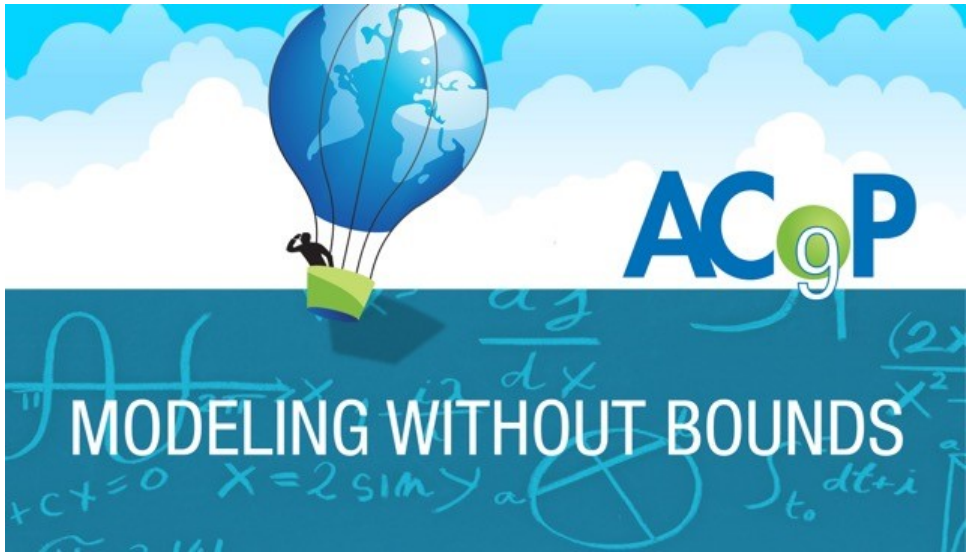
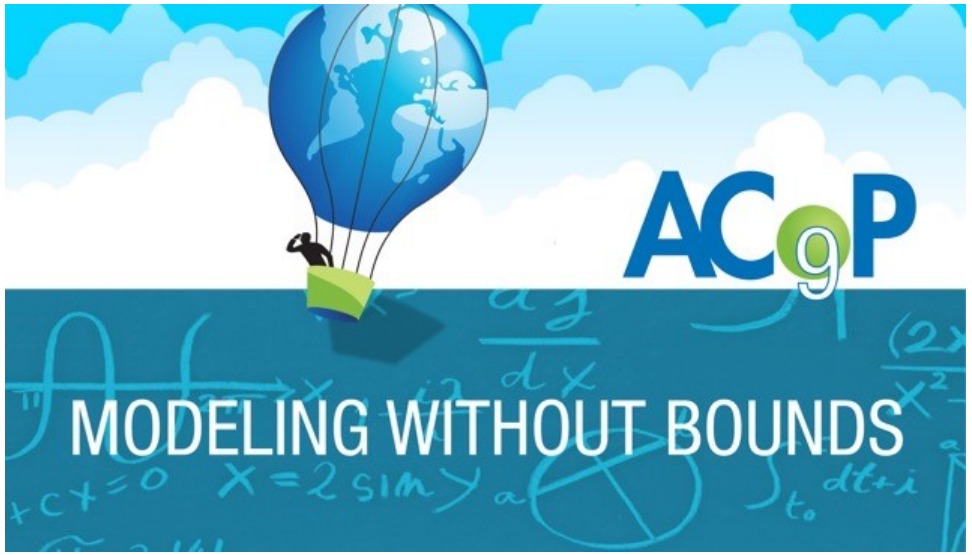


Session 4b:
Selected topics that would benefit from enhanced collaboration between statisticians and pharmacometricians
Chairs:
France Mentré and Robert Bies

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



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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.

ASA Statistics and Pharmacometrics Interest Group (SxP)

AMERICAN STATISTICAL ASSOCIATION
Promoting the Practice and Profession of Statistics®

ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

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 a 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)

ASA Statistics and Pharmacometrics Interest Group (SxP)

AMERICAN STATISTICAL ASSOCIATION
Promoting the Practice and Profession of Statistics®

ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

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

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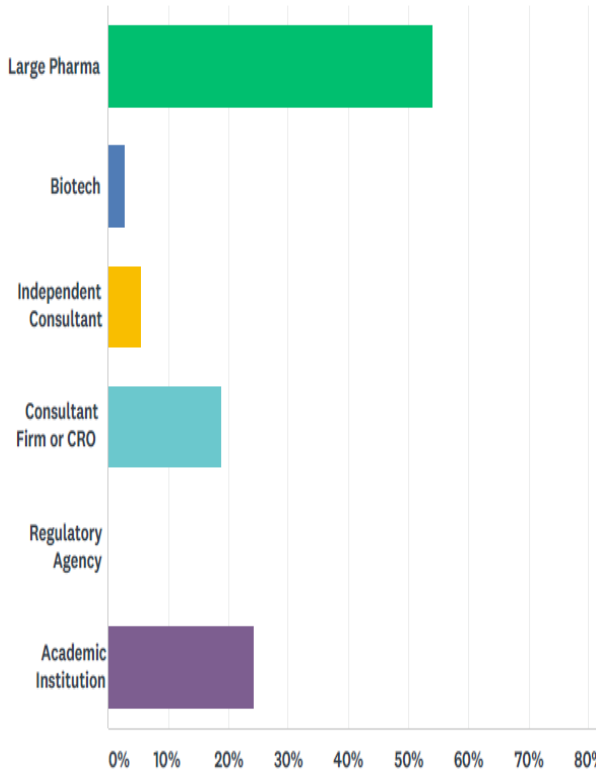
ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

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

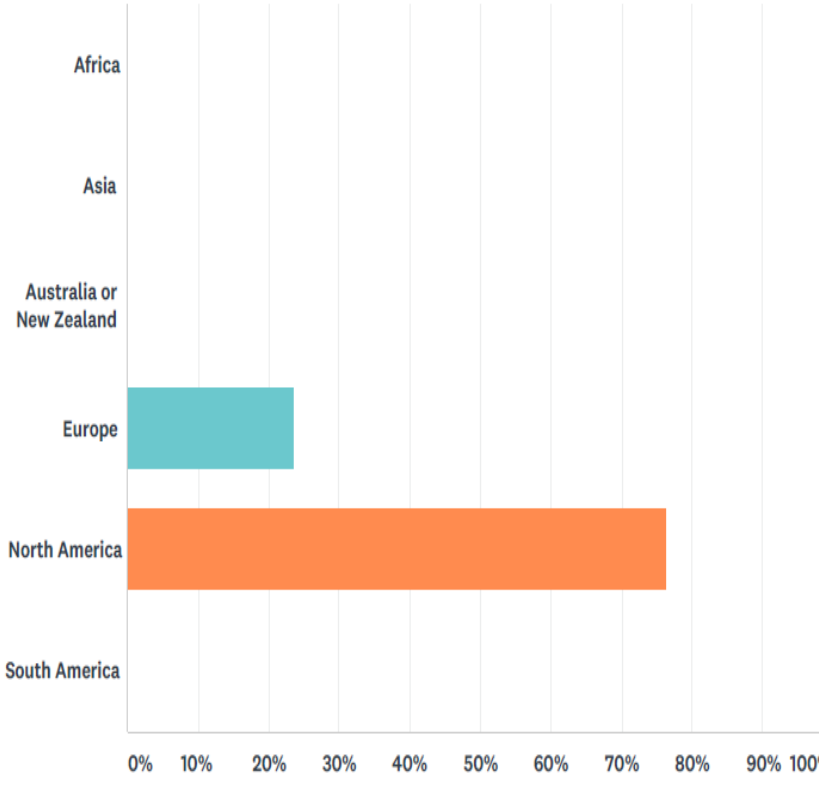
Q1 Who do you work for?

Answered: 37 Skipped: 1



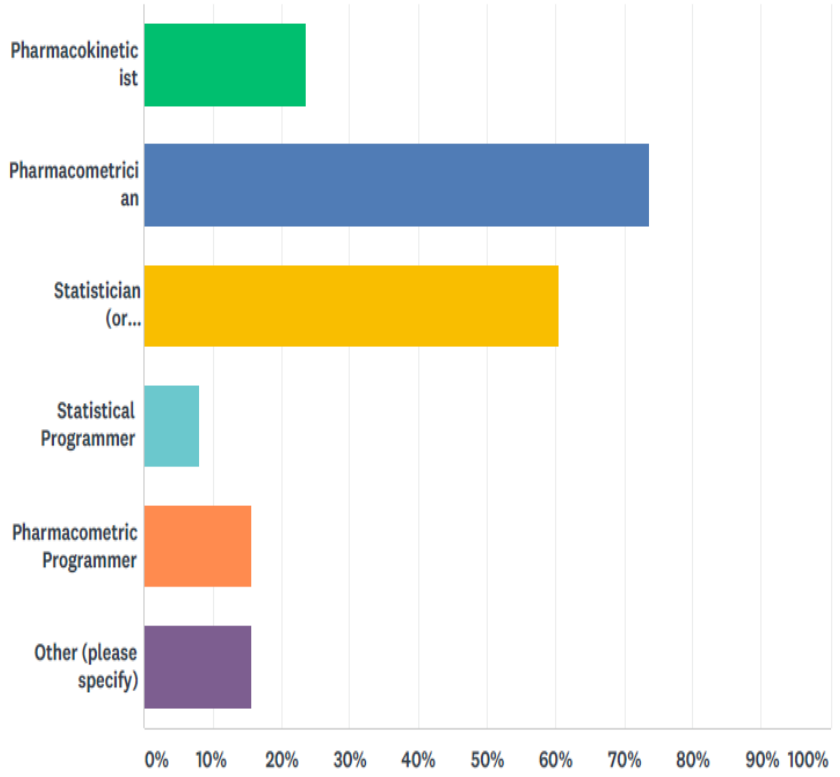
Q2 What is your location?

