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To those affected
their doctors and caretakers
To Groups and Institutions
To Media

Zurich 24th August 2022

Dear Sir/Madam

Dear Contemporaries

You find following the translation of the document that Martina Frei has published on the 16th Augustin the Swiss online magazine Infosperber.

Covid vaccine trials: Independent review is likely to be delayed

Pfizer/Biontech extend their study by 9 months - because of one person. This is likely to affect data sharing.

Independent scientists have been trying for a long time to get the raw data from the large mRNA vaccination studies. The first interim evaluation of the (currently still ongoing) studies formed the basis for the accelerated approval of the mRNA vaccines at the end of 2020. These scientists want now to use the raw data to calculate and check the results themselves.

Pfizer had written in the study protocol that the company would make the data available to qualified scientists two years after the study was completed. However, Pfizer has now pushed back the study's scheduled completion date of May 2023 by nine months. Reason: Only one of around 44,000 people taking part in the study was only vaccinated for the second time in April 2022. That's delaying everything.

The manufacturer Moderna has also postponed the originally expected completion date of its large vaccination study. Instead of October 27, the study is now scheduled to be completed on December 29, 2022.

Independent researchers who want to see the raw data from Moderna or Pfizer may now have to wait longer, writes the British Medical Journal, which reports all this. https://www.bmj.com/content/378/bmj.o1731

If the authorities had had their way, all the documents would only have been accessible after more than 50 years

Of six major drug regulatory agencies in the western world, only two, Japan and the United States, routinely receive the raw data from pharmaceutical manufacturers.

The other drug authorities could get this data on request, according to another search by the British Medical Journal.
https://www.bmj.com/content/377/bmj.o1538

When over 80 professors and scientists asked the US Food and Drug Administration (FDA) to release the raw data from Pfizer/Biontech's large Covid vaccination study so that they could be independently checked, the agency referred to the associated workload.

The FDA offered to open 500 pages per month, so that after about 55 to 75 years all documents would be publicly available. She pointed out that the responsible department only had ten employees who also had to process around 400 other inquiries, reported the "Deutsche Wirtschaftsnachrichten" in December 2021 https://deutsche-wirtschafts-nachrichten.de/516101/US-Lebensmittelbeh However, a court rejected the FDA's request. The FDA snarled at releasing documents.
https://www.bmj.com/content/bmj/377/bmj.o1538.full.pdf

The public is also groping in the dark when it comes to the Omicron booster

Also with regard to the booster vaccine with the omicron component that may be vaccinated next autumn, "the public needs transparent, open details about the studies so that they can decide for themselves whether they want to be vaccinated or not," said Dick Bijl, the President of the International Society of Independent Drug Bulletins https://www.isdbweb.org/what-is-isdb, to the British Medical Journal.
https://www.bmj.com/content/378/bmj.o1731

Unanswered questions about security

Doubts have also been raised recently, this time about the safety of mRNA vaccines. Independent scientists led by US professor Peter Doshi evaluated data from the approval studies and data submitted to the FDA. The result of their study, which has not yet been verified by third parties
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239

Severe side effects, which had already been classified as "of particular interest" in the run-up to the vaccination campaign, occurred in almost 13 per 10,000 mRNA-vaccinated people. According to the scientists, the number of serious side effects from the vaccine was at least twice as high as the hospitalizations prevented by the vaccine.
Other studies, however, came to different conclusions and attested, for example, that the Pfizer/Biontech vaccine had a very small risk of serious side effects.
Given these discrepancies, it would be all the more important for independent scientists to have access to the raw data. If they confirmed the information from Moderna and Pfizer/Biontech, that would be confidence inspiring. The blocking and delaying tactics of both the FDA and the manufacturer, on the other hand, only fuel skepticism.

German text:

https://www.infosperber.ch/gesundheit/public-health/covid-impfstudien-unabhaengige-pruefung-wird-sich-wohl-verzoegern/