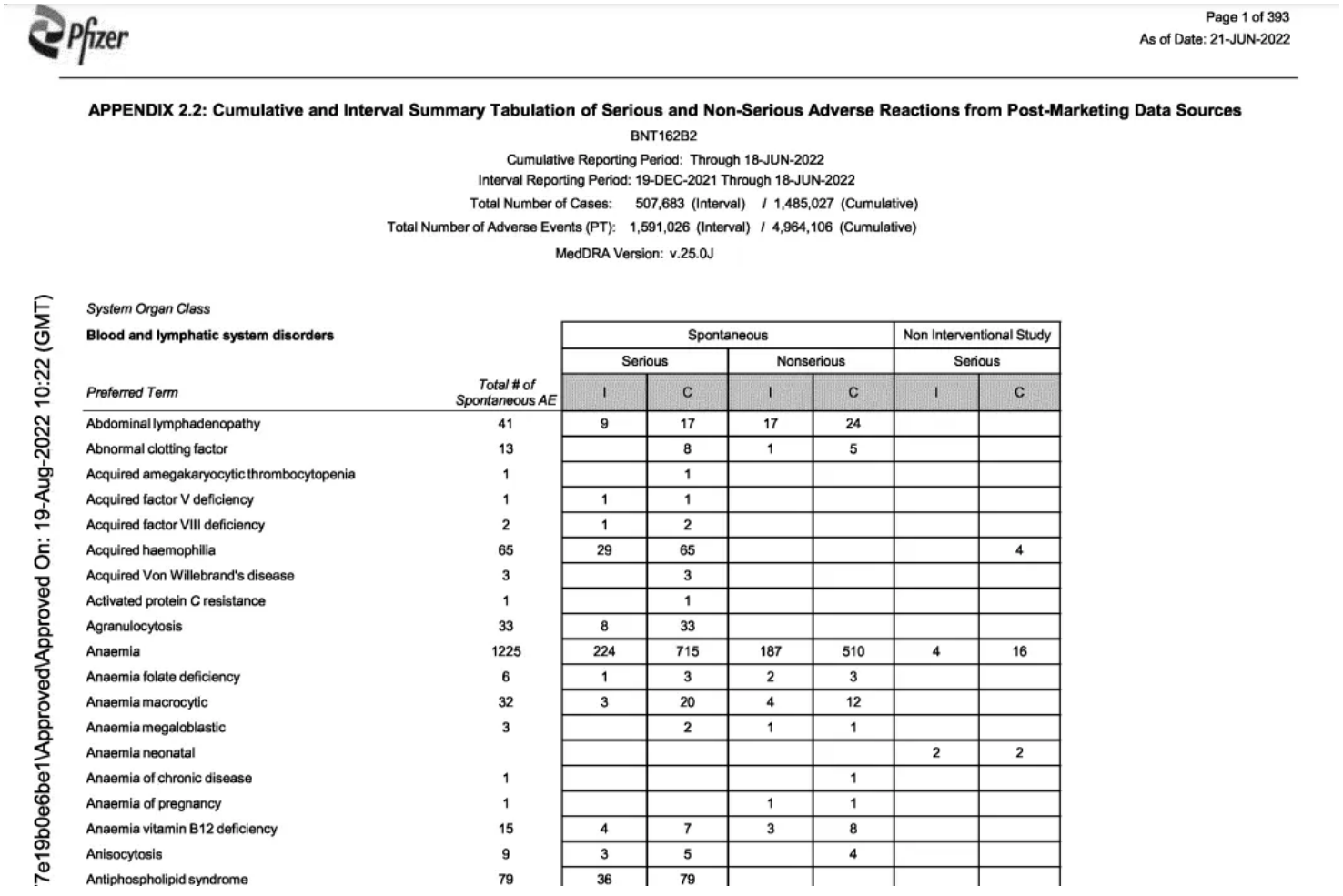
Newly released Internal Pfizer COVID-19 vaccine adverse event surveillance report reveals millions of adverse events, significant portion classified as serious.

