# 16th Conference and Exhibition on European Electronic Data Management and eHealth Topics

## Stop Paper Thinking!

23-25 May 2016
Holiday Inn
Leiden,
the Netherlands

**Advance Programme**

DIA DEVELOP INNOVATE ADVANCE

# 16th DIA Conference and Exhibition on **European Electronic Data Management and eHealth Topics** - Stop Paper Thinking!

## Programme Co-Chairs

**Hans van Bruggen**
Senior Regulatory Affairs Consultant, eCTDconsultancy, The Netherlands

**Karen Roy**
Senior Vice President, Client Solutions, Phlexglobal Ltd, UK

## Programme Committee

**Andrew P. Marr**
Managing Director, Marr Consultancy Ltd, UK

**Eldin Rammell**
Managing Director, Rammell Consulting Ltd, UK

## Overview

The only conference focused on Electronic Content Management that brings together both regulatory agencies and industry to discuss the shift away from paper documentation.
Sessions and speakers provide a life cycle approach to discussing all aspects of content management from documentation writing, through internal and external reviews and submissions, its use in line-of-business applications, and ultimately to archiving.

Come and learn about the benefits and constraints associated with the question “how do we reduce our reliance on paper documents”
- Increase your network of interdisciplinary experts
- Come away with insights into the bigger picture of the issues at hand for eDM
- Increase your exposure to new technologies and ideas aimed at improving your everyday work

Programme Sessions are still in development, however, Highlight Topics include:
- Integrating eTMF and enterprise content management
- Interoperability (e.g. eTMF with eTMF, eTMF with eDM, eTMF with data warehouse)
- eSubmission (eCTD 4.0)
- Portals, common repositories and gateways
- Maintenance of XEVMPD and labelling management
- Preparing for IDMP
- Outsourcing and Infrastructure
- CRO Integration of processes
- Outsourcing and Infrastructure

## Objectives

Come and learn about the benefits and constraints associated with the various topic-related processes and contribute to answering the question how to stop paper thinking.

## Who Will Attend

- Academic researchers
- Agency representatives (e.g. inspectors and reviewers)
- Clinical operations representatives
- CMC regulatory compliance specialists
- CROs, CMOs and service providers
- Document and records managers
- IT and support personnel
- Knowledge/IP professionals
- Labelling specialists
- Medical and technical writers
- Pharmacovigilance professionals
- Quality assurance and compliance professionals
- Regulatory affairs/operations representatives
- Standards implementation specialists and associates
- Validation professionals

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## Topics

- eTMF and content authoring
- Integrating eTMF and enterprise content/document management
- Interoperability (e.g. eTMF with eTMF, eTMF with eDM, eTMF with data warehouse)
- eSubmission (eCTD 4.0)
- Portals, common repositories and gateways
- Electronic application forms
- Structured authoring
- CTMS/Performance metrics
- Big data, data mining (signal detection) and data warehouses
- eDM and structured content management
- Maintenance of XEVMPD and labelling management
- Preparing for IDMP
- Interoperability and taxonomy/standardisation
- eHealth (ePrescription, eHR and Patient IDs)
- Agency updates
- Vendor panel discussion
- CRO Integration of processes
- Outsourcing and Infrastructure
- Publication and access to clinical data
- Clinicaltrials.gov and Eudravigilance
- Integrating eDC, eDM, eSubmission and RIM (incl. XEVMPD and IDMP)
- Controlled vocabularies and reference sources
- Coding and verification systems
- Approving content and documents electronically
- Integrating electronic signatures into business applications
- Long term digital preservation of electronic content
- Compliance tracking, analytics and management reporting
- eISF and investigator portals

For more information, please call Customer Services on +41 61 225 51 51 or contact Carolin Dörflinger at DIA: Carolin.Doerflinger@diaglobal.org

## Exhibition Opportunities Available!

The previous eDM conference attracted delegates from 20 countries. Showcase your product or service to a truly global audience of qualified professionals, from entry level to expert, in the pharmaceutical, biotechnology, devices and related healthcare industries, government, academia and healthcare delivery.

For more information on exhibiting space and facilities, please contact DIA EMEA at +41 61 225 51 38

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## About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation headquartered in Washington, DC, USA with the EMEA office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

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# 16th DIA Conference and Exhibition on **European Electronic Data Management and eHealth Topics** - Stop Paper Thinking!

