War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 16:

Respiratory Adverse Events of Special Interest Review of 5.3.6

Of the 130 total patients in this SOC, **41 (32%) died.**
Of the 137 relevant events, **126 were categorized as serious.**

Respiratory AESIs *Search criteria: Lower respiratory tract infections NEC (HLT)*	• Number of cases: 130 cases (0.3% of the total PM dataset), of which 107 medically confirmed;

AESIs[a] **Category**	**Post-Marketing Cases Evaluation[b]** **Total Number of Cases (N=42086)**
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

- **Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.**
- **In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.**
- **Pfizer identified 130 cases (patients) under these criteria with 137 "relevant events" (diagnoses). The case reports came from 19 countries.**
- **There was female predominance with 72 females and 58 males. Age distribution was 78 elderly, 47 adults, and one adolescent.**

This category includes conditions of damaged lung structure or impaired oxygen or carbon dioxide exchange. Acute respiratory distress syndrome (ARDS) is a lung injury with fluid leaking from the blood vessels into the lung tissue as well as the air spaces (alveoli). This results in stiffness of the lung requiring markedly increased work to breathe, as well as reduced oxygen and carbon dioxide exchange.

Low blood oxygen level and high carbon dioxide diagnoses are included as well as impaired breathing necessitating use of a mechanical ventilator via a tube into the windpipe (trachea). Hemorrhage into the lung was part of the search criteria but no cases were identified. Coughing up blood was reported separately in the prior Hematological SOC.

Viral and bacterial pneumonia were part of the search criteria but no instances of these were found. Severe acute respiratory syndrome (SARS) was listed as a search term for this SOC. Covid-19 (SARS CoV-2) cases are in a separate SOC.

Regarding the overwhelming number of respiratory events (126 of 137 or 92%) categorized as "serious" in this SOC: According to the FDA, **serious adverse events include**, but are not limited to, patient outcomes such as **death, life-threatening events, hospitalizations, and disability or permanent damage.**

https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

Forty-seven were "resolved/resolving," 18 "not recovered," and **31 had "unknown" outcome.** One hundred and two adverse events had a record of time from injection to onset. The range was from within 24 hours to 18 days with **half of the events reported at one day.**

SOURCE

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

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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02Aug23