THE CANADIAN INDEPENDENT
JUN 15, 2023

As more and more Pfizer documents are being released, this particular one stands out as the most alarming to date. The 393-page Pfizer (BNT162B2) COVID-19 vaccine post-marketing surveillance report covers a six-month period from December 19, 2021, to June 18, 2022. The report includes over 10,000 different categories of adverse events



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APPENDIX 2.2: Cumulative and Interval Summary Tabulation of Serious and Non-Serious Adverse Reactions from Post-Marketing Data Sources

BNT162B2
Cumulative Reporting Period: Through 18-JUN-2022
Interval Reporting Period: 19-DEC-2021 Through 18-JUN-2022
Total Number of Cases: 507,683 (Interval) / 1,485,027 (Cumulative)
Total Number of Adverse Events (PT): 1,591,026 (Interval) / 4,964,106 (Cumulative)
MedDRA Version: v.25.0J

System Organ Class
Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Abdominal lymphadenopathy	41	9	17	17	24		
Abnormal clotting factor	13		8	1	5		
Acquired amegakaryocytic thrombocytopenia	1		1				
Acquired factor V deficiency	1	1	1				
Acquired factor VIII deficiency	2	1	2				
Acquired haemophilia	65	29	65				4
Acquired Von Willebrand's disease	3		3				
Activated protein C resistance	1		1				
Agranulocytosis	33	8	33				
Anaemia	1225	224	715	187	510	4	16
Anaemia folate deficiency	6	1	3	2	3		
Anaemia macrocytic	32	3	20	4	12		
Anaemia megaloblastic	3		2	1	1		
Anaemia neonatal						2	2
Anaemia of chronic disease	1				1		
Anaemia of pregnancy	1			1	1		
Anaemia vitamin B12 deficiency	15	4	7	3	8		
Anisocytosis	9	3	5		4		
Antiphospholipid syndrome	79	36	79				

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* I=Interval, C=Cumulative
* AE=Adverse Event
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According to the report, nearly 5 million adverse events have been reported since the initiation of Pfizer's (BNT162B2) vaccine roll-out surveillance, with almost 1.6 million adverse events reported specifically within the timeframe covered by this six-month report.

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System Organ Class
Blood and lymphatic system disorders

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Acquired factor V deficiency	1	1	1				
Acquired factor VIII deficiency	2	1	2				
Acquired haemophilia	65	29	65				4
Acquired Von Willebrand's disease	3		3				

Before I dive into the significant findings, it is important to provide explanations of certain terms within this report to enhance your understanding of the information you are reading and analyzing.

Post-marketing Data: This refers to monitoring the vaccine's safety and effectiveness after it has been distributed to the population. It aims to track any adverse events or side effects that occur in real-world conditions.

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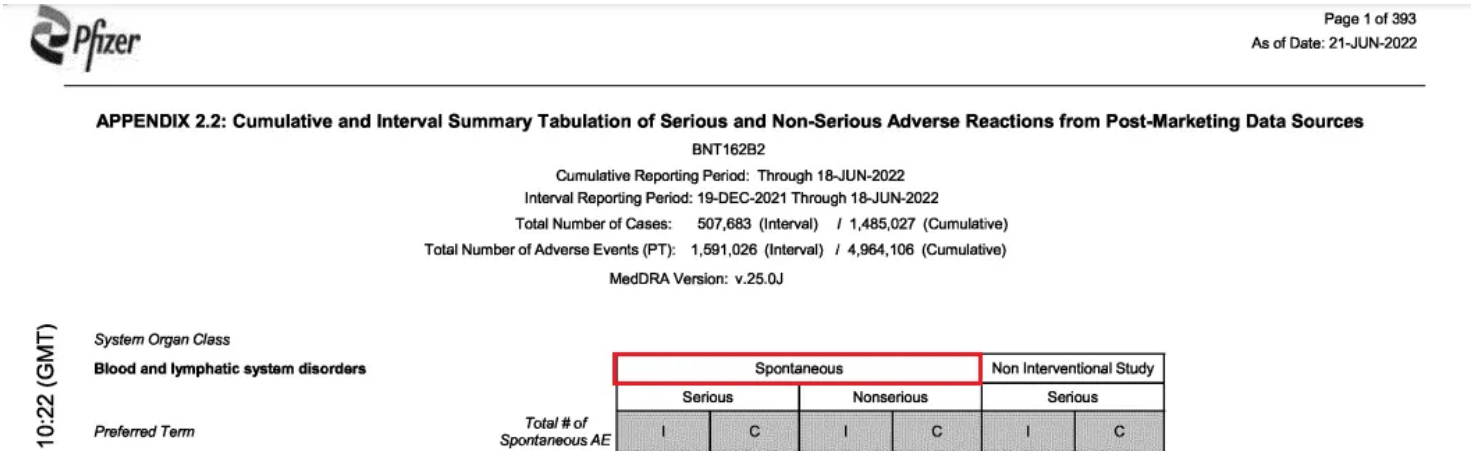
Spontaneous report: This term refers to adverse events or side effects that are reported voluntarily by healthcare professionals or citizens. These reports are often made to a vaccine side effect program such as the Vaccine Adverse Event Reporting System (VAERS) in the United States.



