DRUG INFORMATION ASSOCIATION

Three Worlds - One Voice

14th Annual European Clinical Data Management Conference

4th Annual European Validation Conference

1st European Information Technology Conference

This Conference has been designed to integrate CDM, Validation and IT

NOVEMBER 8-10, 2004

RAI AMSTERDAM INTERNATIONAL EXHIBITION & CONGRESS CENTRE, AMSTERDAM, THE NETHERLANDS

In keeping with DIA's strategic goal to diversify the breadth of products and services offered to members, DIA is pleased to announce a conference designed to explore the interface and integration of Clinical Data Management, Information Technology and Validation. The programme for this innovative conference is jointly developed by the Clinical Data Management, Information Technology, and Validation SIACs (Special Interest Area Communities). Delegates will have the option of joining one of four parallel tracks dedicated to their core discipline or attending specific talks or sessions covering the other disciplines. This joint conference is also intended to further build affiliation amongst DIA volunteer members as well as providing increased content and opportunities to share information.

Programme Chairpersons

Suzanna De Cordt, Serono International, Switzerland
Stephen Dobson, Pfizer Ltd., UK
Bryan Doherty, AstraZeneca, UK
Andreas Staudt, Bayer HealthCare AG, Germany

Programme Committee

Richard L. Chamberlain, Executive Consultant Services, USA
Pierre-Yves Lastic, sanofi-aventis, France
Jens Reinhold, Berlex Inc., USA
Stephane Rouault, F. Hoffmann-La Roche Ltd., Switzerland
Teri E. Stokes, GXP International, USA
Peter Stokman, NV Organon, The Netherlands
Maritza Witteveen, Factory CRO for Medical Devices, The Netherlands

Programme Advisors

Barry Burnstead, Phase Forward, UK
Earl W. Hulihan, META Solutions, Inc., USA

Learning Objectives

- Acquire a broad scope and state-of-the art insight into data management, IT and validation
- Improve your interaction with professionals and providers in different expertise areas and/or cultures
- Describe the rationale for standardization and apply standards to your daily work
- Recognize and implement strategies for effective management of people, processes and systems
- Discuss the impact of EDC and other enabling technologies on roles and processes of your operations
- Better plan for compliance with regulatory requirements
- Identify the potential for and plan for re-engineering and continuous process improvement
- Gain knowledge of emerging technologies
- Understand the regulatory requirements impacting on the pharma industry

Target Audience

From the expertise area point of view:

- Clinical Data Management
- Information Systems and Technology
- Study Management
- Quality Control/Quality Assurance
- Validation
- Systems Owners/Users
- Networks/Infrastructure

From the organisational point of view:

- Pharma, Biotech and Medical Devices Companies
- Academic and Governmental Bodies
- Contract Research Organisations
- Software Systems and Services Providers
- Consultants, Experts and Support Organizations

From the job profile point of view:

- Professionals and Specialists including Data Coordinators and Reviewers, Data Managers, CRF and Database Designers, Medical Coders
- Auditors, Application Developers and Integrators
- Managers of Projects, People, Systems, Infrastructure and Applications
- Experts and Advisers
- IT Professionals
- Regulatory Affairs
- Biostatisticians

Exhibition

DIA will provide the opportunity for pharmaceutical industry support organisations to exhibit their materials and services at this meeting. To obtain details on exhibiting space and facilities, interested exhibitors should contact:

Drug Information Association
Phyllis Suter, Exhibit Department
Elisabethenanlage 11, Postfach, 4002 Basel, Switzerland
Tel.: +41 61 225 51 54 - Fax: +41 61 225 51 52
Email: phyllis.suter@diaeurope.org

THIS PROGRAMME WAS DEVELOPED BY THE CLINICAL DATA MANAGEMENT, INFORMATION TECHNOLOGY, AND VALIDATION SPECIAL INTEREST AREA COMMUNITIES

SIAC

Visit our Website www.diahome.org

Meeting Contact and Information

For meeting information, contact Tamara Kohler, Meeting Manager at the DIA European Branch Office in Basel, Switzerland, by telephone +41 61 225 51 62, fax +41 61 225 51 52 or email tamara.kohler@diaeurope.org

Special Interest Area Communities (SIACs)

Each DIA SIAC provides a discipline-specific, global community where members can share common experiences and knowledge and connect with others in their particular field. Members will also find opportunities for leadership and networking within each SIAC.

SIAC Role in DIA

SIACs provide a forum for volunteers to network and exchange information. SIACs also assist DIA in identifying professional development needs in particular interest areas and in providing information to members in career and professional development, to meet those needs.

SIAC Participation

Participation in a SIAC is open to all current DIA members. SIACs are discipline-specific and global in scope and encourage balanced representation from professionals in industry, academia, contract service organizations, and government. All DIA SIACs are global in nature. European participation is encouraged and necessary for the success of each SIAC.

SIAC Leadership

SIACs have a chairperson or co-chairpersons who take responsibility for the overall activities of the SIAC. A core committee facilitates the work of each SIAC.

Clinical Data Management SIAC

The mission of the CDM SIAC is to

- Establish a global forum to share, evaluate, and disseminate information on processes, standards, and technologies for the management of clinical data.
- Encourage participation by professionals in the biopharmaceutical and healthcare industries.
- Promote education, training, and career development of clinical data management professionals.
- Promote multidisciplinary collaboration and understanding.
- Increase the visibility and recognition of clinical data management as a professional discipline.

Information Technology SIAC

The mission of the Information Technology SIAC is to

- Provide an opportunity for Information Technology professionals in the pharmaceutical industry to exchange information and ideas,
- Contribute to the professional growth of its membership, and thus to ultimately benefit the entire industry.

The audience we hope to influence consists of infrastructure staff and managers, application developers and managers, application integrators and managers, IT support organizations, individuals who interact with IT on a regular basis, and IT consultants and partners.

Validation SIAC

The Validation SIAC's mission is to

- Be a unified voice that defines "best practices" for system validation and validation within the pharmaceutical, device, and manufacturing industry, influencing vendors and communicating with regulatory agencies, globally, in regard to validation standards and technologies.
- Interpret current and developing health authority guidances and regulations and their impact on business practices and to provide a common language from which to present ideas.
- Establish effective communication channels to agencies and vendors.

If you would like to join a SIAC, please go to www.diahome.org or fill out the postcard in your membership kit.

Conference at a Glance

Sunday, November 7, 2004

13:00	Tutorial Registration
13:30-17:30	Parallel Tutorial 1

Parallel Tutorial 1
Computerized System Validation (CSV) - A Reality Check for Managers - Document Case Study and Formal Testing Experience

14:00-17:30	Parallel Tutorials 2, 3, 4 and 5

Parallel Tutorial 2	Parallel Tutorial 3	Parallel Tutorial 4	Parallel Tutorial 5
CDISC Standards End to End	E-Clinical	Advanced Auditing of Clinical Research Systems for Validation	Roles and Responsibilities of the User for Computer Systems Validation

Monday, November 8, 2004

08:00	Tutorial Registration
09:00-12:30	Parallel Tutorials 6, 7 and 8

Parallel Tutorial 6	Parallel Tutorial 7	Parallel Tutorial 8
FDA Tutorial	Computer Systems Validation: Back to Basics	Audit Preparation: What You Should Know About Being Audited

12:30	Lunch for Tutorial Participants in the Exhibition Area
12:30	Conference Registration and Exhibition Opening
14:00	OPENING PLENARY FOR ALL CONFERENCE PARTICIPANTS: REGULATORY 1
15:30-16:00	Coffee Break in the Exhibition Area
16:00-17:30	Parallel Tracks

PARALLEL TRACK 1	PARALLEL TRACK 2	PARALLEL TRACK 3	PARALLEL TRACK 4
CLINICAL DATA MANAGEMENT	CLINICAL DATA MANAGEMENT	VALIDATION	INFORMATION TECHNOLOGY
Session 1 Regulatory 2	Session 1 Metrics	Session 1 Regulatory Issues	Session 1 IT Infrastructure

