Cumulative Analysis of Post-authorization Adverse Events Through 2/28/2021
Tables 1-6 AES

Relevant Adverse Events: Subjects			
Table 1	N =	42086	
Gender	F	29914	71%
	М	9182	22%
	ND	2990	7%
	Total	42086	
Age	<12	34	
	<16	46	
	<= 17	95	
	18-30	4953	
	31-50	13886	
	51-64	7884	
	65-74	3098	
	>=75	5214	
	Ukn	6876	
	Total	42086	
Outcome	N =	42086	
Of (total)-(unknown)	Recovered/Recovering	19582	60%
Of (total)-(unknown)	Not recovered	11361	35%
Of 42,086	Unknown*	9400	22%
	Fatal*	1223	4%
Of (total)-(unknown)	Recovered with sequelae*	520	2%
	N - Unknown =	32686	
Estimated range in all cases not	D'al anna (Daaraa l	40.070/	
recovered after removing unknowns	Died or not Recovered	40-87%	
Percent recovered to percent not recovered	Recovered e	Not Kecovered	
9 to 1	17624	1958	
6 to 4	11749	7833	
5 to 5	9791	9791	
4 to 6	7833	11749	
1 to 9	4209	15373	
		Estimated	
Recovered/Recovering Estimation	Estimated Not	percent not	
Calculations	Recovered + Died	recovered	
Fatal + Not recovered + Sequelae	13104	40%	
Fatal + NR + S + estimated recovering*	15062	46%	
* Scaled estimated Recovering	20937	64%	
_	22895	70%	
	24853	76%	
	28477	87%	

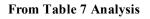
"Relevant" Adverse Events: Subjects

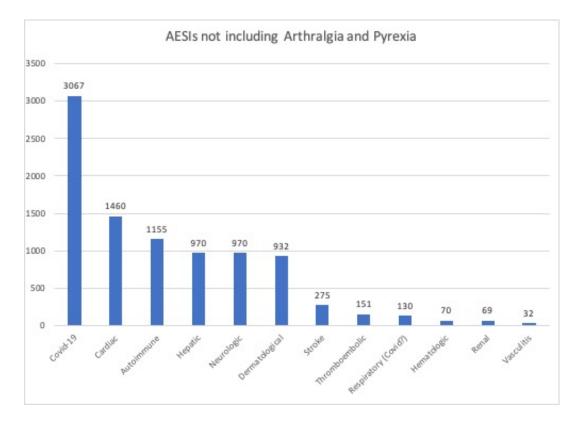
Table 1 Disorders >= 2%	WHERE IS THIS DATA?		
General and admin site	51335	122%	Compare with 42086
Nervous System	25957	62%	
MS & Connective Tissue	17283	41%	
GI	14096	33%	
Resp, Thoracic, and Mediastinal	8848	21%	
Skin and SubCu	8476	20%	
Injury, poisioning, and procedural	5590	13%	WHERE IS THIS TOXICITY DATA?
Covid-19	1927	5%	
Investigations	3693	9%	????
Total	137205	93473	????
Table 2 Events >=2% Cases		N = 42086	
	Blood and lymphatic	1972	4.69%
	Cardiac Table 2	1098	"Tachycardia"
	Cardiac Table 7	1403	Table 2 + 7
	Auto immune Myocarditis	25	
	Auto immune Pericarditis	32	
	Total Cardiac	1460	3.47%
	GI	8760	20.81%
	General and admin site	39451	93.74%
See total from Table 7	COVID19	1927	4.58%
Total procedureal errors	Procedural complications	1708	4.06%
3416	Off label use	880	2.09%
	Product use issue	828	1.97%
	Musculoskeletal & CT	12399	29.46%
	Nervous system	16350	38.85%
	Respiratory, Thoracic, Mediastinal	4151	9.86%
	Skin and SubQ	5657	13.44%
	Total number of events	93473	2.2 per subject