Answered: 38 Skipped: 0



Q3 Select all that you consider yourself to be.

Answered: 38 Skipped: 0



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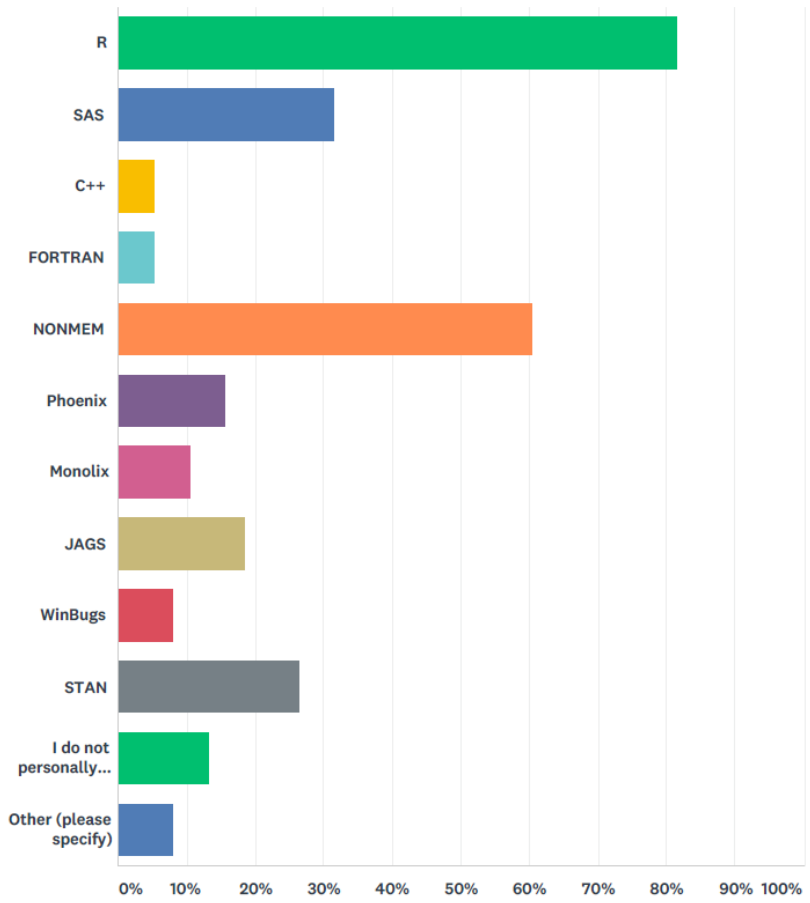
ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

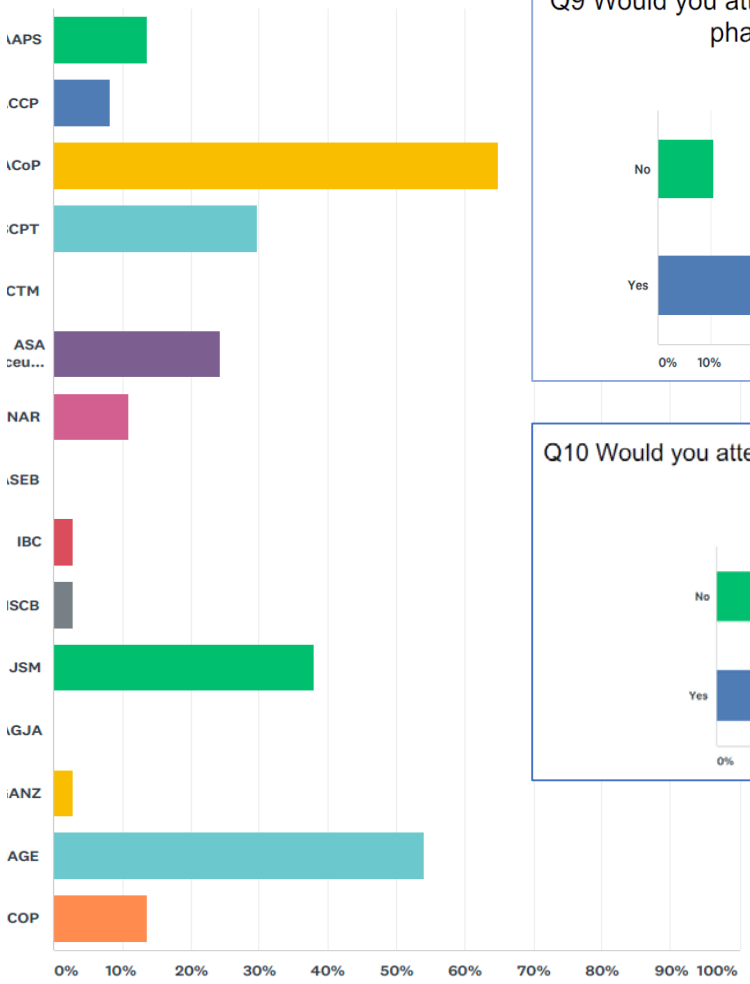
Q7 What software packages and languages do you use in your practice of pharmacometrics?

