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DRUG INFORMATION ASSOCIATION

The Quest to Enable the Electronic Clinical Trial:
Finding Clarity in a Confusing World

December 6-7, 2006 | Sheraton Inner Harbor Hotel, Baltimore, MD, USA

Presented by DIA in collaboration with

ACRO — Association of Clinical Research Organizations

AMIA — American Medical Informatics Association — Leaders Shaping the Future of Health Information Technology

CDISC

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HL7

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Electronic Patient Reported Outcomes (ePRO) Update: The Quest to Move From Paper to Plastic

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President, CDISC

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PROGRAM COMMITTEE

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Senior Director, Medical Information Sciences, Eli Lilly and Company

EDWARD S. TRIPP
Program Director, eSubmissions Abbott Laboratories

PRECONFERENCE TUTORIALS

Tuesday, December 5 – 1:30-5:00 pm
See page 3 for further details.

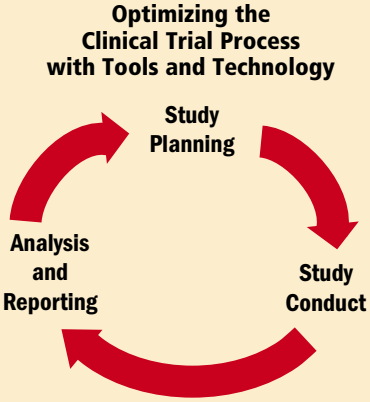
#1 Health Level Seven (HL7) and the Link to CDISC and the Biopharmaceutical Industry

#2 Introduction to Biomedical and Health Informatics

#3 eClinical

#4 Validation Basics

OVERVIEW



The clinical development life cycle has become increasingly complex and challenging scientifically while remaining inefficient and costly. The financial commitment needed to bring drug products to market continues to soar. It is crucial to develop technology solutions that work together and increase the speed and quality of the clinical trial process so that better answers about the safety and efficacy of investigational and marketed products are available to sponsors, agencies, investigators and the public more rapidly. With electronic healthcare just around the corner, industry faces increasing pressure to adopt enabling technology to optimize and accelerate drug development. But which technology, which tools, what initiatives are the most important ones to keep on your radar screen? If you are struggling with these questions, this conference is for you!

CONTACT INFORMATION

Mini-exhibits: Jeff Korn, Phone +1-215-442-6184/email Jeff.Korn@diahome.org

Conference: Ellen Diegel, Phone +1-215-442-6158/email Ellen.Diegel@diahome.org

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

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Principal, Don Rosen Consulting

John W. Snapp (Clinical Data Management)
Manager, Technical Resources, Duke Clinical Research Institute

Carmen Tamayo, MD (Natural Health Products)
Director, Research and Development, Flora, Inc.

Gary G. Walker (Electronic Regulatory Submissions)
Associate Regulatory Director, Global Data Management, Quintiles Transnational Corp.

TARGET AUDIENCE

Any users, producers, and supporters of technology, including but not limited to:

- Clinical program and project managers
- Clinical investigators and clinical researchers
- IT professionals (business and clinical)
- Medical writing scientists
- Medical communications professionals
- Regulatory operations personnel
- Quality assurance and compliance officers
- Data managers
- Statisticians
- Clinical development scientists

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 5 *AMA PRA Category 1 Credit(s)*™. Physicians should only claim credit commensurate with the extent of their participation in the activity. **Only sessions 2, 3, 5, and 6 are approved for this credit.**

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.7 continuing education units (CEUs) to participants who successfully complete this program and one tutorial.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

Disclosure Policy: It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

Continuing Education Credit Allocation

Tutorials 1, 2, 3, and 4 are each approved for 0.3 IACET CEUs.

Conference is approved for 1.4 IACET CEUs.

Sessions 2, 3, 5, and 6 are each approved for 1.25 *AMA PRA Category 1 Credit(s)*™.

