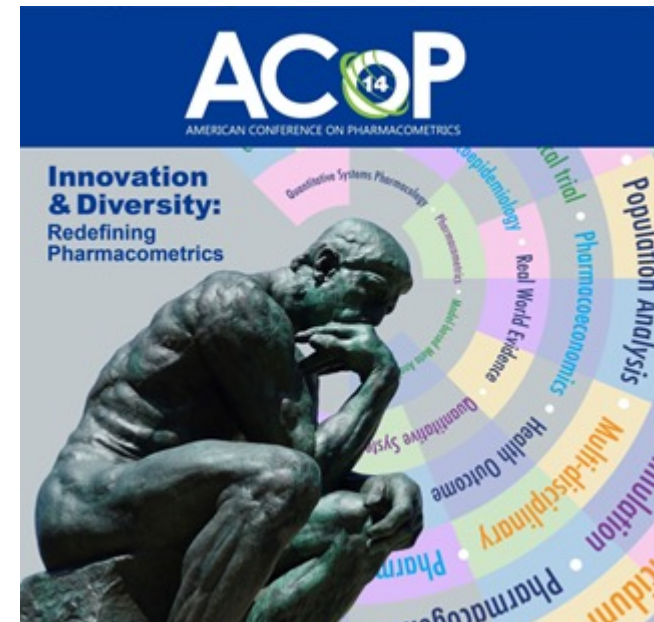


SxP SIG membership meeting

Co-chairs: Luke Fostvedt
Tim Waterhouse



Agenda

- Welcome – Luke Fostvedt
- Leadership and Steering Committee – Luke Fostvedt
- Year in Review – Tim Waterhouse
- ASA Biopharmaceutical Section – Jim Rogers
- Communications Committee – Pavan Vaddady
- Education Committee – Ram Goteti
- MBMA SubSIG – Phyllis Chan
- PKPD Programming SubSIG – Neelima Thanneer
- AI/ML SubSIG – Souvik Bhattacharya
- SxP SIG Trainee Award presentation – Madison Snyder
- Open discussion

Join SxP

- Join the SxP- even if you are already a member 😊
- Website continues to be actively updated (<https://sxpsig.github.io/>)!
- Questions or comments about SXP?
 - Contact us at our new email address: sxp.sig@gmail.com!



SxP Leadership - for Now

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



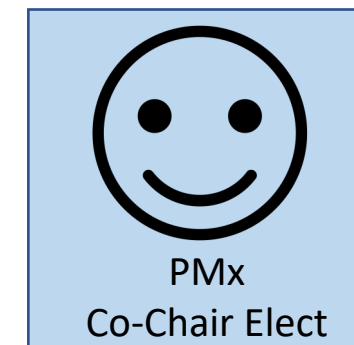
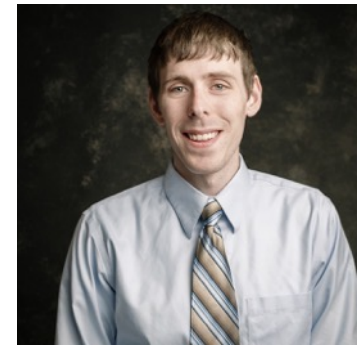
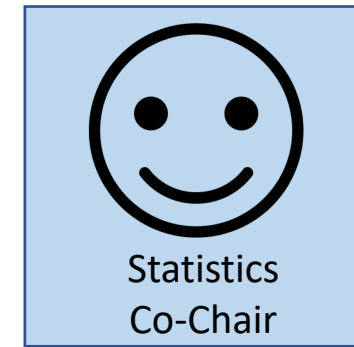
Outgoing:
Thank-you Stacey and Pavan!!



SxP Leadership to be!

- Tim Waterhouse- PMx Co-Chair
- Luke Fostvedt- Statistics Past Co-Chair
- ??? – PMx Co-Chair Elect
- ??? – Statistics Co-Chair

- Curtis Johnson – Communications Committee Chair
- ??? - Education Committee Chair



Year in Review

Tim Waterhouse

Year in Review

Webinars:

- Hosted 4 quarterly webinars

Engagement with ASA

- SxP is officially a Special Working Group in BIOP
- Jointly hosted webinar with BIOP in September
- Lead a session at the ASA Biopharmaceutical Regulatory-Industry Statistics Workshop: *Model informed drug development to support new drug development and regulatory decision making*
- Poster at the Boston ASA statistics symposium on the SxP special interest group.