Answered: 38 Skipped: 0



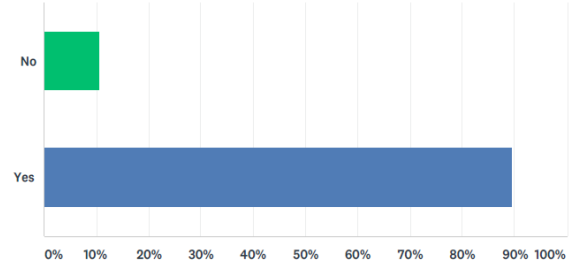
Q8 What conferences do you attend?

Answered: 37 Skipped: 1



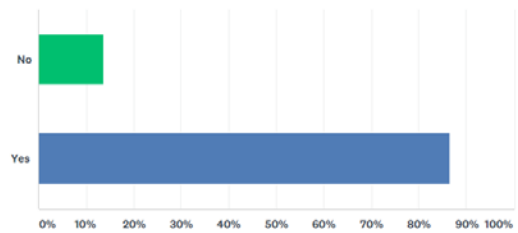
Q9 Would you attend statistical methodological sessions at pharmacometrics conferences?

Answered: 38 Skipped: 0



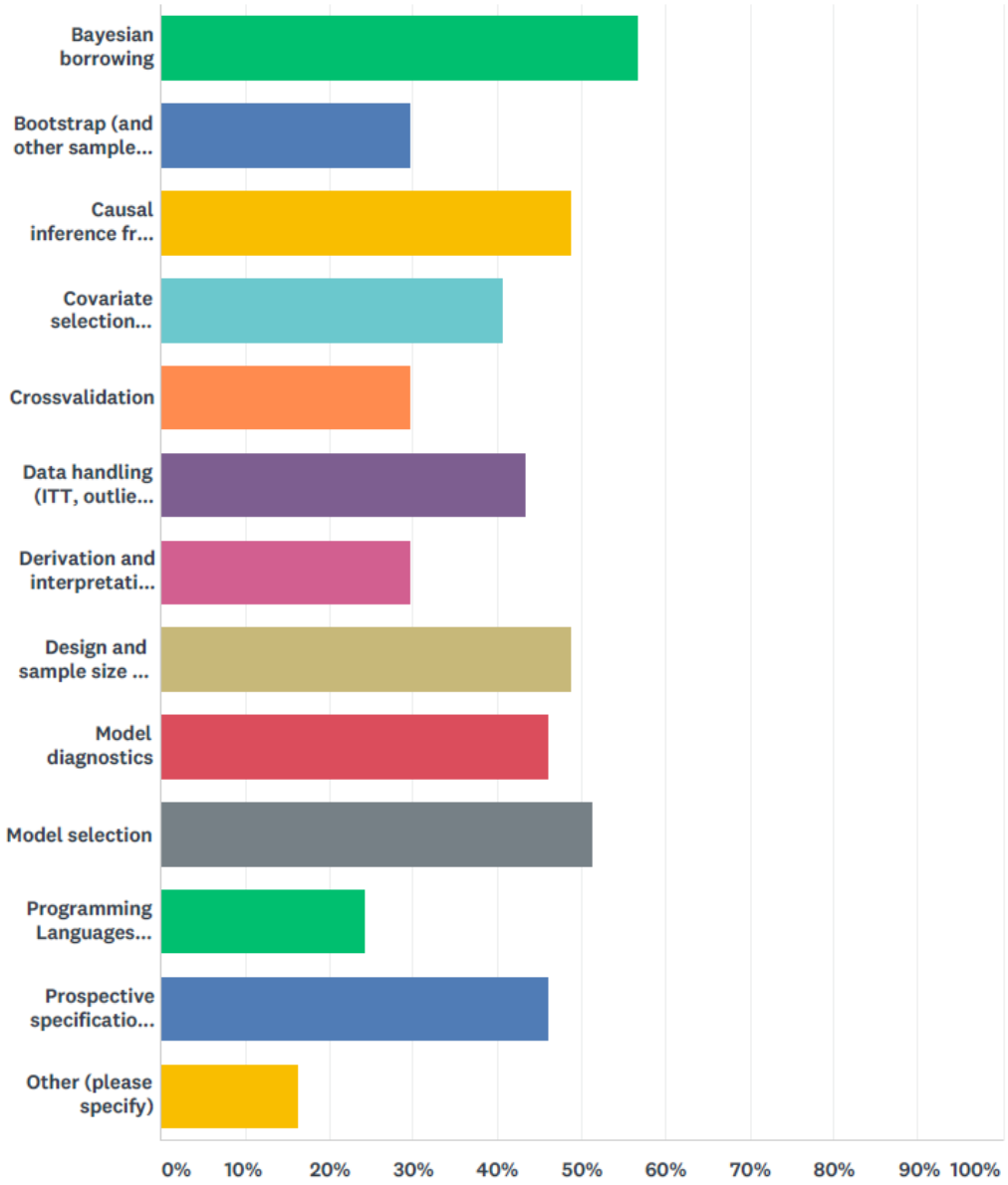
Q10 Would you attend sessions focusing on pharmacometrics instruction at statistics conferences?

