PRISME Forum

Pharmaceutical R&D Information Systems Management Executives

6th PRISME Forum

TECH MEETING

PRISME Forum Chair: Matteo di Tommaso, *Pfizer Inc.*

October 16, 2013

Boston, MA, USA

Accommodations:
Le Meridien Cambridge

Download our PRISME Forum 2013 TECH Meeting App

or access it through: http://my.yapp.us/PRISMETECH

Registration

https://docs.google.com/spreadsheet/viewform?formkey=dExqWTJlVmN4THpTSmh2VWIMM1ZfaHc6MA#gid=3

Accommodations

Le Meridien Cambridge, 20 Sidney St, Cambridge, MA 02139

Meeting Venue

Harvard Medical School's JB Martin Conference Center—77 Ave Louis Pasteur, Boston 02115

Contacts

Program Coordinator: +44.77.68.173.518

Secretariat: +1.312.622.1234

THEME:

Implications of Real Word Evidence for Pharmaceutical R&D IT

Building on the success of the PRISME Forum sponsored meeting at AstraZeneca in May 2012 on the topic of "Patient Centred Approaches to R&D", as well as its recent meeting at Sanofi in May 2013 on the topic of "How Is Pharma R&D Exploiting Big Data?", the PRISME Forum has chosen for its next technical meeting to address the theme of Real World Evidence in pharmaceutical industry R&D. Working in close collaboration with the Department of Clinical Informatics at Harvard, the PRISME Forum will consider this topic in Boston in October 2013.

Key business drivers that underpin the relevance of this meeting include:

- Strategic opportunities in Safety Pharmacovigilance, Patient Recruitment, Patient Monitoring and more
- Advances in Sensors and Mobile Technologies
- The explosion in the sources of "Real World Evidence", and the need for standardised access and methodologies for secondary research
- The emergence of powerful and scalable "Big Data" technologies including the "cloud"

To compete effectively, Pharmaceutical companies will need to develop innovative medicines that payers will recognise as delivering improved patient outcomes and differentiated products with cost-effective benefits. To lower the high costs of pharmaceutical R&D, pharmaceutical companies will need to exploit real-world evidence and 'omics' data to identify patient sub-populations for whom their medicines will demonstrate value. In an increasingly collaborative R&D environment, the pharmaceutical industry will need to leverage real world data to understand and evaluate stakeholders including patient-care organisations, academic collaborators, CROs, regulatory agencies and payers.

For R&D IT groups the implications of these developments are profound. The role of R&D IT, its strategy, organization, skills and infrastructure will all have to evolve to benefit patient and the industry.

This PRISME Forum Technical Meeting will focus on real-world data, integration of very large data sets to support translational science approaches, adaptive clinical trial methodologies and provision of regulatory-compliant IT platforms – perhaps in the "cloud" - to support wide collaboration.

Jason Swift (AZ) is the chair of the PRISME Forum Technical Meeting coordination team supported by Andy Gaughan (AZ), Karsten Tittman (Bayer) and Mike Montello (Shire).

PRISME Forum Meeting Steering Committee

Matteo di Tommaso, *Vice-President, Research Business Technology, Pfizer Inc. (PRISME Forum Chair)*

Andrew Gaughan, *Global Director, Payer and Real World Evidence Informatics, AstraZeneca*

Mike Montello, Director, *R&D IT Business Partner, Shire Pharmaceuticals*

Errol Sandler, *Treasurer/Board Secretary, PRISME Forum*

Jason D. Swift, *Director, R&D Information, AstraZeneca (Tech Meeting Steering Committee Chair)*

Karsten Tittman, *Global Head Research & Development IT, Bayer Healthcare*

John C. M. Wise, *Program Coordinator, PRISME Forum*

PRISME Forum Statement of Compliance

"All meetings, working groups and communications will be open to all Members and any records thereof will be non-confidential and available for inspection by any Member. The Members acknowledge that discussing any commercially sensitive topics, including costs, volumes, inventories, sales level methods, channels of distribution, access to future products, markets, current or future prices, profitability, ***contract pricing or trading terms*** is prohibited. The Members of PRISME will strictly comply with all laws relevant to their activities, including US state and federal anti-trust laws and European competition laws."

PROGRAM

TUESDAY, October 15, 2013	
18:20	Meet in Le Meridien Hotel Lobby for transport to dinner. Le Meridien is located at 20 Sidney St, Cambridge, MA 02139. Due to limited parking options, we suggest all those who plan to drive directly to the restaurant to join the group instead and take advantage of the arranged transportation. *Onsite PRISME Forum contacts: +44.77.68.173.518 or +1.312.622.1234*
19:00	Dinner venue: Erbaluce 69 Church Street (Bay Village) Boston, MA 02116 +1 617 426 6969
22:00	Bus will return to the hotel at 10 pm.

PROGRAM (cont.)

Sessions will be held at Harvard Medical School's JB Martin Conference Center—77 Ave Louis Pasteur, Boston 02115 (shuttle transfers provided)

WEDNESDAY, October 16, 2013		
7:00	*Gather in hotel lobby for departure to conference venue (bus will depart promptly at 7:10am)*	
8:15	**Welcome Notes**	**Matteo di Tommaso**, VP, Research Business Technology, *Pfizer Inc.* **Jason Swift**, *Director, R&D Information, AstraZeneca*
SESSION 1: INDUSTRY PERSPECTIVE		**CHAIR: Mark Crowder,** Global Head R&D-IT Clinical and Drug Safety, *Bayer Healthcare*
8:20	**Evolving Role of Real World Data in Pharmaceuticals**	**Aaron Galaznik**, Sr. Director, Real World Data and Analytics, *Pfizer Inc.*
8:45	Q&A	
8:55	**New Ways to Create True and Systematic Evidence in RWE**	**Christian Reich**, Investigator at Observational Medical Outcomes Partnership (OMOP), *AstraZeneca*
9:20	Q&A	
SESSION 2: ACADEMIC PERSPECTIVE		**CHAIR: Jason Swift,** *Director, R&D Information, AstraZeneca*
9:30	**Medicine Based upon Data**	**Charles Safran**, Chief Division of Clinical Informatics, *Harvard Medical School*
9:55	Q&A	
10:05	**Translational Science and Real World Evidence**	**Paul Avillach**, Assistant Professor, Biomedical Informatics, *HEGP Hospital - University Paris Descartes*
10:30	Q&A	
10:40	Coffee Break	
SESSION 3: TECHNOLOGY AND INNOVATION SOLUTIONS		**Chair: Susie Stephens,** Senior Director, Oncology & West Coast R&D Business Technology, *Pfizer Inc.*
11:00 POSTER SESSION	**Find New Value in Existing Data Using an Enabling Technology for Data Discovery Resulting in Rapid Hypothesis Testing**	**David Anstey**, Global Head LifeSciences, *YarcData* and **Ted Slater**, Sr. Solutions Architect, Life Sciences, *YarcData*
	The Race for Real World Data — Outcomes Data, Analytics, and Convergence with Translational Research and Drug Safety	**Dan Housman,** Chief Technology Officer, *Recombinant By Deloitte and Deloitte Health Informatics* and **Raveen Sharma,** Subject Matter Advisor, *Recombinant By Deloitte and Deloitte Health Informatics*
	Patients Like Mine: A Scalable Model for Medical Discovery	**Noah Zimmerman**, VP Data Science, Co-Founder, *Kyron*
	Entagen	**Christopher Bouton**, CEO, *Entagen*
	Electronic Health Record Analytics	**Steve Gun,** VP Operations, LifeSciences, *Humedica* and **Mike Sanky**, *Account Manager, Humedica*
12:15	Lunch	
SESSION 4: PAYER and REGULATORY PERSPECTIVE		**CHAIR: Mike Montello**, Director, R&D IT Business Partner, *Shire Pharma*
13:15	**LECTURE 5**	**Meghan Dierks**, Assistant Professor of Medicine, *Harvard Medical School;* Director of Clinical Systems Analysis, *Beth Israel Deaconess Medical Center*
13:40	**Win-Win Opportunities for Pharmas and Payers**	**Joseph Singer**, VP, Clinical Affairs, *Healthcore*
14:05	Q&A	
SESSION 5: BRINGING IT ALL TOGETHER		**CHAIR: Matteo di Tommaso**, VP, Research Business Technology, *Pfizer Inc.*
14:25	**Optum Labs: A Seat at the Table**	**Paul Bleicher**, CEO, *Optum Labs, Optum*
15:00	Coffee Break	
SESSION 6: TECHNOLOGY PANEL		**MODERATOR: Paul Bleicher**, CEO, *Optum Labs, Optum*
15:30	**Real World Data and Evidence—A Framework and Process for Engagement**	**Andrew Kress**, Senior Vice President, Healthcare Value Solutions, *IMS*
15:55	**Active Pharmacovigilance Using Bayesian Confidence-Propagation Neural Network-based Machine-learning**	**Douglas McNair**, President, *Cerner Math Inc.*
16:20	**Clinical Cloud Computing, Clinical Analytics & Interchangeable Parts**	**John Murphy**, VP Clinical Analytics, *Quintiles*
16:45	***PANEL DISCUSSION***	
17:15	**DISCUSSION/SUMMARY**	**Jason Swift et al.**
17:30	Close	

