Preprint File available

Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines

Research Gate 2025. Sept 9 doi.org/10.13140/RG.2.2.16568.40961

DOI: 10.13140/RG.2.2.16568.40961

David M Wiseman

David Wiseman, PhD, MRPharmS

Synechion, Inc., Dallas, TX 75252

david.wiseman@synechion.com

@AdhesionsOrg

Very Short

Hundreds of COVID vaccine safety signals were lost in FDA's Empirical Bayesian analysis

Short

Hundreds of COVID vaccine safety signals were lost in FDA's Empirical Bayesian analysis due to truancy, masking, and filtering.

Longer

The hundreds of COVID vaccine safety signals lost from FDA's analysis represent still mostly uninvestigated **potential** risk FDA was **legally** required to consider **without** needing to determine causality.

Four foundations

1. *A statistical signal is declared when the number of reports for adverse event Y occurring after drug X meets certain statistical criteria*

Four foundations

1. *A statistical signal is declared when the number of reports for adverse event Y occurring after drug X meets certain statistical criteria*

2. *A signal means that we can reasonably suspect that drug X may have caused adverse event Y*

Four foundations

1. *A statistical signal is declared when the number of reports for adverse event Y occurring after drug X meets certain statistical criteria*

2. *A signal means that we can reasonably suspect that drug X may have caused adverse event Y*

3. *Further investigation is needed to establish that drug X caused adverse event Y*

Four foundations

1. *A statistical signal is declared when the number of reports for adverse event Y occurring after drug X meets certain statistical criteria*

2. *A signal means that we can reasonably suspect that drug X may have caused adverse event Y*

3. *Further investigation is needed to establish that drug X caused adverse event Y*

4. *Statistical signals are safety signals that represent potential risk FDA is required to consider for an EUA, without needing to establish causality*

Typical FDA weekly alert, listing signals found by Empirical Bayesian Data Mining (current to April 29, 2022)

Total 124 signals

Janssen 110 signals

Moderna 6 signals

Pfizer 8 signals

Highlight added

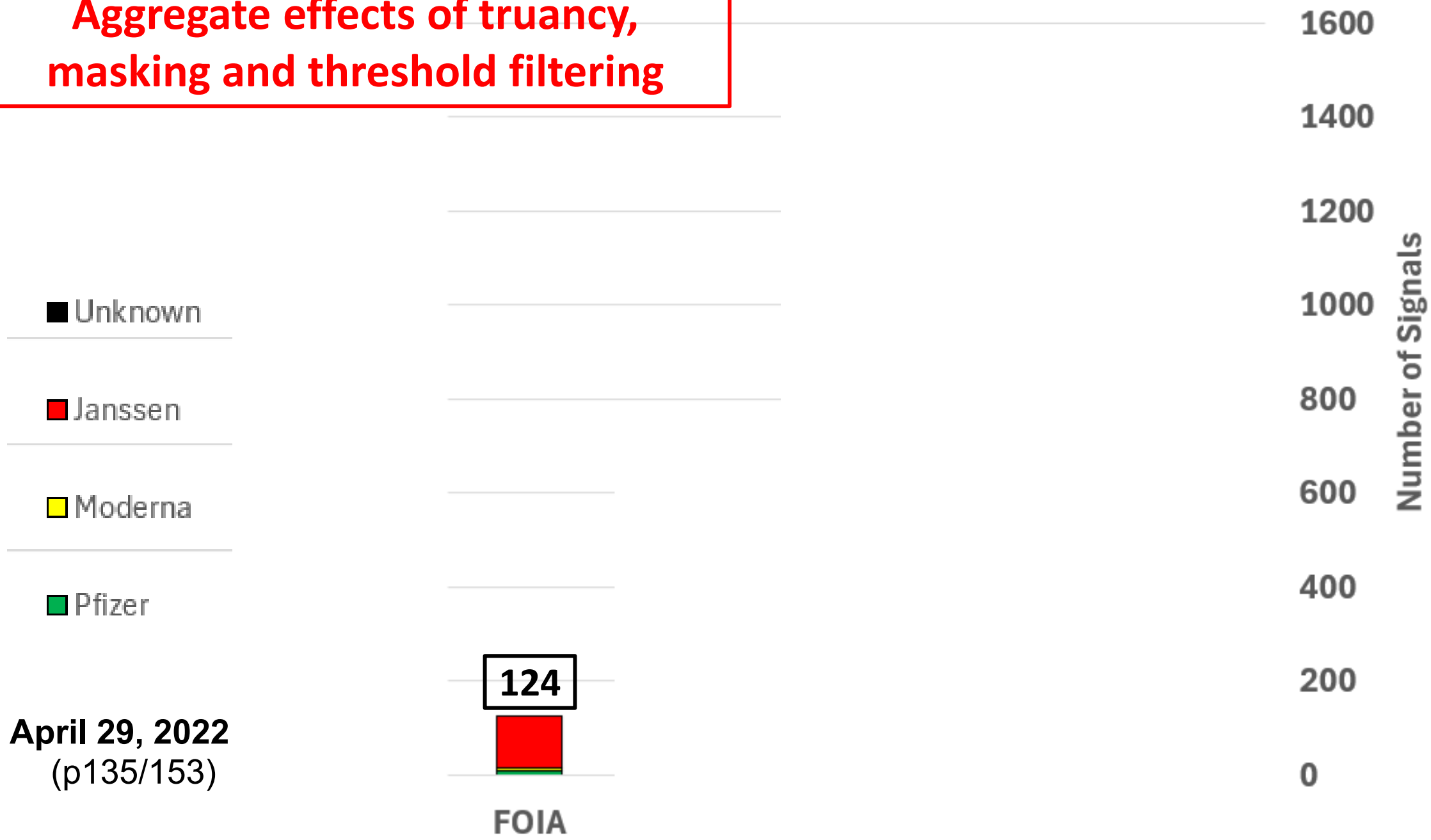
9-22 x excess of Janssen and dearth of Pfizer and Moderna signals

Varicose vein
Vasodilatation
Venogram
Venogram abnormal
Venogram normal

Exposure via breast milk
Interchange of vaccine products
Mechanical urticaria
Product administered to patient of inappropriate age
Product dose omission issue
Vaccination complication

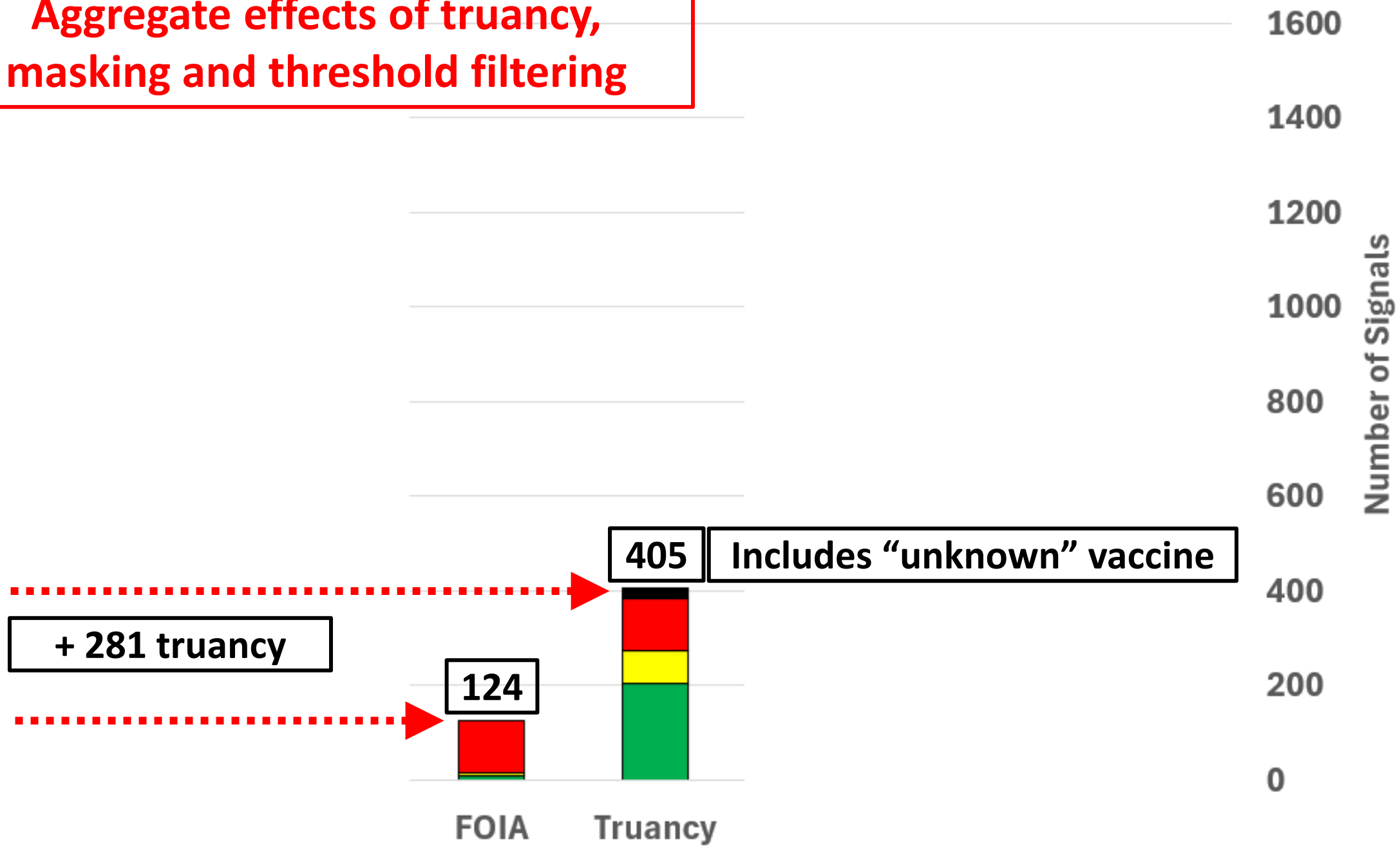
Body height
Disease recurrence
Drug ineffective
Exposure via breast milk
Immunisation
Investigation
Product preparation issue
Weight

Aggregate effects of truancy, masking and threshold filtering



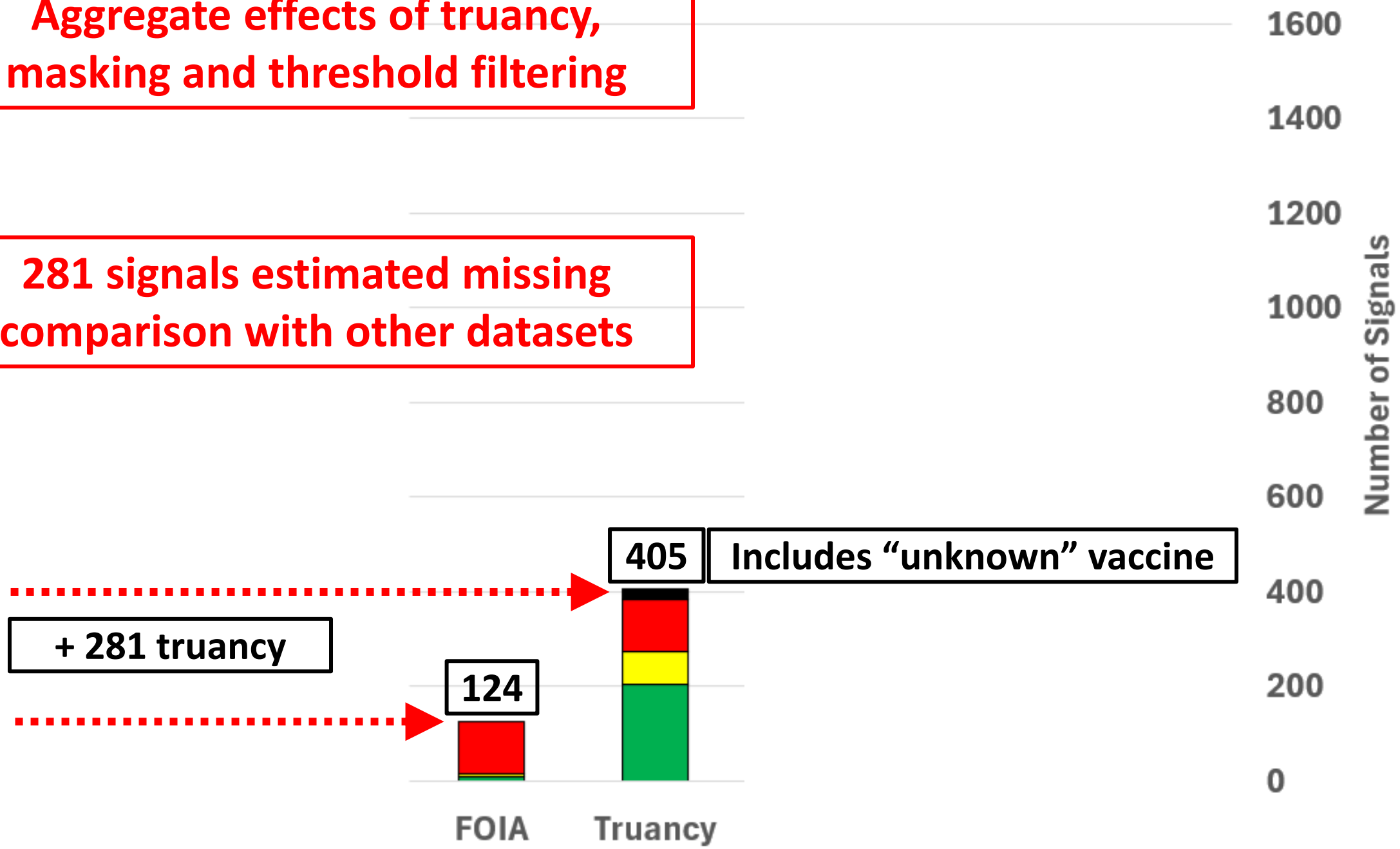
April 29, 2022
(p135/153)

