

Webinar Q&A Report:

Data Integrity in Decentralized Clinical Trials (DCTs)

- 1. Do you think that small trialists will leave the field of clinical investigation to large trialists because the former can no longer mobilize the necessary resources (training, IT, specialized healthcare professionals (HCPs)) to meet its new challenges?**

The review of the clinical trials landscape by K Getz of Tufts suggests that this change is not a random event. A plausible explanation is the increasing complexity of clinical trials.

- 2. If statistical monitoring techniques are not as effective when the data volume is low, what's the best approach to use for small studies?**

The approach and the principles remain valid and applicable even with low data volume and small sample sizes, regardless of whether one can rely on the results of the statistical tests. However, for smaller studies, one has to focus more on identifying the trends through qualitative analysis and judgment, rather than relying on statistical significance. Better understanding of the data helps.

- 3. Do you have an idea of how the HCPs involved in clinical trials (CTs) have embraced their evolving role in the context of decentralized clinical trials (DCTs)?**

We have not done a survey to address that question and we do not know anybody else having done that although it would be reasonable to think that large contract research organizations (CROs) have. The very high turnover of HCPs involved in CTs (as privately reported to us by a very large CRO) might be an indication either of the high demand and low supply for those competences or a general dissatisfaction with the current situation of HCPs.

- 4. Would it help if companies involved in conducting clinical trials come together to create training programs specifically for HCPs and monitors/data managers to deal with the peculiar requirements of DCTs?**

In theory, yes but in practice these good intentions might be pushed aside by the competition to retain talent and competences at the lowest effective cost.

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