LINCOLN HEALTH NETWORK

TRIAL MASTER FILE + CLINICAL DOCUMENT MANAGEMENT CONFERENCE

SEPTEMBER 10-12, 2019 // ANAHEIM MARRIOTT

MAINTAINING COMPLIANCE AND ACCURACY DURING THE DEVELOPMENT OF DATA AND INFORMATION ASSOCIATED WITH CLINICAL TRIALS

REGISTER TODAY!

www.trialmasterfileconference.com

(619) 597-7236

Join the Conversation:
#TMFConf

REGISTER BEFORE JUNE 13TH & SAVE $700!

WELCOME

Dear Colleague,

Mark your calendar and make plans to attend the **Trial Master File + Clinical Document Management Conference** on September 10-12, 2019 at the Anaheim Marriott in Anaheim, California!

I am excited to announce this year's event which will bring together professionals from across the pharmaceutical, life science, and biotech industries for high-level learning, networking and fun. Our agenda features an outstanding roster of speakers from innovative companies who are transforming the way we manage operations and compliance around clinical trials, as well as solution providers who offer state-of-the-art solutions, tools and services for TMF professionals.

Now more than ever, teams are being asked to navigate an increasingly complex landscape, ensuring their clinical trials are compliant, and planning strategically for the future. Hitting on the topics that are top of mind for today's compliance and clinical operations leaders, we've aimed high and succeeded to craft a well-rounded program.

We'll cover topics in the following areas:

- ✓ **Regulatory Updates & Compliance**
- ✓ **Emerging Technology & Tools**
- ✓ **eTMF Selection & Migration**
- ✓ **Inspection Readiness**
- ✓ **Monitoring, Metrics & Reporting**
- ✓ **Managing Risk & Governance**
- ✓ **TMF Operations**

You'll discover the latest best practices at work in ensuring accurate and compliant TMF and clinical documents today, as well as learn strategies for adapting and thriving in tomorrow's evolving TMF landscape. If you haven't done so already, I encourage you to take a moment to browse some of the learning sessions and activities planned at the event.

I look forward to seeing you in Anaheim!

Sincerely,

Amy Walsh

Amy Walsh
Program Director
TMF + Clinical Document Management Conference

A perfect combination of practical application, regulations & compliance, legal, preparation & readiness, and technology.

- JoAnn Pfeiffer,
Director and Associate Professor,
Clinical Research Management
& Regulatory Science
Masters Program,
Arizona State University

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WHO SHOULD ATTEND?

This conference is designed for professionals involved in clinical research and trials in the health, pharmaceutical, life science, biotechnology and medical device sectors with responsibilities in the following areas:

Clinical Development/Study Management
Clinical Document Coordination
Clinical Document Management
Clinical Operations
Clinical Research Coordination/Management
Clinical Trial Administration
Clinical Trial Compliance
Clinical Trial Documentation
Clinical/TMF Project Management
Global Development
Quality Assurance/Control/Operations
Quality Control/Quality Management
R&D IS Management
R&D Quality Management
Regulatory Affairs/Operations
Strategic Operations and Planning
TMF™/eTMF Systems Management
Trial, Document and Records Management

SOLUTION PROVIDERS WITH A POWERFUL MESSAGE FOR ATTENDEES MAY PARTICIPATE AS **EXHIBITORS** OR **SPONSORS.**

LINCOLN HEALTH NETWORK

ABOUT LINCOLN HEALTH NETWORK

Lincoln Health Network is the pharmaceutical, medical devices, and life sciences go-to source for thought leadership and industry news. Our research is driven through industry case studies – providing actionable data, benchmarking, and insights into leading programs. Along with our leading regulatory and compliance information, our events provide a dynamic platform for professionals to gain new education, expand your network and drive business results. Lincoln Health conferences, summits, and workshops connect decision makers with peer networking, technology solutions, and cutting-edge peer-driven content.

www.lincolnhealthnetwork.com

KEYNOTES, PANELS, AND CASE STUDIES TO FUEL FRESH IDEAS FOR YOUR ORGANIZATION AND TEAM

WHY THE TRIAL MASTER FILE AND CLINICAL DOCUMENT MANAGEMENT CONFERENCE IS A MUST ATTEND EVENT

1 People, Process & Technology

Discuss an integrated approach to ensuring accurate and compliant TMF and clinical documents.

2 Location. Location. Location.

Located in Anaheim, CA, the Trial Master File + Clinical Document Management Conference is located centrally to those in the industry.