Aggregate effects of truancy, masking and threshold filtering

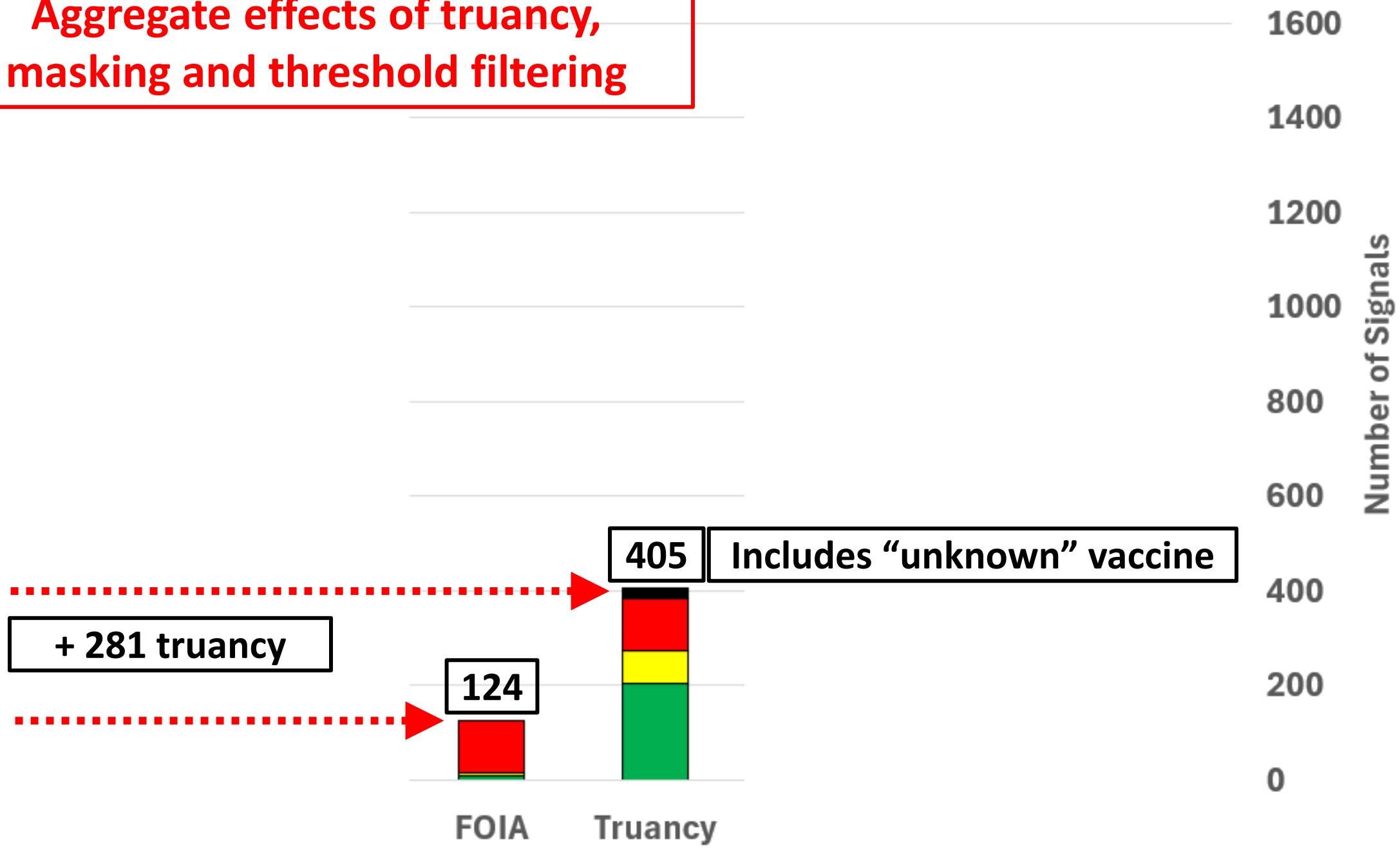


Aggregate effects of truancy, masking and threshold filtering

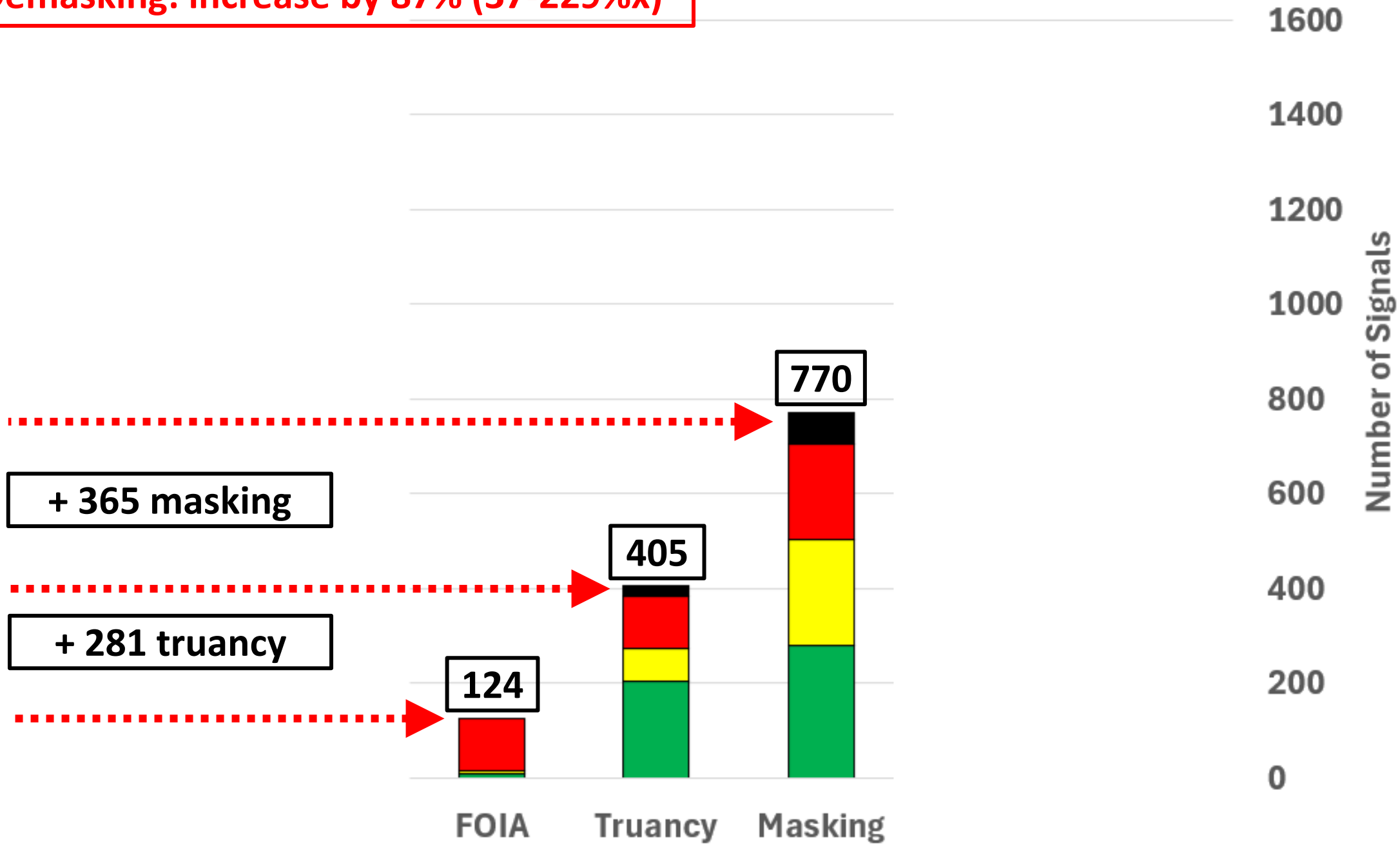
281 signals estimated missing comparison with other datasets



Aggregate effects of truancy, masking and threshold filtering

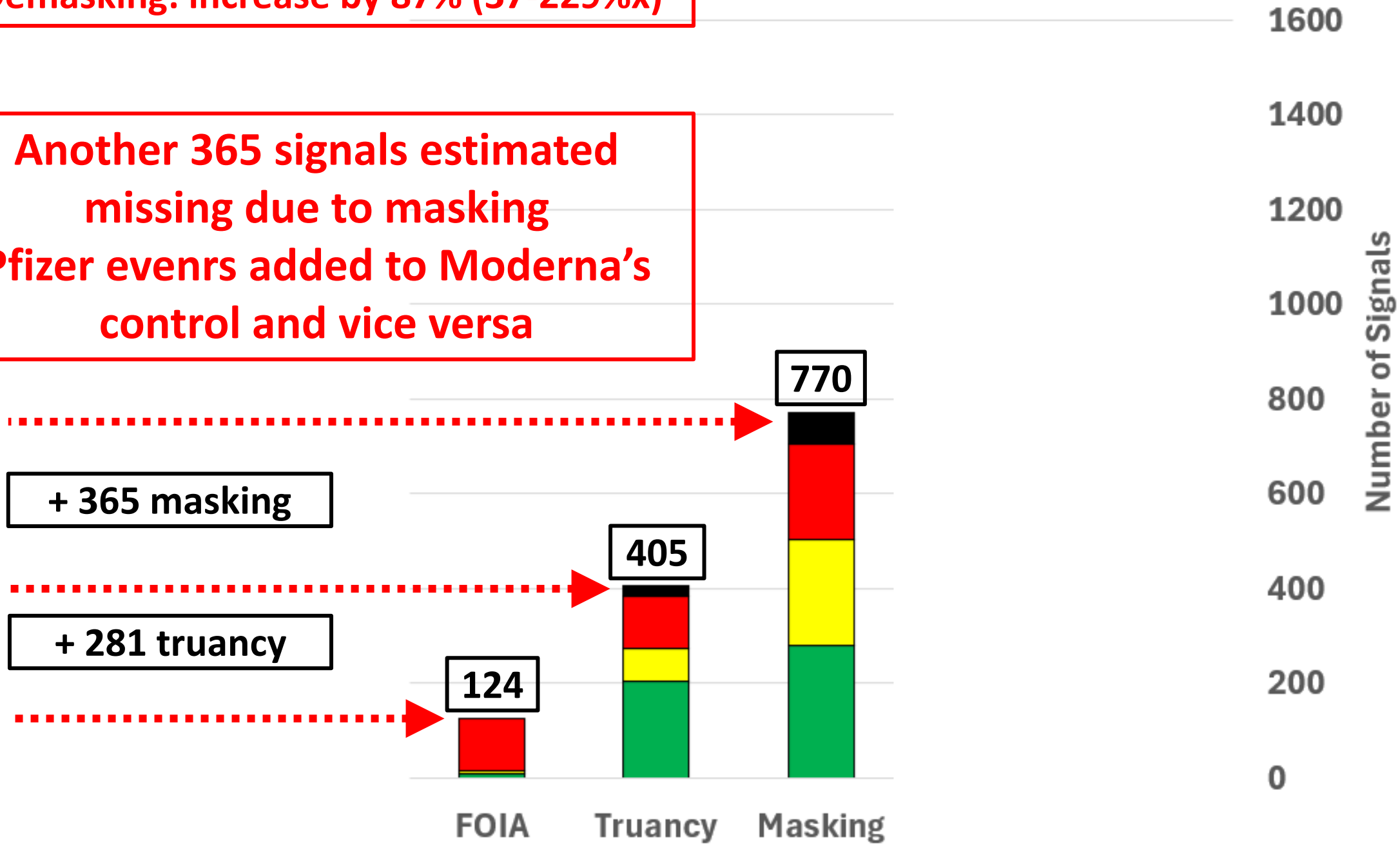


Demasking: increase by 87% (37-229%x)

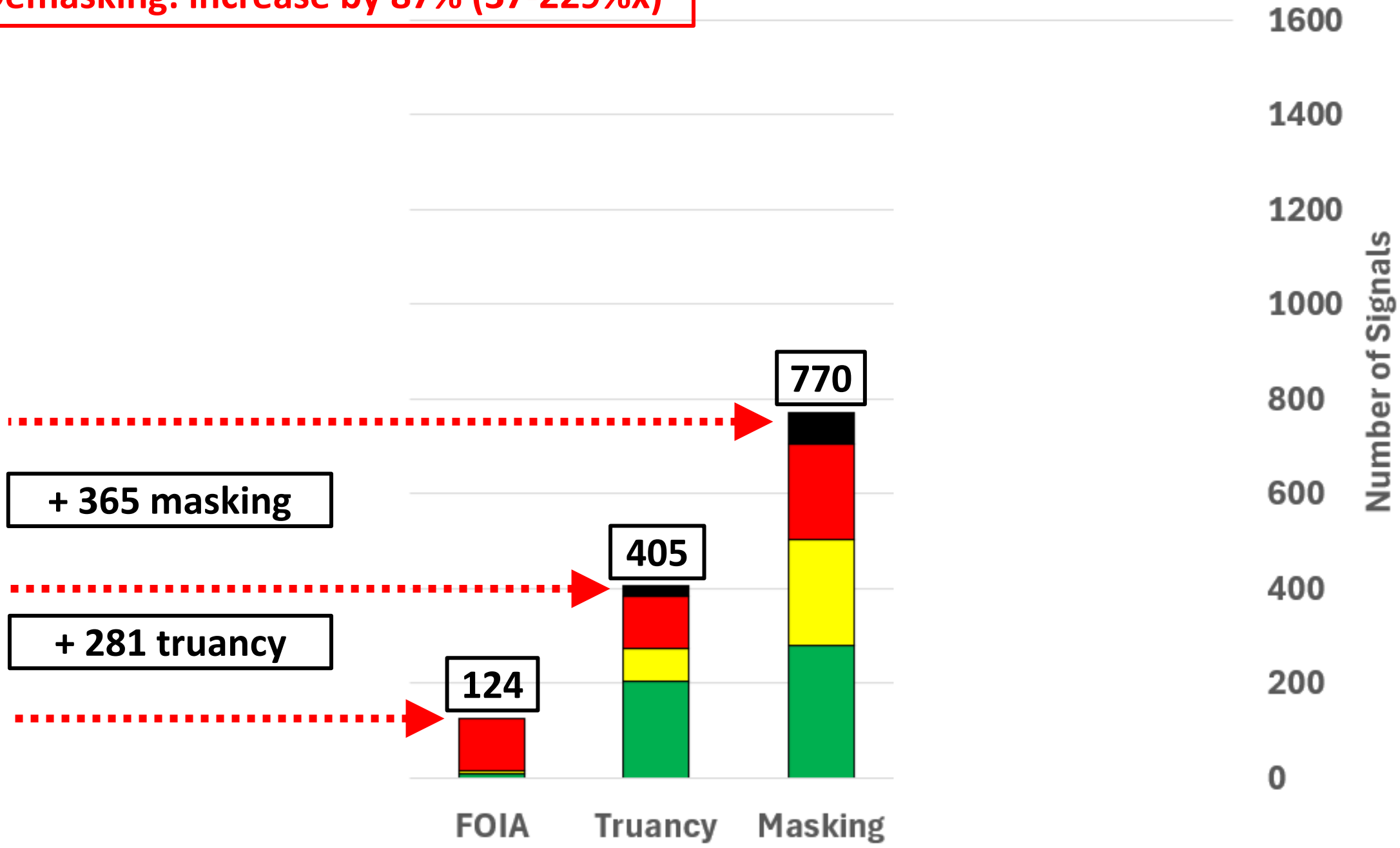


Demasking: increase by 87% (37-229%x)

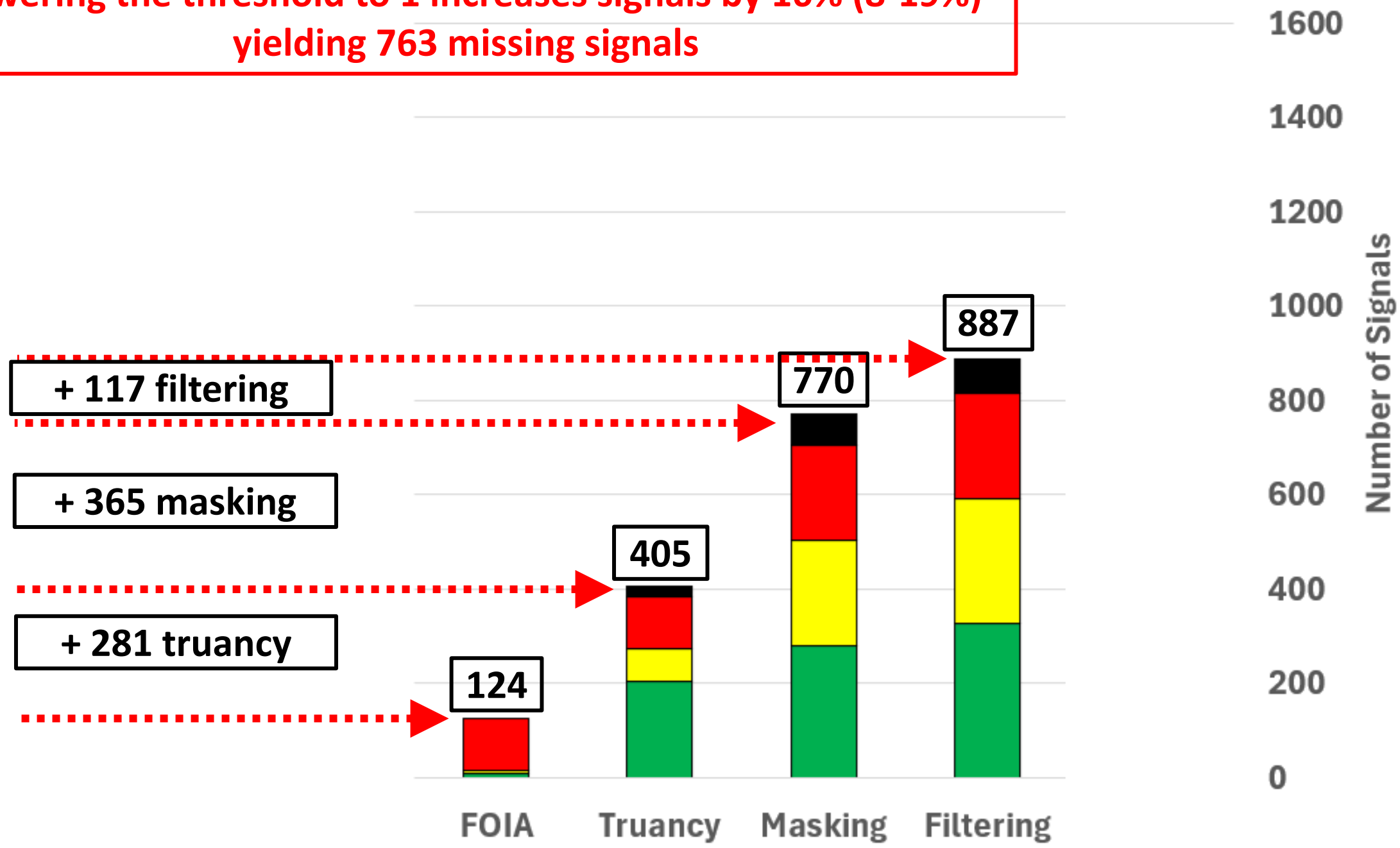
Another 365 signals estimated missing due to masking
Pfizer evenrs added to Moderna's control and vice versa



Demasking: increase by 87% (37-229%x)