Table 3-5 Safety Concerns	Cases	
Anaphylaxis BC1-4	1002	4 patients died on the same day the injection was given
Potential Anaphylaxis Cases	2958	9.4%
Vaccine Enhanced Disease	138	317 events
Use in Pregnancy and Lactation	413	84 S/329 NS
Pregnancy outcomes	N = 270	
No Outcome	238	88%
Outcome Pending	5	
Known outcome	27	
Spontaneous abortions	23	85%
Premature birth neonatal death	2	7%
Spontaneous abortion intrauterine death	2	7%
Spontaneous abortion neonatal death	1	4%
<u>Normal outcome</u>	<u>1</u>	<u>4%</u>
Mother cases	124	
Spontaneous abortion	25	20%
Myalgia	16	13%
Pyrexia	16	13%
Lymphadenopathy	7	6%
Chest pain	6	5%
Dizziness	6	5%
Asthenia	6	5%
Malaise	5	4%
Covid-19	5	4%
Uterine contraction	1	1%
Premature membrane rupture	1	1%
Abortion	1	1%
Abortion missed	1	1%
Fetal death	1	1%

Serious foetus/baby cases	4	
Fetal growth restriction/premature baby	2 each	
Neonatal death	1	
Breast feeding baby cases	133	
No adverse events	116	87%
Breast feeding infant child reactions	17	13%
Of those with Aes		
Fever	5	29%
Rash	4	24%
Irritability	3	18%
Vomiting	2	12%
Diarrhea	2	12%
Insomnia	2	12%
Illness	2	12%
Poor feeding	1	6%
Lethargy	1	6%
Abdominal discomfort	1	6%
Vomiting	1	6%
Allergy to vaccine	1	6%
Increased appetite	1	6%
Anxiety	1	6%
Crying	1	6%
Poor quality sleep	1	6%
Eructation	1	6%
Agitation	1	6%
Pain	1	6%
Urticaria	1	6%
Breast feeding mother cases	6	
Chills, malaise, and pyrexia	1	
Suppressed lactation	4	
Unknwn AE	1	
Breast milk discoloration	1	

Pediatric age <12	34	132 AEs	
Age range (Youngest 28 days not 2 months)	2 mos. To 9 years	3.7 years average	
Serious	24	71%	
Non-serious	10	29%	
Product administered to Pt of inappropriate age	27	1 seven year old had a stroke	
Off label use	11		
Pyrexia	6		
Product use issue	5		
Fatigue	4		
Headache	4		
Nausea	4		
Injection site pain	3		
Abdominal pain	2		
COVID-19	2		
Facial paralysis	2		
Lymphadenopathy	2		
Malaise	2		
Pruritis	2		
Swelling	2		
"Vaccine" effectiveness	Table 6		
Failure	19	7 days after two doses	Confirmed C19
"Vaccine" ineffective	1649	Unknown: 2 doses?,# days since 1st dose, unk. Time since 2nd.	Suspected C19
COVID-19	3067		
Outcome unknown	1230	74%	
Fatality	65	15%	





Covid is the leading adverse event after arthralgia and fever

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

"Relevant" Adverse Events: Subjects	N = 42086	
Autoimmune (# and % of AEs)	1155	3%
Gender	838	
Female	682	
Male	156	
Age	944	
12-17	2	
18-64	746	
>=65	196	
Diagnoses	855	
Hypersensitivity	596	
Arthritis*	70	*From Musculoskeletal
Peripheral neuropathy	49	
Rheumatoid arthritis*	26	*From Musculoskeletal
Dermatitis	24	
Encephalitis	16	
Diabetes	16	
Psoriasis	14	
Bullous dermatitis	13	
Autoimmune disorder	11	
Reynaud's phenomena	11	
Polyarthritis*	5	*From Musculoskeletal
Polyneuropathy*	4	*From Musculoskeletal
Outcome	1078	
Other	517	
Unknown	312	28.9%
Not resolved	215	
Resolved with sequelae	22	2.0%
Fatal	12	1.1%

