THE **ORIGINAL** CREATORS OF THE EUROPEAN TRIAL MASTER FILE SUMMIT

12-13 October 2015

Radisson Blu Edwardian Bloomsbury Street
London, UK

4th EUROPEAN TRIAL MASTER FILE SUMMIT

Efficiently Manage, Develop and Create a Compliant TMF Structure that Enhances TMF Quality, CRO Collaboration, Inspection Readiness and Operational Efficiency

CONFERENCE CO-CHAIRS:

VITTORIA SPARACIO
Head, Document Management and Archiving
GLAXOSMITHKLINE

KAREN ROY
Senior Vice President, Client Solutions
PHLEXGLOBAL

KEYNOTE:

ANDY FISHER
Senior GCP Inspector
MHRA

FEATURED SPEAKERS:

AMER ALGHABBAN
Quality Assurance Director
POLYPHOR

MARTIN HAUSTEN
Project Compliance Manager
BOEHRINGER INGELHEIM

JANE TWITCHEN
ASSOCIATE DIRECTOR OF RECORDS SYSTEMS AND OPERATIONS,
BIOGEN

SIGNE JUUL
Senior Clinical Process Manager
LEO PHARMA

JOIN THE TMF FAMILY IN LONDON TO:

Hear 6+ case studies covering eTMF implementation, preparing for an inspection, increasing TMF quality and more

Master how to improve or create a TMF process that increases quality and allows for inspection readiness

Explore the latest eTMF platforms while debating whether a sponsor- or CRO-owned platform is best for your trial

Learn about TMF accessibility and availability from the MHRA

Network and learn with the largest community of TMF professionals

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DEAR COLLEAGUE,

We are currently operating in a regulatory environment where the Trial Master File is one of the most important aspects to a clinical trial: It proves that GCP standards were upheld. This creates a challenge unlike any other for novice and experienced TMF professionals alike. Whether you are dealing with a TMF in electronic or paper form, it is essential your document is properly compiled, managed, checked for quality, monitored and ready for inspection at a moment's notice.

Now in its fourth year, ExL Pharma's **European Trial Master File Summit** — convening on 12-13 October 2015 in London, UK — will continue to provide an educational platform for professionals to explore best practices to enhance their eTMF or paper TMF platform in order to increase quality and ensure inspection readiness.

This year's meeting features:

- A keynote presentation from the MHRA's senior GCP inspector, Andy Fisher, who will be discussing an inspector's expectation of TMF accessibility and availability
- 6+ case study presentations from representatives of Actelion, Polyphor, Boehringer Ingelheim, Leo, Phlexglobal and other organizations
- A pre-conference workshop on how to develop and enhance your TMF process and structure to meet business, technology and regulatory needs
- 9+ hours of networking with the largest community of TMF professionals
- Roundtable sessions that allow you to break off into small groups and discuss challenges and solutions related to an issue that is relevant to you
- An agenda full of timely topics, including:
  - TMF processes
  - Change management to support an eTMF implementation
  - TMF accessibility for paper and electronic platforms
  - The need for a TMF steering committee
  - Centralized eTMFs
  - The DIA reference model
  - How to implement random quality checks in your TMF plan
  - eTMF interoperability
  - eISF document collection enhancement
  - The debate over whether a CRO-owned or sponsor-owned eTMF is best for a trial

I look forward to welcoming you to London this October!

Sincerely,

Scott Grossman

Scott Grossman
Division Head, Conference Production
ExL Events
sgrossman@exlevents.com

Who Should Attend:

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

- TMF and eTMF Management
- Clinical Document/Data Management
- Clinical Trial Administration
- Clinical Operations/Process
- Regulatory Affairs/Operations
- Trial, Document and Record Management
- Document and Record Specialist
- Clinical Document Coordination
- Clinical Development/Study Management
- Quality Assurance/Control/Operations
- Competency Development
- Strategic Operations and Planning
- Quality Management
- Informatics
- Clinical IT

This program will also be of interest to:

- eTMF Service Providers
- Data/Records Management Vendors
- Clinical Research Organizations
- Paper and Electronic Archiving Solution Providers

Venue Information:

RADISSON BLU EDWARDIAN BLOOMSBURY STREET

9-13 Bloomsbury Street
Nr Covent Garden
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To make reservations please call +44 (0)20 7636 5601 and provide the code **1011EXL**. You may also make reservations online using the following weblink: **http://www.radissonblu-edwardian.com/exl**. The group rate is available until **8 September 2015. *Please note: There will be heavy demand over the block dates, so the hotel is strictly enforcing this deadline.** Please book your room early as rooms available at this rate are limited.

