Event-Specific Questionnaire for HCP Teratogenicity Pregnancy Background

24 h phone: +371 22038854 vigilance@grindeks.lv

Date (dd/mmm/y	vvv).					
Reporter's Infor						
Name, Surname	macion					
riamo, samamo						
Reporter's						
occupation						
Phone No			E-mail			
Institution			Country, city			
Patient's Prescri	ibing Physician	's Information	<u> </u>			
Name, Surname	Ibilig Filysicial	i s Illioilliatioi		Date (dd/r	mmm/yyyy):	
rame, samame						
Physician's						
occupation						
Phone No			E-mail			
Institution			Country, city			
T						
Information abo	ncy of a patient					
	ancy of a patient					
	are of a pregnan	•				
Pregnant woman's		t Terriale				
Patient code ¹ :	IIIIOIIIIacioii	Da	ate of birth (dd	/mmm/yy	νν.).	
rationi code :			ite of birtir (dd	, , , y y	,,,,,.	
Height:		We	eight:			
Patient's information	on (if different)	L		ı		
Patient code	, i	Da	te of birth (dd	/mmm/yy	/уу):	
(who received						
drug):						
Height:			eight:			
	reatment infor	mation: lenali				
Dose Start date			Frequen	•		
(dd/mmm/yyyy)				last dose		
Female partner of	male nationt: da	ate of exposure		m/yyyy)		
Exposure of pregn						
Indication to use	dire remaie: gest	acional age at e	Aposure (Weer	(3)		
	cy information					
Date of last mense						
			dd.m	nmm.yyy		
Pregnancy test typ	e:					
Pregnancy test dat						
Female is currently		We	eeks pregnant	OR 🗌 ı	no longer pregnant	unknown
Female has elected	d to:					
☐ Carry to term		Expected date	of delivery:			
☐ Terminate preg	gnancy	Date performe	ed or pending:			

 $^{^1}P$ lease use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

3. Prenatal	Tests						
	Date (dd/mm/yyyy)	Result					
Ultrasound							
Ultrasound							
Ultrasound							
Amniocentesis							
Maternal serum AFF							
Has the patient already been referred to a specialist/gyneacologist?							
If yes, please speci	fy his/her name and contact info	ormation:					
4. Backgrou	nd information on reason fo	r nreanancy					
T. Dackgrou	The information on reason to	pregnancy					
Pregnant patient	/ Pregnant partner of a pation	ent					
	idered not to be of childbear		Yes 🗌	No 🗆			
		3,1	_				
			<u>I</u>				
If yes, mark reason	for considering not to be of chi	Idbearing potential					
		c for ≥ 1 year (Amenorrhoea following	Yes 🗌	No 🗆			
		pes not rule out childbearing potential)	_				
Premature	ovarian failure confirmed by a	specialist gynaecologist	Yes 🗌	No 🗆			
	ilateral salpingo-oophorectomy,	· · · · · · · · · · · · · · · · · · ·	Yes 🗌	No 🗆			
	pe, Turner syndrome, uterine ag	· · · · · · · · · · · · · · · · · · ·	Yes 🗆	No 🗆			
3: ::,,	,	,					
If no, mark from lis	t below what contraception was	used					
Implant			Yes 🗌	No 🗆			
	strel-releasing intrauterine syst	om (IUS)	Yes 🗆	No 🗆			
Levollorge	rogesterone acetate depot	em (103)	Yes 🗆	No 🗆			
, · · · · · · · · · · · · · · · · · · ·			Yes 🗆	No 🗆			
	ercourse with a vasectomised in by two negative semen analyse	nale partner only; vasectomy must be					
	inhibitory progesterone-only pill		Yes 🗌	No 🗆			
	gesteron-only pills	s (i.e. desogestiei)	Yes 🗆	No 🗆			
	oral contaceptive pill		Yes 🗆	No 🗆			
	a-uterine devices		Yes 🗌	No 🗆			
Condoms			Yes 🗌	No 🗆			
Cervical ca	an		Yes 🗆	No 🗆			
Sponge	·F		Yes 🗌	No □			
Withdrawa	1		Yes 🗌	No □			
Tubal steri			Yes 🗌	No □			
Other, spe							
	,						
• None			Yes 🗌	No 🗌			
Mark from the list	t below the reason for contra	ceptive failure	•				
 Missed ora 	l contraception		Yes 🗌	No 🗆			
Other med	lication or intercurrent illness in	teracting with oral contraception	Yes 🗌	No 🗆			
	mishap with barrier method		Yes 🗌	No 🗆			
 Unknown 			Yes 🗌	No 🗌			
 Intentiona 	I interruption of contraception		Yes* 🗌	No 🗌			
		ld, side effects, health concerns, inconv	enient to u	se, etc.):			
	· · · · ·	•		-			