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

AEs	N = 42	2086
Cardiac (# and % of AEs)	1460	3.5%
Gender	1403	
Female	1076	
Male	291	
Unknown	36	
Age	1346	
2-11	1	
12-17	1	
18-64	1078	
>= 65	266	
Diagnoses	1498	
Arryth mia ¹	1200	
Myocardial Infarction	130	
Cardiac Failure	91	
Pericarditis*	32	From Autoimmune
Myocarditis*	25	From Autoimmune
Cardiogenic shock	7	
Postural orthostatic tachycardia syndrome	7	
Coronary artery disease	6	
¹ 7666 subjects had "pyrexia". Fever is	Assuming	
accompanied by elevation in heart rate 10	tachycardia listed	
beats/min for females per degree C and 7 b/m	in Table 7 refers	
for males per degree C.	to SVT etc.	
Outcome	1444	
Other	767	
Unknown	380	26.0%
Not resolved	140	
Fatal*	136	9.3%
Resolved with Sequelae	21	
*May not include Myopericarditis fatalities		

	AEs		N = 42086
COVID-19 (# and % of total AEs)		3067	7.3%
Gender		3067	
Female		1650	
Male		844	
Unknown		573	
Age		1880	
Infant*		2	*28 days to 27 mos.
2-11		1	
12-17		2	
18-64		1315	
>= 65		560	
Diagnoses		3356	
COVID-19		1927	
SC2 test +		415	
Suspected C19		270	
Ageusia		228	
Anosmia		194	
SC2 Antibody test negative		83	
Exposure to SC2		62	
SC 2 Antibody test positive		53	
C 19 pneumonia		51	
Asymptomatic C19		31	
Coronavirus infection		13	
Occupational exposure SC2		11	
SC2 false positive test		7	
SC2 test positive		6	
SC 2 test negative		3	
SC 2 antibody test negative		2	
Outcome		3360	
Unknown		2110	62.8%
Other		558	
Fatal		136	4.0%
Resolved with sequelae		9	
Not resolved		547	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

	AEs	N= 42086	
Dermatological (# and % of total AEs)	20)	0.05%
Gender	19)	
Female	17	7	
Male	1		
Unknown	1		
Age	1	9	
Infant	0	1	
2-11	0)	
12-17	0	1	
18-64	1	8	
>= 65	1		
Diagnoses	20	0	
Erythema multiforme	13	3	
Vasculitis	7	,	
Outcome	2	1	
Not resolved	8		
Other	7	,	
Unknown	6		29%

	AEs N =	42086
Hematological (# and % of Total AEs)	932	
Gender	898	Bleeding
Female	676	731
Male	222	87%
Unknown	N/A	
Age	837	
Infant	1	
2-11	0	
12-17	0	
18-64	543	
>= 65	293	
Diagnoses	888	
Epistaxis	127	
Contusion	112	
Site bruising	96	
Site hemorrhage	51	
Petechia	50	
Hemorrhage	42	
Hematochezia	34	
Thrombocytopenia	33	
Site hematoma	32	
Conjunctival hemorrhage	29	
Vaginal bleeding	29	
Hematoma	27	
Hemoptysis	27	
Menorrhagia	27	
Hematemesis	25	
Eye hemorrhage	23	
Rectal hemorrhage	22	
Immune thrombocytopenia	20	
Hematuria	35	
Neutropenia	16	
Purpura	16	
Hemorrhagic diarrhea	15	
Outcome	1082	
Other	393	
Unknown	371	34%
Not resolved	267	
Fatal	34	3.1%
Resolved with sequelae	17	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021 Table 7: Adverse Events of Special Interest