17:30	Reception in the Exhibition Area
19:00	Departure for Social Event

Tuesday, November 9, 2004

09:00-17:30	Parallel Tracks

PARALLEL TRACK 1	PARALLEL TRACK 2	PARALLEL TRACK 3	PARALLEL TRACK 4
CLINICAL DATA MANAGEMENT	CLINICAL DATA MANAGEMENT	VALIDATION	INFORMATION TECHNOLOGY
09:00 Session 2 CDISC Theory	Session 2 Vendor/Partner Relationship	Session 2 Risk Assessment	Session 2 IT-Management
10:30 Coffee Break in the Exhibition Area			
11:00 Session 3 CDISC Practice	Session 3 CRO Platforms	Session 3 Common Interest - E-clinical	Session 3 New Technologies
12:30 Lunch in the Exhibition Area			
14:00 Session 4 Diverse Data Type	Session 4 Devices	Session 4 Methodology 1	Session 4 Preclinical IT
15:30 Coffee Break in the Exhibition Area			
16:00 Session 5 Dictionaries	Session 5 E-Pro Cirque	Session 5 Methodology 2	Session 5 IT Support of Global Applications
17:30 End of Day			

Wednesday, November 10, 2004

08:30-16:15	Parallel Tracks

PARALLEL TRACK 1	PARALLEL TRACK 2	PARALLEL TRACK 3	PARALLEL TRACK 4
CLINICAL DATA MANAGEMENT	CLINICAL DATA MANAGEMENT	VALIDATION	INFORMATION TECHNOLOGY
08:30 Session 6 E-clinical - Keynote	Session 6 Data Handling	Session 6 SDLC Issues	Session 6 Outsourcing IT
10:00 Coffee Break in the Exhibition Area			
10:30 Session 7 E-clinical - Implementation	Session 7 Process Management	Session 7 Inspection Trend	Session 7 IT Governance
12:00 Lunch in the Exhibition Area			
13:30 Session 8 E-clinical	Session 8 Human Interactions	Session 8 Regulatory Issues - Panel/Q&A	Session 8 IT - Current/Future Challenges
15:00 International Forum of Clinical Data Management Organisations		Closing Plenary	Closing Plenary
16:30 End of Conference			

Sunday, November 7, 2004

13:00 **Tutorial Registration**

Note: Tutorials 1, 2, 3, 4 and 5 are parallel - You can only attend one (Each tutorial will have a 15 minutes break)

13:30-17:30 — PARALLEL TUTORIAL 1

COMPUTERIZED SYSTEM VALIDATION (CSV) - A REALITY CHECK FOR MANAGERS DOCUMENT CASE STUDY AND FORMAL EXPERIENCE

Instructor:

Teri E. Stokes, GXP International, USA

This interactive tutorial gives managers a personal view of the real work involved in computer validation. It is a highly participative experience that includes a case study of validation plan, test plan, traceability matrix, and summary reports for a GLP system and a live exercise to execute three user acceptance test scripts for an excel spreadsheet as the example of a software application to be validated. An interactive tutorial sets the stage for each exercise. Bring a laptop with excel 95 or higher and the ability to upload a file from diskette via a USB port. Or come and be a witness/recorder for testing performed by others.

Learning Objectives

- The structure and content of key documents to be included in the validation package for user acceptance of a regulated application.
- The roles and responsibilities for package sponsor, team leader, package manager, and test coordinator in validation projects.
- How to perform formal testing and produce auditable test records.

Target Audience

This tutorial will benefit the following professionals: any manager with a GXP system to be validated, end-user and IT teams facing a system validation project, quality assurance people auditing GXP systems, suppliers of GXP systems (applications, e-diaries) and suppliers of GXP data services (CROs).

14:00-17:30 — PARALLEL TUTORIALS

PARALLEL TUTORIAL 2

CDISC STANDARDS END TO END

Instructors:

Pierre-Yves Lastic, sanofi-aventis, France
Philippe Verplancke, CRO 4 GmbH, Germany

This tutorial will describe the basics of the main CDISC models (ODM, LAB, SDS & ADaM), with emphasis on the SDS v3.1 model, presenting how all four models can be used together from data capture to regulatory submission.

Learning Objectives

- Understand the basics of the ODM, LAB & ADaM models.
- Get a more in depth understanding of the SDS model.
- Understand how data can be mapped from the LAB into the ODM model, then sent to a regulatory agency using the SDS and ADaM models. Examples are based on real life scenario.

Target Audience

This tutorial is intended for anyone who is involved in designing, maintaining or using clinical information systems, e.g. data managers, database and statistical programmers, statisticians and software designers

PARALLEL TUTORIAL 3

E-CLINICAL

Instructor:

Rebecca Kush, CDISC, USA
David Iberson-Hurst, Assero Ltd., UK

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.

Learning Objectives

At the conclusion of this tutorial, attendees will be able to:

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

Target Audience

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 accross departments.

PARALLEL TUTORIAL 4

ADVANCED AUDITING OF CLINICAL RESEARCH SYSTEMS FOR VALIDATION

Instructors:

Earl W. Hulihan, META Solutions, Inc., USA
Helena van den Dungen,
Health Care Inspectorate, The Netherlands

This tutorial is intended to provide practical training to auditors and auditees alike. We will focus on clinical systems involved in clinical research settings such as data management, information systems, and biostatistics. Systems and programmes that utilize and/or report data from clinical trials will be explored. The documentation package and its ability to verify the quality and integrity of such data will be reviewed. We will explore various system-specific issues in reviewing validation documentation for completeness and quality attributes.

Learning Objectives

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

- Recognize what regulatory inspectors are generally looking for when reviewing a system and the documentation surrounding it
- Identify some of the critical points/issues of various data capturing systems that are used for today's clinical studies
- Describe the standards that other auditors are using in their audits of various types of vendors

Target Audience

This tutorial is designed for personnel who have responsibility for clinical research systems within their company, such as senior management, project managers, monitors, medical monitors, clinical scientists, clinical associates, data managers, IT administrators, investigators, corporate-level managers, statisticians, site coordinators, as well as quality assurance, regulatory compliance, and regulatory affairs.

PARALLEL TUTORIAL 5

ROLES AND RESPONSIBILITIES OF THE USER FOR COMPUTER SYSTEMS VALIDATION

Instructor:

Richard L. Chamberlain, Executive Consultant Services, USA

Learning Objectives

This tutorial will go through the process of computer systems validation and present the various roles and responsibilities of the users of the computer system. We will cover their roles in system "ownership" and in the development of some of the validation documentation. This will include such things as sign-off levels - approval versus review only.

It will go over their responsibilities as members of a project team responsible for implementing the system. We will cover their roles in testing the system whether it is during the testing phase or doing user acceptance testing. The activities of vendor audits, development of acceptance criteria, problem reporting, prioritizing enhancements/changes will also be discussed.

The role of a "Users Group" in the development and use of a computer system will be discussed. The issues surrounding effective communication during the implementation of computer systems will be discussed.

Target Audience

This tutorial is intended for anyone who manages a group of users who are currently or will be implementing a computer system. It is also intended for anyone who is or will be a member of a project team that is implementing a computer system.

Monday, November 8, 2004

08:00 **TUTORIAL REGISTRATION**

NOTE: TUTORIALS 6, 7 AND 8 ARE PARALLEL - YOU CAN ONLY ATTEND ONE (EACH TUTORIAL WILL HAVE A 15 MINUTES BREAK)

09:00-12:30 **PARALLEL TUTORIALS**

PARALLEL TUTORIAL 6

REGULATORY SUBMISSION AND REVIEW OF CLINICAL TRIAL DATA AT THE FDA

Instructors:

Randy Levin; FDA CDER, USA
Stephen Wilson; FDA, USA

Learning Objectives

Participants will review current rules and guidance for the submission of electronic clinical trial data and metadata to the Centre for Drug Evaluation and Research (CDER). This tutorial will describe in detail how medical and statistical reviewers at the agency use eNDA clinical trial data and work with sponsors during the review of regulatory submissions. The latest developments in the standards for electronic submissions to the FDA will be presented.

Target Audience

All individuals interested in an "insider's view" of the FDA review process. This includes, but is not limited to data managers, clinical monitors, statisticians, regulatory affairs and regulatory operation staff, project managers, medical writers and IT staff.

PARALLEL TUTORIAL 7

COMPUTER SYSTEMS VALIDATION: BACK TO BASICS

Instructor:

Leonard A. Grunbaum, META Solutions, Inc., USA

This tutorial will answer the following basic questions regarding validating computerized systems:

- What is validation?
- Why is validation important?
- How can you validate a system effectively and efficiently?
- How much is enough?

