2nd Meeting of the PRISME Forum

Special Interest Group Meeting

"THE VIRTUALIZATION OF R&D"

HOW TO SUPPORT EFFICIENTLY AND EFFECTIVELY INTER-COMPANY AND ACADEMIC COLLABORATION AND BUSINESS-PROCESS OUTSOURCING

October 16-17, 2011

PRISME Chair: Susie Stephens

PRISME SIG Chair: Simon Roach

Vice-Chair: Tom Flores

PROGRAM

Sun 16th Oct 2011 - Pre-SIG Dinner

18:30	**Pre-Sig Dinner** - Cambridge Brewing Company, 1 Kendall Square, Bldg 100, Cambridge Tel: +1 617-494-1994 (~0.4 miles from hotel)

Mon 17th Oct 2011 – SIG "The Virtualization of R&D" – Bio 8 Auditorium

TIME	TITLE	PRESENTER
07:45 – 08:30	Meeting Check-in: Bio 7 Building Lobby	
08:00 – 08:30	Pre-meeting continental breakfast	
08:30 – 08:45	Welcome	**Tom Flores**, *VP R&D IT, GSK*
08:45 – 09:30	Key Note: The virtualization of R&D – implications for CIOs	**Arjun Bedi**, *Global Managing Partner, Life Sciences - R&D Practice, Accenture*
09:30 – 10:00	How should technology and service vendors respond to this industry direction? – Part 1	**Neil de Crescenzo**, *Senior VP and General Manager for the Health Sciences Global Business Unit at Oracle Corp.*
10:00 – 10:30	Coffee Break	
10.30 – 11.00	How should technology and service vendors respond to this industry direction? – Part 2	**Michael Braxenthaler**, *Roche and external liaison officer for the Pistoia Alliance*
11:00 – 11:30	Transforming Business with Immersive and Socio-Collaborative Technologies	**Andrew Masters**, *Head of Enterprise Architecture, PPD*
11:30 – 12:00	Impacting R&D through pharma-payer collaboration: the AstraZeneca-HealthCore Partnership	**John Cai**, *Biomedical Informatics Director, AZ* **Siddhesh Kamat**, *Director of Research, HealthCore*
12:00 – 12:30	Leveraging technology to improve the efficiency and effectiveness of partnership with CROs	**Scot Kennedy**, *Divisional CIO Preclinical Services Business Unit, Charles River Laboratories.*
12:30 – 13:30	Lunch	
13:30 – 13:50	Informatics approaches for agile collaboration between pharma, biotech and academia	**Tim Clark**, *Harvard Medical School & Director of Informatics at MassGeneral Institute for Neurodegenerative Disease*
13:50 – 14:10	Leveraging social and cloud technologies in support of collaboration in the human cloud that represents the Broad Institute of MIT & Harvard.	**Martin Leach**, *Chief Information Officer at the Broad Institute*
14:10 – 14:30	Implementing Clinical Trial Data Standards – Virtually Almost There…	**Bernd Doetzkies**, *Director Informatics, Daiichi Sankyo Pharma Development*
14:30 – 15:00	Panel Discussion	**Tim Clark**, Martin Leach, Bernd Doetzkies
15:00 – 15:30	Coffee Break	
15:30 – 16:00	Collaboration – theory & practice	**Sean Ekins**, *Collaborations Director, Collaborative Drug Discovery*
16:00 – 17:15	4 round tables to discuss what has been heard, messages, insights, prime opportunities for progress etc. *Prepare for readout in PRISME plenary session*	All
17:15 – 17:30	Wrap Up	**Tom Flores**, *VP R&D IT, GSK*
18:30	**Joint SIG <> PRISME Forum Dinner** - The Blue Room, 1 Kendall Square, Cambridge Tel: +1 617 494-9034 (~ 0.4 miles from hotel)	

BIOS/ABSTRACTS

The virtualization of R&D – implications for CIOs
Arjun Bedi, *Global Managing Partner, Life Sciences - R&D Practice, Accenture*

Arjun Bedi is a Partner with Accenture, based in the United States. He is head of Accenture's Global Life Sciences R&D practice. His primary focus for the last 20+ years has been Pharmaceutical R&D. His expertise ranges from defining R&D strategies, to developing and implementing solutions that achieve enhanced business results. Arjun has led major change initiatives for some of Accenture's largest Life Sciences R&D clients. In this capacity he has worked with 9 of the top 10 pharmaceutical R&D organizations. Arjun has published several articles and spoken at numerous global conferences on a broad range of topics, including - Pharmaceutical R&D Productivity, R&D Operating models, R&D IT Strategy, Knowledge Management/ Business Intelligence and Alliance Management. He is a recognized thought leader in these areas.