AEs		N = 42086
Hepatic (# and % of Total AEs)	70	
Gender	70	
Female	43	
Male	26	
Unknown	1	
Age	64	
Infant	0	
2-11	0	
12-17	0	
18-64	37	
>= 65	27	
Diagnoses	82	
LFTs elevated	70	
Hepatic pain	9	
Ascities	3	
Outcome	94	
Unknown	47	
Other	27	
Not resolved	14	
Fatal	5	
Resolved with sequelae	1	
		NI 42096
AEs Musculoskeletal (# and % of total AEs)	3495	N = 42086
Musculoskeletal (# and % of total AEs)	3495 3471	N = 42086 (-)Arthritis/polyneuropathy
Musculoskeletal (# and % of total AEs) Gender	3471	
Musculoskeletal (# and % of total AEs) Gender Female	3471 2760	
Musculoskeletal (# and % of total AEs) Gender Female Male	3471 2760 711	
Musculoskeletal (# and % of total AEs) Gender Female Male Age	3471 2760 711 3372	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant	3471 2760 711 3372 1	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11	3471 2760 711 3372 1 4	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia	3471 2760 711 3372 1 4 2	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64	3471 2760 711 3372 1 4 2 2850	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65	3471 2760 711 3372 1 4 2850 515	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses	3471 2760 711 3372 1 4 2 850 515 3534	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia	3471 2760 711 3372 1 4 2 850 515 3534 3525	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome	3471 2760 711 3372 1 4 2850 515 3534 3525 4	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome	3471 2760 711 3372 1 4 2850 515 3534 3525 4 4	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome Bacterial arthritis	3471 2760 711 3372 1 4 2 2850 515 3534 3525 4 4 1	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome Bacterial arthritis Outcome	3471 2760 711 3372 1 4 2 2850 515 3534 3525 4 4 1 3662	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome Bacterial arthritis Outcome Other	$\begin{array}{c} 3471\\ 2760\\ 711\\ 3372\\ 1\\ 4\\ 2\\ 2850\\ 515\\ 3534\\ 3525\\ 4\\ 4\\ 1\\ 3662\\ 1801 \end{array}$	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome Bacterial arthritis Outcome Other Not resolved	$\begin{array}{c} 3471\\ 2760\\ 711\\ 3372\\ 1\\ 4\\ 2\\ 2850\\ 515\\ 3534\\ 3525\\ 4\\ 4\\ 1\\ 3662\\ 1801\\ 959 \end{array}$	
Musculoskeletal (# and % of total AEs) Gender Female Male Age Infant 2-11 Arthralgia 18-64 >= 65 Diagnoses Arthralgia Post viral fatigue syndrome Chronic fatigue syndrome Bacterial arthritis Outcome Other	$\begin{array}{c} 3471\\ 2760\\ 711\\ 3372\\ 1\\ 4\\ 2\\ 2850\\ 515\\ 3534\\ 3525\\ 4\\ 4\\ 1\\ 3662\\ 1801 \end{array}$	

	Es	N= 42086
A Neurological AESIs (# and % of total AEs		N= 42080
Gender	927	
Female	623	
Male	283	
Unknown	21	
Age	889	
Infant	1	VIIth nerve palsy
2-11	1	1 5
12-17	0	
18-64	642	
>= 65	245	
Diagnoses		
Facial paralysis	401	Facial Nerve Injury =
Seizure	204	492
Epilepsy	83	Seizure =
Facial paresis	64	404
Generalized seizure	33	Demyelinating =
Guillain-Barre syndrome	24	28
Fibromyalgia	17	GB =
Trigeminal neuralgia	17	24
Febrile convulsion	15	2.
Status epilepticus	12	
Aura (petit mal?)	11	
Transverse myelitis	11	
Multiple sclerosis relapse	10	
Optic neuritis	10	
Petit mal epilepsy	9	
Tonic convulsion	9	
Ataxia	8	
Encephalopathy	7	
Tonic clonic movements	7	
Foaming at mouth	5	
Polyneuropathy	4	
Multiple sclerosis	4	
Narcolepsy	4	
Partial seizures	4	
Bad sensation	3	
Demyelination	3	
Meningitis	3	
Post ictal state	3	
Seizure like phenomena	3	
Tongue biting	3	
Outcome	1011	
Other	449	
Not resolved	272	
Unknown	258	
Fatal	16	
Resolved with sequelae	16	