ACoP:

- Poster on ASA BIOP Today (T-123): *Connecting ISoP with Statisticians: An Introduction to the Biopharmaceutical Section of the American Statistical Association*
- xSIG session from all the Special Interest Group immediately after Lunch (Session 3A): *Integration of PMx approaches to model-informed decision making: Across SIG Perspectives*

Next Year Remit & Upcoming Activities

Continue Engagement with ASA and the Biopharmaceutical Section

- Bi-Annual Joint Webinars
- Pre-conference workshop proposal at ASA BIOP Workshop (**deadline Dec 17**)
- Session proposal for ASA BIOP Workshop (**deadline Dec 17**)
- Poster sessions next year at Boston Chapter ASA

ISoP Activities:

- Submit a xSIG session proposal for ACoP15
- Submit a perspective article to CPT:PSP about SxP
- More consistent newsletter (at least quarterly)

ASA Biopharmaceutical Section

Jim Rogers



ASA Biopharmaceutical Section

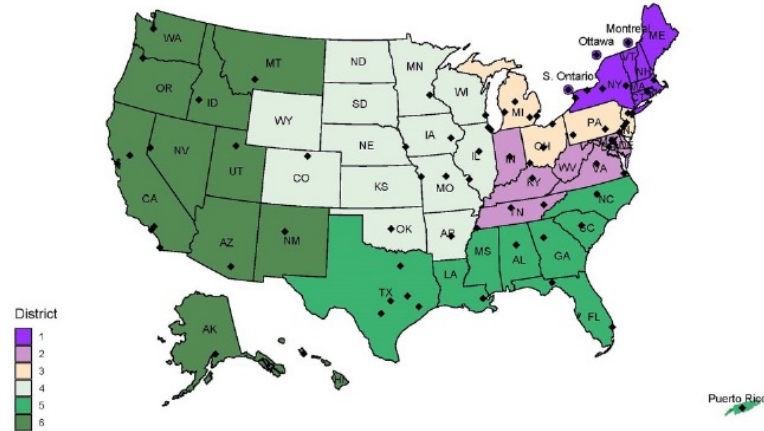
ASA

The American Statistical Association is organized as a collective of:

1. Chapters (including Student Chapters)

Regional communities for statisticians and data scientists, created chapters to support local-level ASA member involvement. Activities include:

- Organize meetings and networking events
- Provide continuing education offerings
- Engage in outreach efforts to local schools to stimulate interest in statistics as a career
- Provide information about the application of statistics



2. Sections & Interest Groups

Subject-area and/or industry-related and provide benefits specific to their members' interests (e.g., health care, manufacturing, defense, and national security)

BIOP = Biopharmaceutical Section of the ASA

Focuses on bringing together statisticians (and other quantitative scientists) interested in the application of Statistics to the development and use of therapeutic drugs and devices in humans and animals.



Connecting ISoP with Statisticians: An Introduction to the Biopharmaceutical Section of the American Statistical Association



Alan Hartford¹, Luke Fostvedt², Timothy Waterhouse³, Kosalaram Goteti⁴, Hrishikesh Kulkarni⁵, Ted Lystig⁶, Brian Millen⁷, Stacey Tannenbaum³, Pavan Vaddady⁸

¹Clene Nanomedicine, Inc, UT, USA, ²Pfizer, CT, USA, ³Metrum Research Group, CT, USA, ⁴EMD Serono Inc, MA, USA, ⁵Alexion Pharmaceuticals, Inc., MA, USA, ⁶BridgeBio Inc., CA, USA, ⁷Biogen Inc., NJ, USA, ⁸Daiichi Sankyo, NJ, USA



