



1.AER Number	(b	0) (6)	С	ase Serio	usness: SE	ERIOUS	Seriousr	iess C	criteria: [Death,Medio	cally Signifi	cant				
						Patient	Demograp	hic								
Sex	Age		Height	(cm)		Weight (kg)	Rad	ce		Country V	Vhere Event	Occured			
MALE	13 YEARS	3						NO	DATA - NO	DATA	UNITED S	TATES				
					Е	vent Inform	ation and N	larrati	ive							
Verbatim Term	Lo	owest Level Terr	n	Preferre	ed Term		Onset Dat	е	Event Serious		Clinical Ou	10	Procedure Causality P Company		Proced Per Re	ure Causality porter
sudden death of a 13-year-old (place)chilc had a second dose of F vaccine	d who Pfizer	ıdden death		Sudden					SERIOU		FATAL		NO DATA		NO DA	
This is a spontaneous r Solution for injection, B sconcomitant medication unspecified date. It was No follow-up attempts a	satch/Lot no ns were no s not repor	umber was not re of reported. It was ted if an autopsy	eported), via reported the was perform	an unspect at remaine ned.	cified route of a d strangely sil	administration ent over the	n on an unst	pecifie	d date as sii	nale dose fa	or COVID-1	9 immunisat	ion The pa	tient's m	nedical h	nistory and
Lab Data:		Unkno	wn			L	ab Data									
Lab Narrative:																
Test Name		Norma	Value	Test Dat	е	Test Result	t		Lab	Comments	5					
‡																
					Susp	ect Product	(s) Therapy	Infor	mation							
Suspect Product(s)		Unit Dose	Total Dail	y Dose	Regimen Do	se Route	of Admin	Thera	py Date(s)	Therapy	Duration	Anatomica Location	Vaccinat Dose No		t No.	Batch No.
BNT162B2						NO DA	ATA	-				NO DATA	2			
					5	Suspect Pro	duct(s) Info	rmatio	on							
Suspect Product(s)		Indication	(s)		Form of Adn	nin First	Total Daily	Dose	Action T	aken	Dechalle	nge	Rechalle	nge	Inte	racting Drug
BNT162B2		COVID-19	immunisatio	า	SOLUTION F INJECTION	OR			NOT AP	PLICABLE	N/A		N/A		NO	DATA
					Pro	duct(s) and	Event(s) In	forma	ation							
Suspect Product(s)		Event(s)			CDS	Latency	/ Group		Rechalleng	je	Causalit	y per Repor	ter	Causal	ity per (Company
BNT162B2		Sudden death	1		N	Unknow	'n		N/A		N/A			N/A		
						Patient I	Medical His	tory								
													FDA-CBER	-2022-58	812-023	5532





1.A	ER Numbe	er	(b) (6)		Case Serio	ousness: SE	ERIOUS	Seriousnes	s Criteria:	Death, Medically Sign	nificant			
Pat	ient/Parer	nt Indicator	Coded Cond	ition	Start Date	Stop Date	Ongoing	g Notes	•					
							Cause of D	Death/Autops	sy					
Oth	er Death I	nformation:												•
Тур	oe .		Patient/Pare	nt Indicator C	oded Conditi	on				Notes				
DE.	ATH		PATIENT	S	udden death									
⇟一		Unknown					Concomi	tant Product	(s)					
∄Co₁	ncomitant	Product(s)		Conmed Tra	dename As I	Reported	Therapy Date	e(s)			Rou	te of Admin		
‡_				•			-							
							Suspect or C	onmed Devi	ces					
	spect Devi				_		,		_		_			
De 	vice Type	Device Indicator	Model No	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available fo Evaluation	Device r Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluatio	n Code
d no	DATA							NO DATA	NO DATA	NO DATA				
Ú,			·		·		Repo	rt History						
Soi			HP/Medica Confirmed	Ily Case Rep	ort Type	Reporter	Occupation	Protocol/S	tudy No.	Center ID & Other II	D Patient	ID Initia Rec	al Safety eipt Date	EUDRACT No.
Spo	ontaneous		N	SPONTAN	EOUS	NA						20-J	UL-2021	
							Refe	erences						
Ref	ference Ty	pe		Reference ID			Reference No	tes						
E 21	B COMPAN	NY NUMBER		(b)	(6)									
₹							Parent Me	dical Histor	/					
Pat	ient/Parer	nt Indicator	Coded Cond	ition	Start Date	Stop Date	Ongoing	g Notes	3					