BIOS and ABSTRACTS

Matteo di Tommaso

Chair, PRISME Forum; VP, Research Business Technology, *Pfizer Inc.*

Matteo leads Research Business Technology for Pfizer where he is responsible for strategy and implementation of IT and informatics services for Pfizer Research. At Pfizer, he has led efforts on cloud solutions for high performance computing (HPC), systems integration resulting from mergers and acquisitions, systems separations as a result of divestitures and IPOs, drug discovery data integration for decision making and insight, translational informatics solutions for patient stratification and integration of clinical and molecular data, laboratory automation services, and data center simplification. His efforts in pre-competitive collaboration have led to opensource tools for Chemistry eNotebook and biomolecule discovery and contributions to efforts including OpenBEL, Pistoia Alliance and tranSMART.

Before joining Pfizer, in 2004, Matteo led the team at Celera Genomics responsible for building Celera's scientific information products and Applied Biosystems' eCommerce solutions. Prior to that he led the development of the "SeqStore" product line for Genetics Computer Group, a set of products and services for pharmaceutical drug discovery. Before GCG, he spent 3 years at the European Bioinformatics Institute (EBI) at the start of the institute in Cambridge, UK. Matteo began his career in IT, at Warner-Lambert Parke-Davis, with a degree in Chemistry from Indiana University, leading the migration and replacement of pre-clinical information systems to improve data quality and usability.

Jason Swift

Director, R&D Information, *AstraZeneca*

Jason has 18 years experience in the Pharmaceutical business working closely with scientists and clinicians across multiple R&D domains and business processes. He has a scientific background with a PhD in computational molecular biology (before it was called Bioinformatics) from Leeds University in the UK. He has held a number of Informatics and IS leadership roles in AstraZeneca from scientific software developer, global programme manager, and head of Scientific Information Services.

Jason is currently Director Business Deliver, R&D Information based in Alderley Park UK. In this role he is responsible for the delivery of a global portfolio of IS and Informatics projects and services to the pre-clinical enabling functions (Discovery Sciences, Global Safety Assessment and Global DMPK) in AstraZeneca. He has led the efforts for global harmonization of IS/IT platforms across the Design, Make, Test and Analyse processes – including Small molecule Screening, Chemistry Platforms and Bio Asset supply. Most recently Jason has led components of the FIPNet (Fully Integrated Pharmaceutical Network) programme within AZ to virtualize and externalize R&D capabilities.

Externally he represents AZ within the PRISME Forum and sits on the board of Pistoia. Jason is also a member of AMIA and has recently spent a short period of time exploring Clinical Informatics approaches at Harvard (DCI).

SESSION 1—INDUSTRY PERSPECTIVE

CHAIR: Mark Crowder

Global Head R&D-IT Clinical and Drug Safety, *Bayer HealthCare*

Mark leads the Clinical & Drug Safety Centre of Expertise (CoE) for Bayer Healthcare where he is globally accountable for all operational and project-specific IT for the Bayer Global Development functions: Clinical Development, Medical Affairs and Pharmacovigilance. Reporting directly to Karsten Tittmann (PRISME member), he also has the role of R&D IT Head of US and additional responsibilities of coordinating R&D IT activities in the GD centre, Beijing and PV centre in Brazil.

He has been with the company since 1995, first with Schering and then, following their acquisition, Bayer. Based in New Jersey since 2006, he began his career in Medical Sales and progressed through roles in Marketing, Sales & IT in the UK.

Christian Reich

Investigator at Observational Medical Outcomes Partnership (OMOP), *AstraZeneca*

Christian Reich is the Global Head of Discovery and Clincial Informatics at AstraZeneca. He is also Principal Investigator at the Observational Medical Outcomes Partnership, a public-private research project between PhRMA and academic research institutions managed by the Reagan-Udall Foundation for the FDA. The partnership is conducting a research initiative to identify methods, technology and governance to evaluate the association between treatments and outcomes, and inform a comprehensive drug surveillance program.

Dr. Reich has more than 15 years of experience in life science research and medicine. He was a practicing physician in Berlin and Ulm, Germany before moving to the European Bioinformatics Institute to work on the Human Genome Project. He then joined the biotech industry in 1998, where he worked in various positions on typical challenges in drug research and development, such as gene sequence and expression analysis, clinical trial design and analysis, systems biology, and outcome research, applying computational methods to large scale biological data. Dr. Reich received his B.S. in preclinical training from Humboldt University in Berlin and holds his MD and doctorate from the Medical University of Lübeck, where he focused his research on T-cell activation and regulation.

Christian.Reich@astrazeneca.com

New Ways to Create True and Systematic Evidence in RWE

There is great opportunity in Real World Evidence from large-scale observational clinical data. We can systematically understand the effect of medical treatment (both beneficial and adverse), the effectiveness and cost of the healthcare system, and learn about unmet medical needs and opportunities. RWE research is currently enjoying a boom in the pharmaceutical industry. However, it faces a number of challenges and problems, preventing these opportunities to come to fruition. This talk will discuss some of the problems of reproducibility, choice of methods and analysis parameters, p-value calculations, definition of outcomes, Standards for known drug effects, and the application of existing clinical trial frameworks to RWE data. It will also sketch an approach to observational research based on the pre-competitive OMOP platform, including a standard data model, standard coding systems, empirical evaluation of methods and analytical choices, and expanding the evidence base beyond simple relative risk calculations with null-hypothesis rejection. This will ultimately create confidence in RWE and improve our the healthcare.