We will look at these issues in the context of applicable regulations (e.g., 21 CFR Part 11) and guidance documents (e.g., computerized systems used in clinical trials, scope and application, ICH E6). A healthy dose of common sense will be mixed in as well. The attendees will learn basic principles regarding fundamental issues such as, but certainly not limited to, the following:

- Planning a validation effort
- The scope of a validation effort
- Assessing and documenting risk
- Testing strategies and tactics
- Validating "off-the-shelf" software
- Validating configurable software
- Auditing vendors
- Validation deliverables
- Role of quality assurance (300 words or less)

Learning Objectives

At the conclusion of the tutorial, the participants will be able to:

- Understand what needs to be validated and why
- Identify the elements of a validation effort
- Develop and/or assess selected validation deliverables

PARALLEL TUTORIAL 8

AUDIT PREPARATION: WHAT YOU SHOULD KNOW ABOUT BEING AUDITED

Instructors:

Kenneth O'Brien, Perceptive Informatics Inc., USA
James Graffam, Perceptive Informatics Inc., USA

Lack of training and preparation is a significant contribution to the fear, apprehension, and stress often associated with being audited. This half-day tutorial is designed to instruct potential auditees in the fine art of preparing for and responding during audits. Three main areas of focus will be covered:

- Preparing for the audit
- Auditee responsibilities, and
- Auditor techniques

Learning Objectives

At the conclusion of this tutorial, attendees will be able to:

- Approach an audit with newfound confidence.
- Recognize how a well-prepared auditee will affect the outcome of the audit in a positive manner.
- Gain an understanding of auditor technique used during audits.

Target Audience

Persons assigned the responsibility of hosting client audits.
Persons who have been assigned to participate in client audits.
Auditees seeking to gain a better understanding and comfort level with client audits.

12:30 **LUNCH FOR TUTORIAL PARTICIPANTS IN THE EXHIBITION AREA**

12:30 **WORKSHOP REGISTRATION**

14:00 **OPENING PLENARY FOR ALL CONFERENCE PARTICIPANTS**

DIA Welcome Address
Wayne Nitchuk; DIA European Branch Office, Switzerland

Conference Welcome Address
Suzanna De Cordt, Serono International S.A., Switzerland
Bryan Doherty, AstraZeneca, UK

Opening Plenary: Regulatory 1
Session Chairperson:
Barry Burnstead, Phase Forward, UK
The environment within which we work is heavily regulated and subject to frequent change. Speakers from the EMEA, FDA and a local Competent Authority will provide updates from their respective agencies and address a number of current topics including:

- Impact of the European CT Directive after the first 6 months
- Usage of the EudraVigilance and EudraCT databases
- Management of Adverse Events in clinical trials (SUSARs or SADRs)
- Interest and adoption of standards (CDISC) by Regulatory Authorities
- eSource and it's validity
- 21 CFR Part 11 understanding and compliance.

FDA Regulatory Aspects
Randy Levin, FDA CDER, USA

Dutch Regulatory Aspects
Helena van den Dungen, Health Care Inspectorate, The Netherlands

EMEA Aspects
Timothy Buxton, EMEA, UK

15:30 COFFEE BREAK IN THE EXHIBITION AREA

Monday, November 8, 2004

16:00 Session 1

DATA DOCUMENT AND ECTD – A REGULATORY OVERVIEW

Session Chairperson:

Barry Burnstead, Phase Forward, UK

Connectivity from source data to analysis to report to submission documentation is a journey full of challenges. Furthermore expectations for connectivity within the eCTD increase. In this session we review the expectations of industry reviewers (and also the auditors) with respect to:

- *Design of eCRT with respect to clinical study reports and requirements to reference data*
- *Cross referencing in eCRTs and building in intra and inter document links*
- *Data integrity and ownership from source to consolidation in databases*
- *Referencing data in documents (inc. SUSARs from clinical trials)*

A general overview of the basic designs and status of eCTD implementation in Europe will be included.

Data Ownership: Further Challenges for EDC
Neil Konopka, Phase Forward, UK

The eCTD and Clinical Study Reporting
Andrew Marr, GlaxoSmithKline, UK

Cross-Referencing during Part Submissions and Document Reuse in the e CTD Environment
Olaf Schoepke, Lorenz Life Sciences, UK

17:30 RECEPTION IN EXHIBITION AREA

19:00 DEPARTURE FOR SOCIAL EVENT

Tuesday, November 9, 2004

09:00 Session 2

CDISC: THE GLOBAL VISION

Session Chairperson:

Pierre-Yves Lastic, sanofi-aventis, France

In the past years CDISC has become THE standard in the Clinical Data Management area. This session will provide an update on CDISC activities; show how CDISC standards can be used from data capture to submission and present recent developments in healthcare that will impact clinical data standards.

Creating End-to-end Solutions for eSubmission
Don Rosen, Don Rosen Consulting, USA

Progress on Data Interchange Standards, from Data Acquisition through Submission
Rebecca Kush, CDISC, USA

NHII: Implications for Global Clinical Trials
Charles Jaffe, AstraZeneca, USA

10:30 COFFEE BREAK IN THE EXHIBITION AREA

11:00 Session 3

CDISC IN PRACTICE

Session Chairperson:

Pierre-Yves Lastic, sanofi-aventis, France

After the general information provided in the precedent session, the following presentations will provide real life examples of CDISC standards implementation.

Indication Extensions to CDISC SDS Version 3.1- First Experience
Dagmar Kottig-Roth, Covidence GmbH, Germany

The Implementation of CDISC Standards (SDS V3.1.) within a CRO
Jason Turner, Quintiles, UK

Papillo, a Data Language
Xavier Gobert, Eli Lilly, Belgium

12:30 LUNCH IN THE EXHIBITION AREA

14:00 Session 4

DIVERSE DATA TYPE

Session Chairperson:

Stephen Dobson, Pfizer Ltd., UK

New technology, data, processes, increasing competition and public expectations; these are just a few of the drivers reshaping strategies, markets and the futureof the pharmaceutical industry. This session will look at a few examples that challenge the conventional clinical trial approach and the changes they may cause for drug development in general.

Technology Enhanced Patient Recruitment
Bill Byrom, Clin Phone Ltd., UK

Securing Patient Privacy in the Era of Personalized Medicine
Michael Swietek, Pfizer Inc., USA

Managing Multiple Digital Data Sources
Mukhtar Ahmed, Kendle International, UK

15:30 COFFEE BREAK IN THE EXHIBITION AREA

16:00 Session 5

DICTIONARIES

Session Chairperson:

Stephane Rouault, F. Hoffmann-La Roche Ltd., Switzerland

Dictionary coding is being used to ensure time saving and cost efficiency increase, but at the same time dictionaries present challenges to the regulators as well as the industry. In this session, MedDRA and WHO Drug are being scrutinized. Furthermore, as a way to optimize the dictionary coding activities and ensure accurate and consistent coding, a presentation will focus on a build-in auto-encoding system experience.

MedDRA in Clinical Development
Tomás Moraleda, MSSO, Spain

WHO Drug Dictionary
Malin Nord, The Uppsala Monitoring Centre, Sweden

Coding Process Embedded in Validated Systems
Karin Verstraeten, Johnson & Johnson PRD, Belgium

17:30 END OF DAY 2

Wednesday, November 10, 2004

08:30 Session 6

E-CLINICAL - KEYNOTE

Session Chairperson:

Pierre-Yves Lastic, sanofi-aventis, France

For more than a decade, only few companies have been really switching from paper based processes to EDC. As one of the leaders in this field our first keynote speaker will share insights about this implementation process. Our second speaker will present the view of a service company.

EDC: Emerging Technology or Process Management?
Sylva Collins, Novartis Corporation, USA

Enhancing the Value Proposition of EDC
Wolfgang Summa, Datatrak, Germany

10:00 COFFEE BREAK IN THE EXHIBITION AREA

10:30 Session 7

E-CLINICAL - IMPLEMENTATION

Session Chairperson:

Stephen Dobson, Pfizer Ltd., UK

The benefits of e-Clinical are frequently sited, and include increased data quality, trial efficiency and the elimination of repetitive rounds of data entry and reconciliation. This second of three E-clinical sessions will examine the practical aspects of implementing E-clinical studies, and introduce some real and unusual examples.

Standard Benchmarks for EDC Performance
Richard Perkins, ConSept Consulting, France

Found in Translation, Web-based EDC in Japan
Mike Nell, Phase Forward, UK

When New Technologies Help to Improve Health in Emerging Countries
Yves Tellier, GlaxoSmithKline, Belgium

12:00 LUNCH IN THE EXHIBITION AREA

13:30 Session 8

E-CLINICAL TODAY AND TOMORROW

Session Chairperson:

Pierre-Yves Lastic, sanofi-aventis, France

This last e-Clinical session will take a closer look at various topics belonging to the wide area of e-Clinical Trials: the all important financial aspect, an example of the integration of several technologies mixing paper and electronic solutions and finally a glance at the future of electronic source data.

