Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Description of Database Characteristics

Database	Description	Claims Type	Update frequency	Data Lag, Time to 80% Completeness[a]	Average No. Enrollees aged 6 months-17 years (2020-2023) [b]	No. IIS Jurisdictions Incorporated into Analysis[c]
CVS Health	CVS Health transforms Aetna health plan enrollment, demographic, and medical and drug claims data, for individuals enrolled from January 2018 forward. The Aetna data includes commercial, including Affordable Care act (ACA) Marketplace, and Medicare Advantage health plans into a patient-centered, comprehensive Common Data Model (CDM).	Fully Adjudicated	Monthly	~ 3-4 months for IP claims, 2-3 months for OP claims, and 1-2 months for professional claims	6 months-4 years: > 1.08m 5-11 years: > 1.47m 12-15 years: > 934k 16-17 years: > 514k	23
Optum Pre-adjudicated Claims	The Optum data includes enrollment, prescription drug and pre-adjudicated hospital and physician health insurance claims. The pre-adjudicated claims database includes claims for privately insured and Medicare Advantage enrollees. Hospital and physician claims undergo initial processing on a daily basis from a large number of providers across the US who accept patients with health insurance.	Pre-Adjudicated	Bi-Weekly	~ 1-2 months for IP, OP, and professional claims	6 months-4 years: > 839k 5-11 years: > 1.18m 12-15 years: > 750k 16-17 years: > 392k	20
Carelon Research	Carelon Research is a wholly-owned, research subsidiary of Elevance Health, Inc., a holding company owning several large US health plans associated with Anthem Blue Cross Blue Shield. Carelon has a US population database including individually insured by commercial and Medicare Advantage plans, the Healthcare Integrated Research Database (HIRD), with longitudinal data on health plan enrollees.	Fully Adjudicated	Monthly	~ 2-3 months for IP claims and 1-2 months for OP and professional claims	6 months-4 years: > 1.32m 5-11 years: > 1.86m 12-15 years: > 1.20m 16-17 years: > 647k	9

[a] Data lag based on 2020 claims delay distribution

[b] Average number of annual enrollees in a given age category is reported for the years 2020-2023 except for Optum where the average is reported through 2021 based on the available data.

[c] IIS = Immunization Information System. IIS jurisdictions are used to supplement claims data in improving the capture of COVID-19 vaccine dose information. The FDA BEST Initiative, through its distributed data network, facilitated linkage of claims data with IIS data to enhance capture of vaccinations in insured populations. IIS jurisdictions were solicited to share COVID-19 vaccination data that were linked to individual-level claims records by individual commercial insurer data partners using personally identifiable information and IIS-specific linkage algorithms.

eTable 2. Monovalent COVID-19 Vaccines Dosing Schedule Associated with Emergency Use Authorizations or Approval

Brand	Age Group (years)	Authorized dose	Date of Authorization/Approval
BNT162b2	6 months – 4	Three-dose primary series (3 micrograms)	EUA: 06/17/2022[1]
	5-11	Two-dose primary series (10 micrograms)	EUA (primary series): 10/29/2021[2]
		Third primary series dose for immunocompromised individuals (10 micrograms)	EUA (third dose): 01/03/2022[2]
		Single booster at least 5 months after completion of primary series (10 micrograms)	EUA (single booster): 05/17/2022 [3]
	12-15	Two-dose primary series (30 micrograms)	EUA (primary series): 05/10/2021[4]
		Third primary series dose for immunocompromised individuals (30 micrograms)	EUA (third dose): 08/12/2021[5]
		First booster at least 5 months after completion of primary series (30 micrograms)	EUA (first booster): 01/03/2022[6]
		Second booster at least 4 months after receipt of first booster for immunocompromised individuals (30 micrograms)	EUA (second booster): 03/29/2022[6]
	16-17	Two-dose primary series (30 micrograms)	Approval (primary series): 08/23/2021[7] EUA (primary series): 12/11/2020 [7]
		Third primary series dose for immunocompromised individuals (30 micrograms)	EUA (third dose): 08/12/2021[5]
		First booster at least 5 months after completion of primary series (30 micrograms)	EUA (first booster): 12/9/2021[6]

Brand	Age Group (years)	Authorized dose	Date of Authorization/Approval
		Second booster at least 4 months after receipt of first booster for immunocompromised individuals (30 micrograms)	EUA (second booster): 03/29/2022[6]
mRNA-1273	6 months – 5	Two-dose primary series (25 micrograms)	EUA (primary series): 06/17/2022[8]
		Third primary series dose for immunocompromised individuals (25 micrograms)	EUA (third dose): 06/17/2022[8]
	6-11	Two-dose primary series (50 micrograms)	EUA (primary series): 06/17/2022[8]
		Third primary series dose for immunocompromised individuals (50 micrograms)	EUA (third dose): 06/17/2022[8]
	12-15	Two-dose primary series (100 micrograms)	EUA (primary series): 06/17/2022[8]
		Third primary series dose for immunocompromised individuals (100 micrograms)	EUA (third dose): 06/17/2022[8]
	16-17	Two-dose primary series (100 micrograms)	EUA (primary series): 06/17/2022[8]
		Third primary series dose for immunocompromised individuals (100 micrograms)	EUA (third dose): 06/17/2022[8]
NVX-CoV2373	12-17	Two dose primary series (5 micrograms)	EUA (primary series): 08/19/2022[9]

eTable 3. Outcomes, Settings, Clean Windows, Risk Windows, and Analysis Type for the BNT162b2, mRNA-1273, and NVX-CoV2373 COVID-19 Vaccinated Population (Ages 6 months to 17 years)

