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April 28 – 30, 2008 • World Trade Center • Boston, MA

Keynote Presentations by:



Linda Avey co-Founder 23andMe, Inc.



Joshua Boger, Ph.D. President & Chief Executive Officer Vertex Pharmaceuticals, Inc.

John Reynders, Ph.D. Vice President & Chief Information Officer Johnson & Johnson, Pharma R&D



2008 Benjamin Franklin Award presented by Bioinformatics.org



Concurrent Tracks:

- Informatics and IT Infrastructure & Operations
- Informatics for Genome Analysis, Biomarkers, and Target Discovery
- Predictive and in silico Science
- eChemistry Solutions
- Clinical and Medical Informatics

Keynote Panel:

The Future of Personal Genomics: A special plenary panel discussion featuring George Church, Ph.D., Harvard Medical School Dietrich Stephan, Ph.D., Navigenics Jeffrey M. Drazen, M.D., New England Journal of Medicine/Harvard Medical School Fred D. Ledley, M.D., Bentley College ...and more

Event Features:

- Access All Five Tracks for One Price
- Network with 1,500+ Delegates
- Hear 85+ Technology and Scientific Presentations
- Choose from Four Pre-conference Workshops, the Oracle Life Sciences and Healthcare User Group Meeting, and Symyx Software Symposium 2008
- Attend Bio-IT World's Best Practices Awards
 INEW
- Connect with Attendees Using CHI's Intro-Net
- Participate in the Poster Competition
- See the Winners of the following 2008 Awards: Benjamin Franklin Best of Show Best Practices
- View Who's Who & What's New in the Exhibit Hall
- And Much More!

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| BioIT World | | Conferen | ce-at-a-Glance | | | | | |
|--|---|--|---|--|--|--|--|--|
| Sunday, April 27 | PRE-CONFERENCE EVENTS (Separate Registration Required) | | | | | | | |
| 11:00-12:00 | OLSUG-2008 Registration and Morning Coffee | | | | | | | |
| 12:00-4:00 | OLSUG-2008 International Oracle Life Sciences and Healthcare User Group Meeting (see page 3 and 4 for details) | | | | | | | |
| Monday, April 28 | PRE-CONFERENCE EVENTS (Separate Registration Required) | | | | | | | |
| 7:00-8:00 | | Pre-Conference Registration and Morning Coffee | | | | | | |
| 8:00-4:00 | OLSUG-2008 International Oracle Life Sciences and Healthcare User Group Meeting Presentations (see page 3 and 4 for details) | | | | | | | |
| 8:00-4:00 | OLSUG-2008 International Oracl | le Life Sciences and Healthcare User (| Group Meeting Hands-on Technical W | orkshops (see page 3 and 4 for | details) | | | |
| 8:00-12:15 | Morning Workshop: (W1) Harne | ssing the Semantic Web for Your Org | anization | | | | | |
| 1:30-4:00 | Afternoon Workshop: (W2) Data | Afternoon Workshop: (W2) Data Visualization for Effective Drug Discovery Decisions | | | | | | |
| 8:00-4:00 | Full-day Workshops: (W3) Next-Generation Sequencing Data Management & (W4) Electronic Lab Notebooks and Collaborative Knowledge Management | | | | | | | |
| 2:00-6:00 | Main Conference Registration | | | | | | | |
| 4:00-5:00 | Plenary Keynote: John Reynders | s, Ph.D., Vice President & Chief Inforn | nation Officer, Johnson & Johnson, Pl | narma R&D | | | | |
| 5:00-7:00 | Welcome Reception in the Exhibit Hall Drop off a business card at the CHI Sales booth for a chance to win 1 of 2 iPod Videos! | | | | | | | |
| Tuesday, April 29 | MAIN CONFERENCE | | | | | | | |
| 7:30-6:00 | Registration | | | | | | | |
| 7:30-8:15 | Morning Coffee | | | | | | | |
| 8:15-9:00 | Plenary Keynote: Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc. | | | | | | | |
| 9:00-9:30 | Reynote Presentation: 2 | 2008 Benjamin Franklin Award (see pa | ge 3 for details) | | | | | |
| 9:30 | Exhibit Hall Opens | | | | | | | |
| 9:30-10:50 | Coffee Break, Exhibits, Poster Vi | ewing and Vendor Theater Presentat | ions | | | | | |
| | Track 1 | Track 2 | Track 3 | Track 4 | Track 5 | | | |
| CONCURRENT TRACKS | Informatics and IT Infrastructure & Operations | Informatics for Genome Analysis, Biomarkers and Target Discovery | Predictive and in silco Science | eChemistry Solutions | Clinical and Medical Informatics | | | |
| 10:50-12:30 | Data Infrastructure and Management | Informatics fo Genome Analysis | Model-simulated Therapeutics & Systems Biology Approaches to Drug Discovery and Development | High-Throughput Screening | Clinical Data Management | | | |
| 12:30-1:45 | Luncheon Workshop Luncheon Workshop (Sponsorship Available) or Lunch on Your Own Sponsored by Microsoft Sponsored by Microsoft | | | | | | | |
| 1:45-3:45 | HTS Data Processing & Management | Informatics for Genome Analysis & Data Biomarkers | Systems Biology Approaches to Drug Discovery and Development | Structure-Based Design and Predicting Targets | EDC | | | |
| 3:15-3:45 | Refreshment Break, Exhibit and Dedicated Poster Viewing | | | | | | | |
| 3:45-4:15 | Refreshment Break, Exhibit and Dedicated Poster Viewing Innovation | Data and Biomarkers | Biomarker Identification and Pre- dictive Bio-simulation | Cheminformatics Platforms and Tools & Safety Profiling | Informatics Tools for Clinical Decision Support & Translational Medicine | | | |
| 5:15-6:15 | | | | | | | | |
| 7:00 | 2008 Best of Show Awards/Reception in the Exhibit Hall (see page 3 for details) | | | | | | | |
| | | Practices Awards/Dinner (see page 3 for | details) | | | | | |
| 6:15 | Exhibit Hall Closes | | | | | | | |
| Wednesday,April 30 | | | | | | | | |
| 7:30-2:30 | Registration | | | | | | | |
| 7:30-8:00 8:00-8:45 | Morning Coffee | | | | | | | |
| 8:45-9:45 | Plenary Keynote: Linda Avey, co-Founder, 23andMe, Inc. | | | | | | | |
| 9:45-2:00 | Keynote Panel: George Church, Ph.D. (Harvard Medical School), Dietrich Stephan, Ph.D. (Navigenics), Jeffrey M. Drazen, M.D. (New England Journal of Medicine/Harvard Medical School), Fred D. Ledley, M.D. (Bentley College) | | | | | | | |
| 9:45-2:00 | Exhibit Hall Opens Coffee Break, Exhibit Viewing, Vendor Theater Presentations, and Poster Competition in the Exhibit Hall | | | | | | | |
| 7.45-10.45 | Track 1 | Track 2 | Track 3 | Track 4 | Track 5 | | | |
| CONCURRENT TRACKS | Informatics and IT Infrastructure & Operations | Informatics for Genome Analysis, Biomarkers and Target Discovery | Predictive and <i>in silco</i> Science | eChemistry Solutions | Clinical and Medical Informatics | | | |
| 10:45-12:30 | Informatics Solutions for Biomedical Research | Informatics for Biomarkers | <i>in silico</i> Tools and Web-based Applications | QSAR & Lead Hopping | Clinical Research Informat- ics/Clinical Trials/EHRs | | | |
| 12:30-2:00 | Luncheon in the Exhibit Hall | | | | | | | |
| 2:00-4:00 | Platform & Storage Design | Informatics for Target Discovery | Causal & Genomic Predictive Models | Driving Informatics Inte- gration (ends at 5:30) | Clinical Research Informat- ics/Clinical Trials/EHRs | | | |
| 2:00-5:30 | Symyx Software Symposium 2008 (see page 3 for details) | | | | | | | |
| 2:00 | Exhibit Hall Closes Exhibit "Match Game" with an iPod® Video! * | | | | | | | |
| 4:00 Thursday, May 1 - Friday, May 2 | Conference Adjourns POST-CONFERENCE EVENTS (Separ | rate Registration Required) | Play the Match Game and you have a chance to win an iPod® Video! Pick up your game card in the Exhibit Hall for details. | | | | | |
| rriday, May 2 | Symyx Software Symposium 2008 (see page 3 for details) Pick up your game card in the Exhibit Hall for details. Content of this raffle. | | | | | | | |
| Thursday, May 1 - Friday, May 2 | POST-CONFERENCE EVENTS (Separ | | chance to win an iPod® Video! Pick up your game card in the Exhibit | Hall for details. | Bio: Work Conference & Expo Mark and Instantion - Instant | | | |

Pre-Conference Events

Solsug States Co-located Oracle User Group* 9th Annua

OLSUG-2008 INTERNATIONAL ORACLE LIFE SCIENCES AND HEALTHCARE USER GROUP MEETING*

Sunday, April 27 12:00-4:00pm • Monday, April 28 8:00am–4:00pm This meeting will consist of exciting keynote presentations from industry renowned individuals. There will be workshops and discussions that are focused on topics of great interest, for example, the Semantic Web and database analytics. Oracle partners will be describing their latest offerings. In addition, there will be many presentations that have been selected to be of interest to scientists, healthcare IT professionals, application developers, architects and DBAs.

Please visit www.Bio-ITWorldExpo.com for program updates.

Monday, April 28

Harnessing the Semantic Web for Your Organization (W1)

(8:00 am-12:15pm)

Increasingly, companies are turning to Semantic Web technologies for help in solving the difficult data inte-Increasingly, companies are turning to Semantic Web technologies for help in solving the difficult data inte-gration challenges that are prerequisite to making effective progress in areas such as translational medicine, understanding mechanism of action, and efficient management of regulatory documentation. This workshop will demonstrate the maturing state of these technologies focusing on deployment strategies for successfully embracing Semantic Web technologies in your organization. Attendees will leave the workshop with: 1) an understanding of the basic components of Semantic Web technology, 2) case study and deployment examples of how organizations are using Semantic Web technology, 3) knowledge of tools and 3rd party organizations to consider using to help implement Semantic Web technology, and 4) having had the opportunity to share their business issue or challenge and receive peer and expert feedback on strategies to handle it. The workshop format will combine lecture presentations and interactive group exercises.

Elgar Pichler, Ph.D., Discovery Information, AstraZeneca R&D Boston

Alan Ruttenberg, Principal Scientist, Science Commons

Jim Golden, Ph.D., CTO, SAIC Life Science Office

Data Visualization for Effective Drug Discovery Decisions (W2) (1:30-4:00pm)

Visual Analytics is the science of analytics reasoning focused on visualization and its interfaces. It attempts to build a science of the transformation of data into information and further into knowledge. This workshop will help participants understand the role of visualization in bioinformatics and medical informatics as applied to the drug discovery process. We will present a variety of visualizations and analytic tools integrated with visualiza-tions, and of systems. Example applications will be discussed.