How should technology and service vendors respond to this industry direction? – Part 1
Neil de Crescenzo, *Senior VP and General Manager for the Health Sciences Global Business Unit at Oracle Corp.*

Neil de Crescenzo is Senior Vice President and General Manager for Health Sciences at Oracle Corporation. He is responsible for managing Oracle's solution groups, strategic planning, product development, sales, service and support for the industry solutions sold into the healthcare and life sciences markets worldwide. He brings over 20 years of operational and IT leadership across healthcare and life sciences to his work with customers and partners worldwide. Oracle is the world's leading supplier of enterprise software, with over $25B in revenues and over 100,000 employees.

Prior to joining Oracle, Mr. de Crescenzo held a number of leadership positions at IBM Corporation for a decade, working with healthcare and life sciences clients worldwide. Prior to entering the information technology industry, he held leadership positions in healthcare operations at medical centers and a major health insurer.

Mr. de Crescenzo has been a keynote speaker at numerous industry conferences worldwide and is quoted frequently on industry issues. In 2005, he was named one of the Top 25 Most Influential Consultants by Consulting Magazine. Mr. de Crescenzo has a B.A. in Political Science from Yale University and an MBA in High Technology from Northeastern University.

How should technology and service vendors respond to this industry direction? – Part 2
Michael Braxenthaler, *Roche and external liaison officer for the Pistoia Alliance*

2009 – current, Pistoia Alliance - External Liaison Officer
1996 – current, Roche, Pharma Research and Early Development Informatics - Global Head Strategic Alliances

1991 – 1993, Maryland Biotech Institute - Postdoc, Computational Biology
1987 – 1991, Universität Tübingen, PhD, Biochemistry

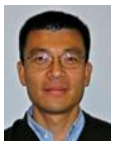
Transforming Business with Immersive and Socio-Collaborative Technologies
Andrew Masters, *Head of Enterprise Architecture, PPD*

October 2009 – Present Executive Director, IT - Enterprise Architecture & Innovation, PPD
Responsible for global Enterprise Architecture. Organizational management includes: IT Security Operations & Administration, IT Performance Testing, Identity & Access Management, and Enterprise Service Bus.
2009 - Technical Director, *Resolvit Resources*
2006– 2009, Chief Architect, Global IT Transformation, *Lenovo International*

2007 – 2008 - Duke University - The Fuqua School of Business, Masters, MBA, Global Executive
2001 – 2005 - University of Phoenix, BS, Accounting
1997 – 1998 - National University, AA, Computer Science Emphasis

---

What our partners are doing? The Healthcare Providers' Perspective
John Cai, *Biomedical Informatics Director, AstraZeneca*
Siddhesh Kamat, *Director of Research, HealthCore*



Zhaohui (John) Cai, MD, PhD is a Director of Biomedical Informatics at AstraZeneca supporting Patient Safety in Clinical Development. He received his MD from China Medical University, PhD from Albany Medical College, and Biomedical Informatics Fellowship training from Harvard Medical School. At AstraZeneca, he is also the US region coordinator of modeling and simulation in Statistics and Informatics. He has been involved in data mining, text mining, as well as providing modeling support to drug projects and safety knowledge groups.

Siddhesh Kamat is an experienced health care professional in the field of evidence based medicine. For the past 7 years, he has collaborated with both drug manufacturers and health plans on initiatives focused on improving quality of care while controlling healthcare costs. Siddhesh has successfully led several engagement teams on initiatives designed to demonstrate the clinical and economic value of pharmaceutical therapies. He has also worked on identifying cost of care reduction strategies for health plans. Siddhesh has a formal training in health economics and is currently pursuing his MBA from the New York University – Stern School of Business.