Answered: 37 Skipped: 1



Q12 Which topics would you like to know more about?

Answered: 37 Skipped: 1

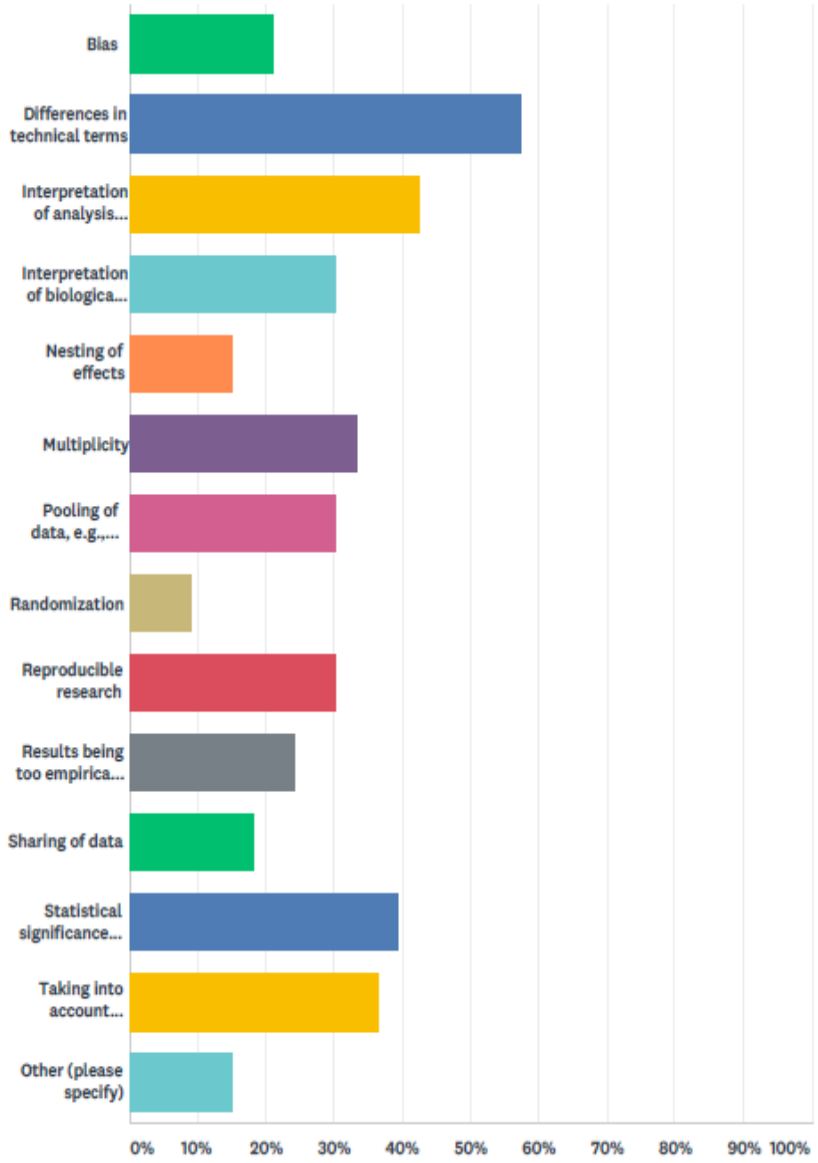


#	OTHER (PLEASE SPECIFY)
1	Utilizing PMx/Stats output for business decision making
2	Meta-analyses; Identifiability; Model averaging; Structural equation models; Unsupervised classification methods;
3	"Bayesian borrowing" sounds like either an complex mortgage product or a new way that my kids would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

