veeda clinical research

V- KONNECT

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“V-KONNECT" with Mr. Ashish Dasgupta - Director Anregen Healthcare Pvt. Ltd.

Veeda through its V-Konnect series interacted with Mr. Ashish Dasgupta and discussed about “India as preferred destination for conducting clinical trials”

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.

About Mr. Ashish Dasgupta

With over 35 years of experience in Clinical Pharmacology and Pharmacokinetics, Mr. Ashish Kumar Dasgupta have handled varied position in operations, business development and strategic organizational development in his past assignments. Anregen Consulting in New Delhi is the consulting group established by Mr. Ashish Dasgupta which is an advisory capacity for several companies from India and overseas. . He has been felicitated with 'Udyog Ratna' award for his precious contributions to CRO industry and honored with 'Best Leadership' at Jubilant for exhibiting exemplary leadership qualities.

Below is the verbatim transcript of the interview.

Q. Do you feel that India is a preferred destination for conducting Clinical studies in comparison to the other developing countries? And Why?
A: Undoubtedly, India is a preferred destination in compared to other developing countries. There were some regulatory hurdles in past; however things have improved now. Also due to factors like availability of patient population, Good investigational sites and very good awareness of GCP India becomes preferred destination in comparison to other developing countries.

Q. Do you think that there is a hesitation in Global MNC’s with respect to outsourcing their clinical development to India considering issues highlighted by various regulatory bodies?
A: Yes, there is definitely hesitation amongst global MNC’s. People are aware that there are lot of regulatory non-compliance by the manufacturing units. And some of the BE centers have also come into limelight in past 3-4 years with problems. Data integrity is always an issue and it is apparent that people have resorted to shorter routes leading to Non-Compliance which does not work.

Q. What should Global MNCs be aware of when choosing a CRO in India?
A: First thing is they have to do a very good due diligence audit of a CRO. While CRO attract the attention of sponsors on cost front it is the quality performance that take precedence. Consistence quality with measurable parameters will always be the first criteria for selection.

Q. What advice would you give to international pharmaceutical companies planning to work with an Indian CRO? How would you differentiate one CRO in India from another especially when they all seem to have good regulatory track record?

A: I would suggest to use a correct independent third party & not the one who is associated with any CRO. To get a better confidence over the CRO, sponsor should get 2-3 audits conducted per year by the third party auditor.

Differentiation would be challenging if all the CRO(s) have good regulatory track record. However, CRO's value addition to the Sponsor can be one of the factors. In addition to the execution of studies from Sponsor, CRO can portray as differentiator in the market in terms of providing scientific inputs, better responsiveness & communication as well ensuring the Quality of project management and bio pharmaceutics support. I would add here that don't over sell; instead have right systems & provide quality work.

Q. What are the emerging trends in BE studies and do you think that Indian CROs are gearing up to meet the requirements of emerging trends?

A: Sponsors are just not looking for conduction of BE studies, they are looking beyond that. Sponsors seek opinion from the CRO(s) on the expertise in designing the product which is bioequivalent. Many small and mid-sized companies are looking for CRO(s) which can assist them in scientific designing of the study by evaluation of the supporting data closely. In addition, CRO(s) who do have expertise in complex bio-studies which are challenging to execute, can be one of the emerging trend in clinical research. The CRO(s) who showcase their expertise in the domain of special studies segments like inhalation, dermatology, ophthalmic, complex bio-analysis, etc. in addition to the conventional BE studies would be able to adapt the emerging trends in the industry.

On a closing note, Mr. Dasgupta mentioned that "Quality is the only way we can support and deliver to the global Pharma Industry. If anybody falls apart than there is black spot on the entire industry".

Disclaimer:

The opinions expressed in this publication are those of the Interviewee and are not intended to malign any ethic group, club, organization, company, individual or anyone or anything. Examples of analysis performed within this publication are only examples. They should not be utilized in real-world analytic products as they are based only on personal views of the Interviewee. They do not purport to reflect the opinions or views of the VEEDA CRO or its management. Veeda CRO does not guarantee the accuracy or reliability of the information provided herein.