Leveraging technology to improve the efficiency and effectiveness of partnership with CROs
Scot Kennedy, *Divisional CIO - Preclinical Services Business Unit, Charles River Laboratories*

Given the continued growth in outsourcing arrangements, this session will provide an overview of how one CRO is working to make their Labs an integrated extension of the customers R&D capability, developing and sharing technologies that in the past would have been proprietary for internal use only. Will also initiate a conversation on opportunities to standardize information and processes for the benefit of Sponsors and CROs.

Scot Kennedy has worked within the Preclinical and Clinical phase I-III space for 20 years, during this time he has been responsible for implementing and deploying infrastructure and key business solutions to meet strategic objectives and optimize businesses in the high volume CRO space. During his time with Charles River he has successfully implemented and harmonized a variety of major systems; ERP, CRM, Data Management, Clinical Trials Management, HR, Portals, Inlife and Lab data collection systems. In addition he has implemented Data Warehouses for both Scientific and Financial data to meet the increasing demand for business real time data. In his current role as Divisional CIO, IT & Reporting he has responsibly for IT and Global Scientific Reporting within the Preclinical space. In this dual role he is focused on optimization of business solutions to cope with an ever changing market place as well as reengineering business process to accelerate delivery of scientific data and reports to Charles Rivers customers.

Informatics approaches for agile collaboration between pharma, biotech and academia
Tim Clark, *Harvard Medical School and Director of Informatics at MassGeneral Institute for Neurodegenerative Disease*

The classic "vertically integrated" pharma is increasingly seen as contributing to the high cost of therapeutic development and the low output of NMEs per research dollar. On this realization some drug companies are looking at agile collaboration strategies in which at least drug discovery is risk-shared across many collaborators with varying roles. However, current informatics strategies for the "vertical" pharma may not always be well adapted to the agile collaboration approach. We will discuss newer informatics approaches which may be better adapted to support this new model of collaboration and risk-sharing across pharma, biotech and academic research groups.

Tim Clark trained as a computer scientist at Johns Hopkins, and began his work in life science informatics as one of the initial developers of the National Center for Biotechnology Information (NCBI) Genbank and a collaborator on the initial NCBI prototype of PubMed. He subsequently served as Vice-President of Informatics at Millennium Pharmaceuticals, where his team built one of the first integrated bio- and chemi-informatics software platforms in the pharmaceutical industry. Tim is a founding Editorial Board member of the journal Briefings in Bioinformatics, an Advisory Committee member of the World Wide Web Consortium (w3.org), and an Advisory Board member for the Neuroscience Information Framework (nif.nih.gov). Tim Clark's research program focuses on multi-modal semantic integration of biomedical web communities, scientific discourse and experimental results. He is the Principal Investigator of the Semantic Web Applications in Neuromedicine (SWAN) (swan.mindinformatics.org) and Science Collaboration Framework (www.sciencecollaboration.org) projects.

Tim's informatics group built the reusable software platform for Stembook (www.stembook.org), an online review of stem cell biology published by the Harvard Stem Cell Institute, and created the Parkinson's Disease (PD) Online Research website (pdonlineresearch.org) in collaboration with the Michael J. Fox Foundation for Parkinson's Research.

Leveraging social and cloud technologies in support of collaboration in the human cloud that represents the Broad Institute of MIT & Harvard.
Martin Leach, *Chief Information Officer at the Broad Institute*

Martin Leach is Chief Information Officer at the Broad Institute. In this role, he oversees and helps integrate the Institute's multi-faceted computing and information technology-related endeavors.

Martin comes to the Broad from Merck & Co., where he led IT for Discovery and Pre-Clinical Sciences across all the North American research sites. Over his career he has provided support and strategic vision for IT, informatics, and data-mining activities at a range of life sciences organizations, from basic research laboratories to large pharmaceutical companies.