Outcomes[a]	Care Setting	Clean Window[b]	Risk Window	Analysis Type[d]
Acute Myocardial Infarction	IP	365 days	1-28 days [10,11]	Descriptive Only
Anaphylaxis	IP, OP-ED	30 days	0-1 day [12,13]	Descriptive and Sequential Testing
Appendicitis	IP, OP-ED	365 days	1-42 days [14,15]	Descriptive and Sequential Testing
Bell's Palsy	IP, OP, PB	183 days	1-42 days [16]	Descriptive and Sequential Testing
Common Site Thrombosis with Thrombocytopenia	[Defined in Footnote] [e]	365 days	1-28 days [17]	Descriptive and Sequential Testing
Deep Vein Thrombosis	IP, OP, PB	365 days	1-28 days [18,19]	Descriptive and Sequential Testing
Disseminated Intravascular Coagulation	IP, OP-ED	365 days	1-28 days [20]	Descriptive and Sequential Testing
Encephalitis or Encephalomyelitis	IP	183 days	1-42 days [21]	Descriptive and Sequential Testing
Febrile Seizures	IP, OP PB	42 days	0-1 days[c]	Descriptive Only
Guillain-Barré Syndrome	IP – Primary Position Only	365 days	1-42 days [22,23]	Descriptive and Sequential Testing[f]
Hemorrhagic Stroke	IP	365 days	1-28 days [10,11]	Descriptive and Sequential Testing[f]
Immune Thrombocytopenia	IP, OP, PB	365 days	1-42 days [24,25]	Descriptive and Sequential Testing
Kawasaki Disease	IP, OP, PB	365 days	1-28 days[c]	Descriptive Only
Multisystem Inflammatory Syndrome in Children	IP, OP-ED	365 days	1-42 days [26]	Descriptive Only
Myocarditis/Pericarditis (All Settings) (1-7 day)	IP, OP, PB	365 days	1-7 days [27]	Descriptive and Sequential Testing
Myocarditis/Pericarditis (All Settings) (1-21 day)	IP, OP, PB	365 days	1-21 days [28]	Descriptive and Sequential Testing
Myocarditis/Pericarditis (IP/OP-ED) (1-7 day)	IP, OP-ED	365 days	1-7 days [27]	Descriptive and Sequential Testing
Myocarditis/Pericarditis (IP/OP-ED) (1-21 day)	IP, OP-ED	365 days	1-21 days [28]	Descriptive and Sequential Testing
Narcolepsy	IP, OP, PB	365 days	1-42 days [29-31]	Descriptive and

Outcomes[a]	Care Setting	Clean Window[b]	Risk Window	Analysis Type[d]
				Sequential Testing[f]
Non-Hemorrhagic Stroke	IP	365 days	1-28 days [10, 11]	Descriptive and Sequential Testing
Pulmonary Embolism	IP, OP, PB	365 days	1-28 days [18,19,32-35]	Descriptive and Sequential Testing
Seizures	IP, OP-ED	42 days	0-7 days [33]	Descriptive and Sequential Testing
Transverse Myelitis	IP, OP-ED	365 days	1-42 days [34]	Descriptive Only
Unusual Site Thrombosis with Thrombocytopenia	[Defined in Footnote] [e]	365 days	1-28 days [35]	Descriptive Only

Definitions:

- **Clean Window** is the interval used to define incident outcomes where an individual enters the study cohort only if the health outcome of interest did not occur during that interval.
- **Risk Window** is the interval during which occurrence of the health outcome of interest will be included in the analyses.
- **Care Setting:** IP refers to inpatient facility claims. OP-ED refers to a subset of outpatient facility claims occurring in the emergency department. OP/PB refers to all outpatient facility claims, and professional/provider claims except those professional/provider claims with a laboratory place of service

[a] Source of the claims-based algorithm: FDA. Appendix 7. Safety AE Codes. https://www.bestinitiative.org/wp-content/uploads/2022/01/C19-Vax-Safety-AESI-Bkgd-Rate-Est-Protocol-Suppl.xlsx

[b] The clean window is the interval prior to vaccination where a patient must not have had the outcome.

[c] References for the duration of these windows could not be located in the literature and are instead based on input from clinicians.

[d] Sequential testing was conducted only when the minimum threshold of observed events was met (at least 3 events). For NVX-CoV2373 (ages 12 to 17 years) and mRNA-1273 (ages 6 to 17 years) sequential testing did not initiate due to not meeting this minimum threshold for any of the outcomes specified above

[e] Both Common thrombosis with thrombocytopenia and Unusual site thrombosis (broad) with thrombocytopenia are combined outcomes consisting of a thrombotic event (made up of other events such as acute myocardial infarction, deep vein thrombosis etc.,) and a thrombocytopenia event (defined in the IP, OP/PB setting). The overall setting
definition for each outcome depends on individual setting definitions for each of these components.

[f] Feasibility of sequential testing of certain outcomes in specific age groups was evaluated based on availability of background rates. Guillain-Barré Syndrome and Hemorrhagic Stroke were sequentially tested in ages <5 years only and Narcolepsy in ages >5 years old only due to lack of estimable background rates in other age groups

eTable 4. Administrative Codes for COVID-19 Vaccine Administration used in claims and IIS databases

HCPCS/CPT[a] Codes	CVX[b] Codes (IIS-Specific)	Manufacturer	Name	Age Group (years)	Vaccine Administration Code	NDC[c] 11 Labeler Product ID (Vial)	Dosing Interval
91308	219	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	6 m- 4	0081A (1st dose) 0082A (second dose) 0083A (third dose)	59267-0078-01 59267-0078-04	• 21+ days between dose 1 and dose 2 • 56+ days between dose 2 and dose 3
91307	218	Pfizer	Pfizer-BioNTech COVID-19 Pediatric Vaccine	5-11	0071A (1st dose) 0072A (2nd dose) 0073A (3rd dose) 0074A (booster dose)	59267-1055-0159267-1055-02 59267-1055-04	• 21+ days between dose 1 and dose 2 • For immunocompromised, 21+ days between dose 1 and dose 2, and 28+ days between dose 2 and additional primary dose (dose 3)
91305	217	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	12-17	0051A (1st dose) 0052A (2nd dose) 0053A (3rd dose) 0054A (booster dose)	59267-1025-01 59267-1025-02 59267-1025-03 59267-1025-04	• 21+ days between dose 1 and dose 2 and 5+ months between dose 2 and third/booster dose • For immunocompromised, 21+ days between dose 1 and dose 2, 28+ days between dose 2 and dose 3. Additionally, booster dose recommended 3+ months after primary series
91300	208	Pfizer	Pfizer-BioNTech COVID-19 Vaccine	12-17	0001A (1st dose) 0002A (2nd dose) 0003A (3rd dose)	59267-1000-01 59267-1000-02 59267-1000-03	• 21+ days between dose 1 and dose 2 and 5+ months between dose 2 and third/booster dose • For

HCPCS/CPT[a] Codes	CVX[b] Codes (IIS-Specific)	Manufacturer	Name	Age Group (years)	Vaccine Administration Code	NDC[c] 11 Labeler Product ID (Vial)	Dosing Interval
					0004A (booster dose)		immunocompromised, 21+ days between dose 1 and dose 2, 28+ days between dose 2 and dose 3. Additionally, booster dose recommended 3+ months after primary series
					0002A (2nd dose)		
					0003A (3rd dose)		
					0004A (booster dose)		
91301, 91306, 91309	207	Moderna	Moderna COVID-19 Vaccine	6 m-17	0011A, 0091A (1st dose)	61434-0043-00 61434-0043-01 80777-0100-11 80777-0100-98 80777-0100-99 80777-0277-05 80777-0279-05 80777-0273-98 80777-0273-10 80777-0273-99 80777-0273-15 80777-0273-98 80777-0273-05 80777-0273-99	• 28+ days between dose 1 and dose 2 • For immunocompromised, 28 days between dose 1 and dose 2, and 28+ days between dose 2 and dose 3.
					0012A, 0092A (2nd dose)		
					0013A, 0093A (3rd dose)		
					0064A, 0094A (booster dose)		
91304	211	Novavax	Novavax COVID-19 Vaccine	12-17	0041A (1st dose)	80631-0100-01 80631-0100-10	• 21+ days between dose 1 and dose 2 including for immunocompromised
					0042A (2nd dose)		

