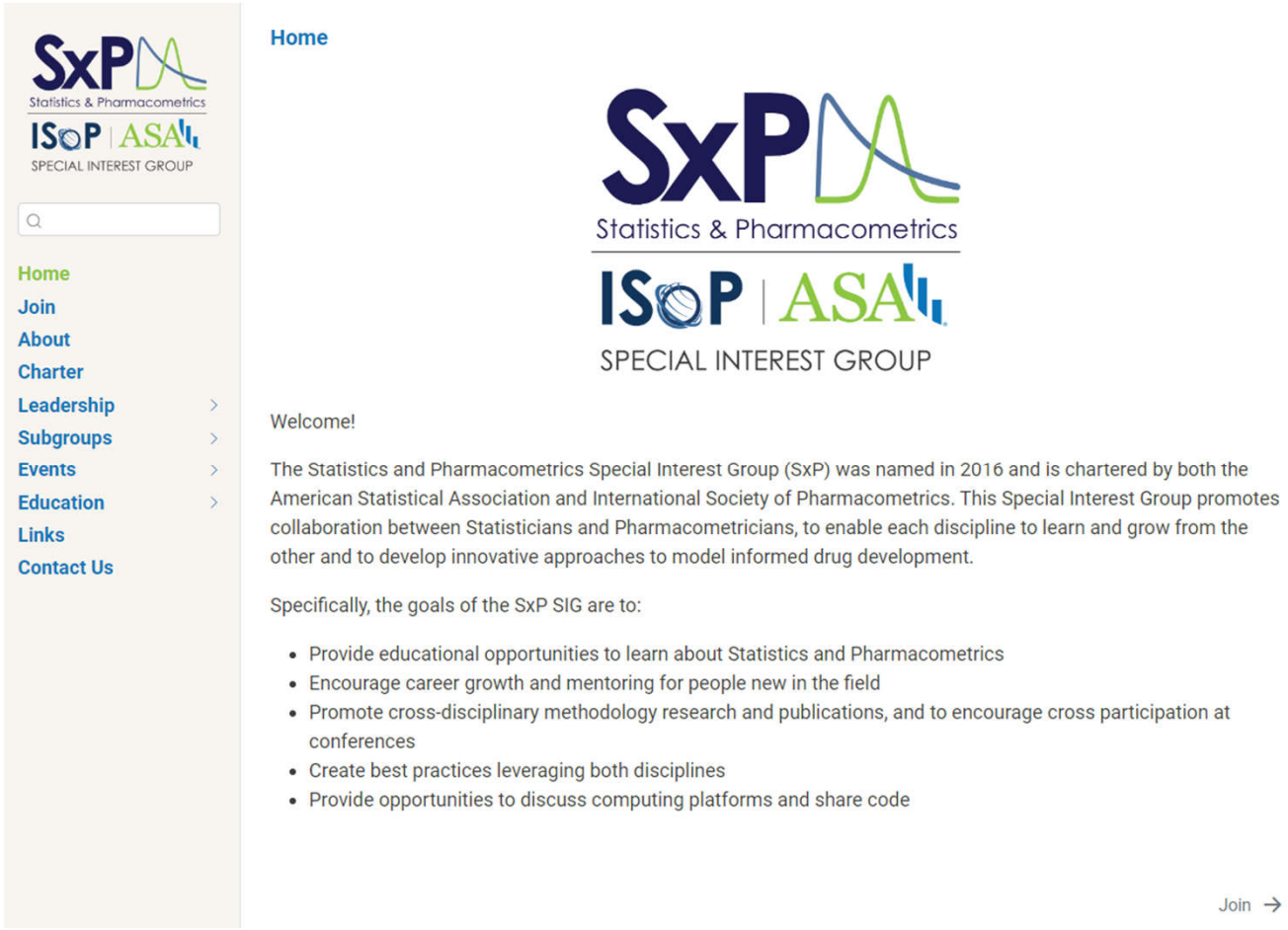
Team

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



