

Appendix 1

Narratives for Deaths in Study ABA 451 (InterSePT)

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Study ABA 451		Narrative Classification: SAE/Death
Subject No. 101-0016/J-S		Atherosclerotic coronary artery disease
Treatment Group: Clozaril		
Age/sex/race of subject:	56/F/Caucasian	
Diagnosis/age at onset:	Schizoaffective disorder/30	
Prior hosp. for psychosis/suicide prev.:	30/12	
Prior suicide attempts:	10	
Final study visit date:	23 Mar 1999	
S A E 1	SAE:	Atherosclerotic coronary artery disease
	Med/daily dose (mg) at time of SAE:	Clozaril/300
	Dates—SAE onset to resolution:	23 Mar 1999
	Listed past medical history:	Mild emphysema, hypertension
	Listed con. meds. at time of SAE:	None listed
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Death
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	Yes
	Outcome:	Death
Narrative: Patient 101-0016/J-S began receiving Clozaril on 8 Dec 1998. On 23 Mar 1999, she was found dead in her bed at her board and care facility. The Jefferson County Coroner attributed the cause of death to atherosclerotic coronary artery disease. The manner of death was listed as natural and a contributory cause of cardiomegaly was stated. It is unknown if resuscitation was attempted on the patient when the event transpired. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient's last dose had been taken on 23 Mar 1999.		

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 105-0007/KBS		Periorbital cellulitis (1)	
Treatment Group: Zyprexa		Arterial insufficiency lower extremities (2)	
		Suicide by acute polypharmacy intoxication (3)	
Age/sex/race of subject:		40/F/Caucasian	
Diagnosis/age at onset:		Schizophrenia/21	
Prior hosp. for psychosis/suicide prev.:		6/6	
Prior suicide attempts:		7	
Final study visit date:		21 Aug 2000	
S A E 1	SAE:	Periorbital cellulitis	
	Med/daily dose (mg) at time of SAE:	Zyprexa/20	
	Dates—SAE onset to resolution:	1 May 2000 to 8 May 2000	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	Citalopram, bupopriion	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Not specified	
	Reason considered serious:	Involved inpatient hospitalization	
	Action taken:	Hospitalization; concomitant medication taken	
	Did SAE lead to perm. disc.?	No	
Outcome:	Completely recovered		
Narrative: Patient 105-0007/KBS began receiving Zyprexa on 16 Jul 1998. On 1 May 2000, she was seen in the emergency room for bruises on her abdomen and a swollen left eye (she denied physical trauma), and was admitted. The diagnosis was noted as palpable purpura, ecchymosis, and vasculitis versus coagulopathy. She was treated with cephalexin. The investigator did not suspect a relationship between the study drug and the SAE. The patient was completely recovered as of 8 May 2000, and continued in the study.			

Subject No. 105-0007/KBS		
S A E 2	SAE:	Arterial insufficiency lower extremities
	Med/daily dose (mg) at time of SAE:	Zyprexa/20
	Dates—SAE onset to resolution:	10 Jul 2000 to 20 Jul 2000
	Listed past medical history:	Angioplasty, coronary artery disease, hypertension, heart attack
	Listed con. meds. at time of SAE:	Citalopram, bupropion, temazepam, pentoxifylline, cimetidine, beclomethasone dipropionate, ipratropium bromide, diazepam
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization, concomitant medication taken; non-drug therapy given
	Did SAE lead to perm. disc.?	No
Outcome:	Completely recovered	
Narrative: Patient 105-0007/KBS fell on 10 Jul 2000 and complained of left leg pain. She was subsequently hospitalized for arterial insufficiency. Study drug was interrupted (date unspecified). She was treated with heparin and morphine, and subsequently received left femoral popliteal bypass surgery. She was also treated with sucralfate suspension, beclomethasone, famotidine, potassium chloride, albuterol nebulizer, Ultra brand saline eye drops, cefazolin, furosemide, oxygen, esmolol, hydrocodone bitartrate with acetaminophen, docusate sodium, and cephalexin. The investigator did not suspect a relationship between the study drug and the SAE. The patient was completely recovered as of 20 Jul 2000 and continued in the study.		