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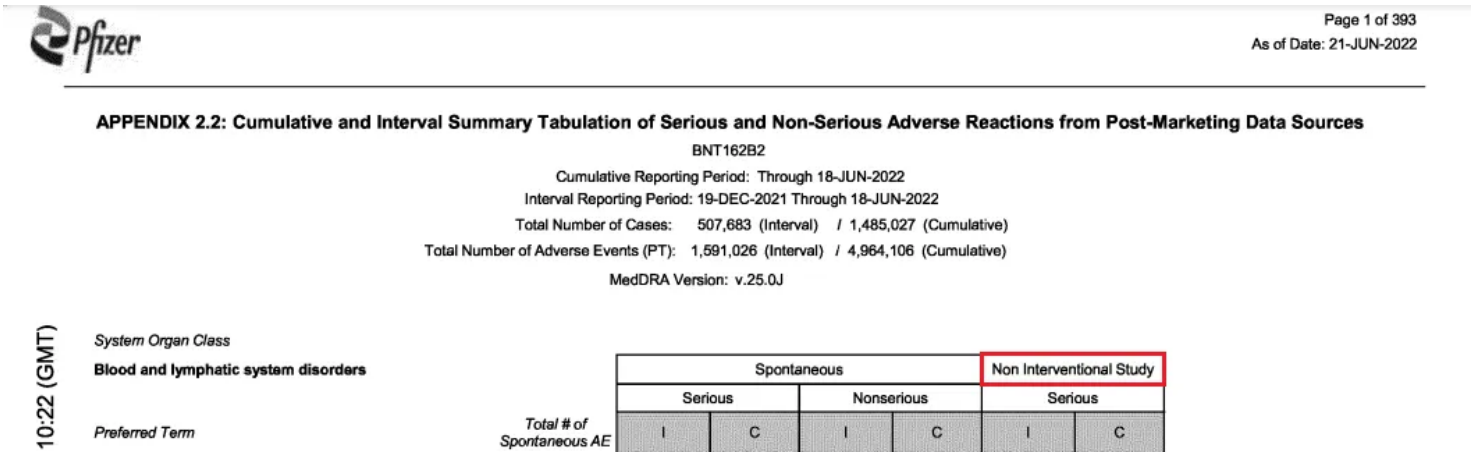
System Organ Class
Blood and lymphatic system disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C

Non-interventional Study: It involves studies like cohort studies, where researchers observe a group of individuals over time. In this type of study, there is no active intervention or manipulation of variables by the researchers.



