DIA

The Evolution of Policy 0070: EMA Clinical Data Publication

6-7 December 2017

Millennium Hotel London Mayfair, London, UK

PROGRAMME COMMITTEE

Robert Paarlberg
Principal, Paarlberg & Associates, United States

Merete Jørgensen
Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark

Matthias Zerm
Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

Julie Holtzople
Director, Clinical Trial Transparency Operations, AstraZeneca, United States

KEY TOPICS

Developments in relation to implementation of Policy 0070:

- The newest on implementation guidance from EMA
- Experience from industry on preparing documents for disclosure in relation to the Policy
- Technical challenges in document handling
- Facing new challenges such as preparing anonymisation reports and providing risk assessments
- Legal aspects to consider
- Thinking ahead when preparing documents ready for Policy 0070 disclosure

OVERVIEW

Transparency of clinical trial information is taking on new dimensions, resulting in trial sponsors and research organisations facing a host of **new requirements in the EU** and the US. This 2017 Workshop leverages learnings from European and US experts as well as prior conference discussions, providing the opportunity to gain insights on how to meet new challenges. The programme is assembled around key themes:

- Impact of the **EU Clinical Trial Regulation** and **EMA Policy 0070** on **trial disclosure** business processes
- Upcoming legal requirements related to **disclosure of clinical research information** for **medicinal products** and **medical devices**
- **Real-world experiences** on implementation of the regulations, including fine-tuning and optimising processes to meet the requirements for **disclosure, data sharing** and **data transparency**
- Approaches to navigating the patient and ethics committee interfaces, as well as interdepartmental discussions

Attendees will learn from **case studies** and the **experiences of experts** and their **peers**.

WHO SHOULD ATTEND?

- Professionals and experts from areas affected by public disclosure across drug and medical device development (regulatory affairs, scientific affairs, medical writing, clinical operations, medical communication, biostatisticians/biometrics, project management, medical affairs, legal, patent departments, etc)
- Consultants, CROs and companies that offer services for clinical registries, publication planning and medical writing
- Patient organisations
- Regulatory agencies
- Academic institutions

OBJECTIVES

- Learn about the **latest developments** relating to the implementation of the EU Policy 0070 from regulators as well as the industry
- Benefit from the **various perspectives** on regulatory, legal aspects and practical challenges from large, mid-sized, and smaller sponsor organisations
- **Leverage best practices** on the **practical implementation** through case studies by the exchanging of views between regulators, industry, patients, academia and other stakeholders

DAY ONE I WEDNESDAY, 6 DECEMBER

12:30 REGISTRATIONS AND LUNCH

14:00 SESSION 1

IMPLEMENTATION STATUS FOR THE EMA CLINICAL DATA PUBLICATION: SETTING THE SCENE

Session Chairs:
Robert Paarlberg, Principal, Paarlberg & Associates, United States
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

The public availability of clinical trial information on the EU Portal and Database is a key element of the Clinical Trial Regulation (CTReg). While Policy 0070 differs from the CTReg in scope, redacted/anonymised versions of clinical study reports (CSRs) of at least some studies will be published under both rules. Apart from references to Policy 0070, no details are yet available on standards and processes for redacted/anonymised versions of CSRs and other clinical documents to be submitted to the EU Portal under the CTReg framework.

This session will focus on the transparency provisions in the CTReg as well as the implementation status of Policy 0070 {backlog, phase II, Technical Anonymisation Group (TAG)} and the status of the Portal used for sharing documents and the technicalities of the process of submitting and accessing documents. The future of the Policy 0070 requirements and process when the CTReg is fully implemented will also be addressed.

CTReg Transparency Provisions and Their Implementation
Matthias Zerm, Lead Expert, Clinical Trial Disclosure and R&D Processes, Merz Pharmaceuticals, Germany

EMA Updates on Policy 70
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency, European Union

How the Portal Works
Noemie Manent, Scientific Administrator, Compliance and Inspection, European Medicines Agency, European Union

Panel Discussion with Q&A

15:30 COFFEE BREAK

16:00 SESSION 2

LEGAL CONSIDERATIONS FOR CLINICAL DATA PUBLICATION

Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark

Publication of Clinical Documents requires a lot of considerations about legal aspects, about Private Personal Data, Company Confidential Information, Copy Rights, and Terms of use of the information made available. Presentations will cover an overview of the different legislation requirements, as they are applicable to the release of documents as specified in EMA's Policy 0070 on proactive data sharing, and on Policy 0043 on Requested Data Access. Views from the aspect of industry as well as from the regulatory authority perspective will be presented.

Drawing the Boundaries of Data Disclosure in Clinical Trials – the Industry Perspective
Marie Manley, Partner and Head of the Regulatory Practice, Bristows, United Kingdom

Drawing the Boundaries of Data Disclosure in Clinical Trials – the EMA's Perspective
Aleksandar Rusanov, Legal Adviser, European Medicines Agency, European Union

Panel Discussion with Q&A
All speakers and
Karen Quigley, Clinical Data Publication Manager, European Medicines Agency, European Union
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency, European Union

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

Conference Venue

Millennium Hotel London Mayfair
44 Grosvenor Square, Mayfair
London W1K 2HP
United Kingdom

Meeting room:
Day One, 6 December: Ballroom
Day Two, 7 December: Mayfair Suite

Continuing Education

SwAPP and SGPM Credits

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

This conference has been accredited with 8.75 credits.

DAY TWO | THURSDAY, 7 DECEMBER

08:00 REGISTRATIONS AND WELCOME COFFEE

09:00 SESSION 3

LESSONS LEARNED

Session Chair:
Julie Holtzople, Director, Clinical Trial Transparency Operations, AstraZeneca, United States

The industry has seen the publication of over 50 clinical redacted document packages by the EMA since the start of the EMA Policy 0070 process. In this session we will look at the delivery process end to end and discuss with members of the pharmaceutical industry and the EMA lessons learned and best practices that have emerged in successful submission and publication.

