OCLA

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Highlights from yesterday's Pfizer documents release👇

1/ The full documents can be downloaded from the link here:

Pfizer's Documents – Public Health and Medical Professionals for Transparency
Public Health and Medical Professionals for Transparency Documents Pfizer's Documents
https://phmpt.org/pfizers-documents/

2/ Pfizer acknowledges that VAERS reports adverse events are adequate to establish safety concerns about its product.

File: 125742_S1_M1_waiver-req-designated-suffix.pdf

BNT162b2
Module 1.12.5 Waiver Request for FDA Designated Suffix for Biologics

2.2. VACCINE SAFETY MONITORING SYSTEMS

Vaccine safety monitoring systems include;

- Vaccine Adverse Event Reporting System (VAERS) is designed to detect safety concerns with vaccines. HCPs and manufactures are required to report adverse events to VAERS. Consumers can also report to this system and further reporting may be burdensome and discouraging.

- Vaccine Safety Datalink (VSD) which utilizes data from doctors' offices, urgent care visits, emergency department visits, and hospital stays to monitors vaccine safety and conduct studies on rare and serious side effects of vaccines. These studies also include concerns raised in literature. The VSD also submits their reports to VAERS.

- The Post-Licensure Rapid Immunization Monitoring System (PRISM) is yet another means by which vaccine safety is evaluated. As part of the Agency's Sentinel system, PRISM is linked to statewide registries and is being used to develop signal detection tools for evaluation of adverse events.

3. CONCLUSION

As outlined above, there are adequate policies and systems in place to ensure the safe dispensing and optimal pharmacovigilance of vaccines which COVID-19 will be subject to. Additional requirements such as a designated suffix may be redundant and burdensome. Toward that end, we respectfully request a waiver from the requirement for an FDA designated suffix for COVID-19 mRNA Vaccine (nucleoside modified), the subject of this BLA application.

3/ Trial participants used an "e-diary" app to grade adverse reactions following injection.

"Pain at the injection site" was severe if it "prevents daily activity"

File: 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf

Table 2. Local Reaction Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Pain at the injection site	Does not interfere with activity	Interferes with activity	Prevents daily activity	Emergency room visit or hospitalization for severe pain
Redness	2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis or exfoliative dermatitis
Swelling	2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis

4/ For the e-diary, vomiting was severe if it required IV hydration

File: 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf

Table 3. Systemic Event Grading Scale

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Vomiting	1-2 times in 24 hours	>2 times in 24 hours	Requires IV hydration	Emergency room visit or hospitalization for hypotensive shock
Diarrhea	2 to 3 loose stools in 24 hours	4 to 5 loose stools in 24 hours	6 or more loose stools in 24 hours	Emergency room visit or hospitalization for severe diarrhea
Headache	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe headache
Fatigue/ tiredness	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe fatigue
Chills	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe chills
New or worsened muscle pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened muscle pain
New or worsened joint pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened joint pain

Abbreviation: IV = intravenous.

5/ Severe vomiting in the trial group.