Subject No. 105-0007/KBS		
S A E 3	SAE:	Suicide by acute polypharmacy intoxication
	Med/daily dose (mg) at time of SAE:	Zyprexa/20
	Dates—SAE onset to resolution:	24 Aug 2000
	Listed past medical history:	Emphysema, left lower extremity bypass graft, vascular insufficiency
	Listed con. meds. at time of SAE:	None listed
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Patient died
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Death
Narrative: Patient 105-0007/KBS completed the study on 21 Aug 2000, taking her last dose of study medication on 24 Aug 2000. She was found dead in her apartment 3 days later, on 24 Aug 2000. She was found to have overdosed on codeine, citalopram, promethazine, hydrocodone, and morphine. The investigator did not suspect a relationship between the study drug and the SAE.		

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 112-0019/BJK		Suicide attempt	
Treatment Group: Zyprexa			
Age/sex/race of subject:	47/M/Caucasian		
Diagnosis/age at onset:	Schizophrenia/25		
Prior hosp. for psychosis/suicide prev.:	3/5		
Prior suicide attempts:	4		
Final study visit date:	6 Jan 1999		
S A E 1	SAE:	Suicide attempt	
	Med/daily dose (mg) at time of SAE:	Zyprexa/15	
	Dates—SAE onset to resolution:	6 Jan 1999	
	Listed past medical history:	Hepatitis A, B, and C; seizure disorder; hypertension; syphilis; hiatal hernia	
	Listed con. meds. at time of SAE:	Amitriptyline	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Not specified	
	Reason considered serious:	Death	
	Action taken:	No action taken	
	Did SAE lead to perm. disc.?	Yes	
Outcome:	Death		
Narrative: Patient 112-0019/BJK began receiving Zyprexa on 23 Dec 1998. On 6 Jan 1999, the patient was found dead with needle marks in his arm at a Salvation Army men's shelter. An autopsy revealed that the cause of death was a heroin overdose. The patient also had taken amitriptyline, Zyprexa, and alcohol at some point prior to the event. No note was left, and any recent major stressors or contributors are unknown. The investigator did not suspect a relationship between the study drug and the SAE. The patient had apparently taken his last dose of study medication on 5 Jan 1999.			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 114-0003/J-M		Psychosis worsening (1)	
Treatment Group: Clozaril		Pulmonary embolism (2)	
Age/sex/race of subject:		31/M/Black	
Diagnosis/age at onset:		Schizophrenia/19	
Prior hosp. for psychosis/suicide prev.:		10/5	
Prior suicide attempts:		1	
Final study visit date:		25 Apr 1999	
S A E 1	SAE:	Psychosis worsening	
	Med/daily dose (mg) at time of SAE:	Clozaril/200	
	Dates—SAE onset to resolution:	30 Sep 1998 to 31 Mar 1999	
	Listed past medical history:	Anemia; obesity; deep vein thrombosis diagnosed Feb 94	
	Listed con. meds. at time of SAE:	Sertraline, Zyprexa	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Progression of underlying illness	
	Reason considered serious:	Involved inpatient hospitalization	
	Action taken:	Hospitalization	
	Did SAE lead to perm. disc.?	No	
Outcome:	Ongoing		
Narrative: Patient 114-0003/J-M began receiving Clozaril on 22 Jul 1998. He was hospitalized on 30 Sep 1998, Study Day 71, for worsening psychosis (paranoid delusions; visual, tactile, and auditory hallucinations; and nightmares). He experienced increased hopelessness and depression because of these disturbances, and reported feeling despondent with intermittent thoughts of committing suicide by walking into traffic. Due to poor compliance, the patient's tapering of his previous medication was still incomplete. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient continued in the study, and had completely recovered as of 31 Mar 1999.			