Georges Grinstein, Ph.D., Professor and Director, Center for Biomolecular and Medical Informatics, UMass Lowell Peter V. Henstock, Ph.D., Marager, Emerging Technologies and Architectures, Pfizer Research Technology Center Michael N. Liebman, Ph.D., Senior Institute Fellow, Windber Research Institute

Keynote Speakers



Linda Avey, co-Founder, 23andMe, Inc.

Linda has over 20 years of sales and business development experience in the biopharmaceutical industry in San Francisco, Boston, San Diego, and Washington, D.C. Prior to starting 23andMe, she developed translational research collaborations with academic and pharmaceutical partners for Affymetrix and Perlegen Sciences. Linda also spent time at Spotfire helping scientists understand the power of data visualization and at Applied Biosystem's during the early days of the human genome project. The advent of high density genome-wide scanning technologies brought huge potential for significant discoveries. However, the lack of sufficient funding to enable adequate studies prompted Linda to think of a new research model. These ideas led to the formation of 23 and Me. Her primary interest is the acceleration of personalized medicine, using genetic profiles to target the right drug to the right person at the correct dose. Linda graduated from Augustana College with a B.A. in biology.



Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc.

Dr. Joshua Boger is the founder, President and Chief Executive Officer of Vertex Pharmaceuticals Incorporated (NASDAQ: VRTX). Prior to founding Vertex in 1989, Dr. Boger held the position of Senior Director of Basic Chemistry at Merck Sharp & Dohme Research Laboratories in Rahway, N.J., where he headed both the Departments of Biophysical Chemistry and Medicinal Chemistry of Immunology & Inflammation. During his ten years at Merck, Dr. Boger developed an international reputation as a leader in the application of computer modeling to the chemistry of drug design and was a pioneer in the use of structure-based rational drug design as the basis for drug discovery programs. Dr. Boger holds a bachelor of arts in Chemistry and Philosophy from Wesleyan University (Connecticut) and a master's and doctorate degrees in Chemistry from Harvard University.



John Reynders, Ph.D., Vice President & Chief Information Officer, Johnson & Johnson, Pharma R&D

John leads the global R&D IT strategy across Pharma R&D operating companies, Global Development Organizations (GDOs) and Medical Affairs groups. John was most recently Information Officer, Lilly Research Laboratories, where he was responsible for Discovery and Development Informatics Systems for Eli Lilly and Company. As such, he successfully led IT across the North America, Europe, and Asia-Pacific organizations, increasing agility through organizational transformation, greater transparency through detailed portfolio and project management discipline, improved business alignment through balanced scorecard deploy-ment, and more rapid execution through capabilities development. Prior to this, he held positions at Celera Genomics, Sun Microsystems, and Los Alamos National Laboratories. He holds a Ph.D. in Applied and Computational Mathematics from Princeton University, as well as a Bachelor of Science in Mathematics, Summa Cum Laude, and a Physics Minor, Concentration in Fluid Mechanics, from Rensselaer Polytechnic Institute. He is currently working toward his Master of Business Administration at the Kellogg School of Business at Northwestern University.

Next-Generation Sequencing Data Management (W3)

(8:00am-4:00pm)

BioTeam has been on the frontlines of next-generation sequencing integration, having helped several orga-nizations with the unique next-gen IT, storage, and data management challenges. This workshop will present real-world customer experiences straight from the trenches. You'll get practical information about the analysis, rear-world costone experiences stratgin nom interfercines. Four ger practical information about the analysis, assessment, design, implementation, resting, and support needed to bring a research organization from technol-ogy adoption to publication in the next-gen world. This informative session will feature special guest speakers from Cold Spring Harbor Laboratory, Broad Institute, Cornell University Biotechnology Resource Center, Har-vard-Lipper Center for Computational Genetics, Naval Medical Research Center, and Intel, as well company representatives from Applied Biosystems, Helicos, Illumina, and Roche.

William Van Etten, PhD, Founding Partner and Director of Consulting Services, BioTeam, Inc. George Church, Ph.D., Professor of Genetics at Harvard Medical School and Director of the Center for Computational Genetics

W. Richard McCombie, Ph.D., Professor, Cold Spring Harbor Laboratory Matthew Trunnell, Group Leader, APSG, Broad Institute of MIT and Harvard Timothy Read, Ph.D., Principle Investigator, Naval Medical Research Center George Grills, Director of Operations of Core Facilities, Cornell University Life Sciences Core Laboratories Center Wilfred Pinfold, Ph.D., General Manager, Integrated Analytic Solutions, Intel Corporation Kevin McKernan, Senior Director, Scientifi c Operations, Applied Biosystems Avak Kahvejian, Ph.D., Product Manager, Helicos BioScience Corporation Abizar Lakdawalla, Ph.D., Senior Product Manager, Illumina, Inc. Timothy Harkins, Ph.D., Marketing Manager, Roche Diagnostic Corporation

Electronic Lab Notebooks and Collaborative Knowledge Management for Life Sciences R&D and Manufacturing (W4) (8:00am-4:00pm)

(E.Ovam-4:00pm) Electronic Lab Notebook Systems (ELNs), and related informatics tools are evolving very rapidly. If implemented well, ELNs completely replace paper-based systems and provide maximum leverage from intellectual property (IP) assets, and help get better quality compliance. If done poorly, they can severely jeopardize both IP and compliance. ELNs are now the most crucial platform for integrated knowledge management in chemical and life sciences R&D and manufacturing. Organizations must learn to apply them well to create a comprehensive scientific informatics strategy for Collaborative Knowledge Management in R&D and manufacturing enterprises. The workshop format will combine lecture presentations and handson exercises.

Richard Lysakowski, Ph.D., Director of R&D and Advisor, The Collaborative Electronic Notebook Systems Association (CENSA)

*Separate registration required



Bio-IT World will present the Awards for its 2008 Best Practices competition at a special evening ceremony during the Bio-IT World Conference & Expo. Entries are currently being sought for outstanding examples of novel technologies and strategies enhancing the success of operations in any part of the research/drug discovery pipeline. Winners

will be selected by a peer-review expert panel in early 2008. Complete information, including online entry forms, is available at www.bio-itworld.com/bestpractices. Join Bio-IT World editors, keynoters, and meet the Best Practices winners at the Best Practices Awards dinner, April 29. This is a premium networking opportunity to meet senior executives and researchers who represent the best of bio-IT.

(Separate registration required. See registration page for details.)



The "Best of Show" Award offers exhibitors an opportunity to distinguish their products from the competition. Judged by a team of Bio-IT World magazine editors and leading industry experts, this award program will identify exceptional innovations in technologies used by life science professionals today. Judged live in the Exhibit Hall!



2008 Benjamin Franklin Award

The Benjamin Franklin Award for Open Access in the Life Sciences is a humanitarian/bio-thics award presented annually by the Bioinformatics Organization to an individual who has, in his or her practice, promoted free and open access to the materials and methods used in the life sciences. Nominations are now being accepted! For more information, visit www.bioinformatics. org/franklin/. The winner will be announced Tuesday, April 29.

Co-located Event

Symposium 2008 Symyx Software Symposium R&D INTEGRATION SUCCESS

April 30 - May 2, 2008 • World Trade Center • Boston, Massachusetts

The Symvx Software Symposium 2008 represents a worldwide community of people who share a vested interest in the successful deployment of software platforms and modular workflows. The 2008 Symposium is designed to present success stories and implementation techniques of how companies are integrating scientific desktops, experimentation systems, and data management across departments, sites and CROs.

The 2008 Symposium is centered on case study presentations from industry leaders and will also serve as a forum for collaborative problem solving and networking through interactive discussions. Symyx executives will discuss the acquisition of MDL Information Systems and provide the software development roadmap. Hands-on scientific application training will be conducted by Symyx field application scientists.

- Key issues to be addressed throughout the Symposium include but not limited to:
- · Quantitative metrics on laboratory efficiency and productivity
- Return on investment (ROI)
- · Implementation issues and solutions for overcoming integration challenges
- · Modeling materials performance in the lab to drive and respond to product performance models for the market
- · Knowledge management and sharing across sites, instruments, scientific domains, and organizations
- · Successes and challenges of collaboration with external clients

Please visit www.symyxsymposium.com for program updates. Separate registration required.



Co-located Oracle User Group* 9th Annual

OLSUG-2008 INTERNATIONAL ORACLE LIFE SCIENCES AND HEALTHCARE USER GROUP MEETING*

Sunday, April 27 • 12:00-4:00pm

Monday, April 28 • 8:00am-4:00pm

This meeting will be held April 27-28, 2008 in conjunction with the Bio-IT World Conference & Expo at the World Trade Center in Boston. Hands-on Technical Workshops will be held Sunday afternoon and all day Monday. Keynotes and technical presentations will be held all day Monday.

OLSUG08 is designed to accelerate success of users by sharing useful information, best practices and novel and innovative use cases of Oracle Database Technology products in life sciences and Healthcare. Exciting keynotes, technical talks by product experts, hands-on workshops, and ISV partner presentations have been selected that will be of interest to scientists, Healthcare IT professionals, application developers, architects and DBAs.

Schedule-at-a-Glance

Sunday, April 27

11:00 am - 12:00 pm 12:00-4:00 pm Registration and Morning Coffee Hands-on Technical Workshops

Monday, April 28

7:00-8:00 am Registration and Morning Coffee
8:00 am Track 1: Presentations Track 2: Hands-on Workshops
12:00 Lunch
1:00 Track 1: Presentations

Track 2: Hands-on Workshops

3:40 OLSUG Wrap-up

Preliminary Agenda and Accepted Talks

The Database as Biomedical Laboratory: The Connectivity Map

The Connectivity Map is a new kind of biomedical database and application where drugs can be matched to diseases using the common language of gene expression. This presentation will introduce The Connectivity Map that is publicly available at the Broad Institute's web site. Examples of how the database is used in cancer research will be shown.

Pablo Tamayo, Ph.D., Program Scientist, Cancer Program, Broad Institute

MyHits: Road from MySQL to Oracle

The MyHits web server is an integrated service dedicated to the annotation of protein sequences and to the analysis of their domains and signatures. This presentation will describe the MyHits application and rationale behind the migration to Oracle. We will also discuss the migration steps taken, highlighting lessons learned and results gained, as well as plans for the future.

Dmitry Kuznetsov, Ph.D., Vital-IT / Swiss Institute of Bioinformatics

How Life Science Customers use the Semantics Features in Oracle Database 11g

Support for semantic technology in Oracle database has been enhanced significantly in 11g release in terms of 1) new functionality and 2) across the board improvement in performance. As we progressed from release 10gR2 of Oracle DB to 11g, Life Science customers' requirements have changed as well both in terms of needs for more sophisticated functionality and for larger scale of data. This presentation will discuss the extent of match between Life Science customers' requirements and the performance and functionality enhancements that went into Oracle DB Semantic Store in 11g. In particular, we will illustrate related aspects by outlining specific use cases from some of the Life Science customers.

