

TRIAL MASTER FILES

EUROPE 2016

13th – 14th September 2016, Barcelona, Spain <http://www.tmfeurope.com>

CONFERENCE DAY 1

9:00 AM Chairman's Welcome

9:10 AM Inspector Expectations: TMF Accessibility and Availability

Examining inspection trends and highlighting the common findings of incomplete TMFs

Discussing a regulator's position on classifying an incomplete TMF as a 'critical finding'

Exploring European TMF requirements to ensure a fully compliant TMF

Highlighting inspector expectations using examples of best practice and identifying common pitfalls

Addressing minimum requirements for paper destruction when using an eTMF system

Danish Medicines Agency (tbc)

9:50 AM Live Inspection Simulation!

A regulatory body simulates a real inspection! The audience will get to watch as a 'real' inspection takes place before them. The inspector will pause at tricky parts of the inspection and ask the audience to say what they would do next, allowing the audience to really think hard about what to do to be 100% inspection ready! All audience questions will be answered, and mistakes corrected.

Walk away from this session ready to perfect your next inspection!

10:30 AM People Bingo: Interactive Speed Networking

A highlight of IQPC events and now at Trial Master Files Europe for you to get involved in!

Be ready to meet your peers and share best practice. You will have several 2 minute conversations to enable you to introduce yourself to your peers and add to your contact pool. There is a prize in it for the winner so get networking!

Please Share:

1. Who you are
2. Scope of your job role
3. What you plan to achieve from attending this event
4. Your #1 challenge

11:10 AM Networking Coffee Break

11:40 AM Hold The Front Page! A Cover Story on Interoperability

This team-building session, which demonstrates the critical interoperability challenges you are facing and wish to overcome, will enable all attendees to come together and produce the front page of TMF International Magazine.

Brainstorm and knowledge share with your peers to come up with the best front page, that features articles covering the biggest challenges! Industry experts will be at each table to help facilitate and offer advice.

Ashley Cole
Senior Clinical Trial Administrator
Mitsubishi Tanabe Pharma

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12:20 PM Interoperability – A Best Practice Guide

Karen Roy

Senior Vice President of Client Solutions

Phlexglobal

1:00 PM Networking Lunch

2:00 PM INTERACTIVE CASE STUDY: Safeguarding TMF Interoperability

Because most companies spread their eTMF across multiple functions, challenges around the interoperability of systems occur that would not if eTMFs were held as a single entity.

In this session, a leading pharma company will:

- Explore the challenges that incompatible TMFs can create
- Offer strategies to mitigate the impact on trial running efficiency
- Identifying key requirements of an eTMF to meet needs and ensure functionality
- Reviewing training necessary to ensure effective system usage

2:40 PM INTERACTIVE PANEL DISCUSSION: Optimizing Performance and Quality Metrics to Improve TMF Processes

Three panel members will kick off this interactive discussion with their viewpoints on utilising performance and quality metrics to help TMF process efficiency. Then, the audience gets their chance to be involved, by firing questions at the panel – the more challenging the better!

3:20 PM Networking Coffee Break

3:50 PM Campfire Round Table Discussions

The best strategies are formed through expert collaboration! Break off into small groups of 8-10 people and collaborate with your peers in these interactive roundtable discussions...with a twist!

A campfire theme gives these round tables an intimate and open feel, with campfire snacks provided to get everyone into the mood! Warm your hands and your imagination.

Topics:

1. Enhancing the quality of your TMF
2. Managing paper and electronic documentation and retention times
3. Differentiating between paper filing and an eTMF – finding definition
4. How to represent a complete TMF when documents are dispersed across several systems

4:30 PM CASE STUDY: Find your File – Indexing for Increased Efficiency

Best practices for indexing of email correspondence

Best practices for linking documents/data created in other repositories (e

Document Management Systems, Clinical Trial Management System, Data Management System with the eTMF to ensure eTMF completeness and without losing document audit trails from original repositories

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CONFERENCE DAY 2

9:00 AM Chairman's Recap of Day One

9:10 AM CRO Interactions – Best Practice Management

Hear a leading CRO share their input on how to best manage CRO/sponsor relations and develop strategies

9:50 AM Live Debate! CRO vs Sponsor Managed TMF

Hear a CRO representative and a pharma TMF lead debate their unique benefits, and stir the pot with your own questions and points!

10:30 AM Networking Coffee Break

11:00 AM CASE STUDY: eTMF Transition – A Best Practice Guide

Hear a Pharma company's journey from paper to eTMF, and their successes and pitfalls along the way!

Develop ideas to assist with your transition

Learn about all the details from CRO oversight to TMF governance

11:40 AM Vendor Spotlight - Welcome to the Dragon's Lair!

This interactive hour packs both fun and challenge into a targeted learning session. Delegates and sponsors will split into teams and conceptualise, research, and create a brand new product to help with their TMF challenges. Once formed, each team's idea will be presented to a team of industry expert judges, who will vote on the best idea!

12:40 PM Networking Lunch

1:40 PM CASE STUDY: UCB Share Their TMF Insights!

Hear about TMF metrics development

Learn about QC check guidance for sponsor oversight

Develop best strategies for CRO and QC reports

2:20 PM Monitoring CROs: Best Practice and Effective Outsourcing

Discover how to handle multiple CROs at once from an experienced manager

Address the question of which eTMF system to use in various situations

Learn to set expectations from the outset to ensure harmonious working relations

3:00 PM Networking Coffee Break

3:30 PM "What If" Round Tables

Each Round Table will discuss a different 'what if scenario' that mirrors a real TMF situation. Develop strategies to overcome these likely scenarios, and share past experiences and ideas.

4:10 PM End your conference with a good old-fashioned pub quiz!

Designed to test what you've learned over the course of the conference, each table is given an answer sheet and will be asked a series of TMF related questions.

4:50 PM Chairman's Reflection and Closing of Conference