eDM 2018 - Clinical and Regulatory Operational Excellence Forum

29-30 November 2018
Hotel Fairmont Rey Juan Carlos I, Barcelona, Spain

PROGRAMME COMMITTEE

Kristen Bretzius
Document Center Manager, PSI Pharma Support America, United States

Eldin Rammell
Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

Karen Roy
Chief Strategy Officer, Phlexglobal, United Kingdom

Hans van Bruggen
Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

Overview

eDM 2018 - Clinical and Regulatory Operations Forum will focus on how can we adapt to this digital era by embracing working solutions and partnerships. This highly interactive forum will enable you to perform complex tasks to the highest operational standards, shortening turnaround times and reducing queries and re-creation in your development programmes. Additionally, this Conference provides multiple opportunities for networking, knowledge sharing, and education for all attendees.

We are bringing together thought leaders across the fields of:

- Clinical Operations
- Regulatory Affairs
- Records and Document Management
- Health Authorities
- Supportive software vendors
- CROs

The meeting will be based on selected abstracts that showcase working solutions and will allow attendees to learn from implemented best practices.

Experience the Conference on the go with the DIA Global App

DIA is going green: what about you?

In 2018, DIA is going paperless. No printed programme will be distributed onsite, so please make sure to download the app in advance.

The DIA Global App is designed to enhance your meeting experience and provide valuable information in one place. Search "DIA Global" in your app store.

- View agenda and speakers
- Connect and network with attendees and exhibitors
- Participate in live session polling
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Who Will Attend

- Clinical Operations and Regulatory Affairs that want to excel in their day-to-day work
- R&D Quality Leads, as well as Trial Managers and Drug Programme Leads & Clinical and Regulatory Project Managers that need to get an overview of the latest gold standards in R&D Operational Excellence to set the standards for high-performing cross functional drug development teams
- Health Care and R&D Professionals in the areas of Electronic Document Management, IT and Process Innovation
- New Technical Solution Vendors

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

Find out more at
DIAglobal.org

DAY ONE | THURSDAY, 29 NOVEMBER

09:00 REGISTRATION AND WELCOME COFFEE

10:00 INTRODUCTION

10:15 KEYNOTE SPEECH

Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

11:00 SESSION 1

SESSION 1: ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING

Session Chair:

Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

What is AI? Extract Knowledge from Unstructured Documentation to Improve Quality and Accuracy

Barry Sacks, Chief Technology Officer, Phlexglobal, United Kingdom

Automated Risk Detection Using Machine Learning Techniques in Clinical Trials

Laura Trotta, R&D Manager, Product Manager, CluePoints, Belgium

Experiences with Automated Solutions at Industry and Agency

Jason Berning, Project Manager R&D, Lorenz, Germany

12:00 LUNCH

13:30 SESSION 2 - PARALLEL SESSION

SESSION 2A

PROCESS AUTOMATION - CLINICAL

Session Chair:

Karen Roy, Chief Strategy Officer, Phlexglobal, United Kingdom

Options for Use of Automation in Clinical Document Management

Gitte Holm Rove, Consultant, NNIT, Denmark

Facilitated Group Discussion

- Barriers to Process Automation
- Opportunities for Process Automation
- Success Factors: How to Make it Work

Group Feedback and Concluding Remarks

SESSION 2B

PROCESS AUTOMATION - REGULATORY

Session Chair:

Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

All the Way Around the RIM: From Registration Data to Documents to Dossiers and Back

Joel Finkle, Associate Offering Management Director, Regulatory Innovation, ACUTA, an IQVIA Company, United States

Transforming Regulatory Affairs through Technology - End to End Tech Platform Approach

Peter Lassoff, Vice President and Head, Global Regulatory Affairs, IQVIA, United Kingdom

Automating Regulatory Maintenance - Better Compliance and Costs

Jim Nichols, Chief Operations Officer, Cunesoft, United States

Claire Colville, Assistant Vice President, Business Development, Genpact, United Kingdom

15:00 COFFEE BREAK

15:30 SESSION 3

RISK AND COMPLIANCE

Session Chair:

Lisa Mulcahy, Owner, Principal Consultant, Mulcahy Consulting, United States

Sisyphus' Rock? A Risk Based Approach to Records Management

Sheila Mahoney Jewels, CEO, LifeSciHub, United States

Validating an EDMS or eTMF System Using a Standardized Protocol

Dimitri Stamatiadis, CEO, MAIA Consulting, Switzerland

Let's Destroy Paper Documents FOREVER! A Review of the Framework for the Destruction of Paper v2.0 and Project Activities

Lisa Mulcahy, Owner, Principal Consultant, Mulcahy Consulting, United States

17:00 NETWORKING RECEPTION

18:00 END OF DAY ONE

| Disclosure Policy

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY TWO | FRIDAY, 30 NOVEMBER

08:00 WELCOME COFFEE

08:30 SESSION 4

DATA AND DOCUMENT INTEGRITY

Session Chair:
Karen Roy, Chief Strategy Officer, Phlexglobal, United Kingdom

Data Integrity and Audit Trail Review
René Kasan, CEO, 37 Centigrades, Switzerland

Data Integrity - A Regulatory Update
Eldin Rammell, Managing Director & Principal Consultant, Rammell Consulting, United Kingdom

Facilitated Group Discussions:
- A Digital World - How Has the Data Integrity Challenge Changed?
- The 'Real Word' vs 'the Inspection' - What Are the Challenges?
- What Are the Future Trends?