Use of a Fax-based System to Fasten CRF and Data Processing
Christophe Cocherel, sanofi-aventis, France

The Future Challenges for eSource
Tim Davis, CRF Inc., UK

Clinical Data Integration
Robin Clark, IBM Business Consulting Services, UK

15:00 International Forum of Clinical Data Management Organisations

Session Chairperson:

Ronald D. Fitzmartin, META Solutions, Inc., USA

This will be an interactive panel session composed of representatives from key international CDM organizations: Society for Clinical Data Management (SCDM); Association for Clinical Data Management (ACDM); Pharmaceutische Statistiek en Data Management (PSDM); German Association for Medical Documentalists (DVMD); Data Management Biomedical (DMB) and DIA Clinical Data Management SIAC.

Each panellist will briefly introduce the mission and objectives of their respective organization. This will be followed by an interactive panel and audience discussion on some of the important operational and strategic issues facing CDM today and in the future.

Panel:
Marianne Plaunt, i3 Statprobe, USA
SCDM Representative

Caroline Fenning, Roche Products Ltd., UK
ACDM Representative

Margarete Rudloff, Kendle International, Germany
DVMD Representative

Joris Cauquil, DMB Representative, France

Closing Remarks
Stephen Dobson, Pfizer Ltd., UK

16:30 END OF CONFERENCE

Monday, November 8, 2004

16:00 Session 1

METRICS

Session Chairperson:

Stéphane Rouault, F. Hoffmann-La Roche Ltd., Switzerland

Everything you always wanted to know about metrics but were afraid to ask...
How is it being used?
How resource forecast and trial metrics have been used successfully?
Example of metrics used successfully in helping management to make decision on FTEs and timelines

Metrics for Data Management Process Control
Nigel Freemantle, Merck Sharp & Dohme, UK

Resource Forecasting Challenges in an Early Stopping Trial
Albert Chau, Albert Chau Consultancy, UK

Our Love/Hate Relationship with Metrics
Joseph S. Anderson, Waife & Associates Inc., USA

17:30 RECEPTION IN EXHIBITION AREA

19:00 DEPARTURE FOR SOCIAL EVENT

Tuesday, November 9, 2004

09:00 Session 2

VENDOR/PARTNER RELATIONSHIP

Session Chairperson:

Jens Reinhold, Berlex Inc., USA

The changing climate in clinical research and development directly leads to growing challenges for collecting, processing and delivering high-quality clinical data most efficiently. In this session this process is examined closely from a cross-company as well as a detailed technology and process point of view. Strategic development, reliability, data security, performance, productivity improvement in vendor/sponsor relationship will be discussed.

Strategic Outsourcing of Clinical Data Management
John R. Shelton, Wyeth Research, UK

Virtual Clinical Data Management
Adrian Hsing, Gilead Sciences Inc., USA

CROs working Remotely on Sponsor Infrastructure
Michèle Cunnane, Quintiles Ltd., Ireland

10:30 COFFEE BREAK IN THE EXHIBITION AREA

11:00 Session 3

CRO PLATFORMS

Session Chairperson:

Jens Reinhold, Berlex Inc., USA

One new strategy in clinical development, particularly within clinical data management, is using the so-called CRO platform. The rationale, advantages, disadvantages and concrete technology concepts will be explored. Furthermore responsibilities, communication lines and pitfalls are outlined.

The CRO Platform Configuration
Emmanuel Aubes, Serono International, Switzerland

CRO Platforms, Multiple Sites, Multiple Locations
Julianne Hull, Wyeth Research, UK

CRO Platform - Practical Guide for Remote Data Management
Eric Gerber, MDS Pharma Services, France

12:30 LUNCH IN THE EXHIBITION AREA

14:00 Session 4

DEVICES

Session Chairperson:

Maritza Witteveen, Factory CRO for Medical Devices, The Netherlands

This session will highlight device studies with emphasis on the comparison of data management for device and drug studies.
The session starts with the regulatory requirements for device studies and the path that brings a device to the market.
An overview of the systems and processes used to conduct data management for devices will be given. A practical presentation will explain the specific details regarding data management for devices.

Regulatory for Devices
Eliane Schutte, IsoTis OrthoBiologics, The Netherlands

Data Management in the Device World
Nancy Stark, Clinical Device Group Inc., USA

Data Management for Device Studies
Ingrid Kennis, Bakken Research Center BV Medtronic, The Netherlands

15:30 COFFEE BREAK IN THE EXHIBITION AREA

16:00 Session 5

E-PRO CIRQUE

Session Chairperson:

Suzanna De Cordt, Serono International S.A., Switzerland

Electronic collection of Patient Reported Outcome data (e-PRO) brings several benefits, both from the point of view of process efficiency and data authenticity and quality. In the e-PRO Cirque, participating vendors will receive specifications and develop their solutions which will then be demonstrated to the audience.

Tanya Hair, CRF Inc., Finland
Rachael King, etrials worldwide Ltd., USA
Wilhelm Muehlhausen, invivodata, inc., USA
Philip Lee, PHT Corporation, USA

17:30 END OF DAY 2

Wednesday, November 10, 2004

08:30 Session 6

DATA HANDLING

Session Chairperson:

Peter Stokman, NV Organon, The Netherlands

Data handling has many aspects, all of which can be steadily improved. The lectures in this session focus on optimizing the process by frequent small quality audits, on a fundamental evaluation of validation bias, and on the merits of a browsing tool to facilitate the data validation process.

Optimized Clinical Trial Data Quality Checks Using SPC
Reza Rostami, Duke Clinical Research Institute, USA

Is the Objective of Data Cleaning to Produce as Many Right Values as Possible?
Mikael Aström, Clinical Data Care, Sweden

Manual Line Listing Reviews. Is There an Alternative?
Peter Buckman, CSS Informatics, UK

10:00 COFFEE BREAK IN THE EXHIBITION AREA

10:30 Session 7

PROCESS MANAGEMENT

Session Chairperson:

Peter Stokman, NV Organon, The Netherlands

Clinical Data Management is a highly critical process in Clinical Development, involving line management and cross-functional teams. Process and team optimization therefore deserve continuous attention. The presenters in this session will discuss theory and practice of different avenues towards excellence, both from team and line perspective.

7-Step Problem Solving Methodology
Dominic J. Marion, KLA Tencor, Ireland

Rapid Scale-up of a Data Team for Early Closeout of a Large Trial
Ingrid Martin, Pfizer, UK

Metrics & Best Practices: Applying Six Sigma on the Clinical Data Management Process to Shorten Query Generation Timelines
Peter Sas, Johnson & Johnson PRD, Belgium

12:00 LUNCH IN THE EXHIBITION AREA

13:30 Session 8

HUMAN INTERACTIONS

Session Chairperson:

Maritza Witteveen, Factory CRO for Medical Devices, The Netherlands

Effective human interaction is the basis for achieving projected output, and it is the first requirement for a professional career. This session will discuss the interactions between data management professionals and between project team members. The emphasis will be put on communication, also addressing this in an international/global setting. Examples and methods to achieve an effective working relationship and to overcome cultural barriers will be presented.

Bridging the Gap
Geraldine Boylan, Quintiles Ltd., Ireland

Communication, Collaboration, Cooperation in Clinical Data Management
Frances Bradshaw, PharmaNet, UK

Case Study of Globally Resourced Trial: The Dimensions of Cultural Diversity, S.A.
Reza Shafaatian, Serono International, Switzerland

15:00 International Forum of Clinical Data Management Organisations

Session Chairperson:

Ronald D. Fitzmartin, META Solutions, Inc., USA

This will be an interactive panel session composed of representatives from key international CDM organizations: Society for Clinical Data Management (SCDM); Association for Clinical Data Management (ACDM); Pharmaceutische Statistiek en Data Management (PSDM); German Association for Medical Documentalists (DVMD); Data Management Biomedical (DMB)and DIA Clinical Data Management SIAC.

Each panellist will briefly introduce the mission and objectives of their respective organization. This will be followed by an interactive panel and audience discussion on some of the important operational and strategic issues facing CDM today and in the future.

Panel:
Marianne Plaunt, i3 Statprobe, USA
SCDM Representative

Caroline Fenning, Roche Products Ltd., UK
ACDM Representative

Margarete Rudloff, Kendle International, Germany
DVMD Representative

Joris Cauquil, DMB Representative, France

Closing Remarks
Stephen Dobson, Pfizer Ltd., UK

16:30 END OF CONFERENCE

Monday, November 8, 2004

16:00 Session 1

REGULATORY ISSUES

Session Chairperson:

Bryan Doherty, AstraZeneca, UK

It is important to keep up with the changing regulatory environment. This is particularly true with changes to 21 CFR Part 11 and many inspectional issues.