History of BIOP

Year	Achievement
1968	Established as subsection of the ASA
1981	Established as a section of the ASA
1983	Manual of Operations
1986	Short course on "Fundamentals of Clinical Trials" by Dave DeMets and Gordon Lan
1991	Creation of Best Contributed Paper Award
1992	Biopharmaceutical Report. First editor: Avital Cnaan
1994	Creation of Best Student Paper Award
1996	Creation of BIOP Website
1997	ASA Biopharmaceutical Section Regulatory/Industry Statistics Workshop
2007	ASA journal "Statistics in Biopharmaceutical Research (SBR)". First editor: Joe Heyse
2007	First webinar
2009	Best Poster Award
2012	First Podcast
2014	Launch of the Mentoring Program
2016	20th Anniversary of the Regulatory-Industry Statistics Workshop
2017	Nonclinical Biostatistics joins the section
2018	Scholarship award initiated
2019	BIOP YouTube Channel initiated
2021	LinkedIn Presence
2022	RISW moved to Rockville
2023	SxP became a BIOP Working Group

Current BIOP Working Groups

- Alzheimer's Disease
- Cell & Gene Therapy
- Centralized Statistical Monitoring and Quality Tolerance Limits
- Estimands in Oncology
- Nonclinical Biostatistics
- Pediatric Drug Development
- Real World Evidence Scientific Working Group
- Re-Randomization
- Safety Scientific Working Group
- **Statistics and Pharmacometrics Special Interest Group**
- Software Engineering Working Group
- Statistical Methods in Oncology
- Health Technology Assessment Scientific Working Group

ASA Biopharmaceutical Section

Conferences and Journals

2023
NCB Nonclinical
Biostatistics *Conference*

RUTGERS
THE STATE UNIVERSITY
OF NEW JERSEY

June 19-21, 2023

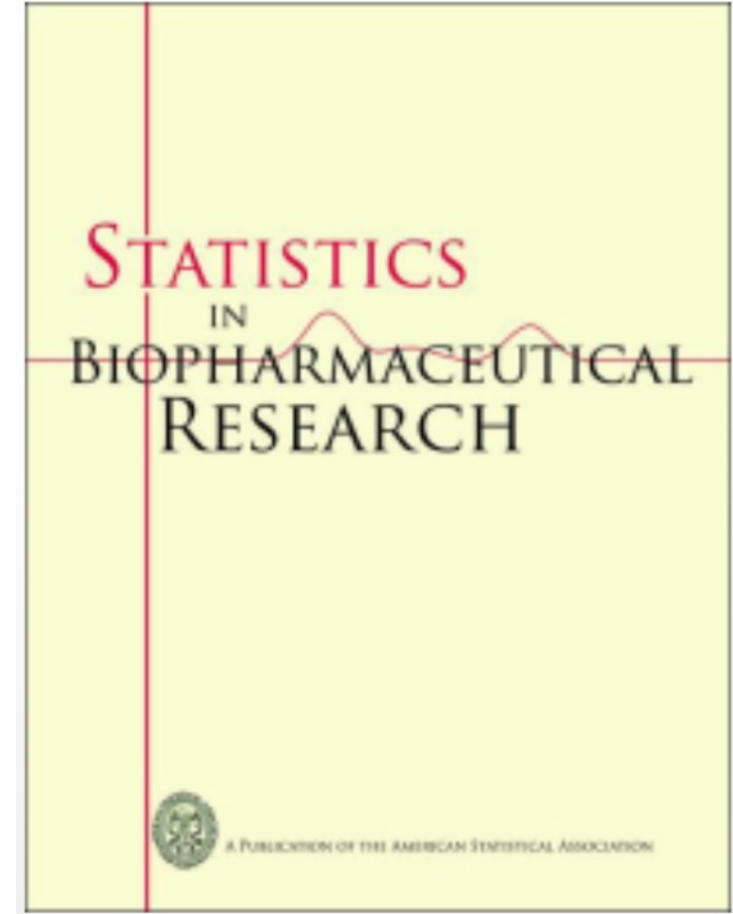
$(y_{ij}) = (\sum_b + \frac{\sum_e}{n})$
 $x \ln(\theta)$

