Cytel
Shaping the Future of Drug Development

Key Takeaways from ASCPT 2017

Session Insights from Cytel Quantitative Pharmacology and Pharmacometrics Experts

Trends in Model-Informed Drug Development: Our ASCPT Takeaways

The ASCPT is the largest scientific and professional organization serving the disciplines of Clinical Pharmacology and Translational Medicine, and its annual conference is one of the most important events on the calendar for those involved in Quantitative Pharmacology and Pharmacometrics (QPP). Cecilia Fosser, Nand Kishore Rawat and Tina Checchio represented Cytel's expanding QPP team at this year's event in Washington DC. In their experience, the meeting represents an excellent opportunity to keep up to speed with new trends and techniques within the space, and the quality of presentations is consistently high. In this synopsis, we summarize some of the particular highlights from the sessions that our team members attended, along with other takeaways from the event.

SYMPOSIUM: Using Biomarkers to Predict Registration Endpoints: A Look inside the Crystal Ball

This symposium was co-chaired by our Director Quantitative Pharmacology and Pharmacometrics Cecilia Fosser. The session incorporated presentations exploring a number of topics including efforts underway for an evidentiary pathway to qualification of surrogate endpoints and the use of biomarkers and quantitative models to guide dose selection.

Bret Musser of Merck presented on the biomarker to Phase 3 dose-finding – adaptive drug development strategy that was developed along with Cytel's Nitin Patel, Jim Bolognese, and Jaydeep Bhattacharyya.

Richard Lalonde, PharmD of Pfizer presented on linking exploratory clinical development endpoints to phase 3 endpoints. In his talk, Lalonde highlighted the troubling fact that lack of efficacy continues to be the biggest reason for drug failure during phase 3 development. He went on to note that Probability of Success (PoS), is very important in trial designs, as well as power calculations, and highlighted the important distinction between the two, cautioning that researchers should not ignore PoS.

Since PoS accounts for expected treatment effect and uncertainty and statistical power is typically based on an assumed effect size, a statistical power of 90% could actually result in a very low Probability of Success. Lalonde suggested that this may account for high Phase 3 attrition. He went on to present a case study on how biomarkers can be used to help understand the variability of response expected in a registration endpoint, which ultimately led to the decision to run a smaller trial.

It is a testament to the importance and popularity of these topics that the room reached maximum capacity for this session and an overflow room was opened.

Organs-on-Chips: a technology platform for translation and precision medicine.

Geraldine A. Hamilton, PhD, Emulate, Inc. Boston, MA.

A number of our team were excited about this presentation and the potential applications for the technology. The organs-on-chips technology platform enables human cells from many different organs to be grown in a dynamic microenvironment that simulates the actual physiological environment found in human cells - all inside a small, flexible chip. This has the potential to provide researchers with more informative, predictive information at an earlier stage.

Bridging the Gap Between Pharmacometricians and Statisticians in Clinical Pharmacology and Therapeutics France Mentré, MD, PhD, University of Paris Diderot, Paris, France

This talk was both well attended and very interesting. France highlighted many important contributions statisticians have made to the field of pharmacometrics and discussed a number of model optimization approaches that have been greatly improved with statistical approaches.

Integration of Genomics and Translational Clinical Pharmacology to Guide Development of Precision Medicines

Using examples from two different therapeutic areas, this session set the scene from a clinical perspective, illustrating why there is a need for optimizing therapy and what information drives the decision making. The session included an interesting discussion around the need for effective integration of information on drug concentrations and biomarkers with decision support tools such as dashboards to allow physicians to generate tailored treatment recommendations for patients.

Networking Discussions and Poster Session

During discussions with colleagues in the networking breaks, our Tina Checchio learned more about the potential upcoming development of an industry-wide consortium on Non-Compartmental Analysis (NCA). The objective of this consortium will be to standardize NCA across the industry and so has the potential to improve consistency and efficiency. We will watch with interest for further news and developments on this topic.