Aaron Galaznik

Senior Director, Real World Data & Analytics, *Pfizer*

Aaron Galaznik is an Enterprise Liaison for the Real World Data and Analytics Group at Pfizer. He has a background in Health Economics and Outcomes Research, where he had brand support as well as national account support responsibilities. He has also worked in Market Analytics, where he supported Commercial Development activities for in-line and pipeline compounds. His therapeutic experience includes pain, inflammation, respiratory and cardiovascular/metabolic disease. Prior to coming to Pfizer he was at King Pharmaceuticals in Strategic Marketing Research. He received his AB in Biology from Harvard University, his MD from Weill Medical College of Cornell University, and his MBA in Healthcare Management from the Wharton School. He has also authored and co-authored publications and posters on the impacts of managed care policies on drug utilization and persistence.

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Evolving Role of Real World Data in Pharmaceuticals

The evolving landscape of Big Data in healthcare is impacting pharmaceutical companies in areas from research and development, to commercialization, to customer engagement. Of its many forms and facets, Real World Clinical Data is particularly poised for increasing usage. With the generation of Real World Data burgeoning across both the public and private sector comes the ability to shape the discussion on pharmaceutical products' benefits and risks by stakeholders throughout the healthcare system. Pharmaceuticals and life science companies will need to shift away from a clinical trials-focused mindset to effectively function and communicate in this new environment.

SESSION 2—ACADEMIC PERSPECTIVE

Chair: Jason Swift

Director, R&D Information, *AstraZeneca*

Charles Safran

Chief of the Division of Clinical Informatics, *Beth Israel Deaconess Medical Center;* Associate Professor of Medicine, *Harvard Medical School*

Charles Safran is a primary care internist who has devoted his professional career to improving patient care through the creative use of informatics. He is Chief of the Division of Clinical Informatics, Beth Israel Deaconess Medical Center and Associate Professor of Medicine Harvard Medical School. He is the past President and Chairman of American Medical Informatics Association and was previously Vice-President of the International Medical Informatics Association. He is an elected fellow of both the American College of Medical Informatics and the American College of Physicians.

Dr. Safran is co-Editor of the International Journal of Medical Informatics and a council member of the Health on the Net (HON). Dr. Safran has helped develop and deploy large institutional integrated clinical computing systems at the Beth Israel Deaconess Medical Center and the Brigham and Women's hospital.

At the Beth Israel Deaconess Medical Center he led the development and deployment of their electronic health records which are used in all areas of ambulatory clinical practice. He has also worked on clinical decision support systems to help clinicians implement care guidelines, select diagnostic strategies for cancer patients, and treat patients with HIV/AIDS. He has developed telemedicine solutions to support parents with premature infants called Baby CareLink that he brought to the national market through a company he founded.

Dr. Safran has over 150 publications and speaks to national and international audiences. He has testified for the U.S. Congress on Health IT. He graduated cum laude in Mathematics and hold a Masters degree in mathematical logic and a Doctor of Medicine all from Tufts University.

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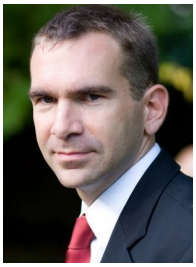
Medicine Based upon Data

The dream of evidence-based medicine is that quality evidence exists to guide clinicians through the clinical conundrums they routinely face – which test to order; how to interpret the test results and what therapy to try. Ideally we would like to find this evidence within the results of a randomized controlled trial (RCT), but we know that RCTs are expensive and cover only small fraction of clinical situations. Moreover, the inclusion and exclusion criteria mean that rarely is the evidence generated by RCTs strictly about "patients like my patient." If we cannot always turn towards the literature for evidence, will humongous databases of routinely collected clinical data be an acceptable alternative? However, clinical data are messy. Data are missing and may be inaccurate. Unlike data prospectively collected as part of a research protocol, there is no quality control, normalization, or regularity of the data. Much of the data we capture in electronic health records is unstructured clinical narrative and hence not easily used for analysis. I will discuss the prospects and limitations of using routinely collected clinical data for research and personalized health care.

SESSION 2—ACADEMIC PERSPECTIVE

Paul Avillach

Assistant Professor, *Paris Descartes University* and Post-Doctoral Fellow, *Center for Biomedical Informatics, Harvard Medical School*



Paul Avillach holds an MD in Public Heath, Epidemiology, Biomedical Informatics and PhD in Biomedical Informatics. He is Assistant Professor at Paris Descartes University and has started a Postdoctoral training at the Center for Biomedical Informatics, Harvard Medical School, under the supervision of Professor Isaac Kohane.

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Translational Science and Real World Evidence: Creating comprehensive clinical & genomic databases using a translational research platform: tranSMART

The open source tranSMART platform provides researchers a single self-service web portal with access to phenotypic, 'omics, and unstructured text-based data from multiple internal and external sources, combined with search and analysis capabilities. All the data integration is hypothesis free. The tranSMART platform helps scientists develop and refine research hypotheses by investigating correlations between genomic and phenotypic data. The architecture of the tranSMART platform is based on the i2b2 clinical data warehouse model.

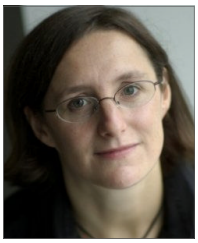
Two Experiences on how I investigated such hypotheses will be presented on

1) metastatic colon cancer from Pompidou Hospital in Paris and
2) autism at Harvard/Children's Hospital in Boston. Analysis using clinical data from cohorts & EHR data, Biobank data, Gene expression data, miRNA and variant annotation of Exomes will be demonstrated.

SESSION 3—TECHNOLOGY AND INNOVATION SOLUTIONS

Chair: Susie Stephens

Senior Director, Oncology & West Coast R&D Business Technology, *Pfizer Inc.*



Susie Stephens is responsible for R&D IT for the West Coast for Pfizer. As such she provides support for Oncology, Vaccines, Rinat, San Diego and San Francisco Centers for Therapeutic Innovation, and Partner Lines. She is responsible for strategy and delivery of IT services, products, and processes to achieve successful outcomes for R&D.

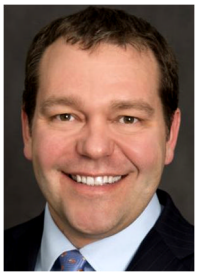
Susie has cross-disciplinary experience in informatics, science and business from leading pharmaceutical and IT companies. Prior to joining Pfizer, Susie was Head of In Silico Immunology, Janssen Pharmaceutical Research and Development, where she had overall responsibility for in silico science for the Immunology Therapeutic Area. She has also worked for Eli Lilly where she was responsible for Open Innovation for Research IT, Oracle where she created and guided the implementation of their product development strategy for the database for the life sciences, and Sun Microsystems where she was market segment manager for the life science.

Susie has a PhD in Physiology from the University of Exeter, UK; post-doctoral experience in Molecular Biology from the University of Manchester, UK; and is an alumnus of Harvard Business School.

