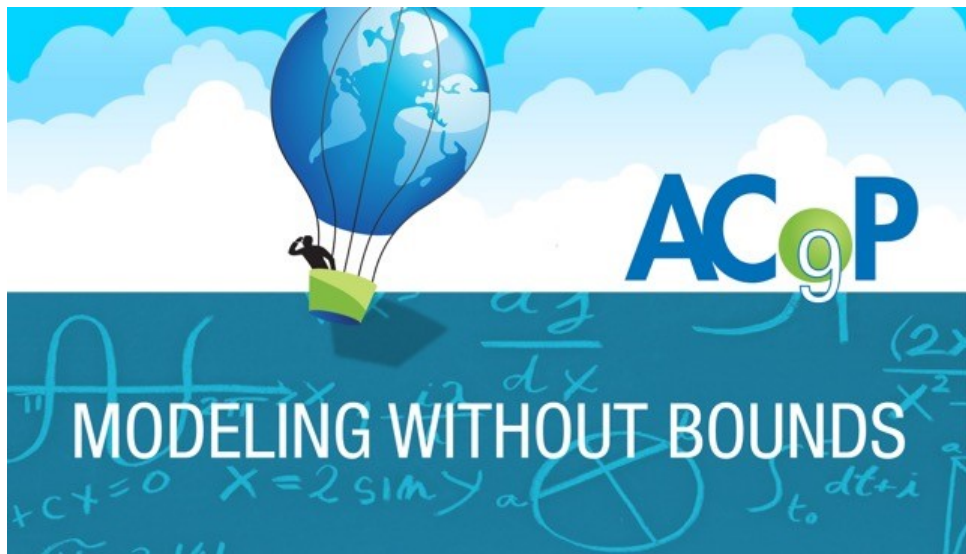


Session 4b:
**Selected topics that would benefit from
 enhanced collaboration between statisticians
 and pharmacometricians**

Chairs:
France Mentré and Robert Bies

France Mentré	Introduction and overview of the SxP Pharmacometrician and Statistician Survey
Jose Pinheiro	Multiplicity issues with covariate analysis: strategies and perspectives on pre-specification of pharmacometric analyses
Jim Rogers	Causa Nostra: the potentially legitimate business of drawing causal inferences from observational data
Andreas Krause	Common concerns regarding the visualization of data and models
Panel Discussion	Robert Bies, Andreas Krause, Chao Liu (FDA), France Mentré, Bret Musser, Jose Pinheiro, Junshan Qiu (FDA), Jim Rogers



Session 4b:
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**Introduction and
overview of the SxP Pharmacometrician and Statistician Survey**

France Mentré, University Paris Diderot

- **SxP**: Special Interest Group created in 2016
 - Promote collaboration between Statisticians and Pharmacometricians
 - to enable each discipline to learn and grow from the other
 - to develop innovative approaches to model informed drug development
- **Steering Committee (new one since 2018)**
 - Co-chairs: **Bret Musser** (Regeneron) & **France Mentre** (U Paris Diderot & INSERM)
 - **Fred Balch** (U Utah), **Rob Bies** (U Buffalo), **Kevin Dykstra** (qPhametra), **Manolis Efthymios** (EMA), **Jonathan French** (Metrum), **Lena Friberg** (U Uppsala), **Vijay Ivaturi** (U Maryland), **Jose Pinheiro** (J&J), **Dionne Price** (FDA), **Gary Rosner** (Johns Hopkins), **Matt Rotelli** (Lilly), **Mike Smith** (Pfizer), **Jing Su** (Merck), **Stacey Tannenbaum** (Astellas Pharma), **Neelima Thaneer** (BMS), **Jingtao Wu** (Takeda), **Yaning Wang** (FDA)
 - ISoP board liason: **Siv Jonsson** (U Uppsala)
- **Membership open to everyone** <http://community.amstat.org/sxp/home>
 - N= 263 (end of August)

Website

- Slides of conferences
- PKPD programmer forum
- Blog
- Discussion

Jingtao Wu, Ph.D.
Associate Director, Biostatistics
Takeda Development Center Americas, Inc.

The screenshot shows the homepage of the American Statistical Association (ASA) Interest Group (SxP). At the top, there are navigation links for Contact Us, Code of Conduct, ASA Community, and ASA Home. The main header features the ASA logo (American Statistical Association, Promoting the Practice and Profession of Statistics) and the ISOP logo (International Society of Pharmacometrics). Below the header is a navigation menu with links for Home, About Us, Events, Blog, PK/PD Programmer Forum, Discussion, Library, Join, and Links, along with a search bar. The main content area is divided into two columns. The left column is titled 'About Us' and contains a link to 'Announcing the New Statistics and Pharmacometrics Interest Group (SxP)'. It describes the group's formation in 2016 and its goals, which include providing educational opportunities, encouraging career growth, promoting cross-disciplinary research, and providing opportunities to discuss computing platforms. The right column features a 'Join the Discussion' banner with a 'Get Started' button and an 'Announcement' section listing three items: new additions to the library, a new blog site, and a member survey. Below the announcements is an 'Ongoing/Up Coming Events' section listing several sessions from the MBSW 2018 conference. At the bottom, there are two buttons: 'General Discussion Board' and 'PK/PD Programmers Discussion Board'. The footer contains copyright information for 2011 ASA and a note that the site is powered by Higher Logic.