	AEs	N= 42086
Other AESIs (# and % of total ASEs)	81	52
Gender	78	29
Female	59	69
Male	18	60
Unknown	N/	A
Age	74	79
Infant	6	<u>)</u>
2-11	9)
12-17	9)
18-64	63	30
>= 65	11	25
Diagnoses	82	Fever = 94% of category.
Pyrexia	76	
Herpes zoster (shingles)	25	-
Inflammation	13	2
Oral herpes	8	0
Multiple organ dysfunction synd.	1	8
Herpes virus infection	1	7
Herpes simplex	1	3
Ophthalmic herpes	1	0
Herpes ophthalmic	6	5
Herpes zoster reactivation	6	
Outcome	82	
Other	50	
Unknown	16	
Not resolved	14	
Fatal	9	6 1%

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

	AEs	N= 42086	
Renal AESIs (# and % of total ASEs)	69		
Gender	69)	
Female	46	5	
Male	23	3	
Unknown	N/2	A	
Age			
Infant	1		
2-11	0		
12-17	0		
18-64	7		
>= 65	60)	
Diagnoses			
Acute kidney injury	40)	
Renal failure	30)	
Outcome	70)	
Fatal	23	3	33%
Unknown	22	2	32%
Not resolved	15	5	
Other	10)	
	AEs	N= 42086	
Respiratory AESIs	13	0	
Gender	13	0	
Female	72	2	
Male	58	3	
Unknown	N/z	A	
Age	12	6	
Infant	0		
2-11	0		
12-17	1		
18-64	47	7	
>= 65			
	78		
Diagnoses	13 ' 44		
Respiratory failure	44		
Hypoxia Bosnimtom, disorder	42		
Respiratory disorder ARDS	10		
Chronic respiratory syndrome	32		
Severe acute respiratory syndrome			
Outcome Other	13' 47		
Fatal	4) 41		32%
	41		
Unknown Nat recovered			24%
Not recovered	18	>	

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

	AEs	N= 42086
Stroke AESIs (# and % of total ASEs)	275	
Gender	273	
Female	182	
Male	91	
Unknown	N/A	
Age	265	
Infant	0	
2-11	1	
12-17	0	
18-64	59	
>= 65	205	
Diagnoses	292	
Ischemic	237	81%
Cerebrovascular accident	160	
Ischemic stroke	41	
Cerebral infarction	15	
Cerebral ischemia	3	
Cerebral thrombosis	3	
Cerebral venous sinus thrombosis	3	
Ischemic cerebral infarction	3	
Lacunal infarction	3	
Basal ganglia stroke	2	
Cerebellar infarction	2	
Thrombotic stroke	2	
Hemorrhagic	55	19%
Cerebral hemorrhage	26	
Hemorrhagic stroke	11	
Hemorrhage intercranial	5	
Subarachnoid hemorrhage	5	
Cerebral hematoma	4	
Basal ganglia hemorrhage	2	
Cerebellar infarction	2	
Outcome	300	
Not resolved	85	
Unknown	83	28%
Fatal	61	20%
Other	61	
Resolved with sequelae	10	

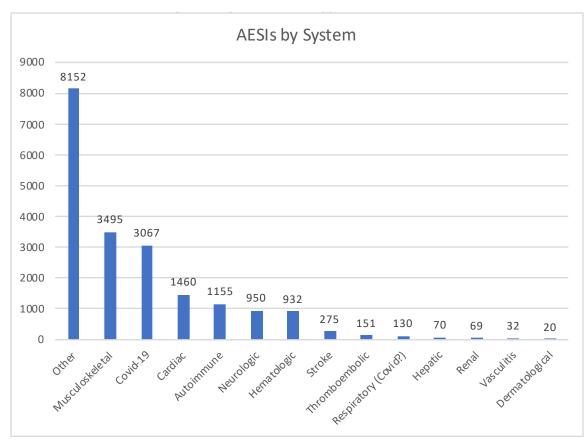
5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