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		Serious		Nonserious		Serious	
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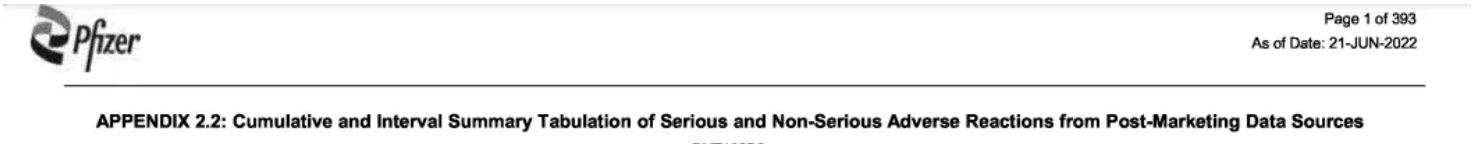
Interval or (I): In a statistical context, an interval refers to a specific range or period of time or value. So in this case the interval would be from December 19, 2021 to June 18, 2022.



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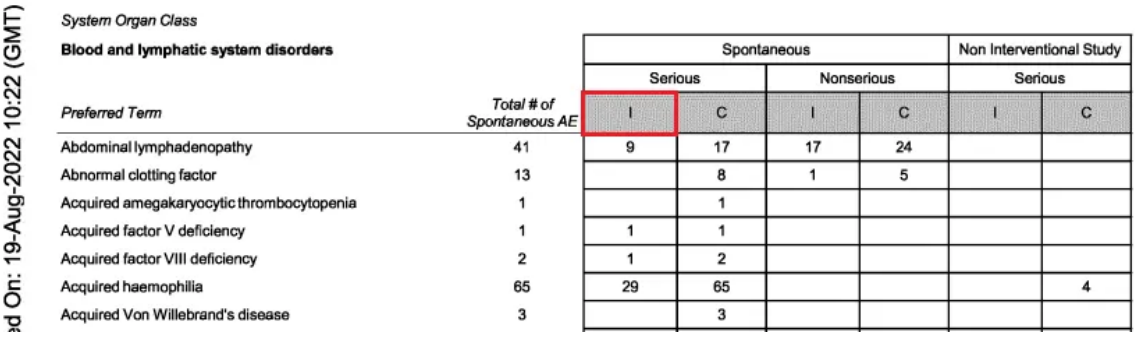

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Abnormal clotting factor	13		8	1	5		
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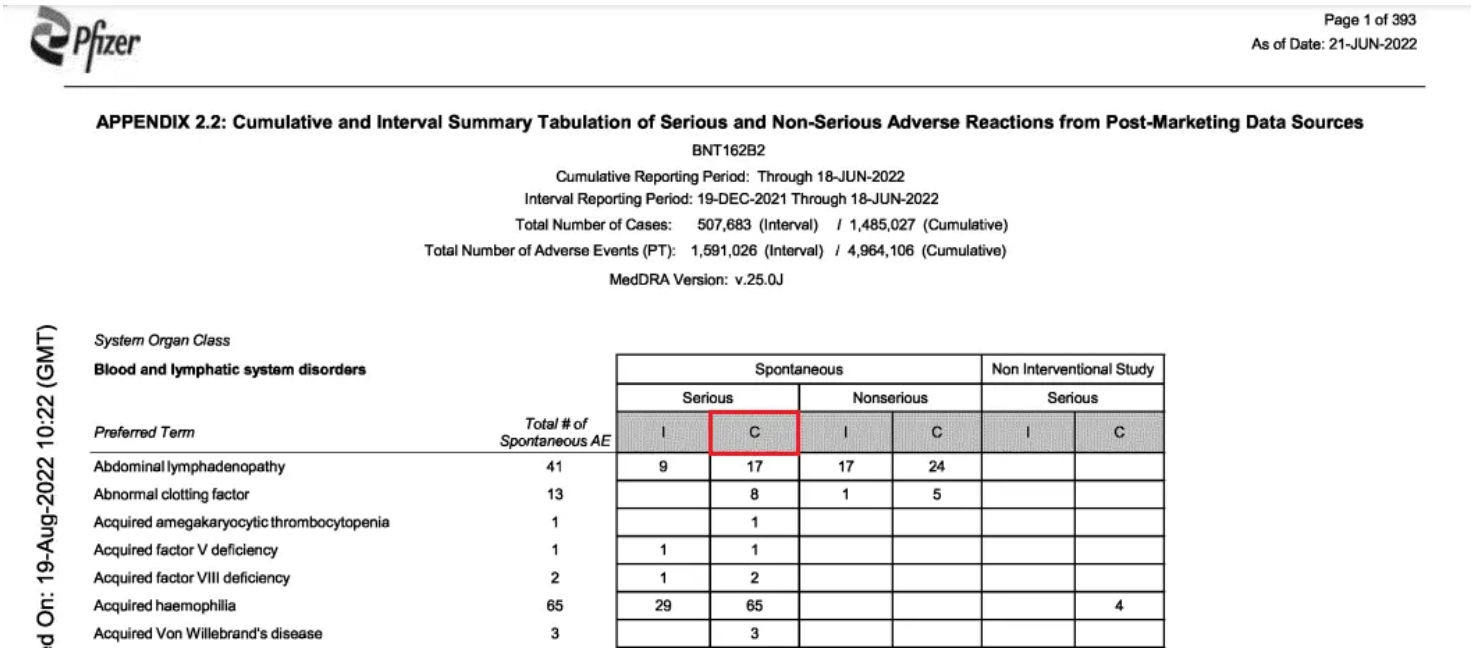
Acquired factor V deficiency	1	1	1				
Acquired factor VIII deficiency	2	1	2				
Acquired haemophilia	65	29	65				4
Acquired Von Willebrand's disease	3		3				

