Raritan
Transforming Data Visualization – A Peek into the Future of Clinical Data Analysis
June 8th 2017
Janssen, Raritan
Dear Attendees,

Welcome to our PhUSE Single Day Event (SDE) at Janssen of Johnson & Johnson, in Raritan, NJ. Raritan is located in one of America’s oldest counties, Somerset County, which was established from parts of Middlesex County in 1688 and named for the English county of Somerset. It was primarily an agricultural county until the 1960s, when suburban communities began to develop, largely due to the growth of the pharmaceutical and technology industries in the area.

Serving as a hallmark of Somerset County are over 12,552 acres of county parkland. From the rose gardens of Colonial Park, to the hiking and biking trails of Washington Valley Park and the Sourland Mountain Preserve, to the horseback trails of Lord Stirling Park, these parklands are not to be missed. If you like to shop, then Somerset (and neighboring counties) is the place to be. You’ll find great deals at the Liberty Village Premium Outlets in Flemington and Bridgewater Commons in Bridgewater, two popular outlet shopping destinations. Or, if history is more to your liking, you’ll find many quaint downtown areas where you’ll find local shopping flavor, including Somerville borough, home of the Wallace House (a state historic site) headquarters for General George Washington during the American Revolution in the winter of 1778-1779. In addition, a short distance from Somerset is Princeton, NJ, which is best known as being the home of Princeton University, as well as a popular shopping destination.

Presence of a number of pharmaceutical companies and CROs in the vicinity makes this a perfect location for a PhUSE SDE. Currently within the industry, one of the biggest challenges is sorting and managing large amounts of clinical data spread across multiple sources. The future of clinical data analysis requires data-visualization tools that provide the opportunity to drill down through multiple levels of detail to aid in analysis and provide real-time access and greater metric reporting. This Single Day Event will serve as a forum to share, discuss and enhance knowledge and understanding of how data visualization can transform the future of clinical analysis.

During this PhUSE Single Day Event, speakers will present and demonstrate data-visualization tools, templates, challenges and examples of how tools such as Spotfire can foster collaboration. We will also receive an update from the PhUSE Data Visualization Working Group, which is targeting key focus areas in terms of best practices, use of visualizations for subject level and anomaly detection. This forum will be a great opportunity to learn, collaborate and share the various topics of the day.

Best regards,

Lisa Lyons and Jennifer True
PhUSE Raritan Single Day Event Chairs

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### Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Title and speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30–09:00</td>
<td>Registration</td>
</tr>
<tr>
<td>09:00–09:15</td>
<td>Opening remarks&lt;br&gt;Lisa Lyons, Samar Noor, Janssen &amp; Jennifer True, GSK</td>
</tr>
<tr>
<td>09:15–10:00</td>
<td>Ongoing Medical Review of Clinical Trial Data with TIBCO Spotfire &amp; Beyond&lt;br&gt;Yves Snoeckx, Janssen</td>
</tr>
<tr>
<td>10:00–10:45</td>
<td>GSK Data Visualization: Successful Integration of Scalable, Enterprise-ready Delivery Solutions for Spotfire® Tools, Combined with Technical Expertise from Clinical Programming, is Transforming Data Analytics at GlaxoSmithKline&lt;br&gt;Dan Schrake &amp; Jason Szewczyk, GSK</td>
</tr>
<tr>
<td>10:45–11:00</td>
<td>Morning break</td>
</tr>
<tr>
<td>11:00–11:30</td>
<td>PhUSE Data Visualization Working Group Update&lt;br&gt;Melissa Wisner, Medidata &amp; Mike Rubison, Capิตigroup International</td>
</tr>
<tr>
<td>11:30–12:00</td>
<td>We Saw it Coming - Review and Trends in Visual Analytics&lt;br&gt;Nina Mian, AstraZeneca</td>
</tr>
<tr>
<td>12:00–12:45</td>
<td>Lunch and networking</td>
</tr>
<tr>
<td>12:45–13:00</td>
<td>PhUSE Overview&lt;br&gt;Chris Hurley, MMS Holdings - PhUSE US Director</td>
</tr>
<tr>
<td>13:00–13:45</td>
<td>Importance of Semantic Integration of Disparate Clinical Sources&lt;br&gt;Prior to Data Visualization&lt;br&gt;Suresh Madhavan &amp; Jerry Zaborowski, PointCross Life Sciences</td>
</tr>
<tr>
<td>13:45–14:15</td>
<td>Empowering People in Data Review through Interactive Visualization&lt;br&gt;Rebekah Revis, Eli Lilly</td>
</tr>
<tr>
<td>14:15–14:45</td>
<td>Next-generation Graphics&lt;br&gt;Susan Kramlik, Merck</td>
</tr>
<tr>
<td>14:45–15:00</td>
<td>Afternoon break</td>
</tr>
<tr>
<td>15:00–15:45</td>
<td>Benefits of a Rapidly Growing Library of Clinically Relevant Visualization Templates/Patterns&lt;br&gt;Eric S. Herbel, Integrated Clinical Systems</td>
</tr>
<tr>
<td>15:45–16:30</td>
<td>Visualizing Oncology Data through Customized Graphics&lt;br&gt;Hima Bhalla &amp; Rita Tsang, ICON</td>
</tr>
</tbody>
</table>