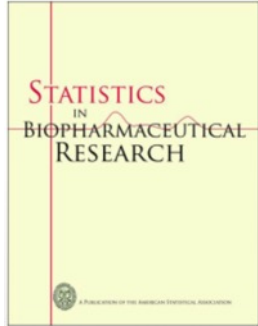


**THE ASA BIOPHARMACEUTICAL
SECTION REGULATORY-INDUSTRY
STATISTICS WORKSHOP**

September 27–29, 2023 • Rockville, MD

Statistical Thinking and Innovation with Global Impact





Statistical Innovation in Healthcare: Celebrating the Past 40 Years and Looking Toward the Future - Special issue for the 2021 Regulatory-Industry Statistics Workshop

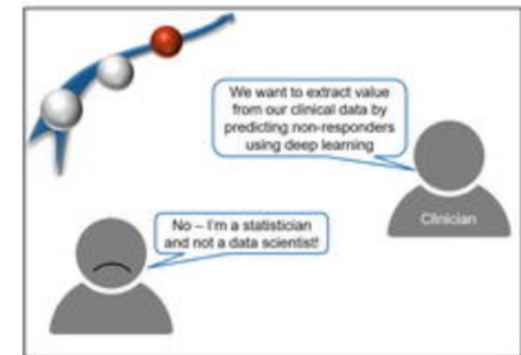
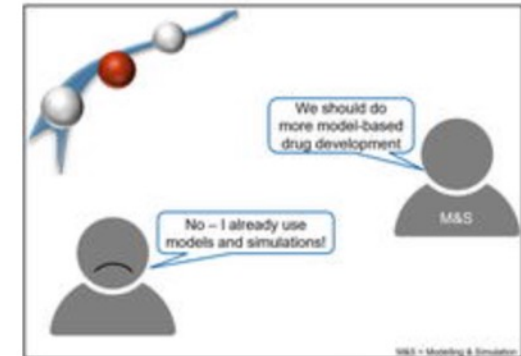
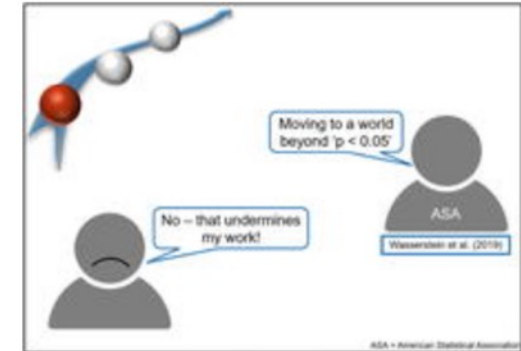
The Role of Statistical Thinking in Biopharmaceutical Research

Frank Bretz   & Joel B. Greenhouse 

Pages 458-467 | Received 19 Dec 2021, Accepted 19 May 2023, Published online: 24 Jul 2023

“The second dialogue happened more than 15 years ago, at a time when pharmacometricians started to add a new dimension to drug development by promoting a broader use of model-based analyses. The reaction from junior and senior statisticians throughout the pharmaceutical community was, repeatedly, “No - I already use models and simulations.” The disconnect here was a problem of communication. Whereas our pharmacometrics colleagues had much broader classes of models in mind, many statisticians, at least at that time, were thinking in terms of analysis-of-covariance models or, at best, mixed-model repeated measures analyses, and were using simulations primarily for power and sample size calculations.”

Fig. 3 Three dialogues.



We Need ASA BIOP to adopt a
BIG TENT mentality



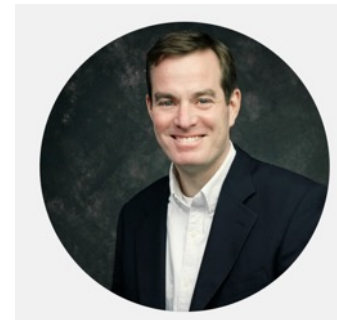
Ted Lystig, Chair-elect of BIOP Executive Committee

We Need ASA BIOP to adopt a
BIG TENT mentality



Ted Lystig, Chair-elect of BIOP Executive Committee

Cool!
What can PMx do to help?