AEs		N= 42086	
Thromboembolic event (# and % of total ASEs)	151		
Gender	144		
Female	89		
Male	55		
Unknown	N/A		
Age	136		
Infant	0		
2-11	0		
12-17	0		
18-64	66		
>= 65	70		
Diagnoses	151		
Pulmonary embolism	60		
Thrombosis	39		
DVT	35		
Thrombophlebitis peripheral	6		
Venous thrombosis	4		
Embolism	3		
Microembolism	3		
Thrombophlebitis	3		
Venous thrombosis	3		
Blue toe syndrome	2		
Outcome	169		
Other	54		
Not resolved	49		
Unknown	42		25%
Fatal	18		11%
Resolved with sequelae	6		

5.3.6 Cumulative Analysis of Post Authorization Adverse Event Reports Through 2/28/2021
Table 7: Adverse Events of Special Interest

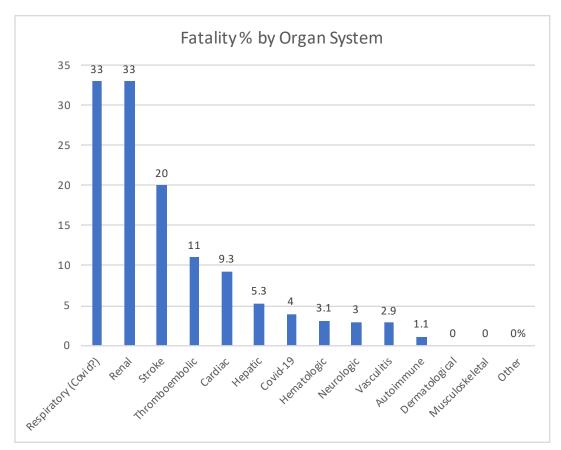
	AEs	N= 42086
Vasculitis (# and % of total ASEs)	32	
Gender	32	
Female	26	
Male	6	
Unknown	N/A	
Age	31	
Infant	0	
2-11	0	
12-17	0	
18-64	15	
>= 65	16	
Diagnoses	32	
Vasculitis	14	
Cutaneous vasculitis	4	
Vasculitic rash	4	
Giant cell arteritis	3	
Peripheral ischemia	3	
Bechet's syndrome	2	
Hypersensitivity vasculitis	2	
Palpable purpura	1	
Takayasu's arteritis	1	
Outcome	34	
Other	13	
Not resolved	12	
Unknown	8	24%
Fatal	1	3%

5.3.6 Adverse Events of Special Interest AESIs by Organ System



Category*	N =
Other	8152
Musculoskeletal	3495
Covid-19	3067
Cardiac	1460
Autoimmune	1155
Neurologic	950
Hematologic	932
Stroke	275
Thromboembolic	151
Respiratory (Covid?)	130
Hepatic	70
Renal	69
Vasculitis	32
Dermatological	20
	19958

5.3.6 Adverse Events of Special Interest AESIs by Organ System



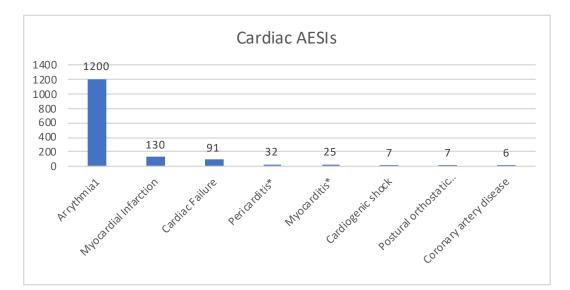
Category	% Fatality	% Unknown	# Unknown	Outcome
Respiratory (Covid?)	33	31%	22	70
Renal	33	31%	22	70
Stroke	20	28%	83	300
Thromboembolic	11	25%	42	169
Cardiac	9.3	26%	380	1444
Hepatic	5.3	52%	47	90
Covid-19	4	63%	2110	3360
Hematologic	3.1	34%	371	1082
Neurologic	3	30%	161	544
Vasculitis	2.9	24%	8	34
Autoimmune	1.1	29%	312	1078
Dermatological	0	29%	6	21
Musculoskeletal	0	30%	853	2809
Other	0%	26%	1685	6533
	Totals		6102	17604
AESI Outcome	% Unknown outcome	31%		

