



### After the unexplained change on February 15, 2021, what were the new Vaccine Effectiveness coding conventions?

For “**drug ineffective**,” the new definition included any of the following:

- Infection was not confirmed by a lab test
- Unknowns present:
  - vaccine doses followed proper local regimen
  - how many days since first dose
  - whether seven days passed since second dose
- COVID onset between 14 days after first dose and through six days after second dose

For “**vaccination failure**,” the new definition required **all three** of the following:

- Both doses received per local regime
- At least seven days since the second dose
- Infection with confirmed lab test positive for SARS-CoV-2

Based on the revised criteria, Pfizer classified 1,649 cases as “drug ineffective.” One thousand six hundred and twenty-five (**98.5%**) of these cases were labeled “**serious**,” but no reasoning for this label was given. **The FDA has formally defined a “serious adverse event,” but that specific term was not used in Table 6;** and the FDA Glossary of Terms does not include a definition for “clinical events” or “serious clinical events.” Did the patients have serious illness, or was inadequate performance of the inoculation considered serious?

Information is provided on how many doses of BNT162b2 had been given for only 927 cases. Table 6 states “lack of efficacy was reported after the first dose in 788 cases.” By the Pfizer definition of lack of efficacy, these 788 were definitely not drug failure. One hundred and thirty-nine cases occurred after the second dose of BNT162b2. An additional 722 of the 1,649 cases (44%) had “unknown timing” regarding whether the infection was after one or two doses of BNT162b2. This means some or all of the 861 cases (139 plus 722) could have been classified as drug failure if missing information had been available. Without obtaining more details on the remaining 861 cases, there is no way to know whether they were “drug ineffective” or “drug failure.” **Only 788 of the 1,649 (47.8%) drug ineffective cases can be stated categorically *not* to have been drug failure.**

Latency was reported in 654 cases and was missing in 995 cases (60%). Of those with latency reported *after the second shot*, 27 occurred between eight and 21 days. Had a COVID test been documented, some or all of those 27 might have been classified as vaccine failure. Another 409 cases did not include the number of vaccine doses but recorded the latency from the last dose. One hundred twenty-eight of these 409 had COVID-19 diagnosed eight to 44 days after the last dose. These 128 might also represent drug failure. Remember, 1,625 of the 1649 “drug ineffective” cases were classified “serious.”

However, in Table 6, using the revised coding conventions, only 16 cases were specifically classified as “vaccination failure.” Six had “asymptomatic COVID-19” and 10 had “COVID-19.” This is a suspiciously low number for drug failure. Up to another 861 might have been true drug failure had missing data been collected.

### Why did Pfizer revise the coding conventions just 13 days before the 90-day reporting period ended?

An educated guess suggests the revised coding added a requirement for positive COVID-19 testing rather than only accepting clinical symptoms. This would be a necessary feature for a peer-reviewed study; but, in the midst of a pandemic when testing was not necessarily readily available or considered a high priority by a sick, homebound person, it may have been viewed as a convenient way to exclude troublesome cases. The inescapable conclusion is that the revision was *not* to make the data on drug failure look *worse*.

What does it mean in the coding conventions that the subject “has received the series of two doses *per the dosing regimen in local labeling*” (italics added)? Are there different regimens in different localities or different parts of the world?

To conclude with two other unresolved points: Why does Pfizer avoid the standard FDA classifications of adverse events? What does it mean that there were 1,625 serious “cases”?

The evasive phrasing throughout renders this table even more obscure than those previously analyzed.

#### SOURCE:

[https://www.phmpt.org/wp-content/uploads/2022/04/reissue\\_5.3.6-postmarketing-experience.pdf](https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf)

SEQUELAE: an abnormal condition resulting from a previous disease, injury, or other trauma

#### AGE GROUPS defined in 5.3.6

(p. 25 footnote) :

Adult	18 - 64
Elderly	≥ 65
Child	2 - 11
Adolescent	12 - < 18
Infant	1 – 23 months



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