TITLE	
	GENDER-NET Plus
	Promoting gender equality in H2020 and the ERA
	G-Ulder has recorded underly to the European User's Notices This project has recorded underly to the European User's Notices (20) observed and environities programme user's grant agreement for
	7400 £
	CRF 03 – Immune-Related Adverse Event Log
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Date	February 20 th 2020
CTCAE Guidelines (v	ersion 5.0)
Grade 1 (mild) asymindicated;	ptomatic or mild symptoms; clinical or diagnostic observations only; intervention not
Grade 2 (moderate) activities of daily living	minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ng (ADL);
	ere or medically significant but not immediately life-threatening; hospitalization or italization indicated; disabling limiting self care ADL;
Grade 4 (life threate	ning) life threatening consequences; urgent intervention indicated;
Grade 5 (fatal) Deatl	n (loss of life) as a result of an adverse event.
Log Opened By	
· /	
Log opened on	
Month D	ay Year
ICI treatment on	going ICI treatment not ongoing specify:
☐ Yes ☐ No	going for troutinont not ongoing opeony.
	Cause:
	Tumor Relapse/ Progression (update the "Follow-up Log")Toxicity
	Other reason

Date of last ICI infusion:

Month

Day

Year

TITLE	GENDER NET Plus Promoting gender equality in H2020 and the ERA G-DEFINER The project has not considered upon the furguest black agreement black Tristal and Tristal and Tristal and Tristal and Tristal CRF 03 — Immune-Related Adverse Event Log
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Adverse Event	Start Date	Stop Date	CTCAE	Frequency	Immune	Treatment	Causality	Treatment	Action taken with the	Sign & Date & MCN
		or	Grade		related?	required		(multiple choice	study medication	
		ongoing	v.5.0					possible)		
				□ Continuous	□ Yes	□ None	□ Certain	□ CTLA-4	□ No Action Taken	Investigator:
				□ Intermittent	□ No	□ Concomitant	□ Probable/likely	□ PD-1	□Permanently Discontinued	MCN:
		□ Ongoing			□ Na	Medication	□ Possible	□ PD-L1	□Interrupted	Date:
								□ Other (spec)	□ Reduced	
									□ Omitted	
								_	□ Delayed	
				□ Continuous	□ Yes	□ None	□ Certain	□ CTLA-4	□ No Action Taken	Investigator:
				□ Intermittent	□ No	□ Concomitant	□ Probable/likely	□ PD-1	□Permanently Discontinued	MCN:
		□ Ongoing			□ Na	Medication	□ Possible	□ PD-L1	□Interrupted	Date:
								□ Other (spec)	□ Reduced	
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				□ Continuous	□ Yes	□ None	□ Certain	□ CTLA-4	□ No Action Taken	Investigator:
				□ Intermittent	□ No	□ Concomitant	□ Probable/likely	□ PD-1	□Permanently Discontinued	MCN:
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		or	Grade		related?	required		(multiple choice	study medication	
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		□ Ongoing			□ Na	Medication	□ Possible	□ PD-L1	□Interrupted	Date:
								□ Other (spec)	□ Reduced	
									□ Omitted	
								_	□ Delayed	
				□ Continuous	□ Yes	□ None	□ Certain	□ CTLA-4	□ No Action Taken	Investigator:
				□ Intermittent	□ No	□ Concomitant	□ Probable/likely	□ PD-1	□Permanently Discontinued	MCN:
		□ Ongoing			□ Na	Medication	□ Possible	□ PD-L1	□Interrupted	Date:
								□ Other (spec)	□ Reduced	
									□ Omitted	
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				□ Continuous	□ Yes	□ None	□ Certain	□ CTLA-4	□ No Action Taken	Investigator:
				□ Intermittent	□ No	□ Concomitant	□ Probable/likely	□ PD-1	□Permanently Discontinued	MCN:
		□ Ongoing			□ Na	Medication	□ Possible	□ PD-L1	□Interrupted	Date:
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Appendix: Event list	

Organ System	Common	Rare
Dermatologic	☐ Rash (maculopapular, lichenoid),	☐ Acneiform rash,
	☐ pruritus,	□ alopecia,
	□ vitiligo	□ bullous pemphigoid,
	☐ Other	_ □ papulopustular rosacea,
		□ psoriasis,
		☐ Stevens–Johnson syndrome,
		□ toxic epidermal necrosis,
		□ DRESS,
		☐ Sweet syndrome
		□ Other
Gastrointestinal	☐ Diarrhea,	☐ Enteritis
	□ colitis,	☐ gastritis,
	☐ lichenoid mucositis	□ pancreatitis
	□ Nausea	☐ Other
	□ Vomit	
	□ Other	_
Hepatic	☐ Transaminitis	
	☐ hepatitis	
Endocrine	☐ Hypothyroidism	☐ Autoimmune type 1 diabetes,

				Ī		
Patient code						

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Organ System	Common	Rare
	☐ Hyperthyroidism	☐ primary adrenal insufficiency
	☐ thyroiditis,	Other
	☐ hypophysitis	
	Other	
Respiratory	☐ Pneumonitis	☐ Pleuritis,
	Other	
		Other
Renal	 Increase in serum creatinine, 	
	☐ Nephritis	
	Other	
Rheumatic	☐ Arthralgia,	☐ Dermatomyositis,
	☐ inflammatory arthritis,	□ myositis,
	□ myalgia	□ polymyalgia-like syndrome,
	Other	Sjögren syndrome,
		□ Vasculitis
		☐ Other
Cardiac		☐ Cardiomyopathy,
		☐ myocarditis,
		☐ pericarditis
Opthalmic		☐ Uveitis,
		□ conjunctivitis,
		□ scleritis,
		episcleritis,
		☐ blepharitis,

Patient code					

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Organ System	Common	Rare
		□ retinitis
		Other
Hematologic		□ plastic anemia,
		☐ hemolytic anemia,
		☐ idiopathic thrombocytopenia purpura,
		☐ lymphopenia,
		☐ hemophilia
		Other
Neurologic	☐ Sensorimotor neuropathy	☐ Aseptic meningitis,
	Other	autonomic neuropathy,
		encephalitis,
		☐ facial nerve palsy,
		☐ Guillain−Barré syndrome,
		☐ myasthenia gravis,
		 posterior reversible leukoencephalopathy
		☐ transverse myelitis
		Other
Hypersensitivity/Infusion		
Reaction		
Systemic symptoms	☐ Hypersensitivity/Infusion reaction	
	☐ Asthenia,	
	□ Fever	
	☐ Fatigue	
	□ Anorexia	

Patient code			canceance of the cancea		

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Organ System	Common	Rare
	□ Other	