LEARNING OBJECTIVES

At the conclusion of this conference, participants should be able to:

- Discuss medical informatics opportunities to improve the benefit-risk assessment of drugs
- Explain standard controlled terminology and its current and future use
- Summarize how changes in the drug development industry impact people and processes
- Discuss how clinical research can help drive the adoption of healthcare information technology (HIT) standards
- Describe how increasing data transparency can benefit the public interest
- Describe the benefits of in silico research
- Summarize how technology and standards can enable a better process for an eClinical trial

THIS PROGRAM WAS DEVELOPED BY THE FOLLOWING SPECIAL INTEREST AREA COMMUNITIES

CLINICAL DATA MANAGEMENT
CLINICAL RESEARCH
ECLINICAL
ELECTRONIC REGULATORY SUBMISSIONS
INFORMATION TECHNOLOGY
MEDICAL WRITING
NATURAL HEALTH PRODUCTS
REGULATORY AFFAIRS
VALIDATION

TUESDAY • DECEMBER 5

12:30-1:30 PM TUTORIAL REGISTRATION

1:30-5:00 PM Preconference Tutorials

#1 Health Level Seven (HL7) and the Link to CDISC and the Biopharmaceutical Industry

Instructors

Charles Mead, MD
Senior Director, Healthcare and Life Sciences Strategy,
Booz Allen Hamilton
HL7, NCI, and caBIG

Pierre-Yves Lastic
sanofi-aventis and CDISC Board

Health Level Seven (HL7) is seen as the world's leading standard for the electronic interchange of healthcare information. HL7 is a global organization that was founded approximately two decades ago. They have developed a sophisticated Reference Information Model (RIM) upon which the Version 3 HL7 messages are based. In 2001, the Clinical Data Interchange Standards Consortium (CDISC) was invited by HL7 to have a formal relationship (Associate Agreement), which was renewed and strengthened in 2004. There is a joint commitment to harmonize CDISC and HL7 standards.

CDISC and HL7 formed the Clinical Trials Special Interest Group, which became the Regulated Clinical Research Information Management (RCRIM) Technical Committee. The mission of this committee states: "this committee supports the HL7 mission to create and promote its standards by developing standards to improve or enhance information management during research and regulatory evaluation of the safety and efficacy of therapeutic products or procedures worldwide."

As its domain analysis model, the RCRIM Technical Committee has adopted the Biomedical Research Integrated Domain Group (BRIDG) model, which was initiated by CDISC and follows the HL7 Development Framework and is now a collaborative project among HL7, CDISC, NCI and FDA. RCRIM has developed and balloted numerous standards to support regulated product development over the past 5 years, including the Structured Product Label (SPL), the Regulated Product Submission (RPS), Individual Case Safety Report (ICSR) based upon ICH E2B, Annotated ECG, Periodic Reporting of Clinical Laboratory Data based upon the CDISC LAB model, Protocol Representation Standard and others.

This tutorial will provide: a) an introduction to the processes of Health Level Seven (HL7) to develop, ballot and obtain accreditation for standards through ANSI and ISO, b) an introduction to the work of the RCRIM Technical Committee, and c) an overview of the HL7 Development Framework, exemplified by the BRIDG model.

Tutorial Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Summarize the processes of Health Level Seven to develop, ballot and obtain accreditation for standards through ANSI and ISO
- Describe the work of the RCRIM Technical Committee
- Discuss the HL7 Development Framework, as exemplified by the BRIDG model

#2 Introduction to Biomedical and Health Informatics

Instructors

H. Dominic Covvey
Professor, NSERC/Agfa Research Chair in Health Informatics
Director, Waterloo Institute for Health Informatics Research, Canada

John H. Holmes, PhD
Assistant Professor of Medical Informatics in Epidemiology at HUP
Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine

This is an intense, multi-instructor, half-day tutorial intended to introduce those with little or no knowledge of informatics, to the nature, key concepts, and applications of this discipline. We examine what the discipline is about and how it can

Tutorial Descriptions continues on page 4

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This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

TRAVEL AND HOTEL The most convenient airport is Baltimore/Washington International Airport and attendees should make airline reservations as early as possible to ensure availability. The Sheraton Inner Harbor Hotel is holding a block of rooms at the reduced rate below until November 13, 2006, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $189 **Double $189**