Statistics and Pharmacometrics Interest Group (SxP)

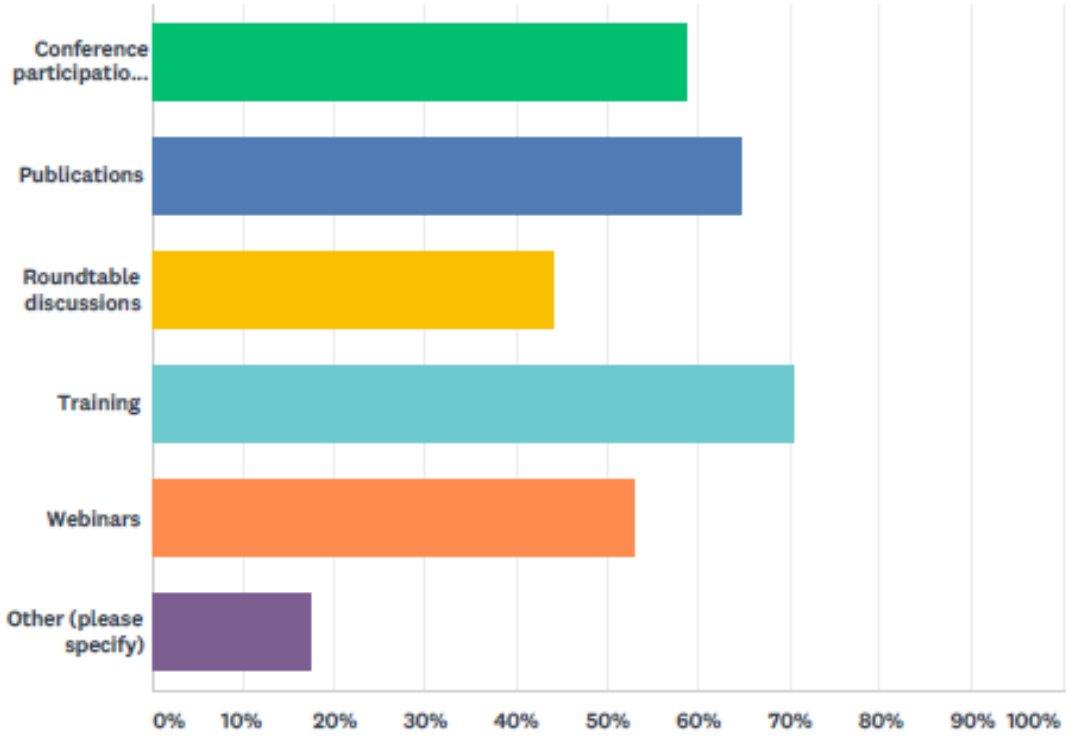
Q13 When statisticians and pharmacometricians collaborate, what are the most confusing or troubling topics discussed?

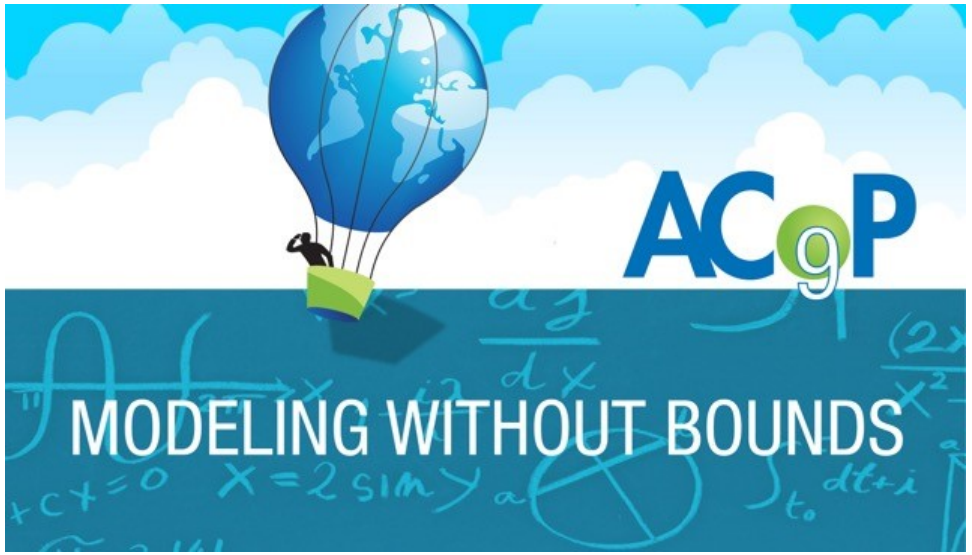
Answered: 33 Skipped: 5



Q14 How should these difficulties from Question 13 be addressed?

