

Mahajan, Vinay

From: Kenny, Dermot
Sent: Friday, February 23, 2018 2:20 AM
To: DO_DU_ORG_GBL
Cc: Leconte, Olivier; Gallagher, James; Walsh, Simon; Ebert, Leianne; Ramesh, Venkataramana; Thata, Raghuram; Clark, Sarah; CHEN, Wei J; Nishida, Shinji
Subject: IMPORTANT : Alleged misconduct with external contractor resource.

Dear DODU team,

I wanted to give you a brief update on an issue we are managing with our CRO partners and which is creating some noise internally..

Background :

We were made aware through separate whistle-blower allegations that there may be resources at our CRO partners (both ICON and GCE) who are employed in MCC locations but who are actually using a screen share technology to have their work done by a third party from a low cost location. To be clear, the allegation is not that the CROs are doing this but that the resources they have hired (who work remotely) are doing this independently. The scope appears at this point to be limited to statistical programming activities. This clearly creates a number of issues for us around data quality, data integrity and data privacy. In a further anonymous allegation it has been alleged that internal Novartis staff may be involved in this arrangement but with no detail around what form this involvement may take.

What are we doing ?

We have launched an investigation to try to address the concerns and validate or dismiss the allegation.. there are a number of streams to this investigation, summarized below. In addition, all suspected associates have been removed from the Novartis account with immediate effect.

Compliance : Our QA/REG colleagues are working with the CRO partners to determine whether or not this alleged breach creates compliance issues that require Health Authority notification. So far, we have not determined that a notification is required although we are assessing this regularly

Quality : Both partners have performed a full QC on all work product produced or validated by suspected associates since the beginning of our engagement. This effort is ongoing but to date, no critical quality issues have been identified. At this point, we have no confirmed concerns that any of our work product is adversely impacted.

Security : Our IT security colleagues are working with our CRO counterparts to ensure the right mechanisms are in place to prevent such issues in the future and to look beyond the whistleblower list to identify any other potential issues. Our internal IT colleagues will also be looking to see if there is any evidence that Novartis staff may be implicated in this.

Legal : Our legal team are working with those of our partners to determine what, if any actions we can take against the suspected associates.

BPO : Given that there is an allegation against unnamed internal Novartis staff, we have engaged the NVS BPO and they will launch their own investigation.

What do we need from you ?

Right now, nothing. . . I am sending you this note so that you are aware of the issue and are not blindsided if asked about it by your customers. Please do not proactively communicate anything around this issue at this point and **please do not forward this message**. If asked about this by your customers, you should be clear and concise in your response and limit it to the facts as they are known . .

1. An anonymous allegation has been made impacting both of our CRO partners
2. We have not found any hard evidence to corroborate this allegation
3. We have launched an internal investigation to address the issue at all levels (security, compliance, legal, quality)
4. We have completed QC activities and we do not believe that any work product has been compromised
5. If and when we make further discovery that impacts your programmes we will contact you straight away

If you have any further questions or concerns or if you need any more information, please do not hesitate to reach out to me directly.

Many Thanks

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Sent from my iPad