



## War Room/DailyClout Pfizer Document Analysis

### Post-Marketing Team Micro-Report 8:

#### Facial Paralysis System Organ Class (SOC) Review of 5.3.6

#### 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)

#### 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.”

#### 5.3.6 AE CASES/EVENTS:

TOTAL AE CASES: 42,086

TOTAL AE EVENTS: 158,893

#### 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

#### AUTHORS:

Dr Joseph Gehrett MD  
Dr Barbara Gehrett MD  
Dr Chris Flowers MD  
Loree Britt



08Mar23

Facial Paralysis	
Search criteria: PTs Facial paralysis, Facial paresis	<ul style="list-style-type: none"> <li>Number of cases: 449 (1.07% of the total PM dataset), 314 medically confirmed and 135 non-medically confirmed;</li> <li>Country of incidence: US (124), UK (119), Italy (40), France (27), Israel (20), Spain (18), Germany (13), Sweden (11), Ireland (9), Cyprus (8), Austria (7), Finland and Portugal (6 each), Hungary and Romania (5 each), Croatia and Mexico (4 each), Canada (3), Czech Republic, Malta, Netherlands, Norway, Poland and Puerto Rico (2 each); the remaining 8 cases originated from 8 different countries;</li> <li>Subjects' gender: female (295), male (133), unknown (21);</li> <li>Subjects' age group (n=411): Adult (313), Elderly (96), Infant and Child (1 each);</li> <li>Number of relevant events<sup>a</sup>: 453, of which 399 serious, 54 non-serious;</li> <li>Reported relevant PTs: Facial paralysis (401), Facial paresis (64);</li> <li>Relevant event onset latency (n = 404): Range from &lt;24 hours to 46 days, median 2 days;</li> <li>Relevant event outcome: resolved/resolving (184), resolved with sequelae (3), not resolved (183) and unknown (97);</li> </ul>
	<p>Overall Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue. Causality assessment will be further evaluated following availability of additional unblinded data from the clinical study C459101, which will be unblinded for final analysis approximately mid-April 2021. Additionally, non-interventional post-authorization safety studies, C4591011 and C4591012 are expected to capture data on a sufficiently large vaccinated population to detect an increased risk of Bell's palsy in vaccinated individuals. The timeline for conducting these analyses will be established based on the size of the vaccinated population captured in the study data sources by the first interim reports (due 30 June</p>

Table 7. AESIS Evaluation for BNT162b2

AESIS <sup>a</sup> Category	Post-Marketing Cases Evaluation <sup>b</sup>
	Total Number of Cases (N=42086)
	2021. Study C4591021, pending protocol endorsement by EMA, is also intended to inform this risk.

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

The data collected and reported here are commonly referred to both medically and in lay terminology as Bell's Palsy, though the search criteria was limited to facial paralysis and facial paresis. Under these terms, Pfizer reports **449 persons with this syndrome or 1.07% of the total patients reporting adverse events during this time period.**

**Of the “relevant events,” 399 (88%) were classified as serious.** Of the 404 events where time of onset was recorded, the time from vaccination to the adverse event becoming apparent ranged from within the first 24 hours to 46 days, with **half of the facial events observed within two days.**

The outcomes of this SOC were as follows: 184 (39%) were reported as “resolved or resolving,” though we do not know about the final degree of resolution in the “resolving” patients. Three (<1%) resolved with sequelae, **183 (39%) were not resolved, and in 97 (21%) there was no assessment as to resolution.**

- 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.
- The demographics of the cases included 295 (66%) female, 133 male (30%), and 21 (5%) not reported.
- Age was reported for 411 persons with elderly 96 (21%), adult 313 (70%), and one each in the infant and child age groups.

In this SOC there is only one clinical finding: damage to the 7<sup>th</sup> cranial nerve resulting in weakness or paralysis of the side of the face that is supplied by that nerve. The consequences can be eye damage from inability to close the eyelid, impaired speech and impaired mouth closure (drooling) with eating, impaired social engagement, and potentially impaired employment.

**A one-year-old infant developed a Bell's palsy one day after vaccination. It was unresolved at the time of the 5.3.6 report. These details were discovered in a footnote at the end of Table 7. The vaccine was not approved for use in children or infants at the time.**

#### Emerging Patterns in 5.3.6 Table 7 Patients:

- Adverse Events in Women > Men at the rate of 2:1
- Inconsistent SOC categorization diluting full impact of adverse events
- Well over half the AEs with latency reported occurred within five days