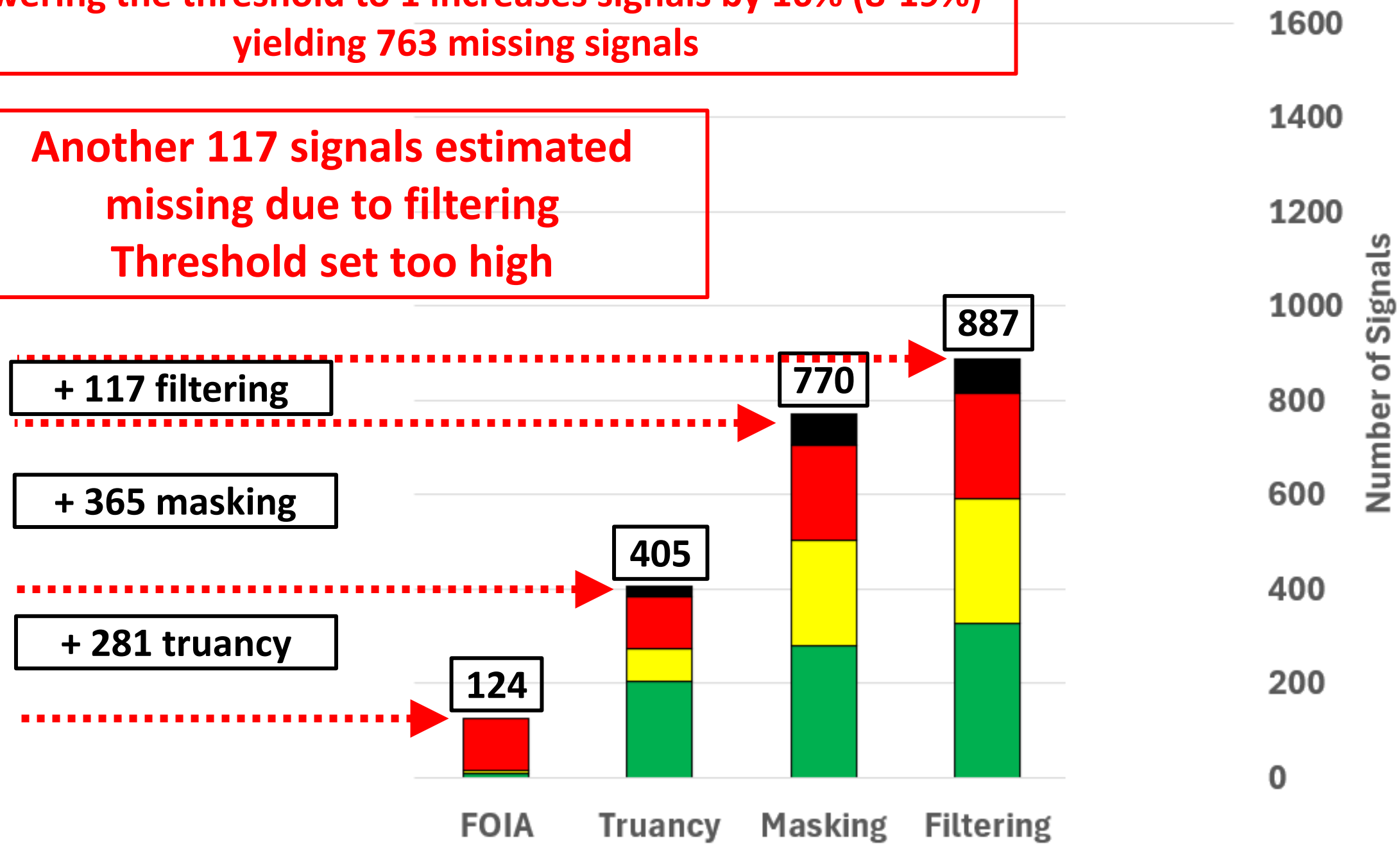


Lowering the threshold to 1 increases signals by 16% (8-19%) yielding 763 missing signals

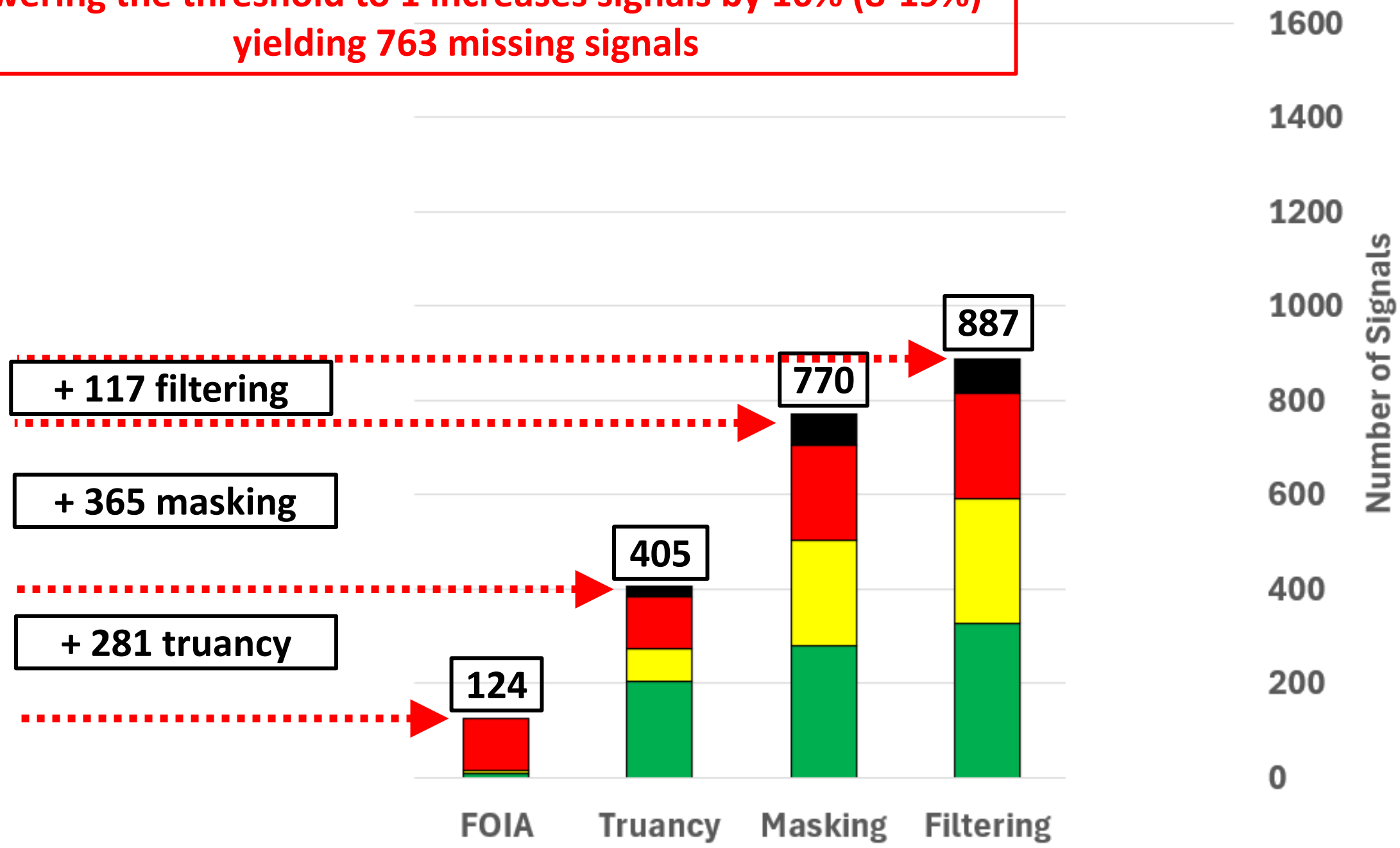


Lowering the threshold to 1 increases signals by 16% (8-19%) yielding 763 missing signals

Another 117 signals estimated missing due to filtering
Threshold set too high



Lowering the threshold to 1 increases signals by 16% (8-19%) yielding 763 missing signals



~ 763 signals missing from Empirical Bayesian data mining
+ ?? unmined borderline signals

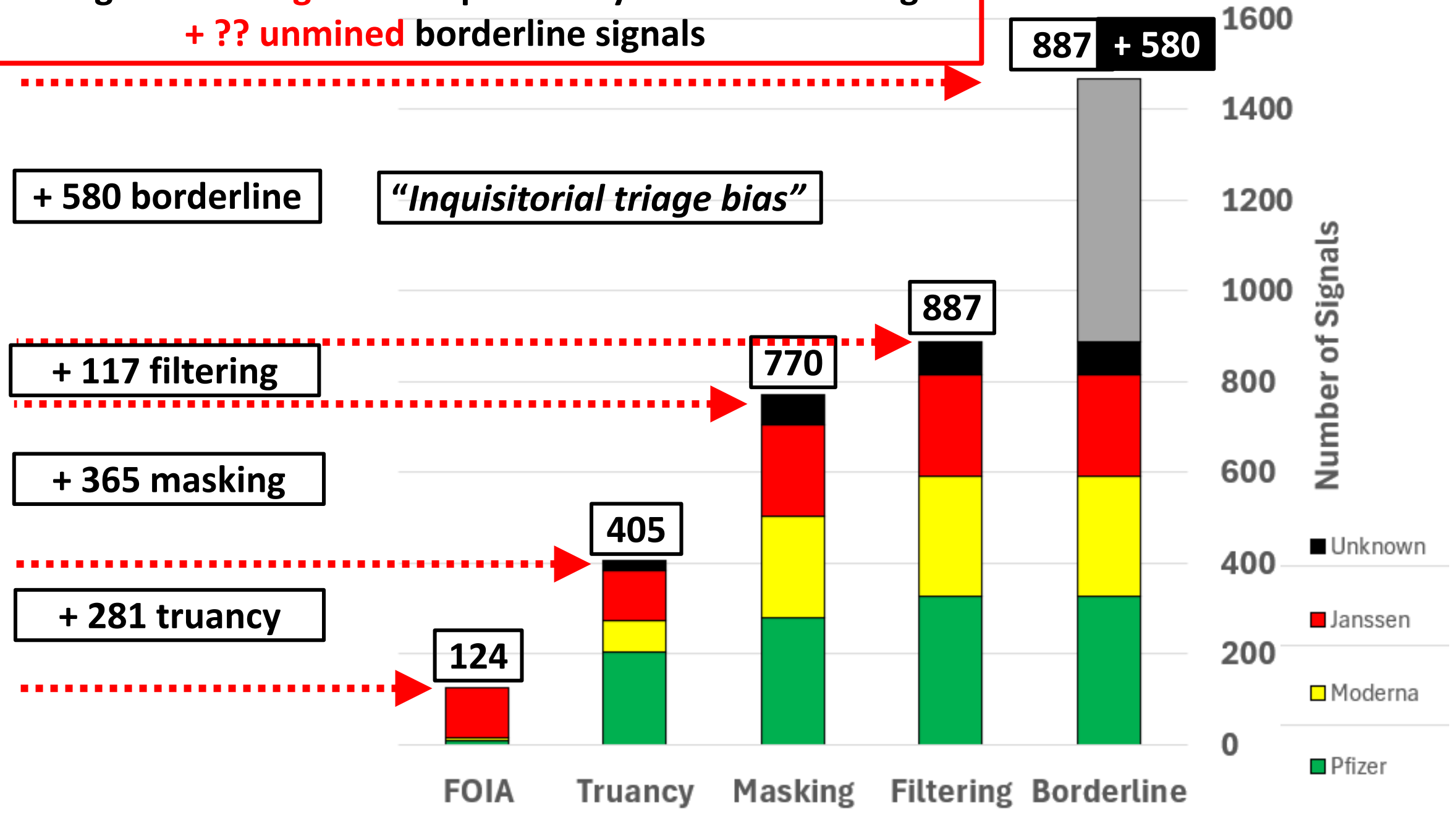
+ 580 borderline

"Inquisitorial triage bias"

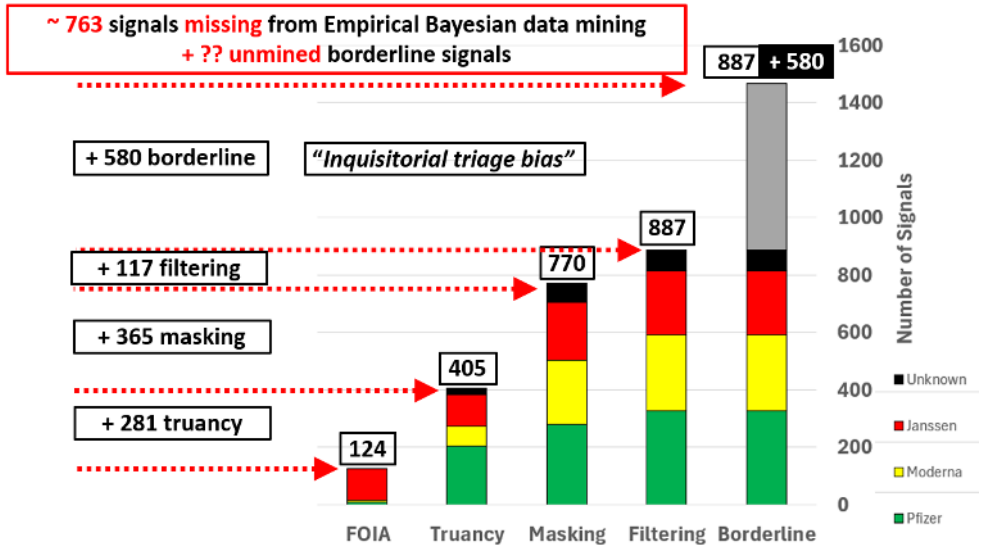
+ 117 filtering

+ 365 masking

+ 281 truancy

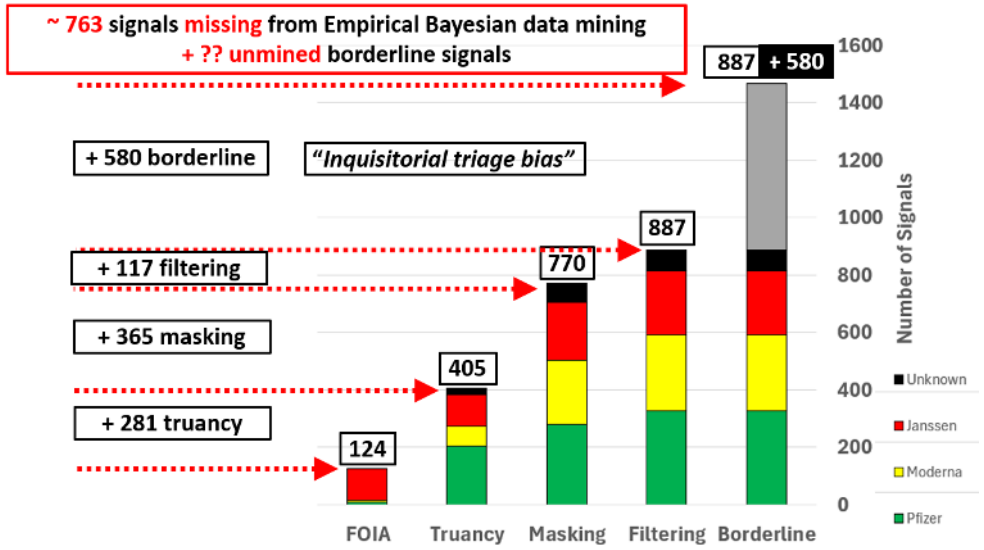


Safety signal loss and underestimation of potential risks and suspected adverse reactions due to truancy, masking, and filtering in FDA's analysis of VAERS data associated with COVID-19 pro-vaccines



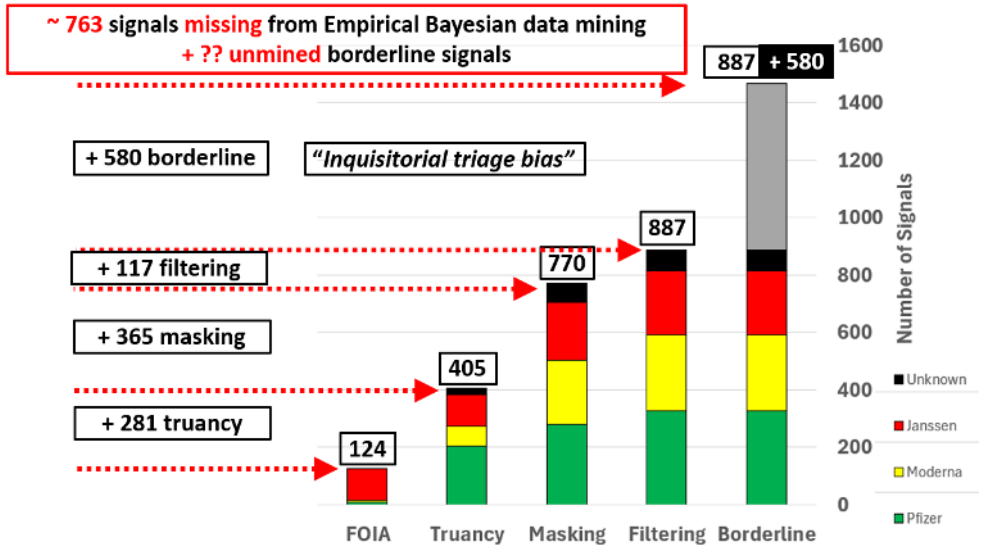
- **Hundreds** (763 - up to 6765) of **safety signals** were **lost** from FDA's Empirical Bayesian Data Mining of VAERS safety data through truancy, masking and filtering

Safety signal loss and underestimation of potential risks and suspected adverse reactions due to truancy, masking, and filtering in FDA's analysis of VAERS data associated with COVID-19 pro-vaccines



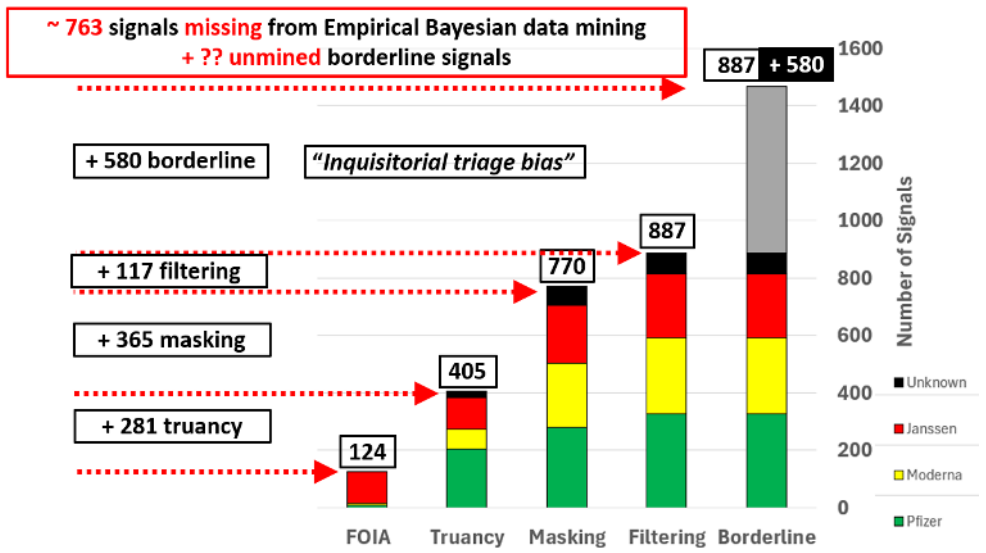
- **Hundreds** (763 - up to 6765) of **safety signals** were **lost** from FDA's Empirical Bayesian Data Mining of VAERS safety data through truancy, masking and filtering
- Losses represent mostly uninvestigated **potential risk** FDA was required to consider **without** needing to determine **causality**