Subject No. 114-0003/J-M		
S A E 2	SAE:	Pulmonary embolism
	Med/daily dose (mg) at time of SAE:	Clozaril/400
	Dates—SAE onset to resolution:	20 Apr 1999 to 26 Apr 1999
	Listed past medical history:	Anemia, morbid obesity, deep vein thrombosis, hypertension
	Listed con. meds. at time of SAE:	Enalapril
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization; death
	Action taken:	Hospitalization; concomitant medication taken; non-drug therapy given
	Did SAE lead to perm. disc.?	Yes; last dose was taken 20 Apr 1999
	Outcome:	Death
	Narrative: Patient 114-0003/J-M was hospitalized on 20 Apr 1999 due to shortness of breath, chest pain, and dizziness and was subsequently treated with oxygen. He left the hospital against medical advice on 23 Apr 1999, and was re-admitted 2 hours later through the emergency room after falling and hitting his head while walking. A CT scan was negative. He again experienced shortness of breath, and was treated with heparin, oxygen, docusate sodium, furosemide, and enalapril. He was intubated. On 25 Apr 1999, the shortness of breath worsened, and the patient became nonresponsive. He died on 26 Apr 1999 of probable pulmonary embolism. No autopsy was performed. The investigator did not suspect a relationship between the study drug and the SAE.	

Study ABA 451 Subject No. 117-0004/RRG Treatment Group: Clozaril		Narrative Classification: SAE/Death Auditory hallucinations, suicidal ideation (1) Suicidal ideation, alcohol intoxication (2) Alcohol intoxication (3) Auditory hallucinations (4) Suicidal ideation (5-8) Increased auditory hallucinations, suicidal ideation, intentional left forearm scratches (9) Suicidal ideation (10) Suicidal ideation and gesture (11) Cardiac arrhythmia (12)	
Age/sex/race of subject:		37/M/Caucasian	
Diagnosis/age at onset:		Schizoaffective disorder/37	
Prior hosp. for psychosis/suicide prev.:		7/4	
Prior suicide attempts:		5	
Final study visit date:		12 Jun 1999	
S A E 1	SAE:	Auditory hallucinations, suicidal ideation	
	Med/daily dose (mg) at time of SAE:	Clozaril/75	
	Dates—SAE onset to resolution:	12 Oct 1998 to 29 Oct 1998	
	Listed past medical history:	Obesity; peptic ulcer disease; gastritis; esophagitis	
	Listed con. meds. at time of SAE:	Zyprexa, valproic acid	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Lack of efficacy	
	Reason considered serious:	Involved inpatient hospitalization	
	Action taken:	Hospitalization	
	Did SAE lead to perm. disc.?	No	
Outcome:	Completely recovered		
Narrative: Patient 117-0004/RRG began receiving Clozaril on 25 Sep 1998. He was hospitalized for auditory hallucinations and suicidal ideation on 12 Oct 1998. He presented with somnolence and lethargy, and reported feeling worthless and wanting to kill himself by jumping in front of a subway train. The investigator did not suspect a relationship between the study drug and the SAE, citing lack of efficacy. The patient recovered on 29 Oct 1998 and continued in the study. He received a non-study supply of Clozaril while hospitalized, and resumed taking Clozaril from his study supply on 29 Oct 1998.			

Subject No. 117-0004/RRG		
S A E 2	SAE:	Suicidal ideation, alcohol intoxication
	Med/daily dose (mg) at time of SAE:	Clozaril/450
	Dates—SAE onset to resolution:	30 Oct 1998to 20 Nov 1998
	Listed past medical history:	Obesity; peptic ulcer disease; gastritis; esophagitis alcoholism
	Listed con. meds. at time of SAE:	Glycopyrrolate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization, concomitant medication taken, trial drug adjusted, non-drug therapy given
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
	Narrative: Patient 117-0004/RRG was hospitalized via the emergency room for suicidal ideation and alcohol intoxication on 30 Oct 1998. The patient presented with flat affect, depressed mood, and some paranoia, hallucinations, and delusions. He was also having some extrapyramidal symptoms. This patient normally sought help when experiencing suicidal ideation. His medications were stabilized, and the patient attended therapy and education sessions that emphasized the importance of compliance and sobriety. The investigator did not suspect a relationship between the study drug and the SAE. He was completely recovered and discharged on 20 Nov 1998, and continued in the study.	