Clarification of FDA Thinking: Compliance with 21CRF Part 11

John Wise, Tavistock Europe Ltd., UK

A Review of the New FDA Draft Guidance for Clinical Systems Used in Clinical Trials

Richard L. Chamberlain, Executive Consultant Services, USA

Full Electronic Reporting of PK Samples & Biomarkers

Jan Dankers, Analytico Medinet, The Netherlands

17:30 RECEPTION IN EXHIBITION AREA

19:00 DEPARTURE FOR SOCIAL EVENT

Tuesday, November 9, 2004

09:00 Session 2

RISK ASSESSMENT

Session Chairperson:

Martin Browning, EduQuest Inc., USA

The integration of risk assessment into validation is an important, relatively new concept for some. It is a vital part of most regulatory issues.

Automated Risk Assessment

Kjeld Wetlesen, tpi consulting gmbh, Switzerland

Structured Testing of Regulated Systems According to TMap®

Yves Dène, Gitek NV, Belgium

Validation of an EDMS System: A Risk Based Approach

Danilo Neri, Pharma Quality Europe, Italy

10:30 COFFEE BREAK IN THE EXHIBITION AREA

11:00 Session 3

COMMON INTEREST - E-CLINICAL

Session Chairperson:

Maryann McKendry, McKendry Associates, USA

The validation of e-clinical systems is of major importance to most companies. As new systems are implemented the validation can often pose many challenges.

Using Validation & Enterprise EDC Solutions for Competitive Advantage in Drug Development

Key-factors and Benefits from a Validation Model

Björn Dahlöf, Statistical Consulting Group, Sweden

Role of Metrics in EDC Implementation

Mayuri Trehan, Merck & Co., USA

12:30 LUNCH IN THE EXHIBITION AREA

14:00 Session 4

METHODOLOGY 1

Session Chairperson:

Teri E. Stokes, GXP International, USA

Meeting the ever changing challenges of business requires flexible software applications. In regulated applications, the discipline of computer validation is required. In this session, speakers with many years of practical experience will discuss methods for software validation from the perspective of the real world issues arising for applications used in regulated environments.

Validation in a Flexible Clinical Data Management Environment

Jan Kesteloot, Johnson & Johnson PRD, Belgium

Validation of Clinical Study Databases

Norbert Fritz, F. Hoffmann-La Roche Ltd., Switzerland

Using Software for Validation Cost Reduction

Breffni Martin, Regintel, Ireland

15:30 COFFEE BREAK IN THE EXHIBITION AREA

16:00 Session 5

METHODOLOGY 2

Session Chairperson:

Breffni Martin, Regintel, Ireland

Case Studies Validation Cost Reduction

Thomas Quinn, The Hollis Group Inc., USA

The "Business" of Computer Systems Validation

Leonard A. Grunbaum, META Solutions Inc., USA

Auditing EDC Suppliers - Software, Systems and Services

Teri E. Stokes, GXP International, USA

17:30 END OF DAY 2

Wednesday, November 10, 2004

08:30 Session 6

SDLC ISSUES

Session Chairperson:

Jan Kesteloot, Johnson & Johnson PRD, Belgium

The systems life cycle is the heart of most computer validation. There continues to be extensions and enhancements to this methodology.

Production of Documentation to Support the Validation of Systems

David Bridges, eChange Solutions Ltd., Ireland

Implementation of a CRF Workflow and Imaging System

Fred Daniels, Covance CAPS, UK

How to Achieve a Sensible Risk Assessment in a Supplier Audit?

Hans Poland, Schering AG, Germany

10:00 COFFEE BREAK IN THE EXHIBITION AREA

10:30 Session 7

INSPECTION TREND: CURRENT REGULATORY AND INDUSTRY EXPECTATIONS FOR "e"MEDICAL/CLINICAL RESEARCH RECORDS

Session Chairperson:

Earl W. Hulihan, META Solutions Inc., USA

This session will take a look at current regulatory and industry expectations for documentation created as a part of the medical/clinical research process. Our session will feature speakers from regulatory agencies and industry representatives, and then be followed by a panel discussion. This session will be in two parts overlapping the break.

Speakers invited from Regulatory Agencies include:

- *Helena van den Dungen, Health Care Inspectorate, The Netherlands*
- *James McCormack, FDA, USA*
- *Jean Saint-Pierre, Health Canada, Canada*

12:00 LUNCH IN THE EXHIBITION AREA

13:30 Session 7 (Cont'd)

REGULATORY ISSUES: PANEL + QUESTIONS AND ANSWERS

Session Chairperson:

Earl W. Hulihan, META Solutions Inc., USA

Speakers invited from Regulatory Agencies include:

- *Helena van den Dungen, Health Care Inspectorate, The Netherlands*
- *James McCormack, FDA, USA*
- *Jean Saint-Pierre, Health Canada, Canada*

15:00 CLOSING PLENARY VALIDATION TRACK

16:15 END OF CONFERENCE

Please go to www.diahome.org and update your profile, or fax this page to +41 61 225 51 52

Name _____

Company _____

DIA Pin # _____

Primary Professional Interest Areas:

Please select six interest areas and indicate the one which is your primary interest area. _____

AH	____	Academic Health Centers
AM	____	Alternative/Herbal Medicine
BT	____	Biotechnology
CD	____	Clinical Data Management
CH	____	Chemistry
CL	____	Clinical Laboratory Data
CM	____	CMC
CP	____	Clinical Safety/Pharmacovigilance
CR	____	Clinical Research & Development
CS	____	Clinical Supplies
DC	____	Dictionaries/Data Standards
DE	____	Devices
DM	____	Document Management
FI	____	Finance
GC	____	GCP
GE	____	Generic Manufacturing
GL	____	GLP
GM	____	GMP
IM	____	Information Management
IS	____	Investigator Site
IT	____	Information Technology/e-Business
MA	____	Marketing/Advertising
MC	____	Medical Communications/Information
MH	____	Managed Healthcare
MN	____	Manufacturing: Drug Substance, Drug Product, Packaging
MW	____	Medical/Scientific Writing
NC	____	Non-clinical Safety & Efficacy/Toxicology
OS	____	Outsourcing/Virtual Development
OT	____	Over-the-Counter
PC	____	Pharmaceutics
PD	____	Professional Development
PE	____	Pharmacoepidemiology/Quality of Life/ Health Economics/Outcomes Research
PH	____	Pharmacology
PK	____	Pharmacokinetics/Metabolism/ Pharmacodynamics
PM	____	Project Management
PP	____	Public Policy/Law
QC	____	Quality Control/Quality Assurance
RA	____	Regulatory Affairs/Policy/Drug or Device Approval/GRP
RD	____	Research & Development/Strategic Issues
ST	____	Statistics/Biostatistics/Modeling
TR	____	Training
VA	____	Validation

Monday, November 8, 2004

16:00 Session 1

IT-INFRASTRUCTURE

Session Chairperson:

Thomas Quinn, The Hollis Group, Inc., USA

This Session addresses the role of the company Infrastructure in implementing "validated" computer systems.

IT-Infrastructure Qualification Assessment in a Global Environment

Marc Brooks, ALTANA Pharma AG, Germany

IT SOPs' Are They Really Necessary?

KT Oxford, META Solutions, Inc., USA

17:30 RECEPTION IN EXHIBITION AREA

19:00 DEPARTURE FOR SOCIAL EVENT

Tuesday, November 9, 2004

09:00 Session 2

IT-MANAGEMENT

Session Chairperson:

Richard L. Chamberlain, Executive Consultant Services, USA

IT is a key service group within the pharmaceutical industry. This session focus on what can be done to best manage this resource to provide best service within the current management and regulatory boundaries?

Handling Patches in a Regulated, Qualified Computer and Network Infrastructure

Thomas Quinn, The Hollis Group, Inc., USA

Managing IT for Remote Data Entry: Clinical Trials - Some Realities

Philip Bartle, Imperial College, UK

10:30 COFFEE BREAK IN THE EXHIBITION AREA

11:00 Session 3

NEW TECHNOLOGIES 1

Session Chairperson:

Philip Bartle, Imperial College, UK

IT is often the group most impacted during the implementation of new technologies. What is the best way to take advantage of new technologies and still provide sound interrupted service? This question will be addressed in this session.