Group Feedback and Concluding Remarks

10:00 COFFEE BREAK

10:30 SESSION 5

INFORMATION GOVERNANCE

Session Chair:
Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

The Impact of GDPR on Clinical Document Management
Francis P. Crawley, Executive Director, Good Clinical Practice Alliance - Europe (GCPA), Belgium

World Class RIM Survey
Hans van Bruggen, Regulatory Affairs Scientist, eCTDconsultancy, The Netherlands

Impact of Brexit on Regulatory Submissions for CP and MRP/DCP
Gordon Elger, Regulatory Affairs Affiliate Lead , Astellas, United Kingdom

12:00 LUNCH

13:15 SESSION 6 - PARALLEL SESSION

SESSION 6A

DOCUMENT FLOW AND INTEROPERABILITY

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

Interoperability – A Path to Automated Quality Checking in eTMFs?
Jaclyn Morrill, Director of Clinical Operations, LMK Clinical Research Consulting, United States

Transformation through Innovative Information Management
Doug McKinnell, Director Risk Advisory, Deloitte, Switzerland
Niamh McNamara, Roche Products Ltd, United Kingdom

TMF Reference Model eTMF-EMS - Towards a First Industry Standard for Interchange
Paul Fenton, CEO, Montrium, Canada

SESSION 6B

RELIABLE DATA AND APPLIED TECHNOLOGY

Session Chair:
Frits Stulp, Managing Director Iperion Life Sciences Consultancy, The Netherlands

The use of SPOR/IDMP and the Impact on Regulatory Affairs and RIM Solutions in the EU
Remco Munnik, Regulatory Information Director, Asphalion, Spain

eCTDs for NPs and Validation Issues for NP and MRP/DCP
Armand Vermaire, Regulatory Operations Manager, Qdossier, The Netherlands

Global Submission Management
David Ross, Global Regulatory Operations Strategy and Change Management, AstraZeneca, United States

14:45 COFFEE BREAK

15:00 SESSION 7

STANDARDISATION

Session Chair:
John Cogan, Head of Innovation, Kinapse, United Kingdom

IDMP - Overall Setting and Current Status
Dimitri Stamatiadis, Maia Consulting, Switzerland

EU-SRS
Frits Stulp, Managing Director, Iperion Life Sciences Consultancy, The Netherlands

CDISC CTR2
Paul Houston, Formerly CDISC, France

Panel Discussion
Comment on "Standardisation topics from a Clinical Document Management Perspective"
Paul Fenton, CEO, Montrium, Canada

16:30 END OF CONFERENCE

EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link: https://bit.ly/2lEz0aH

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on the DIA website.

To access presentations, go to www.diaglobal.org and click on Sign in at the very top. Once you have successfully logged in, click on Welcome on the top, then My Account and on the left, go to My Presentations

No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with the presentation. Updated versions of the slides will be made available shortly after the conference.

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be sent to all attendees electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on Basel@DIAglobal.org or call +41 61 225 51 51.

Hotel Information

Fairmont Rey Juan Carlos I
Av. Diagonal 661 - 671
08028 Barcelona
Spain

A limited number of rooms are available from 28-30 November at a special DIA rate at the Fairmont Rey Juan Carlos I

Tel (+34)93/638343568
E-Mail Laura.Orduna@Fairmont.com
Contact accommodation: Laura Orduña
Group code: DIA Europe November 2018.

Single room: €200, double room: €225, including 10% VAT, including breakfast.

The room rate is available until 28 October or until the room block is sold-out, whichever comes first.

Please book your accommodation via this link.

Closest airport: Aeropuerto de Barcelona
Distance to the hotel: 25km
How to get to the hotel? Please click here.

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Get the app:

- Download & Install: type "DIA GLOBAL" in the App store or in Google Play
- Sign in with the email address you used to register for the event
- If needed, use the reset password link to set your password
- Need assistance? Please feel free to ask one of our staff.

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA. For groups of 5 or more individuals, please contact Zsofia.Molnar@DIAglobal.org for a custom group rate.

REGISTRATION FORM | ID# 18103

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Early-bird discount

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird applies to industry representatives with active DIA membership only.

Early bird discount: register by 15 October 2018 **€ 1'230.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'430.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 715.00 ❑	€ 870.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Special rates for students and patient representatives on offer, subject to avaibility. Group rates available. A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA in Basel for more information. Registration fee includes: refreshments and lunches.

*All fees are subject to the applicable VAT. 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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PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID# 18103 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA in Basel.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here.**

Date	Signature

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no additional cost**

TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA office in Basel four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (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 reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA 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 office in Basel of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here.

You agree that your personal data will be transferred to DIA in the US

The DIA will be pleased to assist you with your registration from Monday to Friday between 08:30 and 17:00 CET.

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