This session will feature five interactive poster presentations. Participants will be divided into five groups. Each presentation will be given 15 minutes and will be repeated for each of the five groups. Each of the five participant groups will visit each of the five interactive poster presentations (color-coded badges will indicate group "affiliation" while the session chair will announce the rotation to the next poster).

David Anstey

Global Head LifeSciences, *YarcData*



David Anstey is the Global Head of Life Sciences at YarcData, offering an in-depth knowledge of the Pharmaceutical and Biotechnology industries. Dave is responsible for developing and managing the business strategy to deliver YarcData's solutions within the Life Science markets.

Dave joined YarcData from IDBS where he was Director of Healthcare, North America. Over the past 11 years at IDBS, Dave focused on growing IDBS' account base and revenue through direct selling and sales management roles. Dave has close to 20 years of experience "selling science" and held key sales roles with Molecular Devices Corp. and Fisher Scientific Canada Ltd prior to IDBS.

Dave holds a BSc in Biology from Carleton University, Ottawa, and an MBA from the University of Ottawa focusing on business strategy and international business.

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Find New Value in Existing Data Using an Enabling Technology for Data Discovery Resulting in Rapid Hypothesis Testing

Big data graph analytics at scale, and in near-real time hypothesis testing can help life sciences organizations take full advantage of their existing data by enabling the capture and exploration of relationships between data. This talk will discuss how large-scale graph analytics approaches can help researchers move beyond the rigid limitations of traditional search to support rapid iterative questioning of diverse data sets. Scalable graph analytics can bring data together in new ways that enables ground breaking discoveries and identifies new targets and opportunities in oncology, neurobiology and other disease areas.

Ted Slater

Sr. Solutions Architect, Life Sciences, *YarcData*

Ted Slater had recently joined YarcData. Prior to this, he was CTO, OpenBEL Consortium at Selventa, Inc., and Executive Director at Broad Reach Strategic Advising LLC. He is an expert in the application of knowledge- and semantics-based methods to pharmaceutical R&D. He holds an MA in Molecular Biology from the University of California, Riverside, and an MS in Computer Science from New Mexico State University.

SESSION 3—TECHNOLOGY AND INNOVATION SOLUTIONS

Dan Housman

Chief Technology Officer, *Recombinant By Deloitte and Deloitte Health Informatics*

Dan is a software veteran with a demonstrated track record of providing valuable and innovative decision support systems to large, complex organizations. Dan leads Recombinant By Deloitte's strategy, product planning, and development, and is very active in Recombinant By Deloitte client engagements with a focus on translational research, bioinformatics and innovative approaches to data capture, analysis, and reporting for clinical quality and performance improvement. He has conceived and delivered a wide range of effective web-based analytical solutions including clinical performance dashboards, analytic and reporting solutions for performance metrics.

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Raveen Sharma

Subject Matter Advisor, *Recombinant By Deloitte and Deloitte Health Informatics*

Raveen is currently leading the client relationship management function at Recombinant by Deloitte. He has over 20 years of experience in implementing Business Intelligence, Data Warehouse, and Healthcare & Life Sciences Informatics solutions. Raveen has led projects and managed client relationships with academic medical centers, healthcare providers, and pharmaceutical organizations. Projects typically involved data capture, integration of phenotypic and 'omic data, data preprocessing (normalization, conditioning), analytics (bioinformatics) and delivery to researchers and clinical investigators. Raveen is also active in developing and growing the tranSMART community and has established collaborations for precompetitive technology sharing between several major pharmaceutical organizations.

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The Race for Real World Data: Outcomes Data, Analytics, and Convergence with Translational Research and Drug Safety

A solution to bring real world healthcare insights to help transform health outcomes for life science customers.

With healthcare costs on the rise and a movement from volume to value of care occurring, life science companies, providers, and payers require affordable access to data and insights capable of informing outcomes-based decisions. Deloitte's product suite can help address some of these most pressing issues in healthcare today.

Deloitte and Intermountain Healthcare have established a collaboration that brings together Deloitte's leading-class professional services and informatics capabilities with Intermountain's access to patients and pioneering experiences in data-driven care. This collaboration will provide market-leading health analytics solutions that will enable providers and manufacturers to unlock the power of big data, improve quality, and drive efficiencies in the delivery of care and the development of new therapies.

http://www.recomdata.com

Christopher Bouton

CEO, *Entagen*

Dr. Bouton received his BA in Neuroscience (Magna Cum Laude) from Amherst College in 1996 and his Ph.D in Molecular Neurobiology from Johns Hopkins University in 2001. Dr. Bouton is the CEO of Entagen (http://www.entagen.com), a software company founded in 2008 that provides innovative products including Extera and TripleMap. Entagen's technologies have won numerous awards including the "Innovative Technology of the Year Award for Big Data" from the Massachusetts Technology Leadership Council in 2012 and Entagen was recognized as a Gartner "Cool Vendor" in the Life Sciences in 2013. Prior to his role as the CEO of Entagen Dr. Bouton worked as a computational biologist at LION Bioscience Research Inc. and Aveo Pharmaceuticals from 2001 and 2004, leading the microarray data analysis functions at both companies. In 2004 he accepted the position of Head of Integrative Data Mining for Pfizer and led a group of Ph.D. level scientists conducting research in the areas of computational biology and large-scale 'omics data analysis. While at Pfizer, Dr. Bouton conceived of and implemented an organization-wide wiki called Pfizerpedia for which he won the prestigious 2007 William E. Upjohn Award in Innovation. Dr. Bouton is an author on over a dozen scientific papers and book chapters and his work has been covered in a number of industry news articles.

chris@entagen.com

Entagen, founded in 2008, provides software and services for "Big Data" environments such as life sciences and healthcare organizations. Entagen's flagship products are "TripleMap", a big data analytics application and "Extera", Entagen's proprietary Semantic Data Core (SDC) technology. With these technologies Entagen tackles complex Big Data integration and analytics for its clients with a productized software solution that can be securely deployed behind a firewall or in the cloud.

Extera is the dynamic, high-performance semantic data core that bridges the divide between structured and unstructured sources within an organization, allowing for derivation of full value from an organization's wealth of information and insights. Extera administrators build aggregated representations of entities (e.g.protein targets, compounds, diseases, pathways), their meta-data properties and their associations by connecting to internal and external Big Data sources. This process allows for the creation of a massive interconnected data graph which is continuously updated as it aggregates data from across an organization's sources such as relational databases, live XML feeds, RDF data sources, Sharepoint TeamSites and literature sources.

TripleMap allows users to constantly scan, create and share structured knowledge maps, thereby connecting the dots in big data and identifying unexpected associations which can drive better hypothesis generation and increase efficiency. Users are dynamically prompted with entities related to their search results, allowing them to explore and visualize the associated information space around their search terms. Knowledge maps also allow users to see who else within their organization has worked on the same entities in the past and to receive alerts to new information as soon as its available from anywhere internal or external to an organization.

http://www.entagen.com

SESSION 3—TECHNOLOGY AND INNOVATION SOLUTIONS

Steve Gun

VP Operations, LifeSciences, *Humedica*

Steve serves as Vice President of Life Sciences Operations at Humedica and is responsible for defining, aligning and delivering analyses stemming from partnerships with life sciences clients as well as new product development. Steve brings an array of consulting, analytic and forecasting experience to his role. Prior to Humedica, Steve was Vice President, Strategic Consulting in the healthcare division of Epsilon. Prior to Epsilon, Steve led the consulting and product management divisions of Verispan, L.L.C. for seven years. Steve began his career in forecasting at M/A/R/C Group as a New Product Analyst, after completing his MBA at Emory University and his BA at Middlebury College.