[a] HCPCS: The Healthcare Common Procedure Coding System produced by the Centers for Medicare and Medicaid Services (CMS)[36]
CPT: The Current Procedural Terminology codes[36]
[b] CVX: Vaccine administered code set developed and maintained by the Centers for Disease Control and Prevention's (CDC) National Center of Immunization and Respiratory Diseases (NCIRD)[37]
[c] NDC: National Drug Codes used to identify and report drugs using a unique, three-segment number which serves as the Food and Drug Administration's (FDA) identifier for drugs[38]

eTable 5. Vaccine Dose Counts for Monovalent BNT162b2, mRNA-1273, NVX-CoV2373 COVID-19 Vaccines Administered to the Pediatric Population Across All Data Sources[a]

Vaccine Dose	BNT162b2		mRNA-1273		NVX-CoV2373	
	N	%	N	%	N	%
Total	8,121,591	100	322,628	100	136	100
Dose 1	3,843,778	47.33	173,857	53.89	63	46.32
Dose 2	3,235,442	39.84	140,734	43.62	43	31.62
Dose 3/Monovalent Booster	1,033,036	12.72	5,284	1.64	§	§
Unknown/Unclear	9,335	0.11	2,753	0.85	§	§

[a] Combines Optum data through 4/2023, Carelon Research data through 3/2023, CVS Health data through 2/2023
[§] Cell sizes 1-10 and cells that can be used to back-calculate small cell sizes were masked for confidentiality

eTable 6. Descriptive Summary of Outcomes Included in Descriptive Analysis Only

Outcome	Brand	All Data Sources		Carelon Research[a]		CVS Health[b]		Optum[c]	
		No. Vaccine Doses	No. Outcomes	No. Vaccine Doses	No. Outcomes	No. Vaccine Doses	No. Outcomes	No. Vaccine Doses	No. Outcomes
Acute myocardial infarction	BNT162b2	6,650,342	§	2,589,974	§	2,120,805	§	1,939,563	0
	mRNA-1273	252,959	0	94,878	0	85,473	0	72,608	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Febrile Seizure	BNT162b2	7,932,684	76	3,064,741	26	2,565,776	27	2,302,167	23
	mRNA-1273	315,520	37	119,174	14	108,685	§	87,661	§
	NVX-CoV2373	133	0	21	0	28	0	84	0
Guillain-Barré syndrome	BNT162b2	6,650,324	§	2,589,971	§	2,120,793	§	1,939,560	§
	mRNA-1273	252,959	0	94,878	0	85,473	0	72,608	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Hemorrhagic stroke	BNT162b2	6,650,157	14	2,589,902	§	2,120,744	§	1,939,511	§
	mRNA-1273	252,950	0	94,874	0	85,473	0	72,603	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Kawasaki disease	BNT162b2	6,648,712	79	2,589,367	26	2,120,267	23	1,939,078	30
	mRNA-1273	252,810	§	94,809	§	85,441	§	72,560	§
	NVX-CoV2373	98	0	18	0	18	0	62	0
Multisystem inflammatory syndrome in children (MIS-C)	BNT162b2	6,650,003	15	2,589,829	§	2,120,710	§	1,939,464	§
	mRNA-1273	252,949	0	94,878	0	85,469	0	72,602	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Narcolepsy	BNT162b2	6,649,400	65	2,589,563	26	2,120,525	22	1,939,312	17
	mRNA-1273	252,954	0	94,877	0	85,472	0	72,605	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Transverse myelitis	BNT162b2	6,650,321	§	2,589,967	§	2,120,801	0	1,939,553	§
	mRNA-1273	252,959	§	94,878	§	85,473	0	72,608	0
	NVX-CoV2373	98	0	18	0	18	0	62	0
Unusual site thrombosis with thrombocytopenia	BNT162b2	6,650,303	§	2,589,961	§	2,120,793	§	1,939,549	0
	mRNA-1273	252,959	0	94,878	0	85,473	0	72,608	0
	NVX-CoV2373	98	0	18	0	18	0	62	0

[a] Data through 3/2023 [b] Data through 2/2023 [c] Data through 4/2023

§ Cell sizes 1-10 and cells that can be used to back-calculate small cell sizes were masked for confidentiality

eTable 7. Background Annual Rate of Seizures Per 100,000 Person-Years by Data Source in Children Aged 2-4 Years and 2-5 Years, 2020 (Baseline), 2019 and 2022

	Ages 2-4 years					Ages 2-5 years				
Data Source	**2020 (baseline)**	**2019[a]**	**2022[b]**	**Difference 2019 vs 2020 (Ratio)**	**Difference 2022 vs 2020 (Ratio)**	**2020 (baseline)**	**2019[a]**	**2022[b]**	**Difference 2019 vs 2020 (Ratio)**	**Difference 2022 vs 2020 (Ratio)**
Carelon Research	234.35	416.25	551.18	1.78	2.35	207.03	355.82	470.51	1.72	2.27
CVS Health	190.55	363.01	434.57	1.91	2.28	166.72	306.90	369.11	1.84	2.21
Optum	192.96	371.54	448.26	1.93	2.32	168.13	314.92	378.07	1.87	2.25

[a] For all three data sources, this includes background rates data through 12/2019
[b] For all three data sources, this includes background rates data through 12/2022

eTable 8. Sequential Testing Results for the Pediatric Population Receiving BNT162b2 or mRNA-1273 Ancestral Monovalent COVID-19 Vaccines Stratified by Vaccine Dose and Outcome