New Technologies and the Role Played by IT in the Drug Development

Chris Montgomery, Celltech, UK

Advanced Portal Capabilities for Data Management

Dirk Grosse, Schering AG, Germany

Computerized System Validation: An Ongoing Effort

Jean Paty, invivodata inc., USA

12:30 LUNCH IN THE EXHIBITION AREA

14:00 Session 4

PRECLINICAL IT

Session Chairperson:

Mike Harwood, Instem LSS, UK

IT support for laboratory and other preclinical systems poses continuing challenges. Implementing new instrumentation, changes in regulations, and increased workloads require special tools. All these will be discussed in this session.

Current IT Issues for Providing Services and Support to Preclinical Areas

Manfred Kohler, ALTANA Pharma AG, Germany

Risk-based Validation

Alun Nelms, QuisIT, UK

Electronic Submission of Non-clinical Data Responding to the FDA SEND Initiative

Phil Ledsome, Instem LSS, USA

15:30 COFFEE BREAK IN THE EXHIBITION AREA

16:00 Session 5

IT SUPPORT OF GLOBAL APPLICATIONS

Session Chairperson:

Richard L. Chamberlain, Executive Consultant Services, USA

The management of risk is a major component in the current regulations. How does IT deal with these risks for all of the applications that use their Services?

Management of Global Applications

Daniel Gissinger, Wyeth Research, France

Standards for the Electronic Representation of Information and their Impact on Clinical Data Management

Robbert P. van Manen, Phase Forward Inc., USA

17:30 END OF DAY 2

Wednesday, November 10, 2004

08:30 Session 6

OUTSOURCING IT

Session Chairperson:

Thomas Quinn, The Hollis Group, Inc., USA

Outsourcing much of the IT function seems to be gaining in popularity. This session will present some of the issues and some potential solutions.

Silicon Reality & Beyond Mere Survival

Herbert Vander Elst, IBM Business Consulting Services, Belgium

Some of the Legal Issues of Outsourcing - Avoiding "Gotchas"

Martin Braun, Mayer, Brown, Rowe & Maw LLP, Germany

Jim Kunick, Mayer, Brown, Rowe & Maw LLP, Germany

10:00 COFFEE BREAK IN THE EXHIBITION AREA

10:30 Session 7

IT GOVERNANCE

Session Chairperson:

This session will be a workshop covering the interaction of IT with its many clients. Discussion will focus on communication, documentation, and staffing issues.

Stephan Amling, Accenture, Germany

12:00 LUNCH IN THE EXHIBITION AREA

13:30 Session 8

IT - CURRENT/FUTURE CHALLENGES

Session Chairperson:

Richard L. Chamberlain, Executive Consultant Services, USA

Since this meeting is the first of it's kind in Europe, a panel of experienced presenters from industry will discuss possible directions for facing current and future challenges for those responsible for IT in the pharmaceutical industry.

Panel:

Richard L. Chamberlain, Executive Consultant Services, USA,

Daniel Gissinger, Wyeth Research, France

Martin Braun, Mayer, Brown, Rowe & Maw LLP, Germany

15:00 CLOSING PLENARY INFORMATION TECHNOLOGY TRACK

16:15 END OF CONFERENCE

Hotel Information

AMSTERDAM RAI

Novotel Amsterdam****

Europaboulevard 10
Amsterdam, 1083 AD , The Netherlands

Distance to meeting site: 0,75 kilometers
The hotel is within walking distance from the RAI Congress Center.

Novotel Amsterdam is located in the immediate vicinity of the RAI complex. It is only 10-15 minutes walking distance to the RAI, in the commercial centre of Amsterdam and near the World Trade Centre. The RAI railway, metro and tram station offer frequent direct connections to Schiphol Airport and the city centre of Amsterdam.

Airport Transportation

- Airport Shuttle: a hotel shuttle service to and from Schiphol Airport is available every 30 minutes at a charge. The bus stops directly in front of the hotel. Total travel time approximately 30 minutes.
- Public Transportation: trains to RAI Station leave every 15 minutes. From RAI Station it is a short walk to the hotel. Total travel time approximately 20 minutes.
- Taxi: total travel time approximately 20 minutes.

Best Western Eden Hotel***

Amstel 144
Amsterdam, 1017 AE
The Netherlands

Distance to meeting site: 4 kilometers
Tram 4 from 'Rembrandtplein' goes straight to the RAI Congress Center.
Total travel time approx. 15 minutes.

Located in the very heart of Amsterdam, right between the beautiful Amstel river and the night life center the 'Rembrandtplein'. It is within walking distance of the flowermarket and popular museums, the old fashioned building is part of historic Amsterdam.

Airport Transportation

- Airport Shuttle: a hotel shuttle to and from Schiphol Airport is available every half hour at a charge. The bus stops by NH Schiller Hotel, a short walking distance of the Best Western Eden. Total travel time approx. 30 minutes.
- Public Transportation: trains to Amsterdam Central Station go every 15 minutes. From Central Station trams 4 and 9 go to 'Rembrandtplein', running every 10 minutes. From 'Rembrandtplein' it is a short walk to the hotel. Total travel time approx. 30 minutes.
- Taxi: total travel time approx. 25 minutes.

NH City Centre***

Spuistraat 288-292
Amsterdam, 1012 VX, The Netherlands

Distance to meeting site: 5 kilometers
Tram 4 from Rokin/Spui goes directly to the RAI Congress Center.
Total travel time approx. 20 minutes

Located in the heart of Amsterdam, near Dam Square. Closeby, many major business centres and touristic attractions can be found.

Airport Transportation

- Airport Shuttle: a hotel shuttle service to and from Schiphol Airport is available every half hour, at a charge. The bus stops directly in front of the hotel. Total travel time approximately 30 minutes.
- Public Transportation: trains to Amsterdam Central Station leave every 15 minutes. From Central Station tram 1, 2 and 5 go to Spui. From there it is a short walk to the hotel. Total travel time approximately 25 minutes.
- Taxi: total travel time approximately 25 minutes.

AMS Museum Hotel***

P.C. Hooftstraat 2
Amsterdam, 1071 BX
The Netherlands

Distance to meeting site: 3 kilometers
Tram 7 or 10 to Frederiksplein, there number 4 to the RAI Congress Center.
Total travel time approx. 25 minutes.

The AMS Museum Hotel is a historic landmark at the corner of the Stadhouderskade and the P.C. Hooftstraat. All famous sites in Amsterdam are within walking distance.

Airport Transportation

- Airport Shuttle: a hotel shuttle service to and from Schiphol Airport is available every half hour at a charge. The bus stops at the NH Amsterdam City Center Hotel, just a short walk from the AMS Museum Hotel. Total travel time approximately 30 minutes.
- Public Transportation: trains to Amsterdam Central Station go every 15 minutes. From Central Station tram 1,2 and 5 go to the 'Hobbemakade', from there it is a short walk to the hotel. Total travel time approximately 30 minutes.
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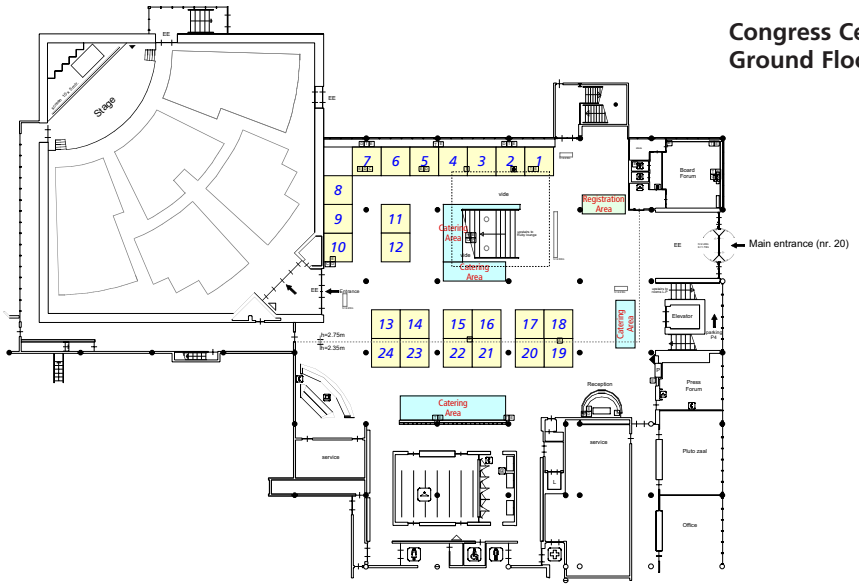
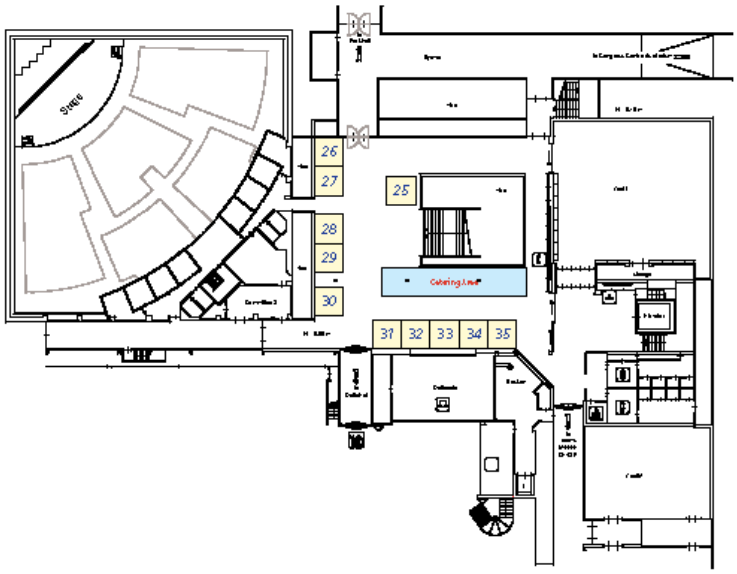
Exhibit Hall Floor Plans