Steve.gun@humedica.com

Mike Sanky

Account Manager, *Humedica*

Throughout his career, Mike has specialized in leveraging Big Data solutions to drive health care strategy. Prior to joining Humedica, Mike was a Consultant at the Amundsen Group, where he worked extensively with longitudinal patient data to better understand patient behavior, quality of access, and drivers of product performance. His experience in the biopharmaceutical industry began with the Center for Pricing and Reimbursement at United BioSource Corporation. Mike received his MS in Marketing Analytics from the McCallum School of Business at Bentley University (where he published a health care intervention study in the Journal of Medical Marketing) and his BS from the Walsh School of Foreign Service at Georgetown University.

Michael.Sanky@humedica.com

Electronic Health Record Analytics

Humedica is the foremost clinical intelligence company that provides private cloud-based business solutions to the health care industry. Humedica NorthStar™ leverages Spotfire to deliver Humedica's high-quality Electronic Health Record (EHR) data in a userfriendly, flexible format. The platform is designed to foster the discovery of areas of opportunity within highly detailed clinical segments, to identify the triggers for specific brand choices within those segments, and to refine marketing approaches.

In our presentation, we will utilize NorthStar™ to demonstrate unique insights stemming from clinical data and physician notes information captured in EHR.

Clinical Data

EHR contains a wealth of real-world clinical data including lab results (like A1C) and vital signs (like BMI). In the Diabetes market, A1C and BMI are very important factors that determine prescribing decisions.

The graph below shows class-level market share by each patient's pre-Rx A1C cohort (the most recent A1C that is within 90 days of the Written Prescription). As patients have more severe A1Cs, we see that they are more likely to get prescribed Insulin. (Figure 1)

In addition to A1Cs, we now layer information related to BMI in the graph below (Figure 2). GLP-1s are frequently prescribed to obese patients because of a weight-loss side effect, making its market niche clear.

Physician Notes

In addition to rich clinical data, physician notes offer another unique attribute in EHR data. The graph below (Figure 3) shows discontinuation rationale by Signs, Diseases, and Symptoms that are mapped to the Medical Dictionary for Regulatory Activities (MedDRA). In the example below, when a physician notes a clinical reason for a sulfonylurea discontinuation, more than half of the time it is due to endocrine reasons (the majority of which are hypoglycemia). Brand managers looking to increase Line 2 post-metformin market share should refine their messaging to increase awareness around patients who are not good candidates for sulfonylureas because of hypoglycemia risk.

http://www.humedica.com

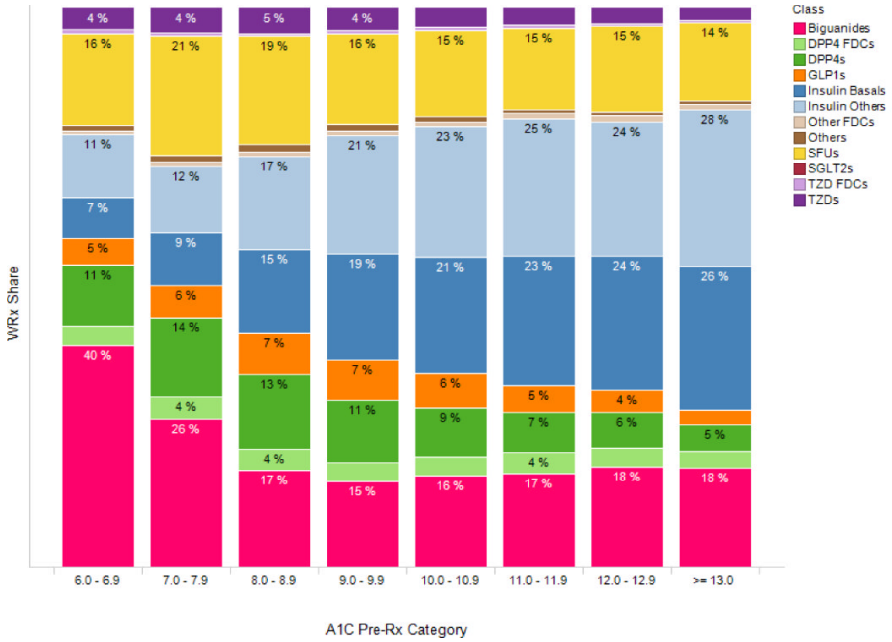

Fig 1
Class-Level Market Share by Pre-Rx A1C (Jan 2010 – May 2013)

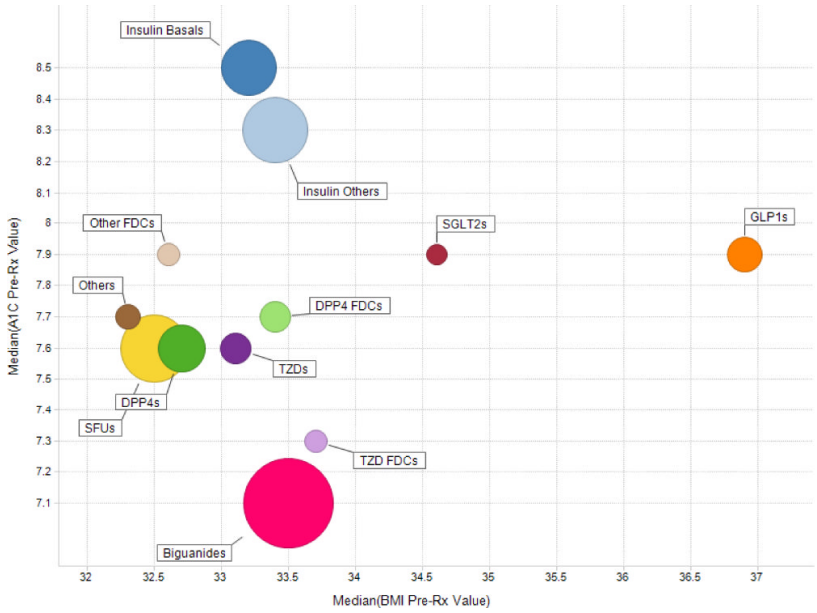

Fig 2
Median Pre-Rx A1C and BMI by Class (Jan 2010 – May 2013)