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Abstract

At Janssen, we have transformed the medical review of ongoing clinical trials. Spotfire is the cornerstone of our application, delivering on its core strengths (such as great graphics, tables, drill-down and filtering capabilities). On top of that, we have added a review status module so you can keep track of what you have reviewed and a communication module to involve your team members.

The presentation will include a brief demo, struggles along the way and future aspirations.

Biography

For over two years, Yves Snoeckx has been the business owner for the Spotfire-based tool for medical review at Janssen. In addition, his team also delivers Spotfire visualizations for different areas including Analytical Risk-based Monitoring (ARM) and operational data such as cycle times and study status metrics. Prior to this, Yves has spent most of his time at Janssen in the Pharmacovigilance/Glacial Medical Safety area, focusing on medical safety analysis of both clinical and post-marketing data. His first industry job was a CRA/Study Monitor for PPD in Europe. Yves has a Master’s of Pharmacy degree from the University of Antwerp (Belgium) and a passion for data visualization and analytics. His spare time is focused around his family, with two young daughters, and squash (the sport—not the vegetable).

The use of data visualization within GSK Clinical Development has expanded, and a number of key issues arose that led to unexpected challenges during implementation, specifically: the appropriate governance for data-visualization tools, regulatory documentation, risk analysis & mitigation, and determination of workflow fitness for purpose. Finally, several examples will be shared which demonstrate how the use of data visualization has successfully fostered collaboration among the various scientific roles. Data visualization has provided rapid answers to key clinical questions with enhanced clarity, efficiency, and importantly, increased cost & time savings.

Biographies

Dan Schramek has 19 years’ industry experience spanning preclinical through to late-phase clinical development. Currently, Dan is a manager of clinical programming in the oncology therapy area, where he has led projects from early phase to submission and has implemented in-stream data visualization solutions for clinical trials within GSK.

Jason Szewczyk is a scientific leader, with 16 years’ pharmaceutical experience, impacting data visualization, discovery science, medicinal & process chemistry and clinical development. This work spans several therapeutic areas, notably: oncology, diabetes, cardiovascular, neuroscience, and respiratory. Recently, Jason has focused on the areas of strategic planning and change management to implement data-visualization solutions at GSK for Clinical Development with Enterprise Level scalability. Jason has been at GSK for two years and is currently the Head of the Data Visualization Organization (DVO), supporting Safety, Risk-based Monitoring, and Clinical Development.

The presentation will discuss DV WG plans for 2017 (collaboration projects, white papers, scripts development) in the above focus areas, how they fit into the overall Emerging Trends & Technologies Working Group, and the potential impact on our industry.