## MONDAY, 23 MAY 2016

**08:30 REGISTRATION & WELCOME COFFEE**

09:00 – 17:30

### TUTORIAL 1 - ELECTRONIC TRIAL MASTER FILES (ETMF) – MORE THAN A DOCUMENT REPOSITORY

Co-Instructors:

**Eldin Rammell,** Managing Director, Rammell Consulting, UK

**Karen Jane Roy,** Senior Vice President, Client Solutions Phlexglobal, United Kingdom

With initiatives such as the TMF Reference Model, we have seen a significant increase in the level of knowledge, involvement and understanding in the area of trial master file management. Implementing an electronic trial master file is now regarded by many as an essential requirement. However, trial sponsors still struggle with many aspects of TMF creation, management and oversight. This tutorial will focus on just 3-4 topics related to the management of trial master files, providing delegates with extended time to review and discuss these subjects in detail. Whilst the instructors will provide an overview of each topic and will contribute their experience and expertise to the discussion, this will be highly interactive tutorial providing delegates an opportunity to discuss specific questions with their industry peers.

**Discussion topics may include*:**

- Selecting an eTMF vendor – what criteria should be considered?
- TMF quality and compliance – what does it mean? what can you measure?
- Eliminating paper records – can this be achieved?
- Electronic versus digital signatures – which one wins?

**Learning Objectives**

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

- Avoid common eTMF implementation issues
- Evaluate the health of their TMF using industry standard metrics
- Apply an efficient TMF process

**Target Audience**

Professionals involved in the following areas:

- Clinical Records Managers/Archivists
- eTMF Project Managers (IT & Business)
- TMF Stakeholders

* the exact content will depend on interests of registered delegates

**TUTORIAL BREAKS**

| | |
|---|---|
| 10:30 - 11:00 | COFFEE BREAK |
| 12:30 - 14:00 | LUNCH BREAK IN THE RESTAURANT |
| 15:15 - 15:45 | COFFEE BREAK |

09:00 – 17:30

### TUTORIAL 2 – REGULATORY INFORMATION MANAGEMENT AND IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP)

Co-Instructors:

**Frits Stulp**, IDMP Program Manager, Astellas Pharma, Netherlands

**Jasper Riksen**, XEVMPD / IDMP Consultant, Astellas Pharma, Netherlands

**Michiel Stam**, Regulatory Operations Scientist, eCTDconsultancy, Netherlands

The implementation of IDMP in the EU is now gathering pace with agreements on the scope of Iteration 1 for Authorised Medicinal Products, on Organisation information and how Controlled Vocabularies will be managed. The scope of Iteration 1 is greater than that of XEVMPD and will bring some challenges in obtaining and maintaining data. Companies will need to address how they manage these challenges, in the shorter-term for Iteration 1 and in the longer-term for subsequent iterations which will have much wider scope and be significantly more complex to address. The tutorial will address the shorter-term requirements for Iteration 1 and the longer-term strategic needs of managing IDMP data for regulatory compliance, use in healthcare scenarios and for internal business benefit and efficiency.

Moreover, various use cases on IDMP will be discussed. This includes a first IDMP implementation at an MAH; one of the first pharma companies to go live with a system for Iteration 1 submissions. Therefore the instructors will not only share their personal views on IDMP but can also share from a wealth of practical experience on implementing IDMP solutions.

**Discussion topics will include:**

- Status of implementation of IDMP implementation in EU (and other regions)
- Medicinal Product data for Iteration 1 (e.g. differences from XEVMPD, challenges)
- Impacts of requirements for Substances, Organisations and managing Controlled Vocabularies
- Implementing IDMP – use cases from various companies, including building the business case
- Strategic approaches to IDMP data management (RIM, MDM, EDM, RDM, Structured Content Authoring)

**Learning Objectives**

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

- Understand the impacts of Iteration 1
- Understand the key challenges in implementing IDMP
- Understand some of the opportunities driven by IDMP

**Target Audience**

Professionals involved in the following areas:

- Regulatory Information Management
- Regulatory Information Technology
- Reference- and Master Data Management
- Supply Chain
- XEVMPD
- Pharmacovigilance
- Quality Assurance
- Standardisation and Harmonisation