File: 125742_S1_M1_priority-review-request.pdf

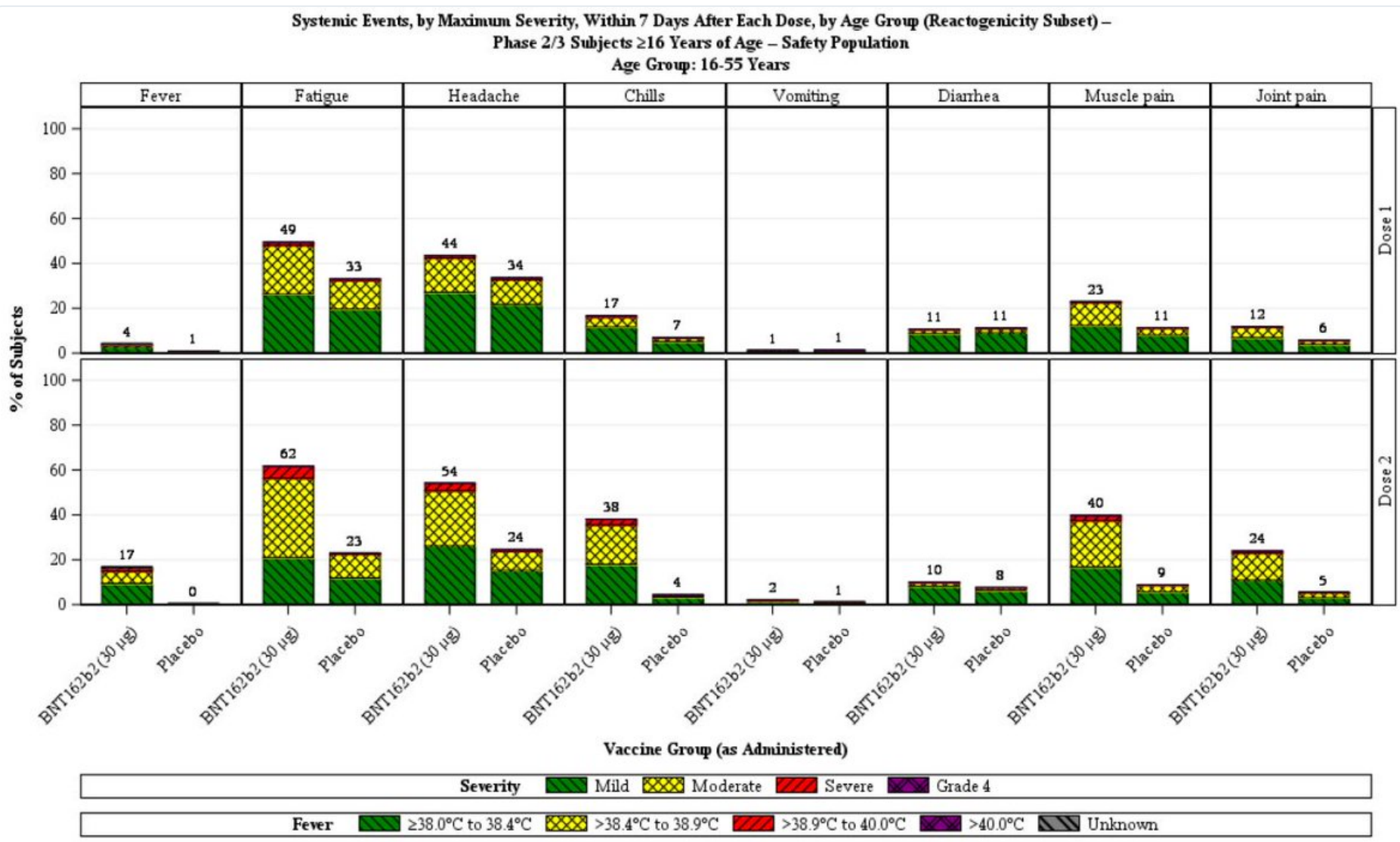
	Vomiting[f] ~~Vomiting[e]~~						
	Any	4368	69 (1.6)	(1.2, 2.0)	4334	31 (0.7)	(0.5, 1.0)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Baseline SARS-CoV-2 Status (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

			Vaccine Group (as Administered)					
			BNT162b2 (30 µg)			Placebo		
Baseline SARS-CoV-2 Status	Dose	Systemic Event	N[a]	n[b] (%)	(95% CI[c])	N[a]	n[b] (%)	(95% CI[c])
		Mild	4368	51 (1.2)	(0.9, 1.5)	4334	23 (0.5)	(0.3, 0.8)
		Moderate	4368	13 (0.3)	(0.2, 0.5)	4334	8 (0.2)	(0.1, 0.4)
		Severe	4368	5 (0.1)	(0.0, 0.3)	4334	0	(0.0, 0.1)
		Grade 4	4368	0	(0.0, 0.1)	4334	0	(0.0, 0.1)

6/ Many more "systemic events" including moderate and severe in the trial group than the placebo group.