Biographies

Melissa Wissner brings over 15 years’ experience working with dozens of global clinical trial organizations to increase efficiency and drive value in running clinical trials using technology. At Medidata, Melissa is responsible for consulting, training, and supporting clients in clinical development, particularly in dealing with the aspects of data anomaly detection and study execution. Prior to joining Medidata, Melissa served as a data manager and technical analyst at Merck and Co., where she was responsible for building studies, managing lab vendors, supporting ePRO technologies, and leading medical coding teams. Melissa received an M.S. degree in technology management from Stevens Institute of Technology and a B.S. degree in computer science with a minor in biology from Rutgers University.

Michael Rubison holds a Ph.D. degree in Statistics from Indiana University. He has more than 25 years’ experience in the pharmaceutical industry; most recently, holding positions at Abbott and Capsh International as Global Director, Development Operations and Senior Director, Global Medical Research and Registration.
In 2008, Michael founded Flint Hills Consulting LLC based on his experience in drug and medical device development with expertise in statistics and data management, data safety monitoring boards, IS/IT systems for pharmaceutical product development, regulatory submissions and licensing evaluations. In 2012, he joined Capish as Business Development Lead for North America.

Michael is a member of the Drug Information Association, CDISC and PhUSE. In support of collaborations with PhUSE, he is Co-Chair of the Data Visualization Working Group within the Emerging Trends & Technologies Working Group.

**11:30–12:00**

**We Saw it Coming – Review and Trends in Visual Analytics**

Nina Mian, AstraZeneca

**Abstract**

This presentation will outline how learning from other areas of the pharmaceutical value chain has been applied to the late-stage portfolio – the successes and challenges, and a glimpse into where we are going next. It will touch on specific technologies, strengths (and otherwise) of commercial applications, and the ‘people’ side – behaviours and the science of change. Perhaps perversely, it will also raise arguments against data visualization in specific circumstances, and make the case for automation and sophisticated rules sets.

**Biography**

Nina Mian is Head of Biomedical Informatics in AstraZeneca’s Advanced Analytics Centre (AAC). The AAC has a remit to enhance drug development decision-making through applied data science. In her role, Nina drives the Global Medicines Development Visual Analytics strategy, which includes ongoing and end-of-study visualization for safety and efficacy across therapy areas.

**13:00–13:45**

**Importance of Semantic Integration of Disparate Clinical Sources Prior to Data Visualization**

Suresh Madhavan & Jerry Zaborowski, PointCross Life Sciences

**Abstract**

The general need for visualisation of clinical data for research and translational medicine, or, more specifically, for precision-targeted therapies is far broader than the planned data visualization that results from regulatory analysis of clinical trial data using analysis data sets to generate tables, figures and listings to statistical analysis plans. Here, the need is broad because of the need to look at clinical trial data together with the molecular or other biomarkers generated from NGS/WGS or IHC from bio-samples gathered during disease progression or therapies. The entirety of this data, which is very large, needs to be harmonized, indexed before it can be analyzed or visualized against bioinformatics data from various public and subscription data registries. The benefit is in the ability to select stratified cohorts based on a broad spectrum of data and to visualize the big trends hidden in all of the data of those patients. Some of the challenges in this process will be discussed.

**Biographies**

Suresh Madhavan founded and serves as CEO of PointCross Life Sciences. He received his BA from Indian Institute of Technology, Delhi and later received his PhD from Stony Brook University.

Suresh’s background includes having worked in enterprise software for ontologies of knowledge-intensive industries such as biopharmaceutical R&D, drug safety and regulatory in addition to upstream oil and gas exploration and production. Prior to founding PointCross Life Sciences, Suresh worked in defense simulation, training, and war-gaming, as well as electronic sensing and controls and advanced high-efficiency turbomachinery.

