

**AE Flow Sheets
EA6141 - Baseline**

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					
Diarrhea		0	1	2	3	4	5	1	2	3	4	5
Nausea		0	1	2	3	4	5	1	2	3	4	5
Fatigue		0	1	2	3	4	5	1	2	3	4	5
Rash maculo-papular		0	1	2	3	4	5	1	2	3	4	5
Colitis		0	1	2	3	4	5	1	2	3	4	5
Fever		0	1	2	3	4	5	1	2	3	4	5
Pruritus		0	1	2	3	4	5	1	2	3	4	5
Adrenal insufficiency		0	1	2	3	4	5	1	2	3	4	5
Pneumonitis		0	1	2	3	4	5	1	2	3	4	5
Uveitis		0	1	2	3	4	5	1	2	3	4	5
Peripheral motor neuropathy		0	1	2	3	4	5	1	2	3	4	5
Peripheral sensory neuropathy		0	1	2	3	4	5	1	2	3	4	5
Hyperthyroidism		0	1	2	3	4	5	1	2	3	4	5
Hypothyroidism		0	1	2	3	4	5	1	2	3	4	5
Other Adverse Events?		Yes No		If yes, specify below.								
ADVERSE EVENT	SPECIFY AE	GRADE					ATTRIBUTION					
CTCAE Version 4.0 Unless Otherwise Stated	ex. Fatigue	0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5
		0	1	2	3	4	5	1	2	3	4	5

OF STOOLS/DAY: 0 1 2 3

NICOTINE USE

Age Started: _____

Cigarettes:

Yes / No # of packs/day _____

PERFORMANCE STATUS: 0 1 2 3 4

Yes / No # of cans/day _____

Yes / No # of months used _____

INVESTIGATOR SIGNATURE: _____

DATE: _____