Contact Us | Code of Conduct | ASA Community | ASA Home

ASA AMERICAN STATISTICAL ASSOCIATION Promoting the Practice and Profession of Statistics

ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

Home About Us Events Blog PK/PD Programmer Forum Discussion Library Join Links search

About Us

[Announcing the New Statistics and Pharmacometrics Interest Group \(SxP\)](#)

The Statistics and Pharmacometrics Interest Group (SxP) was named in 2016 and is chartered by both the [American Statistical Association \(ASA\)](#) and [International Society of Pharmacometrics \(ISOP\)](#). This 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 Interest Group 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 us [here](#) or e-mail sxp_asa_isop@gmail.com.

Join the Discussion

Ask or answer questions with your peers. Our dynamic discussion groups provide the tools you need to communicate with leaders and partners in your field.

[Get Started](#)

Announcement:

1. New Additions to our Library: [This isn't Peewee Soccer: Building Teamwork Between Statisticians and Pharmacometricians](#), By Brett J. Musser, at 2018 ICSA
2. Please visit our [New Blog Site](#).
3. Please take a look at our first member survey: [2017 SxP survey](#).

Ongoing/Up Coming Events:

- **SxP-hosted sessions in MBSW 2018**
 - Ronda Rippley, Regeneron: Translating from Lab to Clinic: The Utility of Quantitative Pharmacology Approaches
 - Bill Gillespie, Metrum: Bayesian data analysis using Stan/Torsten for pharmacometric applications
 - Richard Allen, Pfizer: Virtual Patients and Populations in Quantitative Systems Pharmacology Models
 - William Kielbasa, Eli Lilly: PKPD Approaches and Considerations in Pediatric Drug Development: Extrapolation and Dose Optimization

[General Discussion Board](#) [PK/PD Programmers Discussion Board](#)

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Letter to the editor (submitted October 2)

Dear editors of “Pharmaceutical Statistics”,

We read with interest your recent publication by Jaki et al. on “A proposal for a new PhD level curriculum on quantitative methods for drug development.” This letter is intended to provide comments, additional information, and a proposal for close collaboration from a closely related discipline, pharmacometrics (frequently named ‘modeling and simulation’ and often known for “population PK/PD modeling”). **We believe that while both biostatistics and pharmacometrics have had successful impact on drug development, more can be gained by further collaboration.**

.....

The SIG SxP could take on the task of profiling both disciplines (i.e., quantitative biostatistics and pharmacometrics) to have their own aims or unifying them into a single joint curriculum. **The pharmacometrics community will be glad to have closer collaboration with the (bio)statistical colleagues.**

This letter reaches out for **dialogue between the two communities**. Yours sincerely,

Andreas Krause, Charlotte Kloft, Wilhelm Huisinga, Mats Karlsson, José Pinheiro, Robert Bies, James Rogers, and France Mentré and Bret Musser for the joint ISOP/ASA Special Interest Group on Statistics and Pharmacometrics (SIG SxP)



Statistics and Pharmacometrics
Interest Group (SxP)