Congress Centre Forum
Ground Floor: Lounge Forum



Congress Centre Forum
First Floor: Ruby Lounge

Exhibiting Companies

Company	Country	Booth No.
ARIS Global UK Ltd.	United Kingdom	06
Bassilichi SPA	Italy	08
CDISC	USA	20
Clinical Trial Operations, CTO	The Netherlands	01
ClinPhone Group Plc.	United Kingdom	15
Clinsource NV	Belgium	09
Covance	United Kingdom	28
Covidence	Germany	25
CRF Inc.	United Kingdom	30
DataTrak International	USA	27
DataTrial	United Kingdom	21
DOCS International	The Netherlands	32
Ease GmbH	Germany	35
E-Clinics	Belgium	19
ENTIMO AG	Germany	05
etrials worldwide	USA	31
IBM Corporation	USA	23
Image Solutions (ISI)	Germany	12
INCDMA	United Kingdom	24
InPrint	The Netherlands	04
Inveresk	United Kingdom	22
invivodata	United Kingdom	26
Kendle International	United Kingdom	10
KEY People	United Kingdom	07
MDS Pharma Services	USA	03
META Solutions, Inc.	USA	14
METRONOMIA	Germany	34
NNIT	Switzerland	17, 18
PharmaForms GmbH	Germany	11
Phase Forward	United Kingdom	29
PHT Corporation	USA	33
Quintiles	Ireland	16
Thorin BV	The Netherlands	13
VIASYS Healthcare Clinical Services	Germany	02

Conference Venue Information

The Conference will take place in the Forum Centre at the:
RAI Amsterdam International Exhibition & Congress Centre
Europaplein 22, NL-1078 GZ Amsterdam, The Netherlands

Amsterdam RAI has its own railway station and is less than ten minutes' travelling time by train from Schiphol Airport. Although the RAI Exhibition and Congress Centre is located on the outskirts of Amsterdam, the city centre with its attractive canals, pavement cafés, tourist attractions and a wide range of entertainment is just fifteen minutes away by public transport. The express trams are ideal for longer journeys within the city boundaries, and the ordinary trams stop right in front of the RAI and provide a quick and convenient service to all parts of Amsterdam. And last but not least, Amsterdam RAI has its own harbour on the side of the complex that borders on the park. This provides a direct connection to Amsterdam's extensive canal network.

By air

You can reach Amsterdam RAI from Amsterdam Airport Schiphol by car or public transport in less than 15 minutes. Schiphol Airport is one of Europe's biggest airports and offers passengers a high standard of service. From Schiphol there is a train going to Amsterdam RAI station four times an hour.

By Tram & Bus

If you arrive at Amsterdam Central Station (CS), you can take the Amstelveen express tram 51 (travelling time: 12 minutes, exit at the Amsterdam RAI station) or tram 4 (travelling time: 30 minutes, exit at the RAI Europaplein). If you are travelling by train to the Amstel station, you can take the Amstelveen express tram 51 (travellig time: 5 minutes) or the bus (route 15, 69 or 169), which will bring you to the RAI within 10 minutes. In this case you should get off at RAI Europaplein. From Amsterdam Sloterdijk station, the best way to reach the RAI is with express tram 50.

By Train

The intercity trains from Roosendaal/Belgium connect at Schiphol with trains going to the Amsterdam RAI station. At Schiphol you can change trains on the same platform. The fastest way to reach the RAI if you are coming from Arnhem/Germany, is to take the train to Amsterdam Duivendrecht station. Here you can change trains for the Amsterdam RAI station. There is also direct train connection with the Amsterdam RAI station from Rotterdam, the Hague, Leiden, Weesp, het Gooi and the Flevo polders.

Social Event

An optional social event will be arranged on **Monday, November 8, 2004,** to provide attendees an opportunity for informal conversation with old friends and new acquaintances in just the right atmosphere.

This is an optional event and is not included in the registration fee. To participate, please book your place at time of registration by ticking the appropriate box on the registration form at an additional charge of EUR 60.00 per person. More detailed information will be posted on the DIA website closer to the actual date.

Conference Cancellation Policy

All cancellations must be in writing and be received at the DIA office **by 17:00 on November 3, 2004**. Registrants who do not cancel by November 3, 2004 and do not attend, will be responsible for the full registration fee. *Registrants are responsible for cancelling their own airline and hotel reservations.* You may transfer your registration to a colleague at any time. 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 airfare, hotel or other costs incurred by registrants. Speakers and programme agenda are subject to change. Cancellations received in writing on or before November 3, 2004 will be processed as follows:

Full Meeting Cancellation

Member and Nonmember = EUR 200.00 will be deducted from paid fee
Government/Academia/Nonprofit (Member/Nonmember) = EUR 100.00 will be deducted from paid fee

Tutorial Cancellation

All tutorial registrants = EUR 50.00 will be deducted from paid fee

Hotel Information

The DIA has blocked a number of rooms at special rates in the hotels indicated below. Attendees must make their own hotel reservation by faxing, emailing or mailing the **enclosed official hotel booking form to the RAI Hotel Service.**

IMPORTANT: to be assured of accomodation in the selected hotel, registrants are recommended to complete their hotel reservation, if possible, by September 8, 2004. Thereafter, rooms and rates are subject to availability.

Novotel Amsterdam****
Europaboulevard 10
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ACCOMMODATION BOOKING FORM

1 FORM PER RESERVATION

DIA® DRUG INFORMATION ASSOCIATION

THREE WORLDS - ONE VOICE - 14TH ANNUAL CLINICAL DATA MANAGEMENT CONFERENCE,
4TH ANNUAL VALIDATION CONFERENCE, 1ST EUROPEAN INFORMATION TECHNOLOGY CONFERENCE

RAI AMSTERDAM INTERNATIONAL EXHIBITION & CONGRESS CENTRE, AMSTERDAM, THE NETHERLANDS - I.D. # 04104

To make a reservation, complete this form and fax to +31 20 549 1946 or email to hotelservice@rai.nl .

For online reservations please visit www.rai.nl/hotelservice.

TO ENSURE YOUR PREFERRED ACCOMMODATION, PLEASE BOOK YOUR ROOM NO LATER THAN SEPTEMBER 8, 2004

Guest

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Please type or use BLOCK LETTERS - Please make sure to keep a copy for your own records.

Last Name | Company

First Name & Middle Initial | Job Title

Street Address / P.O. Box

Postal Code | City | Country

Telephone | Telefax

Email

Hotels	Location	Standard room single use	Standard room double use	Breakfast p.p.p.d.	City tax
Novotel**	1	EUR 105.00	EUR 125.00	EUR 17.00	5%
Best Western Eden**	2	EUR 100.00	EUR 110.00	EUR 14.00	5%
NH City Centre**	2	EUR 100.00	EUR 100.00	EUR 16.00	5%
AMS Museum**	2	EUR 99.00	EUR 109.00	incl.	5%

All quoted rates are per room, per night and in Euro, including VAT.

In case you prefer a hotel which is not on our list of selected hotels, please do not hesitate to contact RAI Hotel Service.