• Othe	er, specify:									
Was lenalid	omide sta	rted d	espite patient	already	bein	ng preg	nant?		Yes 🗌	No 🗌
_		e edu	cational mater	ials on t	he p	otentia	al risk o	f	Yes 🗌	No 🗌
teratogenic										
			alidomide edu						Yes 🗌	No 🗆
Did the pati material?	ent under	stand	the information	on in the	lena	alidomi	ide edu	cational	Yes 🗌	No 🗆
	ent receiv	o inct	ructions on no	ed to av	oid r	areana	ncv2		Yes 🗌	No 🗆
Did the patient receive instructions on need to avoid pregnancy? Yes □ No □ 5. Previous obstetric history										
Number of pr										
Outcome of p				1						
Year of Type of										
Outcome Gostational age 11.										delivery
	Spontane	ous	Therapeutic	Live bir	th	Still b	irth			
	abortion		abortion							
			<u> </u>	🗀						
	Spontane abortion	ous	Therapeutic abortion	Live bir	tn	Still b	oirtn			
				\vdash						
	Spontane	OUS	Therapeutic	Live bir	th	Still b	irth			
	abortion		abortion							
	Spontane	ous	Therapeutic	Live bir						
	abortion		abortion							
Birth defect								T		
Was there an	ly birth def	ect fro	m any pregnanc	:y?	Ш,	Yes		☐ No		
										Unknown
If yes, please	provide de	etails h	elow:							
. ,, p										
6. Mat	ernal past		cal history	T-			1			
Condition		From	nmm/yyyy)	To (dd/mm	m/v	,,,,,)	Treatn	nent	Outcom	е
		(uu/II	111111/9999)	(uu/IIII	ш у	ууу)				
				1						

7. Maternal current meding Risk factors or conditions that				
Risk factors or conditions that				
occupational exposure e.g. hype	rtension, heart dise	ase, epilepsy, diabet	es, (pre)-eclamps	sia, thyroid disorders,
autoimmune diseases, depression				
Condition	From (dd/mm/y		Treatr	
Condition	TTOIII (du/IIIII/ y	777)	iieati	nenc
8. Maternal social history	(Check all that a	nnlv)		
☐ Alcohol		nt/units per day:		
LI AICOTO	11 yes, aiii0ui	ny unito per uay.		
		.,		
☐ Tobacco	If yes, amou	nt/units per day:		
☐ IV or recreational drug use	If yes, amou	nt/units per day:		
· ·	' '	. , ,		
9. Family history:				
History of congenital abnormality	nsychomotor reta	rdation in the family	(nlease specify n	aternal/maternal and
relationship) and provide details:				
10. Specific questions abo	out current pregna	ncy:		
			Yes* □	No 🗆
Were any other medicines (in	cluding herbal, al	ternative and over-		No 🗆
Were any other medicines (in the-counter and dietary su	cluding herbal, all oplements) used	ternative and over-	*If Yes, please	No 🗆
Were any other medicines (in	cluding herbal, all oplements) used	ternative and over-		No 🗆
Were any other medicines (in the-counter and dietary supend and/or in 4 weeks before preg	cluding herbal, ali oplements) used gnancy?	ternative and over- during pregnancy	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary su	cluding herbal, ali oplements) used gnancy?	ternative and over-	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary supend and/or in 4 weeks before preg	cluding herbal, ali oplements) used gnancy?	ternative and over- during pregnancy andication for use:	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before presented in the super s	cluding herbal, ali oplements) used gnancy? II A	ternative and over- during pregnancy ndication for use: :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pregname of drug(s): A: B:	cluding herbal, ali oplements) used gnancy? II A B	ternative and over- during pregnancy ndication for use: :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before presented in the super s	cluding herbal, ali oplements) used gnancy? II A B	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before presented in the property of the property	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before presented in the super s	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before presented in the property of the property	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use A: B:	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before present the super	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use A: B:	cluding herbal, ali oplements) used gnancy? II A B C	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use A: B: C: D:	Icluding herbal, alta pplements) used gnancy? In A B C D d:	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before present the super	Icluding herbal, alta pplements) used gnancy? In A B C D d:	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use A: B: C: D:	Icluding herbal, alta pplements) used gnancy? In A B C D d:	ternative and overduring pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary sup and/or in 4 weeks before pressure of drug(s): A: B: C: D: Dose, units, frequency, route use A: B: C: D:	Justing herbal, all plements) used gnancy? Justin A B C D d:	ternative and over- during pregnancy ndication for use: : :	*If Yes, please	No
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before present the super	Justing herbal, all plements) used gnancy? Justin A B C D d:	ternative and over- during pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before present the super	Justing herbal, all plements) used gnancy? Justin A B C D d:	ternative and over- during pregnancy ndication for use: : :	*If Yes, please	No 🗆
Were any other medicines (in the-counter and dietary super and/or in 4 weeks before present the super	Justing herbal, all plements) used gnancy? Justin A B C D d:	ternative and over- during pregnancy ndication for use: : :	*If Yes, please	No