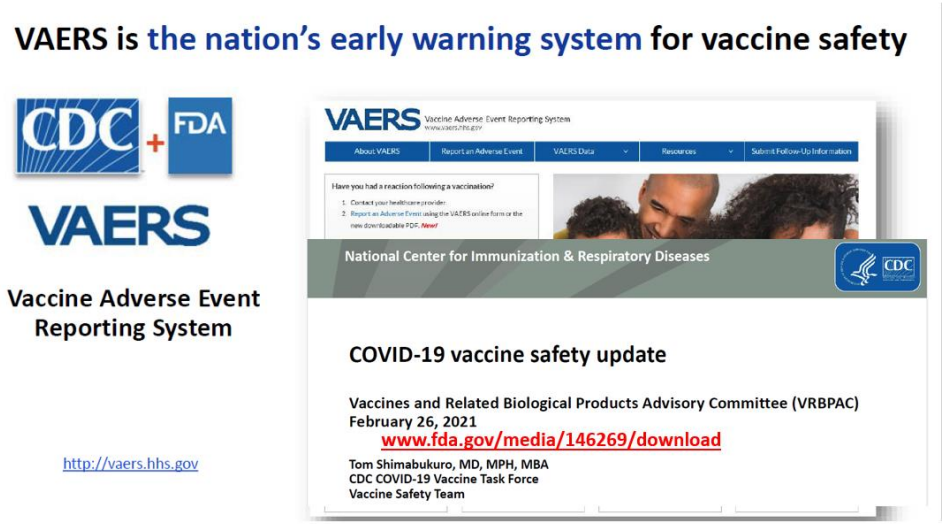
Safety signal loss and underestimation of potential risks and suspected adverse reactions due to truancy, masking, and filtering in FDA's analysis of VAERS data associated with COVID-19 pro-vaccines



- **Hundreds** (763 - up to 6765) of **safety signals** were **lost** from FDA's Empirical Bayesian Data Mining of VAERS safety data through truancy, masking and filtering
- Losses represent mostly uninvestigated **potential risk** FDA was required to consider **without** needing to determine **causality**
- **Different standards** were applied to the assessment of **safety** and **efficacy**

Safety signal loss and underestimation of potential risks and suspected adverse reactions due to truancy, masking, and filtering in FDA's analysis of VAERS data associated with COVID-19 pro-vaccines





- **Hundreds** (763 - up to 6765) of **safety signals** were **lost** from FDA's Empirical Bayesian Data Mining of VAERS safety data through truancy, masking and filtering
- Losses represent mostly uninvestigated **potential risk** FDA was required to consider **without** needing to determine **causality**
- **Different standards** were applied to the assessment of **safety** and **efficacy**
- These anomalies **impugn** the reliability of regulatory & compensation decisions, and VAERS as "the nation's early warning system for vaccine safety."

Signal = Suspected Adverse Reaction for a specific AE-drug pair

"Suspected adverse reaction means any adverse event for which there is a **reasonable possibility** that the **drug caused the adverse event."**

A signal means that we can reasonably suspect that drug X caused adverse event Y

Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. For the purposes of IND safety reporting, "reasonable possibility" means there is **evidence to suggest a causal** relationship between the drug and the adverse event. Suspected adverse reaction implies a **lesser degree of certainty** about causality than adverse reaction, which means any adverse event caused by a drug.

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-B/section-312.32

VAERS reports

Not causal

Does a certain adverse event happen more often after a particular drug than after other drugs?

Is there a signal? Is this a *Suspected Adverse Reaction ?*
(statistical association between event and drug)

Not causal, hypothesis-generating

Further investigation

Causality Confirmed: Adverse Reaction

Failure to confirm causality is not proof of non-causality

VAERS reports

Not causal

Does a certain adverse event happen more often after a particular drug than after other drugs?

Is there a signal? Is this a *Suspected Adverse Reaction ?*
(statistical association between event and drug)

Not causal, hypothesis-generating

Further investigation

Causality Confirmed: Adverse Reaction

Failure to confirm causality is not proof of non-causality

Data Mining by Disproportionality Signal Analysis (DSA)

Does a certain adverse event happen more often after a particular drug than after other drugs?

	Specific event	All other events	Measure of difference for AE between this & other drugs	PRR
Specific drug	a	b	$\frac{\%\text{ reports for specific drug}}{\%\text{ reports all drugs}}$	$\frac{a/(a+b)}{c/(c+d)}$
All other drugs	c	d		

PRR: CDC

Proportional Reporting Ratio

Described by Evans et al., 2001

Modeling →

EBGM: FDA

Empirical Bayesian Geometric Mean

Empirical Bayesian Data Mining (EBDM): reduces noise associated with low case counts using MGPS modeling

A ***"signal of disproportionate reporting"*** (SDR) occurs when the PRR or EBGM exceeds a **threshold** and a measure of statistical significance (e.g. p-value, confidence interval, chi-squared value)

A statistical signal is still a safety signal

"Statistical signal of disproportional reporting (SSDR)

≠

safety signal"

(FOIA disclosure)

*"based on the **totality** of the scientific evidence available, it is **reasonable** to **believe** that the product **may be effective***

(EUA Guidance p12/49)

- Absence of a DSA signal does not confirm absence of a safety signal nor negate a signal otherwise detected
- Other known limitations of DSA
- Similar terms denote how close an investigation is to declaring causality:
  - signal of disproportionate reporting" (SDR) "signal of suspected causality" (SSC

www.fda.gov/media/97321/download

A statistical signal is still a safety signal

"Statistical signal of disproportional reporting (SSDR)

≠

safety signal"

(FOIA disclosure)

*"based on the **totality** of the scientific evidence available, it is **reasonable** to **believe** that the product **may be effective***

(EUA Guidance p12/49)

It's OK to say that a vaccine *"may be effective"* but not OK to say it "may be unsafe" ?

www.fda.gov/media/97321/download

A statistical signal is still a safety signal

"Statistical signal of disproportional reporting (SSDR)

≠

safety signal"

(FOIA disclosure)

*MedDRA terms identified as **safety signals** due to **elevated PRR** and/or a **statistically significant finding on data mining** will be reviewed as appropriate."*

(VAERS SOP, p18/43)

Statistical signals are safety signals and must be disclosed to properly assess risk

Different standards were applied to assess safety and efficacy

www.fda.gov/media/97321/download

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Safety of seasonal inactivated influenza vaccines in children 6 months–17 years of age in the Vaccine Adverse Events Reporting System (VAERS) 2018–2023: before, during, and after the COVID-19 pandemic public health emergency

E. Gloria Anyalechi [a,*], Paige L. Marquez [a], Mary N. Rubin [b], Sally-Ann P. Johannsen [a], Krystal Kohlman [a], Jyothi Gunta [a], Kimberly N. Works [a], Jared Woo [a], Brittney Romanson [a], Matthew B. Crist [a], John R. Su [a], Pedro Moro [a]

[a] *Immunization Safety Office, US Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases, Division of Healthcare Quality Promotion, 1600 Clifton Rd NE, Atlanta, GA 30333, United States*

[b] *Division of Pharmacovigilance, US Food and Drug Administration, Office of Biostatistics and Pharmacovigilance, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, MD 20993, United States*

Statistic of disproportional reporting …SDRs are not necessarily safety signals and should be considered hypothesis- generating.

A strength of our analysis is that VAERS is a large national database designed to detect early signals of potential vaccine safety concerns.

https://doi.org/10.1016/j.vaccine.2026.128569

Statistical signal of disproportional reporting (SSDR) ≠ safety signal (FOIA disclosure)

Data Mining Introduction*

- Statistical method for identifying disproportionality (excess of reported adverse event [AE] for a product relative to other products)
- Hypothesis generating
  - Statistical signal of disproportional reporting (SSDR) ≠ safety signal
- Absence of disproportionality does not confirm absence of safety signal nor negate a signal otherwise detected

*Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff (November 2019; Draft). Available at https://www.fda.gov/media/130216/download

FOIA disclosure to ICAN regarding EBDM and PRR VAERS analyses. 2025 Jan 22.

SEC. 564. [21 U.S.C. 360bbb–3] AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(c) **CRITERIA** FOR ISSUANCE OF AUTHORIZATION.—The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, […] the Secretary concludes—[…]

(2) that, based on the **totality** of scientific evidence available to the Secretary, including data from adequate and well controlled clinical trials, if available, it is **reasonable to believe** that—

(A) the product **may be effective** in diagnosing, treating, or preventing—

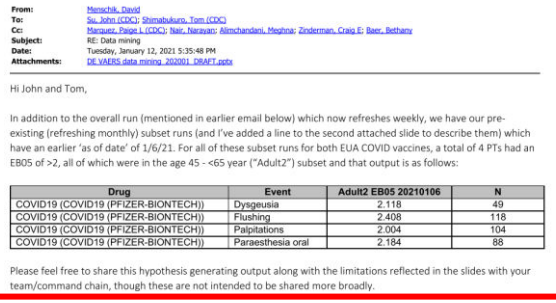
(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this Act, or licensed under section 351 of the Public Health Service Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the **known and potential benefits** of the product, when used to diagnose, prevent, or treat such disease or condition, **outweigh the known and potential risks** of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

The FOIA Dataset released January 2025

FDA EBDM signal alerts
Alerts EB05>2 signals, US
~ weekly, Jan 2021 - July 2022



From: Menschik, David
To: Su, John (CDC); Shimabukuro, Tom (CDC)
Cc: Marquez, Paige L (CDC); Nair, Narayan; Almchandani, Meghna; Zinderman, Craig E; Baer, Bethany
Subject: RE: Data mining
Date: Tuesday, January 12, 2021 5:35:48 PM
Attachments: DE VAERS data mining_202001_DRAFT.pptx

Hi John and Tom,

In addition to the overall run (mentioned in earlier email below) which now refreshes weekly, we have our pre-existing (refreshing monthly) subset runs (and I've added a line to the second attached slide to describe them) which have an earlier 'as of date' of 1/6/21. For all of these subset runs for both EUA COVID vaccines, a total of 4 PTs had an EB05 of >2, all of which were in the age 45 - <65 year ("Adult2") subset and that output is as follows:

Drug	Event	Adult2 EB05 20210106	N
COVID19 (COVID19 (PFIZER-BIONTECH))	Dysgeusia	2.118	49
COVID19 (COVID19 (PFIZER-BIONTECH))	Flushing	2.408	118
COVID19 (COVID19 (PFIZER-BIONTECH))	Palpitations	2.004	104
COVID19 (COVID19 (PFIZER-BIONTECH))	Paraesthesia oral	2.184	88

Please feel free to share this hypothesis generating output along with the limitations reflected in the slides with your team/command chain, though these are not intended to be shared more broadly.

CDC PRR analyses
May to July 2022, US
Same disclosures in 2023, which included March & May 2022

Oracle dataset (Harpaz et al., 2022)
EBDM and PRR for seven AEs
Jan – October 2021, **US + Foreign**
Originator of EBDM method
FDA staff in non-official capacity

Drug Safety (2022) 45:765–780
https://doi.org/10.1007/s40264-022-01186-z

ORIGINAL RESEARCH ARTICLE

Check for updates

Signaling COVID-19 Vaccine Adverse Events

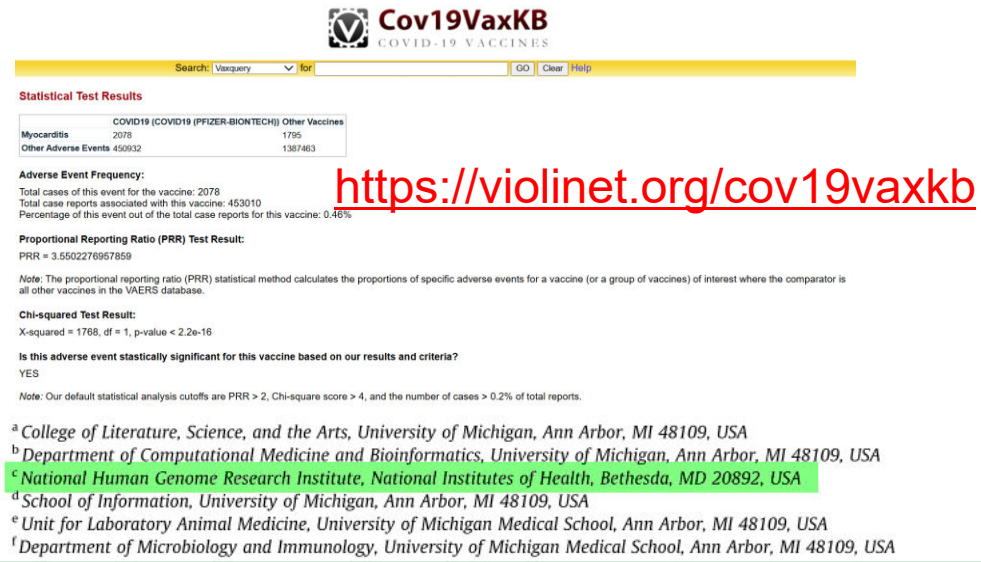
Rave Harpaz[1] · William DuMouchel[1] · Robbert Van Manen[1] · Alexander Nip[1] · Steve Bright[1] · Ana Szarfman[2] · Joseph Tonning[3] · Magnus Lerch[1,4]

1 Oracle Health Sciences, Burlington, MA, USA

2 U.S. FDA, Silver Spring, MD, USA

3 U.S. Public Health Service/U.S. FDA retired, Silver Spring, MD, USA

VIOLIN dataset (Huang et al., 2021)
Online tool calculates PRR, **all AEs**
US only, April 30,2022
NIH funded, included NIH staff



Cov19VaxKB
COVID-19 VACCINES

Search: Vaxquery for GO Clear Help

Statistical Test Results

	COVID19 (COVID19 (PFIZER-BIONTECH))	Other Vaccines
Myocarditis	2078	1795
Other Adverse Events	450932	1387463

Adverse Event Frequency:
Total cases of this event for the vaccine: 2078
Total case reports associated with this vaccine: 453010
Percentage of this event out of the total case reports for this vaccine: 0.46%

Proportional Reporting Ratio (PRR) Test Result:
PRR = 3.5502276957859

Note: The proportional reporting ratio (PRR) statistical method calculates the proportions of specific adverse events for a vaccine (or a group of vaccines) of interest where the comparator is all other vaccines in the VAERS database.