LEGEND

1- hotel located in walking distance to the RAI Congress Centre (max. 15 minutes)

2- hotel located in the city centre of Amsterdam

Preferred hotel choice: | **Second hotel choice:**

Arrival date: | **Departure Date:**

Number of rooms: ❑ **Single:** ❑ **Double:**

Additional guest names:

Special requests:

Terms and conditions

- Notification of cancellations and amendments should always be made to RAI HOTEL SERVICE directly and can only be accepted in writing. Changes on reservations with arrival in the weekend or on Monday/Tuesday can only be processed if received before Friday 5 pm (CET). Cancellations will be charged with administration costs of EUR 35,00. For cancellations received within 48 hours prior to the arrival date and no shows, the hotel is entitled to charge the first night's room rate.
- On all our reservations the UVH (the Uniform Hotel Conditions) are applicable. These can be sent upon request. A different cancellation and deposit policy is applicable on room reservations (10 rooms or more). We will enclose these conditions with the confirmation.

Payment

Credit card details - All hotel reservations need to be guaranteed by a valid credit card . Guests are responsible for payment of all charges at checkout.

❑ **American Express** ❑ **Diners** ❑ **Euro/Master** ❑ **Visa**

Credit card number: | **Expiry date:** | **CVC*:**

** last 3 digits on the back of the card. Only required for Euro/Master and Visa*

I understand the terms and conditions stated above.

Name: | **Date:** | **Signature of cardholder:**

RAI Hotel Service, P.O. Box 77777, 1070 MS Amsterdam, The Netherlands
Tel: +31 20 549 1927 - Fax: +31 20 549 1946 - Email: hotelservice@rai.nl - www.rai.nl/hotelservice

REGISTRATION FORM - I.D. CODE # 04104

FAX TO: +41 61 225 51 52

DRUG INFORMATION ASSOCIATION

Three Worlds - One Voice

14th Annual Clinical Data Management Conference, 4th Annual Validation Conference, 1st European Information Technology Conference

RAI Amsterdam International Exhibition & Congress Centre, Amsterdam, The Netherlands

Please consider this form an INVOICE - Registration will be accepted by mail, fax , email or online - Registration includes conference material, coffee-breaks, luncheons and reception

** If DIA cannot verify your membership at time of registration, you will be charged the nonmember fee*

MEMBER REGISTRATION FEES

Member	EUR 1'250.00 ❑
Charitable Nonprofit/Academia (Full-Time), Member	EUR 875.00 ❑
Government Member	EUR 625.00 ❑
Student Member *(Proof of student status must be provided)*	EUR 313.00 ❑

Join DIA now to qualify for the member fee, save and receive all the benefits of membership for a full year! www.diahome.org/docs/Membership **EUR 130.00** ❑

NONMEMBER REGISTRATION FEES

Nonmember	EUR 1'625.00 ❑
Charitable Nonprofit/Academia (Full-Time), Nonmember	EUR 1'138.00 ❑
Government Nonmember	EUR 813.00 ❑
Student Nonmember *(Proof of student status must be provided)*	EUR 406.00 ❑
I will also attend the Social Event on November 8, 2004	EUR 60.00 ❑

TUTORIAL REGISTRATION

The tutorial registration fee is EUR 200.00

Please indicate which Tutorial(s) you wish to attend by checking the appropriate box.

Note: Tutorial 1, 2, 3, 4 and 5 are parallel and Tutorial 6, 7 and 8 are parallel.

❑ Tutorial 1 ❑ Tutorial 2 ❑ Tutorial 3 ❑ Tutorial 4 ❑ Tutorial 5

❑ Tutorial 6 ❑ Tutorial 7 ❑ Tutorial 8

Please indicate which track you are interested in attending:

❑ **Track 1 - Clinical Data Management 1**
❑ **Track 2 - Clinical Data Management 2**
❑ **Track 3 - Validation**
❑ **Track 4 - Information Technology**

PLEASE INDICATE THE TOTAL AMOUNT TO BE PAID: **EUR**_____

Please check the applicable category:

❑ Academia ❑ Government ❑ Industry ❑ CSO ❑ Student

Persons under 18 are not allowed to attend DIA meetings

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agendas are subject to change without notice. Audiovisual taping of any DIA meeting is prohibited without prior written consent from DIA.

REGISTRANT

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code

City

Country

(*)Telephone

(*)Telefax

(*)Email

(*) A telephone, fax number and/or email are required for confirmation

PAYMENT METHODS

❑ **Cheques** should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethenanlage 11, Postfach, 4002 Basel, Switzerland.

❑ **Bank transfers should be made in EURO to following bank:**
UBS, Postfach, 4002 Basel, Switzerland - DIA Account Number: 233-635384.60C
SWIFT: UBSWCHZH80A - IBAN: CH96 0023 3233 6353 8460 C
Your name and company must be included on the transfer document to ensure payment to your account.

❑ **Please charge my credit card** - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ **Visa** ❑ **MC** ❑ **AMEX**

Card Number:

Exp.date:

Cardholder's Name:

Date: Cardholder's signature:

Group Discount Available! Send 3, the 4th is FREE!

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must be registered and prepay at the same time.**

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. Substitutions of enrolled delegates of similar membership may be made at any time. Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company and return them together to DIA.

❑ **Please indicate that this form is part of a group registration by ticking this box.**

Please indicate the full names of the other three registrants from your company

2. Name 3. Name 4. Name

EUROPEAN BRANCH OFFICE
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4002 BASEL, SWITZERLAND
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E-MAIL: DIAJAPAN@DIAJAPAN.ORG

DRUG INFORMATION ASSOCIATION

NOVEMBER 8-10, 2004

SPECIAL REGULATORY DAY

Monday, November 8th, 2004

at the "Three Worlds - One Voice" CDM/Validation/IT Conference

RAI AMSTERDAM INTERNATIONAL EXHIBITION & CONGRESS CENTRE, AMSTERDAM, THE NETHERLANDS

This Special Regulatory Day, which is part of the official CDM/Validation/IT conference, is offering the opportunity to regulatory affairs professionals to join colleagues from neighbouring disciplines for information exchange and discussions on regulatory initiatives such as standard adoption, electronic submissions and eCTD. People unable to attend the full three day conference can register for this one day "Special Regulatory Day" (FDA Tutorial, Regulatory Opening Plenary and Session 1) at a reduced rate of EUR 625.00 for DIA members (EUR 813.00 for non-members).

It includes:

09:00-12:30

Tutorial on Regulatory Submission and Review of Clinical Trial Data at the FDA

Instructors: Randy Levin and Stephen Wilson, FDA CDER, USA

Participants will review current rules and guidance for the submission of electronic clinical trial data and metadata to the Centre for Drug Evaluation and Research (CDER). This tutorial will describe in detail how medical and statistical reviewers at the agency use eNDA clinical trial data and work with sponsors during the review of regulatory submissions. The latest developments in the standards for electronic submission to the FDA will be presented.

14:00-15:30

Regulatory Opening Plenary

Randy Levin, FDA CDER, USA; Helena Van den Dungen, Health Care Inspectorate, The Netherlands, Timothy Buxton, EMEA, UK

The environment within which we work is heavily regulated and subject to frequent change. Speakers from EMEA, FDA and the Health Care Inspectorate, The Netherlands, will provide updates from their respective agencies and address a number of current topics.

16:00-17:30

Session 1 - Data Document and eCTD - A Regulatory Overview

Neil Konopka, Phase Forward, UK; Andrew Marr, GlaxoSmithKline, UK; Olaf Schoepke, Lorenz Life Sciences, UK

Connectivity from source data to analysis to report submission documentation is a journey full of challenges. Furthermore expectations for connectivity within the eCTD increase. This session will focus on the expectations of industry reviewers and auditors.

REGISTRATION FORM - I.D. CODE # 04104RD

FAX TO: +41 61 225 51 52

DRUG INFORMATION ASSOCIATION

"Three Worlds - One Voice" - SPECIAL REGULATORY DAY

RAI Amsterdam International Exhibition & Congress Centre, Amsterdam, The Netherlands

SPECIAL OFFER

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REGISTRATION FEES

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EUR 130.00 ❑

I WILL ALSO ATTEND THE SOCIAL EVENT ON

NOVEMBER 8, 2004

EUR 60.00 ❑

REGISTRANT

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name First Name

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Street Address / P.O. Box

Postal Code City Country

(*)Telephone (*)Telefax

(*)Email

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PAYMENT METHODS

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❑ **Bank transfers should be made in EURO to following bank:**

UBS, Postfach, 4002 Basel, Switzerland - DIA Account Number: 233-635384.60C

SWIFT: UBSWCHZH80A - IBAN: CH96 0023 3233 6353 8460 C

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