ASA AMERICAN STATISTICAL ASSOCIATION Promoting the Practice and Profession of Statistics

Statistics and Pharmacometrics Interest Group (SxP)

ISOP INTERNATIONAL SOCIETY OF PHARMACOMETRICS

- 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
  - Co-chairs: Bret Musser (Merck) & Matt Rotelli (Lilly)
  - Fred Balch (U Utah), Rob Bies (U Buffalo), Brian Corrigan (Pfizer), Kevin Dykstra (qPhametra), Manolis Efthymios (EMA), Jonathan French (Metrum), Lena Friberg (U Uppsala), Alan Hartford (Abbvie), France Mentre (U Paris Diderot & INSERM), Jose Pinheiro (J&J), Dionne Price (FDA), Garry Rosner (Johns Hopkins), Vikram Sinha (FDA), Brian Smith (Novartis), Jing Su (Merck), Neelima Thaneer (BMS), Jingtao Wu (Takeda)

- Membership open to everyone
- Join http://community.amstat.org/sxp/home

SxP organizes sessions in both statistics & pharmacometrics conferences

- **PAGE (June 2016):** First announcement of SxP
- **ACOP7 (Oct 2016):** Meet the ASA/ISoP Stat SIG
- **Joint Statistical Meeting (July 2016):** A mixer on SxP SIG

- **WCoP 2016 (August 2016)**
  Session: Bridging the gap between pharmacometricians and statisticians
- **ASA/FDA Regulatory-Industry Statistics Workshop (Sept 2016)**
  Panel session: Moving pharmacometrics and statistics beyond a marriage of convenience - Improving discipline synergy and drug development decision making
- **ASCPT (March 2017)**
  Symposium: Using biomarkers to predict registration endpoints: a look inside the crystal ball
- **Joint Statistical Meeting (July 2017)**
  Session: Pharmacometric Programming
- **Joint Conference on Biometrics & Biopharmaceutical Statistics (August 2017)**
  Session: Collaboration space between statistics and pharmacometrics: Opportunity and Challenges
- **ACOP8 (Oct 2017)**
  Symposium: Integrating quantitative disciplines - Making model-informed discovery and drug development (MID3) work in practice
- .....

Statistics and Pharmacometrics - Why I care

By Matthew D. Rotelli posted 10 days ago

1 Recommend

I'm a statistician and a pharmacometrician. Some people think I'm better as one than the other; some don't think I'm very good at either. I've been a statistician longer, but I've been a pharmacometrician for the last six years. Personally, I'd like to excel at both. Then I would be able to do a better job of capturing what I have learned and observed in experiments through models. I could use those models to improve my next design. I could use the new data to refine my models, and so on. By the end of development, I could use what I have learned from my experiments and models to provide stronger evidence and better information about the safe and efficacious use of the drugs. I'd be able to use the data that subjects and patient volunteers have taken the time and had the courage to provide to drive better decisions about whether and how a drug should be developed. I could get the drugs that are safe and effective to the broader patient population more quickly. That's the main reason most of us got into the pharmaceutical area; so I definitely wish I could do it better. Then, maybe the more efficient approach to development (quicker abandonment of bad molecules, higher probabilities of success for good molecules, and more efficient designs) will lead to reductions in spending on medicines and, through better outcomes, the even more important reductions in the overall spend on healthcare. That's a side effect I could tolerate!

But try as I might, I just can't seem to learn everything I need to know about statistics and pharmacometrics. So I need to lean on the expertise of my colleagues in both those fields. Fortunately, there are some statisticians who have a great understanding of pharmacometrics, and some pharmacometricians who have a great understanding of statistics. More likely, on any given project, I encounter a really good statistician and a really good pharmacometrician. It's amazing when they work together really well. However, too often, whether due to organizational structure or workload, they don't spend enough time interacting. It is often difficult to understand the other's approach, particularly when seeing it for the first time. It can be frustrating when either one objects to the conclusions drawn by the other. My experience has been that it is very rare that one is right and the other is wrong. They each apply different philosophies, they often are seeking to answer different questions, they use different terminology, and they almost always start with different assumptions. I'm hoping I can use my combined background to facilitate bridging the two disciplines. It's not as convenient as being able to do it all myself of course, but it's much more feasible. It should also be a great relief to those that don't think I'm very good at either!

When the different approaches do result in the same conclusions, that's great! We can be more confident in what we have learned. The data is clear, the signal is strong, and we have a good understanding of the underlying processes. It's when the different approaches don't agree that there is a great opportunity for learning and improvement. Something unexpected has happened, or there is a gap in our knowledge. Often, the in-depth discussion of the different approaches can lead to good hypotheses which can be subsequently evaluated. Sometimes, it highlights the need for more data or additional experiments. Either way, our knowledge and certainty will improve or we can highlight the uncertainties remaining.

To achieve the vision of efficient drug development, we must realize the synergies between statistical and pharmacometric approaches. We need to take the time to explain our models, understand the differences in approaches, understand what it implies if conclusions are similar or if they're not, and leverage each approach to continually inform and improve the other. I may never be as good at either discipline as I'd like to be, but at least my experience has taught me the value of both. I hope we continue to find ways to work together to bring better medicines to patients faster.

All Time ▾

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We build too many walls
and not enough bridges.
~ Isaac Newton