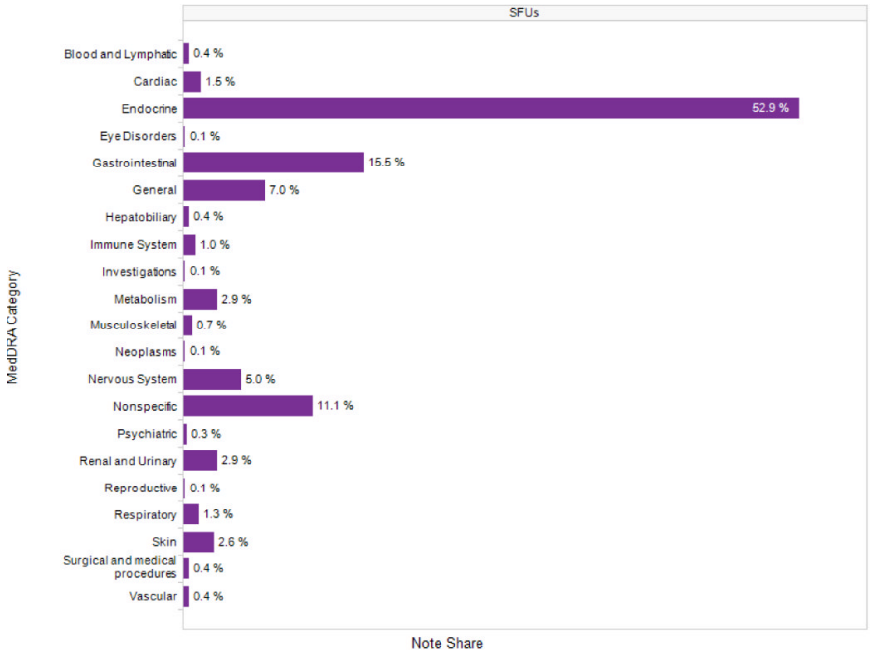

Fig 3
Physician Considerations for Sulfonylurea Discontinuation (Jan 2010 – May 2013)

Noah Zimmerman

VP Data Science, Co-Founder, *Kyron*

Noah Zimmerman has a background in computer science with training in statistics, immunology and medicine. Prior to Kyron, he was a Senior Data Scientist at Pivotal where he helped build the data science practice for the healthcare & life-science vertical.

He completed his doctoral work in Biomedical Informatics at Stanford, and was a member of the founding team of 2 startups in the healthcare/life-science space.

In addition to his data science duties, Noah is an instructor for a course he co-created at the Stanford d.school that explores the intersection of science and design.

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Patients Like Mine: A Scalable Model for Medical Discovery

The current paradigm of evidence-based medicine through prospective clinical trials does not scale. Among Americans aged 60 and over, more than 75% use two or more prescription drugs and 37% use five or more. A half-million trials would be required to test all of the possible 2-drug combinations that close to 40 million Americans are currently taking, and 10 million more trials to test all of the 5-drug combinations.

The volume of potential interactions and population-level heterogeneity (ethnicity, co-morbidities, environment, etc.) make the problem intractable. Therefore, we need new techniques for (a) post-market drug surveillance and (b) data-driven prioritization of follow-up studies. These methods will complement the prospective clinical trial, providing a view into drug safety and efficacy experiments *in the wild*.

Every day, clinical decision-making *in the wild* results in tens of thousands of micro-experiments. In aggregate, these micro-experiments enable learning of real-world outcomes. Analysis of Electronic medical records (EMR) enables systematic examination of factors leading to differential outcomes in highly targeted patient populations.

At Kyron, we are developing advanced tools to process EMR data for rapid search, query and data mining. Our core technology transforms the textual notes from a patient record into a structured patient profile consisting of concepts from medical ontologies, which allows search and query of patient records at varying levels of granularity along the concept hierarchies.

These patient profiles have been used as a substrate for multiple applications including drug safety surveillance and off-label drug-use. In some state of the art studies, the technology underlying Kyron could detect major adverse events associated with 6 of the last 9 major drug recalls in the last decade ~2 years before the recall occurred, could detect roughly 80% of known drug-drug interactions, and demonstrated the safety of a highly effective drug for peripheral vascular disease.

http://www.kyron.com

SESSION 4—PAYER and REGULATORY PERSPECTIVE

Chair: Michael Montello

Director, IT Business Partner, Shire Pharmaceuticals, Inc.

Mike is responsible for the IT Business Partner capability for Shire R&D. In his current capacity, Mike drives collaboration efforts with IT and R&D leadership in the development of business strategy and a business aligned IT investment portfolio. He leads the implementation of strategic and operational excellence capabilities to optimize and grow Shire's business across Non-Clinical Development, Health Economics and Outcomes Research, Quality & Compliance, Clinical Development, Pharmacovigilance and Risk Management, Medical Affairs, and Product Strategy. Mike is a key leader in IT integration activities driven by acquisitions to Shire's pipeline.

Prior to joining Shire, Mike worked 12 years at Accenture as a management consultant and outsourcing delivery executive within Accenture's Life Sciences R&D practice. He partnered with 5 top global biopharmaceutical companies to drive business results through the planning and implementation of new strategic technology capabilities, the transition and delivery of IT managed services, and execution of post-merger IT integration.

Meghan Dierks

Assistant Professor of Medicine, *Harvard Medical School;* Director of Clinical Systems Analysis, *Beth Israel Deaconess Medical Center*

Dr. Meghan Dierks is Assistant Professor of Medicine, Harvard Medical School, in the Division of Clinical Informatics at Beth Israel Deaconess Medical Center in Boston MA. She also holds a position of Director of Clinical Systems Analysis at Beth Israel Deaconess Medical Center. In these roles, Dr. Dierks conducts a broad range of both operational and research activities in the areas of Clinical Systems Analysis, Risk Analysis, Decision Analysis and Human Factors Engineering (emphasis on Cognitive Engineering and Macroergonomics).

Dr. Dierks is a board certified general surgeon who trained at Washington University, St. Louis, MO and the Lahey Clinic, Burlington, MA. She completed the Harvard-MIT Program in BioMedical Informatics supported by an NLM-training grant and was the Douglas Porter Fellow in Informatics at the Beth Israel Deaconess Medical Center. She has a baccalaureate degree from Brown University, and an MD from the University of Texas Health Science Center – Houston. In addition to her academic position at Harvard Medical School, she has been a Visiting Scholar and Research Affiliate at MIT, and is Adjunct Faculty at the University of Maryland's Division of Reliability Engineering.

She is a former Executive Medical Director for GE Healthcare IT where she provided clinical input to design controls and was responsible for risk analysis for Healthcare IT. Dr. Dierks spent three years with the FDA's Center for Devices and Radiological Health working on a range of cross-departmental projects under the Deputy Director that focused on risk analysis, mitigation and strategic planning around medical devices shortages. She is a former consultant to the Harvard Risk Management Foundation.

SESSION 4—PAYER and REGULATORY PERSPECTIVE

Joe Singer

VP, Clinical Affairs, *Healthcore*

Joseph Singer, MD, Vice President Clinical Affairs, is responsible for working with project teams to optimize the clinical, coding nuances, and insurance industry perspectives embedded within projects.

Dr. Singer has been board certified in Family Practice since 1986 and received a Certificate of Added Qualification in Geriatrics in 1990. In addition to working in clinical practice for many years, Dr. Singer also was a faculty member in a family medicine program affiliated with the University of Medicine and Dentistry of New Jersey. He has held numerous executive positions within the managed care industry, among them Chief Medical Officer, health plan President and General Manager, and Regional Executive Vice President. An active member of regional and national organizations focused on health outcomes, pharmacoeconomics, and pharmacoepidemiology, Dr. Singer has received awards recognizing his contributions.

After receiving his undergraduate degree in Biology from LaSalle University in Philadelphia, PA, Dr. Singer earned his medical degree from Hahnemann University, Philadelphia, PA.