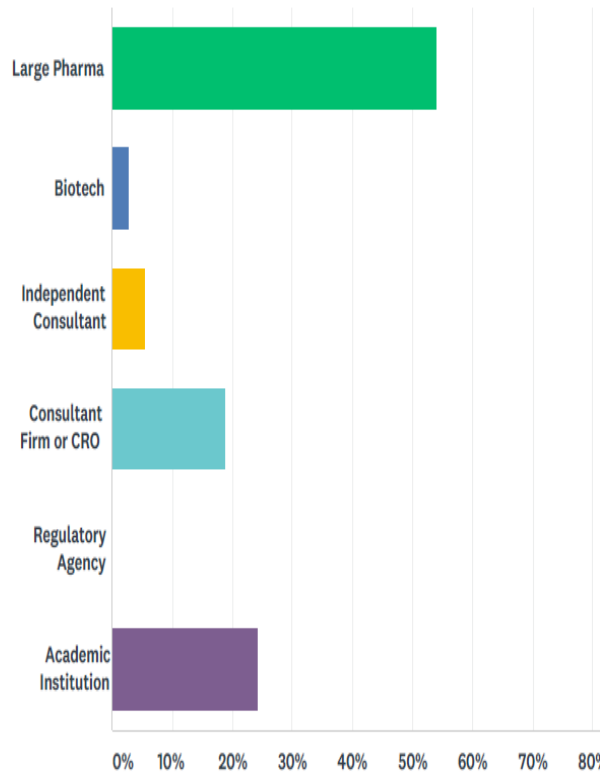


Survey performed in December 2017: Sent to 222 members, answered by 38

Survey performed in December 2017: Sent to 222 members, answered by 38

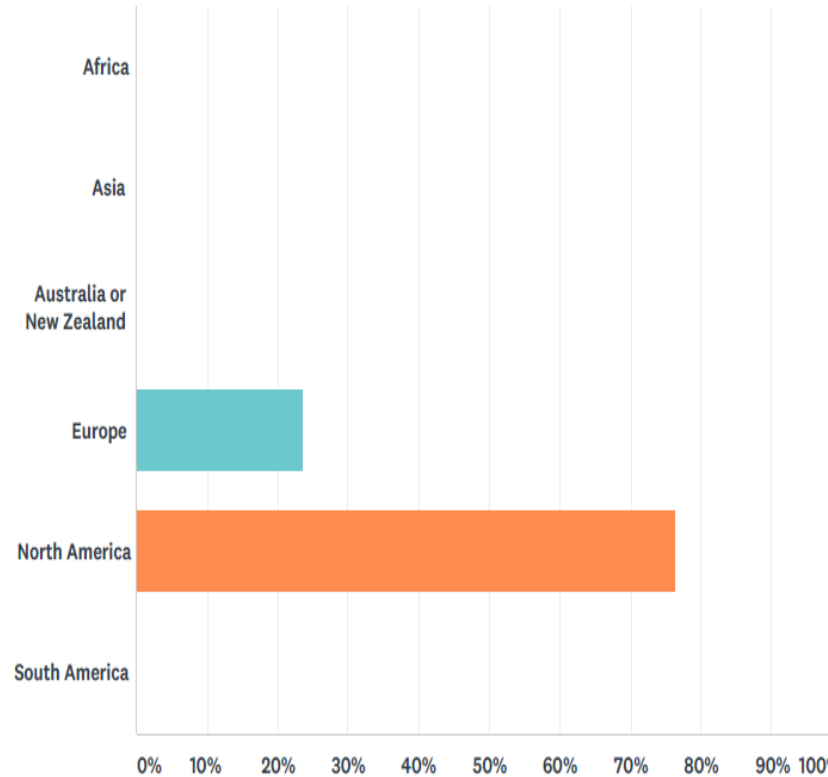
Q1 Who do you work for?

Answered: 37 Skipped: 1



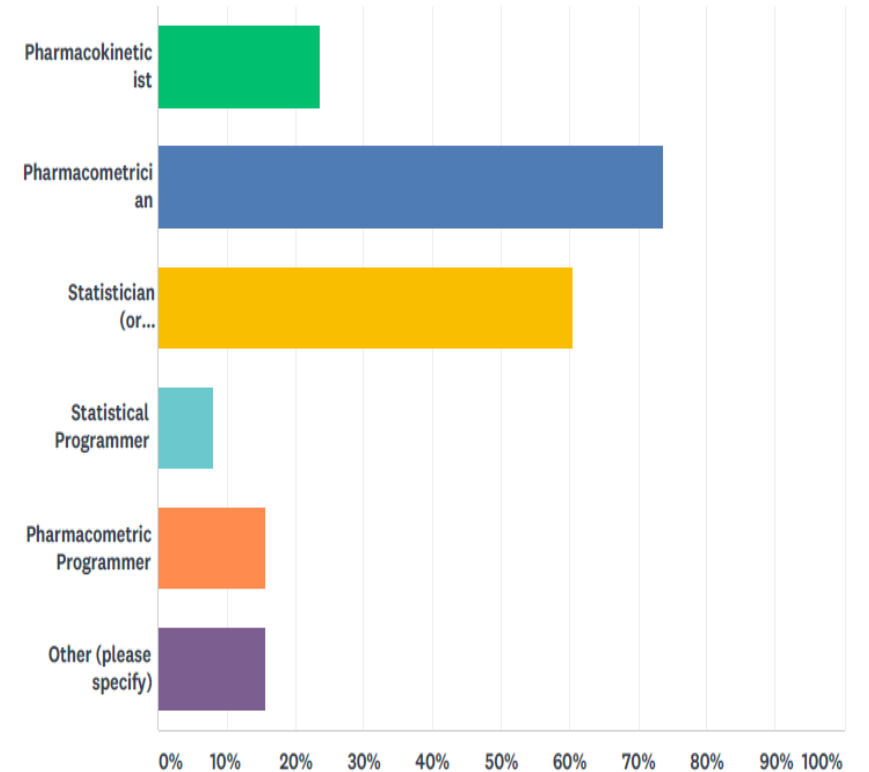
Q2 What is your location?

Answered: 38 Skipped: 0

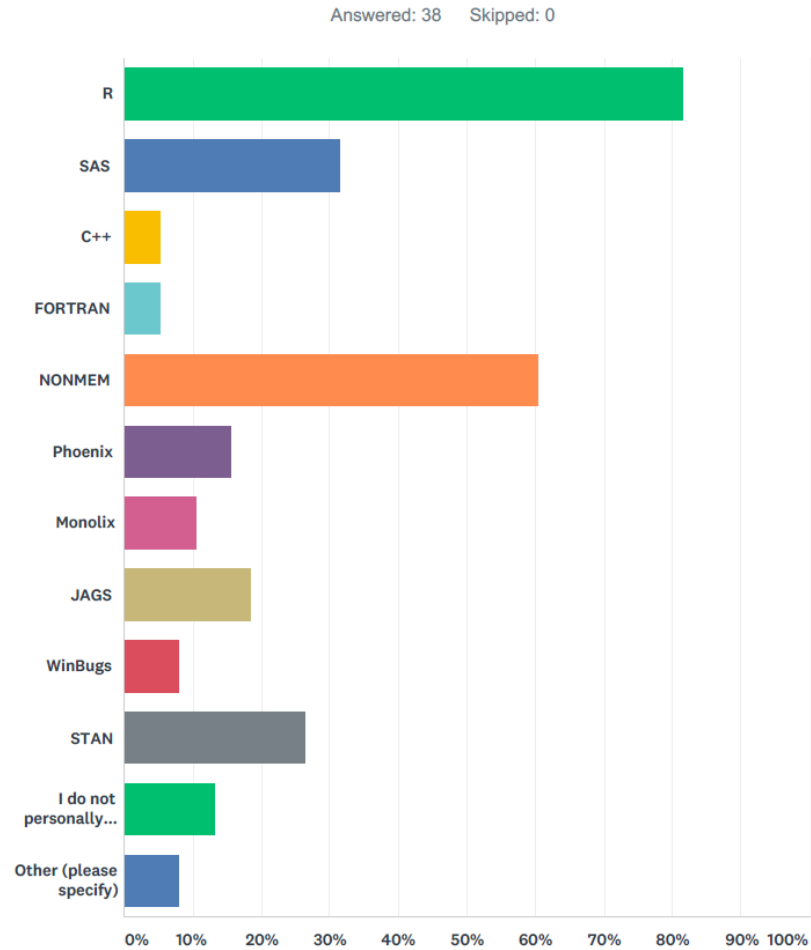


Q3 Select all that you consider yourself to be.