Start Date (do	d/mm/yyyy)	End Date or Duration	(dd/mm/yyyy)	Outcome	Пр	and und with an avalan
				Resolved		solved with sequelae
				Resolving	☐ Fa	tal
				☐ Not resolved	☐ Un	known
Caucal relation	onship to lenalidomide:	If no, what me	adication disease	e states, etc, caused the advers	a avant2	
Yes	No	II IIO, WIIdt IIIe	edication, disease	s states, etc, caused the advers	e event?	
Is adverse	If Yes, please, select criteria bel	ow				If 'death', specify the cause
event serious?	☐ Death	/ /	☐ Persistent or	Significant Disability/ Incapacity		1
Yes		/mm /yyyy)				
☐ No	☐ Life-Threatening		Congenitai A	bnormality or Birth Defect		
	☐ Hospitalization/ Extended Ho	spitalization	☐ Other Signific	cant Medical Event		
B: Diagnosis	of adverse event. If diag	nosis is not known, pr	ovide symptom	(s)		
S		Te in in in	(11/	I a .		
Start Date (do	d/mm/yyyy)	End Date or Duration	(dd/mm/yyyy)	Outcome	□ Re	solved with sequelae
				Resolved	1_	
				Resolving	☐ Fa	known
				☐ Not resolved		KNOWN
Causal relation	onship to lenalidomide:	If no, what me	edication, disease	e states, etc, caused the advers	e event?	
Is adverse	If Yes, please, select criteria bel	ow				If 'death', specify the cause
event serious?	☐ Death	1 1	☐ Persistent or	Significant Disability/ Incapacity		
☐ Yes		/mm /yyyy)				
□ No	☐ Life-Threatening		☐ Congenital A	bnormality or Birth Defect		
	☐ Hospitalization/ Extended Ho	spitalization	☐ Other Signific	cant Medical Event		
C: Diagnosis	of adverse event. If diag	nosis is not known, pr	ovide symptom	(s)		
Start Date (do	d/mm/yyyy)	End Date or Duration	(dd/mm/yyyy)	Outcome	I⊓ Re	solved with sequelae
				Resolved		
				Resolving	☐ Fa	
				☐ Not resolved	☐ Un	known
Causal relation	onship to lenalidomide:	If no, what me	edication, disease	states, etc, caused the advers	e event?	
☐ Yes	□ No					
	Lesy 1					Trees are as
Is adverse event serious?	If Yes, please, select criteria bel	ow				If 'death', specify the cause
	Death	//	☐ Persistent or	Significant Disability/ Incapacity		
Yes	☐ Life-Threatening	/mm /yyyy)	☐ Congenital A	bnormality or Birth Defect		
□ No	Life-Timeatening		Othor Signific	cant Medical Event		
	☐ Hospitalization/ Extended Ho	spitalization	Other Signini	Lant Medical Event		
ere any di	isease course(s) co	mplications diag	nosed durin	g Yes* □		No 🗌
	pregna	ncy?				
				*If Yes,		
				please		
				specify		
				below		