Please contact the Sheraton Inner Harbor Hotel by telephone at +1-410-962-8300 or +1-800-325-3535 or by fax at +1-410-962-8211 and mention the DIA event. The hotel is located at 300 South Charles Street, Baltimore, MD 21201, USA.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! ***All 4 individuals must register and prepay at the same time – no exceptions.*** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.**

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Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

help us address key challenges in the health field. Major objectives of the tutorial include enhancing the value of the conference to the participant and helping the participant discover specific topics of interest that can be explored both during and after the conference. Although no tutorial of this duration can cover all topics, the material targets the high profile areas of informatics such as clinical or health care informatics, bioinformatics, and public health informatics, and points the participants in the direction of broader and deeper enquiry. We also point the participant to on-line AMIA and other material to enhance this tutorial.

This tutorial was developed by the American Medical Informatics Association.

Tutorial Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Discuss the current landscape of the science and practice of Health Informatics
- Explain how to better determine and define your areas of interest in informatics
- Identify and utilize Health Informatics information resources

Tutorial Target Audience

Healthcare professionals (physicians, nurses, and allied professionals), health system administrators, CIOs and managers, medical librarians, other information professionals, academics from other fields interested in Health Informatics.

#3 eClinical

Instructors

Dave Iberson-Hurst
Chief Executive Officer, Assero Limited, UK

Rebecca D. Kush, PhD
President, CDISC

This tutorial will provide an overview of what eClinical Trials are and how to achieve them. Specifically, it will cover basics on the planning and implementation of eClinical Trials, including process redesign, metrics, data quality, regulations, technology and industry standards.

Tutorial Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Define processes for a true eClinical Trial (contrast with EDC, RDE)
- Recognize ways to leverage new technologies in clinical trials
- Discuss relevant standards and their value to eClinical Trials
- Identify appropriate metrics for measuring success

Tutorial Target Audience

This tutorial is designed for anyone who is involved in implementing new technologies and/or data standards to streamline clinical trials, especially project managers, CRAs, data managers and those involved in managing or implementing trials across departments.

#4 Validation Basics

Instructors

Richard L. Chamberlain, MS, PhD
President, Executive Consultant Services

Earl W. Hulihan, MEd
Vice President, Global Regulatory Affairs and Quality Assurance
Medidata Solutions, Inc.

This tutorial will cover the whats, the whys, and the hows of validating computerized systems and will touch on what to look for at software vendors or contract research organizations.

Tutorial Learning Objectives

At the conclusion of this tutorial, participants should be able to:

- Describe validation
- Discuss why validation is important
- Identify the basic components of a validation project
- Describe what is expected from software vendors or contract research organizations

Tutorial Target Audience

IT staff and software developers, users who are faced with implementing a computerized system, and QA staff involved in computerized system validation.

Conference Begins

WEDNESDAY • DECEMBER 6

7:15-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM WELCOME AND OPENING REMARKS
Kenneth A. Getz, MBA, MS
Senior Research Fellow
Tufts Center for the Study of Drug Development
Tufts University and Chairman, CISCRP

8:15-9:00 AM **KEYNOTE ADDRESS**
Janet Woodcock, MD
Deputy Commissioner of Operations and Chief Operating Officer
Office of the Commissioner
FDA

9:00-10:15 AM **SESSION 1**

The Regulatory Environment and eSource

Chairperson

Stephen E. Wilson, DrPH, CAPT. USPHS
Director, Office of Business Process Support
Deputy Director, Division of Biometrics II
CDER, FDA

Sponsors, vendors, scientists, consumers and regulators are interested in promoting technology that will improve healthcare systems and clinical research. In 21 CFR 11, the Agency stated that this regulation is "intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health." With the current development of standards, the efforts to promote electronic medical records, and the introduction of new technologies, we are all asking, "How do we make this happen?" What are the advantages? What are the constraints? Do we need more guidance? What about inspections? Who is responsible for what? Do we need new regulations? The regulatory piece of this puzzle needs to fall in place.

The CDISC eSDI (Electronic Source Data Interchange) Group has produced a document that attempts to align "multiple factors in the current regulatory environment to encourage the use of eSource data." This session will focus on how we can make eSource work in our regulatory/clinical research environment.

