veeda clinical research

V- KONNECT

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“V-KONNECT" with WHO TEAM.

Veeda through its V-Konnect series interacted with Dr. Elham Kossary - (Lead inspector for WHO) and Ms. Joy van Oudtshoorn - (Co-inspector for WHO) during their Inspection at Veeda Clinical Research.

About the V- Konnect

V-Konnect interview series, is a program to get in touch with specialized industry experts to know their views on opinions on current relevant subject matters.

Below is the transcript of the Interview.

Q.Looking to the current scenario and regulatory standard what according to you are the biggest challenges to comply with digital and electronic systems in the industry.
A: Proper validation of the computerized system used by the CROs, specifically based on their own User Requirement Specification (URS), presents a challenge for many organizations. Also, the management of data privacy and protection of source data, together with the arrangement of proper backup and later restoration for control purposes, are often compromised.

Q. What additional measures industry should take for improving the transparence in clinical research and strengthen the scientific data integrity.
A: Organizations should ensure that all data and modifications made to any generated data in the clinical research are adequately and consistently traceable. Sufficient audit trail for each step of the activities should be implemented. Audit trails should be designed to facilitate searching by different categories.

Q. How effective do you think is the designing of clinical studies in terms of risk is to benefit ratio across the industry?
A: The question is not clear. However, it can be mentioned that in designing bioequivalence studies, the availability of adequate in vitro methods should also be considered to minimize the risk of the study.

Q. Looking to the clinical trial registration part trends from which country do you think the registration of new trials is increasing?

A: The majority of the WHO-inspections take place in India, so we don't have that information.

Q. How do you see India in terms of GxP compliance across the world?

A: A. Considering the abovementioned limitation and also my area of expertise (Only GCP and BE-studies' inspection), I don't have that information either. But, out of my experience, the overall GCP and GLP compliance of the CROs is acceptable.

Q. What is your view on the reporting of the study results from Clinical trials and recommendation to improve the reporting?

A: The study reports and results are received by the assessment team of the WHO-pre qualification team. They make an assessment whether the report and the study results are complete. Inspectors verify the study report and results by checking the source data and compliance with the relevant guidelines. Ensure that the study reports are compiled in accordance with the applicable guidelines and adequate quality control and quality assurance of the study activities, documents/records and results are performed.

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