Dose	Age group	BNT162b2				mRNA-1273			
		Doses, No.	Outcomes, No.	Person-time, d	Signal status	Doses, No.	Outcomes, No.	Person-time, d	Signal status
Anaphylaxis									
Doses 1 and 2	6 mo-4 or 5 y	454 003	NR	903 139	NT	304 501	NR	606 089	NT
	5 or 6-11 y	2 715 842	NR	5 428 277	NS	1687	0	3346	NT
	12-15 y	2 444 395	NR	4 887 562	NS	1558	0	3093	NT
	16-17 y	1 245 735	NR	2 490 728	NT	1315	0	2604	NT
Dose 1	6 mo-4 or 5 y	248 106	NR	493 859	NT	166 491	0	331 645	NT
	5 or 6-11 y	1 467 128	NR	2 932 681	NT	1068	0	2120	NT
	12-15 y	1 309 249	NR	2 617 844	NS	957	0	1896	NT
	16-17 y	676 147	NR	1 351 857	NT	834	0	1646	NT
Dose 2	6 mo-4 or 5 y	205 897	NR	409 280	NT	138 010	NR	274 444	NT
	5 or 6-11 y	1 248 714	NR	2 495 596	NT	619	0	1226	NT
	12-15 y	1 135 146	NR	2 269 718	NT	601	0	1197	NT
	16-17 y	569 588	0	1 138 871	NT	481	0	958	NT
Dose 3	6 mo-4 or 5 y	102 335	0	204 292	NT	3391	0	6671	NT
	5 or 6-11 y	269 600	0	538 724	NT	725	0	1448	NT
	12-15 y	383 763	NR	767 272	NT	589	0	1178	NT
	16-17 y	237 024	NR	473 794	NT	320	0	640	NT
Appendicitis									
Doses 1 and 2	6 mo-4 or 5 y	351 986	NR	11 874 618	NT	241 915	NR	8 789 224	NT
	5 or 6-11 y	2 213 650	206	72 789 318	NS	1212	0	43 060	NT
	12-15 y	2 035 023	302	66 600 250	NS	1187	0	42 059	NT
	16-17 y	1 043 311	166	34 406 004	NS	1013	0	34 656	NT
Dose 1	6 mo-4 or 5 y	190 648	NR	5 463 829	NT	131 372	NR	4 385 416	NT
	5 or 6-11 y	1 182 865	92	30 910 940	NS	755	0	26 302	NT
	12-15 y	1 078 396	130	27 055 551	NS	703	0	23 821	NT
	16-17 y	559 908	74	14 413 948	NS	632	0	20 186	NT
Dose 2	6 mo-4 or 5 y	161 338	NR	6 410 789	NT	110 543	NR	4 403 808	NT
	5 or 6-11 y	1 030 785	114	41 878 378	NS	457	0	16 758	NT
	12-15 y	956 627	172	39 544 699	NS	484	0	18 238	NT
	16-17 y	483 403	92	19 992 056	NS	381	0	14 470	NT
Dose 3	6 mo-4 or 5 y	83 010	NR	3 397 223	NT	2845	0	92 282	NT
	5 or 6-11 y	239 487	27	9 790 542	NS	645	0	23 859	NT
	12-15 y	352 339	54	14 545 967	NS	532	0	20 146	NT

	16-17 y	214 951	41	8 754 099	NS	285	0	10 536	NT
Bell palsy									
Doses 1and 2	6 mo-4 to 5 y	410 400	NR	14 065 149	NS	277 737	NR	10 222 194	NS
	5 or 6-11 y	2 485 011	35	81 704 667	NS	1467	0	53 845	NT
	12-15 y	2 223 492	56	72 869 846	NS	1410	0	51 392	NT
	16-17 y	1 129 439	24	37 292 252	NS	1216	0	43 061	NT
Dose 1	6 mo-4 or 5 y	221 585	NR	6 444 275	NT	150 082	NR	5 063 381	NT
	5 or 6-11 y	1 334 662	14	35 013 473	NS	916	0	32 855	NT
	12-15 y	1 179 765	18	29 755 101	NS	849	0	29 484	NT
	16-17 y	607 786	NR	15 737 104	NS	760	0	25 173	NT
Dose 2	6 mo-4 or 5 y	188 815	NR	7 620 874	NT	127 655	NR	5 158 813	NT
	5 or 6-11 y	1 150 349	22	46 691 194	NS	551	0	20 990	NT
	12-15 y	1 043 727	38	43 114 745	NS	561	0	21 908	NT
	16-17 y	521 653	NR	21 555 148	NS	456	0	17 888	NT
Dose 3	6 mo-4 or 5 y	96 939	NR	3 984 353	NT	3233	0	110 964	NT
	5 or 6-11 y	259 078	NR	10 618 052	NS	699	0	27 077	NT
	12-15 y	370 606	16	15 297 175	NS	562	0	22 080	NT
	16-17 y	229 588	NR	9 335 942	NS	310	0	12 020	NT
Common site thrombosis with thrombocytopenia[a]									
Doses 1 and 2	6 mo-4 or 5 y[b]	244 267	0	6 241 793	NT	81 661	0	2 219 079	NT
	5 or 6-11 y[b]	2 215 973	NR	55 992 946	NT	621	0	16 404	NT
	12-15 y	2 038 360	NR	51 169 805	NT	1188	0	31 617	NT
	16-17 y	1 045 098	NR	26 329 445	NT	1016	0	26 702	NT
Dose 1	6 mo-4 or 5 y[b]	131 743	0	3 201 944	NT	43 906	0	1 196 821	NT
	5 or 6-11 y[b]	1 184 106	NR	27 642 091	NT	398	0	10 492	NT
	12-15 y	1 080 146	0	24 623 090	NT	704	0	18 802	NT
	16-17 y	560 874	NR	12 913 395	NT	634	0	16 526	NT
Dose 2	6 mo-4 or 5 y[b]	112 524	0	3 039 849	NT	37 755	0	1 022 258	NT
	5 or 6-11 y[b]	1 031 867	0	28 350 855	NT	223	0	5912	NT
	12-15 y	958 214	NR	26 546 715	NT	484	0	12 815	NT
	16-17 y	484 224	NR	13 416 050	NT	382	0	10 176	NT
Dose 3	6 mo-4 or 5 y[b]	59 404	0	1 638 795	NT	778	0	19 250	NT
	5 or 6-11 y[b]	239 716	NR	6 602 510	NT	352	0	9147	NT
	12-15 y	352 878	0	9 765 325	NT	533	0	14 234	NT
	16-17 y	215 309	0	5 886 780	NT	285	0	7596	NT
Deep vein thrombosis									
Doses 1 and 2	6 mo-4 or 5 y	351 932	NR	9 020 709	NT	241 877	0	6 579 967	NT
	5 or 6-11 y	2 215 893	NR	55 988 930	NT	1212	0	32 099	NT
	12-15 y	2 038 235	NR	51 163 432	NS	1188	0	31 617	NT
	16-17 y	1 044 870	NR	26 321 797	NS	1016	0	26 702	NT
Dose 1	6 mo-4 or 5 y	190 617	0	4 651 184	NT	131 352	0	3 581 264	NT