2.AER Number		(b) (6)		Ca	se Serio	usness: SE	RIOUS	S S e	eriousne	ess Crit	teria: D	eath,Medic	ally Signifi	cant				
							Pa	tient Dem	nographi	ic								
Sex	Age			Height	(cm)		Weigl	ht (kg)		Race			Country V	/here Event	Occured			
FEMALE	13 YE	ARS								NO D	ATA - NO	DATA	UNITED S	TATES				
						Е	vent Ir	nformation	n and Na	rrative)							
Verbatim Term		Lowest L	evel Term.		Preferre	ed Term		Ons	set Date				linical Ou	Į (Causality Pe			
dead from second dos Pfizer Covid 19 vaccin		Unknown	cause of d	eath	Death						SERIOUS	S F	ATAL	1	NO DATA	N	O DAT	Ā
13-year-old female pa 13-year-old for covid-1 immunisation. A 13 ye unknown if an autopsy	tient red 9 immu ars old i was pe	eived bnt1 inisation. T female is d erformed.	62b2 (BNT The patient lead from s	162B2), dos medical his econd dose	se 2 via ar tory and c of Pfizer	n unspecified r oncomitant mo Covid 19 vacc	oute of edicatio ine. Bo	administra ons were n	ation on a ot report	an unsp ed. The	ecified da patient p	ite (Batch/L reviously re	ot number ceived the	was not report first dose of	orted) as DOS bnt162b2 (B	SE 2, SIN NT162B2	NGLE 2) for a	at the age of covid-19
Lab Data:			Unknow	'n				Lab D	ata									
Lab Narrative:																		
Test Name			Normal	Value	Test Dat	e	Test F	Result			Lab	Comments	3					
<u> </u>	_																	
						Susp	ect Pro	oduct(s) T	herapy I	nforma	ition							
Suspect Product(s)		U	nit Dose	Total Daily	Dose	Regimen Do	se F	Route of A	Admin T	herapy	Date(s)	Therapy I	Duration	Anatomica Location	Vaccinatio Dose No.	n Lot N	lo.	Batch No.
BNT162B2							N	IO DATA		-				NO DATA	2			
						5	uspec	t Product	(s) Infor	mation								
Suspect Product(s)		Ir	ndication(s	5)		Form of Adn	nin	First Tota	al Daily I	Dose	Action T	aken	Dechalle	nge	Rechalleng	je	Inter	acting Drug
BNT162B2		С	OVID-19 ir	nmunisation		SOLUTION F INJECTION	OR				NOT APF	PLICABLE	N/A		N/A		NO [DATA
						Pro	duct(s) and Eve	ent(s) Info	ormatio	on							
Suspect Product(s)	Event Information and Narrative retroating to the property of the part of the patients of the																	
BNT162B2		Dea	ith			N	Ur	ıknown		N/	A		N/A		N	I/A		
							Pat	ient Medi	cal Histo	ory								
Patient/Parent Indica	tor C	oded Con	dition	Star	t Date	Stop Date	C	ngoing	Note	es								
							Cau	se of Dea	th/Autor	osy				F	DA-CBER-2	022-581	2-023	5534



