7th Trial Master File Summit

Date : Jan 22, 2018 - 07:00 AM - Jan 24, 05:00 PM

Event URL : http://www.nyeventslist.com/events/7th-trial-master-file-summit-jan-2018

Organizer : tmfsummit

Venue :

Location : TBD Orlando, Florida,
Orlando, Florida, US, ZIP: Florida
Phone: +1 929 900 1853

A TMF is more than a living archive of a clinical trial's progress; it is a system required by regulatory authorities and is critical for clinical oversight. By developing, implementing and utilizing a sound TMF plan, you will be able to monitor a trial as it advances, ensure high-quality documents and prepare your organization for an inspection at any stage. Additionally, by creating a TMF process, the clinical trial's sponsors, CRO and site will be able to demonstrate their continued adherence to GCP during the trial.

At the 7th Trial Master File Summit, 40+ speakers will share best practices on a wide range of topics including:

- Quality TMF improvement
- System migration and eTMF implementation.
- Determining and Managing Relevant communications in the TMF.
- Completeness review by the study team and how to streamline this process.
- Maintaining a real time TMF/Implementing Processes to maintain a real time eTMF.
- Senior Management acceptance/funding/championing of eTMF implementation.
- Metrics with CRO and internal staff.
- How to construct a successful TMF team.
- Involving functions in TMF.
- Relevant correspondence, working with CRO partners, Inspection Readiness.
- Document management and processes.
- TMF QC or TMF Process Implementation.
- Inspection Readiness, Metrics, Sponsor Oversight Responsibilities.
- Nothing specific at this time.
- CRO's and their SOP's and standards.
- Study Close-out/Transfer.
- How to set up a successful TMF staff. How to reduce the number of correspondence by downsizing the number of emails.

Top Five Reasons to Attend

1. Learn from case studies and best practices for designing and implementing a TMF plan for global trials and inspectional readiness.
2. Networking and learn with over 250 TMF colleagues.
3. Hear updates on the DIA reference model and MCC’s metrics working group.
4. Develop a TMF strategy to ensure proper TMF oversight.

5. Explore the latest trends, preparations and expectations for TMF inspections from the FDA, EMA, MHRA and PMDA.

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
- Regulatory Affairs/Operations
- Trial, Document and Record Management
- Clinical Document Coordination
- Clinical Development/Study Management
- Quality Assurance/Control/Operations
- Competency Development
- Strategic Operations and Planning
- Quality Management
- Informatics
- Clinical IT

This event is also of interest to:

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

Please contact the event manager Marilyn below for the following:

- For Tickets/Registrations,
- Discounts for registering 5 or more participants.
- If you company requires a price quotation.

Event Manager Contact:

marilyn.b.turner(at)nyeventslist.com or Contact: +1 929 900 1853

You can also contact us if you require a visa invitation letter, after ticket purchase.
We can also provide a certificate of completion for this event if required.

NO REFUNDS OR TRANSFER ALLOWED ON REGISTRATIONS

This Event Listing is Promoted by New York Media Technologies LLC in association with EXL Events Inc.

http://www.NyEventsList.com
http://www.BostonEventsList.com
http://www.SFBayEventsList.com

Event Categories : BUSINESS & MANAGEMENT CONFERENCES, COMPUTERS AND INTERNET CONFERENCES, Finance, HEALTH AND MEDICINE CONFERENCES, Healthcare, Life Sciences, Biotechnology, SCIENCE AND TECHNOLOGY CONFERENCES, SOCIETY CONFERENCES, Technology ,