	5 or 6-11 y	1 184 060	NR	27 640 017	NT	755	0	20 038	NT
	12-15 y	1 080 081	NR	24 620 103	NS	704	0	18 802	NT
	16-17 y	560 752	NR	12 909 608	NS	634	0	16 526	NT
Dose 2	6 mo-4 or 5 y	161 315	NR	4 369 525	NT	110 525	0	2 998 703	NT
	5 or 6-11 y	1 031 833	0	28 348 913	NT	457	0	12 061	NT
	12-15 y	958 154	NR	26 543 329	NT	484	0	12 815	NT
	16-17 y	484 118	NR	13 412 189	NT	382	0	10 176	NT
Dose 3	6 mo-4 or 5 y	83 015	0	2 291 244	NT	2845	0	68 640	NT
	5 or 6-11 y	239 708	0	6 601 838	NT	648	0	17 106	NT
	12-15 y	352 852	NR	9 763 925	NT	533	0	14 234	NT
	16-17 y	215 265	NR	5 885 237	NT	285	0	7596	NT
Disseminated intravascular coagulation									
Doses 1 and 2	6 mo-4 or 5 y	352 017	NR	8 897 561	NT	241 928	0	6 501 186	NT
	5 or 6-11 y	2 215 973	NR	55 933 013	NT	1212	0	30 713	NT
	12-15 y	2 038 363	0	51 163 245	NT	1188	0	30 749	NT
	16-17 y	1 045 113	0	26 325 916	NT	1018	0	25 832	NT
Dose 1	6 mo-4 or 5 y	190 665	NR	4 597 312	NT	131 380	0	3 546 479	NT
	5 or 6-11 y	1 184 106	NR	27 614 907	NT	755	0	19 448	NT
	12-15 y	1 080 148	0	24 619 938	NT	704	0	18 402	NT
	16-17 y	560 883	0	12 911 429	NT	635	0	15 982	NT
Dose 2	6 mo-4 or 5 y	161 352	0	4 300 249	NT	110 548	0	2 954 707	NT
	5 or 6-11 y	1 031 867	NR	28 318 106	NT	457	0	11 265	NT
	12-15 y	958 215	0	26 543 307	NT	484	0	12 347	NT
	16-17 y	484 230	0	13 414 487	NT	383	0	9850	NT
Dose 3	6 mo-4 or 5 y	83 022	0	2 278 221	NT	2845	0	64 854	NT
	5 or 6-11 y	239 717	0	6 579 046	NT	648	0	16 295	NT
	12-15 y	352 881	NR	9 759 909	NT	533	0	13 650	NT
	16-17 y	215 316	0	5 884 863	NT	285	0	7132	NT
Encephalitis or encephalomyelitis									
Doses 1 and 2	6 mo-4 or 5 y	410 448	0	13 758 825	NT	277 773	NR	10 024 797	NT
	5 or 6-11 y	2 485 324	NR	81 547 753	NT	1469	0	49 843	NT
	12-15 y	2 223 796	NR	72 859 944	NS	1410	0	48 910	NT
	16-17 y	1 129 627	NR	37 287 987	NT	1216	0	40 559	NT
Dose 1	6 mo-4 or 5 y	221 610	0	6 325 107	NT	150 101	NR	4 984 704	NT
	5 or 6-11 y	1 334 839	NR	34 943 578	NT	916	0	30 912	NT
	12-15 y	1 179 935	NR	29 750 039	NT	849	0	28 438	NT
	16-17 y	607 886	NR	15 734 035	NT	760	0	23 715	NT
Dose 2	6 mo-4 or 5 y	188 838	0	7 433 718	NT	127 672	NR	5 040 093	NT
	5 or 6-11 y	1 150 485	NR	46 604 175	NT	553	0	18 931	NT
	12-15 y	1 043 861	NR	43 109 905	NS	561	0	20 472	NT
	16-17 y	521 741	NR	21 553 952	NT	456	0	16 844	NT

Dose 3	6 mo-4 or 5 y	96 950	0	3 945 744	NT	3233	0	101 347	NT
	5 or 6-11 y	259 110	NR	10 548 412	NT	699	0	24 341	NT
	12-15 y	370 652	0	15 282 789	NT	563	0	20 192	NT
	16-17 y	229 634	0	9 331 463	NT	310	0	10 873	NT
Guillain-Barré syndrome									
Doses 1 and 2	6 mo-4 or 5 y	352 025	0	11 830 401	NT	241 936	0	8 761 303	NT
Dose 1	6 mo-4 or 5 y	190 670	0	5 446 456	NT	131 384	0	4 374 485	NT
Dose 2	6 mo-4 or 5 y	161 355	0	6 383 945	NT	110 552	0	4 386 818	NT
Dose 3	6 mo-4 or 5 y	83 022	0	3 391 294	NT	2845	0	90 746	NT
Hemorrhagic stroke									
Doses 1 and 2	6 mo-4 or 5 y	351 997	NR	8 970 006	NT	241 927	0	6 548 151	NT
Dose 1	6 mo-4 or 5 y	190 654	NR	4 629 520	NT	131 379	0	3 567 371	NT
Dose 2	6 mo-4 or 5 y	161 343	0	4 340 486	NT	110 548	0	2 980 780	NT
Dose 3	6 mo-4 or 5 y	83 017	0	2 285 757	NT	2845	0	66 970	NT
Immune thrombocytopenia									
Doses 1 and 2	6 mo-4 or 5 y	351 972	NR	12 028 216	NT	241 891	NR	8 887 610	NS
	5 or 6-11 y	2 215 661	23	72 925 239	NS	1212	0	44 796	NT
	12-15 y	2 038 029	25	66 706 657	NS	1188	0	43 176	NT
	16-17 y	1 044 876	15	34 462 183	NS	1018	0	35 938	NT
Dose 1	6 mo-4 or 5 y	190 643	0	5 522 961	NT	131 361	NR	4 424 088	NT
	5 or 6-11 y	1 183 941	NR	30 969 110	NS	755	0	27 077	NT
	12-15 y	1 079 968	NR	27 098 483	NS	704	0	24 320	NT
	16-17 y	560 757	NR	14 438 389	NS	635	0	20 921	NT
Dose 2	6 mo-4 or 5 y	161 329	NR	6 505 255	NT	110 530	NR	4 463 522	NT
	5 or 6-11 y	1 031 720	NR	41 956 129	NS	457	0	17 719	NT
	12-15 y	958 061	NR	39 608 174	NS	484	0	18 856	NT
	16-17 y	484 119	NR	20 023 794	NS	383	0	15 017	NT
Dose 3	6 mo-4 or 5 y	83 012	0	3 415 558	NT	2845	0	97 403	NT
	5 or 6-11 y	239 675	0	9 830 404	NT	647	0	24 998	NT
	12-15 y	352 826	0	14 573 683	NT	533	0	21 004	NT
	16-17 y	215 255	NR	8 769 474	NT	285	0	11 128	NT
Myocarditis or pericarditis (all settings) (1-7 d)									
Doses 1 and 2	6 mo-4 or 5 y	351 988	0	2 443 114	NT	241 924	0	1 679 814	NT
	5 or 6-11 y	2 215 815	NR	15 455 303	NS	1212	0	8392	NT
	12-15 y	2 038 160	72	14 241 393	S(3)	1188	0	8197	NT
	16-17 y	1 044 928	56	7 299 458	S(3)	1018	0	7014	NT
Dose 1	6 mo-4 or 5 y	190 650	0	1 323 939	NT	131 378	0	912 801	NT
	5 or 6-11 y	1 184 019	NR	8 261 973	NT	755	0	5244	NT
	12-15 y	1 080 046	NR	7 547 573	NS	704	0	4859	NT