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## TUESDAY, 24 MAY 2016

**08:00 REGISTRATION & WELCOME COFFEE**

**09:00 SESSION 1 - TRACK A & B**

### WELCOME AND INTRODUCTION

Session Chair: **Hans Van Bruggen**, Sr. Regulatory Affairs Consultant, eCTDconsultancy B.V., Netherlands

Companies and Health Authorities have changed from capturing information in paper format to digitalised formats. However, the digitalised formats still mirror the paper contents structure. Though the shipment is easier and documents are available remotely, one has to open the documents, interpret the content, put it is context of information coming from other documents to evaluate Quality, Efficacy and Safety of medicinal products. Our Keynote Speaker will inspire you to make the next transition from digitalised paper to electronic data. Subsequently it will be explained how big data analytics can improve insight in performance management of, and understand the use of tools to support decision making in clinical trials.

**Keynote: Stop Paper Thinking! What else?**
Irene Polikoff, CEO and Co-founder, TopQuadrant, USA

**Performance and Risk in Clinical Trials**
Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

**10:30 COFFEE BREAK IN THE EXHIBITION AREA**

**11:00 SESSION 2 - TRACK A & B**

### OUTSOURCING

Session Chair: **Karen Jane Roy**, Senior Vice President, Client Solutions Phlexglobal, United Kingdom

Working with outsourcing partners is a reality of clinical research. This session will consider all aspects of outsourcing – from outsourcing of functions such as regulatory submissions to outsourcing of clinical trials and the challenges of getting data and documents back, with a specific focus on trial master file document exchange. Outsourcing has profound effects on an organization, regardless of the scope of outsourcing, and this session will also focus on these effects on culture, resources, structure, operations, systems, processes, finances, collaboration, information management, compliance, and performance.

**Finding Your Best Fit: Case Studies in Regulatory Submission Outsourcing**
Jillian E. Carinci, Submission Manager, Global Regulatory Services, Accenture Accelerated R&D Services, United States

**Change Management**
Russell Joyce, Director & Principal Consultant Heath Barrowcliff Consulting, United Kingdom

**Facilitating Interactions, Integration and Interchange of TMF Artifacts Between Sponsors and CROs**
Paul K. Fenton, CEO, Montrium Inc., Canada

**12:30 LUNCH & DISCUSSIONS IN THE EXHIBITION AREA**

1. **When to get ready for eCTD version 4.0?**
   Andrew P. Marr, Managing Director Marr Consultancy, United Kingdom
2. **How to get eTMF Reference Model on the agenda within your organization?**
   Karen Jane Roy, Senior Vice President, Client Solutions Phlexglobal, United Kingdom
3. **How to involve non-RA departments in IDMP?**
   Hans Van Bruggen, Sr. Regulatory Affairs Consultant, eCTDconsultancy B.V., Netherlands
4. **What user requirements for an eDMS?**
   Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

# 16th DIA Conference and Exhibition on **European Electronic Data Management and eHealth Topics** - Stop Paper Thinking!

## 14:00 PARALLEL SESSION 3 - TRACK A

### PREPARING YOUR COMPANY FOR IDMP

Session Chair:
**Timm Pauli,** Sr. Director, eSubmission Services, Head of Regulatory Operations, PharmaLex GmbH, Germany

As companies begin to ramp up to implement IDMP there are many options for how they address implementation from a technical and process perspective, how to organise governance and to support maintenance. This session will address how companies can prepare for IDMP compliance within a wider context of systems and processes.

**Building the IDMP-Agile Enterprise**
Joel Finkle, Solution Lead, IDMP CSC Life Sciences BPS, United States

**How to best leverage your eDMS for and with the IDMP**
Pierre Stanislawski, Product Manager, Ennov, France

**Beyond IDMP: Exploring the Broader Importance of Data Integration and Governance**
Catherine Gambert, Senior Consultant, Regulatory Affairs and Regulatory Information Systems, Productlife Group, France

## 14:00 PARALLEL SESSION 3 - TRACK B

### ARCHIVING

Session Chair:
**Eldin Rammell**, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

The publication of Regulation 536/2014 confirmed a minimum retention time of 25 years for clinical trial documents in the EU. In a digital age, preserving the authenticity and reliability of records for these periods of time – and longer- can be a challenge. This session will review the regulatory requirements, the technology landscape and options, and business strategies to ensure long-term access to archived records.