Trustworthy Data in the Electronic Age: How CDISC Can Help

Dave Iberson-Hurst
Chief Executive Officer, Assero Limited, UK

Panelists

Joseph P. Salewski
Deputy Director, Division of Scientific Investigations
CDER, FDA

Dana N. Stone, MS, PhD
Manager, Technology Architecture and Innovation
IT Enterprise Architecture, Merck & Co., Inc.

10:15-10:45 AM **REFRESHMENT BREAK AND MINI-EXHIBITS**

10:45 AM-12:00 PM **SESSION 2**

Medical Informatics Opportunities to Improve the Benefit-risk Assessment of Drugs

Chairperson

Melvyn Greberman, MD, MS, MPH, FACPM
President
Public Health Resources, LLC

Medical, health, and biomedical informatics include the planning, development, implementation, and evaluation of systems and methods to improve the access, analysis, understanding, organization, management, communication, and use of information, including data, in health care and research. Electronic systems that use standards and information technology to facilitate the use of health information in diverse locations and for multiple applications are of increasing importance to public-private sector efforts to improve the benefit-risk assessment of drugs. Investments in applications of medical informatics by AHRQ, FDA, and NLM are speeding drug information from clinical trials to the public via the use of health data standards and the DailyMed Web site. The panel will discuss the current and future benefits of such systems, the building blocks that permit health information to flow to the point of care, and research and implementation investments in health informatics applications. Also explored will be the relation between these investments and the major issues of patient safety and quality of care that face us today. Regional health information exchanges may provide important opportunities for pharmaceutical development, testing, and monitoring. The Indiana Network for Patient Care (INPC) is one of the oldest and largest health information exchanges, and the panel will share experiences using the INPC for clinical trials and post marketing assessments of drug benefit and risk. In addition, the panel will discuss scientific issues that must be addressed in order to take full advantage of these emerging information resources to insure that drugs are used effectively and safely. Investigators and regulators faced with multiple drug exposure/outcome associations will need to consider potential patient and physician biases, confounders, and other biases that may explain risk/benefit pictures that emerge from these large data resources.

Informatics Building Blocks and Their Applications: Accelerating the Flow of Drug Information from Clinical Trials to the Consumer

J. Michael Fitzmaurice, PhD, FACMI
Senior Science Advisor for Information Technology
Agency for Healthcare Research and Quality
Department of Health and Human Services

Medications and the Indiana Experience: Clinical Trials, Adverse Events, Unanticipated Benefits and What to Do about Them

J. Marc Overhage, MD, PhD, FACMI
President and CEO, Indiana Health Information Exchange
Professor of Medicine, Indiana University School of Medicine
Senior Scientist, Regenstrief Institute, Inc.

Scientific Challenges in Employing Emerging Information Resources

Stanley A. Edlavitch, PhD, MA
Professor of Epidemiology and Director of Epidemiology Research
University of Missouri Kansas City School of Medicine

12:00-1:30 PM **LUNCHEON PRESENTATION**

Video Presentation

Introductory Remarks

Les Jordan
Industry Technology Strategist, Life Sciences
Microsoft Corporation

1:30-2:45 PM **SESSION 3**

Clinical Data Standards

Chairperson

Edward S. Tripp
Program Director, eSubmissions
Abbott Laboratories

Development of Therapeutic Area Data Standards: Case Studies for Cardiology and Tuberculosis

Bron W. Kisler
CDISC Terminology Program Director
Co-Chair, HL7 Cardiology Special Interest Group
Team Leader, International TB Data Standards Working Group

Case Study Using CDISC Lab Model with an EDC Tool

Robert F. Lyons, MS, PhD
Chief Technology Officer
Nextrials, Inc.

2:45-3:15 PM **REFRESHMENT BREAK AND MINI-EXHIBITS**

3:15-4:30 PM **SESSION 4**

Impact of a Changing Drug Development Environment on People and Processes

Chairperson

Patrick Genyn, MA
Senior Director, Strategy & Planning, Global Clinical Operations,
Johnson and Johnson

The drug development industry is rapidly changing due to a variety of reasons. A number of technologies are enabling the processes in drug development to be more efficient, as an example; Electronic Data Capture is creating a bigger footprint today in Clinical R&D and mutually accepted Clinical Data Standards are available allowing for a more efficient collection and exchange of data. Increased complexity, cost pressures and globalization are important trends, which has forced the industry to redefine the way clinical trials will be performed today and in the future. People are at the center of the clinical trial processes and must adapt quickly to these changes. The future will require rethinking the scope and performance of current jobs in the effort to evaluate and perform each step of clinical trials in an effective and efficient manner.