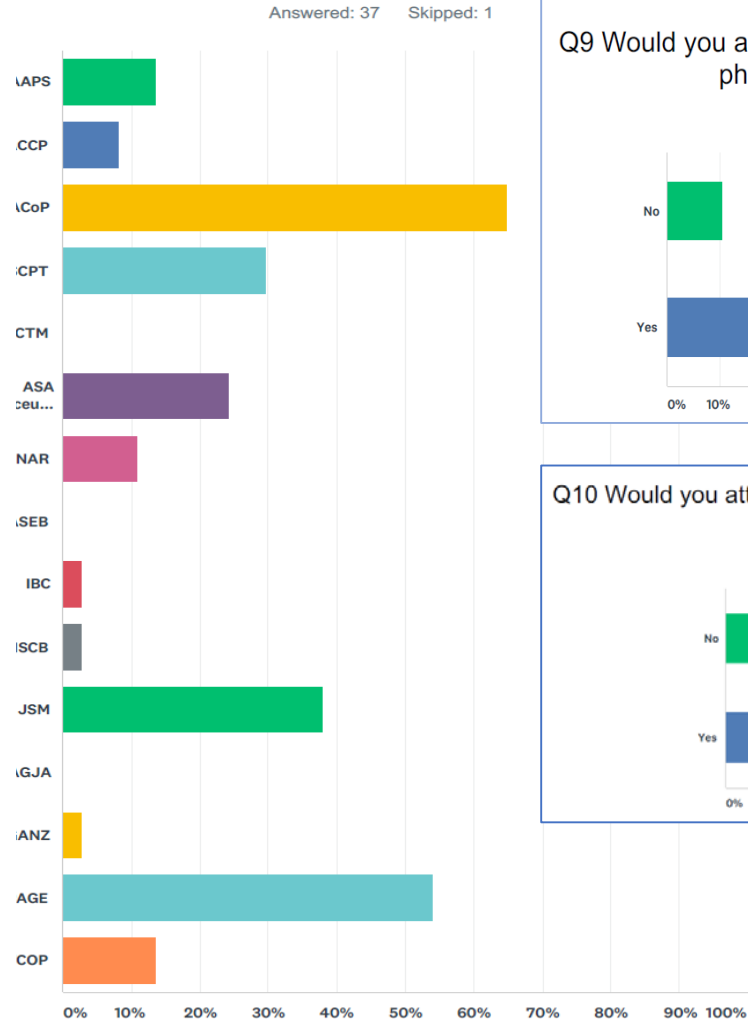
Answered: 38 Skipped: 0



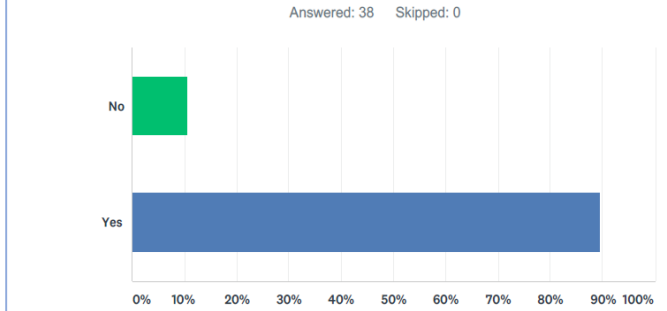
Q7 What software packages and languages do you use in your practice of pharmacometrics?



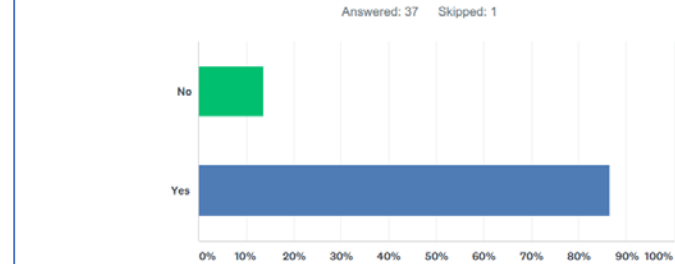
Q8 What conferences do you attend?



Q9 Would you attend statistical methodological sessions at pharmacometrics conferences?