**We Have to Keep the TMF for How Long? What the Regulations Really Say about Archiving**
Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

**Keep Calm.... and do Practical Record Preservation**
Matthew Addis, Arkivum, UK

**Business Concepts to Master Challenges of Electronic Document Preservation – A Case Study**
Jens Kerim Ergueden, Bayer Pharma AG, Germany

## 15:30 COFFEE BREAK IN THE EXHIBITION AREA

## 16:00 PARALLEL SESSION 4 - TRACK A

### PREPARING FOR THE FUTURE OF E-SUBMISSION

Session Chair:
**Andrew P. Marr**, Managing Director Marr Consultancy, United Kingdom

The current ICH and EU specifications for eCTD are well embedded in many organisations and processes for e-submission operationalised. The status quo is not really an option as there are changes are around the corner with the next major version of eCTD and changes to the EU Module 1. Furthermore, process optimisation should be a focus in order to increase efficiency and reduce costs. This session will look how eCTD v4.0, a revised version of EU Module 1 and process optimisation all need to be considered moving ahead.

**EU Regional Implementation of the eCTD Specification v4.0 – Requirements, Challenges and Advantages**
Klaus Menges, Project Manager BfArM, Germany

**Change of the eCTD EU Module 1 Specification – Reasoning and Future Options**
Mickel Hedemand, Special Adviser, Medicines Licensing & Availability, Workflow, Danish Medicines Agency, Denmark

**Optimizing Dossier and Submission Management Process**
Timm Pauli, Sr. Director, eSubmission Services, Head of Regulatory Operations, PharmaLex GmbH, Germany

## 16:00 PARALLEL SESSION 4 - TRACK B

### COLLABORATION / CROS

Session Chair:
**Jamie Marie Toth,** MS Director TMF Operations, Daiichi Sankyo, United States

One of the key complexities in the eTMF space is the Sponsor CRO relationship. How do they best work together? Who's systems should be used? What are the different ways that efficiencies can be achieved? How do Sponsor's get what they need? This session focuses on these questions from both a CRO and a Sponsor perspective.

**Which One? eTMF System Evaluation Best Practices: A CRO Perspective**
Gareth Sully, Vice President, Site Startup and Regulatory Inc Research, United Kingdom

**Integration of CRO's processes into Sponsor's for TMF Success**
Jamie Marie Toth, MS Director TMF Operations, Daiichi Sankyo, Inc., United States

**Open Discussion on eTMF CRO/Sponsor Integration Topic**

## 17:30 DRINKS RECEPTION IN THE EXHIBITION AREA

## 18:30 END OF THE DAY

# 16th DIA Conference and Exhibition on **European Electronic Data Management and eHealth Topics** - Stop Paper Thinking!

## WEDNESDAY, 25 MAY 2016

**08:00 WELCOME COFFEE IN THE EXHIBITION AREA**

### 08:30 PARALLEL SESSION 5 - TRACK A

#### SEMANTIC INTEROPERABILITY BY LINKED DATA: CONNECTING DISJOINTED BUSINESS PROCESSES TO OPTIMISE DATA RELIABILITY

Session Chair:
**Dimitri Stamatiadis,** CEO, MAIA Consulting, Switzerland

Talking about interoperability, people immediately think about agreement between the various counterparts that want to work together. Subsequently, the general next step is integration of computer systems. However, to allow for a successful integration of tools, we often miss the semantic interoperability. This session will explain how the concept of "Linked data" and state of the art semantic technology can help companies making the transitions towards enterprise wide structured data management.

**Managing Regulatory Information: Documents, Data, and Governance**
Michiel Stam, Regulatory Operations Consultant, eCTDconsultancy B.V.

**Applying Linked Data in the Pharma Domain: A Field Report**
Christian Blaschke, Senior Consultant, Semantic Web Company GmbH, Austria

**Entity Extraction for IDMP: Challenges and Solutions**
Jan Voskuil, CEO, Taxonic, The Netherlands

### 08:30 PARALLEL SESSION 5 - TRACK B

#### PRACTICAL TMF MANAGEMENT

Session Chair:
**Karen Jane Roy**, Senior Vice President, Client Solutions Phlexglobal, United Kingdom

So you have an eTMF, now what? This session will look at many aspects of TMF management – the current hot topics across the Industry. This will range from TMF structure (and keeping it current) to quality management (and asking if we are making too much of it); the session will challenge you on whether you are getting it right!