3 Stay Ahead of the Game

Featuring deep dives into emerging technologies impact on TMF and industry trends, you won't get left behind.

4 Be Inspection Ready 100% of the Time

Learn best practices, metrics and KPIs to ensure that your TMF is accurate, updated and in compliance regardless of when it's inspection time.

5 Make the Move to eTMF

In depth how to's and case studies that help ensure your migration to eTMF is speedy, accurate and trouble free.

6 Sponsor, Site or CRO – We've Got You Covered

With two tracks and 4 workshops, our wide range of topics will exceed your requirements, regardless of your role in the industry.

REAL-WORLD, APPLICABLE KNOWLEDGE, SOLUTIONS AND TIPS FROM LEADING CLINICAL TRIAL PROFESSIONALS

INTERACTIVE PEER-TO-PEER LEARNING AND UNPARALLELED NETWORKING TO STRENGTHEN YOUR CROSS INDUSTRY CONNECTIONS

AGENDA AT-A-GLANCE

PRE-CONFERENCE WORKSHOPS // TUESDAY, SEPTEMBER 10, 2019

8:00AM – 9:00AM	Registration and Coffee for Workshop Attendees
9:00AM – 12:00PM	Morning Workshops

WORKSHOP A:
Digital Transformation: Best Practice TMF/eTMF Documentation Processes

JACKIE MORRILL, *Executive Director of Clinical Operations,*
LMK CLINICAL RESEARCH CONSULTING

WORKSHOP B:
Human Factors in TMF: People, Process and Governance

Fran Ross, *TMF Ref Model SC Member, Consultant, Life Sciences R&D,*
CGI

12:00PM – 1:00PM	Networking Lunch for Workshop Attendees
1:00PM – 4:00PM	Afternoon Workshops

WORKSHOP C:
TMF Inspection Readiness

JOANN PFEIFFER, *Director/Associate Professor, Clinical Research Management & Regulatory Science Masters Programs,*
ARIZONA STATE UNIVERSITY

WORKSHOP D:
Remediation Strategies for Rescuing the TMF

DAWN NICCUM, *Sr Director, Quality Assurance & Compliance,*
INSEPTION GROUP

WORKSHOPS ARE AN ESSENTIAL PART OF YOUR CONFERENCE EXPERIENCE. HERE'S WHY:

- **Speakers are hand selected** for their extensive backgrounds and expertise with renowned brands, executives, and practitioners.
- **Meet with trainers** prior to each workshop to submit specific questions you'd like answered during each session.
- **Attendance is limited** to ensure that you have dedicated one-on-one time with each workshop trainer.

PRE-CONFERENCE WORKSHOPS constitute a very important part of the event curriculum - providing you with the opportunity to experience a more intimate and interactive setting with other attendees, as well as an opportunity for one-on-one interaction with workshop facilitators to address personal business challenges.

The three-hour classroom style sessions are uniquely tailored to your needs - based on discussion, hands-on activities, group work, and application of strategies and techniques in real time with your professional peers.

SIGN UP EARLY TO SECURE YOUR SPOT IN A PRE-CONFERENCE WORKSHOP TO DIVE DEEP BEFORE THE GENERAL CONFERENCE BEGINS.

BEST VALUE!

Save $100
when you register for the All Access pass and get access to both an AM and PM workshop.

AGENDA AT-A-GLANCE

DAY 2: GENERAL CONFERENCE // WEDNESDAY, SEPTEMBER 11, 2019

8:00AM - 8:45AM	**Registration and Coffee**
8:45AM - 9:00AM	**Conference Chair Welcome**
9:00AM - 9:45AM	**FIRESIDE CHAT: A Regulators View - Insights from the FDA/MHRA/EMA** **MODERATED BY:** JoAnn Pfeiffer, *Director/Associate Professor, Clinical Research Management & Regulatory Science Masters Programs,* **Arizona State University** **INVITED PANELISTS:** Rachel Skeete, MD, MHS, *Team Leader, Good Clinical Practice Compliance Oversight Branch,* **FDA/CDER/OC/OSI/DCC**; *among others*
9:45AM - 10:30AM	**PANEL: Who Cares about The TMF? Insights on How to Drive Study Team Engagement** **MODERATOR:** Fran Ross, *TMF Ref Model SC Member, Consultant, Life Sciences R&D,* **CG** **PANELISTS:** Aryn Knight, BS, CCRP, *Assistant Administrative Director, Center for Clinical Research,* **Texas Heart Institute;** Cherry Standen, *TMF Manager,* **Robarts Clinical Trials** **INVITED:** Stephanie Viscomi, *Associate Director, Clinical Trial Office,* **ImmunoGen, Inc** **Monica Alaimo,** *Director, TMF Operations,* **Syneos Health**
10:30AM - 10:45AM	**Networking Break**