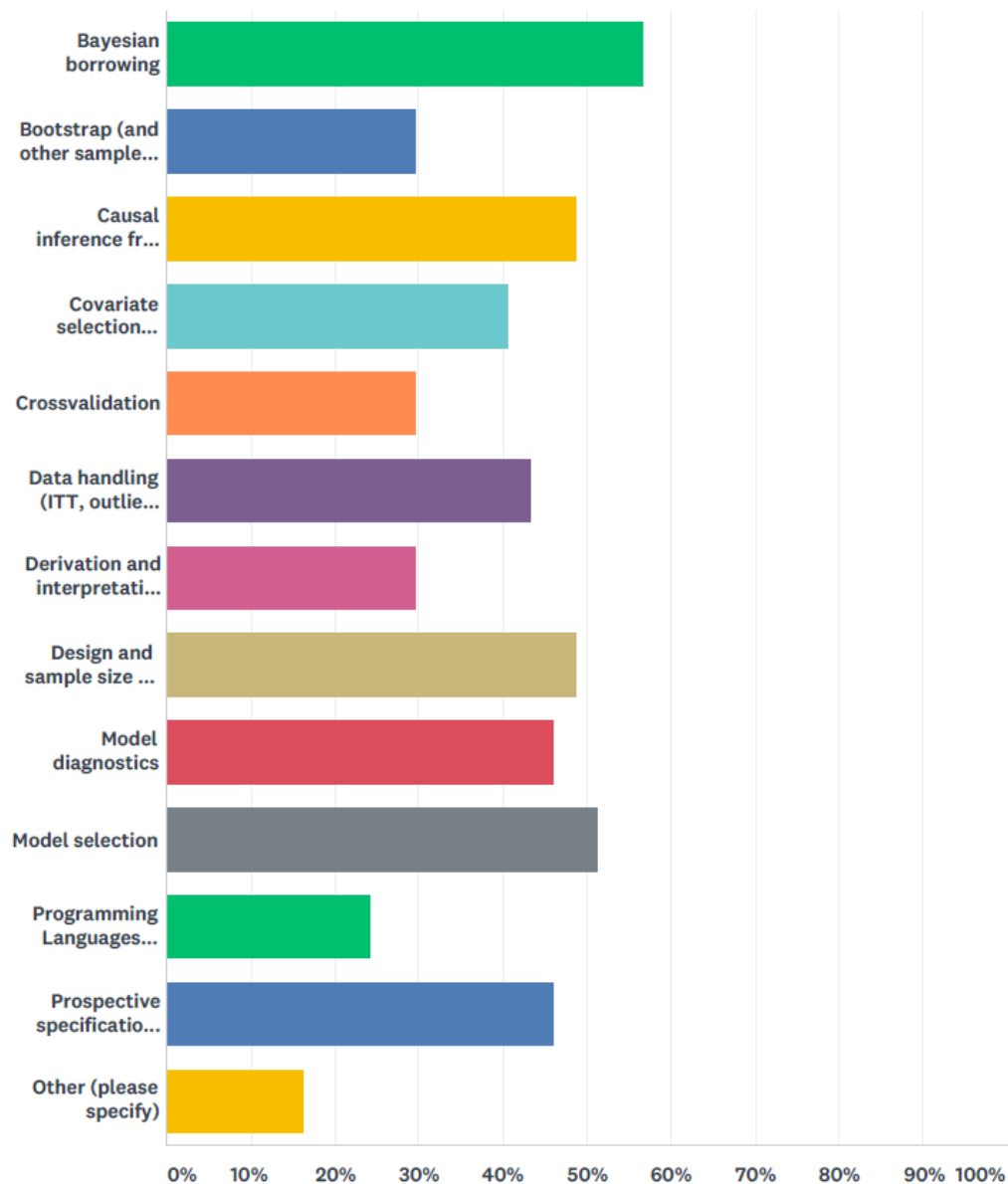


Q10 Would you attend sessions focusing on pharmacometrics instruction at statistics conferences?



Q12 Which topics would you like to know more about?