Cumulative or (C): Cumulative, on the other hand, involves the accumulation or aggregation of values over time or across multiple intervals. So in this case it would be the number of reports received since the vaccine roll-out surveillance began up to June 21, 2022, when this report was finalized.



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System Organ Class

Blood and lymphatic system disorders

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		Serious		Nonserious		Serious	
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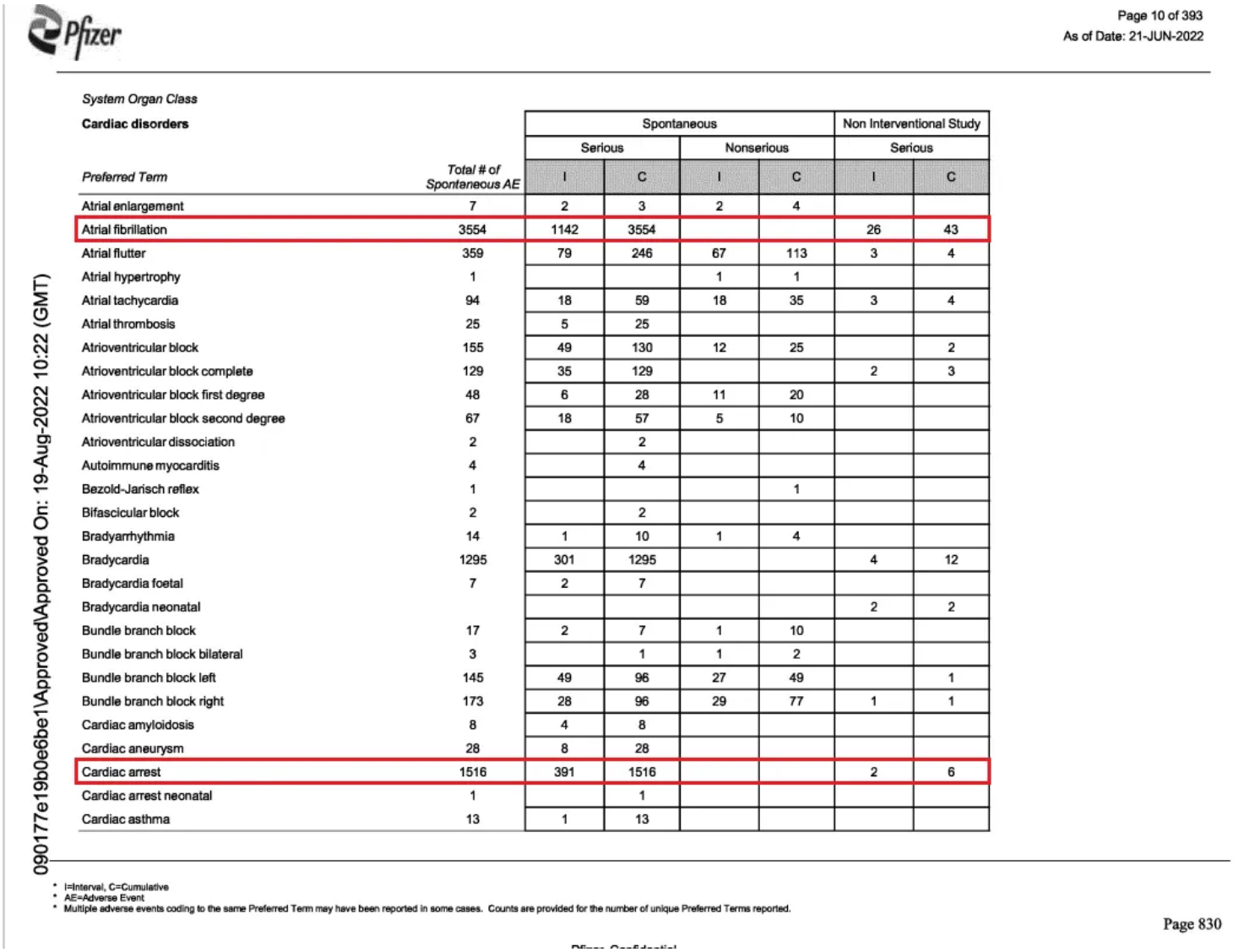
Abnormal clotting factor	13		8	1	5		
Acquired amegakaryocytic thrombocytopenia	1		1				
Acquired factor V deficiency	1	1	1				
Acquired factor VIII deficiency	2	1	2				
Acquired haemophilia	65	29	65				4
Acquired Von Willebrand's disease	3		3				