TRACK A: TMF TECHNOLOGY & TOOLS

TRACK MODERATOR: Dawn M. Niccum, *Sr Director, Quality Assurance & Compliance,* **inSeption Group (on website)**

10:45AM - 11:30AM

Utilizing Technology to the Fullest Extent in TMF Operations
Speaker TBA

11:30AM - 12:15PM

CASE STUDY: Leveraging Technology and Clinical Trial Data Sources to Improve TMF Quality
Cristin Freeman, MPH, MBE, *Associate Principal Scientist, Global Genomics Policy, Process and Compliance (GPPC),* **Merck Research Laboratories**

TRACK B: REPORTING, MONITORING & METRICS

TRACK MODERATOR:
Andy Lawton, *Consultant,* **Risk Based Approach Ltd**

10:45AM - 11:30AM

Leveraging Technology for Oversight & Metrics
Joy Mehlenbacher-Mohamed, *Manager, Clinical Support and Quality Documentation,* **Boehringer Ingelheim (Canada) Ltd**

11:30AM - 12:15PM

PANEL: Collaborative Oversight: Modern Working with Internal and External Partners
MODERATOR: Kathy Goin, *Principal Consultant,* **Clinical Works**
PANELISTS: Kristen Bretzius, *Document Center Manager,* **PSI Pharma Support America**
Aryn Knight, BS, CCRP, *Assistant Administrative Director, Center for Clinical Research,* **Texas Heart Institute**

12:15PM - 1:15PM	**Networking Lunch**
1:00PM – 4:00PM	**Afternoon Workshops**

TRACK C: eTMF SELECTION & MIGRATION

TRACK MODERATOR: Dawn M. Niccum, *Sr Director, Quality Assurance & Compliance,* **inSeption Group (on website)**

1:15PM - 2:00PM

CASE STUDY: Selecting an eTMF
Speaker TBA

2:00PM - 2:45PM

Migrating to an eTMF from Start to Finish
Speaker TBA

TRACK D: TMF INSPECTIONS

TRACK MODERATOR:

1:15PM - 2:00PM

PANEL: Ensuring Constant Inspection Readiness - Where Good Clinical Practice and Good TMF Practice Intersect
Speaker TBA

2:00PM - 2:45PM

CASE STUDY: TBA
Speaker TBA

AGENDA AT-A-GLANCE

DAY 2: GENERAL CONFERENCE // WEDNESDAY, SEPTEMBER 11, 2019

2:45PM - 3:15PM	**Networking Break**
3:15PM - 4:00PM	**Contextualizing Emerging Technology: The Future of Clinical Operations** Andy Chu, *Director, Regulatory Affairs - Regulatory Systems Strategy,* **Biogen**
4:00PM - 4:45PM	**LEGAL: TMF & Privacy Regulations: Are You Compliant?** Jackie Morrill, **Executive Director of Clinical Operations, LMK Clinical Research Consulting**
4:45PM - 5:00PM	**Conference Chair Closing Comments**
5:00PM - 6:00PM	**Networking Reception**

DAY 3: GENERAL CONFERENCE // THURSDAY, SEPTEMBER 12, 2019

8:00AM - 8:45AM	**Registration and Coffee**
8:45AM - 9:00AM	**Conference Chair Welcome**
9:00AM - 9:45AM	**PANEL DISCUSSION: TMF Reference Model & eTMF Exchange Mechanism Standard** Kristen Bretzius, *Document Center Manager,* **PSI Pharma Support America** Scott McCulloch, *TMF Reference Model Steering Committee Member and Director, GCP Quality,* **InClin Inc.** *among others*
9:45AM - 10:30AM	**AI, ML & NLP: What Can TMF Practitioners Learn from Automation of Digital Data Transfer?** Speaker TBA
10:30AM - 10:45AM	**Networking Break**

TRACK E: eTMF SELECTION & MIGRATION

TRACK MODERATOR: Dawn M. Niccum, *Sr Director, Quality Assurance & Compliance,* **inSeption Group (on website)**

TRACK F: TMF INSPECTIONS

TRACK MODERATOR:

10:30AM - 11:15AM

PANEL: Where's My Reg Binder? The Site's Record Management ExperienceF

MODERATOR: Fran Ross, *TMF Ref Model SC Member, Consultant, Life Sciences R&D,* **CGI**