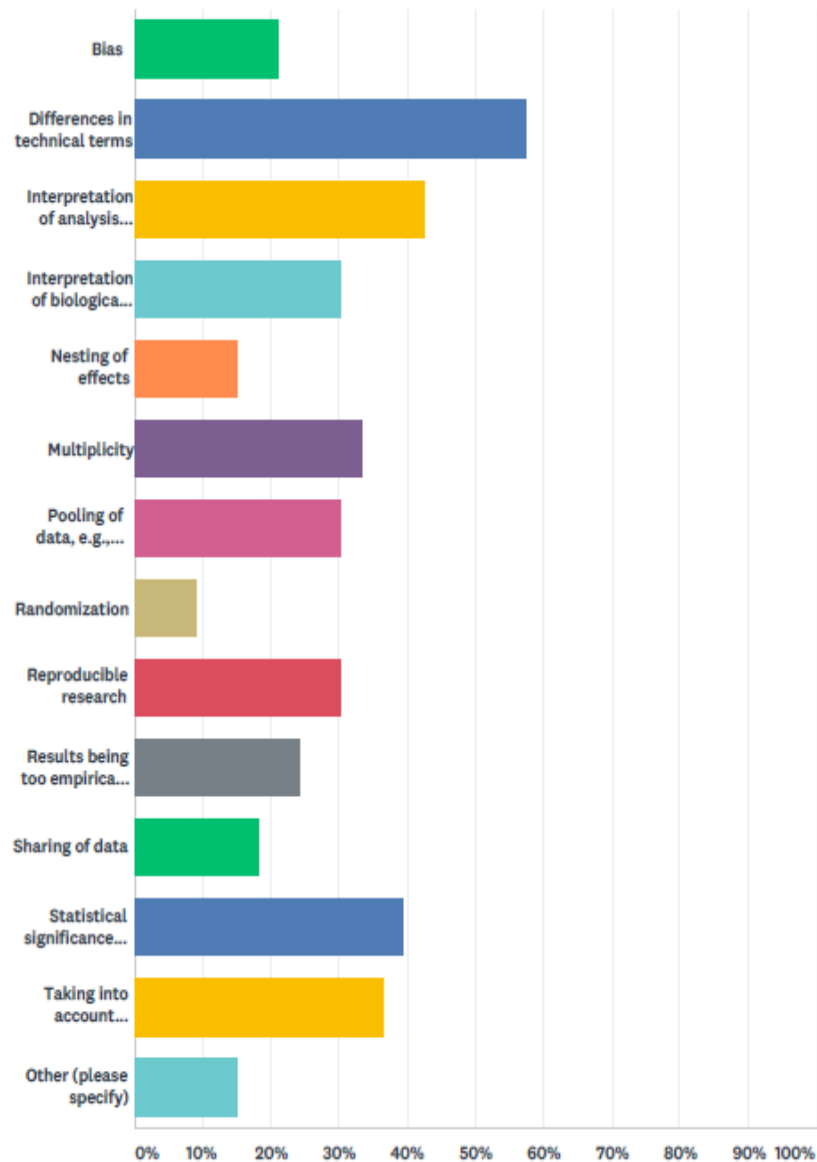
Answered: 37 Skipped: 1



#	OTHER (PLEASE SPECIFY)
1	Utilizing PMx/Stats output for business decision making
2	Meta-analyses; Identifiability; Model averaging; Structural equation models; Unsupervised classification methods;
3	"Bayesian borrowing" sounds like either an complex mortgage product or a new way that my kids would be taught to do subtraction.
4	Adaptive trial design best practices
5	Adaptive dose individualization
6	model-based meta-analysis

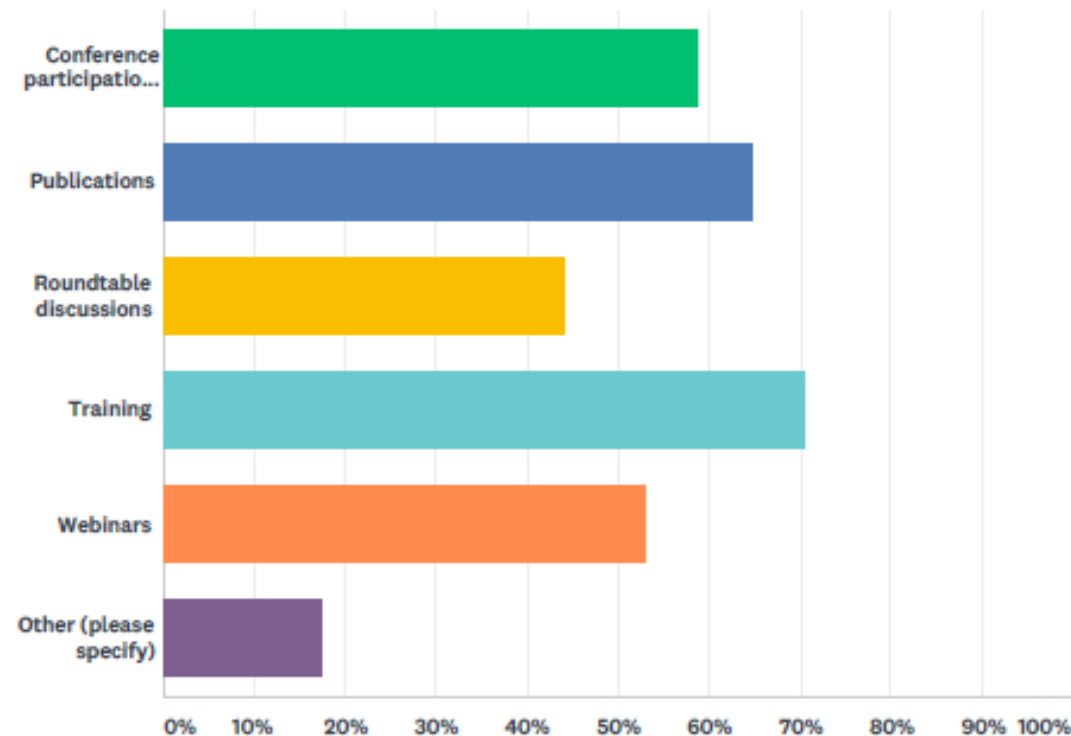
Q13 When statisticians and pharmacometricians collaborate, what are the most confusing or troubling topics discussed?

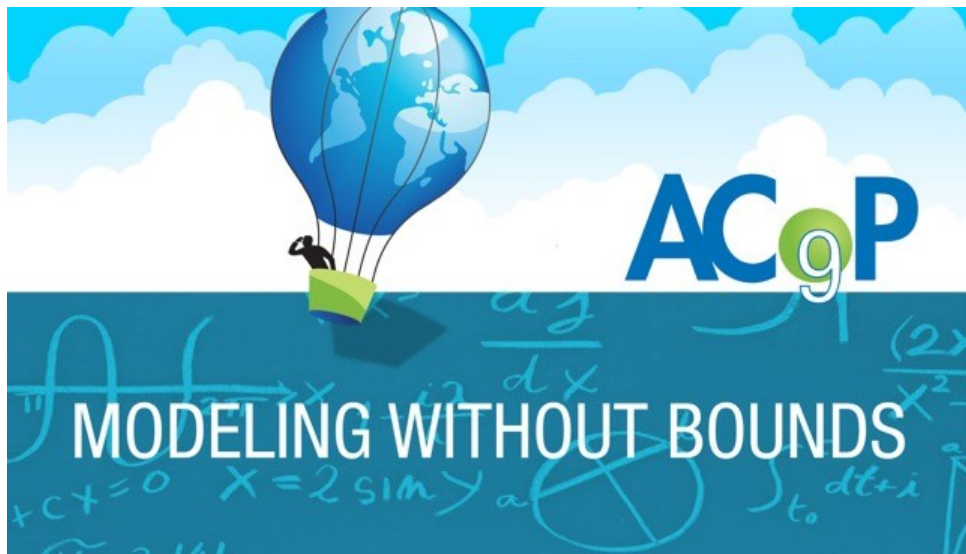
Answered: 33 Skipped: 5



Q14 How should these difficulties from Question 13 be addressed?