Souripriya Das, Ph.D., Oracle

Additional speakers and sessions to be confirmed. Please visit www.Bio-ITWorldExpo.com or www.OLSUG.org for program updates.

* Separate registration required



TRACK 1: INFORMATICS AND IT INFRASTRUCTURE & OPERATIONS



4:00 pm

Event Chairperson's Opening Remarks Cindy Crowninshield, Conference Director, Cambridge Healthtech Institute

PLENARY KEYNOTE

4:15 Informatics: Integration & Convergence

John Reynders, Ph.D., Vice President & Chief Information Officer, Johnson & Johnson, Pharma R&D

Monday, April 28

Sponsored by 5:00 Welcome Reception in the Exhibit Hall

Drop off a business card at the CHI Sales booth for a chance to win 1 of 2 iPod ® Videos!



Tuesday, April 29

7:30 am

Registration and Morning Coffee 8:15 **Event Chairperson's Opening Remarks**

Phillips Kuhl, Co-founder and President, Cambridge Healthtech Institute

PLENARY KEYNOTE



and Opportunities Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc.

9:00

Benjamin Keynote Presentation & 2008 Benjamin **Franklin Award** (see page 3 for details)

9:30 Coffee Break, Exhibit and Poster Viewing in the **Exhibit Hall**

Data Infrastructure and Management

10:50 Track Chairperson's Remarks

11:00 Internal-External Scientific Data Integration

The sheer volume of public and internal data for scientific decision-making within Merck is growing exponentially, outpacing our ability to capture, integrate, and make it widely accessible. This is partly due to the rapid growth of biomedical literature, the proliferation of high-throughput methods in genomics and other fields, and dynamic state of biological knowledge and vocabulary. This presentation discusses a strategy used at Merck to capture and integrate gene-related information, and to distribute the data across the company using custom software tools that have helped increase the efficiency of basic research. We will also discuss the potential extensibility of this strategy to other domains, and scalability as part of a larger data and information management solution.

Jason Johnson, Ph.D., Senior Director, Molecular Informatics, Rosetta Inpharmatics/ Merck & Co., Inc.

11:30 HPC Trends from the Trenches

This talk will review some of the BioTeam's recent work with biotech, pharmaceutical, government and enterprise clients. As an independent consulting firm, the BioTeam is able to see how HPC problems in life science informatics have been approached by organizations of varying type and size. We will address common problems and observed trends in computing, workflows and data movement, along with details on particularly clever solutions observed in production environments around the world.

Chris Dagdigian, Founding Partner and Director of Technology, BioTeam, Inc.

12:00 pm Computing Architectures for Large-Scale Proteomics

Proteomics technology is used to systematically identify and characterize proteins and their modifications within biological samples. It holds great promise to uncover medical breakthroughs at the molecular level, but requires unprecedented complex pattern matching in order to match the profile of a protein fragment to a subsequence within a protein sequence dataset. Special computing architectures have been developed to address the high-throughput analysis needs, some using FPGAs and multi-core CPUs. Here we present the algorithmic challenges and the architectures used to solve them.

David Chiang, CEO, R&D, Sage-N Research, Inc.

12:30 Luncheon Workshop Sponsored by Microsoft Microsoft BioIT Alliance: An Update

At the April 2006 Bio-IT World Conference & Expo, Microsoft Corp. announced the formation of the BioIT Alliance, a cross-industry group working to further integrate science and technology as a first step toward making personalized medicine a reality. The alliance unites the pharmaceutical, biotechnology, hardware and software industries to explore new ways to share complex biomedical data and collaborate among multidisciplinary teams to ultimately speed the pace of drug discovery and development. Now the Alliance has a worldwide presence and a broad set of over 70 members. We will present the latest activities of the Alliance.

Rudy Potenzone, Ph.D., WW Industry Technology Strategist for Pharmaceuticals, Microsoft Corp.

HTS Data Processing & Management

The Cutting Edge Can Hurt You - Real World Integra-1:45 tion Challenges in Building a Genomic Lab

Integrating next-generation sequencing instruments into a genomics lab is not a simple proposition. Questions of lab information management, networks, automated analysis, annotation, and data coherence loom large. The BioTeam has worked with several groups through this adoption period, performing requirements analysis, shaping technology choices, installing and configuring hardware, and developing custom software to build a coherent, usable system. This talk will share real-world experiences and specific insights into the challenges that many labs will face this year.

Chris Dwan, Director of Products and Principal Investigator, BioTeam, Inc.

2:15 Handling Data for High-Throughput, Large-Scale **Projects**

This session brings together data experts to discuss the data management challenges of the life sciences in comparison with other research disciplines. We will explore IT solutions from both academic and commercial research platforms. The applicability of data management solutions from other industries will be discussed for problems facing data architects in the Life Sciences today. We will share best practices and case study examples.

James Reaney, Director, Research Markets, BlueArc Corporation

3:45 **Refreshment Break, Exhibit and Dedicated Poster** Viewing

4:15 A Google Approach to Universal Search for Life Sciences

While life sciences is an information-intensive industry, finding information inside the enterprise is not always the simplest of tasks. Researchers spend considerable time looking for past experiment data, scientific names of drugs, clinical trials documents, and a myriad of other documents. Enterprise search is an emerging technology whereby researchers and other knowledge workers can instantly find any and all documents within the enterprise through a simple search. As the leader in search technology, Google has developed universal search for enterprises, which provides the ability to search all enterprise content - including intranets, file shares, databases, real-time business data, and content management systems -through one simple search box. Learn how this universal search can benefit pharma organizations, improve productivity and collaboration, and provide value.

The speaker is to be determined.

Innovation

4:45 **Innovation for IT Managers**

Innovation is the process of creating MEASURABLE economic value from a product or service. It requires IT managers to build high-performance organizations, learn how to define and execute on customer requirements, and to develop continuous quality improvement processes to measure the performance and value of information systems. This discussion will focus on the definition of innovation for IT managers, provide examples of innovation inside and outside biosciences and healthcare, and introduce methods and tools to encourage IT professionals to contribute to innovation in their enterprises. The complex interactions among critical success factors, the engineering organization, definitions of failure and success, requirements management, and continuous quality improvement will be discussed. Our goal is to help an IT manager understand what innovation means for his or her organization, how to design a high-performance organization, and measure its results and successes. Strategically, our goal is to help the biosciences avoid the process and engineering failures experienced in other industries.

Moderator: Bernard Wess, President, ProtonCare and PERSEID Software

5:15-6:15 2008 Best of Show Awards/Reception in the Exhibit Hall (see page 3 for details)

6:15 Exhibit Hall Closes

7:00 **EXAMPLE 1** 2008 Bio-IT World's Best Practices Awards/ Practices Dinner (see page 3 for details)

Wednesday, April 30

7:30 am Registration and Morning Coffee8:00 Event Chairperson's Opening Remarks

Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World

Keynote Introduction:

Ron Ranauro, President and CEO, GenomeQuest, Inc.

PLENARY KEYNOTE 8:05 Personalized Genetics: Advancements & Driving Change

Linda Avey, co-Founder, 23andMe, Inc.

8:45 The Future of Personal Genomics

George Church, Ph.D., Professor of Genetics and Director of the Center for Computational Genetics, Harvard Medical School

Dietrich Stephan, Ph.D., Co-founder and Chief Science Officer, Navigenics, Inc. Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine; Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School

Fred D. Ledley, MD, Professor and Chair, Bentley College; Founder and Chairman, My Genome

John Halamka, MD, MS, CIO, Harvard Medical School

9:45 Coffee Break, Exhibit Viewing, Vendor Theater Presentations, and Poster Competition in the Exhibit Hall

Informatics Solutions for Biomedical Research

10:45 Track Chairperson's Remarks 11:00 Enabling the Molecular Medicine

Revolution: Getting Connected with caBIG Track 5 This talk will explore strategies for embracing evidence-based patient care using the cancer Biomedical Informatics Grid, or caBIG. caBIG is an unprecedented initiative led by the NCI to create a seamless technology network that accelerates information and data translation, and enables molecular approaches to research, as well as adaptive clinical trials. caBIG connects its collaborators as a voluntary, open-source network of infrastructure, tools, and ideas that enables the collection, analysis, and sharing of data and knowledge along the entire research pathway from laboratory bench to patient bedside. This discussion will illustrate how IT is bridging the gap between clinical and research informatics.

Kenneth Buetow, Ph.D., Director, NCI Center for Biomedical Informatics and Information Technology, National Cancer Institute

11:30 Designing a Bioinformatics Data Warehouse Using Pentaho

Several databases exist at the UNC Lineberger Cancer Center that maintain information about tissue samples, microarray data and analysis, and clinical information about cancer patients. A new data warehouse, being implemented with the open-source Pentaho data warehouse suite, will ultimately integrate information from these disparate data sources. The experiences gained from integrating these data sources with Pentaho will be described.

David Jordan, Research Associate, Bioinformatics Group, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill

12:00 pm Driving BioPharma Innovation

A major inhibitor to innovation is the glut of systems and data that researchers must plow through on a daily basis. Utilizing systems that leverage open architectures and open standards allows researchers to focus on the results of the data instead of the system. This talk will look at some cutting-edge proposals and directions that the industry is moving towards, including a reference architecture called the "Scientist Workbench" that integrates information from bench equipment, provides visualization and analysis capabilities, and provides a mechanism for reporting results into Portfolio Management reports.

Les Jordan, Industry Technology Strategist, Life Sciences, Microsoft Corp.

12:30 Luncheon in the Exhibit Hall

2:00 Exhibit Hall Closes

Platform & Storage Design

2:00 A Community-Based Collaborative Drug Discovery Platform for Neglected Infectious Diseases and Cancer

A community-based platform is being used openly to help develop new treatments for neglected infectious diseases such as malaria, Chagas Disease, and African Sleeping Sickness and securely against commercial cancer targets. This new collaborative technology allows researchers to build up networks of technical experts around therapeutic or target areas, facilitating discovery of new drug candidates. It allows scientists to accelerate research by simultaneously sharing unpublished data in the race to overcome drug resistance. Case studies from collaborative groups and the search for drug candidates for commercial and humanitarian markets will be presented.

Barry Bunin, Ph.D., CEO & President, Management, Collaborative Drug Discovery, Inc.

2:30 Using Service-Oriented Architecture (SOA) to Manage Biobank Privacy Data

The Taiwan Biobank collects biological materials, tracks clinical outcomes and obtains longitudinal information for population genetic analyses and disease progression studies. This project uses a state-of-the-art SOA design for flexible privacy data management. It was initiated with a pilot study in 2005, with 15,000 participants and subsequently increased to 200,000 participants. The IT platform was designed to foster the exchange of information between electronic health records, subject coding systems, demographic information, genetic profiles, and laboratory processes. Here we will discuss the benefits of SOA design for privacy data management, the imperatives for IT infrastructure, and technologies to address these requirements.