SPONSORING AND EXHIBITING OPPORTUNITIES

Do you want to spread the word about your organization's solutions and services to potential clients who will be 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. To learn more about these opportunities, please contact:

Eric Morrin
Senior Business Development Manager
+1 212-400-6228 or emorrin@exlevents.com

DAY ONE — 12 OCTOBER 2015

WORKSHOP

8:00 REGISTRATION OPENS AND CONTINENTAL BREAKFAST FOR WORKSHOP PARTICIPANTS

9:00 **PRE-CONFERENCE WORKSHOP: Develop and Enhance Your TMF Process and Structure to Meet Business, Technology and Regulatory Needs**

In this day and age, there is a focus to reduce paper and increase the use of technology. This is also true for a Trial Master File, but before you can consider a move to an eTMF platform, your organization must develop a TMF process that demonstrates high quality, ensures completeness and is inspection ready. During this workshop, you will develop a set of standards to ensure your TMF process and structure are optimized before you consider a new eTMF rollout or transition to an eTMF platform. If you are already involved in a TMF migration or implementation, the workshop also has content specifically for you. Participants will:

- Explore best practices to increase the chance of your project's success
- Gain practical tools to be able to turn theory into practice to guarantee TMF completeness and quality
- Discover how the TMF reference model fits into your process
- Ensure information and data governance
- Craft ways to support your TMF project through project management techniques
- Create a TMF structure and a process
- Find steps to ensure you are optimized for an eTMF platform

Martin Thorley, *Senior Information Manager,* **PFIZER**

Eldin Rammell, *Consultant,* **RAMMELL CONSULTING**

There will be a 30-minute networking break as part of this workshop.

12:00 LUNCHEON FOR WORKSHOP ATTENDEES

MAIN CONFERENCE DAY ONE

12:00 MAIN CONFERENCE REGISTRATION

13:00 **Co-Chairs' Welcome and Opening Remarks**

Karen Roy, *Senior Vice President, Client Solutions,* **PHLEXGLOBAL**

Vittoria Sparacio, *Head, Document Management and Archiving,* **GLAXOSMITHKLINE**

13:15 **KEYNOTE: Inspector Expectation of TMF Accessibility and Availability**

- Analyze current trends and critical findings related to TMF accessibility in paper and electronic formats
- Review incomplete TMFs on inspection
- Evaluate the impact of an incomplete TMF on the sponsor and the inspection process
- Understand inspector expectations to ensure a complete and fully accessible TMF
- Address the most common issues with TMFs presented during inspections

Andy Fisher, *Senior GCP Inspector,* **MHRA**

14:00 **CASE STUDY: Develop a Plan and Implement TMF Governance**

- Outline and understand the current TMF status and environment
- Define the future status of eTMF maturity
- Measure TMF maturity assessment
- Set requirements and identify baseline data critical to TMF success
- Evaluate and define TMF accountability
- Define indicators to measure TMF success
- Develop a TMF improvement plan and deliverables
- Establish a TMF governance structure
- Maintain the TMF improvement portfolio
- Check the effectiveness of implemented actions toward integrated eTMF

Martin Hausten, *Project Compliance Manager,* **BOEHRINGER INGELHEIM**

Benedicte Querton, *Group Leader - Regional Documentation Management,* **BOEHRINGER INGELHEIM**

14:45 NETWORKING AND REFRESHMENT BREAK

15:15 **CASE STUDY: TMF Standardisation with Flexibility**

- Full update on version 3.0 of the TMF reference Model
- Presenting the Model in a different way – visualization and interoperability
- TMF Reference Model survey highlights
- Using the Reference Model to drive standardization and TMF best practices
- Achieving flexibility in standardization with CRO partners