Answered: 34 Skipped: 4



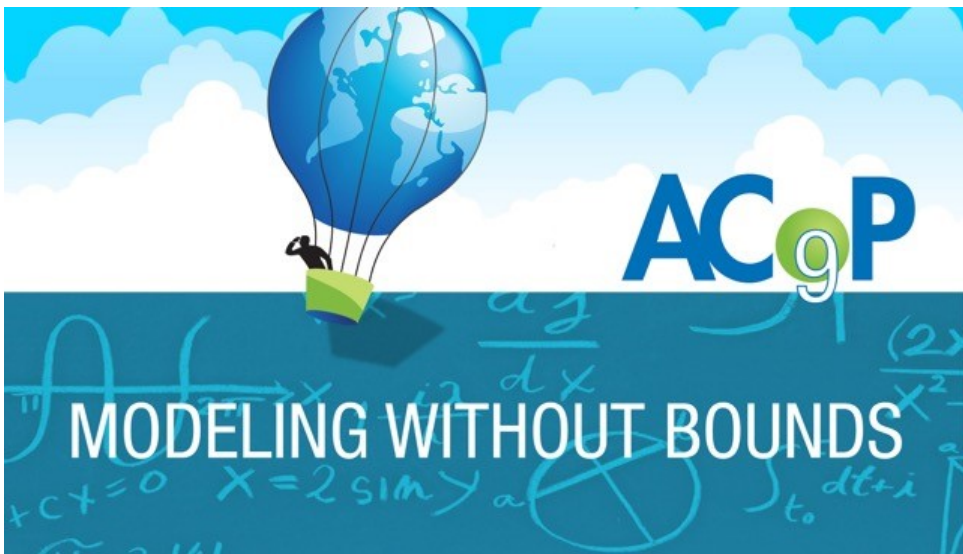


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Multiplicity issues with covariate analysis: strategies and perspectives on pre-specification of pharmacometric analyses

José Pinheiro, J&J

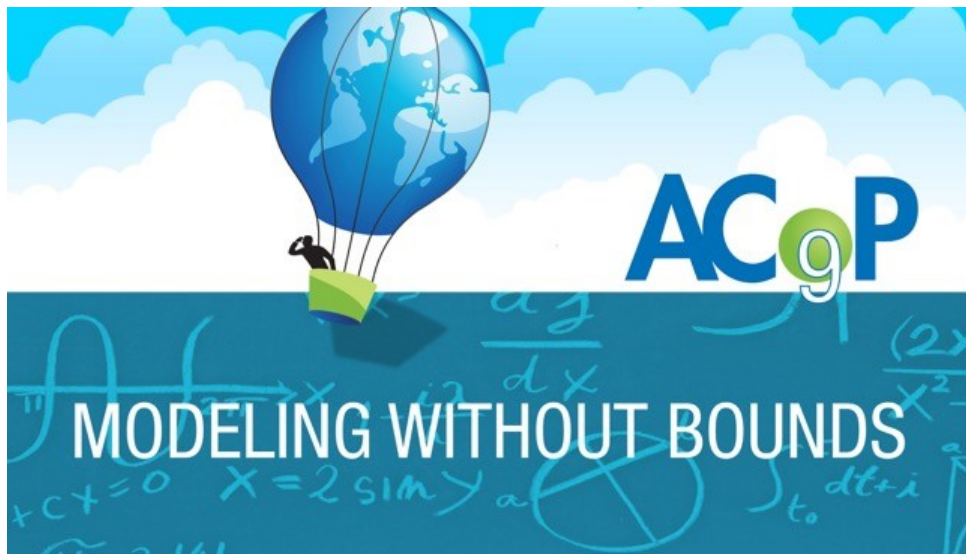


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**Causa Nostra: the potentially legitimate business of drawing causal inferences
from observational data**

Jim Rogers, Metrum

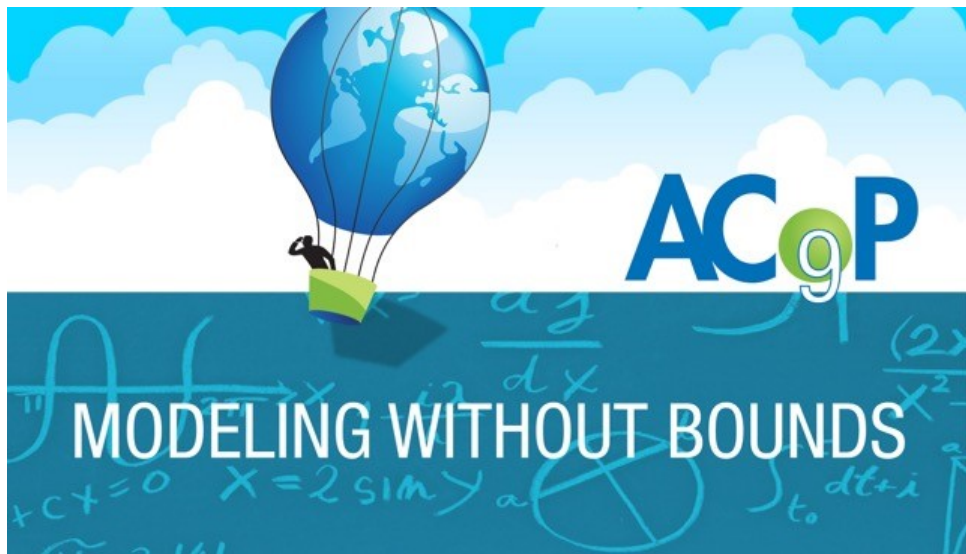


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Common concerns regarding the visualization of data and models