Belinda Chen, Ph.D., Deputy Director, Innovative DigiTech-Enabled Applications & Services Institute (IDEAS), Institute for Information Industry

3:00 GRID Computing and Storage Design for Life Sciences Operations

The IT team for the J. Craig Venter Institute has been researching ways to remove IT obstacles that hinder the pace of genomics research. Here we describe the institute's storage and grid environment, and discuss the challenges involved in designing infrastructures for such dynamic workloads, including lessons learned and practices adopted to optimize growth. We will also discuss emerging technologies such as storage grids, virtualization, thin provisioning and their impact on the evolving role of IT in the life sciences.

Vadim Sapiro, Vice President for IT, J. Craig Venter Institute

3:30 Technology Highlights Sponsored by Saccelrys[®] 4:00 Conference Adjourns



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INFORMATICS FOR GENOME ANALYSIS, BIOMARKERS AND TARGET DISCOVERY



Monday, April 28

4:00 pm Event Chairperson's Opening Remarks

Cindy Crowninshield, Conference Director, Cambridge Healthtech Institute



PLENARY KEYNOTE 4:15 Informatics: Integration & Convergence

> John Reynders, Ph.D., Vice President & Chief Information Officer, Johnson & Johnson, Pharma R&D

5:00 Welcome Reception in the Exhibit Hall

Drop off a business card at the CHI Sales booth for a chance to win 1 of 2 iPod® Videos!

Tuesday, April 29

7:30 amRegistration and Morning Coffee

8:15 Event Chairperson's Opening Remarks Phillips Kuhl, Co-founder and President, Cambridge Healthtech Institute

PLENARY KEYNOTE



Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc.

9:00

Benjamin Keynote Presentation & 2008

Storid Benjamin Franklin Award (see page 3 for details)
 Coffee Break, Exhibit and Poster Viewing in the Exhibit Hall

Informatics for Genome Analysis

10:50 Track Chairperson's Remarks

Jean-Jacques Codani, Founder and Chief Scientific Officer, GenomeQuest, Inc.

11:00 Towards Personal Genomics - Tools for Navigating the Human Reference Genome

The Human Reference Genome, published in September 2007 by the J. Craig Venter Institute, is the first high-quality diploid genome of a human. We will describe the web based analysis tools developed for navigating the diploid reference genome, and look forward to an era where hundreds of individual human genome sequences will be available.

Saul Kravitz, Ph.D., Director, Software Engineering, J. Craig Venter Institute

11:30 pm Use of Genomics as a Tool to Identify Stage-Appropriate Therapeutic Intervention Strategies

Genomic patterns have the potential to reveal the progression of host responses during illness and help to pinpoint early indicators of tissue involvement or organ failure. In combination with limited proteomics, these findings can be used to identify markers that will permit therapeutic efforts to be focused to divert impending serious outcomes. Our studies using a systems approach to integrate clinical, physiological, -omics and mathematical modeling have revealed stages of illness progression during which time certain standard therapies may no longer be effective, yet they also reveal other therapeutic strategies. The aim is to identify sets of biomarkers that could be rapidly determined for near-real-time assessment of patient status.

Marti Jett, Ph.D., Chief, Department of Molecular Pathology, Walter Reed Army Institute of Research

12:00 Next Generation Sequencing: A Solution in Search of a Problem?

40 years after the first DNA sequencing in 1968, we appear to be on the verge of profound changes in sequencing technology that increase the efficiency (throughput and cost) of DNA sequencing dramatically. Indeed the throughput is reaching levels such that harnessing the data generated by the next generation technologies is a non-trivial informatics problem. We will discuss the problems which can be solved with high speed sequencing. Even simple analysis of this torrent of data requires sophisticated computational platforms and high throughput analysis work-flows. Without such informatics support, next generation sequencing may not be a solution looking for a problem but rather a partial solution.

Kamalakar Gulukota, Senior Director, Content Development, GenomeQuest, Inc.

12:30 Luncheon Workshop: Metabolomic Profiling of Bacterial Leaf Blight in Rice

Bacterial leaf blight is a destructive bacterial disease of rice caused by Xanthomonas oryzae pv. oryzae (Xoo). To understand the mechanisms of infection and resistance gene Xa21-mediated resistance, metabolic profiling using time-of-flight mass spectrometry was performed on rice variants challenged with variants of Xoo. Statistical analysis and Principal Component Analysis on the collected data identified metabolites related to infection and resistance. This talk demonstrates a data analysis workflow that allows researches to identify the few metabolites relevant to the biology under examination from high dimensional extracted mass feature data.

Thon de Boer, Ph.D., Product Manager, Agilent Technologies, Inc.

1:45 Linking Genetic Epistasis and Genomic Pathways to Complex Health Outcomes

Evaluating the complex health outcomes of common diseases and identifying the genetic and genomic factors that determine effectiveness and risks of a drug for a particular patient or group of patients is crucial to guide development, assist with dosing, and avoid disproportionate restrictions or even unwarranted withdrawal. Many of the statistical methods currently used, however, are based on the (generalized) linear model and, thus, not well suited to comprehensively analyze data with different, non-linear scales (binary, ordinal, and quantitative). The talk will explore how new statistical approaches, enabled by novel informatics tools, facilitate innovative uses of personalized medicine.

Knut Wittkowski, Ph.D., D.Sc., Director, Biostatistics, Epidemiology, and Research Design, Center for Clinical and Translational Science, The Rockefeller University

2:15 Technology Highlights Sponsored by Saccelrys

Better appreciate the interplay of the research and technology drivers impacting pharmaceutical and biotechnology companies, and learn to apply them productively within your own organizations. Find out more about these products and services to help you tackle your daily challenges. For sponsorship information, contact Katelin Fitzgerald at kfitzgerald@healthtech.com.

Data and Biomarkers

2:45 Microarrays: Bench-to-Bedside

Functional genomics and proteomics approaches have rapidly evolved over the last years and have provided the basis for groundbreaking discoveries in basic and clinical research. As the technologies become more mature and validated, bench-to-bedside clinical applications rapidly emerge. Our focus has been to identify gene signatures in patients with various types of cancer for early detection, cancer progression, metastasis, survival as well as resistance or sensitivity to therapy. We have developed novel bioinformatics approaches for biomarker discovery and individualized gene expression analysis that are enhancing the identification of aberrant signaling pathways in individual patients and clinical applications in renal, prostate and breast cancer will be presented together with the implementation of the new fully automatized Affymetrix platform for high-throughput 96 well microarray analysis.

Towia Libermann, Ph.D., Associate Professor of Medicine, Beth Israel Deaconess Medical Center

3:15 Refreshment Break, Exhibit and Dedicated Poster Viewing

3:45 Pathways to Targets: Qualitative Reasoning and Quantitative Modeling

Much of the complexity in biology exists within the dynamic nature of its pathways and processes. To improve the ability to identify and validate biomarkers for use as diagnostics and potential therapeutic targets, it is critical to be able to handle incomplete information about coordinated molecular interactions in a manner that supports rational experimental design and the integration of experimental data with literature data into operational models. We have been using both Petri nets and Stochastic Activity networks to evaluate the use of Herceptin in breast disease and to model the impact of SNP's on developmental processes that can stratify individual patient's risk for disease, e.g. breast and ovarian cancer, osteoporosis, cardiovascular disease. Both the methods and the results will be presented. *Michael Liebman*, *Ph.D.*, *Executive Director*, *Windber Research Institute*

4:15 Institution-Wide Copy Number Variation Analysis and Reporting Systems

Array CGH and SNP arrays become widely accepted for diagnostics of many diseases and for development of personalized medicine. Availability of terabytes of public array CGH datasets outside institutions and accumulation of proprietary Copy Number Variation (CNV) data inside institutions calls for efficient and robust IT systems to manage and analyze the data. We would like to highlight major challenges in analyzing CNV profiles in the framework of very large highresolution datasets and in presence of various biological factors. We would like to demonstrate our approach to solving such problems as cross-platform array data compatibility, seamless integration with publicly available data sources (GEO, ArrayExpress etc), data management for accumulated CNV and expression profiles and data fusion for very large aberration datasets.

Anton Petrov, Ph.D., Director, Cytogenetics, infoQuant, Ltd.

| 4:45 Protein Microarrays and Quantum Dot-Probes for | | | | | |
|--|--|--|--|--|--|
| Cancer Biomarkers Early Detection | | | | | |
| This talk will describe a novel approach for detection of cancer markers using Quan- | | | | | |
| tum Dot Protein Microarrays. Quantum dots and protein microarrays are relatively | | | | | |
| new technologies that offer very unique features that together allow detection of cancer markers in biological specimens at picogram/ml concentrations. | | | | | |
| Tatyana Zhukov, Ph.D., Assistant Professor, Cancer Prevention and Control | | | | | |
| Division, H. Lee Moffitt Cancer Center & Research Institute | | | | | |
| | | | | | |
| 5:15-6:15 2008 Best of Show Awards/Reception in | | | | | |
| the Exhibit Hall (see page 3 for details) | | | | | |
| 6:15 Exhibit Hall Closes | | | | | |
| 7:00 Best 2008 Bio-IT World's Best Practices Awards/ | | | | | |
| Practices Dinner (see page 3 for details) | | | | | |
| | | | | | |
| Wednesday, April 30 | | | | | |
| 7:30 am Registration and Morning Coffee | | | | | |
| 8:00 Event Chairperson's Opening Remarks | | | | | |
| Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World | | | | | |
| Keynote Introduction: | | | | | |
| Ron Ranauro, President and CEO, GenomeQuest, Inc. | | | | | |
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| PLENARY KEYNOTE 8:05 Personalized Genetics: Advancements & | | | | | |
| 8:05 Personalized Genetics: Advancements & Driving Change | | | | | |
| Net of the second se | | | | | |
| Linda Avey, co-Founder, 23andMe, Inc. | | | | | |
| 8:45 The Future of Personal Genomics | | | | | |
| George Church, Ph.D., Professor of Genetics and Director of the Center for | | | | | |
| | | | | | |
| Computational Genetics, Harvard Medical School Dietrich Stephan, Ph.D., Co-founder and Chief Science Officer, Navigenics, Inc. Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine; Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School | | | | | |
| | | | | | |
| Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine; | | | | | |
| Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School | | | | | |
| Fred D. Ledley, MD, Professor and Char, Bentley College; Founder and Char- | | | | | |
| man, My Genome | | | | | |
| John Halamka, MD, MS, CIO, Harvard Medical School | | | | | |
| 9:45 Coffee Break, Exhibit Viewing, Vendor Theater Presen- tations, and Poster Competition in the Exhibit Hall | | | | | |
| Tanons, and Poster Compension in the Exhibit Hall | | | | | |
| Informatics for Biomarkers | | | | | |
| 10:45 Track Chairperson's Remarks | | | | | |
| 11:00 An Integrated Framework for Multiple | | | | | |
| Myeloma Research Track 3 | | | | | |
| The Computational Biology and Functional Genomics Laboratory at the Dana Far- | | | | | |
| ber Cancer Institute, in collaboration with InforSense, is developing a novel web- | | | | | |
| based application to support Multiple Myeloma research. The application provides | | | | | |
| research scientists an integrated view of clinical and laboratory data that allows | | | | | |
| them to better understand the relationships that exist. Scientists can identify the | | | | | |
| mechanisms that can be linked to poor response to chemotherapy and use that in- | | | | | |
| formation to develop new therapeutics. This application supports a range of research | | | | | |
| activities performed by various users, including study designers, biologists, statisti- | | | | | |
| cians and software developers. Its functionality allows researchers to utilize features | | | | | |
| that support their specific needs: Study designers can check participant metrics and | | | | | |
| sample availability, biologists can access statistician data and link to public-domain data sources, statisticians can export formatted data sets, and developers can rapidly | | | | | |
| develop and deploy new applications to accommodate evolving research needs. In | | | | | |
| this talk, we will cover the specifics of the application, as well as the ROI that has | | | | | |
| been achieved in terms of both cost and science. | | | | | |
| John Quackanhush Ph D. Professor of Biostatistics and Computational Biology | | | | | |