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Win-Win Opportunities for Pharmas and Payers

Recent changes in the US healthcare system regarding implementation of the Affordable Care Act, the evolution of provider payment innovation strategies and shifting of industry focus on product development to niche products have necessitated increasingly sophisticated approaches to data acquisition and management, analytics and health economics and outcome reporting. Pressure to reduce the overall cost of care, while also improving clinical outcomes is driving focus on the development of targeted therapies for highly specified patient cohorts. Payment innovation strategies for large physician groups, integrated delivery systems and new forms of risk bearing/gain sharing entities are yielding increasing pressures for physicians to provide evidence-based interventions to achieve optimal value and outcomes resulting from their interventions. Understanding these drivers, the nuances of creating and structuring the databases needed for clinically enhanced analytics and its interplay with new analytic solutions are critical issues for decision makers and researchers to understand.

Real world evidence consisting of health plan administrative data being integrated with abstracted information from clinical registries, electronic medical record systems, genomic and biometric data and patient reported information is essential to understanding the real world environment impacting care delivery. This clinically enhanced longitudinal patient data is essential to enable provision of the comprehensive insight needed by industry, payers and providers. Alignment of reimbursement mechanisms and corporate business models based upon establishment of a comprehensive view of population and individual pharmacoeconomics and pharmacoepidemiology can enable economic success for industry and payers through alignment of tactics to optimize clinical outcomes for patients.

http://www.healthcore.com

SESSION 5—BRINGING IT ALL TOGETHER

Chair: Matteo di Tommaso

Chair, PRISME Forum; VP, Research Business Technology, *Pfizer Inc.*

Paul Bleicher

CEO, Optum Labs

Paul Bleicher, MD, PhD, is the Chief Executive Officer of Optum Labs, an open, collaborative health care innovation center established by Mayo Clinic and Optum to attract research partnerships between various stakeholder groups in healthcare and accelerate the "speed of innovation" in the pursuit of improved patient health.

Prior to his current role, he was Chief Medical Officer for Humedica, a next-generation clinical informatics company that provides novel business intelligence solutions to the health care and life science industry. At Humedica, which was acquired by Optum in January 2013, he was involved in all aspects of medical informatics, data analytics privacy and regulatory compliance, and product development. Prior to this, he was the founder and original CEO of Phase Forward where he helped grow the organization over an 11 year period from a concept to a publicly traded company serving in various capacities as Chief Strategy Officer and as a member of the Board of Directors until its 2010 acquisition by Oracle Corporation. Prior to founding Phase Forward, Dr. Bleicher served as Vice President of Clinical Affairs at Alpha-Beta Technology with responsibility for Phase I through III clinical development of a novel carbohydrate drug. Dr. Bleicher was previously the Director, Early Phase Services at PAREXEL International where he assisted pharmaceutical and biotechnology companies with the initial development of novel therapies.

Dr. Bleicher currently serves on the editorial boards of Applied Clinical Trials, the Drug Information Journal, and Research Practitioner. He has held various leadership positions in the Drug Information Association, including Chairman of the Steering Committee of North America for the Drug Information Association, a member of their Board of Directors and a member of the Board of the DIA Foundation. He served as a member of the Massachusetts Life Sciences Leadership Council.

In 2002, Dr. Bleicher won the Ernst and Young Entrepreneur of the Year Award in New England and was appointed to the Ernst and Young Entrepreneur's Hall of Fame. He was in the first group of PharmaVoice's 100 Most Inspiring Leaders in Life Sciences, and was named a Champion in Healthcare by the Boston Business Journal.

Dr. Bleicher received his BS from Rensselaer Polytechnic Institute, and his MD and PhD from the University of Rochester School of Medicine and Dentistry, specializing in cellular immunology. He trained in internal medicine at the Beth Israel Hospital, and dermatology at Harvard Medical School/Massachusetts General Hospital. He did a post-doctoral fellowship at the Dana Farber Cancer Institute in molecular biology, and began his career as a physician/investigator and Assistant Professor at the Massachusetts General Hospital and Harvard Medical School.

Optum Labs: A Seat at the Table

Optum Labs was launched in January 2013 as an open innovation center for the healthcare and life sciences industry to collaborate on research and innovation focused on improving patient care and lowering the costs of care. Optum's founding partner in the labs is Mayo Clinic, and they will be joined by a number of pharma, medical device, provider, university, technology, consumer, government, and payer organizations who will be actively participating in research, clinical translation, and innovation projects. The core assets of Optum Labs is 149 M lives of administrative claims data, 40 M lives of EHR data, advanced tools and substantial expertise in health economics, outcomes, and comparative effectiveness research. The goal of Optum Labs is to create a unique, unparalleled environment with the data, tools, and infrastructure necessary for leading experts and scientists to perform cutting edge research on the key challenges in healthcare today, and for innovators to bring the findings from this research into the clinic as novel tools and processes.

http://www.optum.com/optumlabs.html

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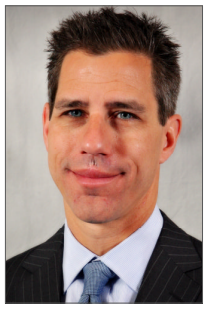
SESSION 6—TECHNOLOGY PANEL

Chair: Paul Bleicher

CEO, *Optum Labs*

Andrew Kress

Senior Vice President, Healthcare Value Solutions, *IMS*



Andrew Kress is senior vice president, Healthcare Value Solutions for IMS Health. In this role, he leads IMS Health initiatives that connect healthcare stakeholders through real-world evidence to demonstrate the value of medicines, enhance quality and drive improved outcomes. Andrew is responsible for a portfolio of growth platforms, including Health Economics and Outcomes Research and Real World Evidence Solutions, Clinical Trial Optimization Services and IMS Health's Government, Payer and Provider businesses. Andrew joined IMS Health in 2011 with the acquisition of SDI Health, a leading U.S.-based healthcare market insights and analytics firm, where he served as president and CEO since 2006. In this role, Andrew led the company's expansion from primary market research into the longitudinal patient-level data space, guided product development activities and advanced relationships with key data suppliers. Prior to this appointment, he held roles of increasing responsibility with SDI, including president from 1998 to 2006 and, from 1992 to 1998, vice president responsible for sales to pharmaceutical and consumer products clients in the U.S. and other markets. He joined the organization in 1991.

Andrew holds a BA degree from Yale University.

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Real World Data and Evidence- A Framework and Process for Engagement

Real World Evidence assessments extend the traditional hurdles of efficacy, safety, quality, and value for money from a one-time sprint to an ongoing process across the lifecycle of a product. However, life science companies are increasingly disadvantaged by information asymmetry between themselves and key stakeholders such as payers, providers, and regulators. In response, most pharmaceutical companies are rapidly advancing initiatives to build capabilities around real world data. The complication is that, unlike many legacy functions in pharma, RWE impacts and transforms processes across a broad set of internal areas, including research and development , market access, safety, and commercial operations. Combined with the rapidly evolving availability of real world data and novel technologies, many companies struggle to industrialize RWE capabilities, determine where they should be based, drive skill sets and tools are needed for full RWE value capture, determine what functions are best performed in-house versus outsourced, and what each company can do to be competitively positioned relative to its peers.