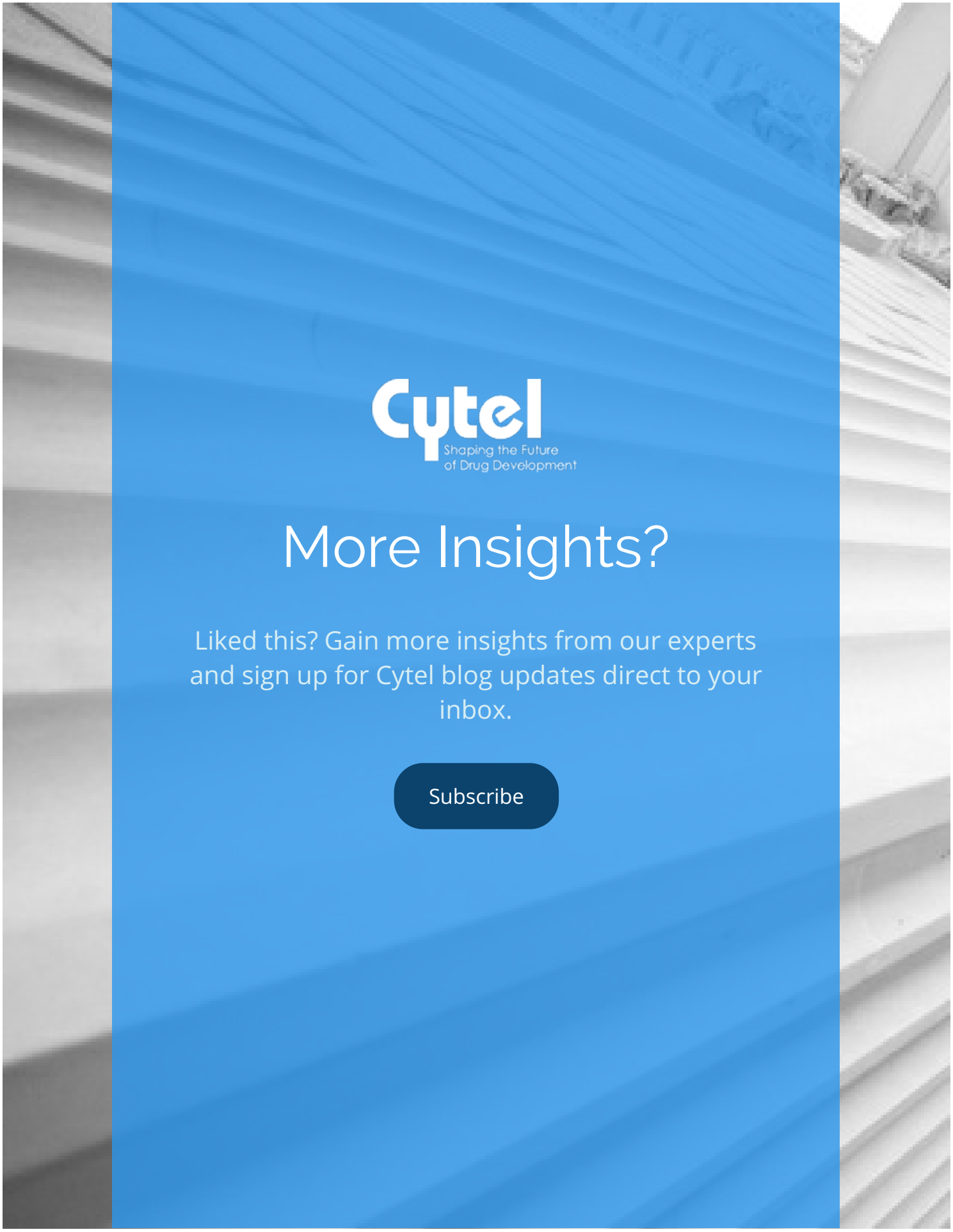
Our Nand Kishore Rawat noted the excellent ongoing opportunities throughout the meeting to discuss and evaluate new tools and technologies through networking with developers, customers, and vendors. In Special Interest Group sessions it was also possible to exchange implementation tips and techniques with industry peers.

The poster session attracted some exceptionally high-quality contributions from Pharma, Biotech, CRO, and academic stakeholders. This kind of cross-sector collaboration is essential for advancing scientific knowledge in the field, and there were good opportunities for discussion with the poster presenters.

The Netherlands' CHDR shared a number of its top rated posters with ASCPT delegates including

- **A study to assess the tolerability, pharmacokinetics and pharmacodynamics of ONS-3010 (Adalimumab, Oncobiologics Inc.) compared to Humira® EU/US, AbbVie) in healthy subjects**

The ASCPT Conference successfully brings together a multi-disciplinary field of experts dedicated to improving outcomes in clinical development by promoting best in class science. By combining pharmacometrics, biostatistics and pharmacokinetic techniques, and applying them across the product life cycle, we can aim to develop a deeper understanding of a drug candidate's properties and make better decisions, earlier.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