Continuous Data Management: How EDC is Driving Change – The Importance of Process Change in Realizing the Full Benefits

Martin Young, MBA
Vice President, Services, North America
Phase Forward

Optimizing Project Delivery: The Pfizer Clinical Trial Blueprint

Mike Collins
Vice President
Pfizer Inc

Sustained Compliance for Business Advantage: Frameworks and Methodologies

Subrato Majumdar
Client Principal - Life Sciences
Hewlett Packard Consulting and Integration

4:30-5:30 PM **PANEL DISCUSSION**

This panel discussion will include a recap of the day's highlights and a discussion of implications.

5:30-7:00 PM **NETWORKING RECEPTION AND MINI-EXHIBITS**

Sponsored by the **Clinical Data Management, Clinical Research, eClinical, Electronic Regulatory Submissions, Information Technology, Medical Writing, Natural Health Products, Regulatory Affairs,** and **Validation** Special Interest Area Communities

THURSDAY • DECEMBER 7

7:15-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-8:15 AM WELCOME AND OPENING REMARKS
Rebecca D. Kush, PhD
President
CDISC

8:15-9:00 AM **KEYNOTE ADDRESS**

John D. Halamka, MD, MS
Chief Information Officer of Harvard Medical School; Chief Information Officer of Beth Israel Deaconess Medical Center; Chairman of the New England Health Electronic Data Interchange Network (NEHEN); Chief Information Officer of the Harvard Clinical Research Institute (HCRI); and an Associate Professor of Emergency Medicine at Harvard Medical School

9:00-10:15 AM **SESSION 5**

Electronic Medical Records (EMRs), Personal Health Records (PHRs), and Electronic Clinical Trials (ECTs): Pathways to Convergence

Chairperson

William A. Rosen, MS
Executive Director
Pfizer Inc

Efforts to create an interoperable clinical environment for patients through harmonization of health information technology (HIT) standards are an increasingly important activity on a global scale. Although not well coordinated, the U.S. and many Member States in the EU are moving forward quickly to adopt HIT standards. Most efforts are focused on particular domains such as clinical care and improved information management that potentially lead to improved patient healthcare. Unfortunately, insufficient consideration has been given to how clinical research activities or patient and investigator acquisition fit into the broader picture of patient care. During this session, presenters will discuss how clinical research can become a primary driver of HIT adoption through the convergence of clinical trial activities and routine patient clinical care on a global basis. Some questions that will be considered include:

- What standards need to be developed or matured in order to see single source data use become commonplace?
- How can validated data from personal health records (PHRs) be incorporated into the clinical trial process?
- How can data from clinical trials be returned to the patient or derived from personal health records so as to be relevant in their routine care?
- Will the pharmaceutical industry become an embedded part of healthcare's transformation through HIT?

Closing the Patient Information Loop with Personal Health Record (PHR) and Clinical Trial Information Exchange

Ross Martin, MD, MHA
Director
Pfizer Healthcare Informatics

EHR->EDC: Overcoming the Challenges in Real Life

Hugh Donovan
General Manager, Clinical Trials Business
Siemens Medical Solutions Health Services Corp.

CDISC-IHE Integration Profile: A Short Pathway to Partial Convergence

Landen Bain
CDISC Liaison to Healthcare
CDISC

10:15-10:45 AM **REFRESHMENT BREAK AND MINI-EXHIBITS**

10:45 AM-12:00 PM **SESSION 6**

Data Transparency in the Public Interest

Chairperson

Suzanne L. Markel-Fox, PhD
Director, Strategy & Process Excellence
GlaxoSmithKline

Healthcare information technologies, such as electronic healthcare records and computerized ordering systems, bring a new level of transparency to healthcare delivery system encounters and transactions. Disease registries provide epidemiologists and public health systems with information critical for monitoring patterns of disease outbreak and potential epidemics.