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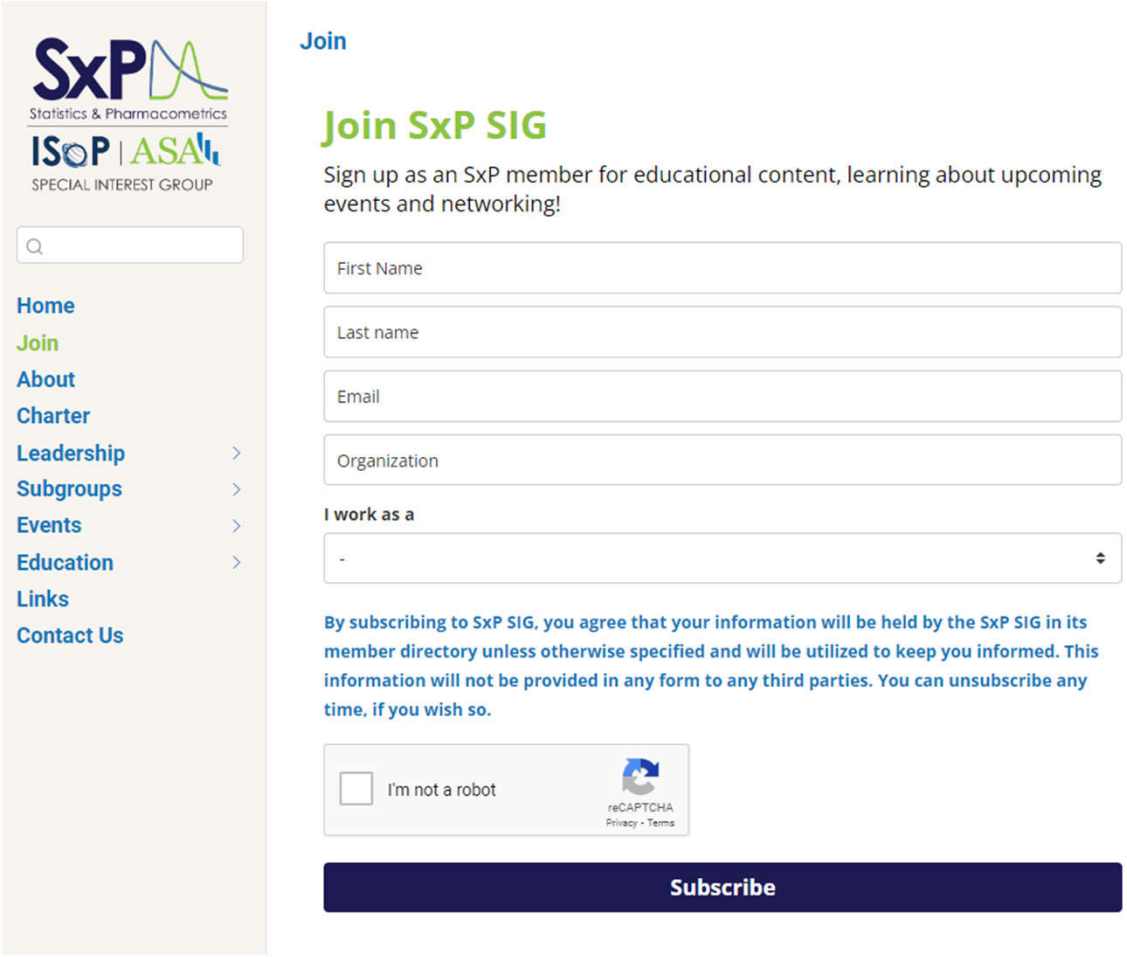
Join us!