John Quackenbush, Ph.D., Professor of Biostatistics and Computational Biology, Dana-Farber Cancer Institute

11:30 **Understanding Biology: Multi-Modal Correlation Net**works for Biomarker Discovery and Qualification

The project involved a multi-party collaboration including federal, corporate biotechnology and informatics software institutions applying biotechnology and information technology to data integration, process management and biomarker activity modeling for diagnostics. This talk will demonstrate how semantic network tools can be successfully applied to complex multi-modal data environments to qualify and validate biomarkers and to gain insights on biological functions which can be used in modeling system's processes more accurately.

Alan Higgins, Ph.D., Vice President, Preclinical Development, Viamet Pharmaceuticals

12:00 pm Towards Quantitative Metabolomics

Metabolomics is an emerging field of 'omics' research that is concerned with the high-throughput characterization and comparison of the small molecule metabolites in the metabolome. Traditionally, metabolomics researchers have used chemometric, statistical and pattern recognition techniques to characterize metabolic variation, without much of a focus on metabolite quantification and identification. In this presentation I will describe some of the emerging techniques (in NMR, LC-MS and GC-MS) and newly developed database resources that are allowing metabolomics researchers to systematically identify and quantify large numbers of metabolites. This "quantitative" approach to metabolomics not only complements traditional methods, but it should open the door to identifying many new disease biomarkers.

David Wishart, Ph.D., Professor of Computing Science and Biological Sciences, University of Alberta

12:30 Luncheon in the Exhibit Hall

2:00 **Exhibit Hall Closes**

Informatics for Target Discovery

2:00 **Evaluating Genomic Response of Xenografts to DNA** Interference (DNAi®) Treatments

This discussion provides key insights into the development of an emerging DNAbased potential oncology treatment regime utilizing therapeutic oligonucleotides, leveraging widely-available bio-IT tools and technologies. Methods and technologies for the use of gene expression profiling to identify the molecular impact of DNAi therapies on human Prostate cancer xenografts will be discussed. This case study outlines how potential biomarkers for assessing DNAi therapy efficacy in future preclinical and clinical studies, as well as how data illuminating a specific DNAi drug's mechanism of action was generated. Given enormous recent interest in RNAi-based potential therapeutics, this talk will discuss and contrast the DNAi approach.

Richard Gill, Ph.D., President and Chief Executive Officer, ProNAi Therapeutics, Inc.

2:30 **Rapid RNAi Informatics Development with PointDragon™**

The ability to rapidly implement and evolve laboratory workflows in an environment of changing platform technologies is a constant challenge. We will show how at Sirna Therapeutics (a wholly owned subsidiary of Merck & Co., Inc.) we have addressed this using the PointDragon Platform to develop a custom LIMS implementation that integrates sample tracking and annotation, data translation and long-range planning and resource management in a single application. The system provides the flexibility to support Sirna's discovery pipeline using standardized business rules for decision-making, while allowing ready access to underlying data for long-term process analysis. We will describe lessons learned and comparisons to our experience with other LIMS solutions.

Alex Birch, LIMS Developer, Sirna Therapeutics (a wholly owned subsidiary of Merck & Co., Inc.)

3:00 Molecular Profiling of Clinical Stem Cell Products

Production of adult stem cells for clinical use requires extensive safety testing, and demonstration that biological potency is retained over significant population doublings in expansion. We have utilized chromosomal SNP analysis to augment karyotypic stability measurements, and transcriptional profiling and gene methylation analysis to demonstrate equivalency of early and late expansion products. Use of differential profiling strategies has allowed discovery of novel marker sets which distinguish primitive from more mature adult stem cell types.

Robert Deans, Senior Vice President, Regenerative Medicine, Athersys, Inc.

4:00 **Conference Adjourns**

Advisory Board

- Samuel (Sandy) Aronson, Executive Director of Information Technology, Harvard Medical School Partners Healthcare Center for Genetics and Genomics
- Alex Bangs, CTO and Co-Founder, Entelos, Inc.
- Sylva Collins, Ph.D., Vice President, Global Biometrics, Kendle
- · Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World
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- Andrew Hopkins, Ph.D., Chair, Chemical Informatics, University of Dundee · Phillips Kuhl, Co-Founder and President, Cambridge Healthtech Institute

- Martin D. Leach, Ph.D., Executive
- Director, Basic Research & Biomarker IT Merck & Co., Inc.
- Michael Liebman, Ph.D., Executive Director, Windber Research Institute
- · Eric Neumann, Ph.D., Clinical Semantics Group Consulting
- · Ulrik Nielsen, Ph.D., Vice President, Research, Merrimack Pharmaceuticals
- · Rudy Potenzone, Ph.D., WW Industry Technology Strategist for Pharmaceuticals Microsoft
- · James Rogers, CEO, Nextrials Don Rule, Technical Program Manager, Health Solutions Group, Microsoft Corporation
- John Russell, Executive Editor, Bio-IT World

James Reaney, Director, Research Markets, BlueArc Corp.

- Ierald S. Schindler, Ph.D., Vice President, Biostatistics and Research DecisionSciences Late Stage Clinical Development Statistics, Merck Rese arch Labora
- Dietrich Stephan, Ph.D., Director and Senior Investigator, Translational Genomics Research Institute
- Susie Stephens, Ph.D., Principal Research Scientist, Eli Lilly
- · Jeff Williams, CEO, CLINIPACE, Inc

4:45 CK 2: INFORMATICS FOR GENOME ANALYSIS, BIOMARKERS, AND TARGET DISCOVERY

| | | Monday | , April 28 | 3 | |
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| | | Tuesday | y, April 29 | | |
| 7:30 am | R | egistration | and Morniı | ng Coffee | |
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| 8:2 Josh | and wa Boger, Pl | E g Developme Opportuniti h.D., President & euticals, Inc. | es | | jes |
| 9:00 | Benjamin Franklin Award | Keynote Pr Benjamin F | | | e 3 for details) |
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Model-Simulated Therapeutics

10:50 Track Chairperson's Remarks

John Russell, Executive Editor, Bio-IT World

11:00 Model-Simulated Design of Cancer Therapies

Computational biology is improving our understanding of complex biological systems. Using very large biological datasets of cell signaling, we have constructed detailed, mechanistic models. These may be used to predict network responses to targeted therapeutics such as monoclonal antibodies and small molecule inhibitors. Using growth factor signaling as an example, we will present how computational modeling can be used to simulate the best therapy with single agents or combinations of targeted inhibitors.

Ulrik Nielsen, Ph.D., Vice President, Research, Merrimack Pharmaceuticals, Inc.

Systems Biology Approaches to Drug **Discovery and Development**

12:00 pm The Future of Systems Biology in Drug Discovery

The molecular characterization of pathological pathways requires a combination of computational biology and interaction discovery techniques. Future discoveries will emerge from computational modeling of pathological pathways using a variety of information sources relevant to human pathophysiology, from protein interactions to small metabolites. This seed model will be extended by including information from other organisms and determining missing data. The final step will be to perturb the system to confirm that it behaves as predicted by the model. This will revolutionize drug discovery, along with other applications such as prediction of adverse events and new indications for existing drugs. This talk will present the most recent examples and solutions regarding target discovery, adverse event prediction, and repurposing of existing drugs. Patrick Aloy, Ph.D., Chief Scientific Officer, Anaxomics Biotech; Institute for Research in Biomedicine - Barcelona Science Park

12:30 Luncheon Workshop (Sponsorship Available) or Lunch on Your Own

1:45 Systems Approach to Drug Development: Bio-**Simulation and Bio-Mathematics**

Drug development needs to find innovative ways to increase the probability of success. Disease modeling using bio-simulation and bio-mathematics is a promising approach, however succeeding in this area requires an inter-disciplinary effort involving biologists, chemists, mathematicians and engineers. This session will discuss the use of mathematical and/or statistical models for diseases, and for variations amongst individual patients, that would greatly facilitate the task of predicting how a particular drug would interact with a patient population.

Moderator: M. Vidyasagar, Ph.D., Executive Vice President, Tata Consultant Services

Panelists:

Discussion

Zvia Agur, Ph.D., President, Institute for Medical BioMathematics (IMBM); Chairperson and CSO, Optimata

David de Graaf, Ph.D., Head, Systems Biology, Pfizer Inc.

Vikram Sinha, Ph.D., Head, Global PK/PD & TS - U.S., Lilly

3:15 **Refreshment Break, Exhibit and Dedicated Poster** Viewing

Biomarker Identification and Predictive Bio-Simulation

Technology Highlights (Sponsorship Available) 3:45

Better appreciate the interplay of the research and technology drivers impacting pharmaceutical and biotechnology companies, and learn to apply them productively within your own organizations. Find out more about these products and services to help you tackle your daily challenges. For sponsorship information, contact Katelin Fitzgerald at kfitzgerald@healthtech.com.

- 2008 Best of Show Awards/Reception in 5:15-6:15 the Exhibit Hall (see page 3 for details)
- **Exhibit Hall Closes** 6:15
- 7:00 Best 2008 Bio-IT World's Best Practices Awards/ Practices Dinner (see page 3 for details)



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Tuesday, April 29 • 9:15-10:45 am Tuesday, April 29 • 3:15-3:45 pm

Other Poster Viewing Hours Include: Wednesday, April 30 • 9:45-10:45 am

Wednesday, April 30

Event Chairperson's Opening Remarks

7:30 am Registration and Morning Coffee

8:00

Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World

Keynote Introduction:

Ron Ranauro, President and CEO, GenomeQuest, Inc.

PLENARY KEYNOTE 8:05 Personalized Genetics: Advancements & Driving Change

Linda Avey, co-Founder, 23andMe, Inc..

8:45 The Future of Personal Genomics

George Church, Ph.D., Professor of Genetics and Director of the Center for Computational Genetics, Harvard Medical School

Dietrich Stephan, Ph.D., Co-founder and Chief Science Officer, Navigenics, Inc.

Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine; Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School

Fred D. Ledley, MD, Professor and Chair, Bentley College; Founder and Chairman, My Genome

John Halamka, MD, MS, CIO, Harvard Medical School

9:45 Coffee Break, Exhibit Viewing, Vendor Theater Presentations, and Poster Competition in the Exhibit Hall

in silico Tools and Web-based Applications

10:45 Track Chairperson's Remarks

11:00 An Integrated Framework for Multiple Myeloma Research



John Quackenbush, Ph.D., Professor of Biostatistics and Computational Biology, Dana-Farber Cancer Institute

11:30 Immunogenicity Assessment of Protein Therapeutics

With over 50 therapeutic proteins on the market, and several hundred in clinical trials, the biotherapeutics are currently the largest growing drug segment. Over the past years, the challenges related to protein drugs become more obvious, and predictive methods to assess immunogenicity have become of age. This presentation will discuss strategies for pre-clinical prediction of immunogenicity with in silico tools, and evaluate how in silico tools can be used to optimize the protein engineering and lead selection process. *Philippe Stas*, *CEO*, *AlgoNomics*

12:00 pm Technology Highlights (Sponsorship Available)

Better appreciate the interplay of the research and technology drivers impacting pharmaceutical and biotechnology companies, and learn to apply them productively within your own organizations. Find out more about these products and services to help you tackle your daily challenges. For sponsorship information, contact Katelin Fitzgerald at kfitzgerald@healthtech.com.

12:30 Luncheon in the Exhibit Hall

2:00 Exhibit Hall Closes

Causal & Genomic Predictive Models

2:00 Integrating Phospho Proteomic Data into Causal Models of Cancer Drug Mechanisms

The development of targeted cancer therapies has focused largely on the identification of antagonists for protein kinases and phosphatases that regulate networks and pathways leading to cell proliferation and apoptosis. The development of large-scale phospho proteomic measurements using mass spectrometry presents a valuable resource for reconstructing the altered signaling networks that result from drug treatment. This talk will present the integration of these large-scale measurements into causal models of cell proliferation, to elucidate network changes that result in sensitivity (and resistance) to targeted cancer therapeutics.

Christian Reich, Vice President, Scientific Research, Research, Genstruct, Inc.

2:30 Developing Genomic Predictive Models for Common Diseases

Genetic prediction is at the heart of personalized medicine. The promise of new tailored medicines rests on our ability to forecast disease risk and treatment response based on a patient's genetic makeup. However, common diseases are likely to be caused by the interaction of multiple genetic factors. While current SNP microarrays can query virtually all of the variations in the human genome, current methods tend to focus on one SNP at a time. This talk will show how to identify the multigenic profiles underpinning complex traits and to develop prognostic models to predict individual risk based on genetic variations. We will describe the use of Bayesian networks for developing models and introduce a novel set of techniques and search algorithms specifically tailored to the analysis of genome-wide association studies. Applications to the identification of genomic predictive models to common diseases, such as stroke, asthma and nicotine dependence, will be described.

Marco Ramoni, Ph.D., Assistant Professor, Harvard-MIT Division of Health Sciences and Technology, Harvard Medical School

3:00 GenoCAD: Computer-Assisted Design and Fabrication of Synthetic Genetic Systems

A gap exists between the few academic groups who have the capability of running small-scale, proof-of-concept projects in synthetic biology and the people who could identify and benefit from biomedical and industrial applications of this technology. We are creating the infrastructure for non-specialists to design large-scale genetic systems that could be used in basic biological research or product development programs. We are adapting the workflow developed by the electronics industry to automate the design and fabrication of electronic circuits, to the design and assembly of Very Large Scale Integrated genetic systems. This talk will describe the molecular tools, algorithms, and software applications in development that will make the computer assisted design and fabrication of genetic systems a reality within five years.

Jean Peccoud, Ph.D., Associate Professor, Virginia Bioinformatics Institute, Virginia Tech

4:00 Conference Adjourns

Intro-Net

CHI's

CHI's Intro-Net: Networking at Its Best! Maximize Your Experience Onsite at the Bio-IT World Conference & Expo!

Maximize Your Experience Onsite at the Bio-IT World Conference & Expo! The Intro-Net offers you the opportunity to set up meetings with selected attendees before, during and after this conference, allowing you to connect to the key people that you want to meet. This online system was designed with your privacy in mind and is only available to registered session attendees of this event. Registered conference attendees will receive more information on how to access the Intro-Net in the weeks leading up to the event!



4:00 pm Event Chairperson's Opening Remarks

Cindy Crowninshield, Conference Director, Cambridge Healthtech Institute PLENARY KEYNOTE

4:15 Informatics: Integration & Convergence

John Reynders, Ph.D.,Vice President & Chief Information Officer, Johnson & Johnson, Pharma R&D

5:00 Welcome Reception in the Exhibit Hall

Drop off a business card at the CHI Sales booth for a chance to win 1 of 2 iPod $\ensuremath{\mathbb{R}}$ Videos!

Tuesday, April 29

7:30 am Registration and Morning Coffee

8:15 Event Chairperson's Opening Remarks

Phillips Kuhl, Co-founder and President, Cambridge Healthtech Institute

PLENARY KEYNOTE



8:20 Drug Development: Evolving Challenges and Opportunities

Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc.

9:00 Renjamin Award Keynote Presentation & 2008 Benjamin Franklin Award (see page 3 for details)

9:30 Coffee Break, Exhibit and Poster Viewing in the Exhibit Hall

High-Throughput Screening

10:50 Track Chairperson's Remarks

11:00 Merging High-Content Screening and *in silico* Approaches for Compound Profiling and Mode-of-Action Analysis

High-content screening observes the reaction of a cell to an administered compound by multidimensional microscopy and it provides a potentially more information-rich complement to single-readout conventional assays. On the other hand, microscopy-based screening can also be more 'opaque' in the way that no mechanistic explanation for the observed effect is provided per se. By merging high-content screening with in silico target prediction, we present a method to merge the best of both worlds: by high-content screening we are able to observe the systems response, while at the same time providing hypotheses for the observed effects via the predicted targets of compounds. We screened more than 6k compounds in high-content screenings and discuss cases where the phenotypic response and the predicted targets agree with each other, but also the even more interesting 'atypical' cases where similar phenotypes are observed by very different predicted targets (which might for example be located in the same pathway).

Andreas Bender, Assistant Professor for Cheminformatics, Leiden/Amsterdam Center for Drug Research and Novartis Institutes for BioMedical Research, Inc.

11:30 Elucidating Activity in Primary Screens Using Diversity-Oriented Chemical Libraries

This talk will explore how the Broad Institute Chemical Biology and Novel Therapeutics platforms are creating chemical libraries using diversity-oriented synthesis and are performing high throughput screening on those libraries using phenotypic, cell-based screens to look for potential leads and probe compounds. This approach allows projects to begin with a much richer data set and enables more intelligent design of follow-up studies. Data generated within the platform are made publicly available through our website, Chembank, which also provides rich tools for cross-sectional analysis of screening data. David DeCaprio, Director of Informatics, Chemical Biology and Novel Therapeutics, Broad Institute/MIT

12:00 Large-Scale Annotation of Small-Molecule Libraries Using Public Databases

The recent rapid expansion of the NIH PubChem database provides an opportunity to link existing biological databases with compound catalogs and provides relevant information that potentially could improve the information garnered from large-scale screening efforts. We will demonstrate an annotation pipeline based on integrating multiple databases. We will also discuss how annotations can be applied to in-house HTS databases in identifying signature biological inhibition profiles of interest and expediting the assay validation process. The automated annotation of thousands of screening hits in batch is becoming feasible and has the potential to play an essential role in the hit-to-lead decision making process.

Yingyao Zhou, Ph.D., Director of Informatics, Genomics Institute of the Novartis Research Foundation

12:30 Luncheon Workshop (Sponsorship Available) or Lunch on Your Own

Structure-Based Design and Predicting Targets

1:45 Structure-Based Drug Discovery of CDK2 Inhibitors

A series of pyrazolopyrimidines- and imidazopyrazines-containing inhibitors of CDK2 was discovered through high-throughput screening. The crystal structures of these inhibitors and two more related bicyclic cores show that there are is a dominant binding mode featuring hydrogen bonds to the backbone of the kinase hinge region. Even though ab initio computations indicated that the imidazopyrazine core would bind more tightly to the hinge, pyrazolopyrimidines gain an advantage in potency through an H-bond network involving two catalytic residues and bridging water molecules. Further insight into inhibitor/CDK2 interactions was gained from analysis of additional crystal structures and significant improvements in potency were realized by optimization of hydrophobic substituents into the gatekeeper region of the ATP binding site. Good selectivity was achieved by the most potent inhibitors.

José S Duca, Ph.D., Principal Scientist, Schering-Plough Research Institute

2:15 Protein-Protein Interactions Involving Macrocycle Compounds

Ensemble Discovery uses DNA programmed chemistry to generate large numbers of macrocycle compounds. This technique creates molecules with attached instructions, encoded in a piece of DNA, of how that molecule was built. This DNA is used as both a barcode to quantitatively identify the amount of each molecule during a biochemical screening process and to identify the most active molecule structures. This data allows SAR analysis and the development of additional compounds, to further improve binding and specificity. We have focused on macrocycles because they present a larger surface area than traditional small 'rule of 5' compliant molecules, and can bind shallow clefts on protein surfaces involved in protein-protein interactions that are traditionally only addressed by large biologics.

Nathan Walsh, Ph.D., Principal Informatics Scientist, Ensemble Discovery Corporation

2:45 Technology Highlights (Sponsorship Available)

Better appreciate the interplay of the research and technology drivers impacting pharmaceutical and biotechnology companies, and learn to apply them productively within your own organizations. Find out more about these products and services to help you tackle your daily challenges. For sponsorship information, contact Katelin Fitzgerald at kfitzgerald@healthtech.com.

3:15 Refreshment Break, Exhibit and Dedicated Poster Viewing

<u>Cheminformatics Platform and</u> <u>Tools & Safety Profiling</u>

3:45 CONTOUR: Drug Discovery Platform

CONTOUR was developed with the concept of creating a new generation of structurebased design technology tightly integrated with medicinal chemistry. It allows us to generate thousands of possible novel designs and visualize most relevant ones with chemists. The goals of the design are to generate novel ideas, explore wide range of chemistries, assess synthetic feasibility, increase potency and selectivity, minimize off-target activity, and design against metabolic activation and toxic liabilities. We will discuss our technology platform, and its application to the therapeutic programs. *Suresh Singh, Director, Computational Drug Design, Vitae Pharmaceuticals*

4:15 Introducing Canvas, Schrödinger's New Cheminformatics Platform

The successful application of cheminformatics tools in drug discovery requires not only the right science but also the right integration. Schrödinger has developed a new cheminformatics platform, Canvas, which has a wealth of modular cheminformatics tools with an open API so they can be easily integrated with existing interfaces, such as the open source workflow tool KNIME, or used through the Canvas interface. *B. Woody Sherman, Ph.D., Director of Applications Science, Schrödinger, Inc.*

4:45 Side Effect Profile Prediction - How to Deal With Drug Safety Issues Early On

This talk will describe a novel method to predict adverse side effects from the chemical structure only. By employing clinical databases along with chemical information, the chemical features can be identified that are most likely the reason for a certain side effect. This information can then be employed in early drug discovery.

