

**AE Flow Sheets
EA6141**

Patient Name: _____

Patient ID: _____

Cycle: _____

Date of Evaluation: _____

<u>AE's To Be Evaluated Each Cycle</u>	<u>GRADE</u>	<u>ATTRIBUTION:</u> 1-unrelated, 2-unlikely, 3-possible 4-probable, 5-definite	<u>AE Immune Mediated?</u>
Diarrhea	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Nausea	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Fatigue	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Rash maculo-papular	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Colitis	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Fever	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Pruritus	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Adrenal insufficiency	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Pneumonitis	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Uveitis	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Peripheral motor neuropathy	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Peripheral sensory neuropathy	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Hyperthyroidism	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Hypothyroidism	0 1 2 3 4 5	1 2 3 4 5	Yes / No
Other Adverse Events?	Yes No	If yes, specify below.	
ADVERSE EVENT	<u>GRADE</u>	<u>ATTRIBUTION</u>	<u>AE Immune Mediated?</u>
CTCAE Version 4.0 Unless Otherwise Stated			
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No
	0 1 2 3 4 5	1 2 3 4 5	Yes / No

OF STOOLS/DAY: 0 1 2 3

PERFORMANCE STATUS: 0 1 2 3 4

INVESTIGATOR SIGNATURE: _____ DATE: _____