Andreas Krause, Idorsia



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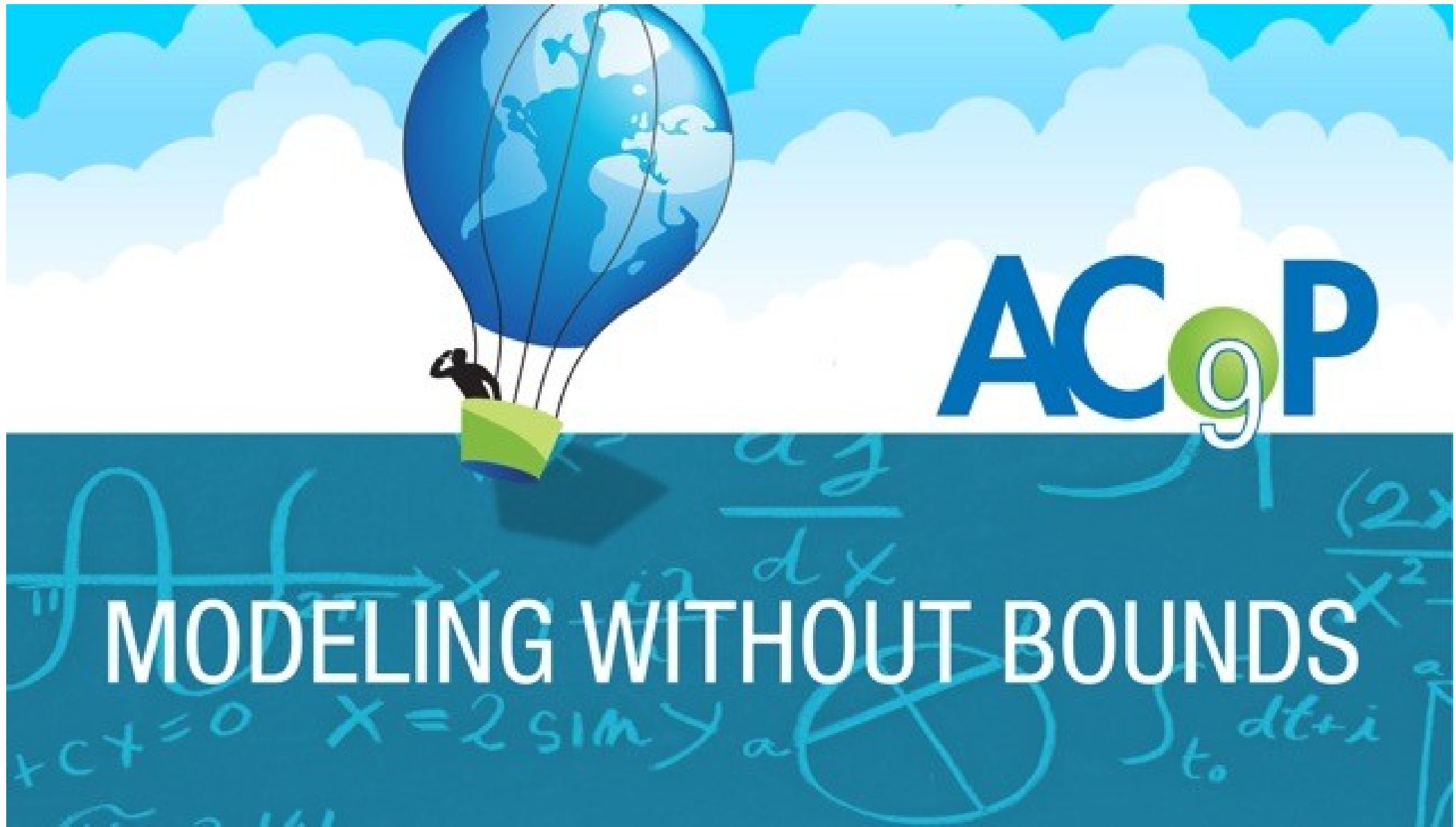
Chairs:
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Panel Discussion

**Robert Bies, Andreas Krause, Chao Liu (FDA), France Mentré, Bret Musser,
Jose Pinheiro, Junshan Qiu (FDA), Jim Rogers**

Dr. Chao Liu is a Team Leader in Department of Pharmacometrics (DPM) who covers cardiovascular products, anti-infectives, anti-virals, and oncology. He has a background in statistics and multiple projects overlapping with colleagues in the Office of Biostatistics (OB).

Dr. Junshan Qiu is formerly from OB where she covered submissions for neurology. She recently joined DPM and offers a valuable perspective on bridging mindsets and skillsets between the two disciplines.



San Diego, California

October 7 – 11, 2018