The clinical trial registration process, such as that undertaken by the NIH, leaders in the biopharmaceutical industry, and the WHO, makes key clinical trial information and summary results more openly available. With the growing acceptance of the Internet, patient portals are enabling patients to access their healthcare information online and to create Personal Health Records, which can potentially be shared with providers and registries.

Short presentations followed by an open panel discussion will focus on how the public interest is served by timely and appropriate access to and secondary use of, electronic healthcare data.

BreastCancerTrials.org: A Patient-centered Online Matching Tool for Screening Clinical Trial Eligibility
Elly Cohen, PhD
Project Manager, BreastCancerTrials.org
University of California San Francisco
Center of Excellence for Breast Cancer Care

Disease-state Patient Registries: Our Experience with a Severe Sepsis Registry
Alan Impicciche
Manager, Information Technology
Global Clinical Data Management
Eli Lilly and Company

Data Use in a Service-oriented Network: The National Child Traumatic Stress Network
Patrick Loebs, MSW, MPH
Project Leader
Duke Clinical Research Institute

12:00-1:30 PM **LUNCHEON PRESENTATION**

"Information Transforms" (video presentation)

Introductory Remarks

David Isom
Senior Director - Development Informatics
Regulatory and Healthcare Informatics
Pfizer Inc

1:30-2:45 PM **SESSION 7**

Modeling and Simulation Tools for Enhancing Drug Development

Chairperson

Stephen Ruberg, PhD
Senior Director, Medical Information Sciences
Eli Lilly and Company

The cost of clinical trials continues to grow at an alarming rate. Despite the increased expenditures, failed clinical trials and failed drug development programs are all too common. During the most recent decade, enormous strides have been made in information technology – both digital and genetic. The convergence of these two powerful forces has led to substantial advances in modeling biological systems and simulating disease processes, treatment interventions and clinical outcomes. As our knowledge of biological processes expands and computing power becomes ever-cheaper and faster, the possibility of *in silico* research is emerging not only as a possibility, but as a dynamic tool – a tool to increase the probability of successful treatment paradigms and entire clinical development programs as well as to decrease costs. Increased use of modeling and simulation will be transformative for drug development and medicine in general. This session will have two renowned speakers who will address some of the leading ideas for *in silico* research, accompanied by some specific examples.

Innovation and Knowledge Management in Drug Development: Role of Quantitative Clinical Pharmacology
Jogarao Gobburu, PhD
Pharmacometrics, Office of Clinical Pharmacology
FDA

The Electronic Clinical Trial: A Preview of Coming Attractions
David Eddy, PhD
Founder and Medical Director
Archimedes, Inc.

2:45-3:15 PM **REFRESHMENT BREAK AND MINI-EXHIBITS**

3:15-4:00 PM **SESSION 8**

End-to-end Solutions Towards an eClinical Trial

Chairperson

Rebecca D. Kush, PhD
President
CDISC

The true eClinical Trial is defined as "a clinical trial in which primarily electronic processes are used to plan, collect (acquire), access, exchange and archive data required for conduct, management, analysis and reporting of the trial." Hence, the PLAN for a trial – the protocol will be addressed first. Specifically, the value of a machine-readable (electronic) protocol and progress in this regard will be covered in terms of its potential contribution towards a pure eClinical Trial.

An end-to-end approach by CDISC, through its technical roadmap, will then be presented in the context of how technology and standards can enable a better process for an eClinical Trial; specifically, there will be details on how the CDISC standards integrate from protocol through submission, how they link with healthcare standards (HL7) and the acquisition of eSource (e.g. EHR) data for eClinical Trials. A case study illustrating an end-to-end approach data exchange for an eClinical Trial will be included.

The Role of the Structured Machine-readable Protocol in Enabling eClinical Trials
Cara E. Willoughby
Member, HL7-CDISC Protocol Representation Group
Eli Lilly and Company

The eClinical Trial: CDISC's Roadmap for a Better Process
Dave Iberson-Hurst
Chief Executive Officer, Assero Limited, UK

4:00-5:30 PM **SESSION 9**

Panel Discussion: Lessons from the Conference – Where Are the Holes in the Quest to Enable the Electronic Clinical Trial?