Chi-squared Test Result:
X-squared = 1768, df = 1, p-value < 2.2e-16

Is this adverse event stastically significant for this vaccine based on our results and criteria?
YES

Note: Our default statistical analysis cutoffs are PRR > 2, Chi-square score > 4, and the number of cases > 0.2% of total reports.

https://violinet.org/cov19vaxkb

[a] College of Literature, Science, and the Arts, University of Michigan, Ann Arbor, MI 48109, USA
[b] Department of Computational Medicine and Bioinformatics, University of Michigan, Ann Arbor, MI 48109, USA
[c] National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, USA
[d] School of Information, University of Michigan, Ann Arbor, MI 48109, USA
[e] Unit for Laboratory Animal Medicine, University of Michigan Medical School, Ann Arbor, MI 48109, USA
[f] Department of Microbiology and Immunology, University of Michigan Medical School, Ann Arbor, MI 48109, USA

Typical FDA weekly alert, listing signals found by Empirical Bayesian Data Mining (current to April 29, 2022)

Total 124 signals

Janssen 110 signals

Moderna 6 signals

Pfizer 8 signals

Highlight added

9-22 x excess of Janssen and dearth of Pfizer and Moderna signals

Varicose vein
Vasodilatation
Venogram
Venogram abnormal
Venogram normal

Exposure via breast milk
Interchange of vaccine products
Mechanical urticaria
Product administered to patient of inappropriate age
Product dose omission issue
Vaccination complication

Body height
Disease recurrence
Drug ineffective
Exposure via breast milk
Immunisation
Investigation
Product preparation issue
Weight

What FDA saw

Selection of EB05>2 Data Mining Alerts in FOIA dataset (color added)

Drug	Event
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding
COVID19 (COVID19 (JANSSEN))	Interchange of vaccine products
COVID19 (COVID19 (JANSSEN))	Menstruation irregular
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism
COVID19 (COVID19 (JANSSEN))	Syncope
COVID19 (COVID19 (JANSSEN))	Thrombosis
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal
COVID19 (COVID19 (MODERNA))	Injection site pruritus
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight

p34/153, April 27, 2021

Drug	Event
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis
COVID19 (COVID19 (JANSSEN))	Dysmenorrhoea
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer
COVID19 (COVID19 (JANSSEN))	Gaze palsy
COVID19 (COVID19 (JANSSEN))	Heavy menstrual bleeding
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal
COVID19 (COVID19 (JANSSEN))	Menstruation irregular
COVID19 (COVID19 (JANSSEN))	Platelet count
COVID19 (COVID19 (JANSSEN))	Platelet count normal
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism
COVID19 (COVID19 (JANSSEN))	Syncope
COVID19 (COVID19 (JANSSEN))	Therapy non-responder
COVID19 (COVID19 (JANSSEN))	Thrombosis
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal
COVID19 (COVID19 (JANSSEN))	Venogram abnormal
COVID19 (COVID19 (JANSSEN))	Venogram normal
COVID19 (COVID19 (MODERNA))	Poor quality product administered
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation
COVID19 (COVID19 (PFIZER-BIONTECH))	Off label use
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Product use issue
COVID19 (COVID19 (PFIZER-BIONTECH))	SARS-CoV-2 test
COVID19 (COVID19 (PFIZER-BIONTECH))	Vaccination site pain
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight

p37/153, May 11, 2021

Drug	Event
COVID19 (COVID19 (JANSSEN))	Fall
COVID19 (COVID19 (JANSSEN))	Feeling cold
COVID19 (COVID19 (JANSSEN))	Loss of consciousness
COVID19 (COVID19 (JANSSEN))	Syncope
COVID19 (COVID19 (JANSSEN))	Syringe issue
COVID19 (COVID19 (JANSSEN))	Vital signs measurement
COVID19 (COVID19 (PFIZER-BIONTECH))	Body temperature

p30/153, April 13, 2021

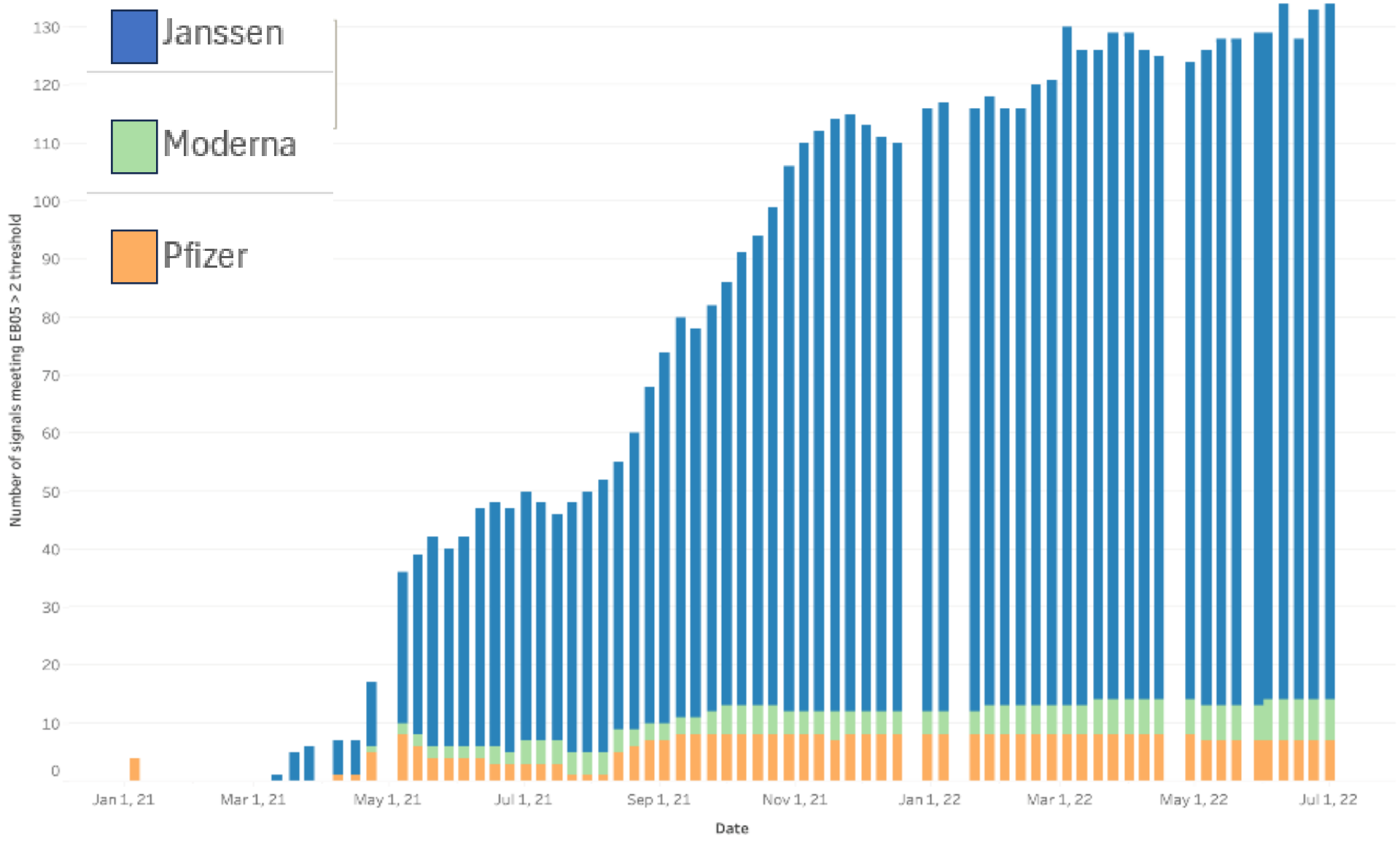
Drug	Event
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Chills
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer normal
COVID19 (COVID19 (JANSSEN))	Gaze palsy
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal
COVID19 (COVID19 (JANSSEN))	Off label use
COVID19 (COVID19 (JANSSEN))	Peripheral embolism
COVID19 (COVID19 (JANSSEN))	Platelet count
COVID19 (COVID19 (JANSSEN))	Platelet count normal
COVID19 (COVID19 (JANSSEN))	Platelet factor 4
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism
COVID19 (COVID19 (JANSSEN))	Pyrexia
COVID19 (COVID19 (JANSSEN))	Therapy non-responder
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial
COVID19 (COVID19 (JANSSEN))	Thrombosis
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal
COVID19 (COVID19 (JANSSEN))	Ultrasound scan
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal
COVID19 (COVID19 (JANSSEN))	Venogram abnormal
COVID19 (COVID19 (JANSSEN))	Venogram normal
COVID19 (COVID19 (MODERNA))	Poor quality product administered
COVID19 (COVID19 (MODERNA))	Product temperature excursion issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Drug ineffective
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight

p42/153, June 1, 2021

Drug	Event
COVID19 (COVID19 (JANSSEN))	Activated partial thromboplastin time prolonged
COVID19 (COVID19 (JANSSEN))	Adverse drug reaction
COVID19 (COVID19 (JANSSEN))	Angiogram cerebral abnormal
COVID19 (COVID19 (JANSSEN))	Angiogram pulmonary abnormal
COVID19 (COVID19 (JANSSEN))	Anticoagulant therapy
COVID19 (COVID19 (JANSSEN))	Blood fibrinogen decreased
COVID19 (COVID19 (JANSSEN))	Body temperature
COVID19 (COVID19 (JANSSEN))	CSF protein increased
COVID19 (COVID19 (JANSSEN))	Cerebral haemorrhage
COVID19 (COVID19 (JANSSEN))	Cerebral mass effect
COVID19 (COVID19 (JANSSEN))	Cerebral venous sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Computerised tomogram head abnormal
COVID19 (COVID19 (JANSSEN))	Computerised tomogram thorax abnormal
COVID19 (COVID19 (JANSSEN))	Deep vein thrombosis
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer
COVID19 (COVID19 (JANSSEN))	Fibrin D dimer increased
COVID19 (COVID19 (JANSSEN))	Gaze palsy
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test
COVID19 (COVID19 (JANSSEN))	Heparin-induced thrombocytopenia test positive
COVID19 (COVID19 (JANSSEN))	International normalised ratio normal
COVID19 (COVID19 (JANSSEN))	Jugular vein thrombosis
COVID19 (COVID19 (JANSSEN))	Magnetic resonance imaging head abnormal
COVID19 (COVID19 (JANSSEN))	Off label use
COVID19 (COVID19 (JANSSEN))	On and off phenomenon
COVID19 (COVID19 (JANSSEN))	Peripheral embolism
COVID19 (COVID19 (JANSSEN))	Platelet count
COVID19 (COVID19 (JANSSEN))	Platelet count normal
COVID19 (COVID19 (JANSSEN))	Platelet factor 4
COVID19 (COVID19 (JANSSEN))	Poor quality product administered
COVID19 (COVID19 (JANSSEN))	Pulmonary embolism
COVID19 (COVID19 (JANSSEN))	Therapy non-responder
COVID19 (COVID19 (JANSSEN))	Thrombophlebitis superficial
COVID19 (COVID19 (JANSSEN))	Thrombosis
COVID19 (COVID19 (JANSSEN))	Transverse sinus thrombosis
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler abnormal
COVID19 (COVID19 (JANSSEN))	Ultrasound Doppler normal
COVID19 (COVID19 (JANSSEN))	Ultrasound scan
COVID19 (COVID19 (JANSSEN))	Ultrasound scan abnormal
COVID19 (COVID19 (JANSSEN))	Ultrasound scan normal
COVID19 (COVID19 (JANSSEN))	Venogram
COVID19 (COVID19 (JANSSEN))	Venogram abnormal
COVID19 (COVID19 (JANSSEN))	Venogram normal
COVID19 (COVID19 (MODERNA))	Accidental exposure to product
COVID19 (COVID19 (MODERNA))	No adverse event
COVID19 (COVID19 (MODERNA))	Poor quality product administered
COVID19 (COVID19 (MODERNA))	Product administered to patient of inappropriate age
COVID19 (COVID19 (PFIZER-BIONTECH))	Investigation
COVID19 (COVID19 (PFIZER-BIONTECH))	Product preparation issue
COVID19 (COVID19 (PFIZER-BIONTECH))	Weight

p53/153, July 6, 2021

9-22 x weekly excess of Janssen and dearth of Pfizer and Moderna EBDM signals



Is this plausible?

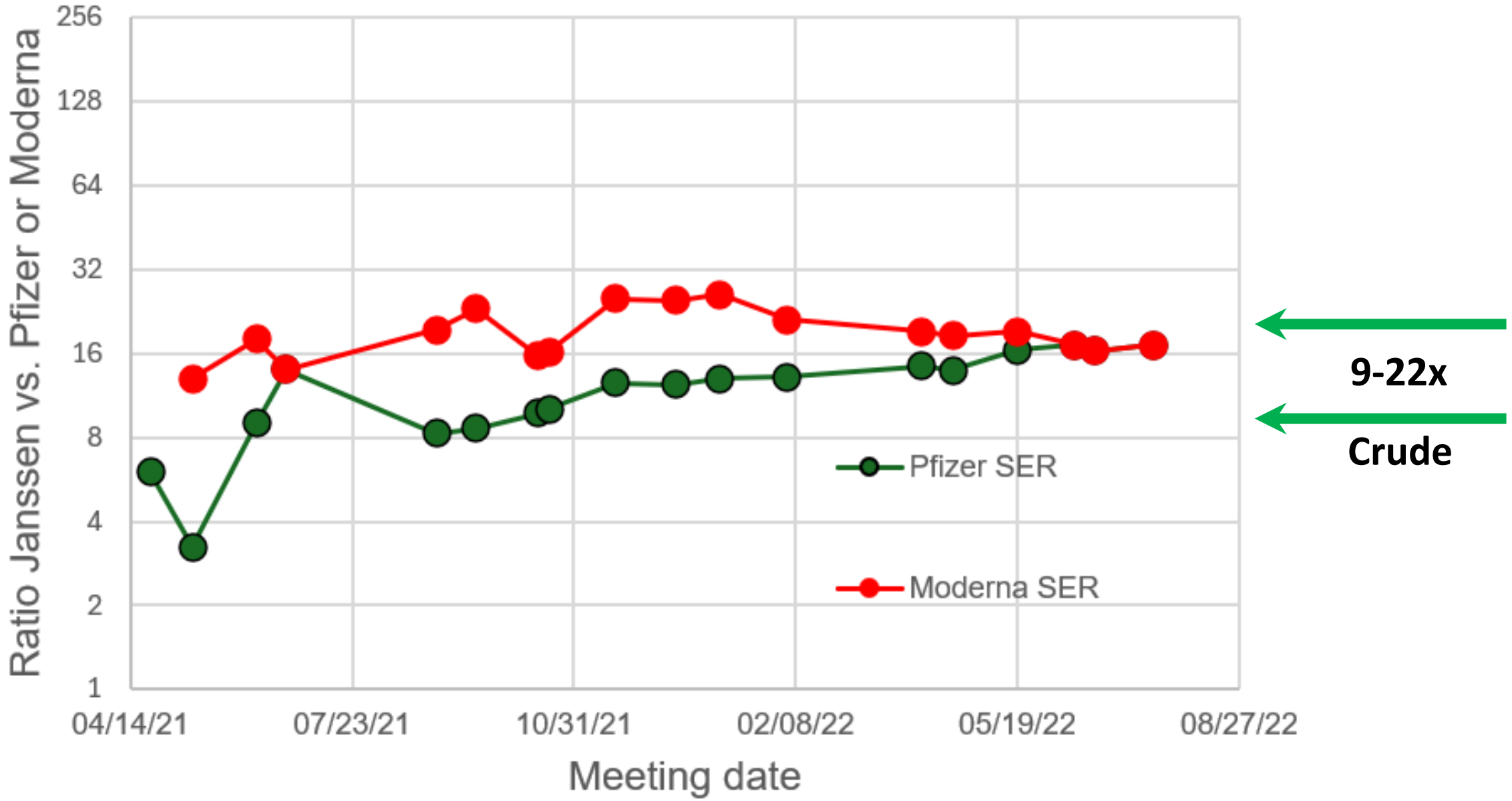
The numbers of signals in CDC and FDA analyses differ by orders of magnitude

CDC PRR			FDA FOIA EBDM		
Comparison	**Date**	**N**	**Comparison**	**Date**	**N**
Pfizer vs. Moderna	7/8/22	225	Pfizer vs. all	7/1/22	7
Moderna vs. Pfizer	7/8/22	94	Moderna vs. all	7/1/22	7
mRNA vs non-COVID	7/1/22	901			
Janssen vs non-COVID	Not done		Janssen vs. all	7/1/22	120

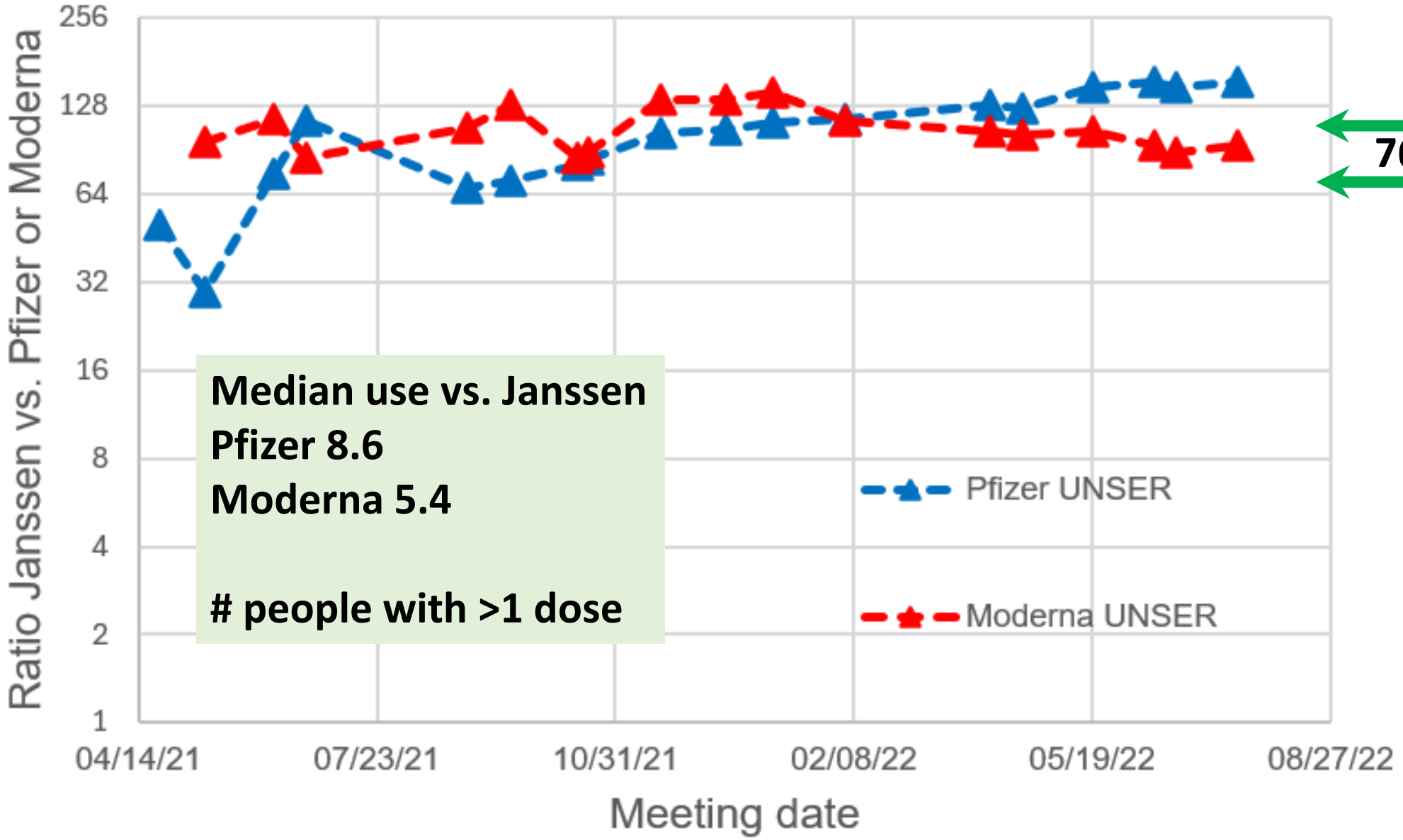
CDC: PRR analyses *"generally corroborated findings from Empirical Bayesian (EB) data mining"*