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



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SxP SIG Education Committee

Ram Goteti

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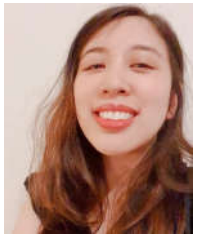
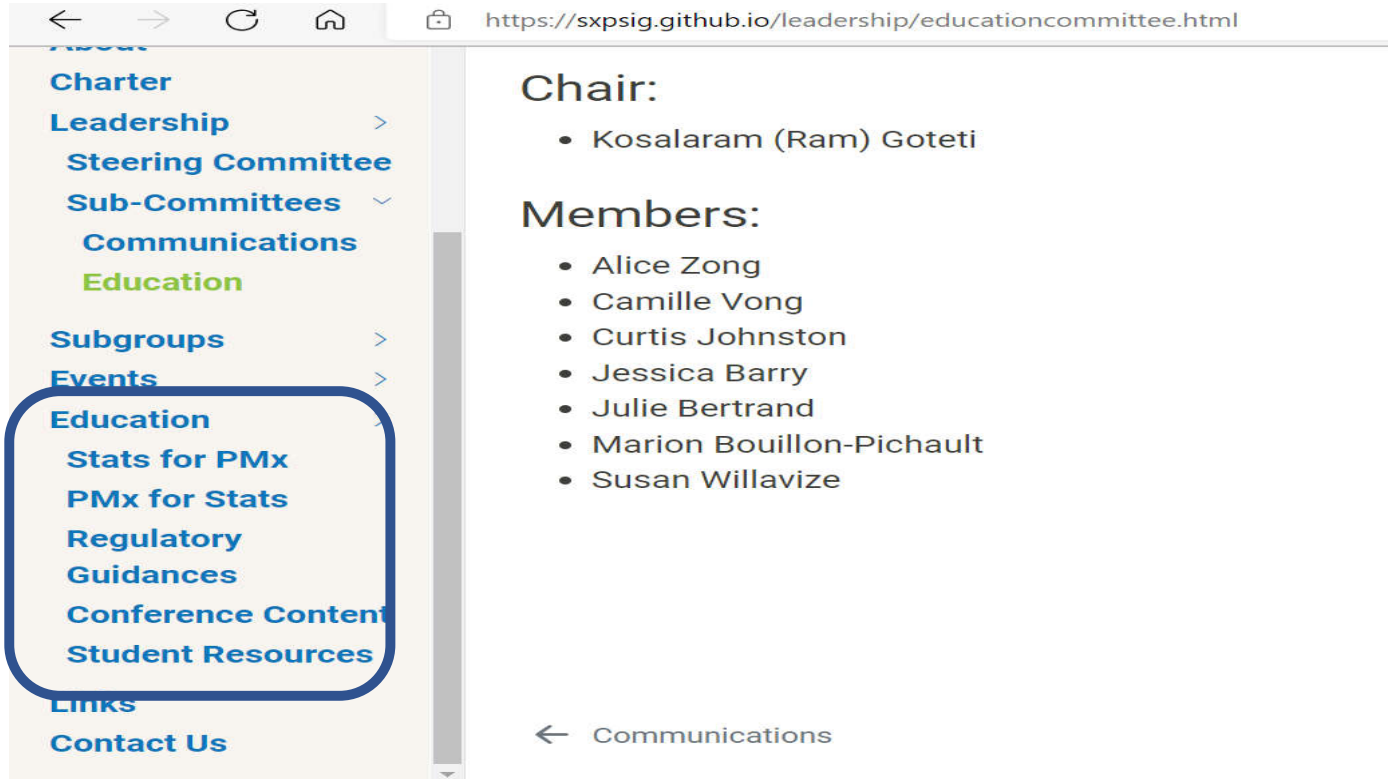
Membership

