6th IABS Statistics Workshop

**Approaches for Improving Statistical Partnership in
CMC Development, Manufacturing, and Regulation of Biologicals**

**November 2-5, 2020
A Virtual Meeting
v. September 16, 2020**

CMC statisticians work in partnership with development, manufacturing, and regulatory colleagues providing solutions and leadership to the biologicals industries. This 6th IABS Statistics Workshop will explore both hurdles and achievements related to successful administration of sound statistical practices in the planning and implementation of development studies, in the advancement of strategic lifecycle management plans, and in contributions to the regulatory landscape. Areas of exploration will include the roles of CMC statisticians as practitioner, teacher, student, and leader, and how this may differ from institution to institution and across an organization. Special attention will be given to organization and communication skills required for the CMC statistical community to be successful in integrating into the broader biologicals culture. Synergies and distinctions among statisticians, data scientists, and software will be evaluated, while timely topics such as p-values, equivalence testing, reproducible research and Bayesian analysis will be explored. The workshop will invite viewpoints from CMC statistics management and personnel, from development and manufacturing partners, and from organizations such as CROs, compendia, and regulatory authorities. Rounds of presentations will be accompanied by panel discussions where workshop participants can engage the speakers and other experts on the value of and pathways to improvement of partnership between CMC statisticians and the rest of the biologicals community.

Scientific / Organizing Committee

Tim **SCHOFIELD**, Co-Chair, IABS, CMC Sciences, LLC
   Theodoro **KOULIS**, Genentech
   Rick **BURDICK**, Burdick Consulting
   Tsai-Lien **LIN,** FDA/CBER
   Guillermo **MIRO-QUESADA,** AstraZeneca
   Laura **PACK,** Seattle Genetics
   Christian **SEIFERT**, Boehringer-Ingelheim
   Jyh-Ming **SHOUNG,** Janssen

Kristi **GRIFFITHS**, Co-Chair, Eli Lilly & Company
   Katherine **GIACOLETTI,** Synolostats, LLC
   Ruojia **LI**, Bristol-Myers Squibb
   Jia **LIU,** Pfizer
   Julia **O'NEILL,** DirexaConsulting
   José **RAMIREZ,** Amgen
   Meiyu **SHEN,** FDA/CDER

DAY 1 – MONDAY, NOVEMBER 2, 2020

10:00am*   Introduction to the meeting and IABS
Tim SCHOFIELD, on behalf of IABS

10:10am   Alzheimer's Disease drug development: How statistics and teamwork create a story of resilience, collaboration, learning, and informed hope
Phyllis FERRELL, Eli Lilly & Company

Session I	*CMC statistics partnerships across the entire biologicals community*

Collaboration thrives in teams with a shared sense of purpose and urgency. Statisticians are recruited as key partners in some of the most intense projects supporting development, validation, and root cause investigations of biological products and test methods, and routine commercial production or testing. These partnerships are especially rich when the project continues with a core of consistent team members over a timeframe long enough to develop a shared language and common understanding of the scientific background, assumptions and priorities. Statisticians play an important role in evaluating evidence to challenge or support scientific assumptions. In these presentations, speakers will describe their experiences working as partners in high-intensity teams across the product or test method lifecycle.

Chairpersons: **Julia O'NEILL**, Direxa Consulting; Katherine **GIACOLETTI**, SynoloStats

10:40am   Session Introduction
Julia O'NEILL, Direxa Consulting

10:45am   Support for breakthrough designation approval
George ATKINS, GlaxoSmithKline Pharmaceuticals

11:15am   Just in time on the job (JITOTJ) statistical training
Melissa MATZKE, **Seth CLARK**, Merck & Co., Inc.

11:45am   **Break**

12:10pm   Driving product robustness through collaboration: statistics – a key pillar
Maneesha ALTEKAR, AstraZeneca

12:40pm   **Panel Discussion**
     Facilitator: Ruojia LI, Bristol-Myers Squibb
       Panelists: **Phyllis FERRELL, George ATKINS, Elissa MATZKE, Seth CLARK, Maneesha ALTEKAR**

1:40pm   **End Day 1**

* Times are Eastern Standard Time

DAY 2 – TUESDAY, NOVEMBER 3, 2020

Session II	*Roles of CMC statisticians*

CMC statisticians play different roles depending upon the areas they support (development, manufacturing, and regulatory authorities) and the cultures within their organizations. These roles have evolved over time with the introduction of new ideas and techniques, such as Six Sigma, and more recently with the advent of data science. In addition, the digital transformation revolution is redefining the role of the CMC statistician. As a result, CMC statisticians need to think strategically about how best to support a wide array of opportunities with limited resources. To be effective, CMC statisticians need to learn and employ various skills, such as communication, collaboration and leadership skills. This session will offer talks from CMC statisticians on their views and experiences as they relate to their alignment with and support to the biologicals CMC community.