Subject No. 117-0004/RRG		
S A E 3	SAE:	Alcohol abuse
	Med/daily dose (mg) at time of SAE:	Clozaril/450
	Dates—SAE onset to resolution:	21 Nov 1998to 14 Dec 1998
	Listed past medical history:	Obesity; peptic ulcer disease; gastritis; esophagitis alcoholism
	Listed con. meds. at time of SAE:	Glycopyrrolate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
Narrative: Patient 117-0004/RRG requested admission to the hospital on 21 Nov 1998 for help with alcohol abuse after drinking all day, and was readmitted. The patient's father died during this hospitalization. He grieved appropriately and had renewed bonding with other family members. The investigator did not suspect a relationship between the study drug and the SAE. The patient recovered and was discharged on 14 Dec 1998, and continued in the study.		
S A E 4	SAE:	Auditory hallucinations
	Med/daily dose (mg) at time of SAE:	Clozaril/25
	Dates—SAE onset to resolution:	30 Dec 1998to 31 Dec 1998
	Listed past medical history:	Obesity; peptic ulcer disease; gastritis; esophagitis alcoholism
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
Narrative: Patient 117-0004/RRG presented to the hospital on 30 Dec 1998 complaining of auditory hallucinations (telling him to hurt himself and leave his sober house), and was admitted. He denied suicidal ideation. The patient had begun full-time work as a cashier on 28 Dec 1998. The investigator did not suspect a relationship between the study drug and the SAE. The patient recovered and was discharged on 31 Dec 1998 and continued in the study.		

Subject No. 117-0004/RRG		
	SAE:	Suicidal ideation
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	10 Jan 1999 to 18 Jan 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis
S	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
A	Relationship to therapy (PI):	Not suspected
E	Event causality:	Progression of underlying illness
	Reason considered serious:	Involved inpatient hospitalization
5	Action taken:	Hospitalization, concomitant medication taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG was hospitalized on 10 Jan 1999 for suicidal ideation (heard voices telling him to cut his wrist with a razor blade). Stressors included his father's death in Nov 1998, stress at his job as a cashier, and a lack of therapeutic services at his sober house. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient recovered on 18 Jan 1999 and continued in the study.</p>		

Subject No. 117-0004/RRG		
S A E 6	SAE:	Suicidal ideation
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	20 Jan 1999 to 4 Feb 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization; trial drug dosage adjusted
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG was hospitalized on 20 Jan 1999 for suicidal ideation (he had drunk alcohol, voices were “killing him” and telling him to hang himself, and he had lost a job as a cashier). Upon admission, his blood alcohol level was 229 mg/dl. The patient reported that he had no friends at his sober house and felt isolated. The patient’s dosage of Clozaril was increased. He was also prescribed benztropine mesylate and fluphenazine. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient recovered on 4 Feb 1999 and continued in the study.</p>		
S A E 7	SAE:	Suicidal ideation
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	4 Feb 1999 to 11 Feb 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG was re-hospitalized on 4 Feb 1999 for suicidal ideation (became intoxicated after following command auditory hallucinations to drink). The patient told some people that voices were telling him to leave the hospital and jump in front of a bus. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient recovered on 11 Feb 1999 and continued in the study.</p>		

Subject No. 117-0004/RRG		
S A E 8	SAE:	Suicidal ideation
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	14 Apr 1999 to 4 May 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization, concomitant medication taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
	Narrative: Patient 117-0004/RRG was hospitalized on 14 Apr 1999 for suicidal ideation (auditory hallucinations to hurt himself by jumping in front of traffic or to start drinking). Recent stressors included problems with a roommate and changes in his employment. He was treated with quetiapine. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient recovered on 4 May 1999 and continued in the study.	