Karen Roy, *Senior Vice President, Client Solutions,* **PHLEXGLOBAL**

16:00 **CASE STUDY: Utilize the DIA Reference Model as the Foundation to Improve the TMF Process**

- LEO Pharma's process for developing and maintaining the TMF Reference Model, including involving relevant stakeholders and preparing for the implementation of a new eTMF solution
- LEO Pharma's version of the TMF Reference Model — what has been added, how it was added and how it is used to ensure inspection readiness via clear definitions of:
  - Accountability, document ownership and filing responsibilities
  - Location of document
  - Requirements for timely filing on a document level

Signe Juul, *Senior Clinical Process Manager,* **LEO PHARMA**

16:45 **Evaluate Your TMF Infrastructure in Order to Develop a Mature System for CROs and Sponsors**

- Evaluate your organization's TMF to understand where your process is in order to move forward
- Understand where the industry is at the moment
- Learn how to mature your TMF and enhance your infrastructure
- Support the business case to influence the TMF
- Locate problems within the TMF and understand where to enhance your TMF process and system

Scott McCulloch, *Director of Strategy, Vault eTMF,* **VEEVA SYSTEMS EUROPE**

17:15 **TMF BEST PRACTICE ROUNDTABLES**

During this roundtable session, you will have the ability to choose a topic that is relevant to you and sit down with our roundtable leaders over canapés and wine. This interactive setting will inspire discussions about best practice strategies while facilitating networking opportunities and promoting knowledge sharing between groups of TMF professionals.

Roundtable topics:

- **Change Management to Support an eTMF Implementation**
- **Define Essential Documents That Need to Be in Your TMF**
- **CRO Interactions and Document Management**
- **Best Practices to Migrate Paper TMF to an Electronic Format**
- **Ensure High Data Quality Through Implementing Random Quality Checks**
- **Create a TMF Operational Efficiency System**

Tables Led By:

Anne-Mette Varney, *Competency Development Manager,* **NOVO NORDISK**

Vittoria Sparacio, *Head, Document Management and Archiving,* **GLAXOSMITHKLINE**

Amer Alghabban, *Quality Assurance Director,* **POLYPHOR**

18:15 CONCLUSION OF DAY ONE

DAY TWO — 13 OCTOBER 2015

8:15 REGISTRATION OPENS AND CONTINENTAL BREAKFAST

9:00 **Co-Chairs' Recap of Day One**

Karen Roy, *Senior Vice President, Client Solutions,* **PHLEXGLOBAL**

Vittoria Sparacio, *Head, Document Management and Archiving,* **GLAXOSMITHKLINE**

9:15 **PANEL SESSION: Managing Both Internal and External Email Correspondence Within the Trial Master File**

- Address what email correspondences need to be put within the TMF
- Learn how to file a large number of emails sent between sponsors, CROs and investigators
- Develop strategies and guidances for filing emails
- Utilize technology to enhance and integrate filing within an eTMF
- Determine which technology platform can assist your organization
- Explore best practices for handling email attachments

Kathie Clark, *eTMF Product Manager,* **WINGSPAN TECHNOLOGY INC.**

Sameera Thanathparambil, *Principal Advisor, Global Quality Compliance,* **GLAXOSMITHKLINE**

Angela Salden, *Associate Director, Global Study Standards, Processes& Tools,* **ASTRAZENECA**

10:00 **Prepare Your TMF Activity from the Start of Your Trial in Order to Have an Inspection-Ready TMF at the End**

- Understand the amount of resources your TMF will take
- Establish a process and resource allocation plan to ensure quality
- Identify the start and end data points within your TMF
- Assess the cross-functional resources needed within the TMF process
- Analyze your TMF within your study teams
- Create a platform that will increase the quality of the TMF from the start of the trial

Linda James, *Senior Specialist, GCO Document Quality, Process and Operations Quality Operational Capabilities,* **BIOGEN**

10:45 NETWORKING AND REFRESHMENT BREAK

11:15 **PANEL SESSION: Enhance the Collection and Management of Electronic Investigator Site Files (eISF) Documents**