	16-17 y	560 782	NR	3 917 140	NS	635	0	4355	NT
Dose 2	6 mo-4 or 5 y	161 338	0	1 119 175	NT	110 546	0	767 013	NT
	5 or 6-11 y	1 031 796	NR	7 193 330	NS	457	0	3148	NT
	12-15 y	958 114	NR	6 693 820	S(3)	484	0	3338	NT
	16-17 y	484 146	NR	3 382 318	S(3)	383	0	2659	NT
Dose 3	6 mo-4 or 5 y	83 014	0	579 161	NT	2845	0	19 413	NT
	5 or 6-11 y	239 708	0	1 672 699	NT	648	0	4517	NT
	12-15 y	352 832	NR	2 465 354	S(1)	533	0	3719	NT
	16-17 y	215 272	13	1 497 801	S(2)	285	0	1990	NT
Myocarditis or pericarditis (all settings) (1-21 d)									
Doses 1 and 2	6 mo-4 or 5 y	351 988	NR	7 252 205	NT	241 924	0	4 987 361	NT
	5 or 6-11 y	2 215 815	12	45 978 229	NS	1212	0	24 750	NT
	12-15 y	2 038 160	103	42 443 102	S(3)	1188	0	24 182	NT
	16-17 y	1 044 928	71	21 746 581	S(3)	1018	0	20 541	NT
Dose 1	6 mo-4 or 5 y	190 650	0	3 932 631	NT	131 378	0	2 711 909	NT
	5 or 6-11 y	1 184 019	NR	24 573 073	NT	755	0	15 431	NT
	12-15 y	1 080 046	19	22 468 619	S(1)	704	0	14 352	NT
	16-17 y	560 782	16	11 655 098	S(1)	635	0	12 742	NT
Dose 2	6 mo-4 or 5 y	161 338	NR	3 319 574	NT	110 546	0	2 275 452	NT
	5 or 6-11 y	1 031 796	NR	21 405 156	NS	457	0	9319	NT
	12-15 y	958 114	84	19 974 483	S(3)	484	0	9830	NT
	16-17 y	484 146	56	10 091 483	S(3)	383	0	7799	NT
Dose 3	6 mo-4 or 5 y	83 014	0	1 728 090	NT	2845	0	54 542	NT
	5 or 6-11 y	239 708	0	4 980 481	NT	648	0	13 186	NT
	12-15 y	352 832	NR	7 349 009	S(1)	533	0	10 924	NT
	16-17 y	215 272	14	4 436 604	S(1)	285	0	5871	NT
Myocarditis or pericarditis (IP, OP, and ED) (1-7 d)									
Doses 1 and 2	6 mo-4 or 5 y[b]	352 019	0	2 427 241	NT	152 637	0	1 053 032	NT
	5 to 6-11 y[b]	2 215 967	NR	15 450 396	NT	621	0	4208	NT
	12-15 y	2 038 335	55	14 242 747	S(3)	1188	0	8114	NT
	16-17 y	1 045 077	40	7 300 604	S(3)	1018	0	6924	NT
Dose 1	6 mo-4 or 5 y[b]	190 667	0	1 316 715	NT	82 934	0	573 125	NT
	5 or 6-11 y[b]	1 184 102	NR	8 259 674	NT	398	0	2691	NT
	12-15 y	1 080 136	NR	7 548 270	NT	704	0	4819	NT
	16-17 y	560 863	NR	3 917 764	NS	635	0	4297	NT
Dose 2	6 mo-4 or 5 y[b]	161 352	0	1 110 526	NT	69 703	0	479 907	NT
	5 or 6-11 y[b]	1 031 865	NR	7 190 722	NT	223	0	1517	NT
	12-15 y	958 199	NR	6 694 477	S(3)	484	0	3295	NT
	16-17 y	484 214	NR	3 382 840	S(3)	383	0	2627	NT
Dose 3	6 mo-4 or 5 y[b]	83 021	0	578 025	NT	1185	0	7882	NT
	5 or 6-11 y[b]	239 718	0	1 671 051	NT	352	0	2405	NT