Now that we have addressed that, let's examine some of the discoveries outlined in the report.

Let's look into some of the notable serious adverse events reported and the associated experiences. Firstly, focusing on the Cardiac disorders section of the report, the findings reveal that within the timeframe covered by this report, 391 individuals suffered from cardiac arrest, while since the beginning of Pfizer's vaccine roll-out monitoring, a total of

1,516 cases of cardiac arrest have been recorded.

Another observation relates to atrial fibrillation, which is characterized as an irregular and often rapid heart rhythm (arrhythmia) that can potentially result in blood clots within the heart. Atrial fibrillation increases the risk of stroke, heart failure, and other heart-related complications. As per this report, 1,142 individuals experienced atrial fibrillation, and throughout the entire surveillance period, a total of 3,554 cases were documented.



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System Organ Class
Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Atrial enlargement	7	2	3	2	4		
Atrial fibrillation	3554	1142	3554			26	43
Atrial flutter	359	79	246	67	113	3	4
Atrial hypertrophy	1			1	1		
Atrial tachycardia	94	18	59	18	35	3	4
Atrial thrombosis	25	5	25				
Atrioventricular block	155	49	130	12	25		2
Atrioventricular block complete	129	35	129			2	3
Atrioventricular block first degree	48	6	28	11	20		
Atrioventricular block second degree	67	18	57	5	10		
Atrioventricular dissociation	2		2				
Autoimmune myocarditis	4		4				
Bezold-Jarisch reflex	1				1		
Bifascicular block	2		2				
Bradyarrhythmia	14	1	10	1	4		
Bradycardia	1295	301	1295			4	12
Bradycardia foetal	7	2	7				
Bradycardia neonatal						2	2
Bundle branch block	17	2	7	1	10		
Bundle branch block bilateral	3		1	1	2		
Bundle branch block left	145	49	96	27	49		1
Bundle branch block right	173	28	96	29	77	1	1
Cardiac amyloidosis	8	4	8				
Cardiac aneurysm	28	8	28				
Cardiac arrest	1516	391	1516			2	6
Cardiac arrest neonatal	1		1				
Cardiac asthma	13	1	13				

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Lets examine the Cardiac failure section. The report categorizes cardiac failure into four distinct groups, and within the span of this six-month report alone, a total of 737 instances of cardiac failure were documented. Cumulatively, since the commencement of the vaccine roll-out monitoring, there have been 2,502 reported cases of cardiac failure types across all four categories.