**Case Studies on the Application of the TMF RM V3.0**
Karen Jane Roy, Senior Vice President, Client Solutions Phlexglobal, United Kingdom

**TMF Topics - What's HOT this Year and Why you Should Care**
Lisa D. Mulcahy, Owner, Principal Consultant Mulcahy Consulting, United States

**Practical TMF Management**
Vittoria Sparacio, GSK, United Kingdom

**Panel Discussion**

**10:00 COFFEE BREAK IN THE EXHIBITION AREA**

### 10:45 PARALLEL SESSION 6 - TRACK A

#### BEYOND E-PAPER: DATA DRIVEN AUTHORING AND VALIDATING LITERATURE MONITORING SEARCHES

Session Chair:
**Hans Van Bruggen**, Sr. Regulatory Affairs Consultant, eCTDconsultancy B.V., Netherlands

Authoring documents is often documenting a train of thought in a narrative way. However, how can we reduce the recreation of a train of thought and how can we gain knowledge from somebody else's thinking and reuse the same content in different contexts (e.g. from a single study to across studies)? This session will focus on both aspects, (1) preparing content considering optimal reuse and (2) extracting content and obtaining the reliable information for pharmacovigilance purposes.

**Beyond e-Paper: Key Benefits and Considerations for Topic Based Authoring**
Jim Nichols, Vice President, Life Sciences & US Operations, DitaExchange Inc., US & Denmark, United States

**Validated Text Mining for Safety Literature Screening**
Joyce de Langen –Wouterse, Senior Solution Manager, Pharmacovigilance, Elsevier Life Science Solutions, Netherlands

Julio dos Anjos, Professional Services Consultant, Elsevier Life Science Solutions, Netherlands

### 10:45 PARALLEL SESSION 6 - TRACK B

#### OPTIMISING TMF CONTENT

Session Chair:
**Russell Joyce,** Director & Principal Consultant, Heath Barrowcliff Consulting Ltd, United Kingdom

eTMF implementations have matured significantly over recent years. We have moved away from a situation where these systems are seen as stand-alone repositories for closed trial documents to being a central tool to facilitate trial management and oversight. This has required alignment and integration with other related technologies and embedding of those technologies into core clinical processes.

**Sustaining TMF Compliance through Integrated Document Management**
Lorrie Dixon, Trial Master File Manager, F. Hoffmann-La Roche, Switzerland

**Enhancing TMF Operations with Electronic Signatures**
Betsy Fallen, Global Head of Program and Business Development, SAFE-BioPharma Association, United States

**Panel Discussion** - Continuing the Themes Introduced by the Speakers and Including an Open Q&A Forum
Lorrie Dixon, Trial Master File Manager, F. Hoffmann-La Roche, Switzerland, Betsy Fallen, Global Head of Program and Business Development, BAFallen Consulting, United States, Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom, Russell Joyce, Director & Principal Consultant, Heath Barrowcliff Consulting Ltd, United Kingdom

# 16th DIA Conference and Exhibition on **European Electronic Data Management and eHealth Topics** - Stop Paper Thinking!

**12:15 LUNCH IN THE EXHIBITION AREA**

**13:30 SESSION 7 - TRACK A & B**

### MASTER DATA MANAGEMENT

Session Chair: **Romuald Braun,** Managing Director, uanotau GmbH, Switzerland

In many drug development business processes, entities like vendor, trial site, route of administration, name and location play a central role. These entities are known as master data and many companies suffer today from low-quality master data scattered across the enterprise in various application silos. Improving master data quality and managing it more efficiently to optimize business processes is known as Master Data Management (MDM). This session will help attendees to understand the principles of MDM and some of the benefits achievable from optimised MDM.

**Regulatory Information Management (RIM) versus Master Data Management (MDM) – Opportunities and Challenges on the Journey to Content-driven Authoring**
Romuald Braun, Managing Director, uanotau GmbH, Switzerland

**Enterprise Content Integration – Challenges and Solutions for eTMF integration with Enterprise Content Systems**
Martin David Thorley, Associate Director - Senior Information Manager, Pfizer, UK

**Master Data Management - What is it and How Does it Relate to Electronic Document Management?**
Jens-Olaf Vanggaard, Senior Manager R&D, Highpoint Solutions, Switzerland

**14:30 COFFEE BREAK IN THE EXHIBITION AREA**

**15:00 SESSION 8 - TRACK A & B**

### DOCUMENT AND DATA MANAGEMENT: THE REGULATORS/INSPECTORS VIEW OF THE FUTURE

Session Chair:
**Klaus Menges**, Project Manager, BfArM, Germany

The future of document and data management in a regulatory environment is clearly influenced by the Regulators themselves, the type of data and documents that they need to manage for their own business and what they expect to see when a company is inspected or required to provide for compliance purposes. This session will provide an opportunity to hear directly from Regulators and Inspector regarding how they see the future for document and data management.