Jim Rogers, BIOP Exec Comm. Member at large



Born to Saxons

Trained in Statistical
Civilization



Raised by Danes

Career in the Wilderness of
Pharmacometrics



The Hero of a United and
Prosperous England

We have a key role to play now!

www.amstat.org



ASA Biopharmaceutical Section

Product	Unit Price	Total
BIOP Section	\$7.00	\$7.00
Boston Chapter	\$10.00	\$10.00
Connecticut Chapter	\$10.00	\$10.00
New York City Metro Area Chapter	\$8.00	\$8.00
Regular Membership Dues	\$180.00	\$180.00
	Discounts Applied:	\$0.00
	Subtotal:	\$215.00
	Shipping:	\$0.00
	Taxes:	\$0.00
	Grand Total:	\$215.00

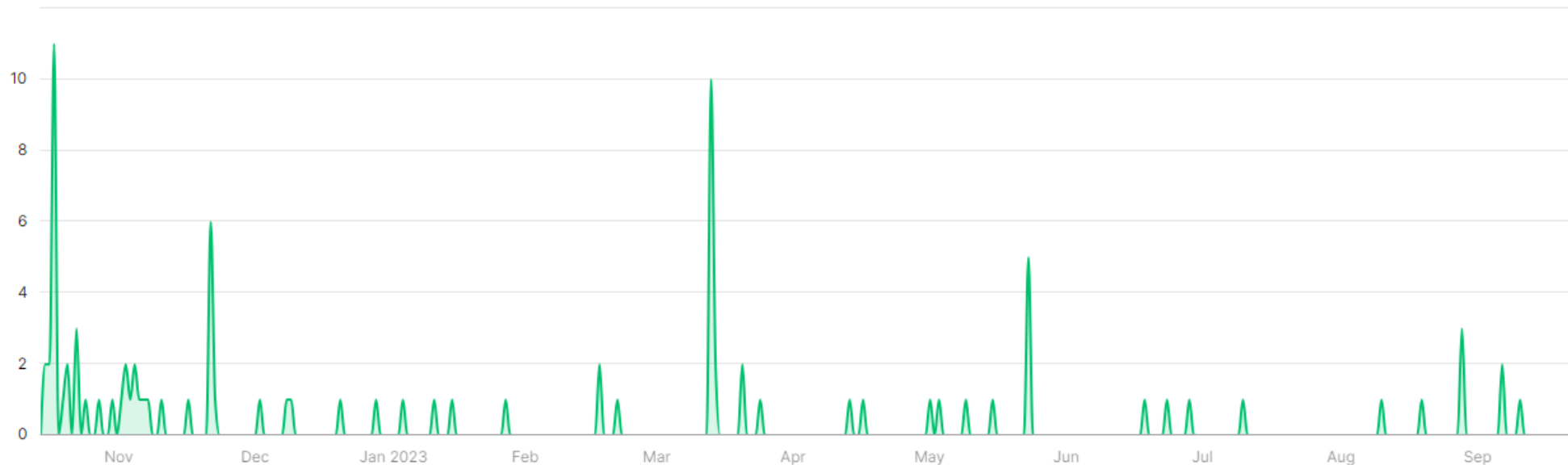
This was my summary of charges for 2023. Your miles may vary.

SxP SIG Communication Committee

Pavan Vaddady

Communications Committee - Update

- Subscriptions and Email Campaigns
 - 272 Active subscribers
 - Added 92 new subscribers since last ACoP
 - 12 campaigns were sent out (Webinar announcements, Voting, Call for Volunteers, Information sharing)



Communications Committee - Update

- Website:
 - Up-to-date and fully functional with significant amount of content
 - Repo for relevant events
 - 13 Past Events with relevant YouTube links
 - 2 Upcoming Events
 - Lots of educational materials posted (working with Education Committee)
 - Stat content for pharmacometricians
 - PMx content for statisticians
 - AI/ML
 - Relevant regulatory guidances
 - Student resources

<https://sxpsig.github.io>



Communications Committee - Update

- Next Steps:
 - Newsletter
 - Discussion Board
 - Outreach campaigns

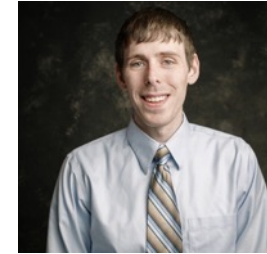
Special thanks to all who contributed to the activities of this committee:



Pavan Vaddady



Siv Jönsson



Curtis Johnston



Julie Bertrand



Erin Dombrowsky

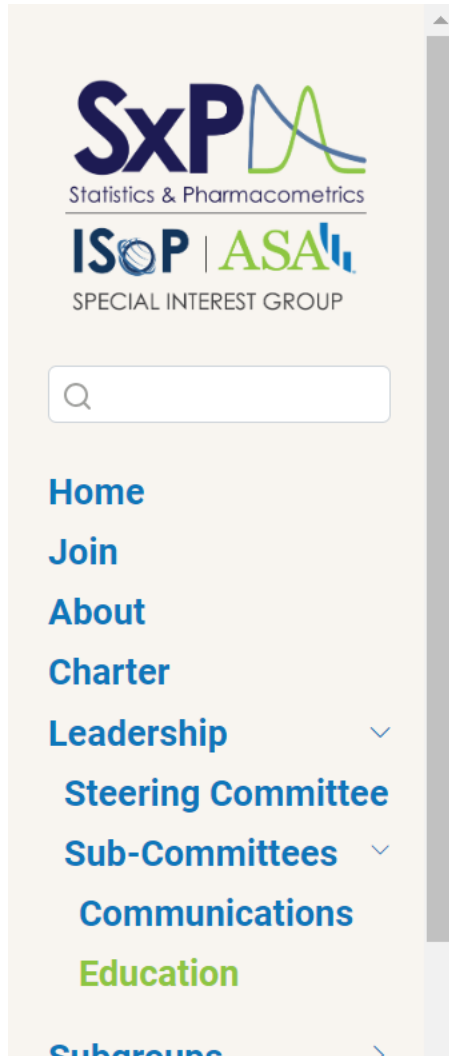


Tim Waterhouse

SxP SIG Education Committee

Ram Goteti

Website & Content






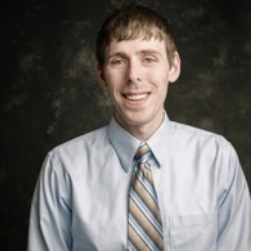








Education

Chair:

- Kosalaram (Ram) Goteti

Members:

- Alice Zong
- Akiyuki Suzuki
- Camille Vong
- Curtis Johnston
- Diane Longo
- Jessica Barry
- Julie Bertrand
- Marion Bouillon-Pichault
- Souvik Bhattacharya
- Akash Khandelwal
- Yuan Xiong

 <p>Alice Zong</p>	 <p>Camille Vong</p>	 <p>Ram Goteti</p>	 <p>Curtis Johnston</p>
 <p>Julie Bertrand</p>	 <p>Marion Bouillon-Pichault</p>	 <p>Diane Longo</p>	 <p>Akiyuki Suzuki</p>
 <p>Yuan Xiong</p>	 <p>Souvik Bhattacharya</p>	 <p>Akash Khandelwal</p>	 <p>Jessica Barry (Student Representative)</p>

Activities in 2023

- Home
- Join
- About
- Charter
- Leadership >
- Subgroups >
- Events >
- Education >
- Stats for PMx
- PMx for Stats
- AI/ML
- Regulatory
- Guidances
- Conference Content
- Student Resources
- Links
- Contact Us

AI/ML

Artificial Intelligence (AI)/Machine Learning (ML)

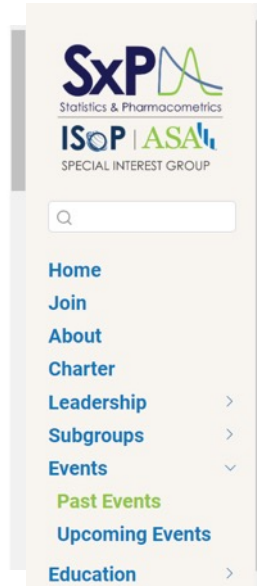
- [Deep learning prediction of patient response time course from early data via neural-pharmacokinetic/pharmacodynamic modeling, Luet. AI, 2021, Nature Machine Intelligence](#)

The article presents a neural-PK/PD framework that combines key pharmacological principles with neural ordinary differential equations. Using deep learning approaches the author showed that the governing differential equations can be learnt directly from longitudinal patient data.
- [Pharmacometrics and Machine Learning Partner to Advance Clinical Data Analysis, Koch et. Al, 2020, Clinical Pharmacology & Therapeutics](#)

