



Indian Society for Clinical Research

Presents

Virtual Clinical Data Management Workshop on 19th & 20th Nov 2021

Title: Creation of Edit checks specifications for Electronic Data Capture (EDC) studies

Highlights: The primary objective of Clinical Data Management (CDM) is to ensure timely delivery of high-quality data which is necessary to satisfy both GCP requirements and also the statistical analysis and reporting needs. CDM data validation via the Edit checks & listings in EDC studies plays a crucial role in ensuring the data is processed & validated as per the Protocol requirements & ensures data quality.

Edit checks are rules, constraints or conditions, often programmed to flag when the data entered or collected in the study does not meet the defined criteria. Considering that the creation of the Edit checks is a quality determining step, a thorough holistic understanding of this area is essential for data validation activities.

This workshop caters to emphasize on the key aspects to be considered during edit checks creation. The agenda is designed to navigate through the protocol understanding, creation of specifications, dealing with complexities, understanding a programmer's perspective. It also includes interactive hands-on sessions and quizzes to ensure practical knowledge application and learning.

Who should attend: Experienced & aspiring Clinical data management professionals, Students and Academics

Workshop Convener: Sachin Tonapi (LabCorp, Covance)

Workshop Organizers : Aditi Bhat (GSK), Alok Gunhal (LabCorp, Covance),



Agenda:

No.	Time	Title	Timing	Speaker
Day 1 – 19th Nov 2021				
1	10.00 -10.15 am	Introductions and Objectives	15 min	Aditi Bhat- GSK / Alok Gunhal- LabCorp
2	10.15-10.30 am	Pre-session Quiz	15 min	Aditi Bhat- GSK / Alok Gunhal- LabCorp
3	10.30 -10.55 am	Protocol Overview – Data Management Perspective	25 min	Abhijit Magar, Sr. Principal Data Manager- Novartis
4	10.55- 11.15 am	Quiz on Protocol Overview	20 mins	Abhijit Magar, Sr. Principal Data Manager- Novartis
----- 15 min break-----				
5	11.30 – 12.00 pm	Creating Edit check Specifications for Data Validation (part 1)	30 min	Aditi Shinde, Project Data Manager – Syneos Health
6	12.00 – 12.15 pm	Part 1 - Group activity/ Exercises & discussion	15 mins	Aditi Shinde, Project Data Manager – Syneos Health
7	12.15 -12:45 pm	Creating Edit check Specifications for Data Validation (part 2)	30 mins	Nikhat Mulla, Lead Data Manager – Tata Consultancy Services
8	12.45 – 1.00 pm	Part 2 - Group activity/ Exercises & discussion	15 mins	Nikhat Mulla, Lead Data Manager – Tata Consultancy Services
9	1.00 – 1.15 pm	Day 1 Summary & Wrap up	15 mins	Aditi Bhat- GSK / Alok Gunhal- LabCorp
End of Day 1				
Day 2 – 20th Nov 2021				
10	11.00 – 11.15 am	Recap of Day 1	15 mins	Aditi Bhat- GSK/Alok Gunhal- Labcorp
11	11.15 – 12.00 pm	Working with Complex edit checks & listings	45 min	Rashida Rampurawala, Manager Study Data Management - GSK
----- 15 min break-----				



12	12.15-1.00 pm	Clinical Programmer's perspective on Specification Writing – Hints/Tips & Best practices	45 min	Harshavardhan Lad, Manager, Study Design and Programming - LabCorp Drug Development
13	1.00-1.15 pm	Post session Quiz	15 min	Aditi Bhat- GSK/Alok Gunhal- Labcorp
14	1.15 – 1.30pm	Closing remarks & Feedback	15 min	Aditi Bhat- GSK/Alok Gunhal- Labcorp

All registered participants will receive a “Certificate of Participation” from ISCR

Registration fees (By 25 th Oct 2021)	Student / Academia – Rs. 500/-	ISCR Member – Rs. 1000/-	Non ISCR Member – Rs. 1200/-
Registration fees (After 25 th Oct 2021)	Student / Academia – Rs. 750/-	ISCR Member – Rs. 1200/-	Non ISCR Member – Rs. 1500/-

Online Registration: <https://www.iscr.org/events-registrations/>

Online Payment: Once you will complete the registration, you will receive payment details along with the confirmation email 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

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[For any query, please write to: info@iscr.org](mailto:info@iscr.org)

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