

**AE Flow Sheets
E4512-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					
Anemia		0	1	2	3	4	5	1	2	3	4	5
Sinus bradycardia		0	1	2	3	4	5	1	2	3	4	5
Visual impairment		0	1	2	3	4	5	1	2	3	4	5
Flashing lights		0	1	2	3	4	5	1	2	3	4	5
Abdominal pain		0	1	2	3	4	5	1	2	3	4	5
Constipation		0	1	2	3	4	5	1	2	3	4	5
Diarrhea		0	1	2	3	4	5	1	2	3	4	5
Mucositis oral		0	1	2	3	4	5	1	2	3	4	5
Nausea		0	1	2	3	4	5	1	2	3	4	5
Vomiting		0	1	2	3	4	5	1	2	3	4	5
Edema limbs		0	1	2	3	4	5	1	2	3	4	5
Fatigue		0	1	2	3	4	5	1	2	3	4	5
Alanine aminotransferase increased		0	1	2	3	4	5	1	2	3	4	5
Aspartate aminotransferase increased		0	1	2	3	4	5	1	2	3	4	5
Blood bilirubin increased		0	1	2	3	4	5	1	2	3	4	5
Electrocardiogram QT corrected interval prolonged		0	1	2	3	4	5	1	2	3	4	5
Neutrophil count decreased		0	1	2	3	4	5	1	2	3	4	5
White blood cell decreased		0	1	2	3	4	5	1	2	3	4	5
Anorexia		0	1	2	3	4	5	1	2	3	4	5
Dizziness		0	1	2	3	4	5	1	2	3	4	5
Dysgeusia		0	1	2	3	4	5	1	2	3	4	5
Headache		0	1	2	3	4	5	1	2	3	4	5
Neuropathy		0	1	2	3	4	5	1	2	3	4	5
Pneumonitis		0	1	2	3	4	5	1	2	3	4	5
Rash		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
		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

**AE Flow Sheets
E4512-Baseline**

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

OF STOOLS/DAY: 0 1 2 3

PERFORMANCE STATUS: 0 1 2 3 4

Cigarettes:

Smokeless Tobacco:

Age Started: _____

Yes / No # of packs/day _____

Yes / No # of cans/day _____

Yes / No # of months used _____

INVESTIGATOR SIGNATURE: _____

DATE: _____