The article introduced to ML classification methods, provide examples for a ML classification analysis to identify covariates based on specific research questions, examine a clinically relevant example to investigate possible relationships of ML and PMX, and present a summary of ML and PMX tasks to develop clinical decision support tools.
- [Tacrolimus Exposure Prediction Using Machine Learning, Woillard et.al, 2020, Clinical Pharmacology & Therapeutics](#)

On this page

Artificial Intelligence (AI)/Machine Learning (ML)



Sep 12, 2023

The Decision-Equivalence Metric (DEM) method for Evaluating Surrogate Endpoints for Accelerated Clinical Development Using a Combination of Individual Level and Aggregate Level Literature Data: Chandni Valiathan, John Maringwa and Lixia Pei

WEBINAR | STATSFORMPX | ASA BIOPHARM

Define and explore the decision-equivalence metric (DEM) method that leverages both individual and aggregate data and uses practical approaches to assess surrogate markers for clinical development.



- Update Educational Content on MBMA, AI/ML, Regulatory Guidance
- AI/ML SubSIG
- 1st Joint Webinar with ASA
- Poster Presentation at Boston Chapter of ASA

MBMA sub-SIG Updates

Co-chairs: Phyllis Chan (Genentech) & Monica Simeoni (GSK)

Core team: Abhinav Kurumaddali (Daiichi Sankyo)
Clemence Rigaux (Sanofi)
Jian Zhou (BMS)
John Maringwa (Janssen)
Junshan Qiu (FDA)
Li Qin (Certara)
Marion Bouillon-Pichault (BMS)
Matt Zierhut (Certara)
Rachel Jennings (Takeda)
Rana Jreich (Sanofi)
Huijuan Xu (Takeda)



Statistics & Pharmacometrics



SPECIAL INTEREST GROUP

Thank you to past members: Chandni R. Valiathan (Janssen) and Yaming Han (Takeda)

Accomplishments in 2023

- Established a LinkedIn public group page
- Posted two case examples on LinkedIn (private and public groups), launching [MBMA subSIG signature template](#)
- Collated a repository of publications and listed introductory articles on the SxP “[Education: Stats for PMx](#)” webpage
- Continued discussions of technical topics at core member meetings: [Introduction to MBMA](#) (Abhinav), [Leveraging individual- and aggregate-level data](#) (Monica)
- Planned webinar for December 7: [Imputation of missing data](#) (Rana & Phyllis)

Presence at ACoP 2023 and Looking Forward to 2024

- Pre-meeting workshop (Matt) & cross-SIG MIDD session (Phyllis)
- Upcoming core team discussion topics
 - PAGE/ACoP 2023 conference MBMA abstract summary
 - Modeling absolute vs. relative outcomes
 - Longitudinal vs. landmark analysis
 - Bayesian vs. frequentist approach
 - Standardization of MBMA databases
- Sharing technical topics discussion outcomes outside the core team
- Additional case examples and webinars

PKPD Programming SubSIG

Current Leadership



Neelima Thanneer
(co-founder &
co-chair), BMS



Jing Su
(co-founder &
co-chair), Merck



David B Radtke,
Lily



Alice Zong, J&J



Xiaobin Li, GSK



Shweta Vadhavkar,
Genentech



Samarth Patel,
Daichi

Objective:

- Establish a community for pharmacometric and pharmacokinetic programmers across industry and academia
- Collect and share best practices, challenges and examples for programmers supporting PMx/PK analysis
 - Organizing Webinars
 - Discussion board Topics
 - PKPD Programming Library
 - Identifying topics for conferences

PKPD Programming SubSIG

- CDISC ADaM ADPPK standards published
 - Multi year effort by the CDISC ADaM Working Group co-led by Neelima Thanneer
 - Stay tuned for ISoP Webinar on Dec 6th for details on Implementation Guide
- Webinar on Changes to FDA Guidance for PopPK presented in Sep:
<https://sxpsig.github.io/events/pastevents/posts/pkpdprogrammingforum4.html>

Changes to Population PK/PD data and supplemental information based on FDA Guidance for PopPK

WEBINAR

PKPD PROGRAMMING SUBGROUP

FDA GUIDANCE

POPPK

In this presentation the speakers highlight the updates in the latest FDA Guidance for Population PK that impact the PMx Datasets, Report and eSub aspects.