Jerry Zaborowski has over 20 years’ experience in knowledge management and informatics solutions for nearly every stage of pharmaceutical research and development, from early discovery to clinical trials. He played significant roles in a number of start-ups and technology innovators in areas such as bioinformatics, molecular modeling, translational research, high-throughput screening, genomics, big data analytics, and preclinical and clinical data management. At Rosetta Inpharmatics, a provider of software for the analysis and management of gene expression and proteomics data, Jerry directed a worldwide sales team, and assisted in Rosetta’s acquisition and subsequent transition as a subsidiary of the pharmaceutical company Merck.
Empowering People in Data Review through Interactive Visualization

Rebeka Revis, Eli Lilly

Abstract
Interactive data visualization has been a pursuit of statisticians since the late 1960s. However, interactive tools for reviewing clinical trial data are in early stages of development and are not yet broadly used across the industry. Lilly has started to use Spotfire in reviewing clinical data for the support of study-level safety reviews, submissions, regulatory responses, commercialization efforts, etc. The use of Spotfire has gained a lot of internal customer applause. It has improved the customer's review experience and has cut down the waiting time in answering ad hoc questions.

In this presentation, we will provide a demonstration of the contributed ADaM safety review template that is in the PhUSE Script Repository for the review and display of adverse events and labs data. This template is a good starting point and reference for both study-level and integrated data reviews for different study/compound teams across various therapeutic areas. We will focus on how these templates empower users to gain insight into clinical data by "interacting" with data.

Biography
Rebeka Revis has been a statistical analyst at Eli Lilly and Company for five years. Her focus is primarily in safety visualization. She uses Spotfire to create interactive visualization for data reviews and provides internal training to people on how to create and use interactive visuals. Rebeka is also the Co-Lead of the PhUSE Script Discovery and Acquisition project and has recently uploaded a Spotfire safety review package to the PhUSE Code Repository in GitHub.

14:15–14:45
Next-generation Graphics
Susan Kramlik, Merck

Abstract
With the increasing demand for information visualization, not only for CSR's but for safety monitoring and for publication, it is important to have flexible and efficient tools available to produce a wide variety of graphs with various levels of detail. They need to suit the purpose and effectively convey a message, while being user-friendly and easily learned by new staff. This presentation shows an approach that involves multiple levels of programming from standard macros that require no user validation to highly flexible, adaptable yet simple template code that allows users to quickly and easily produce a wide variety of graphs with various levels of detail and sophistication.

Biography
Susan Kramlik is currently the Director of the Statistical Programming Analysis & Reporting Standards & Innovation team at Merck & Co, Inc. She has 25 years' statistical programming and statistical programming management experience in clinical research, primarily in the pharmaceutical industry, in various therapeutic areas. Susan recently joined the PhUSE Information Visualization Working Group.

Benefits of a Rapidly Growing Library of Clinically Relevant Visualization Templates/Patterns
Eric S. Herbel, Integrated Clinical Systems

Abstract
Over the years, many new clinically relevant data visualizations have been defined with specific clinical intent, such as identifying patients with potential drug-induced liver toxicity, potential renal impairment, increased risk of adverse events or targeted adverse events and, of course, different ways to visualize outlier patients. There's a tremendous benefit of continually adding to the library of clinically relevant templates – based on ongoing input from many pharma companies and the US FDA, NCI, etc. The challenge is to not only rapidly provide updates to deploy the new templates but also to provide an easy-to-use interface for users to use the new templates/patterns via a drag & drop interface with any of their data structures – SDTM and ADaM as well as EDC raw data format or legacy data structures.

Biography
Eric S. Herbel is President, Integrated Clinical Systems, Inc. He is principal architect of Integrated Review and a developer on the JReview® product. Before forming Integrated Clinical Systems, Inc. in 1994, Eric was with Hoechst Roussel Pharmaceuticals (now Sanofi) for 17 years, responsible for Clinical Systems – supporting clinical research in the areas of data management, in-house systems development, and SAS programming in support of regulatory submissions. During that period, he was directly involved in systems development in support of clinical research activities.

Next-generation Graphics Benefits of a Rapidly Growing Library of Clinically Relevant Visualization Templates/Patterns

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Conference Co-Chair Katja Glaß, Bayer Pharma

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