Indian Society for Clinical Research Presents

Virtual Workshop on 23rd October 2021

Title: eTMF (electronic Trial Master File)

Highlights: A TMF is the collection of essential documents that is used by sponsors, CROs and investigators/institutions for the management of the trial and by monitors, auditors and inspectors to review and verify whether the sponsor and the investigators/institutions have conducted the trial in line with the applicable regulatory requirements and the principles and standards of GCP. The documentation contained within it should be sufficient to adequately reconstruct the trial activities undertaken, along with key decisions made concerning the trial. eTMF is a way of digitally capturing, managing and storing essential documents and content in clinical trial. In this workshop, you will gain knowledge about how to keep your eTMF inspection ready and will learn about Best practices. You will also engage yourself in determining how completeness and accuracy can be ensured while engaging yourself in live demo session.

The learning objectives will be to:

- Gain insight on regulations around eTMF
- To understand Industry Best practices used in eTMF management & eTMF Health Metrics
- Proactive eTMF risk assessment approaches in keeping eTMF inspection ready
- How technological advancement will change the future of eTMF

Workshop Organizer: North Chapter (ISCR)

Agenda: ** Session time and details may vary slightly and will be updated in the final agenda.*

Topics	Speakers	Time Slots	Time
Introduction to ISCR and the Workshop	**Anirban Roy Chowdhury**	**5 mins**	**10:00 to 10:05**
Introduction to the session & the speakers	**Anjali Singh**	**5 mins**	**10:05 to 10:10**
Paper Vs electronic Trial Master File	**Deep Sharma**	**30 mins**	**10:10 to 10:40**
TMF Plan	**Shailesh Madel**	**30 mins**	**10:40 to 11:10**
How to keep your eTMF Inspection Ready			
Expectation from Stakeholders	**Shailesh Madel**	**20 mins**	**11:10 to 11:30**
Regulations around eTMF	**Shiv Kumar Gupta**	**30 mins**	**11:30 to 12:00**
eTMF metrics & Compliance	**Shailesh Madel**	**30 mins**	**12:00 to 12:30**
Workshop on Inspection Readiness	**Anjali & Shiv**	**45 mins**	**12:30 to 01:15**
Best Practices	**Shiv & Deep**	**30 mins**	**01:15 to 01:45**
Q/A session		**15 mins**	**01:45 to 02:00**
LUNCH BREAK for 30 mins			
Future of eTMF	**Arvind Jagadeeshaan**	**30 mins**	**2:30 to 3:00**
Risk Management in eTMF	**Deep**	**20 mins**	**3:00 to 03:20**
Adoption of eISFs	**Site User**	**30 mins**	**3:20 to 03:50**

Q&A Session with Experts **(Virendra Alate and Priyadarshini A)**	**Moderated by Anjali Singh**	**30 mins**	**3:50 to 4:20**
Wrap Up/Feedback Survey	**Anjali Singh**	**10 mins**	**4:20 to 4:30**

All registered participants will receive a "Certificate of Participation" from ISCR

Registration fees	**INR 500/-**	

Registration will be for limited seats only and on first come basis.
Online Registration: https://www.iscr.org/events-registrations/
Online Payment: Once you will register for the event, you will receive payment link on your registered email id.

Offline Payment: Cheque/DD payable at Mumbai should be made in favor of "Indian Society for Clinical Research" & mailed to us at ISCR Secretariat, c/o Pfizer Limited, The Capital 1802, 18th Floor, Plot No. C-70, 'G' Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

For any query, please write to: info@iscr.org
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