Any other information should be provided here if it is not possible to provide it in the previous sections:

Event-Specific Questionnaire for HCP Teratogenicity

Pregnancy Follow-up

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Date (dd/mmm/yy	уу):	Period Cov	ered:	From:	То:
Reporter's Inform	nation				
Name, Surname					
Reporter's					
occupation Phone No		<u> </u>	E-mail		T
PHONE NO			L-IIIaII		
Institution			Country, ci	ity	
Patient's Prescrib Name, Surname	ing Physician's	Information		Data (dd	//mmm/\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
Name, Sumame				Date (du	l/mmm/yyyy):
Physician's				<u> </u>	
occupation					
Phone No			E-mail		
T					
Institution			Country, ci	ity	
Information abou	t pregnant won	nan			
☐ Pregnar	ncy of a patient				
	ncy of a patient's				
	re of a pregnant f	female			
Pregnant woman's Patient code ² :	information	Dat	e of birth (dd/mmm/	anna ()
ratient code .		Dat	e or birtir (uu/IIIIIIII/)	уууу).
Height:		We	ight:		
Patient's informatio	n (if different)	•			
Patient code		Dat	e of birth (dd/mmm/y	уууу):
(who received					
drug):					
Height:		We	ight:		
Current pregnance	y	110	191101		
1. Prenatal	Tests				
	Date (dd/r	mm/yyyy)	Result		
Ultrasound					
Ultrasound Ultrasound					
Amniocentesis					
Maternal serum AFF	D				
Other tests, specify					

 $^{^2}$ Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

2. Sp	ecific questions abou	ıt current pregn	ancy:				
Were any o	other medicines (incl	uding herbal, alt	ternative a		Yes* 🗌		No 🗌
counter an	d dietary supplemen	ts) used during	pregnancy	?	*If Yes, p		9
					specify be	elow	
Name of dru	ıg(s):		Indication	for use:			
A:			A:				
B:			B:				
C:			C:				
D:			D:				
Dose, units,	frequency, route used	':					
A:							
B:							
C:							
D:							
Adverse e	vents(s) (AE) during	pregnancy:					
A: Diagnosis of	fadverse event. If diagnosi	s is not known, provi	de symptom(s)			
Start Date (dd/n	nm/yyyy)	End Date or Duration	(dd/mm/yyyy)	Outcome		ПВ	solved with sequelae
				Resolved		_	·
				Resolving		☐ Fat	
				☐ Not resolved		Un	known
	hip to lenalidomide:	If no, what me	edication, disease	e states, etc, caused	d the adverse	event?	
☐ Yes [□ No						
	I rev						Legge at a second
Is adverse event serious?	If Yes, please, select criteria belov	V					If 'death', specify the cause
	Death/	/	☐ Persistent or	Significant Disability/ I	incapacity		
Yes	Life-Threatening	nm /yyyy)	☐ Congenital A	bnormality or Birth Def	ect		
□ No	_		Other Signifi	cant Medical Event			
	☐ Hospitalization/ Extended Hosp	pitalization	- Other Signin	cant Hedical Event			
R. Diagnosis of	adverse event. If diagnosi	e ie not known need	de sumptom/-	`			
B: Diagnosis of	adverse event. If diagnosi	s is not known, provi	de symptom(s	,			
Start Date (dd/n	nm/yyyy)	End Date or Duration	(dd/mm/yyyy)	Outcome			
` '	.,,,,		,,,,,			☐ Re	solved with sequelae
				Resolved		☐ Fat	al
				Resolving			known
Causal I II	hin ka lanalidan 11	176	dissais P	□ Not resolved	d also sol		
	hip to lenalidomide:] No	If no, what me	edication, disease	e states, etc, caused	a the adverse (event?	
							