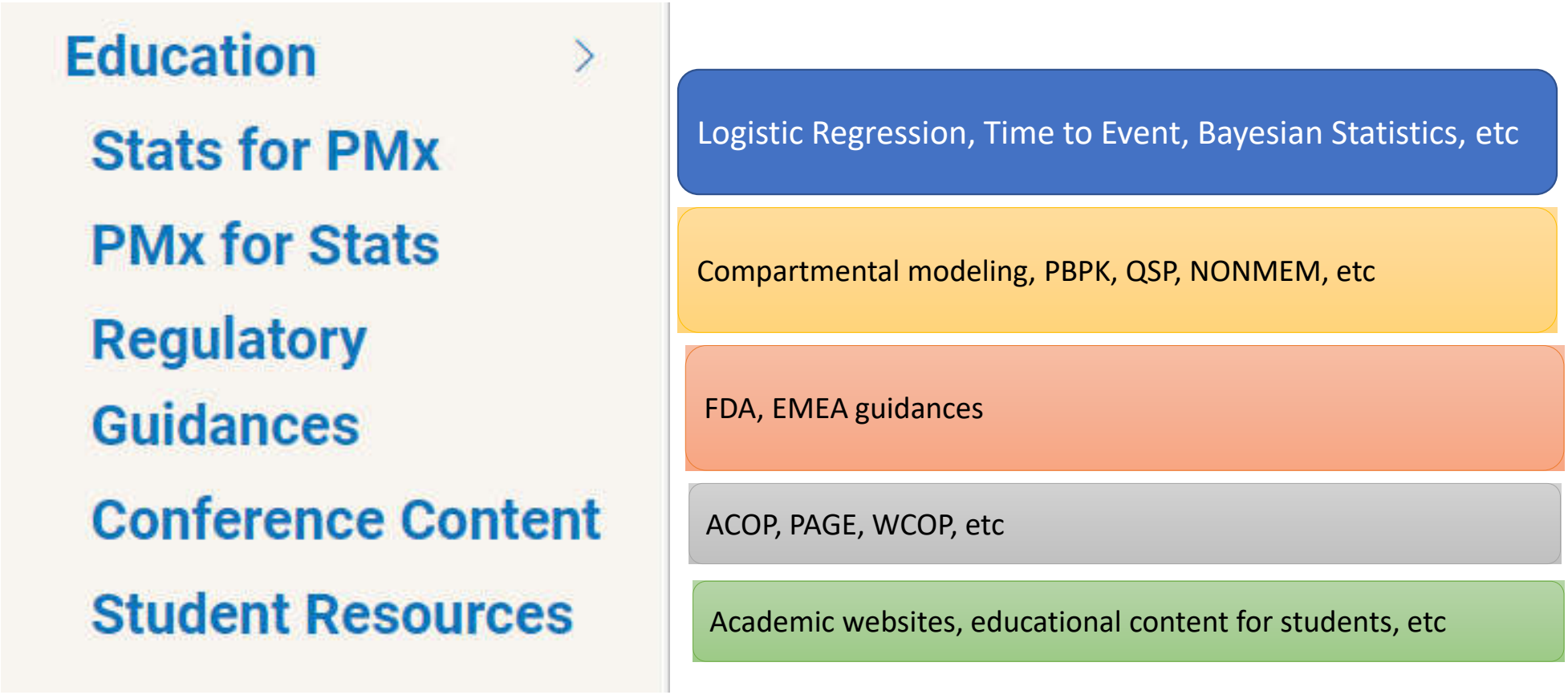
Kosalaram (Ram) Goteti (Education Committee Chair)	**Alice Zong**	 **Camille Vong**	**Curtis Johnston** Also communication committee member
Jessica Barry (Student Representative)	**Julie Bertrand** Also communication committee member	**Marion Bouillon-Pichault**	**Susan Willavize**
Luke Fostvedt (Stats Co-Chair)	**Pavan Vaddady (Communications Chair)**	**Stacey Tannenbaum (PMx Co-Chair)**	

Website & Content

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



Content


Education
Stats for PMx
PMx for Stats
Regulatory
Guidances
Conference Content
Student Resources
Logistic Regression, Time to Event, Bayesian Statistics, etc
Compartmental modeling, PBPK, QSP, NONMEM, etc
FDA, EMEA guidances
ACOP, PAGE, WCOP, etc
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

ROSA

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

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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

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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