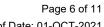


2.AER Num	ber	(b) (6)	l	Case Serio	usness: SE	ERIOUS	Seriousnes	s Criteria: [Death,Medically Sign	nificant			
Other Death	Information:												
Туре		Patient/Pare	nt Indicator	Coded Condition	n				Notes				
DEATH		PATIENT		Death									
ConMed:	Unknown					Concomi	tant Product	(s)					
	nt Product(s)		Conmed T	radename As R	eported	Therapy Date	e(s)			Route	of Admin		
<u> </u>						-							
<u> </u>						Suspect or C	onmed Devi	ces					
Suspect De													
Device Type	e Device Indicator	Model No.	Serial No.		Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation	n Code
NO DATA							NO DATA	NO DATA	NO DATA				
<u>a</u>						Repo	rt History						
Source		HP/Medica Confirmed				Occupation	Protocol/S	tudy No.	Center ID & Other ID	Patient II		I Safety eipt Date	EUDRACT No.
Spontaneou	S	N	SPONTA	NEOUS	NA						23-A	UG-2021	
<u>u</u>						Refe	erences						
Reference 1	Гуре	F	Reference ID		1	Reference No	tes						
MEDICAL IN	NFORMATION	NO.	(b) (6)		((b) (6)							
NO. CASE C	COPIES		(b) (6)		(b) (6)							
E2B LINKED	REPORT		(b)	(6)			(b) (6)						
NCSP		(b) (6)										
E2B COMPA	ANY NUMBER		(b)	(6)									
0						Parent Me	edical Histor	1					
Patient/Pare	ent Indicator	Coded Cond	ition	Start Date	Stop Date	Ongoing	g Notes						





3.AER Number	(b) (6)	Ca	ase Serio	usness: S	ERIOUS	Seriousr	ness Critei	ria: D	eath					
						Patient	Demograpl	hic							
Sex	Age		Height	(cm)		Weight (kg	a)	Race			Country V	Vhere Event	Occured		
MALE	13 YEARS							NO DAT	ΓA - NO I	DATA	UNITED S	TATES			
					E	Event Inform	nation and N	larrative							
Verbatim Term died three days after	Low	est Level Term		Preferr	ed Term		Onset Dat		vent eriousne		Clinical Out	c	rocedure ausality Per company	Proced Per Re	dure Causality porter
died three days after vaccination	Covid Unki	nown cause of d	eath	Death				s	ERIOUS	i	FATAL	N	IO DATA	NO DA	TA
Autopsy showed enl heart and fluid surro the heart	unding	cardial effusion		Pericard	dial effusion			S	ERIOUS		FATAL	N	IO DATA	NO DA	TA
Autopsy showed enl heart and fluid surro the heart	arged Enla unding	rgement heart		Cardion	negaly			S	ERIOUS		FATAL	N	IO DATA	NO DA	TA
of administration in a patient previously re unspecified route of Covid vaccine, the p No follow-up attemp Follow-up (25Jun20) it trail sent regarding No follow-up attemp Lab Data:	ceived first dos administration atient died. Autorites are possible; 21): This is a forthe confirmation.	e of bnt162b2 (fin an unspecifier topsy result shown information about the work of the wor	PFIZER-BIC d anatomica wed enlarge out lot/batch eous report tioned guer	ONTECH (al location ad heart al number o in respon y. New inf	COVID-19 mR on an unspec nd fluid surrou cannot be obta se to ma formation inclu	NA VACCINI ified date as nding the hea ined.	E, Formulatic dose 1, sing art caused by	on: Solutior le for COV	n for inje 'ID-19 im	ction, Bat munizatio	ch/Lot numb on. On an un	per and Expira	ation date not r e, three days a	eported) via	a an
Lab Data:		Unknow	'n			L	.ab Data								
Lab Narrative:															
Test Name		Normal	Value	Test Dat	e	Test Resul	t		Lab (Comment	ts				
					Susn	ect Product	(s) Therapy	Information	on						
Suspect Product(s)		Unit Dose	Total Daily	/ Dose	Regimen Do		of Admin			Therapy	Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2						NO D	ATA	-				NO DATA	2		+





