e[x] events

DEC. 6, 2018 | SONESTA PHILADELPHIA RITTENHOUSE SQUARE | PHILADELPHIA, PA

GDPR

UPDATE FOR GLOBAL ORGANIZATION

Monitor the Latest Regulatory Developments so Your Data Capture and Collection Processes Remain Compliant

IN-DEPTH EXAMINATIONS OF:

- Nontraditional Approaches to Clinical Studies
- Future Global GDPR Trends
- Maintaining Vendor Consent
- Circumstances for GDPR Exemptions
- Building Compliant Activity Records
- Social Media and Data Protection Programs
- Ethical Standards and Exemptions

Everything you need to safeguard patient personal data on the cloud, comply with the right to be forgotten, and avoid being fined up to 4% of your global revenues

CONFERENCE CHAIR

Jo Blyskal
Senior Director and Head of Global Regulatory Medical Writing and Data Disclosure
TEVA PHARM

FEATURED SPEAKERS

Anne Bahr
R&D Privacy Officer
SANOFI

Igor Chechelnitsky
Senior Manager U.S. Data Protection and Privacy Program
MEDTRONIC

Catherine Baldridge
PV Compliance Project Manager
INDIVIOR

Jeppe Manuel
Specialist in Clinical Reporting
NOVO NORDISK

Sameer Thapar
Adjunct Professor, Drug Safety and Pharmacovigilance
TEMPLE UNIVERSITY

DEAR COLLEAGUE,

Remaining compliant to the new GDPR regulations can be a daunting task that can lead to fines as well as damaged organization reputation. The quantity and detail of personal data (like individual biometric readings, information about health history or current health, etc.) collected during a clinical trial make it particularly important that companies prepare to comply with GDPR. While these regulations originate in the EU, any life science organizations engaging in global business must prepare and stay compliant as the regulation continues to evolve forcing organizations to adapt.

U.S. companies who do business with EU residents will be a direct subject to GDPR, as their customers exist under the protections of GDPR. These collaborators and contractors, such as CROs running clinical studies, are required to seek contractual commitments to help them achieve compliance with the GDPR. ExL Events invites you to attend its GDPR Update for Global Organizations. This interactive master-class session gives you the training you need to:

- Navigate GDPR from a global perspective to ensure intelligible consent
- Establish a strong internal and external SOP to ensure compliance
- Learn documentation and right to access standards
- Ensure all new data systems are designed and implemented to ensure privacy by design
- Prepare for potential data breaches or concerns

I look forward to welcoming you to Philadelphia this December!

Sincerely,
Michael Martinez
Conference Production Director
ExL Events, a division of Questex, LLC

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- GDPR
- Data Protection/Privacy
- Compliance/Legal
- Regulatory Affairs
- Regulatory Submissions
- Regulatory Operations
- Transparency
- Data Governance/Control
- IT
- Data Security
- Clinical Development
- Clinical Operations

VENUE INFORMATION

Sonesta Philadelphia Rittenhouse Square
1800 Market Street
Philadelphia, PA 19103

To make reservations, please call **1.800.SONESTA** and request the negotiated rate for **ExL 15th Metrics, 5th Rx-to-OTC, GDPR Update**. You may also make reservations online using the following weblink: **bit.ly/2KD9b4U**). The group rate is available until **November 15, 2018**. Please book your room early, as rooms available at this rate are limited.

**ExL Events is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus or travel companies. ExL Events is affiliated with event company Questex, LLC. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL's reserved guest room block using the details provided.*

SPONSORSHIP OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

THURSDAY // DECEMBER 6

8:00 **REGISTRATION AND CONTINENTAL BREAKFAST**

9:00 **CHAIRPERSON'S OPENING REMARKS**

9:15 **TAKE A NONTRADITIONAL APPROACH DURING CLINICAL STUDIES AND ANALYZE GDPR DIFFERENTIATORS AND PITFALLS**

- Gain insight to properly establish patient data with contracts, IT, vendor relationships, and CRO relationships
- Examine the EU regulation processes that will ultimately pave the way for future global GDPR trends
- Ensure compliance while considering additional privacy concerns related to processing data

Jeppe Manuel, *Specialist in Clinical Reporting*, **NOVO NORDISK**

10:00 **CASE STUDY: NAVIGATING THE US AND EU TRANSPARENCY REQUIREMENTS FOR CLINICAL DATA**

- Explore best practices for data anonymization and redaction to ensure compliance with global disclosure rules
- Discuss tips to overcome common mistakes that may lead to document invalidation
- Allocate resources and budget to build a successful transparency and disclosure team and partnership with external vendors

