IABS 5th Statistics Workshop-Approaches for CMC development and lifecycle management of biotherapeutics and vaccines

November 26 - 28, 2018

USP Headquarters, Rockville

Co-organized by IABS and FDA

This meeting is to bring together regulators, and scientists, or those interested in statistics from academia and industry, who have a background in statistics, to help resolve existing challenges in ensuring the quality of biotechnology medicinal products and to bring high quality medicines to patients. Guidance on how to use statistics for a variety of activities required during biotechnology product development such as method development, improvement and replacement, product comparability, biosimilarity exercises and stability program development will be provided by the speakers and panel members. In addition, the complexity of the types of data and the volume being analysed is ever increasing and how best to manage such data will be discussed. The meeting will bring the right experts together to discuss the issues and through roundtables attempt to reach conclusions that will be valuable globally to public health.

Scientific / Organizing Committee

Tim Schofield	Chair; GlaxoSmithKline	Daniel Obeng	Sanofi
Richard K. Burdick	Arizona State University	Laura Pack	Seattle Genetics
Robert Capen	Merck & Co., Inc.	Jose Ramirez	Amgen
Katherine Giacoletti	SynoloStats	Andrew Rugaiganisa	Merck & Co.
Kristi Griffiths	Eli Lilly & Company	Meiyu Shen	FDA / CDER
Ruojia Li	Bristol-Myers Squibb	Jyh-Ming Shoung	Janssen
Tsai-Lien Lin	FDA	Percival Sondag	Pharmalex
Charles Miller	Merck & Co., Inc.	Yi Tsong	FDA / CDER

AGENDA

Day 1 – Monday, November 26, 2018

Short Course - Bayesian Statistics and Applications Overview (Free with attendance)

Chairpersons: Jose Ramirez, Amgen; **Kristi Griffiths**, Eli Lilly & Company

12:30pm	Registration
1:00pm	Introduction
1:10pm	**Bruno Boulanger**, Pharmalex
3:00pm	Coffee Break
4:50pm	Questions & Wrap-up
5:00pm	End of Short Course

Day 2 – Tuesday, November 27, 2018

7:30am	**Registration & Welcome Coffee**
8:00am	Introduction to the meeting and IABS **Tim Schofield**, GlaxoSmithKline

Keynote Speaker:

8:15am	Bayesian approaches and decision-making: lessons from clinical trials **John Scott,** FDA/CBER

Session 1 – Applications in Early Clinical Development, Big Data, & USP

Chairpersons: Tim Schofield, GlaxoSmithKline; **Andrew Rugaiganisa,** Merck & Co.

8:45am	Unsupervised machine learning for improved understanding, optimization, process monitoring, and fault diagnosis in early development **Nelson Afanador**, Merck & Co.
9:15am	Coffee Break
9:45am	Bayesian inference in USP<1010>?... rationale and examples **Dave LeBlond**, CMC Stats Roundtable discussion
10:15am	**Facilitator: Robert Capen,** Merck & Co. **John Scott**, FDA/CBER; **Nelson Afanador**, Merck & Co.; **Dave LeBlond**, CMC Stats
12:00pm	Lunch

Session 2 - Examples and Challenges in Biotech and Vaccines Development

Chairpersons: Perceval Sondag, Pharmalex; **Tsai-Lien Lin**, FDA/CBER

1:00pm	A sequential learning approach to quantify long term variability in biologics manufacturing processes **Christopher Thompson**, MedImmune
1:30pm	Comparison of tests on means vs ranges in comparability revealing min-max as a cautionary tale **Franz Innerbichler**, Novartis
2:00pm	Coffee Break
3:00pm	Applying modeling and machine learning for bioprocess development **Steffen Sass,** Roche
3:30pm	Roundtable discussion **Facilitator**: **Ruojia Li**, Bristol-Myers Squibb **Christopher Thompson**, MedImmune; **Franz Innerbichler**, Novartis; **Steffen Sass**, Roche
5:00pm	End of Day 2

Day 3 – Wednesday, November 28, 2017

Session 3 – Examples and Challenges in Biotech and Vaccines Manufacture and Control

Chairpersons: Daniel Obeng, Sanofi; **Meiyu Shen,** FDA/CBER

8:15am	Using Bayesian approach in setting specifications for biotech products **Hesham Fahmy**, AbbVie
8:45am	Directly assessing process impact using Monte Carlo simulation to determine comparability of two blood gas analyzers **Todd Regh**, Sanofi
9:15am	Coffee Break
9:45am	Bayesian tolerance bounds for non-normal data **Jose Ramirez**, Amgen
10:15am	Roundtable discussion **Facilitator**: **Chuck Miller**, Merck **Hesham Fahmy**, AbbVie; **Todd Regh**, Sanofi; **Jose Ramirez**, Amgen
12:00pm	Lunch

Session 4 – Industry, Academic, Regulatory Panel

Facilitators: Jyh-Ming Shoung, Janssen; **Katherine Giacoletti**, SynoloStats

Panelists:

Meiyu Shen, FDA/CBER
Tsai-Lien Lin, FDA/CBER
Guillermo Miro-Quesada MedImmune
Bill Pikounis, Janssen
Dean Smith, Health Canada
Silke Werz, Roche

1:00pm	Introduction
1:10pm	Discussion
2:30pm	Coffee Break
3:00pm	Continuation of Panel
4:30pm	Summary of panel discussion
4:40	Workshop Summary **Laura Pack**, Seattle Genetics
5:00pm	End of Day 3