Internal resource constraints mean that companies recognize the need to have an approach that can be deployed more generally, but are leveraging varied points of focus around RWE initiatives. This multi-year journey may start with achieving excellence in one therapeutic area, geography, and for selected internal users. However, it must be able to rapidly scale across these dimensions and eventually support value -added health systems engagement.

To succeed, RWE cannot solely be considered a data or technology problem, but more critically the need for organizational changes. Defining a framework for understanding RWE within the organization, combined with selecting realistic goals against specific targeted initiatives can increase the probability of success of integrating real world data into existing processes.

http://www.imshealth.com/

SESSION 6—TECHNOLOGY PANEL

Douglas McNair

President, *Cerner Math Inc.*

Douglas McNair, MD, PhD, is one of three Cerner Engineering Fellows and is responsible for innovations in mathematical modeling, decision support, and very-large-scale datamining.

McNair joined Cerner in 1986, first as head of Cerner's Knowledge Systems engineering department; then as vice president of Regulatory Affairs, responsible for both submissions and compliance; then as General Manager for Cerner's Detroit and Kansas City branch offices. Subsequently, he was Chief Research Officer, responsible for overseeing Cerner research operations. In 1987, McNair was co-inventor and co-developer of Discern Expert ®, a decision-support engine that today is used in more than 2,000 health care facilities around the world. Between 1977 and 1986, McNair was a faculty member of Baylor College of Medicine, in the Departments of Medicine and Pathology.

McNair came to Cerner from Select Therapeutics, Inc., where he was Senior Vice President for Research and Development. Prior to this role, McNair was Vice President for Clinical Development at Abiomed, where he authored investigational plans and protocols for all products and was responsible for clinical trials of VAD and artificial heart devices, both in North America and in Europe. Between 1977 and 1986, McNair was a faculty member of Baylor College of Medicine, in the Departments of Medicine and Pathology, and co-directed the biostatistics and Design & Analysis Unit under Drs. Tony Gotto and Michael Debakey.

McNair received his bachelor's and graduate degrees from the University of Minnesota. He also was a fellow in laboratory medicine and pathology at the Mayo Graduate School of Medicine. He is certified by the American Board of Pathology and the American Board of Internal Medicine.

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Active Pharmacovigilance using Bayesian Confidence-propagation Neural Network-based Machine-learning

We have developed a novel, cloud-computing-based, machine-learning active pharmacovigilance system and method that is able to automatically discover, establish, and statistically validate safety signals in repositories of electronic medical record (EMR) information. Conventionally, analysis of observational data consists of examining differences in outcome frequency between a group having the exposure of interest, and groups lacking that exposure. But the groups must be similar at 'baseline'. If they are not, then interpretation will have a high rate of false-positive and false-negative errors. However, patient populations receiving different medication regimens are vastly different, with different statistical distributions of diagnoses, disease severity levels, and physiologic reserve. By contrast, our system utilizes Bayesian confidence-propagation neural network (BCPNN) algorithms are one means by which probabilities for various beneficial events and harmful events or outcome states can be jointly computed from multiple concurrent input variables, where the variables' values may be time-dependent or uncertain. We applied the BCPNN-based machinelearning approach to a data warehouse of EMR data from 11,259 acute myocardial infarction in-patients. Illustrative examples of new multi-drug, context-dependent SAE signals discovered using our BCPNN include detection of a 6-fold increase in risk of Grade 4 acute hepatotoxicity and 5-fold increase in risk of in-hospital mortality among AMI patients who received an antiarrhythmic concomitant with a macrolide or fluoroquinolone antibiotic, a phenothiazine or 5-HT(3) inhibitor antiemetic, an SSRI antidepressant, or a triptan serotonin agonist during their inpatient stay. Statistical performance for 3-way and higher -order interactions is superior to Gamma Poisson Spreader, EB05, and other signalascertainment methods.

http://www.cerner.com

SESSION 6—TECHNOLOGY PANEL

John Murphy

VP Clinical Analytics, *Quintiles*

John Murphy is Vice President of Clinical Informatics & Analytic Innovation at Quintiles. He has been working with Pfizer, Merck, J&J, Roche, Bayer and other pharmaceutical companies and a nationwide academic hospital-physician-patient cloud-based health network to create a uniform environment for the conduct of basic, clinical and medical outcomes research.

The **Partnership for Accelerating Clinical Electronic Research** (PACeR) is a 501c3 non-profit collaboration that has been operating for five years and has deployed a nationwide cloud-based clinical research platform that is being used to automate multi-site trials and quality and outcome studies. When he is not working at Quintiles he is an active board member of Sylvan Road Capital and Havenbrook Homes, a multi-billion real estate hedge fund.

Prior to joining Quintiles, his career in drug development includes positions as: Senior Executive Advisor to the Booz, Allen & Hamilton and Booz & Company healthcare and pharmaceutical and lifescience R&D partnerships; Senior Vice President at Pharsight Corporation (16b Officer), and; Senior Vice President and CIO at Curagen (16b Officer), a genomic-based drug development company. His career in Clinical Informatics includes: CEO of Just Medicine Technologies, Incorporated and SVP of Clinical Software Engineering (16b Officer) of Community Health Computing (CHC). In the medical care and delivery space he has served in a variety of positions including Chief Executive Officer within NYS academic medical centers and founded a successful medical device and instrument company. His academic career includes faculty positions at MIT, University of Buffalo Law School and Columbia. As a national policy advisor he served on a White House-based National Commission and was responsible for policy recommendations for federal funding of undergraduate and graduate medical education. He has co-authored two books and hold patents on a variety of medical devices and clinical software applications. In 2000, he was recognized by Columbia University and awarded its Medal of Distinction for his contributions in the fields of medicine, technology & law. He has undergraduate and graduate degrees from Columbia College, Columbia University Faculty of Medicine-Columbia University School of Public Health (Epidemiology).

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Clinical Cloud Computing, Clinical Analytics & Interchangeable Parts

The "American System of Manufacturing" that was first industrialized in the nineteenth century, rests on the concept of interchangeability of parts; a concept credited to Eli Whitney for the manufacture of weapons. Machine tools such as the slide rest lathe, screw-cutting lathe, turret lathe, milling machine and metal planer were invented for this purpose; additional innovation including the jigs, position and fastening blocks and measuring tools and gauges insured accuracy of finish. Without the ability to freely replace one part with another assembly line manufacturing and the modern world as we know it would not have happened. In science, clinical research and drug development our parts are units of data, and those discrete elements collected across laboratories, clinical research sites, at the bedside and external environment need to be made uniform to automate basic, clinical and outcomes (aka: "Big Data") science.

Knowledge Managers within the Pharmaceutical and CRO industry have difficulty standardizing data within their own organizations. How can we expect to standardize across company, university, hospital, physician and patient domains—the assembly line for clinical research?

Cross industry collaboration for the development of standard Policies, Procedures, Methods, Technology and Data (Nomenclature & Semantic) is essential.

The Partnership to Advance Clinical electronic Research, a 501c3 non-profit collaboration, developed by the pharmaceutical industry and Quintiles has adopted the concept of the integrated Knowledge Cube and has implemented a national cloud-based clinical social network and uniform clinical research toolkit to automate and industrialize clinical research. Standardizing nomenclature and semantics is perhaps less of an impediment in this process than developing uniform policies, procedures and methods across clinical sites and the companies represented in this room today.

http://www.quintiles.com

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