Aryn Knight, BS, CCRP, *Assistant Administrative Director, Center for Clinical Research,* **Texas Heart Institute** *and TBA, Investigator*

Bringing the Risk Based Approach to the eTMF

Andy Lawton, *Consultant,* **Risk Based Approach Ltd**

11:30AM - 12:15PM

CASE STUDY: Don't Panic! Scaling Up TMF Operations at a Small CRO Experiencing Dynamic Growth

Cherry Standen, *Senior TMF Associate,* **Robarts Clinical Trials**

Governance of TMF

Kristen Bretzius,*Document Center Manager,* **PSI Pharma Support America** *and* Monica Alaimo, *Director,* **TMF Operations, Syneos Health**

12:15PM - 1:15PM	**Networking Lunch**
1:15PM - 2:15PM	**SPEAKER-LED ROUNDTABLE DISCUSSIONS (Four (4) Concurrent)** **ROUNDTABLE 1:** Change Management **ROUNDTABLE 2:** Human Factors in TMF **ROUNDTABLE 3:** Sponsor/Site/CRO Relationships **ROUNDTABLE 4:** Inspection Readiness
2:15PM - 2:45PM	**Networking Break**
2:45PM - 3:30PM	**Real Time TMF: Ensuring Timeliness & Completeness of Your TMF Documentation** Speaker TBA
3:30PM - 4:15PM	**CLOSING KEYNOTE: Change Management, Culture Change and Stakeholder Management** Speaker TBA
4:15PM - 4:30PM	**Conference Chair Closing Comments**
4:30PM	**Conference Concludes**

WHAT'S INCLUDED?

GENERAL CONFERENCE PASS SEPTEMBER 11 & 12

- Access to all keynote and breakout sessions on **September 11 & 12**
- Customize your event experience by hopping between themed tracks to attend the sessions most relevant to you
- Breakfast, snacks, lunch and networking reception access
- Access to all speaker slides and MP3s on-demand post-conference

ADD-ON PRE-CONFERENCE WORKSHOPS SEPTEMBER 10

- Choose AM or PM hands-on pre-conference workshops (4 options available)
- Attend both AM and PM sessions for a discount!
- These workshops are not included in your general conference pass - ***they are a separate, additional fee.***

EXHIBITING AND SPONSORSHIP

Feature Your Product, Service or Software at This Year's Can't Miss Event

We've been building industry-renowned programs since 2010. We help exhibitors like you leverage our community of pharmaceutical, life science, and biotech practitioners, and decision-makers to create an experience rich in networking and relationship-building with prospects that will generate new business.

Exhibit at the TMF + Clinical Document Management Conference to take advantage of:

- A unique and dynamic opportunity to generate awareness in the pharmaceutical and life sciences industries
- Unparalleled and continuous face time with a highly qualified audience of prospective buyers and decision-makers
- Executives seeking comprehensive solutions to optimize their TMF management and clinical document compliance strategies

To learn more about exhibiting at this year's FWD PHARMA please contact **James Cross** at

james@lincolnhealthnetwork.com

619-810-1939

REAP THE BENEFITS OF SENDING YOUR ENTIRE TEAM!

Send 3 colleagues
Register each for 10% off

Send 4+ colleagues
Register each for 15% off

Contact Andrea Vargas for more information:
andrea@lincolnhealthnetwork.com

NON-PROFIT & GOVERNMENT DISCOUNTS

We honor attending non-profits, educational institutions and government agencies with an additional $200 off the general summit access pass rate. To register a group or with the non-profit/ government discount, Please contact **Andrea Vargas**:

andrea@lincolnhealthnetwork.com

619-597-7236

$200 OFF

TRIAL MASTER FILE CONFERENCE

SEPTEMBER 10-12, 2019 | ANAHEIM MARRIOTT | ANAHEIM, CA

LINCOLN HEALTH NETWORK

REGISTRATION FORM

Pass Type Date	Pre-Sale 6/13/19	Advanced 7/25/19	Regular 8/22/19	Online 9/9/19	At Door Pricing 9/10/19
Conference	❍ **$1,395**	❍ **$1,595**	❍ **$1,795**	❍ **$1,895**	❍ **$1,995**
Conference +	❍ **$1,890**	❍ **$2,090**	❍ **$2,290**	❍ **$2,390**	❍ **$2,490**
All Access	❍ **$2,285**	❍ **$2,485**	❍ **$2,685**	❍ **$2,785**	❍ **$2,885**
1 Workshop Only	–	–	–	❍ **$495**	–
2 Workshops Only	–	–	–	❍ **$890**	–

**ASK ABOUT SPECIAL RATES FOR CLINICAL SITE, ACADEMICS, AND NONPROFITS

INCLUDED: Two-day conference ticket, includes • Access to breakfast, snacks, lunch, and networking reception • Presentation MP3s and speaker slides • Networking cocktail reception with speakers and attendees (September 11) • Pre-Conference Workshops (September 10) • Full pre-conference workshop day discount
(Register for 2 workshops, save $100 on your ticket!)