Jo Ann Blyskal, *Senior Director and Head of Global Regulatory Medical Writing and Data Disclosure*, **TEVA PHARMACEUTICALS**

10:45 **NETWORKING BREAK**

11:15 **RECOGNIZE SPECIFIC GDPR REQUIREMENTS TO PROPERLY MAINTAIN A RECORD OF ACTIVITY UNDER ITS RESPONSIBILITY**

- Demonstrate how other organizations utilize compliance for research and development
- Establish best practices for both the controller and processor in order to properly document activity
- Review Article 30 Data Protection Regulation

Igor Chechelnitsky, *Sr. Manager, U.S. Data Protection and Privacy Program*, **MEDTRONIC**

12:00 **NETWORKING LUNCH**

1:00 **GDPR ROUNDTABLE DISCUSSIONS**

Interact with other audience members and delve into the most pressing issues revolving GDPR. It is crucial for those involved to understand the successes and failures each organization has gone through when setting a precedent for data privacy and security. These processes include a specific policy related to data that can be used to directly or indirectly identify a person.

Each conference participant selects one topic from the following list to discuss in an intimate setting. You'll be asked for your topic selections via email a few weeks out from the conference and will have the opportunity to also sign up onsite.

1. Best practices when ensuring intelligible consent from a global perspective
2. Establishing robust internal and external standard operating procedures to ensure compliance
3. Recognize data privacy frameworks when conducting a gap assessment
4. Discuss the timelines for notification processes and reporting
5. Establish the evolution of cyber security when dealing with data privacy
6. Mitigate risk when collaborating with a third party to streamline GDPR processes

2:15 **PROVIDE A DATA PROTECTION COMPLIANCE PROGRAM WHEN RUNNING CLINICAL TRIALS**

- Collaborate to better use tools to streamline the enrollment process
- Recognize contributing factors that patients and investigators need to take into consideration
- Leverage the use of social media to successfully remain compliant while recruiting patients

Catherine Baldridge, *PV Compliance Project Manager*, **INDIVIOR**

3:00 **NETWORKING BREAK**

3:30 **GRASP WHAT GDPR MEANS FOR LIFE SCIENCE ORGANIZATIONS**

- Maintain consent throughout the entirety of the clinical trial to ensure all data being shared is monitored
- Understand the struggles when working with vendors to establish responsibilities between all parties involved
- Recognize circumstances that allow for GDPR exemption

Sameer Thapar, *Adjunct Professor, Drug Safety and Pharmacovigilance*, **TEMPLE UNIVERSITY**

4:15 **REMAIN COMPLIANT WITH GDPR PRINCIPLES DURING CLINICAL RESEARCH**

- Circumvent restrictions when processing personal research for sensitive data
- Understand exemptions and how specific values will allow researchers to streamline data
- Revolutionize the industry by applying pertinent protection of ethical standards and the research for individual rights

Anne Bahr, *R&D Privacy Officer*, **SANOFI**

5:00 **CHAIRPERSON'S CLOSING REMARKS**
JO BLYSKAL, *Senior Director and Head of Global Regulatory Medical Writing and Data Disclosure*, **TEVA PHARM**

5:15 **END OF CONFERENCE**

To Register, Click Here or

201 871 0474

253 663 7224

register@pmaconference.com

PMA Conference Management
POB 2303
Falls Church VA 22042

EARLY BIRD PRICING
Register by October 26, 2018
Conference: $1,095

STANDARD PRICING
Register After October 26, 2018
Conference: $1,295

ONSITE PRICING
Conference: $1,495

GROUP DISCOUNT PROGRAM

Save 25% Per person when registering four

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

Save 15% Per person when registering three

Can only send three? You can still save 15% off every registration.

Offers may not be combined. Early Bird rates do not apply. To find out more about how you can take advantage of these group discounts, please call 253 663 7224

MEDIA PARTNERS

MEDtube · pharmaLEADERS · pharmaphorum · PharmaTimes · PharmaVOICE · PM360 · TECHNOLOGY NETWORKS

TERMS AND CONDITIONS: By registering for an ExL Events ("ExL") event, you agree to the following set of terms and conditions listed below:
REGISTRATION FEE: The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.
PAYMENT: Make checks payable to PMA Conference Management and write **C1047** on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.
Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.
CANCELLATION AND REFUND POLICY: If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:
·Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
·Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
·Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.
To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 253 663 7224
CREDIT VOUCHERS: Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.
ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.
SUBSTITUTION CHARGES: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.
ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants. ExL Events' liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.
*The opinions of ExL's conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.
Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL's designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL's designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. EXL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.