www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines-4956733

9-22 persistently more Janssen EBDM signals > Pfizer & Moderna



76-126 persistently more Janssen EBDM signals > Pfizer & Moderna, use adjusted



76 - 126x

By use

IQR

More numerous and diverse event types for Janssen

13 in 8 categories

11 in 5 categories

140 in 13 categories

Pfizer			Moderna			Janssen			
EVENT	N[a]	Cat[c]	EVENT	N[a]	Cat[c]	EVENT	N[a]	Cat[c]	Sub[c]
Product preparation issue	59	USE	Product administered to patient of inappropriate age	52	USE	Thrombosis	60	CVG	TE
Drug ineffective	50	P	Exposure via breast milk	42	REP	Ultrasound Doppler abnormal	59	SYN	OTH
Exposure via breast milk	44	REP	Product dose omission issue	38	USE	Therapy non-responder	59	P	
Disease recurrence	33	P	Interchange of vaccine products	30	USE	Pulmonary embolism	59	CVG	TE
Product administered to patient of inappropriate age	9	USE	Mechanical urticaria	22	DER	Cerebral venous sinus thrombosis	59	CVG	TE
Product use issue	3	USE	Poor quality product administered	17	USE	Angiogram cerebral abnormal	59	N	
Vaccination site pain	3	PAIN	Vaccination complication	15	SYN	Adverse drug reaction	59	SYN	
Incorrect dose administered	1	USE	Product temperature excursion issue	12	USE	Venogram abnormal	58	CVG	TE
Off label use	1	USE	Headache	8	PAIN	Magnetic resonance imaging head abnormal	58	N	
Paraesthesia oral	1	N	Accidental exposure to product	7	USE	Jugular vein thrombosis	58	CVG	TE
Dysgeusia	1	GAS	Injection site pruritus	1	DER	Gaze palsy	58	N	
Flushing	1	DER				Deep vein thrombosis	58	CVG	TE
Palpitations	1	ARY				Computerised tomogram head abnormal	58	N	
						Angiogram pulmonary abnormal	58	CVG	TE
						Transverse sinus thrombosis	57		

Frequency and number of alerts for abnormal adverse event EBDM signal types

…..

….etc.

Oracle finds signals missing in the EBDM FOIA dataset

Only 1/8 EBDM signals found in the Oracle dataset were found in the FOIA dataset
7/8 signals were missing from the FOIA dataset

	Pfizer	Moderna	Janssen	All
Appendicitis	**O not F**	**O not F**	Neither O nor F	
Bell's palsy	**O not F**	Neither O nor F	Neither O nor F	
Herpes zoster	Neither O nor F	Neither O nor F	Neither O nor F	
Myocarditis	**O not F**	Neither O nor F	Neither O nor F	
Pericarditis	Neither O nor F	Neither O nor F	Neither O nor F	
Pulmonary embolism	**O not F**	**O not F**	**Both O and F**	
Tinnitus	Neither O nor F	Neither O nor F	**O not F**	
N signals	4	2	2	8
Present in O, present in F	0/4	0/2	1/2	1/8
Present in O, absent in F	4/4	2/2	1/2	7/8

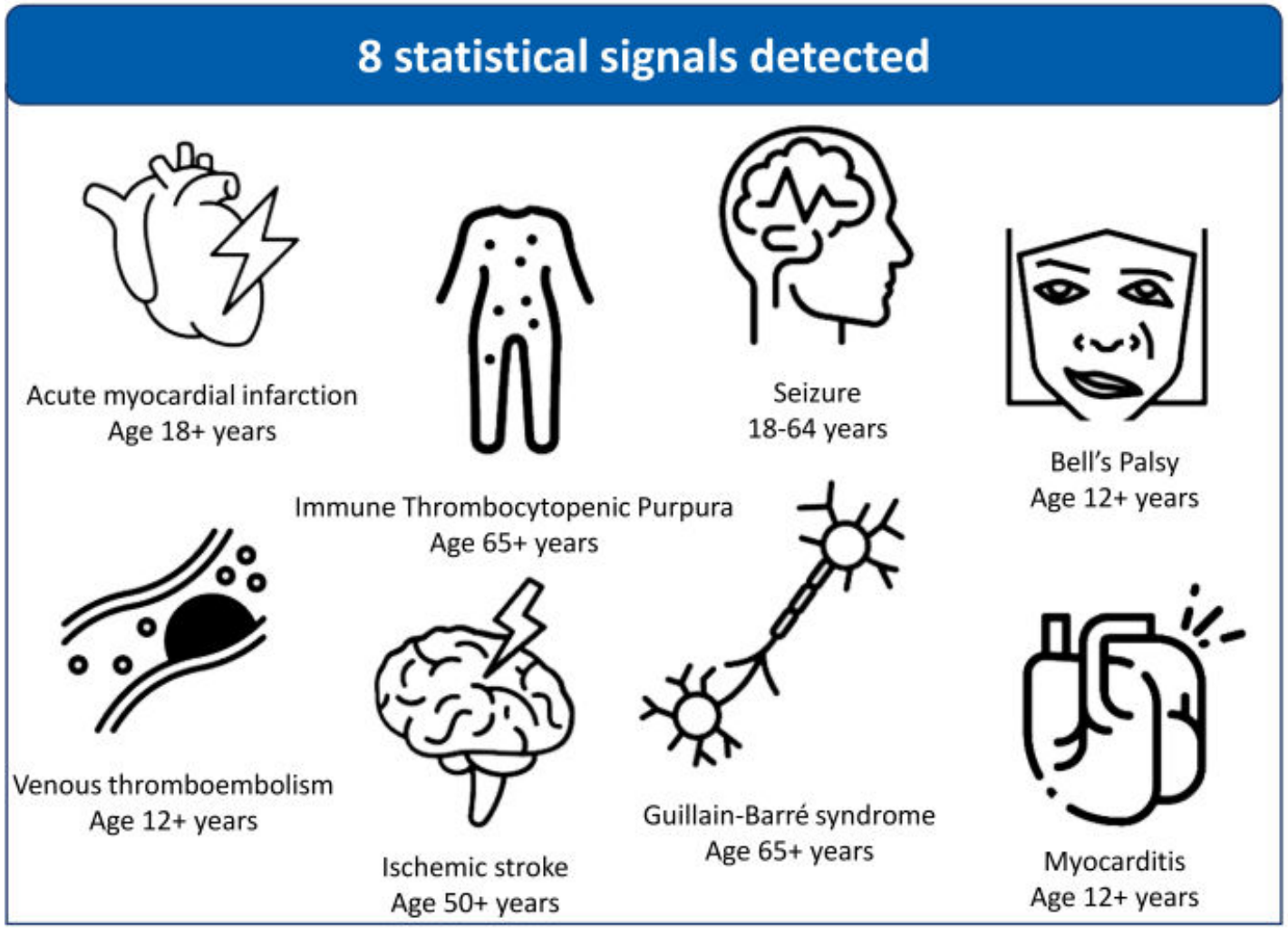
Odds ratio 0.0813, 95%CI 0.0091, 0.7282, p = 0.02, Fisher's Exact test.

Evaluation of Statistical Signals Detected for mRNA COVID-19 Vaccines through VSD's Rapid Cycle Analyses – 2020-2025

Update on CDC's COVID-19 Vaccine Safety Monitoring

Sarah Meyer, MD MPH
Director, CDC's Immunization Safety Office

June 25, 2025



www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf

No adjustment for masking

“signals for a vaccine of interest are hidden by the presence of other reported vaccines”

Pfizer events are added to Moderna’s control group
Moderna’s events are added to Pfizer’s control group

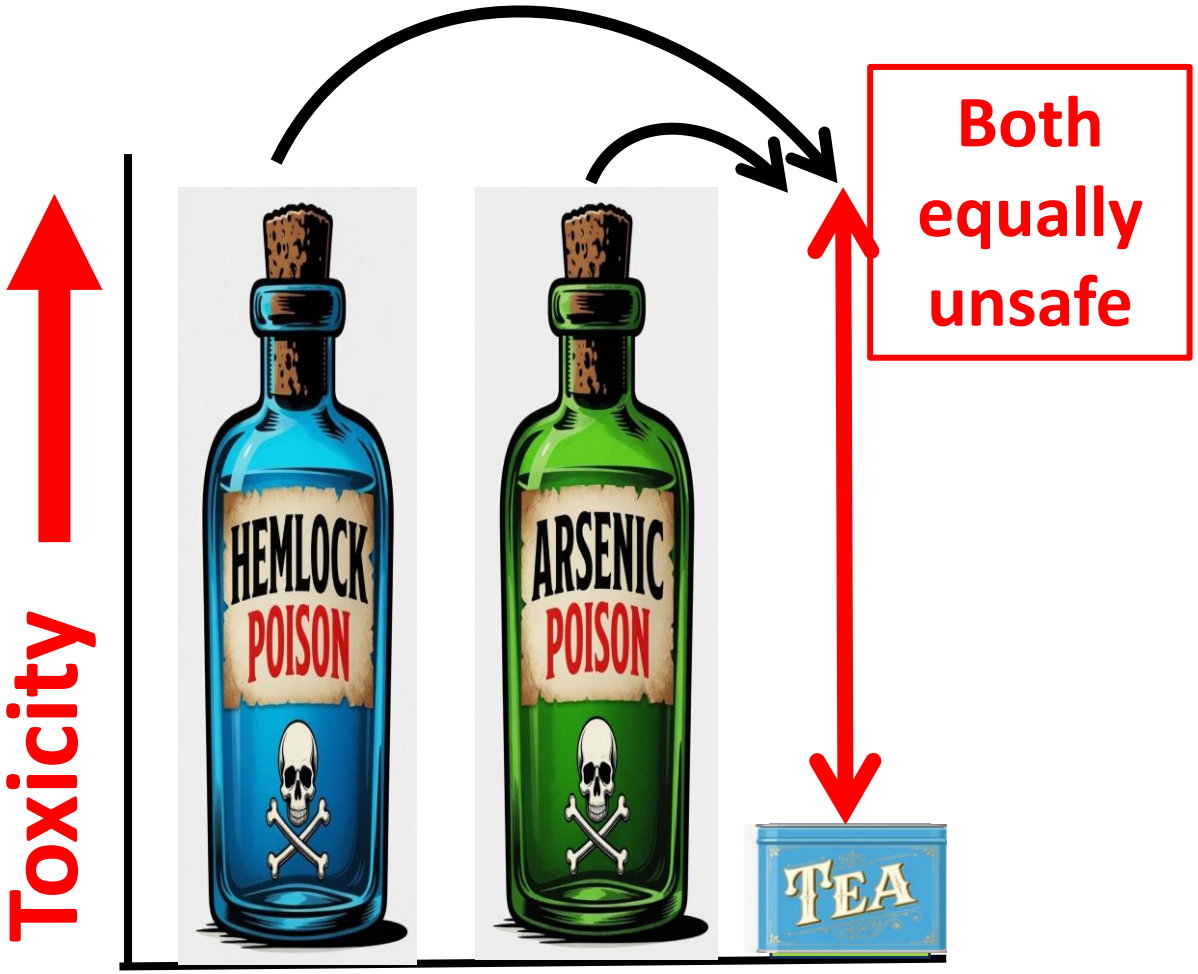
No adjustment for masking

Imagine comparing the toxicity of hemlock, arsenic, and water

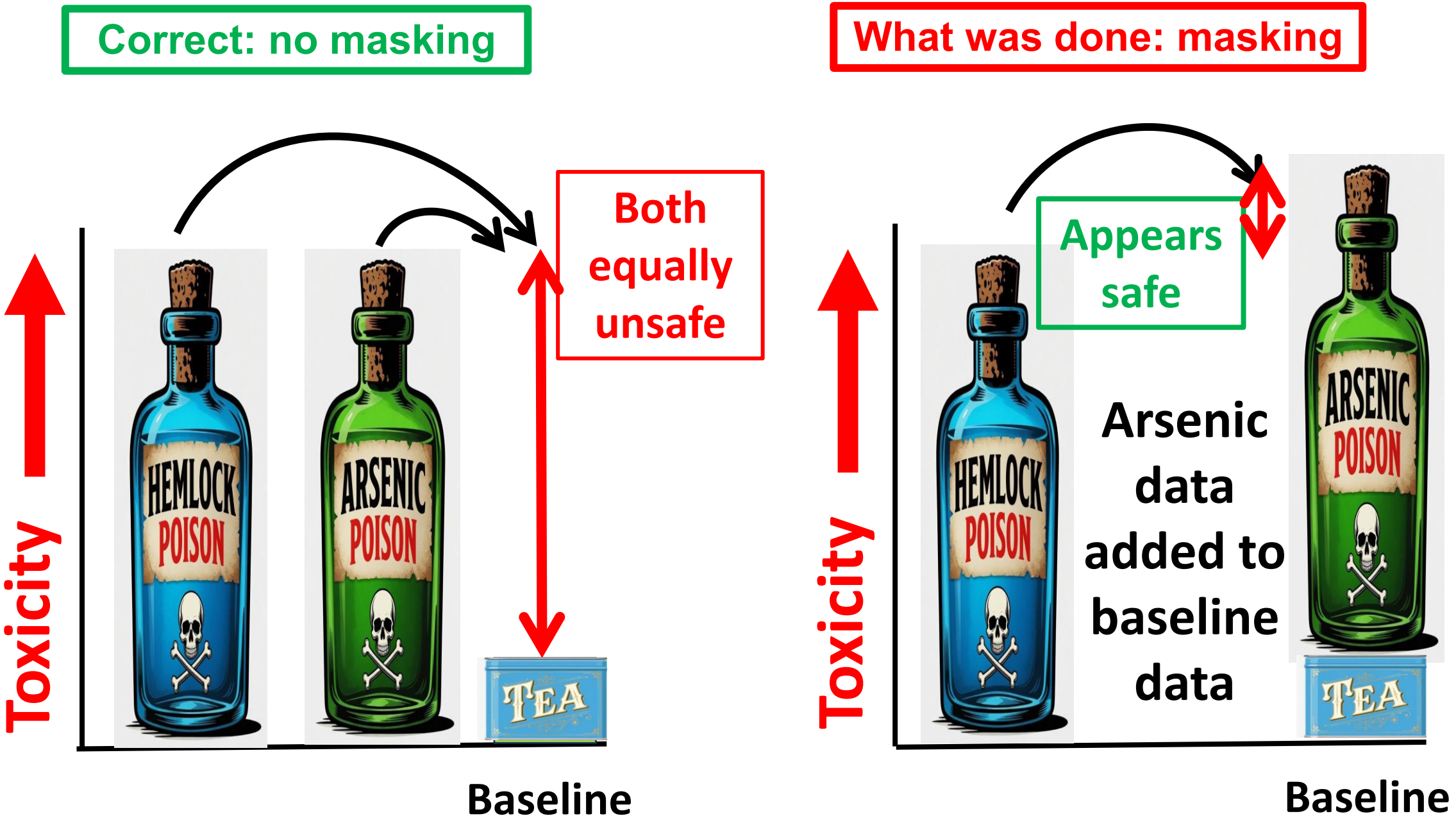
Compared with water, hemlock and arsenic are equally toxic

Compared with arsenic and water data combined, hemlock and arsenic look equally safe

Correct: no masking

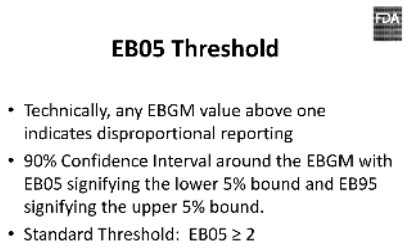


Each appears equally dangerous when compared separately against a non-toxic baseline such as tea.
But hemlock appears safe, and its effects drowned out or masked, when compared with a tea baseline that includes arsenic data.



Each appears equally dangerous when compared separately against a non-toxic baseline such as tea.
But hemlock appears safe, and its effects drowned out or masked, when compared with a tea baseline that includes arsenic data.

Filtering: Threshold set too high



EB05 Threshold

FDA to VaST on April 5, 2021

- Technically, any EBGM value above one indicates disproportional reporting
- Standard Threshold: EB05 ≥ 2

FDA:

- The EB05>2 threshold "*is by no means always optimal* (Szarfman *et al*.)
- "*value of 2 is arbitrarily chosen, and depends on the context.*" (Canida & Ihrie)

Harpaz et al:

"This investigation uses the value 1.0 […] *which for association statistics derived from ratios corresponds to the boundary of no statistical association"*

Is threshold filtering a surrogate for causality analysis?