3.AER Number		(b) (6)		Case Serio	ousness: St	ERIOUS	Seriousnes	ss Criteria:	Death					
					S	Suspect Prod	• •							
Suspect Produ	ct(s)	Indic	ation(s)		Form of Adn	nin First	Total Daily D	ose Action	Taken	Dechall	lenge	Rechalle	nge	Interacting Dru
BNT162B2		COV	D-19 immur	isation	SOLUTION F INJECTION	OR		NOT A	PPLICABLE	N/A		N/A		NO DATA
					Pro	duct(s) and		rmation						
Suspect Produ BNT162B2	ct(s)	Event(s	s)		CDS	Latency	Group	Rechallen	ige	Causali	ty per Repo	orter	Causality	per Company
BNT162B2		Death			N	Unknowr	1	N/A		N/A			N/A	
BNT162B2		Pericard	dial effusion		N	Unknowr	1	N/A		N/A			N/A	
BNT162B2		Cardion	negaly		N	Unknowr	1	N/A		N/A			N/A	
		·				Patient M	edical Histor	у						
Patient/Parent	Indicator I	Coded Condition	on	Start Date	Stop Date	Ongoin	g Note	s						
							Death/Autop							
Other Death Info	ormation:							-,						
уре		Patient/Parent	Indicator	Coded Conditi	on				Notes					
UTOPSY		PATIENT		Cardiomegaly										
UTOPSY		PATIENT		Pericardial effu	sion									
DEATH		PATIENT		Death										
ConMed: Ur	ıknown					Concom	itant Produc	t(s)						
Concomitant P	roduct(s)		Conmed T	radename As F	Reported	Therapy Da	te(s)				Route	e of Admin		
						-								
						Suspect or	Conmed Dev	ices						
Suspect Device	es													
Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluate Manufac	ed by	Single Use	Evaluation Type	Evaluati	on Code
NO DATA							NO DATA	NO DATA	NO DAT	A				
						Den	ut Hiotom							
Source		HP/Medically Confirmed	Case Re	oort Type	Reporter	Occupation	Protocol/S	Study No.	Center ID &	Other ID	Patient II	D Initi	al Safety eipt Date	EUDRACT No
Spontaneous		N	SPONTA	NEOUS	NA								UN-2021	



Section Page: 3

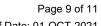
3.AER Number (b) (6) Case Seriousness: SERIOUS Seriousness Criteria: Death

			References	
Reference Type	Reference ID	Refe	erence Notes	
E2B COMPANY NUMBER	(b) (6)			
		ı	Parent Medical H	listory
Patient/Parent Indicator Coded Cor	dition Start Date	Stop Date	Ongoing	Notes





4.AER Number	(b) (6))	C	ase Seriοι	ısness: SE	RIOU	S Serious	ness (Criteria:	Death,Medic	ally Signifi	cant				
						Pa	atient Demograp	hic								
Sex Ag	je		Height	(cm)		Weig	ht (kg)	Rad	ce		Country V	Vhere Event	Occured			
MALE 13	YEARS							NO	DATA - N	O DATA	UNITED S	TATES				
					E	vent li	nformation and I	Narrati	ive							
Verbatim Term	Lowes	st Level Term		Preferre	d Term		Onset Da	te	Event Seriou		linical Ou	c	rocedure ausality l ompany		Proced Per Rep	ure Causality oorter
died in his sleep 3 days at taking the Pfizer covid vaccine	fter Died in	n sleep		Death			16-JUN-20	021	SERIO	US F	ATAL	N	O DATA	1	NO DAT	-A
administration on an unsp Historical Vaccine include Vaccine on 16Jun2021. The Investigation and the auto Information on the lot/bato Follow-up (05Aug2021): The Information is expected.	his is coincion psy was be th number h	dental, this is r ing performed. nas been reque	ot causative. The inform	e. Cause on ation is be	of death was ur ing sent the Cl	nknow DC to	n. No investigatio see if there is a c	n asse orrelat	essment. T tion. The re	he patient die porter mentic	ed on 16Jur ons that we	n2021. The co all know a lo	ounty heal t of 13-yea	lth departi ar-old falli	ment co	onfirmed the for that.
Lab Data:		Unknow	n				Lab Data									
V Lab Narrative:																
Test Name		Normal \	/alue	Test Date)	Test F	Result		La	b Comments	i					
<u></u>																
(Suspe	ct Pro	oduct(s) Therapy	/ Infor	mation							
Suspect Product(s)		Unit Dose	Total Dail	y Dose	Regimen Dos	e F	Route of Admin	Thera	apy Date(s	S) Therapy	Duration	Anatomical Location	Vaccina Dose No	tion Lot	No.	Batch No.
BNT162B2						١	NO DATA	-				NO DATA	2			
					S	uspec	ct Product(s) Info	rmati	on							
Suspect Product(s)		Indication(s)		Form of Adm	in	First Total Daily	/ Dose	Action	Taken	Dechalle	nge	Rechalle	nge	Inter	acting Drug
BNT162B2		COVID-19 in	nmunisatio	า	SOLUTION FO	OR			NOT A	PPLICABLE	N/A		N/A		NO I	DATA
					Pro	duct(s	s) and Event(s) li	nforma	ation		<u> </u>					
Suspect Product(s)	E	Event(s)			CDS	La	atency Group		Rechaller	nge	Causality	per Report	er	Causalit	y per (ompany
BNT162B2		Death			N	Ur	nknown		N/A		N/A			N/A		