System Organ Class
Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cardiac contractility decreased	6	4	5	1	1		
Cardiac discomfort	1241	188	354	563	887	3	4
Cardiac disorder	1570	290	759	356	811	4	10
Cardiac dysfunction	91	28	91				
Cardiac failure	1909	573	1908	1	1	7	11
Cardiac failure acute	249	57	249				1
Cardiac failure chronic	96	37	96				
Cardiac failure congestive	249	70	249				3
Cardiac failure high output	1	1	1				
Cardiac fibrillation	188	78	188			2	3
Cardiac flutter	1196	349	1196			3	10
Cardiac granuloma	1	1	1				
Cardiac hypertrophy	64	17	47	8	17		
Cardiac perforation	3	2	3				
Cardiac perfusion defect	1		1				
Cardiac sarcoidosis	7	3	7				
Cardiac septal hypertrophy	5	1	2	1	3		
Cardiac steatosis	4	3	4				
Cardiac tamponade	108	37	108				
Cardiac valve discolouration	1	1	1				
Cardiac valve disease	56	12	33	13	23		
Cardiac valve sclerosis	3	1	3				
Cardiac ventricular disorder	8	1	3	3	5		
Cardiac ventricular thrombosis	37	9	37				
Cardiogenic shock	229	71	228	1	1		
Cardiomegaly	376	73	235	65	141	2	2
Cardiomyopathy	288	115	287		1	1	1

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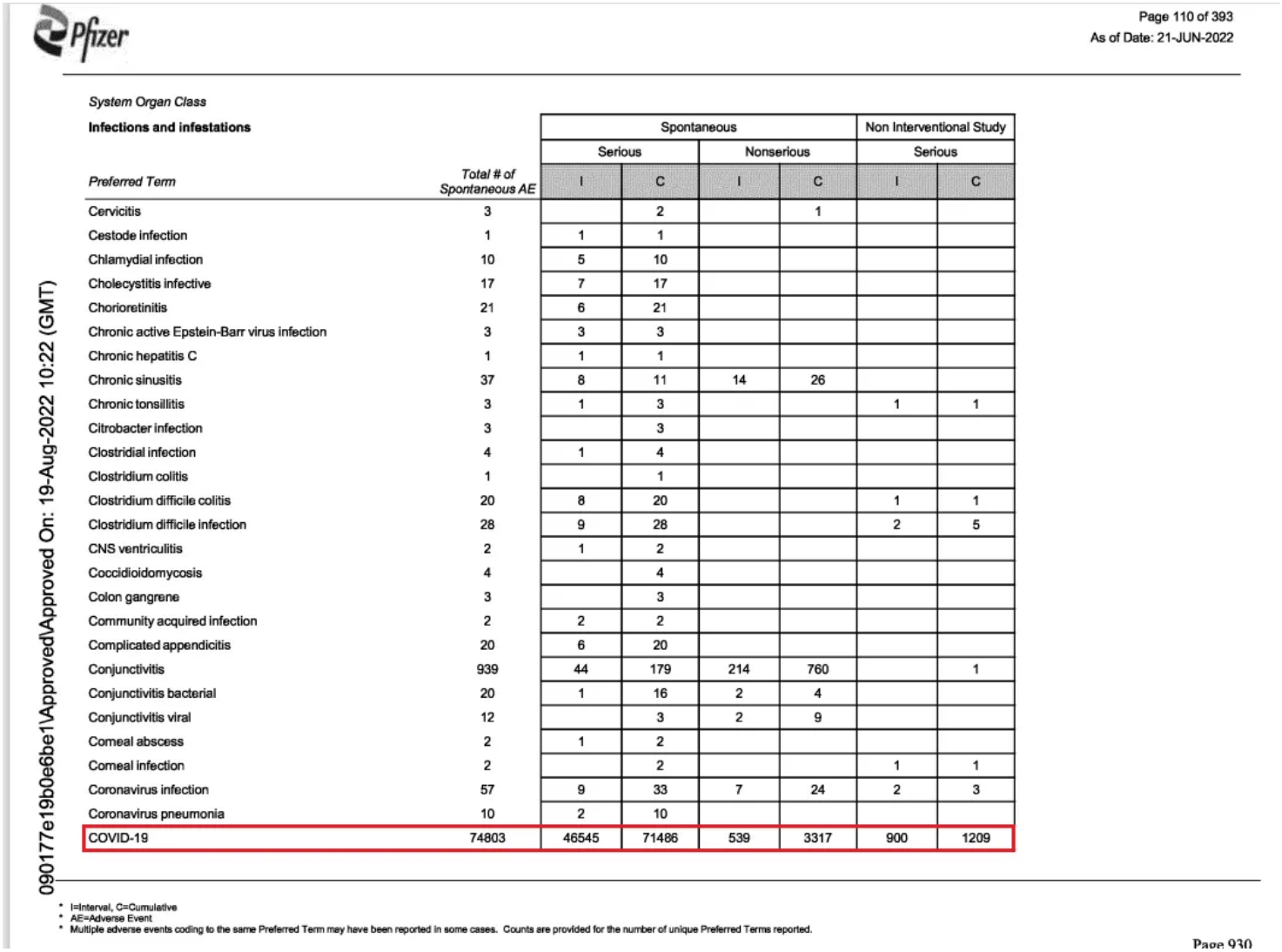
The cumulative data reveals a significant number of cardiac-related disorders, with a total of 126,993 cases reported. Among them, 82,911 cases were classified as serious. This stark contrast indicates that the number of serious cardiac-related disorders outweighs those categorized as non-serious. This observation alone should be ringing alarm bells.