NON-PROFIT & GOVERNMENT DISCOUNTS:

We honor attending non-profits, educational institutions and government agencies with an additional $200 off the general summit access pass rate.

Please contact Andrea Vargas at andrea@lincolnhealthnetwork.com or 619-597-7236 to register a group or with the non-profit/ government discount.

Please fill in the following information and fax back to: (619) 923-3542 Please submit one form for each delegate attending.

GSMI OFFERS 5 WAYS TO REGISTER:

Tel: 619-597-7236 Monday - Friday 8:00 a.m. - 6:00 p.m. US Pacific Time

Fax: (619) 923-3542 24 Hours a Day

Mail: 1501 India St., Suite 103-60, San Diego, CA 92101

Email: andrea@lincolnhealthnetwork.com
Please include your name & telephone number

Web: www.trialmasterfileconference.com

VENUE: TMF + Clinical Document Management Conference will be held at: Anaheim Marriott, 700 West Convention Way, Anaheim, CA 92802

ACCOMMODATIONS: We've secured a room block for attendees and speakers at the venue. Our discounted rate of $229/night plus tax is available through August 19, 2019. Make sure you reference the TMF + Clinical Document Management Conference or the host company GSMI to secure the discounted rate.

You can make reservations: Online: CLICK HERE

By phone: 714-750-8000

We highly suggest you book early — once rooms have sold out or expiration date has passed, GSMI can no longer guarantee availability or the discounted rate.

ADMINISTRATIVE NOTE:
For cancellations received in writing.

- **Four weeks or more prior to the event:** *Full refund or Full Credit Voucher*
- **Four weeks or less prior to the event:** *No Refund; a Credit Voucher minus the $300 cancellation fee*

If you do not cancel your registration by the day of the event you will be charged your full registration fee. Credit vouchers may be applied toward any future GSMI event within one calendar year of the date of the cancellation. If GSMI decides to cancel any part of this event, the Company is not responsible for covering airfare, hotel or any other costs. Speakers, agenda, networking and recreational events are subject to change without notice. For more information regarding refunds please contact the customer service department at: 888.409.4418

SUBSTITUTION POLICY:
Substitutions may be made up to the day of the event.

PAYMENT POLICY: Payments can be made by American express, Visa, MasterCard, Company Check (USD checks must be drawn on a US bank), or by wire transfer. If registering 2 weeks or less prior to the start of the Conference, you must submit your credit card information as a form of payment. If registering more than 2 weeks prior to the start of the Conference and payment is not received at the time of registration, a credit card hold will be required to maintain your registration status. If payment is not received 2 business days prior to the conference date, the respective credit card will be utilized as the form of payment. Please make all checks payable to Global Strategic Management Institute. In the memo area of the check please write the name(s) of the Trial Master File + Clinical Document Management Conference registrants(s).

Name:

Title:

Company:

Department:

Approving Manager Name & Title:

Mailing Address:

City: State:

Zip/Post Code: Country:

Telephone:

Fax:

Email:

Twitter ID:

Linkedin.com Profile:

Will you be attending a Pre-Summit Training (September 10, 2019)? ❍ **Yes** ❍ **No** **If so, which training?**

❍ **Morning Workshop A:** Digital Transformation: Best Practice TMF/eTMF Documentation Processes
❍ **Morning Workshop B:** TBA
❍ **Afternoon Workshop C:** TMF Inspection Readinesst
❍ **Afternoon Workshop D:** Remediation: Strategies for Rescuing the TMF

PAYMENT METHOD: CREDIT CARD: ❍ Amex ❍ Visa ❍ MasterCard ❍ Check

Credit Card Number:

Name on Card:

Expiration Date: CVV

Do you have any dietary restrictions (e.g. kosher, vegetarian)? ❍ Yes ❍ No If so, please specify:

Do you require any accommodations that require special attention? ❍ Yes ❍ No
If so, please specify: (e.g. wheel-chair access)

How did you hear about this event?