Robust provenance & support for bias correction
763 lost signals (86%)

Direct interrogation of large & complete
VIOLIN: 5999-6765 lost signals

Row	Dataset	Signal	Date	Truancy factor derived from				Masking & filtering ratios derived from	Crude c	After adjustment for			Signal loss	
		Type		Target UNSER		Comparator UNSER				Truancy	Masking	Filtering		
				SER a	RUR a	SER b	RUR a			Number of signals			N	%
A	VIOLIN	PRR	4/30/2022	NA	NA	NA	NA	NA	2837	NA	5295	6123	5999	98%
B												6889	6765	98%
C	FOIA	EBDM	~~4/29/2022~~	FOIA 4/29/22	CDC 4/29/22			PRR Signals VIOLIN 4/30/22	124	405	770	887	763	86%
D	FOIA	EBDM				PRR Signals VIOLIN 4/30/22	CDC 4/29/22	EBDM Signals Oracle 10/1/21		405	1134	1856	1732	93%
E			10/1/2021	FOIA 10/1/21	CDC 10/1/21			PRR Signals VIOLIN 4/30/22	86	258	498	573	487	85%
F								EBDM Signals Oracle 10/1/21		258	724	1192	1106	93%
G			7/1/2022	FOIA 7/1/22	CDC 6/29/22			PRR Signals VIOLIN 4/30/22	134	443	842	971	837	86%
H								EBDM Signals Oracle 10/1/21		443	1243	2032	1898	93%
I	VAERS	EBDM	10/1/2021	NA	NA	NA	NA	NA					18717	

CDC: mRNA vs other
778 unique PRR signals
1904 from VIOLIN

Other combinations
from VIOLIN & Oracle
487-1898 lost signals

Larger estimate
Harpaz: VAERS
18717 signals

Delayed signal recognition FOIA dataset

FOIA dataset only Threshold 2, Mask

		MYOCARDITIS	MYOCARDITIS	PERICARDITIS	PERICARDITIS
		Pfizer	Moderna	Pfizer	Moderna
		FOIA	FOIA	FOIA	FOIA
Mask		ON	ON	ON	ON
Threshold		2	2	2	2
Week	Date	EB>2	EB>2	EB>2	EB>2
3	22-Jan				
5	5-Feb				
7	19-Feb				
9	5-Mar				
11	19-Mar				
13	2-Apr				
15	16-Apr				
17	30-Apr				
19	14-May				
21	28-May				
23	11-Jun				
25	25-Jun				
27	9-Jul				
29	23-Jul				
31	6-Aug				
33	20-Aug				
35	3-Sep				
37	17-Sep				
39	1-Oct				

- No EB05>2 signal FOIA
- EB05>2 signal FOIA
- No Emp Bayesain signal Oracle
- Emp Bayesain signal Oracle

When FDA could have seen signals FOIA vs. Oracle

FOIA + Oracle dataset, Non-stratified: Threshold 2, Mask

		MYOCARDITIS		MYOCARDITIS		PERICARDITIS		PERICARDITIS	
		Pfizer		Moderna		Pfizer		Moderna	
		FOIA	Orac	FOIA	Orac	FOIA	Orac	FOIA	Orac
Mask		ON	ON	ON	ON	ON	ON	ON	ON
Threshold		2	2	2	2	2	2	2	2
Week	Date	EB>2	EB>2	EB>2	EB>2	EB>2	EB>2	EB>2	EB>2
3	22-Jan		3				4		
5	5-Feb		6		7		9		4
7	19-Feb		9		16		18		14
9	5-Mar		18		27		25		22
11	19-Mar		21		29		34		24
13	2-Apr		22		32		34		29
15	16-Apr		23		38		39		33
17	30-Apr		51		52		58		49
19	14-May		83		59		84		59
21	28-May		266		130		147		92
23	11-Jun		465		252		261		174
25	25-Jun		671		334		390		234
27	9-Jul		897		382		533		266
29	23-Jul		1186		444		743		310
31	6-Aug		1651		575		1111		423
33	20-Aug		1952		655		1345		469
35	3-Sep		2053		704		1401		493
37	17-Sep		2731		895		1767		570
39	1-Oct		3515		1175		2408		671

- No EB05>2 signal FOIA
- EB05>2 signal FOIA
- No Emp Bayesain signal Oracle
- Emp Bayesain signal Oracle

When FDA could have seen signals FOIA vs. Oracle DEMASKING

FOIA + Oracle dataset, Non-stratified: Threshold 1, no mask

		MYOCARDITIS			MYOCARDITIS			PERICARDITIS			PERICARDITIS		
		Pfizer			Moderna			Pfizer			Moderna		
		FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac
Mask		ON	ON	OFF	ON	ON	OFF	ON	ON	OFF	ON	ON	OFF
Threshold		2	2	1	2	2	1	2	2	1	2	2	1
Week	Date	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1
3	22-Jan		3	3					4	4			
5	5-Feb		6	6		7	7		9	9		4	4
7	19-Feb		9	9		16	16		18	18		14	14
9	5-Mar		18	18		27	27		25	25		22	22
11	19-Mar		21	21		29	29		34	34		24	24
13	2-Apr		22	22		32	32		34	34		29	29
15	16-Apr		23	23		38	38		39	39		33	33
17	30-Apr		51	51		52	52		58	58		49	49
19	14-May		83	83		59	59		84	84		59	59
21	28-May		266	266		130	130		147	147		92	92
23	11-Jun		465	465		252	252		261	261		174	174
25	25-Jun		671	671		334	334		390	390		234	234
27	9-Jul		897	897		382	382		533	533		266	266
29	23-Jul		1186	1186		444	444		743	743		310	310
31	6-Aug		1651	1651		575	575		1111	1111		423	423
33	20-Aug		1952	1952		655	655		1345	1345		469	469
35	3-Sep		2053	2053		704	704		1401	1401		493	493
37	17-Sep		2731	2731		895	895		1767	1767		570	570
39	1-Oct		3515	3515		1175	1175		2408	2408		671	671

- No EB05>2 signal FOIA
- EB05>2 signal FOIA
- No Emp Bayesain signal Oracle
- Emp Bayesain signal Oracle

2/28: Israeli MoH inquiry

4/27: FDA
no new signals for MC

5/17: VaST
Obs not diff from Exp
5/24: VAERS Signal
5/27: Marks *not signaled*

9/17: Pfizer d3 VRBPAC
9/22 EUA & ACIP

4/7: DoD myocarditis preview

5/10: EUA Pfizer >12yo
5/17 12 ACIP

8/23 Pfizer BLA
8/30 ACIP

10/14 d3 for MOD & Jans
10/26 Pfizer >5y

FOIA + Oracle dataset, Non-stratified: Threshold 1, no mask

		MYOCARDITIS			MYOCARDITIS			PERICARDITIS			PERICARDITIS		
		Pfizer			Moderna			Pfizer			Moderna		
		FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac	FOIA	Orac	Orac
Mask		ON	ON	OFF	ON	ON	OFF	ON	ON	OFF	ON	ON	OFF
Threshold		2	2	1	2	2	1	2	2	1	2	2	1
Week	Date	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1	EB>2	EB>2	ER>1
3	22-Jan		3	3					4	4			
5	5-Feb		6	6		7	7		9	9		4	4
7	19-Feb		9	9		16	16		18	18		14	14
9	5-Mar		18	18		27	27		25	25		22	22
11	19-Mar		21	21		29	29		34	34		24	24
13	2-Apr		22	22		32	32		34	34		29	29
15	16-Apr		23	23		38	38		39	39		33	33
17	30-Apr		51	51		52	52		58	58		49	49
19	14-May		83	83		59	59		84	84		59	59
21	28-May		266	266		130	130		147	147		92	92
23	11-Jun		465	465		252	252		261	261		174	174
25	25-Jun		671	671		334	334		390	390		234	234
27	9-Jul		897	897		382	382		533	533		266	266
29	23-Jul		1186	1186		444	444		743	743		310	310
31	6-Aug		1651	1651		575	575		1111	1111		423	423
33	20-Aug		1952	1952		655	655		1345	1345		469	469
35	3-Sep		2053	2053		704	704		1401	1401		493	493
37	17-Sep		2731	2731		895	895		1767	1767		570	570
39	1-Oct		3515	3515		1175	1175		2408	2408		671	671

Pulmonary Embolism: FOIA: Threshold 2, Mask

Delayed signal recognition

FOIA dataset

	FOIA	Oracle	Pfizer	Moderna	Janssen
	date	Date	FOIA	FOIA	FOIA
Mask			ON	ON	ON
Threshold			2	2	2
Week			EB>2	EB>2	EB>2
3	6-Jan	22-Jan			
5		5-Feb			
7		19-Feb			
9	11-Mar	5-Mar			
11	19-Mar	19-Mar			
13	8-Apr	2-Apr			
15	16-Apr	16-Apr			
17	23-Apr	30-Apr			
19	7-May	14-May			
21	28-May	28-May			
23	11-Jun	11-Jun			
25	25-Jun	25-Jun			
27	9-Jul	9-Jul			
29	23-Jul	23-Jul			
31	6-Aug	6-Aug			
33	20-Aug	20-Aug			
35	3-Sep	3-Sep			
37	17-Sep	17-Sep			
39	1-Oct	1-Oct			

Pfizer Moderna Janssen

- No EB05>2 signal FOIA
- EB05>2 signal FOIA
- No Emp Bayesain signal Oracle
- Emp Bayesain signal Oracle

Pulmonary Embolism: FOIA + Oracle, Non-stratified: Threshold 2, Mask

When FDA could have seen signals FOIA vs. Oracle

	FOIA	Oracle	Pfizer	4394		Moder	1475		Jansse	643
	date	Date	FOIA	Orac		FOIA	Orac		FOIA	Orac
Mask			ON	ON		ON	ON		ON	ON
Threshold			2	2		2	2		2	2
Week			EB>2	EB>2		EB>2	EB>2		EB>2	EB>2
3	6-Jan	22-Jan		10			6			
5		5-Feb		20			21			
7		19-Feb		41			38			
9	11-Mar	5-Mar		64			55			
11	19-Mar	19-Mar		81			85			1
13	8-Apr	2-Apr		92			105			8
15	16-Apr	16-Apr		129			155			49
17	23-Apr	30-Apr		276			300			213
19	7-May	14-May		365			363			270
21	28-May	28-May		604			534			325
23	11-Jun	11-Jun		690			703			349
25	25-Jun	25-Jun		769			776			380
27	9-Jul	9-Jul		1366			850			400
29	23-Jul	23-Jul		2329			1027			429
31	6-Aug	6-Aug		3112			1159			482
33	20-Aug	20-Aug		3407			1227			506
35	3-Sep	3-Sep		3495			1266			531
37	17-Sep	17-Sep		3959			1373			582
39	1-Oct	1-Oct		4394			1475			643

- No EB05>2 signal FOIA
- EB05>2 signal FOIA
- No Emp Bayesain signal Oracle
- Emp Bayesain signal Oracle

Pulmonary Embolism: FOIA + Oracle, Non-stratified: Threshold 1, no mask

When FDA could have seen signals FOIA vs. Oracle DEMASKING

	No EB05>2 signal FOIA
	EB05>2 signal FOIA
	No Emp Bayesain signal Oracle
	Emp Bayesain signal Oracle

			Pfizer				Moderna				Janssen		
	FOIA	Oracle	Pfizer	4394	cases		Moder	1475	cases		Jansse	643	cases
	date	Date	FOIA	Orac	Orac		FOIA	Orac	Orac		FOIA	Orac	Orac
Mask			ON	ON	OFF		ON	ON	OFF		ON	ON	OFF
Threshold			2	2	1		2	2	1		2	2	1
Week			EB>2	EB>2	ER>1		EB>2	EB>2	ER>1		EB>2	EB>2	ER>1
3	6-Jan	22-Jan		10	10			6	6				
5		5-Feb		20	20			21	21				
7		19-Feb		41	41			38	38				
9	11-Mar	5-Mar		64	64			55	55				
11	19-Mar	19-Mar		81	81			85	85			1	1
13	8-Apr	2-Apr		92	92			105	105			8	8
15	16-Apr	16-Apr		129	129			155	155			49	49
17	23-Apr	30-Apr		276	276			300	300			213	213
19	7-May	14-May		365	365			363	363			270	270
21	28-May	28-May		604	604			534	534			325	325
23	11-Jun	11-Jun		690	690			703	703			349	349
25	25-Jun	25-Jun		769	769			776	776			380	380
27	9-Jul	9-Jul		1366	1366			850	850			400	400
29	23-Jul	23-Jul		2329	2329			1027	1027			429	429
31	6-Aug	6-Aug		3112	3112			1159	1159			482	482
33	20-Aug	20-Aug		3407	3407			1227	1227			506	506
35	3-Sep	3-Sep		3495	3495			1266	1266			531	531
37	17-Sep	17-Sep		3959	3959			1373	1373			582	582
39	1-Oct	1-Oct		4394	4394			1475	1475			643	643

Pulmonary Embolism: FOIA+ Oracle, Non-stratified: Threshold 1, no mask

2/24: Janssen EUA
2/27: Pfizer CMS PE signal

4/23: Remove pause

8/23 Pfizer BLA
8/30 ACIP

10/14 d3 for MOD & Jans

10/26 Pfizer >5yo

4/13: Pause
4/14 Other TE AEs?

5/10: VaST Pfizer CMS PE signal outstanding

9/17: Pfizer d3 VRBPAC
9/22 EUA & ACIP

10/15: JAN imbalance PE/DVT
FDA Potential safety concern

12/14: JAN TTS c/indication
12/16: ACIP

			Pfizer	4394	cases		Moder	1475	cases		Jansse	643	cases
	FOIA date	Oracle Date	FOIA	Orac	Orac		FOIA	Orac	Orac		FOIA	Orac	Orac
Mask			ON	ON	OFF		ON	ON	OFF		ON	ON	OFF
Threshold			2	2	1		2	2	1		2	2	1
Week			EB>2	EB>2	ER>1		EB>2	EB>2	ER>1		EB>2	EB>2	ER>1
3	6-Jan	22-Jan		10	10			6	6				
5		5-Feb		20	20			21	21				
7		19-Feb		41	41			38	38				
9	11-Mar	5-Mar		64	64			55	55				
11	19-Mar	19-Mar		81	81			85	85			1	1
13	8-Apr	2-Apr		92	92			105	105			8	8
15	16-Apr	16-Apr		129	129			155	155			49	49
17	28-Apr	30-Apr		276	276			309	309			218	218
19	7-May	14-May		365	365			383	383			270	270
21	28-May	28-May		604	604			534	534			325	325
23	11-Jun	11-Jun		690	690			703	703			349	349
25	25-Jun	25-Jun		769	769			776	776			380	380
27	9-Jul	9-Jul		1366	1366			850	850			400	400
29	23-Jul	23-Jul		2329	2329			1027	1027			429	429
31	6-Aug	6-Aug		3112	3112			1159	1159			482	482
33	20-Aug	20-Aug		3407	3407			1227	1227			506	506
35	3-Sep	3-Sep		3495	3495			1266	1266			531	531
37	17-Sep	17-Sep		3959	3959			1373	1373			582	582
39	1-Oct	1-Oct		4394	4394			1475	1475			643	643

"we have not detected any increase in cancers with the Covid-19 vaccines."

Up to 59 cancer event types with PRR signals 4/30/22 VIOLIN dataset

	Events	PRR	PRR	PRR	PRR	PRR=inf
Threshold		2	1	2	1	
		Masked	Masked	Unmasked	Unmasked	
PFIZER-BIONTECH	1303	25	29	31	32	4
MODERNA	948	6	6	18	18	0
JANSSEN	188	4	4	9	9	0
UNKNOWN	10	0	0	0	0	0
Total	2449	35	39	58	59	4

Thresholds of 2 (Yates chi squared >4), or 1 (p<0.05)

CDC: July 2022 PRR Analysis

MedDRA Codes ALL Reports (18+)	12/14/2020-07/29/2022 COVID19 mRNA N=660643	01/01/2009-07/29/2022 NON-COVID19 N=242091	> 4 Chi-Square	> 2 PRR	12/14-07/29 LCL	12/14-07/29 UCL
ADRENAL MASS	42	6	4.3	2.57	1.09	6.03
B-CELL LYMPHOMA	36	4	4.9	3.30	1.17	9.27
BREAST CANCER	59	5	10.8	4.32	1.74	10.77
BREAST CANCER METASTATIC	22	1	4.8	8.06	1.09	59.81
BREAST MASS	444	36	90.3	4.52	3.22	6.35
CHRONIC LYMPHOCYTIC LEUKAEMIA	74	10	8.7	2.71	1.40	5.25
COLON CANCER	47	2	11.7	8.61	2.09	35.45
FOLLICULAR LYMPHOMA	20	1	4.1	7.33	0.98	54.61
HEPATIC MASS	50	1	14.8	18.32	2.53	132.63
INTRACRANIAL MASS	44	5	6.0	3.22	1.28	8.13
LUNG ADENOCARCINOMA	21	1	4.5	7.73	1.04	57.46
LUNG NEOPLASM MALIGNANT	106	16	10.9	2.43	1.44	4.11
METASTASES TO BONE	32	1	8.3	11.73	1.60	85.81
METASTASES TO CNS	29	2	5.5	5.31	1.27	22.27
METASTASES TO LIVER	34	3	5.6	4.15	1.28	13.52
METASTASES TO LYMPH NODES	22	1	4.8	8.06	1.09	59.81
METASTASIS	43	6	4.5	2.63	1.12	6.17
NEOPLASM	101	8	20.0	4.63	2.25	9.50
PANCREATIC CARCINOMA	35	3	6.0	4.29	1.32	13.96
PLASMA CELL MYELOMA	69	10	7.4	2.54	1.31	4.93
PULMONARY MASS	557	68	80.1	3.00	2.33	3.86
THYROID CANCER	13	1	1.8	4.76	0.62	36.42
THYROID MASS	156	21	19.4	2.72	1.73	4.29
VACCINATION SITE MASS	1185	43	339.4	10.10	7.45	13.69

youtubecom/live/c5hYh5XO7qY?si=vFcTiumz_XwQgpte&t=6893

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: On Sep 16, 2021, at 2:01 PM,
To: Bri Dressen [redacted]
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>, "Frantz-Bohn, Susan" <Susan.Frantzbohn@fda.hhs.gov>

React19 communications with CBER Director Dr. Peter Marks

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: On Sep 16, 2021, at 2:01 PM,
To: Bri Dressen [redacted]
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>, "Frantz-Bohn, Susan" <Susan.Frantzbohn@fda.hhs.gov>

Dear Ms. Dressen,

Thank you for reaching out again. As you know, I was unable to join your meeting with FDA on August 23, 2021 because of urgent matters related to the ongoing pandemic. Lorrie McNeill, a senior leader at CBER, who met with you carefully listened to the information on individual experiences after vaccination with the COVID-19 vaccine and shared that information with me and our other subject matter experts who are involved in our vaccine safety surveillance activities. I am so sorry to hear of the serious medical issues you are experiencing and the tremendous impact this has had on your life.