A distinguished panel representing participating organizations will be convened for the final hour to discuss 'holes in the continuum'. They will address what is missing in our quest to enable eClinical Trials, why we are not doing more eClinical Trials today, and what can be done now and/or in the future to fill these holes.

5:30 PM CONFERENCE ADJOURNS

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The Quest to Enable the Electronic Clinical Trial:

Finding Clarity in a Confusing World

Sheraton Inner Harbor Hotel
Baltimore, MD, USA
December 6-7, 2006 | Meeting ID #06029

Tuesday, December 5

PRECONFERENCE TUTORIALS

#1 Health Level Seven (HL7) and the Link to CDISC and the Biopharmaceutical Industry

#2 Introduction to Biomedical and Health Informatics

#3 eClinical

#4 Validation Basics

KEYNOTE ADDRESSES

Wednesday, December 6

JANET WOODCOCK, MD
Office of the Commissioner, FDA

Thursday, December 7

JOHN D. HALAMKA, MD, MS
HCRI, NEHEN, Harvard Medical School, Beth Israel Deaconess Medical Center

In collaboration with ACRO, American Medical Informatics Association, CDISC, CPath The Critical Path Institute, HL7, SAFE

Register online or fax this page to +1-215-442-6199

CONTACT & MINI-EXHIBIT INFORMATION

Attendees may visit the mini-exhibits during the meeting and during receptions (if applicable).

Conference information: Contact Ellen Diegel at the DIA office by telephone +1-215-442-6158, fax +1-215-442-6199 or email Ellen.Diegel@diahome.org.

Mini-exhibit information: Contact Jeff Korn, Exhibits Associate, at the DIA office by telephone +1-215-442-6184, fax +1-215-442-6199 or email Jeff.Korn@diahome.org. For mini-exhibit space, please check the box below.

❑ **To receive a mini-exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)

Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time – no exceptions.
See page 3 for complete details.

Registration Fees *If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.*

MEMBER EARLY-BIRD OPPORTUNITY *Available on nondiscount member fee only*	On or before NOV. 15, 2006	After NOV. 15, 2006
Member Fee	US $1125 ❑	US $1300 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/docs/Membership**

MEMBERSHIP
US $ 130 ❑

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee US $1430 ❑

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	US $ 300 ❑	US $ 430 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 650 ❑	US $ 780 ❑

**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

TUTORIALS

#1	1:30 am-5:00 pm	US $ 350 ❑	**#3**	1:30 am-5:00 pm	US $ 350 ❑
#2	1:30 am-5:00 pm	US $ 350 ❑	**#4**	1:30 am-5:00 pm	US $ 350 ❑

MEMBERS WHO REGISTER FOR BOTH CONFERENCES CAN SAVE 10%!

Members can register for both Conferences (Event #06029 and Event #06025)

	On or before NOV. 15, 2006	After NOV. 15, 2006
Member Fee	US $2025 ❑	US $2340 ❑

This discount applies only to full-industry, member registrations; no one day registrations apply. Registrants taking part of the group registrant discounts are not eligible for this discount.

CANCELLATION POLICY FOR COMBINED EVENTS: On or before NOVEMBER 28, 2006
Cancellation of multi-product purchases combined with promotional offers voids all discounts; cancellation fees for individual products will apply.

❑ **I cannot attend but please keep me informed of DIA's future events.** *(requires completion of name, postal address and email address on this form)*

CANCELLATION POLICY FOR NON-COMBINED EVENT:

On or before NOVEMBER 30, 2006
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

REGISTRATION FORM

Do not remove mailing label. Please return this entire page. **06029**
PLEASE CONSIDER THIS FORM AN INVOICE

Please check the applicable category:
❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student *(Call for registration information)*

Last Name Check if part of group registration ❑ First Name M.I.

Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Company

Address As required for postal delivery to your location Mail Stop

City State Zip/Postal Country

email Required for confirmation

Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

PAYMENT OPTIONS

Register online at www.diahome.org or check payment method

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX *Exp Date* _____

Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your account.