	12-15 y	352 870	NR	2 465 157	S(1)	533	0	3707	NT
	16-17 y	215 311	NR	1 498 007	S(2)	285	0	1966	NT
Myocarditis or pericarditis (IP, OP, and ED) (1-21 d)									
Doses 1 and 2	6 mo-4 or 5 y[b]	352 019	0	7 198 601	NT	152 637	0	3 125 323	NT
	5 or 6-11 y[b]	2 215 967	NR	45 959 404	NT	621	0	12 298	NT
	12-15 y	2 038 335	61	42 446 709	S(3)	1188	0	23 893	NT
	16-17 y	1 045 077	46	21 749 769	S(3)	1018	0	20 217	NT
Dose 1	6 mo-4 or 5 y[b]	190 667	0	3 908 994	NT	82 934	0	1 702 556	NT
	5 or 6-11 y[b]	1 184 102	NR	24 564 532	NT	398	0	7883	NT
	12-15 y	1 080 136	NR	22 470 533	NS	704	0	14 199	NT
	16-17 y	560 863	12	11 656 804	S(1)	635	0	12 513	NT
Dose 2	6 mo-4 or 5 y[b]	161 352	0	3 289 607	NT	69 703	0	1 422 767	NT
	5 or 6-11 y[b]	1 031 865	NR	21 394 872	NT	223	0	4415	NT
	12-15 y	958 199	NR	19 976 176	S(3)	484	0	9694	NT
	16-17 y	484 214	35	10 092 965	S(3)	383	0	7704	NT
Dose 3	6 mo-4 or 5 y[b]	83 021	0	1 723 572	NT	1185	0	22 367	NT
	5 or 6-11 y[b]	239 718	0	4 973 111	NT	352	0	6892	NT
	12-15 y	352 870	NR	7 348 086	S(1)	533	0	10 753	NT
	16-17 y	215 311	NR	4 437 033	S(1)	285	0	5721	NT
Narcolepsy									
Doses 1 and 2	5 or 6-11 y	2 215 928	NR	72 934 272	NS	1212	0	44 796	NT
	12-15 y	2 038 107	16	66 709 380	NS	1188	0	43 176	NT
	16-17 y	1 044 699	24	34 456 767	NS	1017	0	35 896	NT
Dose 1	5 or 6-11 y	1 184 080	NR	30 972 795	NT	755	0	27 077	NT
	12-15 y	1 080 018	NR	27 099 946	NS	704	0	24 320	NT
	16-17 y	560 647	NR	14 435 556	NT	635	0	20 921	NT
Dose 2	5 or 6-11 y	1 031 848	NR	41 961 477	NS	457	0	17 719	NT
	12-15 y	958 089	NR	39 609 434	NS	484	0	18 856	NT
	16-17 y	484 052	NR	20 021 211	NS	382	0	14 975	NT
Dose 3	5 or 6-11 y	239 715	0	9 832 012	NT	648	0	25 021	NT
	12-15 y	352 841	NR	14 574 277	NS	533	0	21 004	NT
	16-17 y	215 221	12	8 768 192	NS	285	0	11 128	NT
Nonhemorrhagic stroke									
Doses 1 and 2	6 mo-4 or 5 y	352 009	0	8 942 566	NT	241 930	NR	6 530 082	NT
	5 or 6-11 y	2 215 960	NR	55 955 653	NT	1212	0	31 259	NT
	12-15 y	2 038 354	0	51 165 669	NT	1188	0	31 151	NT
	16-17 y	1 045 115	NR	26 327 584	NT	1018	0	26 192	NT
Dose 1	6 mo-4 or 5 y	190 661	0	4 617 655	NT	131 381	NR	3 559 300	NT
	5 or 6-11 y	1 184 098	NR	27 625 211	NT	755	0	19 695	NT
	12-15 y	1 080 143	0	24 621 154	NT	704	0	18 574	NT
	16-17 y	560 884	NR	12 912 371	NT	635	0	16 176	NT

Dose 2	6 mo-4 or 5 y	161 348	0	4 324 911	NT	110 549	0	2 970 782	NT
	5 or 6-11 y	1 031 862	0	28 330 442	NT	457	0	11 564	NT
	12-15 y	958 211	0	26 544 515	NT	484	0	12 577	NT
	16-17 y	484 231	NR	13 415 213	NT	383	0	10 016	NT
Dose 3	6 mo-4 or 5 y	83 019	NR	2 282 885	NT	2845	0	66 156	NT
	5 or 6-11 y	239 722	0	6 587 840	NT	648	0	16 549	NT
	12-15 y	352 881	0	9 761 993	NT	533	0	13 822	NT
	16-17 y	215 317	NR	5 885 718	NT	285	0	7299	NT
Pulmonary embolism									
Doses 1 and 2	6 mo-4 or 5 y[b]	239 532	0	6 178 317	NT	160 273	0	4 377 689	NT
	5 or 6-11 y	2 215 976	0	56 012 340	NT	1212	0	32 579	NT
	12-15 y	2 038 334	NR	51 168 510	NT	1188	0	31 876	NT
	16-17 y	1 044 978	NR	26 326 099	NS	1018	0	27 082	NT
Dose 1	6 mo-4 or 5 y[b]	130 125	0	3 196 420	NT	87 477	0	2 391 693	NT
	5 or 6-11 y	1 184 108	0	27 650 979	NT	755	0	20 295	NT
	12-15 y	1 080 133	0	24 622 518	NT	704	0	18 935	NT
	16-17 y	560 809	NR	12 911 833	NS	635	0	16 775	NT
Dose 2	6 mo-4 or 5 y[b]	109 407	0	2 981 897	NT	72 796	0	1 985 996	NT
	5 or 6-11 y	1 031 868	0	28 361 361	NT	457	0	12 284	NT
	12-15 y	958 201	NR	26 545 992	NT	484	0	12 941	NT
	16-17 y	484 169	NR	13 414 266	NT	383	0	10 307	NT
Dose 3	6 mo-4 or 5 y[b]	55 239	0	1 527 770	NT	2067	0	50 277	NT
	5 or 6-11 y	239 722	NR	6 610 019	NT	648	0	17 308	NT
	12-15 y	352 879	0	9 766 897	NT	533	0	14 393	NT
	16-17 y	215 293	NR	5 886 669	NT	285	0	7721	NT
Seizure[c]									
Doses 1 and 2	6 mo-1 y	450 140	25	1 191 471	NS	302 275	15	872 958	NS
	2-4 or 5 y	450 140	36	2 373 696	S(3)	302 275	29	1 522 577	S(2)
	5 to 6-11 y	2 692 535	71	21 462 208	NS	1667	0	13 078	NT
	12-15 y	2 430 285	52	19 407 961	NS	1545	0	12 180	NT
	16-17 y	1 238 940	38	9 890 880	NS	1300	0	10 220	NT
Dose 1	6 mo-1 y	245 400	14	660 359	NS	164 942	NR	486 994	NS
	2-4 or 5 y	245 400	21	1 284 771	S(2)	164 942	NR	821 447	NS
	5 or 6-11 y	1 454 544	41	11 598 717	NS	1051	0	8240	NT
	12-15 y	1 301 389	27	10 393 770	NS	947	0	7458	NT
	16-17 y	671 951	24	5 363 845	NS	821	0	6431	NT
Dose 2	6 mo-1 y	204 740	11	531 112	NS	137 333	NR	385 964	NS
	2-4 or 5 y	204 740	15	1 088 925	S(2)	137 333	NR	701 130	S(2)
	5 or 6-11 y	1 237 991	30	9 863 491	NS	616	0	4838	NT
	12-15 y	1 128 896	25	9 014 191	NS	598	0	4722	NT
	16-17 y	566 989	16	4 527 035	NS	479	0	3789	NT

Dose 3	6 mo-1 y	102 099	NR	231 518	NT	3376	NR	8115	NT
	2-4 or 5 y	102 099	NR	581 953	NS	3376	0	18 177	NT
	5 or 6-11 y	268 990	NR	2 145 055	NS	725	0	5768	NT
	12-15 y	382 249	NR	3 052 406	NS	587	0	4684	NT
	16-17 y	236 352	NR	1 879 834	NS	318	0	2532	NT

