4th Statistical and Data Management Approaches for Biotechnology Drug Development

October 30-November 1, 2017
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

Tony Mire-Sluis	AstraZeneca	Bill Pikounis	Centocor
Richard K. Burdick	Arizona State University	Andrew Rugaiganisa	Pfizer
Robert Capen	Merck & Co., Inc.	Tim Schofield	GlaxoSmithKline
Kristi Griffiths	Eli Lilly and Company	Volker Schnaible	Roche
Ruojia Li	Bristol-Myers Squibb	Meiyu Shen	FDA / CDER
Tsai-Lien Lin	FDA	Harry Yang	Medimmune LLC
Anthony Lonardo	Eli Lilly and Company	Yi Tsong	FDA / CDER
Dan Obeng	Sanofi Genzyme	Lanju Zhang	AbbVie
Laura Pack	Seattle Genetics		

AGENDA

Day 1 – Monday, October 30, 2017

7:30am **Registration & Welcome Coffee**

8:00am Introduction to the meeting and IABS
Tony Mire-Sluis, Chair – IABS Human Therapeutics Committee

Keynote Speaker

8:15am Roles and strategies used by nonclinical statisticians supporting biopharmaceutical development
Tim Schofield, GlaxoSmithKline

Session 1 – Statistical requirements for analytical method analysis, transfers, trending and specifications setting

Chairpersons: Mike Walsh, Health Canada; **Andrew Rugaiganisa**, Pfizer

8:45am Equivalence Margin Considerations for Analytical Method Transfers
Daniel Obeng, Sanofi Genzyme

9:15am Analytical method performance trending
Ruojia Li, Bristol-Myers Squibb

9:45am Coffee Break

10:15am Design and statistical analysis of method transfer studies for biotechnology products
Lixin (Leo) Xu, FDA

10.45am Statistics in the context of clinically relevant commercial specification acceptance criteria
Kristi Griffiths, Eli Lilly and Company

11:15am Roundtable discussion
Chairperson: Mike Walsh, Health Canada
Daniel Obeng, Sanofi Genzyme**; Ruojia Li**, Bristol-Myers Squibb; **Lixin (Leo) Xu**, FDA; **Kristi Griffiths**, Eli Lilly and Company

12:00noon Lunch

Session 2 - Statistical approaches for stability trending

Chairpersons: Meiyu Shen, FDA / CDER**; Jyh-Ming Shoung,** Janssen

1:00pm A fit-for-purpose perspective on Shel-Life and Internal Release Limits determination: objectives and models
Perceval Sondag, Arlenda

1:30pm Trending analysis for stability: predicting expiry for annual lots
Laura Pack, Seattle Genetics

2:00pm Alternative statistical approaches to shelf life estimation
Walter Stroup, University of Nebraska-Lincoln

2:30pm Coffee Break

3:00pm Issues in the statistical inference of stability data
Mike Walsh, Health Canada

3:30pm Going hither and yon: Q1E Stability modeling in practice
Areti Manola, Janssen

4:00pm Roundtable discussion
Chairperson: **Kristi Griffiths**, Eli Lilly and Company
Perceval Sondag, Arlenda; **Laura Pack**, Seattle Genetics; **Walter Stroup**, University of Nebraska-Lincoln; **Mike Walsh**, Health Canada; **Areti Manola**, Janssen

5:00pm End of Day 1

Day 2 – Tuesday, October 31, 2017

Session 3 – Using statistics in process validation and CPV

Chairpersons: Ben Ahlstrom, Amgen; **Mike Rose**, Sanofi Genzyme

8:30am PPQ criteria for intra-batch variability and assessment of homogeneity
Rick Burdick, Elion Labs

9:00am Your Trending Program: Considerations when Setting Decision Criteria and Assessing Performance
Ryan Yamagata, GlaxoSmithKline

9:30am ISPE PQLI PV team – overview of discussion papers
Maneesha Altekar, AstraZeneca

10:00am Coffee Break

10:30am The role of sampling to support process validation and comprehensive process verification of biopharmaceuticals
Mark Johnson, AbbVie

11:00am Estimation of platform process variation from large-portfolio datasets
Roger Hart, Amgen

11:30am Roundtable discussion
Chairperson: **Tim Schofield**, GlaxoSmithKline
Rick Burdick, Elion Labs; **Ryan Yamagata**, GlaxoSmithKline; **Maneesha Altekar**, AstraZeneca; **Mark Johnson,** AbbVie; **Roger Hart**, Amgen

12:15pm Lunch

Session 4 – The interactions and regulatory communications of non-clinical statisticians during product development

Chairpersons: Tilanthi Jayawardena, Biogen**; Rick Burdick**, Elion Labs

1:15pm Ten secrets of a successful non-clinical statistician
Dan Weese, Amgen

1:45pm From DOEs to CPPs: Statistical strategies for product development that begin with the end in mind
Lisa Bernstein, Roche-Genentech**; Oana Danila**, Roche

2:15pm How best to interact with regulators
Harry Yang, MedImmune

2:45pm Coffee Break

3:15pm A regulators experience of non-clinical statistical interactions with industry
Meiyu Shen, FDA

3:45pm Roundtable discussion
Chairperson: Laura Pack, Seattle Genetics
Dan Weese, Amgen; **Lisa Bernstein**, Roche-Genentech**; Oana Danila**, Roche; **Harry Yang**, MedImmune; **Meiyu Shen**, FDA

4:45pm End of Day 2

Day 3 – Wednesday, November 1, 2017

Session 5 - The use of statistics for biosimilar drug development

Chairpersons: Harry Yang, MedImmune; **Hesham Fahmy**, Abbvie

8:15am Tier 1 Statistics
Jose Ramirez, Amgen

8:45am Assessment of analytical similarity: report from an European Working Group
Bruno Boulanger, Arlenda

9:15am Using simulations to explore properties of equivalence testing for analytical similarity
Franz Innerbichler, Novartis, Austria

9:30am Statistical methods for analytical similarity assessment
Yi Tsong, presented by Meiyu Shen, FDA

9:45am Coffee Break

10.30am Roundtable discussion
Chairperson: Tsai-Lien Lin, FDA
Jose Ramirez, Amgen; **Bruno Boulanger**, Arlenda; **Franz Innerbichler**, Novartis, Germany

11.30am Summary of Meeting
Tony Mire-Sluis, AstraZeneca; **Tim Schofield**, GlaxoSmithKline

12:00pm Lunch