Answered: 34 Skipped: 4





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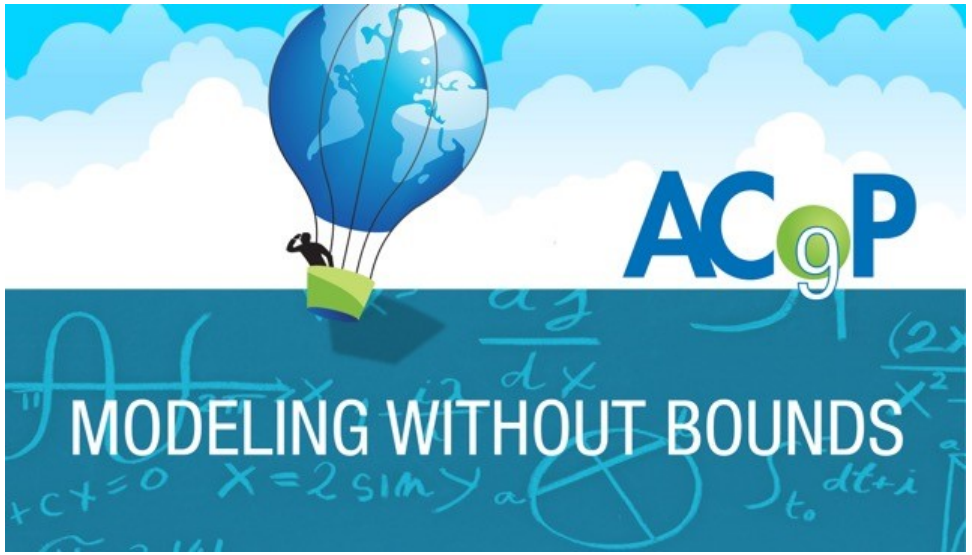
Multiplicity issues with covariate analysis: strategies and perspectives on pre-specification of pharmacometric analyses

José Pinheiro, J&J



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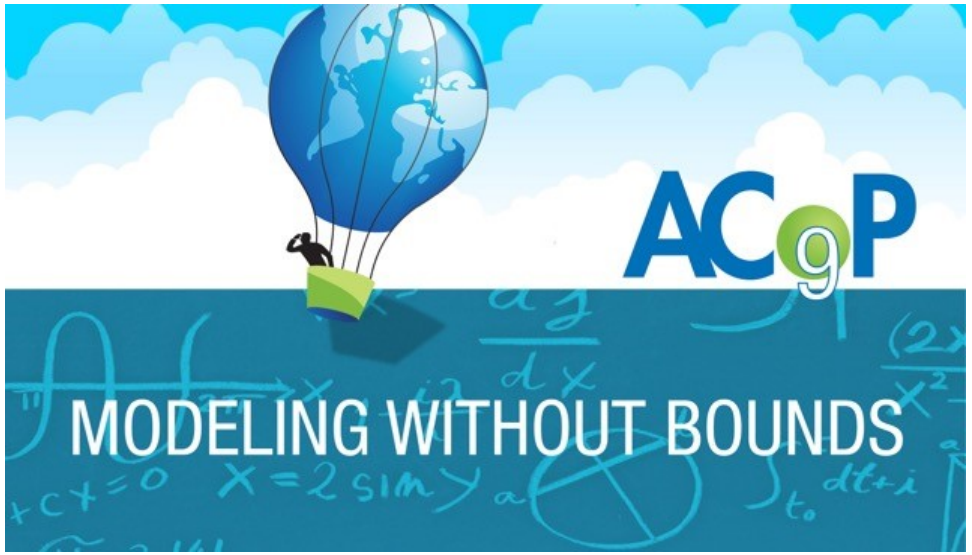
Causa Nostra: the potentially legitimate business of drawing causal inferences from observational data

Jim Rogers, Metrum



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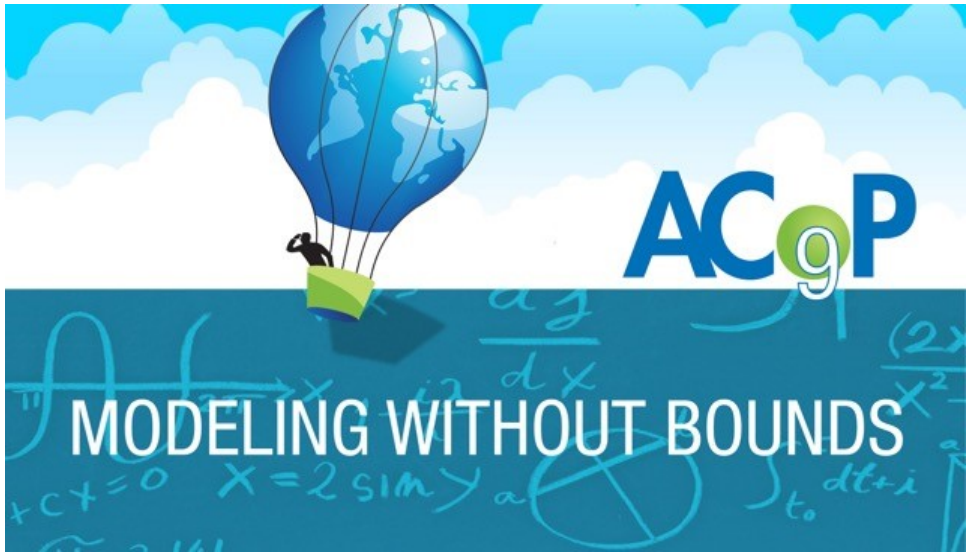
Common concerns regarding the visualization of data and models

