Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel
Federal Institute for Vaccines and Biomedicines

Paul-Ehrlich-Institut

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STATEMENT

CLINICAL TRIAL OF COMIRNATY® FROM BIONTECH

Allegations of failures in clinical trial of BioNTech's COVID-19 vaccine – article in British Medical Journal on 2 November 2021

On 2 November 2021, the British Medical Journal (BMJ) reported from a whistleblower alleging errors and possible falsification of data in BioNTech/Pfizer's pivotal phase 3 trial of COVID-19 vaccine in Texas. The allegations include falsification of data, unblinding of subjects in what should have been a double-blind study design, involvement of inappropriately trained vaccinators, and slow recording of adverse vaccine reactions. These accusations come from an employee of the company (Clinical Research Organisation, CRO) that conducted the clinical trial.

There are very strict guidelines for the conduct of clinical trials, and compliance with these guidelines is checked during the trial not only by possible inspections by the authorities, but also always as part of the monitoring process. In terms of content, the allegations made are to be taken seriously, but it should be noted that the employee who made the allegations only worked at the company concerned for a fortnight.

For the efficacy and safety of the study participants and for all vaccinated persons after the approval of vaccines, it is of central importance that clinical trials are carried out accurately according to the specifications. Deviations such as unblinding, working with scientists or physicians who are not appropriately trained, or possible deception in the documentation are not acceptable. Since the Paul-Ehrlich-Institut was not involved in U.S. inspections on Comirnaty®, concrete statements by the Paul-Ehrlich-Institut on these allegations and their justification are not possible. The primary contact is therefore the U.S. FDA – the U.S. Food and Drug Administration.

It is important to note that the damage that may have been done to the validity of the phase 3 clinical trial by the above-mentioned violations of the prescribed Good Clinical Practice (GCP) could arguably be less to the overall efficacy and safety results presented at the time of approval. Drug regulatory authorities must be confident in the results of clinical trials and this must be justified by rigorous adherence to and control of Good Clinical Practice. After all, citizens and patients must be able to rely on the preclinical and clinical reliability of medicinal products being investigated and evaluated before they are authorised, and in accordance with the prescribed high quality standards of Good Clinical Practice.

The contracting company (Ventavia) against which the allegations were made was responsible for approximately 1,000 study participants. In total, however, more than 40,000 people took part in this phase 3 study in about 150 study centres.

The efficacy and safety of the COVID-19 vaccine Comirnaty® from BioNTech/Pfizer, as well as the corresponding results from the phase 3 clinical trial, have also been confirmed after authorisation in the now millionfold use of the vaccine.