- Delve into how sites can utilize a sponsor's eISF solution and remain compliant
- Ensure segregation between investigator files from sponsor files
- Develop best practices for maintaining a complete eISF through a trial
- Facilitate a quality review process to ensure a high-quality eISF
- Explore whether TransCelerate's shared eISF platform, which includes document management processes, can replace the need for a separate eISF
- Examine the regulatory acceptance of a sponsor/CRO-owned solution for eISF

Sameera Thanathparambil, *Principal Advisor, Global Quality Compliance,* **GLAXOSMITHKLINE**

Jane Twitchen, *Associate Director of Records Systems and Operations,* **BIOGEN**

12:15 LUNCHEON

13:30 **Ensure Interoperability While Utilizing a CRO's or Sponsor's eTMF**

- Craft a checklist to decide which eTMF will be used
- Practice utilization of a CRO's internal system that is well-established and utilized for multiple trials
- Ensure sponsor oversight and quality checks in the eTMF system
- Define which eTMF is right for the trial and company, and which is cost-effective

Lorrie Dixon, *Trial Master File Manager,* **F. HOFFMANN-LA ROCHE**

14:15 **CASE STUDY: TMF Quality and Inspection Readiness Through a Defined Monitoring Process**

- Review your TMF structure, metrics and quality checks
- Implement mock inspections to ensure all documents are stored
- Create an eTMF training process for your inspector to understand your system
- Ensure that your document monitoring system is cost-effective
- Internalize the impact of selecting the right metrics to measure your TMF's quality

Amer Alghabban, *Quality Assurance Director,* **POLYPHOR**

15:00 NETWORKING BREAK AND AFTERNOON REFRESHMENTS

15:30 **CASE STUDY: Implementing an eTMF: Highlights and Lessons Learned After Two Years**

- Learn how to get started with an eTMF implementation by reviewing initial goals and benefits
- Address the scope of the eTMF
- Define the master list and wizards while keeping the DIA reference model in mind
- Implement a pilot phase while having a parallel paper and electronic version of the TMF
- Adopt a ramp-up structure
- Understand how to handle paper documents
- Study best practices and lesson learned while uncovering ways to change the process

Simone Mechler, *Associate Director, eClinical Projects, Clinical Development Informatics,* **ACTELION**

16:15 **Co-Chairs' Closing Remarks**

Karen Roy, *Senior Vice President, Client Solutions,* **PHLEXGLOBAL**

Vittoria Sparacio, *Head, Document Management and Archiving,* **GLAXOSMITHKLINE**

16:30 CONFERENCE CONCLUDES

"VERY INTERESTING TOPICS AND GREAT NETWORKING WITH OTHER TMF COLLEAGUES."

—Clinical Trial Administrator, NOVO NORDISK

"GREAT INSIGHT ON ENHANCING YOUR TMF IN ORDER TO ENSURE INSPECTION READINESS."

—Clinical Quality and Training Manager, PROSENSA

"PRESENTATIONS WERE VERY INFORMATIVE, USEFUL AND PRODUCTIVE."

—Global Study Coordinator, TEVA

"GREAT PRESENTATIONS AND INFORMATION."

—Director of Compliance, ADAPTIMMUNE

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****The opinions of ExL speakers do not necessarily reflect those of the companies they represent or ExL Events, Inc.***

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"WONDERFUL CONFERENCE TO LEARN HOW TO BETTER PREPARE YOUR COMPANY FOR AN ETMF SOLUTION."
—Study Data Manager, CHIESI

"VERY INTERESTING INSIGHT ON HOW TO IMPLEMENT QC IN TO YOUR TMF."
—R&D Assistant, CHUGAI PHARMA

"CURRENT AND THOUGHT-PROVOKING CONTENT."
—Senior Clinical Research Coordinator, MITSUBISHI

"LEARNED A GREAT DEAL ABOUT ETMF PROCESS AND DOCUMENT REQUIREMENTS."
—Clinical Trial Administrator, NOVO NORDISK

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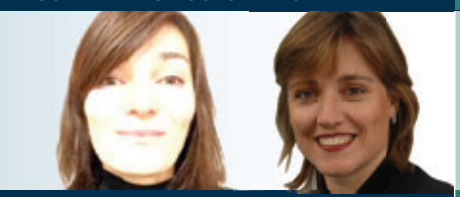

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