4.AER N	Number		(b) (6)		Case Serie	ousness: SE	ERIOUS	Seriousnes	s Criteria:	Death, Medically Sig	nificant			
							Patient Me	edical Histor	у					
	-				T = =			1						
Patient/	/Parent I	ndicator	Coded Condi	tion	Start Date	Stop Date	Ongoing							
Other D	eath Info	rmation:					Cause of E	Death/Autops	sy					
Type	catii iiiic		Patient/Parer	nt Indicator	Coded Condit	ion				Notes				
DEATH			PATIENT		Death					1.10.00				
ConMed	d : Un	known					Concomi	tant Product	(s)					
Concon	mitant Pı	oduct(s)		Conmed	Tradename As I	Reported	Therapy Dat		, ,		Rout	e of Admin		
4							-							
							Suspect or C	Conmed Devi	ces					
Suspec														9
Device	Type	Device Indicator	Model No.	Serial No	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluatio	n Code
NO DAT	ТА							NO DATA	NO DATA	NO DATA				
<u> </u>							Repo	rt History						
Source			HP/Medica Confirmed		eport Type	_	Occupation	Protocol/S	tudy No.	Center ID & Other II	D Patient	Red	al Safety eipt Date	EUDRACT No.
Spontar	neous		N	SPONT	ANEOUS	NA						02-	IUL-2021	
#							Refe	erences						
Referen	псе Туре)	F	Reference ID			Reference No	tes						
LOCAL	REFERE	NCE NO.		(b) (6)			(b) (6)							
CALL C	ENTER	NO.	(1	o) (6)										
NO. CA				(b) (6)			(b) (6)							
· F——		ENCE NO.		(b) (6)	(0)			(b) (6)						
E2B CO	DMPANY	NUMBER		(b)	(6)		Daront Me	edical Histor	,					
Patient/	/Parent I	ndicator (Coded Condi	tion	Start Date	Stop Date	Ongoing							
. attent	n arent i	indicator	ooded oond	tion .	Otal t Date	Otop Date	Jongoni	y Itoles						





