


TITLE	 <p style="text-align: center;">CRF 03 – Immune-Related Adverse Event Log</p>
Document type	Form
Version number	1.0
Date	February 20th 2020

CTCAE Guidelines (version 5.0)

Grade 1 (mild) asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated;

Grade 2 (moderate) minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL);

Grade 3 (severe) severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling limiting self care ADL;

Grade 4 (life threatening) life threatening consequences; urgent intervention indicated;

Grade 5 (fatal) Death (loss of life) as a result of an adverse event.

Log Opened By _____

Log opened on / /

Month Day Year

ICI treatment ongoing

- Yes
- No

ICI treatment not ongoing specify:

Cause:

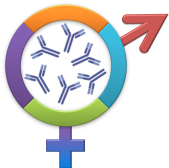


- Tumor Relapse/ Progression (**update the “Follow-up Log”**)
- Toxicity
- Other reason _____

Date of last ICI infusion:

/ /

Month Day Year

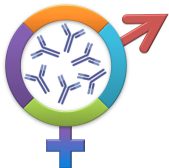


Patient code

TITLE	  GENDER-NET Plus Promoting gender equality in H2020 and the ERA G-DEFINER  <small>This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741874</small>
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CRF 03 – Immune-Related Adverse Event Log

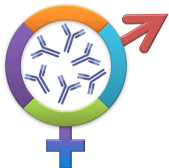

Adverse Event	Start Date	Stop Date or ongoing	CTCAE Grade v.5.0	Frequency	Immune related?	Treatment required	Causality	Treatment (multiple choice possible)	Action taken with the study medication	Sign & Date & MCN
		<input type="checkbox"/> Ongoing		<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Na	<input type="checkbox"/> None <input type="checkbox"/> Concomitant Medication	<input type="checkbox"/> Certain <input type="checkbox"/> Probable/likely <input type="checkbox"/> Possible	<input type="checkbox"/> CTLA-4 <input type="checkbox"/> PD-1 <input type="checkbox"/> PD-L1 <input type="checkbox"/> Other (spec) _____ -	<input type="checkbox"/> No Action Taken <input type="checkbox"/> Permanently Discontinued <input type="checkbox"/> Interrupted <input type="checkbox"/> Reduced <input type="checkbox"/> Omitted <input type="checkbox"/> Delayed	Investigator: MCN: Date:
		<input type="checkbox"/> Ongoing		<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Na	<input type="checkbox"/> None <input type="checkbox"/> Concomitant Medication	<input type="checkbox"/> Certain <input type="checkbox"/> Probable/likely <input type="checkbox"/> Possible	<input type="checkbox"/> CTLA-4 <input type="checkbox"/> PD-1 <input type="checkbox"/> PD-L1 <input type="checkbox"/> Other (spec) _____ -	<input type="checkbox"/> No Action Taken <input type="checkbox"/> Permanently Discontinued <input type="checkbox"/> Interrupted <input type="checkbox"/> Reduced <input type="checkbox"/> Omitted <input type="checkbox"/> Delayed	Investigator: MCN: Date:
		<input type="checkbox"/> Ongoing		<input type="checkbox"/> Continuous <input type="checkbox"/> Intermittent	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Na	<input type="checkbox"/> None <input type="checkbox"/> Concomitant Medication	<input type="checkbox"/> Certain <input type="checkbox"/> Probable/likely <input type="checkbox"/> Possible	<input type="checkbox"/> CTLA-4 <input type="checkbox"/> PD-1 <input type="checkbox"/> PD-L1 <input type="checkbox"/> Other (spec) _____ -	<input type="checkbox"/> No Action Taken <input type="checkbox"/> Permanently Discontinued <input type="checkbox"/> Interrupted <input type="checkbox"/> Reduced <input type="checkbox"/> Omitted <input type="checkbox"/> Delayed	Investigator: MCN: Date:

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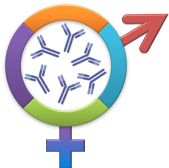


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Appendix: Event list	
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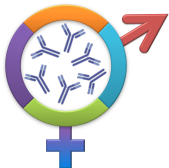

Organ System	Common	Rare
Dermatologic	<input type="checkbox"/> Rash (maculopapular, lichenoid), <input type="checkbox"/> pruritus, <input type="checkbox"/> vitiligo <input type="checkbox"/> Other _____	<input type="checkbox"/> Acneiform rash, <input type="checkbox"/> alopecia, <input type="checkbox"/>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

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Organ System	Common	Rare
	<input type="checkbox"/> Hyperthyroidism <input type="checkbox"/> thyroiditis, <input type="checkbox"/> hypophysitis Other _____	<input type="checkbox"/> primary adrenal insufficiency Other _____
Respiratory	<input type="checkbox"/> Pneumonitis Other _____	<input type="checkbox"/> Pleuritis, <input type="checkbox"/> Sarcoidosis Other _____
Renal	<input type="checkbox"/> Increase in serum creatinine, <input type="checkbox"/> Nephritis Other _____	
Rheumatic	<input type="checkbox"/> Arthralgia, <input type="checkbox"/> inflammatory arthritis, <input type="checkbox"/> myalgia Other _____	<input type="checkbox"/> Dermatomyositis, <input type="checkbox"/> myositis, <input type="checkbox"/> polymyalgia-like syndrome, <input type="checkbox"/> Sjögren syndrome, <input type="checkbox"/> Vasculitis <input type="checkbox"/> Other _____
Cardiac		<input type="checkbox"/> Cardiomyopathy, <input type="checkbox"/> myocarditis, <input type="checkbox"/> pericarditis
Ophthalmic		<input type="checkbox"/> Uveitis, <input type="checkbox"/> conjunctivitis, <input type="checkbox"/> scleritis, <input type="checkbox"/> episcleritis, <input type="checkbox"/> blepharitis,

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Organ System	Common	Rare
		<input type="checkbox"/> retinitis Other _____
Hematologic		<input type="checkbox"/> plastic anemia, <input type="checkbox"/> hemolytic anemia, <input type="checkbox"/> idiopathic thrombocytopenia purpura, <input type="checkbox"/> lymphopenia, <input type="checkbox"/> hemophilia Other _____
Neurologic	<input type="checkbox"/> Sensorimotor neuropathy Other _____	<input type="checkbox"/> Aseptic meningitis, <input type="checkbox"/> autonomic neuropathy, <input type="checkbox"/> encephalitis, <input type="checkbox"/> facial nerve palsy, <input type="checkbox"/> Guillain–Barré syndrome, <input type="checkbox"/> myasthenia gravis, <input type="checkbox"/> posterior reversible leukoencephalopathy <input type="checkbox"/> transverse myelitis Other _____
Hypersensitivity/Infusion Reaction	<input type="checkbox"/> _____	<input type="checkbox"/> _____
Systemic symptoms	<input type="checkbox"/> Hypersensitivity/Infusion reaction <input type="checkbox"/> Asthenia, <input type="checkbox"/> Fever <input type="checkbox"/> Fatigue <input type="checkbox"/> Anorexia	<input type="checkbox"/> _____

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