Josef Scheiber, Ph.D., Postdoctoral Fellow, Lead Discovery Informatics/Safety Profiling, Novartis Institutes for Biomedical Research Center & Research Institute

| 5:15-6:15 | 2008 Best of Show Awards/ Reception in the Exhibit Hall (see page 3 for details) |
|-----------|--|
| 6:15 | Exhibit Hall Closes |
| 7:00 | Practices Awards/ Dinner (see page 3 for details) |

Wednesday, April 30

7:30 amRegistration and Morning Coffee

8:00 Event Chairperson's Opening Remarks

Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World

Keynote Introduction:

Ron Ranauro, President and CEO, GenomeQuest, Inc.



8:05 Personalized Genetics: Advancements & Driving Change

Linda Avey, co-Founder, 23andMe, Inc..

8:45 The Future of Personal Genomics

George Church, Ph.D., Professor of Genetics and Director of the Center for Computational Genetics, Harvard Medical School

Dietrich Stephan, Ph.D., Co-founder and Chief Science Officer, Navigenics, Inc.

Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine;

Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School

Fred D. Ledley, MD, Professor and Chair, Bentley College; Founder and Chairman, My Genome

John Halamka, MD, MS, CIO, Harvard Medical School

9:45 Coffee Break, Exhibit Viewing, Vendor Theater Presentations, and Poster Competition in the Exhibit Hall

QSAR & Lead-Hopping

10:45 Track Chairperson's Remarks

11:00 Machine Learning applied to Biopolymer Sequences for Solubility and Aggregation Profiling

We will demonstrate SeqR's application of machine learning to biopolymer sequence data to generate models with practical sequence profiling capabilities. Although the technology is applicable to many areas, this presentation will focus primarily on predictive models for solubility and aggregation relevant to biotherapeutics. The method has been highly optimized for whole genome mining, sequence optimization, and SAR analysis efforts. The evolution of the technology will be described, from prototyping to enterprise deployment and beyond.

Robert Feinstein, Ph.D., VP & CSO, Kelaroo, Inc.

11:30 Lead-Hopping and Beyond

When "lead-hopping", to identify for example a backup series, recent head-to-head comparisons indicate that ligand shape similarity searching is significantly more effective than docking or Tanimoto 2D fingerprints.

This finding is one of several enhanced drug discovery capabilities that the topomer technologies are enabling: exhaustive searching of 10^20 synthetically more accessible structures, in hours; robust and automatable 3D-QSAR based optimization of biological profiles; computationally addressing synthetic cost as well as biological benefit; and, improved forecasting of off-target biological responses. This talk will explore newly available cheminformatics approaches that offer a wide range of relatively well validated benefits to the different stages of a drug discovery project. *Richard Cramer, Ph.D., Chief Scientific Officer, Tripos*

12:00 pm Technology Highlights (Sponsorship Available)

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12:30 Luncheon in the Exhibit Hall

2:00 Exhibit Hall Closes

Executive Level Pharmaceutical Session

(Joint with Symyx Software Symposium 2008)

Driving the Integration of Informatics to Support Drug Discovery & Development

2:10 Chairperson's Remarks DISCOVERY

2:20 How the Three Pillars of Agility in Research Informatics Support R&D Productivity

Juergen Hammer, Ph.D. MBA, Global Research Informatics Director, Global Head In Silico Sciences, Nutley Head Group Research Information (GRI), GRI Liaison to Pharma Research, Hoffmann-La Roche Inc.

DISCOVERY

2:50 Dynamic Delivery of Services Through Just in Time Application

Chris Waller, Ph.D. Senior Director, Chemical Sciences Platforms, Research and Development Informatics, Pfizer Global Research and Development

The last few years has seen a focus on the greater adoption of a service oriented architecture philosophy within the software development community of practice. The migration from legacy two-tier systems to n-tier systems with distinct middle tier services has necessitated an era of application deconstruction. Service oriented architecture (SOA) is all about "verbs" from my group's perspective (e.g., register, query, display, etc.), and we have filled our mid-tier with these valuable reusable encapsulated services. As a technology manager, this work is appealing from an application development and support perspective. However, as a solution provider, whose value to the organization is tied very tightly to the business value delivered by my services, this work has had limited impact. This last statement has both positive and negative interpretations in that off-loading services from thick clients into the mid-tier should have no beneficial nor detrimental impact on the end-user experience if the work is done properly. Having laid the foundation in the middle tier, we are now refocusing our attention back on the client. This presentation will review my vision to create business process focused applications that deliver services to the end-users in a flexible and dynamic manner.

DEVELOPMENT

3:10 Growing ABCD in the Research & Early Development World

Edward P. Jaeger, Ph.D. Director, Research & Early Development Information Technology, Johnson & Johnson Pharmaceutical Research

This talk will highlight recent developments in ABCD, an integrated drug discovery informatics platform developed at Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ABCD is an attempt to bridge multiple continents, data systems and cultures using modern information technology, and provide scientists with tools that allow them to make informed, data-driven decisions. The first phase of ABCD focused on decision support (data warehousing, retrieval, analysis and visualization) and met with great success, becoming an indispensable tool for more than 1,200 users across all J&JPRD research sites. The system consists of two major components: a data warehouse, which combines data from multiple chemical and pharmacological transactional databases, designed for supreme query performance and a state-of-the-art application suite, which facilitates data upload, retrieval, mining, and reporting. Chemical intelligence, performance, and analytical sophistication lie at the heart of the new system, which was developed entirely in-house. ABCD has delivered on its promise of simplifying data assembly, delivery, comparison and decision-making. It has also driven business process change to create more consistent and better-documented data for discovery analysis. We have now embarked on the development of a new global transactional system that will replace the legacy operational data stores. This presents us with several compelling advantages: an ability to create a common ontology used across the transactional and decision support layers, a simpler, more streamlined and more robust ETL, and a radically different enduser experience through the use of a single, unified application front-end. Indeed, ABCD utilizes a common framework for the entire research data life cycle, including processing, upload, mining, analysis, visualization and reporting.

3:40 Refreshment Break in the Exhibit Hall DEVELOPMENT

4:10 Management of Non-Clinical Study Data

David M. Sedlock, Ph.D. Director Research Systems, Millennium Pharmaceuticals Inc.

The generation of pre-clinical data presents a unique problem for researchers related to data creation, storage, access, and reporting. These data are generally part of a development portfolio consisting of both GLP and non-GLP studies with different data handling requirements generally in place for each study type. This presents a conundrum when looking at overall data management needs due to differing requirements for system validation, archiving strategies, etc. The presentation will look at this issue in some detail to examine ways to address the problems encountered when attempting to integrate these disparate data types.

BRIDGING DISCOVERY TO CLINICAL

4:40 Building Bridges Across the Divide

Ingrid Akerblom, Ph.D. Executive Director, Merck Research Labs IT, Clinical Development

To achieve the promise of Biomarkers to transform discovery research and increase our ability to provide patients value through targeted medicines, there must be a focus on building integrated knowledge across the entire drug development cycle. In addition, there is increased recognition that much of this knowledge exists outside the walls of the pharmaceutical industry. We are piloting integration solutions involving both internal and external partners across several domains such as Clinical Development and Discovery Research to determine how to derive the most value from information connectivity. The successes and the challenges will be discussed.

5:10-5:30 Panel Discussion: INDUSTRY OVERVIEW Integration of Informatics in Support of Pharmaceutical Discovery, Development & Production – What Does the Future Hold

Panel Moderator: Joe Cerro, President & Founder at The Schooner Group, LLC Panelists: All of the above speakers



Monday, April 28

4:00 pm **Event Chairperson's Opening Remarks**

Cindy Crowninshield, Conference Director, Cambridge Healthtech Institute



4:15 Informatics: Integration & Convergence

John Reynders, Ph.D., Vice President & Chief Information Officer, Johnson & Johnson, Pharma R&D

5:00 Welcome Reception in the Exhibit Hall

Drop off a business card at the CHI Sales booth for a chance to win 1 of 2 iPod® Videos!

Tuesday, April 29

7:30 am **Registration and Morning Coffee**

8:15 Event Chairperson's Opening Remarks

Phillips Kuhl, Co-founder and President, Cambridge Healthtech Institute

PLENARY KEYNOTE



9:00

8:20 Drug Development: Evolving Challenges and **Opportunities**

Joshua Boger, Ph.D., President & Chief Executive Officer, Vertex Pharmaceuticals, Inc.

Keynote Presentation & 2008 Benjamin Franklin Award (see page 3 for details)

9:30 Coffee Break, Exhibit and Poster Viewing in the **Exhibit Hall**

Clinical Data Management

10:50 Track Chairperson's Remarks

11:00 CDISC Today and Tomorrow

This talk reviews the industry's efforts to establish a standard platform for data capture and its impact on EDC-based studies. Our CDISC task force for the Society of Clinical Data Management has the goal of educating members on CDISC and contributing to the organization's reference material on the application of the data standard to good clinical practices. We will present an overview of CDISC standards adoption in clinical research, discuss the relationship between CDISC and other data interchange standards. Also discussed: approaches to importing and exporting ODM data sets in clinical trials, privacy and security requirements exchanging CDISC data; and the future of CDISC as an industry-wide data standard.

Khaled El Emam, Ph.D., CTO, TrialStat Corporation; Canada Research Chair in Electronic Health Information, University of Ottawa

11:30 Electronic Data Capture and Data Integration

This presentation will discuss an approach we are using at the Dana-Farber Cancer Institute for electronic collection and aggregation of clinical trial results data. The 'bench to bedside and back' paradigm for achieving personalized medicine requires the seamless and timely exchange, sharing, aggregation, integration and analysis of clinical research data across the cancer research community. However, even when sources of large datasets exist, data integration is challenging because of the lack of completeness of information or lack of semantic integrity and resulting ambiguity. We will describe the problem and present an example strategy to resolve some of the issues. Jomol Mathew, Ph.D., Director, Clinical Research Information Technology, Dana-

Farber Cancer Institute

12:00 pm Collaborative Visualization: Getting the Most from EDC and Data Integration

Transforming clinical trials data into cost savings requires a decision-support system that empowers human interpretation. Common dashboards or portals that centralize reporting only offer a partial solution; data volume and complexity still overwhelm decision-makers. We have leveraged battle-hardened collaborative visualization software and created a radically different environment for exploring and analyzing integrated clinical trials data. Information objects are liquid, pliable, and transferable among display elements, enabled by a semantically-rich information model. We will show how partners Array BioPharma and the Immune Tolerance Network have used collaborative visualization for project management, financial tracking, and clinical data analysis to accelerate drug development and clinical trials.

