Intended for healthcare professionals

Rapid response to:

Feature BMJ Investigation

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

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Rapid Response:

Re: Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

Responses to BMJ investigation

In September, Brook Jackson contacted The BMJ about problems she had encountered while employed at Ventavia Research Group. The BMJ commissioned freelance investigative reporter Paul Thacker to write up the story. The resulting article [1] was subject to The BMJ's usual high level editorial oversight and review. After publication, The BMJ wrote to Ventavia, Pfizer and the U.S. Food and Drug Administration (FDA) to better clarify the scope and implications of the problems identified at Ventavia, as well as what corrective measures were taken.

To date, Ventavia has not responded to The BMJ's repeated requests for information. However, in statements to other media outlets, Ventavia has claimed that its former employee Jackson did not work on Pfizer's covid-19 vaccine clinical trial. This claim is not true. Jackson has contacted media organisations that have published these false allegations, sharing documentation that shows her work on the trial, and asking for corrections. At the time of writing, MedPage Today has updated its article.[2]

During the course of this investigation, Jackson has provided The BMJ with dozens of documents, photos, audio recordings, and emails. These include evidence of her involvement in the clinical trial, and communications in which senior Ventavia employees discuss concerns that the FDA might show up at their clinical sites. These records were reviewed by The BMJ's editors, and the story was externally peer reviewed before publication.

At the time of Jackson's complaint to the FDA, Ventavia had already enrolled more than 1000 participants across its three clinical trial sites and was still actively enrolling participants. Among the full trial's 44,000 participants, the total number recruited by Ventavia is still unknown. Another former Ventavia employee has told The BMJ that Ventavia ultimately recruited many more participants to Pfizer's clinical trial than those reported to the FDA by Jackson. However, neither Pfizer nor Ventavia will respond to questions from The BMJ to help clarify this matter.

Pfizer responded to The BMJ stating that it had received an anonymous complaint about Ventavia in September 2020. "Actions were taken to correct and remediate where necessary. Pfizer's investigation did not identify any issues or concerns that would invalidate the data or jeopardize the integrity of the study."

Pfizer added that the FDA and the study's Institutional Review Board (IRB) were "proactively notified." Pfizer did not clarify whether it was Pfizer or Ventavia that notified the FDA and the IRB.

Pfizer did not respond to our question of whether the data from the Ventavia sites were incorporated into the trial's safety and efficacy analyses.

The BMJ also posed several questions to the FDA including why it had failed to inspect any of Ventavia's sites following Jackson's report, and whether the agency had received other complaints about the conduct of the Pfizer trial. An FDA spokesperson responded that the agency cannot comment further on this as it is an ongoing matter. "FDA has full confidence in the data that were used to support the Pfizer-BioNTech COVID-19 Vaccine authorization and the Comirnaty approval."

References

[1] https://www.bmj.com/content/375/bmj.n2635
[2] https://www.medpagetoday.com/special-reports/exclusives/95484

Competing interests: No competing interests

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