We have met with our colleagues at NIH, and they may be better positioned to conduct the type of clinical research and to offer recommendations for treatment that you and others who have experienced these events seek. FDA is not able to provide medical advice or guidance and does not have a role in active clinical research about treatment of adverse events.

The Vaccine Adverse Event Reporting System (VAERS) has not identified any potential safety signal for the adverse experiences you provided both in your letter and at the meeting. At this point in time, FDA physicians have found that the adverse events reported following COVID-19 vaccination have been consistent with what was found during the clinical trials and is stated in the Fact Sheets for Vaccine Recipients and Health Care Providers.

FDA diligently and carefully reviews reports submitted to VAERS to identify potential signals that would indicate the need for further study. Extremely rare adverse events have been identified using VAERS and FDA has communicated that information to the public and health care providers. One example is from April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

I understand that this may not be the response you'd hoped for. Please know that we take our vaccine safety surveillance responsibilities very seriously. We

The Vaccine Adverse Event Reporting System (VAERS) has not identified any potential safety signal for the adverse experiences you provided both in your letter and at the meeting. At this point in time, FDA physicians have found that the adverse events reported following COVID-19 vaccination have been consistent with what was found during the clinical trials and is stated in the Fact Sheets for Vaccine Recipients and Health Care Providers.

FDA diligently and carefully reviews reports submitted to VAERS to identify potential signals that would indicate the need for further study. Extremely rare adverse events have been identified using VAERS and FDA has communicated that information to the public and health care providers. One example is from April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

https://static.therealpetermarks.com/assets/**2021-08-23**-email.jpg

React19 communications with CBER Director Dr. Peter Marks

Peter Marks / FDA [] there is not huge underreporting in VAERS during the time of COVID. If anything stimulated reporting in VAERS has has occurred because we've encouraged it. So we go through VAERS and we try to understand what signals there are. [] Dr. Nair around that that do this and they have **looked for various signals like transverse myelitis**, Um, and they have looked for other neurologic conditions and they have, **we have not found a rate of transverse myelitis, for instance, that is higher than would be expected in the population**.

.

Nararyan Nair / FDA That's VAERS, [] And just as Dr. Marks says, we look at kind of the and we have received reports of transverse myelitis and we have received reports of Guillain-Barre. I can't tell you with Guillain-Barre syndrome, **we did see increased reports after the Janssen vaccine** and we did add a **warning** to the label. [] For Moderna and Pfizer, we have not seen that for transverse myelitis or other neurologic conditions. We haven't seen any evidence that you're more likely to get those conditions after receiving the vaccination than than if you haven't received the vaccination. We haven't received that in our passive surveillance and we haven't had any information in our active surveillance where we do actually [formal epidemiological] studies, and looking at that, to my knowledge, the FDA databases and CDC databases, we haven't seen it there either. [] **The directive that I've received from Dr. Marks is to leave no stone unturned**, to continue to look at **this very vigorously** and and do everything we can to understand all the safety related to these products.

Peter Marks / FDA I believe the paresthesia that were added to the European label had to do with paresthesia immediately after vaccination, that's tingling immediately after getting a vaccine. I think what they were talking about there is something very different from the longer term neurologic effects that we're talking about.

https://static.therealpetermarks.com/assets/**01_04_22**_FDA_PeterMarks_FollowUp_transcript.pdf

Number of neurological-related PRR signals meeting various criteria (VIOLIN 4/30/22)							
Criteria		Canonical	Alt p<0.05	Canonical	Alt p<0.05	PR5>1	Any
Threshold		2	1	2	1	1	
		Masked	Masked	Demask	Demask	Demask	
PFIZER-BIONTECH		59	112	113	134	141	145
MODERNA		20	75	82	112	117	120
JANSSEN		43	86	92	107	114	116
UNKNOWN		4	4	15	17	22	22
Total		126	277	302	370	394	403

Abnormal dreams, Acute motor-sensory axonal neuropathy, Ageusia, Amnesia, Anosmia, Antiacetylcholine receptor antibody, Aphasia, Aphonia, Asthenia, Attention deficit hyperactivity disorder, Aura, Balance disorder, Basal ganglia stroke, Behaviour disorder, Bell\'s palsy, Brain compression, Brain herniation, Brain hypoxia, Brain injury, Brain stem stroke, Cerebellar stroke, Cerebrospinal fluid leakage, Cerebrovascular accident, Cluster headache, Concussion, Confusional state, Consciousness fluctuating, Craniocerebral injury, CSF pressure, CSF red blood cell count, CSF volume, Deafness neurosensory, Delusion, Dementia, Dementia Alzheimer\'s type, Dementia with Lewy bodies, **Dental paraesthesia**, Depressed mood, Depression, Derealisation, Diabetic neuropathy, Disorganised speech, Disorientation, Disturbance in attention, Dizziness, Dizziness exertional, Dizziness postural, Dysgeusia, Dysstasia, Electric shock sensation, Embolic stroke, Essential tremor, Euphoric mood, Eye paraesthesia, Eyelid sensory disorder, Facial asymmetry, Facial nerve disorder, Facial pain, Facial paralysis, Facial paresis, Facial spasm, Feeling cold, Feeling drunk, Feeling guilty, Feeling hot, Feeling jittery, Feeling of body temperature change, Feeling of despair, Feeling of relaxation, Feelings of worthlessness, Fine motor skill dysfunction, Focal dyscognitive seizures, Generalised tonic-clonic seizure, **Genital paraesthesia**, Guillain-Barre syndrome, Haemorrhagic stroke, Haemorrhagic transformation stroke, Headache, Helplessness, Hemianaesthesia, **Hemiparaesthesia**, Hemiparesis, Hemiplegia, Hemiplegic migraine, Homicidal ideation, Hypervigilance, Hypoaesthesia, Hypoaesthesia eye, Hypoaesthesia oral, Hypoaesthesia teeth, Hypogeusia, Hyposmia, Impaired reasoning, Incoherent, Injection site paraesthesia, Intellectual disability, Ischaemic stroke, Lacunar infarction, Lacunar stroke, Loss of consciousness, Mania, **Memory impairment**, Meniere\'s disease, Mental disorder, Mental fatigue, **Mental impairment**, Mental status changes, Migraine, Migraine with aura, Mood swings, Motor dysfunction, Myelitis transverse, Nerve compression, Nerve stimulation test, Nerve stimulation test abnormal, Nervousness, Neuralgia, Neuropathic muscular atrophy, Neuropathy peripheral, Nightmare, NIH stroke scale, NIH stroke scale abnormal, NIH stroke scale score increased, Occipital neuralgia, Olfactory nerve disorder, Optic ischaemic neuropathy, **Paraesthesia**, **Paraesthesia ear, Paraesthesia oral**, Paranoia, Parkinson\'s disease, Parosmia, Peripheral nerve injury, Peripheral paralysis, Phantom limb syndrome, Pharyngeal paraesthesia, **Postural orthostatic tachycardia syndrome**, Psychogenic seizure, Quantitative sudomotor axon reflex test, Raynaud\'s phenomenon, Restless legs syndrome, Restlessness, Sciatic nerve injury, Seizure, Seizure like phenomena, Self-injurious ideation, Sensory disturbance, Sensory loss, Sensory overload, Sleep paralysis, **Small fibre neuropathy, Subacute inflammatory demyelinating polyneuropathy**, Suicidal ideation, Thrombotic stroke, **Tinnitus**, Transient global amnesia, Transient ischaemic attack, Tremor, Trigeminal nerve disorder, Trigeminal neuralgia, Upper motor neurone lesion, Vaccination site nerve damage, **Vaccination site paraesthesia**, Vascular dementia, ,

Drug Safety (2022) 45:765–780
https://doi.org/10.1007/s40264-022-01186-z

ORIGINAL RESEARCH ARTICLE

Signaling COVID-19 Vaccine Adverse Events

Rave Harpaz[1] · William DuMouchel[1] · Robbert Van Manen[1] · Alexander Nip[1] · Steve Bright[1] · Ana Szarfman[2] · Joseph Tonning[3] · Magnus Lerch[1,4]

✉ Rave Harpaz
rave.harpaz@oracle.com

1 Oracle Health Sciences, Burlington, MA, USA

2 U.S. FDA, Silver Spring, MD, USA

3 U.S. Public Health Service/U.S. FDA retired, Silver Spring, MD, USA

4 Lenolution GmbH, Berlin, Germany

Disclaimer The findings and conclusions expressed in this report are those of the authors and do not necessarily represent the views of the US FDA or the federal government.

"I am not astonished that [FDA's data mining system] was unable to detect these signals [identified by Dr. DuMouchel as being masked]"

Harpaz et al

Table 7 VAERS counts of masked associations

	Number associations	Number masked associations	% masked associations
All vaccines	265,987	1330	0.50%
Non-COVID-19 vaccines	241,016	753	0.31%
COVID-19 vaccines	24,971	577	2.31%
Pfizer-BioNTech/Moderna	18,588	458	2.46%

We found that although the masking effect is rare relative to the entire set of possible associations between vaccines and AEs (representing 0.5% of the total number of unique associations), it is roughly eight times more likely to occur with COVID-19 vaccines than with other vaccines. As mentioned, this may be explained by the unique dynamic and extent of reporting into VAERS for the class of COVID-19 vaccines.

FDA had access to Empirica RGPS demasking software

DE Data Mining Methods

FOIA dataset p3/153

- Empirica™ Signal software (Oracle)

docs.oracle.com/search/?q=rgps%209.0&pg=1&size=10&product=en%2...

Help Center / Industries / Health Sciences Empirica Signal 9.1

Oracle Empirica Signal Installation and Upgrade Instructions 9.1

August 27, 2020

August 27, 2020

Prepare the application server

Help. Install the **RGPS** add-on package to the R library (new installations and upgrade from 8.0.x, 8.1, or 8.1.0.1)If you have R version 3.3 installed, you c...

Set up the listener.properties file

path. For more information, see Install the **RGPS** add-on package to the R library. **rgps_command**=/usr/bin/R rgps_cpus_count Maximum Number o...

Install the RGPS add-on package to the R library (new installations and upgrade from 8.0.x 8.1 or 8.1.0.1)

If you have R version 3.3 installed, you can optionally install the **RGPS** add-on package to enable Regression-adjusted Gamma Poisson Shrinker (**RGPS**)...

Upgrade from Oracle Empirica Signal release 9.0.x to 9.1

Empirica Signal release **9.0**.x to 9.1 Perform these tasks to upgrade from Oracle Empirica Signal **9.0**.x to 9.1. Restore site-specific properties filesTo...

https://docs.oracle.com/en/industries/health-sciences/empirica-signal/9.1/userguide/step-7-submit-data-mining-run.html
https://docs.oracle.com/en/industries/health-sciences/empirica-signal/9.1/userguide/rgps-computations.html

49 examples of extreme masking

Bell's palsy
Paraesthesia ear
Bradykinesia
Product substitution
Sinus rhythm
COVID-19 immunisation
Cardiac telemetry abnormal
AST/ALT ratio abnormal
Diaphragmatic spasm
Mastoid disorder
Cholecystitis acute
Blood pressure systolic
Ejection fraction
SARS-CoV-1 test
Cardiac failure chronic
Acute left ventricular failure
Agonal rhythm
Hypomagnesaemia
Pulmonary infarction
Cerebral artery occlusion
Diastolic dysfunction
Cardiac telemetry normal

Aortic stenosis
Sudden cardiac death
Hypertensive emergency
May-Thurner syndrome
Infusion
Aortic aneurysm rupture
Thalamic infarction
Drainage
Percutaneous coronary intervention
Basal ganglia stroke
Embolic stroke
Cardiac assistance device user
Magnetic resonance imaging heart
Brain natriuretic peptide increased
Ischaemic stroke
COVID-19 pneumonia
Dementia
Acute myocardial infarction
Pneumonia aspiration
Electrocardiogram ST segment elevation
Product administered to patient of inappropriate age
Asymptomatic COVID-19
Cardiac telemetry abnormal
Blood pressure systolic
Brain natriuretic peptide increased
Acute myocardial infarction
COVID-19 pneumonia

March 26, 2021, Dr. Szarfman, shares DuMouchel's analysis - found **"49 examples of extreme masking"** with over twenty of those examples of adverse events now showing a statistically significant safety signal when adjusted for masking.[4]

In September 2021, Dr. Marks informed Dr. Cavazzoni, the then-Director of CDER, that Dr. Szarfman, who is a CDER employee, "has been asked to cease and desist" conducting her data analyses.

March 17-18, 2021: Dr. Menschik requests a "'**special project' run**" of MGPS that adjusts for masking with COVID-19 vaccines He notes that he observed a "**muting trend**" for adverse events, which he attributes to the volume of COVID-19 vaccine reports.

Unmasked:
How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals

U.S. Senate Permanent Subcommittee on Investigations
Chairman Ron Johnson
Majority Staff Interim Report

Released in Conjunction with the Permanent Subcommittee on Investigations' April 29, 2026 Hearing

Although FDA acknowledged and confirmed the problem, these warnings were ignored, met with a **"cease and desist"** notice, and the refusal by senior FDA officials to implement solutions available to FDA to overcome masking. This reticence is perhaps best encapsulated by FDA's Dr. Zinderman, writing to Dr. Szarfman

"Results from adjusting parameters that raise or lower sensitivity of the alerts as the vaccination campaign is underway could lead to confusion and have unintended consequences (e.g. regarding vaccine confidence)."

www.hsgac.senate.gov/subcommittees/investigations/hearings/unmasked-how-biden-health-officials-purposely-turned-a-blind-eye-toward-covid-19-vaccine-safety-signals/

Was the detection of PRR and EBDM VAERS safety signals by FDA and CDC adequate and effective?

1. There were **persistently 76-123 TIMES** more EBDM signals associated with the Janssen product vs. Pfizer and Moderna, lacking obvious regulatory action (use normalized)
2. **96% of Pfizer and 91% of Moderna signals** were missing: (truancy factors 26 and 11).
3. FDA did not correct for **masking**, despite possessing the software to do so.
4. Signals were filtered because the **threshold** was set high at two.
5. FDA failed to consider foreign-originating VAERS reports in its EBDM
6. FDA failed to mine potential signals among borderline signals ("*Inquisitorial triage bias")*
7. Aggregate loss of **763 signals** (range 487-1898; 86% range 85-93%) to 4/29/22.
   Up to: **6765** signals *(direct dataset interrogation, robust supportive 2nd analyses)*
8. CDC did not conduct/ report separate PRR analyses for Janssen, Pfizer & Moderna. Analysis for mRNA pro-vaccines combined is **missing 1026 (54%)** signals
9. True excess of 4.8- and 8.8-more Janssen than Pfizer and Moderna signals. Action?
10. **"Statistical signal"** was **redefined** mean that it did not automatically imply **a** "safety signal."

Conclusion

1. Integration of the **totality** of safety signal data **inadequate and ineffective** by regulators and advisory committees**.**
2. **Different standards** were applied to the assessment of safety and efficacy.
3. The suppression of **potential risk**, FDA **was legally required** to consider, without needing to establish causality, is both a scientific and a regulatory failure.
4. Data inconsistent with statements made by regulators: stroke, cancer, clotting issues, myocarditis.
5. Signal recognition **delayed for weeks or months**
6. Findings incompatible with the "Enhanced surveillance" of Adverse Events Special Interest and the representation of VAERS as *"the nation's **early warning system** for vaccine safety."*
7. Findings impugn the reliability of **regulatory and injury compensation decisions**
8. Even with their limitations, findings **warrant** full disclosure of vaccine safety data, an **investigation** into deficient signal detection and regulatory oversight, and a corrective action plan.
9. **"the volume of reporting for COVID-19 vaccines is likely to influence future statistical associations with other new vaccines." (Harpaz et al.)**