5.AER Number	((b) (6)		Ca	ise Serio	usness: SI	ERIOUS	S Seriou	sness Cri	iteria: [Death						
							Pa	tient Demogra	phic								
Sex	Age			Height	(cm)		Weigl	ht (kg)	Race			Country V	Vhere Event	Occured			
MALE	13 YEA	RS							NO D	ATA - NO	DATA	UNITED S	TATES				
						E	Event Ir	nformation and	l Narrative	9							
Verbatim Term		Lowest L	evel Term		Preferre	ed Term		Onset D	ate	Event Seriousr		linical Ou		Procedure Causality Per Company		ocedur r Repo	e Causality rter
I read a Newsweek he online that said a thirte year old died in his sle after taking the Pfizer vaccine and the CDC investigating. Another headline may have sai was a boy but	een ep is article	Unknown	cause of de	eath	Death					SERIOUS	S F	ATAL	1	NO DATA	NC	DATA	
This is a spontaneous number was not report medications were not to investigating. Another specifics. The patient described by the patient described by the patient of the	ted) via a reported article ho lied on a ther infor	an unspeci . On an un eadline ma n unspecif mation wa	ified route on specified do ay have said fied date. It as requested	of administrate, the rep d it was a b was unkno	ation on a orter read oy, but re wn if an a	in unspecified d a Newsweek porter can't fin utopsy was pe	date as headlir d that a erformed	dose number une online that santicle again. The outcome	unknown, s aid a thirte e reporter of event v	single for c en-year-ol don't have vas reporte	covid-19 imr ld died in his e a subscrip ed as fatal.	munisation. s sleep afte tion to new	The patient or taking the for sweek so co	medical history Pfizer vaccine a ould not read the	and condithe article	oncomit CDC we and ge	tant vas et more
t Lab Data:			Unknowi	າ				Lab Data									
Lab Narrative:			'														
Test Name			Normal \	/alue	Test Dat	е	Test F	Result		Lab	Comments	3					
† 																	
						Suen	ect Pro	oduct(s) Thera	ov Inform	ation							
Suspect Product(s)		Uı	nit Dose	Total Daily	Dose	Regimen Do		Route of Admir		y Date(s)	Therapy I	Duration	Anatomica Location	Vaccination Dose No.	Lot No	o. B	Batch No.
BNT162B2							N	IO DATA	-				NO DATA				
							Suspec	t Product(s) In	formation								
Suspect Product(s)		In	dication(s)		Form of Adr	•	First Total Da		Action T	Taken	Dechalle	enge	Rechallenge		Interac	cting Drug
BNT162B2			OVID-19 im		1	SOLUTION F INJECTION			-		PLICABLE	N/A		N/A		NO DA	





5.AER Number		(b) (6)		Case Seri	ousness: SE	ERIOUS	Seriousnes	ss Criteria:	Death					
					Pro	oduct(s) and E	vent(s) Info	rmation						
Suspect Produ	ct(s)	Eve	nt(s)		CDS	Latency (Group	Rechallen	ge	Causality pe	r Repo	rter	Causality	per Company
BNT162B2		Dea	th		N	Unknown		N/A		N/A			N/A	
						Patient Me	edical Histor	у						
Patient/Parent	Indicator	Coded Cond	dition	Start Date	Stop Date	Ongoing	g Note	s						
1					_	Cause of D	eath/Autop	sy						
Other Death Info	ormation:													
Туре		Patient/Pare	ent Indicator	Coded Condit	ion				Notes					
DEATH		PATIENT		Death										
ConMed: Ur	nknown					Concomi	tant Produc	t(s)						
Concomitant P	roduct(s)		Conmed	Tradename As	Reported	Therapy Date	e(s)				Route	of Admir)	
<u> </u>			•			-								
						Suspect or C	onmed Dev	ices						
Suspect Device	es													
Device Type	Device Indicator	Model No	o. Serial No	. NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available fo Evaluation	Device r Evaluated Manufact	d by		Evaluatio Type	n Evaluatio	n Code
NO DATA							NO DATA	NO DATA	NO DATA	`				
						Repo	rt History			<u> </u>				
Source		HP/Medic Confirme		eport Type	Reporter	Occupation	Protocol/S	Study No.	Center ID & C	Other ID Pa	atient IC		tial Safety ceipt Date	EUDRACT No.
Spontaneous		N	SPONT	ANEOUS	NA							04	-JUL-2021	
						Refe	erences							
Reference Type	е		Reference ID			Reference No	tes			-				
COVAES REFE	RENCE NO).		(b) (6)										
E2B COMPANY	/ NUMBER		(b)	(6)										
\$						Parent Me	edical Histor	у						
Patient/Parent	Indicator	Coded Cond	dition	Start Date	Stop Date	Ongoing	g Note	s						