Artificial Intelligence (AI)/Machine Learning (ML)

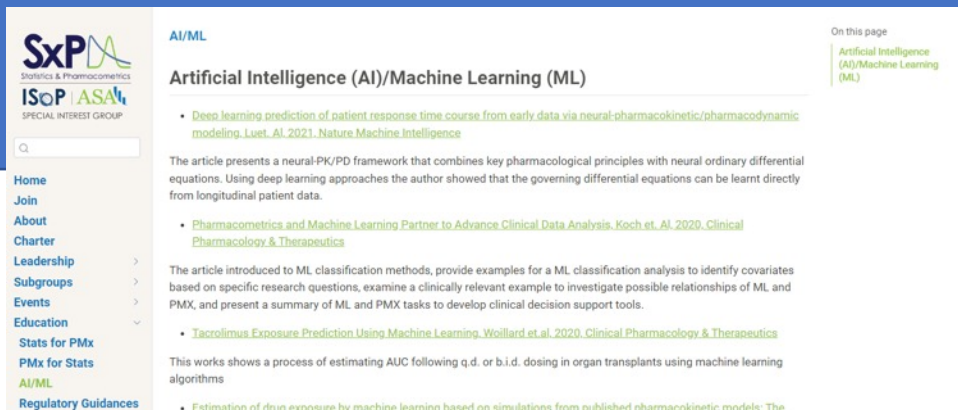
Objectives:

A forum dedicated to fostering the advancement and application of artificial intelligence and machine learning (AI/ML) in pharmacometrics. Our objective is to promote the development, use, and education of AI/ML approaches suited particularly for pharmacometrics.

Resources we have created already

Created a knowledge database for PMX and Stats to learn on the current advancements in the field of AI/ML and its applications in model informed drug development

(<https://sxpsig.github.io/education/aiml.html>)




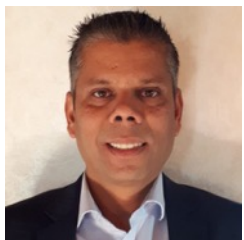

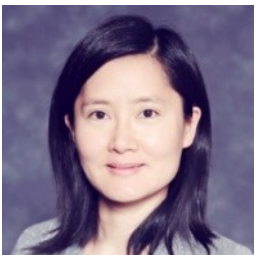


The screenshot shows a website interface for the AI/ML knowledge database. The header includes the SxP logo (Statistics & Pharmacometrics) and the ISoP/ASA logo (Special Interest Group). A search bar is present. The main content area is titled 'Artificial Intelligence (AI)/Machine Learning (ML)' and lists several articles with their titles and authors. A sidebar on the left contains navigation links: Home, Join, About, Charter, Leadership, Subgroups, Events, Education, Stats for PMX, PMx for Stats, AI/ML, and Regulatory Guidances.

Few plans we have for future

- Frequent interactions among team members
- Organizing webinars and sessions at major conferences
- AI/ML local meet-ups to network PMX and Statisticians
- Update AI/ML knowledge database on a regular basis with literature and training materials.

Current Team

Looking for volunteers

 <p>Souvik Bhattacharya (co-chair)</p>	 <p>Akash Khandelwal (co-chair)</p>	 <p>Camille Vong</p>
 <p>Dan Lu</p>	 <p>Hu Huang</p>	 <p>You?</p>



akash.khandelwal@ucb.com
souvik.bhattacharya@astellas.com



SxP Trainee Award Presentation

Meta-analysis of Change in Lung Capacity and Skin Thickening for Interstitial Lung Disease (ILD) with Mixed Connective Tissue Disorders



Madison Snyder
Pfizer, Inc.

Let's talk!

Opportunities to get involved – volunteer for the SIG!

- Join the Steering Committee
- Join a subSIG (MBMA, PKPD programming, AI/ML)
- 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/>



Come see us 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!

SxP 

Statistics & Pharmacometrics

ISOP | **ASA** 

SPECIAL INTEREST GROUP