Patient ID __ __-__ __ __-__ __ __

ADVERSE EVENT FORM

Line	**Date of onset** (mm/dd/yy)	**Event Type** (code) Specify event on back of form	**Serious adverse event?**	**Severity** 1=mild 2=moderate 3=severe 4=life threatening		**Relationship to study drug** 1=unrelated 2=unlikely 3=possible related 4=probably related 5=definitely related		**Effect on study drug dosing** 1=none 2=reduced 3=interrupted 4=discontinued		**Action taken** (other than study drug dose changes) 1=none 2=additional therapy 3=hospitalization 4=re-eval lab results 5=other	**Outcome date** (mm/dd/yy)	**Outcome Status** 1=resolved 2=continuing 3=controlled 4=evolved into SAE
				Initial	**Most severe**	**Rib**	**Int**	**Rib**	**Int**			
1	___/___/____		Y N								___/___/___	
2	___/___/____		Y N								___/___/___	
3	___/___/____		Y N								___/___/___	
4	___/___/____		Y N								___/___/___	
5	___/___/____		Y N								___/___/___	
6	___/___/____		Y N								___/___/___	
7	___/___/____		Y N								___/___/___	
8	___/___/____		Y N								___/___/___	
9	___/___/____		Y N								___/___/___	
10	___/___/____		Y N								___/___/___	

Event type:

1 Overdose of study medication
2 Myocardial infarction
3 Stroke
4 Seizure
5 Sepsis
6 Abscess
7 Immune mediated disease
8 Renal impairment/failure
9 Depression
10 Other neuropsychological
11 Severe respiratory
12 Hepatic encephalopathy
13 Variceal hemorrhage
14 Ascites
15 Jaundice
16 Anemia
17 Leukopenia
18 Thrombocytopenia
19 Neutropenia
20 Dehydration
21 Fatigue
22 Flu-like symptoms
23 Muscular skeletal
24 Gastro-intestinal
25 Cardiac
26 Pulmonary
27 Angina
28 Carcinoma
29 Pancreatitis
30 Dermatologic
31 Ophthalmic
32 Allergy/immunology
33 Epistaxis (nose bleed)
34 Sexual dysfunction
35 Urological
36 Orthostasis
37 Oral
38 Sleep disorder
39 Headache
40 Tinnitus
41 Gynecological
42 Neurological
43 Infection
99 Death, specify COD

Specify event type:

Line 1._____

Line 2._____

Line 3._____

Line 4._____

Line 5._____

Line 6._____

Line 7._____

Line 8._____

Line 9._____

Line 10._____