Martin received his Ph.D. in pharmacology from Boston University School of Medicine and his B.Sc. in cell and molecular sciences from Anglia Polytechnic University

---

Implementing Clinical Trial Data Standards – Virtually Almost There…
Bernd Doetzkies, *Director Informatics, Daiichi Sankyo Pharma Development*

Over the past 14 years, Pharmaceutical and Biotech organizations have been challenged with overcoming resistance to adopting industry standards, particularly CDISC standards, for a number of seemingly well-founded reasons. Companies looking to adopt standards should not be in search of finding and implementing the "Holy Grail" of standards – for this results in organizational paralysis and ineffective intra- and inter-company communications, data exchange, and data analysis. This presentation will focus on the importance and resulting benefits of taking a holistic and evolutionary approach to standards implementation, specifically the CDISC standards, and give examples on how CDASH, SDTM, ADaM, Define XML, and ODM can be developed and implemented over time to meet real business needs in a virtualized and outsourced R&D environment.

Bernd Doetzkies is Director, Informatics, at Daiichi Sankyo Pharma Development where he is responsible for collaborating with Clinical Research functional areas to identify opportunities for process optimization through the innovative exploitation of information management technologies, and for ensuring that these systems are implemented and maintained in a regulatory-compliant manner.

Bernd has over 28 years of experience developing and implementing research-based information management and analytical systems across a number of industries, including 19 years within the pharmaceutical industry. In addition to implementing systems, he has also led many business process improvement initiatives and standards implementation projects within Clinical Development.

Most recently Bernd was responsible for the global implementation of the Clinical Data Repository and Modeling and Simulation Platform at Daiichi Sankyo. This integrated computing environment facilitates access to clinical trial data and advanced analytics, and also promotes collaboration across various functions within Clinical Research.

Life Science Collaboration & Virtualization: A Perspective

Sean Ekins, *Collaborations Director, Collaborative Drug Discovery*

Biomedical research has become increasingly driven by creating and consuming tremendous volumes of complex data. At the same time the pharmaceutical industry is utilizing an extended network of partner organizations of various sorts (CRO's, not-for-profit organizations, clinicians and academics) in order to discover and develop new drugs.
Current areas of interest for delivering new technologies or molecules to the industry are Open Innovation, Collaborative Innovation and of course, Open Source. Due to the mounting costs, collaborative research and development is undoubtedly the future of biomedical research.
These topics and more will be discussed in a forward looking perspective.

Sean Ekins graduated from the University of Aberdeen; receiving his M.Sc., Ph.D. and D.Sc. He is Principal Consultant for Collaborations in Chemistry, Collaborations Director at Collaborative Drug Discovery Inc. and Senior Vice President of Computational Biology at Arnold Consultancy and Technology LLC. In addition he is Adjunct Associate Professor, School of Pharmacy Department of Pharmaceutical Sciences, University of Maryland; Adjunct Professor in the Department of Pharmacology at University of Medicine and Dentistry of New Jersey - Robert Wood Johnson Medical School, Piscataway, NJ. Sean was a postdoctoral fellow at Lilly Research Laboratories in the drug disposition group (1996-1998). He has worked as a senior scientist at Pfizer (1998-1999) and Lilly Research Laboratories (1999-2001) in drug-drug interaction screening and computational ADME/Tox groups, respectively and as Associate Director of Computational Drug Discovery at Concurrent Pharmaceuticals, Inc (2001-2004) and Vice President of Computational Biology at GeneGo (2004-2006).

Sean has authored or co-authored ~170 peer reviewed papers and book chapters as well as edited/ co-edited four books ("Computer applications in pharmaceutical research and development", "Computational Toxicology: Risk Assessment For Pharmaceutical and Environmental Chemicals", with Xu JJ, "Drug Efficacy, Safety, and Biologics Discovery: Emerging Technologies and Tools" and with Hupcey MAZ and Williams AJ "Collaborative Computational Technologies for Biomedical Research"). He is the Reviews Editor for Pharmaceutical Research, Associate Editor of the Journal of Pharmacological and Toxicological Methods, is on the Editorial Board of Drug Metabolism and Disposition, Drug Discovery Today, Mutation Research Reviews and the ChemSpider Journal of Chemistry. He currently serves on the scientific advisory board for Emiliem Inc., Assay Depot and Pistoia Alliance.

NOTES