Is adverse event	If Yes, please, select criteria belov	V					If 'death', specify the cause
serious?	□ Death/	/	Persistent or	Significant Disability/ I	incapacity		
☐ Yes		/ nm /yyyy)		,,	, ,		
□ No	☐ Life-Threatening		☐ Congenital A	bnormality or Birth Def	ect		
	☐ Hospitalization/ Extended Hosp	ded Hospitalization					

		d Date or Duration (dd/mm/yyyy) Outcome Resolved Resolving Not resolved If no, what medication, disease states, etc, caused the adver		Resolved with sequelae Fatal Unknown		
Yes Sadverse event	If Yes, please, select criteria		medication, disease	states, etc, caused the adver	se event?	If 'death', specify the cause
erious? Yes No	☐ Life-Threatening	Death// Persistent o				
sec	tions:					

Event-Specific Questionnaire for HCP Teratogenicity Pregnancy Outcome

24 h phone: +371 22038854 vigilance@grindeks.lv

Data (dd/mmm/yyyy):							
Date (dd/mmm/yyyy): Reporter's Information							
	1						
Name, Surname							
Reporter's occupation							
Phone No				E-mai	I		
Institution				Count	ry, cit	ty	
Patient's Prescribing P	hysiciar	's Info	ormation				
Name, Surname						Date (dd,	/mmm/yyyy):
Physician's occupation							
Phone No				E-mai	I		
Institution				Count	ry, cit	ty	
Information about pat	ient			•			
☐ Pregnancy of	a patien	t					
\square Pregnancy of	a patien	t's part	ner				
☐ Exposure of a	a pregnar	nt fema	ile				
Pregnant woman's inform	nation						
Patient code ³ :				Date of bi	irth (c	ld/mmm/y	vyyy):
Height:				Weight:			
Patient's information (if o	lifferent)						
Patient code (who	-			Date of bi	irth (c	ld/mmm/y	/ууу):
received drug):							
Height:				Weight:			
Pregnancy outcome:							
Date of delivery (dd.m	m.yyy):			Gestation	age a	at deliver	γ:
Tune of delivery							
Type of delivery:							
Normal		 					
C-section Induced		- - -					
Elective termination		- -	Date (dd/n	2m/2022			
		<u> </u>	Weeks from				
Spontaneous abortion			weeks iroi	II LIMP:			
Stillbirth					12.14		l
Examination of foetus (in	case					s ∐ No ∐]Unknown□
of elective termination,	lato		If no, desc	ibe below.			
spontaneous abortion or foetal death)	iate						
roctal death)							

³Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

Obstetrics information	1:				
Complications during pre	egnancy	□No	□Yes	If yes, please specif	y:
Complications during lab	our/delivery	□No	□Yes	If yes, please specif	y:
Post-partum maternal co	omplications	□No	□Yes	If yes, please specif	y:
Foetal outcome					
Live normal infant		□No	□Yes		
Foetal distress		□No	□Yes		
Intra-uterine growth retardation		□No	□Yes		
Neonatal complication		□No	□Yes	If yes, please specify:	
Live birth with congenita	l abnormality	□No	□Yes	If yes, please specif	y:
Sex : ☐Male ☐Female	Birth weight:			Length:	
Apgar score:	1 min:	5 min:		10 min:	Unknown
Any other information	should be provid	ed here if	it is not p	possible to provide	it in the previous sections:

Event-Specific Questionnaire for Pirmary Care Physician or Pediatrician Infant Follow-up

24 h phone: +371 22038854<u>vigilance@grindeks.lv</u>

Date (dd/mmm/yyyy):			
Reporter's Information			
Name, Surname			
Reporter's occupation			
Phone No		E-mail	
To the the			
Institution		Country, city	
Information about patient			
☐ Patient ☐ Patient's partner	(Mother)		
Patient code ¹ :	. ,	Date of birth (dd/	/mmm/yyyy):
		<u> </u>	
Height:		Weight:	
Name of Infant (if known):		T _	T =
Please provide information fo	r the preriod (dd/mm/yyyy):	From:	To:
Anomalies diagnosed since	a initial report:		
Anomanes diagnosed since	с ппси герога	☐ Yes*	☐ None
*If yes, please specify:			
i, yes, piedse speeny.			
Developmental assessmet			
	rmal		
	normal, please specify:		
	, , , , , , , , , , , , , , , , , , , ,		
Infant illnesses, hospitaliz		s:	
Inafant illnesses	Hospitalizations		Drug therapies
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		
	☐ Yes ☐ No		