System Organ Class
Cardiac disorders

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Total:	126993	33519	82303	20300	44690	327	608

One particularly significant and interesting finding in this report concerns the COVID-19

virus itself. According to Pfizer's own report, there were a cumulative total of 72,695 reports of serious COVID-19 cases among vaccinated individuals, in contrast to 3,317 reports categorized as non-serious. This data indicates that, based on their own findings, a higher number of vaccinated individuals experienced severe episodes of COVID-19 compared to nonserious cases.



Pfizer

System Organ Class
Infections and infestations

Preferred Term	*Total # of Spontaneous AE*	Spontaneous				Non Interventional Study	
		Serious		Nonserious		Serious	
		I	C	I	C	I	C
Cervicitis	3		2		1		
Cestode infection	1	1	1				
Chlamydial infection	10	5	10				
Cholecystitis infective	17	7	17				
Chorioretinitis	21	6	21				
Chronic active Epstein-Barr virus infection	3	3	3				
Chronic hepatitis C	1	1	1				
Chronic sinusitis	37	8	11	14	26		
Chronic tonsillitis	3	1	3			1	1
Citrobacter infection	3		3				
Clostridial infection	4	1	4				
Clostridium colitis	1		1				
Clostridium difficile colitis	20	8	20			1	1
Clostridium difficile infection	28	9	28			2	5
CNS ventriculitis	2	1	2				
Coccidioidomycosis	4		4				
Colon gangrene	3		3				
Community acquired infection	2	2	2				
Complicated appendicitis	20	6	20				
Conjunctivitis	939	44	179	214	760		1
Conjunctivitis bacterial	20	1	16	2	4		
Conjunctivitis viral	12		3	2	9		
Corneal abscess	2	1	2				
Corneal infection	2		2			1	1
Coronavirus infection	57	9	33	7	24	2	3
Coronavirus pneumonia	10	2	10				
COVID-19	74803	46545	71486	539	3317	900	1209

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If you would like to review the report for yourself, you can do so at the link provided below. There is certainly a wealth of information in this report. I have briefly glanced over some of the categories, and the results do not appear favorable for Pfizer. It is notable that there are often more reports of serious adverse events than non-serious ones.

https://drive.google.com/file/d/1Dd76YNVHfTp8u-e5LOnLzxQYvGIie5W0/view?usp=sharing