Andreas Krause, Idorsia



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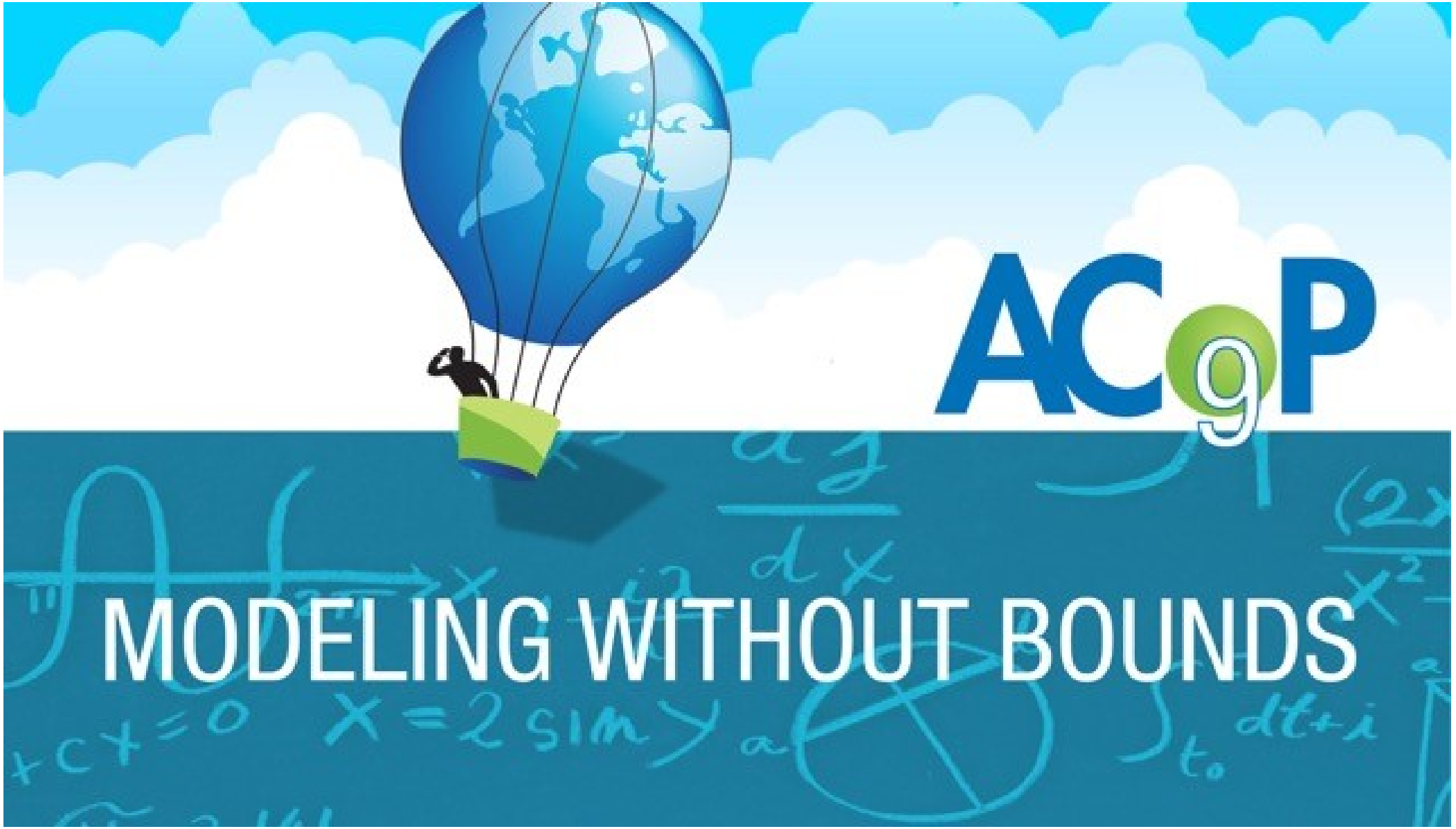
Panel Discussion

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