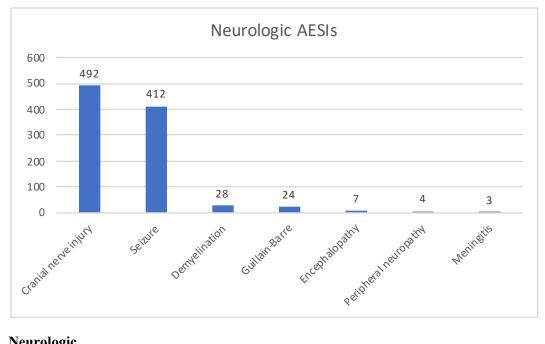
5.3.6 Adverse Events of Special Interest AESIs by Organ System

AESI Fatalities			
Category*	N =	Fatalities	Percent Fatal
Cardiac	1460	136	9%
Covid-19	3067	136	4%
Other	8152	96	1%
Stroke	275	61	22%
Respiratory (Covid?)	130	41	32%
Hematologic	932	34	4%
Renal	69	23	33%
Thromboembolic	151	18	12%
Neurologic	950	16	2%
Autoimmune	1155	12	1%
Hepatic	70	5	7%
Vasculitis	32	1	3%
Dermatological	20	0	0%
Musculoskeletal	3495	0	0%
Totals	19958	579	3%

Table 1 Fatalities	1223
Fatalities accounted for	579
Missing	644
Missing %	53%

AEs + AESIs Table 1	Cases not reported or lost "Relevant cases" per Pfizer	42086
Table 7 Table 1	Organ systems Outcome Unknown Known Outcome	19958 9400 29358
	"Missing"	12728 30%



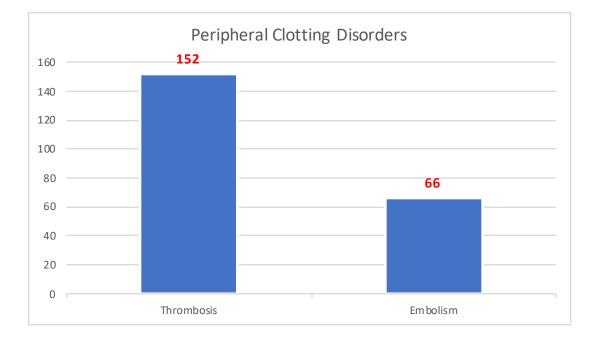


Neurologic

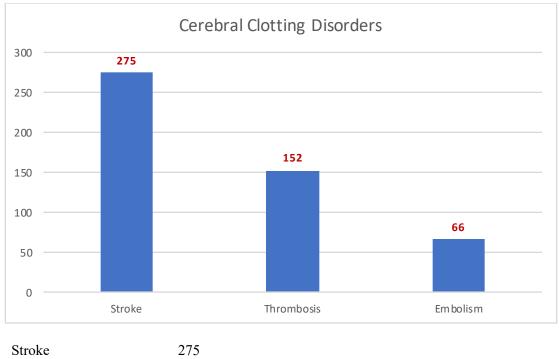
Cranial nerve injury	492
Seizure	412

Selected Organ System Detail Pfizer Document 5.6.3

Demyelination	28
Guillain-Barre	24
Encephalopathy Peripheral neuropathy Meningitis	7 4 3 970



Selected Organ System Detail Pfizer Document 5.6.3



SHORE	215
Thrombosis	152
Embolism	66