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.
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

10:55am  Support for breakthrough designation approval  
George ATKINS, GlaxoSmithKline Pharmaceuticals

11:25am  Just in time on the job (JITOTJ) statistical training  
Elissa MATZKE, Seth CLARK, Merck & Co., Inc.

11:55am  Break

12:10am  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
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**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00am</td>
<td>Session Introduction</td>
</tr>
<tr>
<td></td>
<td><strong>Theodoro KOULIS, Genentech</strong></td>
</tr>
<tr>
<td>10:15am</td>
<td>CMC statistics and data science: working together in peace and harmony</td>
</tr>
<tr>
<td></td>
<td><strong>Lori PFAHLER, Merck &amp; Co., Inc.</strong></td>
</tr>
<tr>
<td>10:45am</td>
<td>CMC statistics as quality function in a network of data scientists</td>
</tr>
<tr>
<td></td>
<td><strong>Timo BAILER, Boehringer Ingelheim</strong></td>
</tr>
<tr>
<td>11:15am</td>
<td>Break</td>
</tr>
<tr>
<td>11:30am</td>
<td>TBD</td>
</tr>
<tr>
<td></td>
<td><strong>David ENCK, Janssen Pharmaceuticals</strong></td>
</tr>
<tr>
<td>12:00pm</td>
<td>Panel Discussion</td>
</tr>
<tr>
<td></td>
<td>Facilitator: Christian SEIFERT, Boehringer Ingelheim</td>
</tr>
<tr>
<td></td>
<td>Panelists: Lori PFAHLER, Timo BAILER, David ENCK, Gary SULLIVAN,</td>
</tr>
<tr>
<td>1:00pm</td>
<td>End of Day 2</td>
</tr>
</tbody>
</table>
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

10:15am  Statistical tools for improving process and product understanding for autologous therapies
Kedar DAVE, Bristol-Myers Squibb

10:45am  Continuous manufacture: opportunities and challenges for statisticians
Stan ALTAN, Johnson & Johnson

11:15am  Break

11:30am  TBC

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

1:00pm  End Day 3
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

10:15am  
Scientific contributions of Sir Ronald Fischer, FRS and Prof. George Box, FRS  
José RAMIREZ, Amgen

10:45am  
The statistician’s roles as teachers and student: an adventure in the CMC pharmaceutical industry  
Rick BURDICK, Burdick Consulting

11:15am  
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  
CMC Statistics in 2020: where we have been and where we can go  
Gary SULLIVAN, Espirer Consulting

1:30pm  
Workshop Summary
1:45pm  Close of workshop