**Telematics goes Global – How can Technology Strengthen Regulatory Systems?**
Klaus Menges, Project Manager BfArM, Germany

**Document and Data Management: The Regulators/Inspectors view of the future**
Jason Wakelin-Smith, GCP Inspector Medicines and Healthcare products, Regulatory Agency (MHRA), United Kingdom

**Global Standardization and Digital Collaboration: Will this Trend Affect NCAs Business and IT Processes Positively?**
Georg Neuwirther, IT Director, Austrian Medicines & Medical Devices Agency (AGES), Austria

**16:00 END OF THE CONFERENCE**

## Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organiation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

## Venue

Holiday Inn Leiden is just a 20-minute drive from Amsterdam Schiphol Airport. For further information visit:
http://www.holiday-inn-leiden.nl/en/index.html

**Holiday Inn Leiden**
Haagse Schouwweg 10, 2332 KG Leiden, The Netherlands

Tel: +31 71 53 55 555

The DIA room rate is € 115,00 per night, including breakfast and internet, excluding city tax (€ 2,00 per person per night).

The DIA rate is guaranteed until 22 April 2016, or until room block is filled. Reservations can be made online, indicating group code DIA.

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## EXHIBITING COMPANIES

| Affiliation | Country |
|---|---|
| AMPLEXOR | Slovenia |
| Cunesoft GmbH | Germany |
| DitaExchange | United States |
| fme AG | Germany |
| i4i | Canada |
| Informed Consulting | Netherlands |
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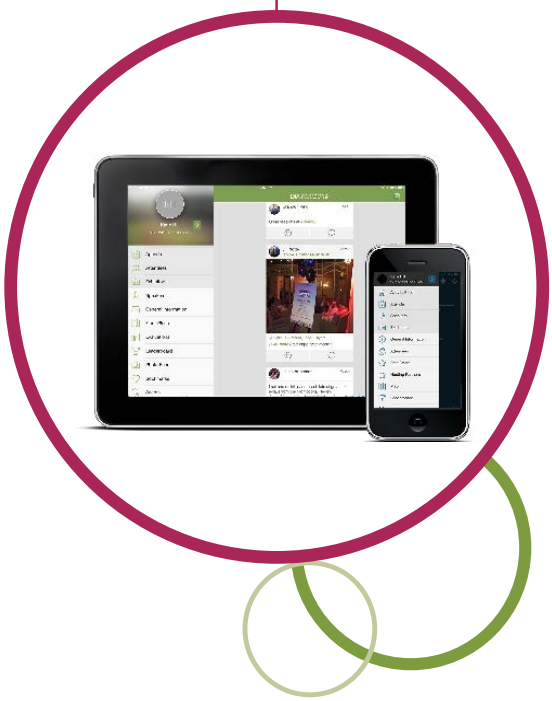

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16th Conference on European Electronic Data Management and eHealth Topics | ID#16110

23-25 May 2016 | Holiday Inn, Leiden, the Netherlands

DIA DEVELOP INNOVATE ADVANCE

## Early-bird discount: Register by 8 April 2016 and save!

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'230.00** ❑

| CATEGORY (AFTER 8 APRIL 2016) | Member* | Non-Member* |
|---|---|---|
| Industry | € 1'430.00 ❑ | € 1'585.00 ❑ |
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| **OPTIONAL PRE-CONFERENCE TUTORIALS ON MONDAY, 23 MAY 2016 (RUNNING PARALLEL - CHOOSE ONE ONLY)** | | |
| Tutorial 1 - ETMF | | € 400.00 ❑ |
| Tutorial 2 - IDMP | | € 400.00 ❑ |

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

Payment due 30 days after registration and must be paid in full by commencement of the event.

**TOTAL AMOUNT DUE: € _____**

## ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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| Date | Signature |
|---|---|
| | |

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All cancellations must be in writing and received at the DIA EMEA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00
Tutorial cancellation = € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

### Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

### Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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