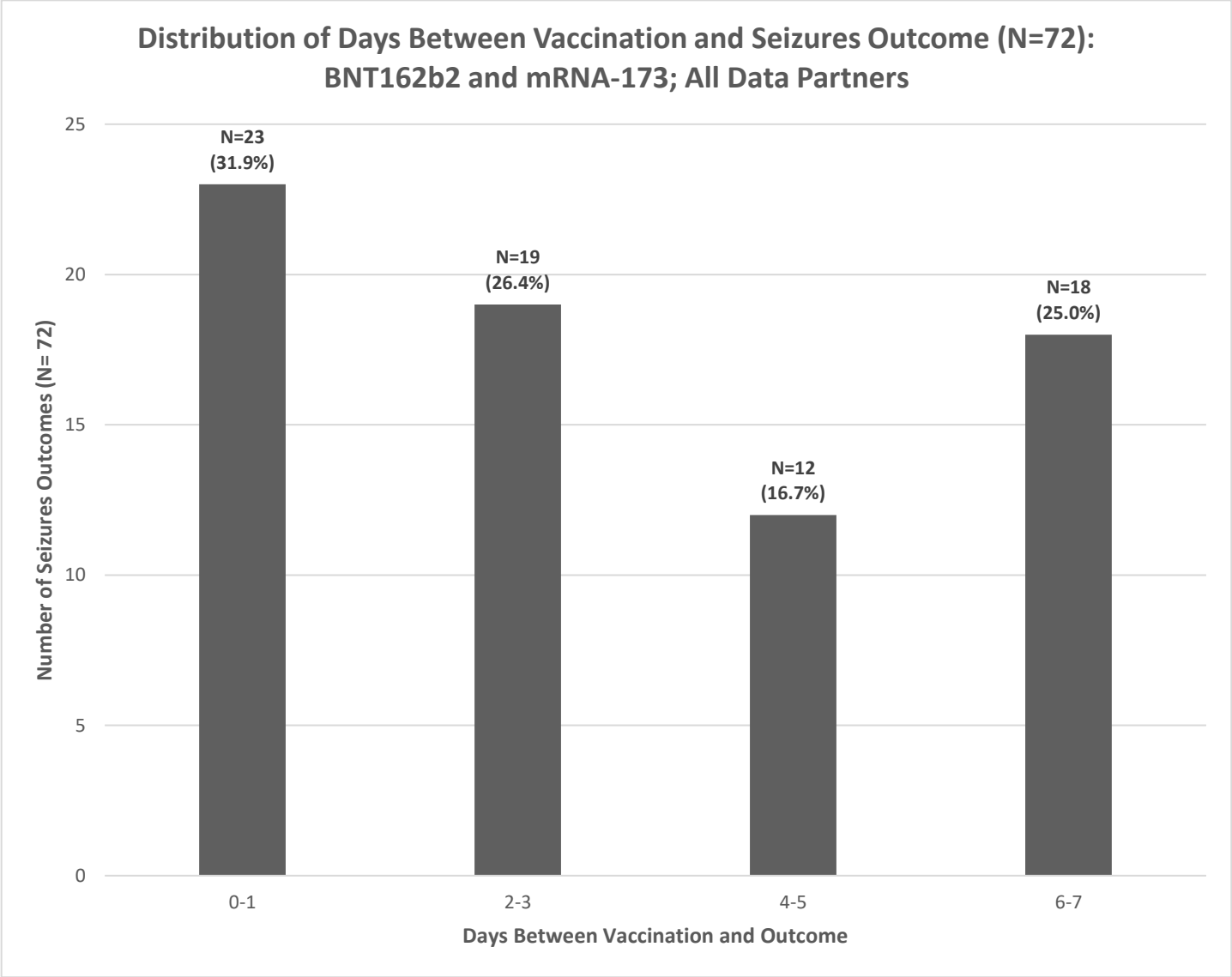
Abbreviations: ED, emergency department; IP, inpatient; NR, not reported (data for sample sizes of 1 to 10 and that can be used to back-calculate small cell sizes were masked for confidentiality); NS, test was initiated (cases >3) but no statistical signal was observed; NT, test was not initiated due to low outcome counts (cases <3); OP, outpatient; S, test met the statistical threshold for a signal (the number in paratheses is the count of databases that had a statistical signal for that specific outcome, dose, age group, and brand).

[a]Common site thrombosis with thrombocytopenia is combined with unusual site thrombosis (broad) with thrombocytopenia consisting of a thrombotic event (made up of other events, such as acute myocardial infarction and deep vein thrombosis) and a thrombocytopenia event (defined in the IP, OP, and physician billing setting). The overall setting definition for the outcome depends on individual setting definitions for each of these components.

[b]For these outcome-age combinations, testing occurred in fewer than 3 data sources because 1 or more data source did not have available background rates; for these outcome-age combinations, number of doses are reported for the data sources for which sequential testing data were available.

[c]For the outcome seizure, the number of doses reported in the age groups 6 months to 1 year and 2 to 4 or 5 years corresponds to the total number of doses monitored descriptively in the age groups 6 months to 4 or 5 years; all other statistics from sequential testing (number of outcomes, person-time, and statistical signal status) are reported for the corresponding age stratifications listed in the table above due to availability of background rates for those age strata. Sequential testing ended earlier in the age groups 5 or 6 to 17 years due to limited accrual of new exposures; therefore, the data cuts used are different from the age group 6 months to 4 or 5 years. For the age group 5 or 6 to 17 years, Optum data through April 2023, Carelon Research data through January 2023, and CVS Health data through December 2022 were used. For the age group 6 months to 4 or 5 years, Optum data through January 2023, Carelon Research data through March 2023, and CVS Health data through February 2023 were used.

eFigure. Distribution of Days Between Vaccination and Seizures (N =72 Seizures Events) After Monovalent BNT162b2 (2-4 years) and mRNA-1273 (Ages 2-5 years) COVID-19 Vaccines[a]



[a] Combines data for all three data sources: Carelon Research: Data through 3/2023, CVS Health: Data through 2/2023, Optum: Data through 4/2023

eAppendix. Medical Record Review

Medical record review was conducted for the myocarditis/pericarditis outcome following identification of a statistical signal. Brighton Collaboration case definitions were used to adjudicate cases.[39] Records meeting the confirmed or probable Brighton classifications were considered true myocarditis/pericarditis cases for the validation analyses.

Of the 153 cases of myocarditis/pericarditis after COVID-19 vaccination among children aged 12-17 years, medical record review was conducted for a sample of 40 cases whose records could be obtained. Twenty-nine of these cases (72.5%) were confirmed as true cases of myocarditis/pericarditis, of which 27 patients were male, and 19 were hospitalized with a median length of hospital stay of 2 days (interquartile range: 1, 3). The median time from vaccination to presentation of myocarditis/pericarditis event was 3 days (interquartile range: 2, 5). Medical record review and further validation efforts for seizure are currently underway.

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