Chairpersons: Christian SEIFERT, Boehringer Ingelheim**; Theodoro KOULIS,** Genentech

10:00am	Session Introduction **Theodoro KOULIS,** Genentech	
10:05am	CMC statistics and data science: working together in peace and harmony **Lori PFAHLER**, Merck & Co., Inc.	
10:35am	CMC statistics as quality function in a network of data scientists **Timo BAILER,** Boehringer Ingelheim	
11:05am	Break	
11:30am	Statisticians as successful business partners in data driven initiatives **David ENCK, Janssen Pharmaceuticals**	
12:00pm	**Panel Discussion** Facilitator: Christian SEIFERT, Boehringer Ingelheim Panelists: Lori PFAHLER, Timo BAILER, David ENCK, Gary SULLIVAN	
1:00pm	**End of Day 2**	

DAY 3 – WEDNESDAY, NOVEMBER 4, 2020

Session III	*Current trends in CMC statistical support of biologicals*

CMC statistical support has historically been marked by specific challenges linked to the molecular and biological complexity of the drugs manufactured. Currently there are multiple trends in this field, including: Cell and Gene therapies, application of novel machine learning and Bayesian techniques, development and control of continuous manufacturing processes, etc. A few examples of the use of statistical methodologies for these trends will be explored in this session.

Chairpersons: Guillermo MIRO-QUESADA, AstraZeneca**; Jia LIU,** Pfizer

10:00am	Session Introduction **Jia LIU,** Pfizer
10:05am	Statistical tools for improving process and product understanding for autologous therapies **Kedar DAVE**, Bristol-Myers Squibb
10:35am	Continuous manufacture: opportunities and challenges for statisticians **Stan ALTAN**, Johnson & Johnson
11:05am	**Break**
11:30am	TBD **Karthik IYER,** FDA/CDER/OPQ/OQS/DQII

12:00pm	**Panel Discussion**
	   Facilitator: Jyh-Ming SHOUNG, Janssen R&D
	      Panelists: Jia LIU, Kedar DAVE, Stan ALTAN

1:00pm	**End Day 3**

DAY 4 – THURSDAY, NOVEMBER 5, 2020

Session IV	*Science, statistics, and the [winding] path to discovery*

Many of the most successful and impactful statisticians started out in other areas of science before focusing on statistical science. In fact, the biography of one of the most eminent statisticians, R. A. Fisher, is titled "R. A. Fisher-The Life of a Scientist". Thus, it is not surprising that statisticians are often sought out to serve as thinking partners in scientific investigations. For successful statisticians, their roles go beyond just data processing and analysis, but they help formulate the scientific problem and develop practical strategies to help answer the scientific question. As this scientific collaboration evolves, opportunities for learning become available for both the statistician and the scientist. Solutions are formed and modified as both partners obtain new learnings and understanding.

This session will present a description of this process, and two testimonials of the benefits of such collaborative efforts. A panel discussion will follow to share more examples.

Chairpersons: José RAMIREZ, Amgen**; Rick BURDICK,** Burdick Consulting

10:00am	Session Introduction **José RAMIREZ,** Amgen
10:05am	Scientific contributions of Sir Ronald Fischer, FRS and Prof. George Box, FRS **José RAMIREZ,** Amgen
10:35am	The statistician's role as teacher, student, and scientific partner: an adventure in the CMC pharmaceutical industry **Rick BURDICK,** Burdick Consulting
11:05am	Break
11:30am	The scientist's roles as a teacher and student: a partnership in the CMC pharmaceutical industry **Amy HUANG**, Amgen

12:00pm	**Panel Discussion**
	       Facilitator: Laura PACK
	              Panellists: **José RAMIREZ**, **Rick BURDICK**, **Amy HUANG**

1:00pm	**Closing Keynote** Seeking a More Perfect Union: Statisticians and Scientists in CM&C **Gary SULLIVAN,** Espirer Consulting
1:30pm	**Workshop Summary** **Tim SCHOFIELD**, CMC Sciences, LLC
1:45pm	**Close of workshop**