Panel Discussion with Q&A
Panellists:
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency, European Union

Despina Poulimenou, Clinical Data Publication Manager, European Medicines Agency, European Union

Stephen Kroll, Director, Medical Communications, Bristol-Myers Squibb Company, United States
Ada Adriano, Clinical Data Publication Manager, European Medicines Agency, European Union

10:30 COFFEE BREAK

11:00 SESSION 4

ANONYMISATION BEYOND REDACTION: CASE STUDIES

Session Chair:
Jennifer Vande Weghe, Director, Clinical Transparency & Disclosure, Amgen, United States

Different methods and approaches are available to anonymise clinical data. Earlier in 2017 the EMA created a Technical Anonymisation Group (TAG). The aims and objectives of the EMA TAG will be presented. Under EMA POL-0070 many companies have initially used redaction to anonymise clinical data, but this method can reduce the utility of the data. Industry sponsors will share case studies of how they have been able to anonymise clinical data using other approaches and highlight key challenges and lessons learnt.

Implementation of EMA Policy 0070
Janice Branson, VP Head of Statistics, Immunology & Dermatology Unit, Novartis Pharma, Switzerland

Patient Level Data De-Identification at LEO Pharma
Jørgen Mangor Iversen, Principal Programmer, Biostatistics, and Vesela Kusheva, Clinical Disclosure Specialist, LEO Pharma, Denmark

EMA Technical Anonymisation Group (TAG) – Mandate and Composition
Monica Dias, Scientific Administrator, European Medicines Agency, European Union

Panel Discussion with Q&A

12:30 LUNCH

13:30 SESSION 5

POTENTIAL TOOLS FOR CLINICAL DOCUMENTS AND DATA ANONYMISATION

Session Chair:
Julie Holtzople, Director, Clinical Trial Transparency Operations, AstraZeneca, United States

Industry has significant experience with use of redaction in delivery of Redacted Clinical Packages and the use of the qualitative risk assessment approach. To drive better clinical utility, we must find tools that support use of additional anonymisation techniques and the ability to measure the risk associated with a submission that can support scalable delivery of Redacted Clinical Packages.

In this session we will seek examples of potential tools which have been developed by vendors to measure risk and/or anonymise beyond redaction. The sessions are designed to ask vendors to demonstrate how their tool goes beyond redaction and supports risk assessment in the anonymisation of clinical documents. The session is designed to allow participants a chance to see all potential tools and seek potential solutions for their companies. This session will focus on tools, not services.

De-Identification Vendor Showcase
Cathal Gallagher, Senior Life Science Consultant, d-Wise, United Kingdom

Automating the Redaction and Anonymisation of Unstructured Patient Data Using Deep Natural Language Processing Software
Stephen Morehouse, Management Consultant, PA Consulting Group, United States
Stephen Doogan, President, Real Life Sciences, United States

Online Structured Authoring is the Key to Automated Document Redaction and Anonymising Data
Jack Yeager, CEO, Sylogent, United States

A Dual Technology Approach to Meeting Policy 0070
Woo Song, Co-Founder, Xogene Services, United States

The attendees will be divided into groups (A-D) and will visit each vendor:

Vendor	Room	13:35 - 14:00	14:05 - 14:30	14:35 - 15:00	15:05 - 15:30
d-Wise	Mayfair	A	B	C	D
PA Consulting Group	Mayfair	B	A	D	C
Sylogent	Manhattan	C	D	A	B
Xogene Services	Manhattan	D	C	B	A

15:30 COFFEE BREAK

16:00 SESSION 5 WRAP UP

The session chair will recap the demonstration session with the audience.

16:05 SESSION 6

ANSWERS TO YOUR BURNING QUESTIONS FROM THE EMA REPRESENTATIVES

Session Chair:
Merete Jørgensen, Senior Trial Disclosure Director, Global Clinical Registry, Novo Nordisk, Denmark

We are all industry and regulators on the road to implement the new requirements aiming for more transparency. During the last days a lot of information on the EMA policy 0070 and the EU Clinical Trial Regulation have been presented. Now is your chance to bring back home the answers to the burning questions you are struggling to find the answers to. And also to learn from the questions your peers have on the challenges they are or have been facing when implementing the new requirements. Use the opportunity to ensure you can bring back the latest for continued discussions in your own environment on which strategy you should be choosing in order to best be prepared for what is coming.

Panel Discussion with Q&A
Panellists:
Anne-Sophie Henry-Eude, Head of Documents Access and Publication Service, European Medicines Agency, European Union

Aleksandar Rusanov, Legal Adviser, European Medicines Agency, European Union

16:45 END OF CONFERENCE

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Exhibiting Companies

1. Privacy Analytics
2. d-Wise Technologies
3. Trialscope
4. Sylogent
5. Xogene

About DIA

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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 has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

Evaluation

We value your feedback on the content and organisation of this conference. The electronic survey can be accessed through the following link: http://bit.ly/2AWB3fK.

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

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Early-bird discount and Advance rate

To qualify for the discount, registration form and accompanying payment must be received by the dates below. Early-bird/Advance rate applies to industry members only.

Early bird discount: register by 12 September 2017 — **€ 1'030.00** ❑

Advance rate: register by 24 October 2017 — **€ 1'130.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'230.00 ❑	€ 1'385.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 615.00 ❑	€ 770.00 ❑

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. Registration fee includes: refreshments, lunches, reception and meeting materials.

*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: € _____

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Date	Signature

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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.

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