Subject No. 117-0004/RRG		
S A E 9	SAE:	Increased auditory hallucinations, suicidal ideation, intentional left forearm scratches
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	4 May 1999 to 5 May 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, benztropine mesylate
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Prolonged inpatient hospitalization
	Action taken:	Hospitalization
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG had been hospitalized for SAE 8 (see above). The patient had recovered and was scheduled for discharge on 4 May 1999. Just prior to discharge, he superficially scratched his left forearm in response to auditory hallucinations. The event was reported as a second incident of suicidal ideation. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness. The patient recovered on 5 May 1999 and continued in the study.</p>		
S A E 10	SAE:	Suicidal ideation
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	12 May 1999 to 20 May 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Fluphenazine, trazodone, quetiapine
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization; concomitant medication taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG was hospitalized on 12 May 1999 for suicidal ideation (increased auditory hallucinations telling him to jump off a bridge; depression; job stressors; drinking on 11 May in response to voices after 6 months of sobriety). During this hospitalization, his dose of quetiapine was increased from 25 to 50 mg/day. Treatment with paroxetine and valproic acid was initiated. On 20 May 1999 he was considered recovered, and was discharged to a sober house with medication changes and the stipulation that he attend a 2-week day hospital program scheduled to begin 24 May 1999. The investigator did not suspect a relationship between the study drug and the SAE. The patient continued in the study.</p>		

Subject No. 117-0004/RRG		
S A E 11	SAE:	Suicidal ideation and gesture
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	21 May 1999 to 7 Jun 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Quetiapine, paroxetine, valproic acid
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Involved inpatient hospitalization
	Action taken:	Hospitalization, concomitant medication taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 117-0004/RRG was seen at the research clinic on 21 May 1999. He denied suicidal ideation or auditory hallucinations at the visit, and returned to the sober house that day. Later in the day, he had an argument with a housemate and stormed out. He drank alcohol, and heard voices telling him to hurt himself. He went to a drugstore and stole a razor, which was later found in his pocket. He called for help, and was admitted to the psychiatric unit at the hospital, where he continued to experience auditory hallucinations telling him to hurt or hang himself. His quetiapine dose was increased to 75 mg/day. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness. The patient was completely recovered as of 7 Jun 1999 and continued in the study.</p>		

Subject No. 117-0004/RRG		
S A E 12	SAE:	Cardiac arrhythmia
	Med/daily dose (mg) at time of SAE:	Clozaril/50
	Dates—SAE onset to resolution:	12 Jun 1999
	Listed past medical history:	Alcoholism; peptic ulcer disease; gastrointestinal bleed, obesity, esophagitis, 2 suicide attempts
	Listed con. meds. at time of SAE:	Paroxetine, quetiapine, trazodone, fluphenazine, valproic acid
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Patient died
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	Yes
	Outcome:	Death
<p>Narrative: Patient 117-0004/RRG was found dead early in the morning on 12 Jun 1999 near a river. An autopsy the next day showed that he had died of natural causes: cardiac arrhythmia in association with acute alcoholism. The patient had been seen on 11 Jun 1999, and at that time denied auditory hallucinations, suicidal ideation, or depression. He was planning on attending a day hospital for 1 month, and Alcoholics Anonymous meetings 3 times a week. His family saw him late in the day on 11 Jun 1999. His last known dose was given 11 May 1999. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness.</p>		

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 117-0005/CIA		Cardiac arrhythmia	
Treatment Group: Zyprexa			
Age/sex/race of subject:		32/M/Caucasian	
Diagnosis/age at onset:		Schizophrenia/28	
Prior hosp. for psychosis/suicide prev.:		7/7	
Prior suicide attempts:		6	
Final study visit date:		4 Jan 1999	
S A E 1	SAE:	Cardiac arrhythmia	
	Med/daily dose (mg) at time of SAE:	Zyprexa/20	
	Dates—SAE onset to resolution:	4 Jan 1999	
	Listed past medical history:	Hypertension, hypertriglyceridemia, insulin-dependent diabetes mellitus, alcoholism, tachycardia	
	Listed con. meds. at time of SAE:	Gemfibrozil, verapamil, NPH insulin	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Progression of underlying illness	
	Reason considered serious:	Death	
	Action taken:	No action taken	
	Did SAE lead to perm. disc.?	Yes	
Outcome:	Death		
Narrative: Patient 117-0005/CIA began receiving Zyprexa on 15 Oct 1998. On 4 Jan 1999, he was experiencing agonal respiration at 6:30 a.m. He was taken to the hospital by ambulance and pronounced dead at 7:22 a.m. An autopsy revealed that the subject died of natural causes, immediately attributed to cardiac arrhythmia with myocardial hypertrophy and interstitial fibrosis. Also significant were the subject's fatty liver, small right coronary artery, diabetes, and renal failure. The investigator did not suspect a relationship between the study drug and the SAE, citing instead progression of underlying illness.			