Jake Kolojejchick, Ph.D., Chief Scientist, General Dynamics

EDC

Now What? Are We Using EDC to Create Its 1:45 **Fullest Possible Business Benefits?**

Can organizations fully realize the larger business benefit that EDC and eClinical trials can bring? Most sponsors are using EDC so that standard, current-state IT can correct basic clinical trial process inefficiencies. Few companies have learned how to really shorten development timelines or accelerate decision-making — two other assumed EDC benefits. But even more is made possible by the catalyst that eClinical Development provides: re-considering clinical development governance and resourcing; radically altering protocol design and development; routinely designing for and benefiting from interim analyses and adaptive design; re-examining the relationships between medical affairs, clinical research and marketing; cultivating higher-quality sites; reducing overall IT expense through cross-application integration; changing fundamental assumptions in site monitoring philosophies; increasing investigational drug supply efficiency; and more. This session will present perspectives and case study examples of organizations that have successfully leveraged their use of EDC and the actionable knowledge it creates.

Moderator: Ronald Waife, President, Waife & Associates, Inc. Steve Shevel, Manager eSolutions, Allergan

Greg Moody, Associate Director, Clinical Systems, Clinical Data Management, Millennium Pharmaceuticals

3:15 Refreshment Break, Exhibit and Dedicated Poster Viewing

Informatics Tools for Clinical Decision **Support & Translational Medicine**

3:45 Linking Clinical Data, Laboratories, and Providers: **Establishing Application Networks to Enable Personal**ized Medicine

As more genetic and genomic-based diagnostics are preformed, it will be increasing difficult for clinicians to track and fully leverage these test results. Clinical decision support systems can assist in this area. Genetic based clinical decision support systems require the integration of genetic data, phenotypic data and genetic knowledge. At times, all of this information exists within a single institution. We will discuss examples of self-contained clinical decision support that operates within our institution. However, the information required for these systems to meet their potential is often spread out across multiple databases in multiple institutions. We will also discuss the types of secure data networks that need to be established to provide broader clinical decision support.

Samuel (Sandy) Aronson, Executive Director of IT, Harvard Partners Center for Genetics and Genomics (HPCGG)

4:15 Informatics Solutions for Translational Research

An information management system has been developed to assist clinical and translational researchers in storing, querying and integrating such diverse data sets efficiently. We have also developed analysis tools to help biomedical researchers and those in the pharmaceutical industry to manage and analyze large volumes of data effectively. This talk will help researchers and clinicians how to: 1) efficiently manage and track laboratory samples, chips, gels and biospecimens; 2) effectively analyze, and interpret high-throughput data from microarrays; 3) visualize microarray, proteomics and sequence data; 4) integrate data and annotations from disparate data sources; and, 4) correlate patient data with experimental data as well as annotations from public databases.

Rakesh Nagarajan, Ph.D., Assistant Professor, Pathology and Immunology, Division of Laboratory and Genomic Medicine, Washington University School of Medicine

Aditya Phatak, Strategic Relationship Manager, Life Sciences, Persistent Systems Inc.

4:45 Technology Highlights (Sponsorship Available)

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5:15-6:15 2008 Best of Show Awards/Reception in the **Exhibit Hall** (see page 3 for details)

6:15 **Exhibit Hall Closes**

12:30 Luncheon Workshop (Sponsorship Available) or Lunch on Your Own

Discussi

7:00 Practices 2008 Bio-IT World's Best Practices Awards/ Dinner (see page 3 for details)

Wednesday, April 30

7:30 am Registration and Morning Coffee

8:00 Event Chairperson's Opening Remarks

Kevin Davies, Ph.D., Editor-in-Chief, Bio-IT World

Keynote Introduction:

Ron Ranauro, President and CEO, GenomeQuest, Inc.

PLENARY KEYNOTE 8:05 Perso

9

8:05 Personalized Genetics: Advancements & Driving Change

Linda Avey, co-Founder, 23andMe, Inc..

8:45 The Future of Personal Genomics

George Church, Ph.D., Professor of Genetics and Director of the Center for Computational Genetics, Harvard Medical School

Dietrich Stephan, Ph.D., Co-founder and Chief Science Officer, Navigenics, Inc.

Jeffrey M. Drazen, M.D., Editor-in-Chief, New England Journal of Medicine;

Distinguished Parker B. Francis Professor of Medicine, Harvard Medical School

Fred D. Ledley, MD, Professor and Chair, Bentley College; Founder and Chairman, My Genome

John Halamka, MD, MS, CIO, Harvard Medical School

9:45 Coffee Break, Exhibit Viewing, Vendor Theater Presentations, and Poster Competition in the Exhibit Hall

Clinical Research Informatics/Clinical Trials/EHRs

10:45 Track Chairperson's Remarks 11:00 Enabling the Molecular Medicine Revolution: Getting Connected with caBIG

This talk will explore strategies for embracing evidence-based patient care using the cancer Biomedical Informatics Grid, or caBIG. caBIG is an unprecedented initiative led by the NCI to create a seamless technology network that accelerates information and data translation, and enables molecular approaches to research, as well as adaptive clinical trials. caBIG connects its collaborators as a voluntary, open-source network of infrastructure, tools, and ideas that enables the collection, analysis, and sharing of data and knowledge along the entire research pathway from laboratory bench to patient bedside. This discussion will illustrate how IT is bridging the gap between clinical and research informatics.

Kenneth Buetow, Ph.D., Director, NCI Center for Biomedical Informatics and Information Technology, National Cancer Institute

11:30 Remote Data Capture for the Cancer Cooperative Groups and caBIG for Drug Development

The NCI is implementing a nationwide interoperable remote date capture solution of clinical trial information for cancer drug development. This talk will explore the major NCI efforts to harmonize clinical trial data amongst the broader cancer research community to enable better collaboration to improve the clinical trials process and accelerate drug development.

George Redmond, M.Sc., M.B.A., Bioinformatician, Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI)

12:00 pm Implementing Ontology Based Reasoning Services to Guide Clinical Trial Protocol Compliance

The Immune Tolerance Network (ITN) has been in collaboration with Stanford Medical Informatics for the last 2 years to increase support for automated clinical trials management. At the core of such efforts is formal modeling of knowledge found in clinical protocols. We are modeling this knowledge in the Epoch clinical trial ontologies developed at Stanford, to encapsulate the knowledge in a computable formalism. Managing protocol compliance, and the large amounts of data associated with a clinical trial requires a study design beyond that of a traditional CTIS. We believe that the work being done with Clinical Trial Ontologies provides such a design. We will present ways of actively using the trail design to support ontology and non-ontology based applications.

Keith Boyce, Associate Director, Bioinformatics, Immune Tolerance Network / UCSF

12:30 Luncheon in the Exhibit Hall

2:00 Exhibit Hall Closes

2:00 Improving Drug Development Using Patient Adherence Technology & Data in Clinical Trials

Patient compliance (adherence) to long-term therapy is emerging as a critical challenge across the drug development and commercial continuum. Implications of poorly characterized patient adherence in clinical trials affect interpretation of PK, dosing, efficacy, and safety. Opportunities exist for new technologies to improve our understanding of patient adherence in clinical trials, as well as to favorably influence adherence. This talk will review existing and emerging technology for monitoring adherence (RFID, printed electronics, drug tagging, etc.), as well as the range of applications of the resulting data.

Craig Lipset, Director, Health Technologies, Pfizer Inc.

2:30 A Complex Protocol Design to Accelerate Clinical Trials: How to Implement Multiple Database Lock in an EDC System

One of the ways pharma companies can simultaneously reduce time and costs of clinical trials is to conduct several studies or portions of a study as "one protocol". In this scenario, it is common that part of the trial is being locked, unblinded, analyzed and reported, while subjects continue to participate in the study and the data continue to be collected. This approach makes scientific and business sense and will likely become the main stream of protocol design. Such complex protocol design brings new challenges to current EDC structure, especially the external data import, common data management process such as database (db) lock. There are enormous implications in clinical and regulatory affairs. In order to prevent inadvertent or unauthorized changes of data once the final analysis and reporting of the trial data have begun, db lock has become a well-defined process for closing a database and change control procedures in data management of a clinical trial. In a protocol with multiple studies, the traditional db lock occurring once at the end of the trial is not sufficient because the data is usually unblinded, analyzed and submitted in the middle of the trial. Therefore, implementing multiple db locks is necessary. We will discuss new requirements for multiple db locks and present a case study to illustrate the challenges and solutions. We have implemented three partial locks for a very complex study, which is comprised of four distinct parts to answer different clinical questions.

Olive Yuan, Ph.D., Senior Clinical Data Manager, Regeneron Pharmaceuticals. Inc.

3:00 Connecting Two Worlds: Electronic Health Record Systems and Clinical Research

eClinical Forum, formed in 2000 by members of the pharmaceutical industry, has been partnering with the PhRMA EDC/eSource Taskforce to address requirements needed to determine how electronic health record (EHR) systems can be used for clinical research. The EHR clinical research profile team is producing a set of functions and criteria in order for EHR systems to be used as a source of data for clinical research. A first draft of this profile was produced in 2007, with work continuing toward HL7 and QRec submissions in 2008. We will describe the EHR/CR Functional Profile and its importance to industry, as well as certification, applications of use cases in real world environment, and lessons learned.

Linda King, Team Leader, Data Management, Eli Lilly and Company

3:30 Clinical Observations Interoperability: Using EHRs for Patient Recruitment

Clinical Data acquired in the patient care process and stored in Electronic Health Records (EHRs) can be re-used for a variety of applications such as Patient Recruitment, Drug Safety Surveillance, Post Launch Drug Use and Virtual Phase IV Clinical Trials. A critical component is the ability to interoperate and exchange clinical observations across clinical research, trials and practice. This presentation will focus on the problem of patient recruitment and illustrate, with the help of detailed examples, the use of Semantic Web Technologies for enabling interoperability between the EHR and Clinical Trials applications. Results of an ongoing collaborative effort in the framework of the W3C Healthcare and Life Sciences Interest Group will be presented.

Vipul Kashyap, Ph.D., Senior Medical Informatician, Clinical Informatics R&D, Partners Healthcare System

4:00 Conference Adjourns

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Katelin Fitzgerald Manager, Business Development 781.972.5458•kfitzgerald@healthtech.com

Nicolas Shostak Manager, Business Development 781.972.5479•nshostak@healthtech.com



Hotel & Travel Information

Seaport Hotel

Conference Venue:

World Trade Center 200 Seaport Boulevard Boston, MA 02210

T: 617-385-5049

One Seaport Lane Boston, MA 02210 T: 617-385-4000 F: 617-385-4001

Room Rate: \$239 s/d

Cut-off Date: April 7, 2008

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Please visit our website to make your room reservation. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.

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