File: 125742_S1_M5_c4591001-T-S-updated-reacto-tlf.pdf



7/ Hundreds of AEs in the trial group were changed ("updated") by clinical investigators. Why and how were these reports changed?

Summary of Differences Between CSR Reactogenicity Data and Updated Reactogenicity Data for Study C4591001 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg)	Placebo
Number of total reactogenicity records	447303	447749
Number (%) records affected[a]	536 (0.12)	140 (0.03)
Number of subjects	2923	2941
Number (%) subjects with any records affected	109 (3.73)	48 (1.63)
Maximum difference (updated data-CSR data) across any local reaction term of the percentage of subjects with a local reaction within 7 days of first vaccination[b]	0.1	0.2

(Table cropped)

Abbreviations: CRF = case report form; CSR = clinical study report
Note: CSR data is data reported in the CSR that was entered into the electronic diary by the subject and symptom resolved page by the investigator. Updated data is the CSR data and the reactogenicity data entered in the AE log CRF page by the investigator.
a. An affected record is any record that changed during the reactogenicity update.
b. Maximum difference is displayed as a percentage and is for reactogenicity data.

8/ In the VAERS database, "dyspnoea" (shortness of breath) was the most common symptom for people who had a "life-threatening" adverse event following a COVID19 vax.

9/ Other common symptoms for life-threatening events post-COVID19-vax in VAERS that were not "e-diary" options in the Pfizer trial:

-Dyspnoea (20% of life-threatening AEs)
-Pulmonary embolism (13%)
-Chest pain (11%)
-Dizziness (7%)
-Nausea (7%)
-Deep vein thrombosis (6%)

10/ Why weren't shortness of breath (dyspnoea), chest pain, dizziness, and nausea, etc., included in the e-diary for Pfizer trial participants?

11/ See OCLA's report on the toxicity of the COVID-19 vaccines for more info on the more severe and deadly reactions: ocla.ca/wp-content/upl...

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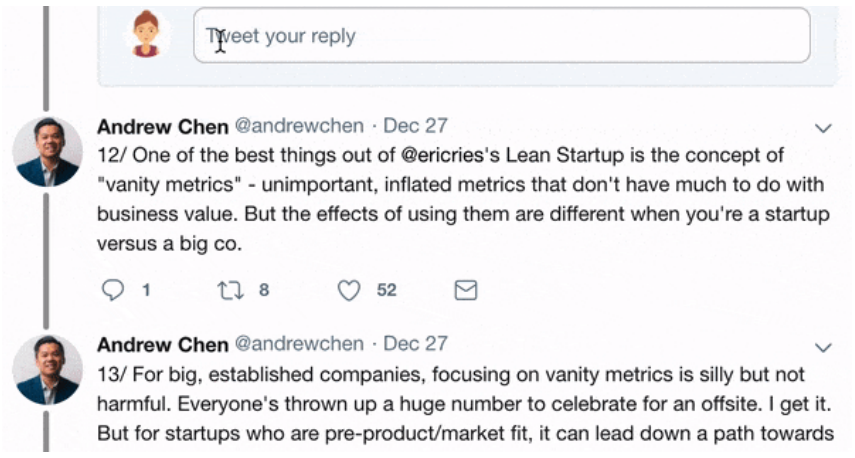

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Feb 27

1/ JFK-esque speech from Governor @RonDeSantisFL, Feb. 24, 2022 "We stood strong.. because we understand what it means to be a leader. Not just be a politician that twists in the wind, but be willing to make the tough decisions.

2/ President Eisenhower warned about the dangers of a rising scientific and technological elite... he said there's a danger that public policy can be held captive by this scientific elite and he said the job of a statesman is not to sub-contract out your policy

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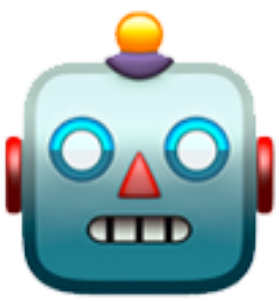

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