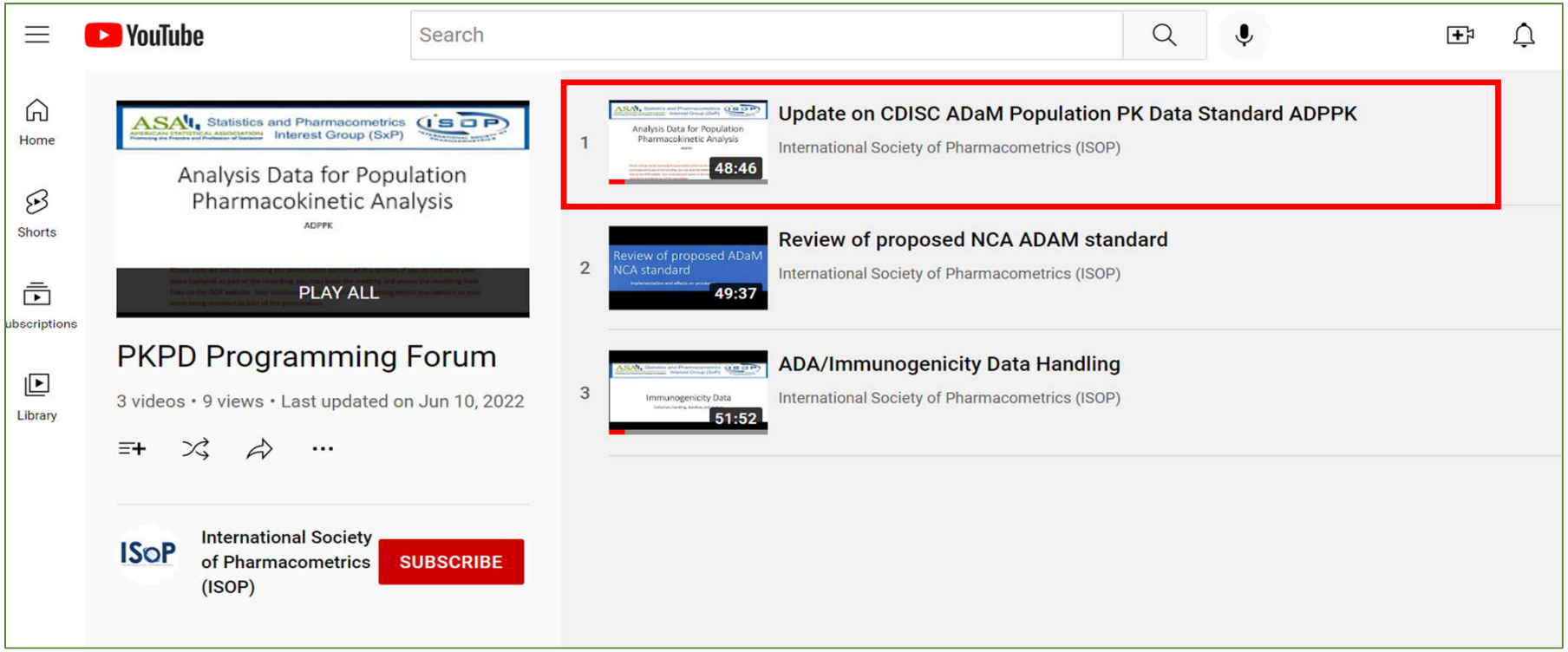
CDISC ADaM Population PK Data Standard Working Group

- 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=PLJEUlD4Y7xnn5T4mCCCKXv1ofIY8D2G6v



The ISoP Statistics and Pharmacometrics Special Interest Group

SxP Statistics & Pharmacometrics

is pleased to present the

SxP Trainee Award

to

Lucie Fayette

ACoP13

November 1, 2022

SxP Trainee Award Presentation

Pharmacometrics Enhanced Bayesian Borrowing

Lucie Fayette

SxP Statistics & Pharmacometrics

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?

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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!

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