Study ABA 451		Narrative Classification: SAE/Death		
Subject No. 122-0010/TJI		Suicide		
Treatment Group: Clozaril				
Age/sex/race of subject:		20/M/Caucasian		
Diagnosis/age at onset:		Schizophrenia/18		
Prior hosp. for psychosis/suicide prev.:		5/4		
Prior suicide attempts:		2		
Final study visit date:		11 Nov 1999		
S A E 1	SAE:	Suicide		
	Med/daily dose (mg) at time of SAE:	Clozaril/none (patient had discontinued)		
	Dates—SAE onset to resolution:	25 Dec 1999		
	Listed past medical history:	None listed (report not filed)		
	Listed con. meds. at time of SAE:	None listed (report not filed)		
	Relationship to therapy (PI):	Not suspected		
	Event causality:	Not specified		
	Reason considered serious:	Involved death		
	Action taken:	None taken		
	Did SAE lead to perm. disc.?	Yes		
	Outcome:	Death		
	Narrative: Patient 122-0010/TJI began receiving Clozaril on 12 Oct 1998. He was discontinued from the study due to administrative problems on 11 Nov 1999, receiving his last dose of study medication on 10 Nov 1999. On 25 Dec 1999, he committed suicide. An SAE report was not filed, because the event occurred more than 30 days after discontinuation from study medication. Therefore full details of the event are not available. However, the investigator did not suspect a relationship between the study drug			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 125-0027/C-M		Stroke	
Treatment Group: Clozaril			
Age/sex/race of subject:	37/F/Black		
Diagnosis/age at onset:	Schizoaffective disorder/16		
Prior hosp. for psychosis/suicide prev.:	20/1		
Prior suicide attempts:	1		
Final study visit date:	21 Jan 2000		
S A E 1	SAE:	Stroke	
	Med/daily dose (mg) at time of SAE:	Clozaril/500	
	Dates—SAE onset to resolution:	16 to 21 Jan 2000	
	Listed past medical history:	Depression, severe tardive dyskinesia, arthritis of knee, anxiety	
	Listed con. meds. at time of SAE:	None listed	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Not specified	
	Reason considered serious:	Patient died; involved inpatient hospitalization; life-threatening	
	Action taken:	Hospitalization; concomitant medication taken; non-drug therapy given, dose discontinued	
	Did SAE lead to perm. disc.?	Yes	
	Outcome:	Death	
Narrative: Patient 125-0027/C-M began receiving Clozaril on 22 Dec 1998. On 16 Jan 2000, she was hospitalized after an apparent stroke (she was unable to speak, move, or eat). She was intubated, given a high dose of steroids, and placed on a ventilator. She was taken off Clozaril on 18 Jan 2000. While in the hospital, multiple therapy was used. The investigator did not suspect a relationship between the study drug and the SAE. The patient died on 21 Jan 2000 (Study Day 397).			

Study ABA 451		Narrative Classification: SAE/Death		
Subject No. 132-0001/JDM		Suicide attempt by overdose		
Treatment Group: Clozaril				
Age/sex/race of subject:		33/F/Caucasian		
Diagnosis/age at onset:		Schizoaffective disorder/24		
Prior hosp. for psychosis/suicide prev.:		100/100		
Prior suicide attempts:		8		
Final study visit date:		30 Sep 1998		
S A E 1	SAE:	Suicide attempt by overdose		
	Med/daily dose (mg) at time of SAE:	Clozaril/25		
	Dates—SAE onset to resolution:	29 to 30 Sep 1998		
	Listed past medical history:	Seizures; anorexia nervosa; hypokalemia		
	Listed con. meds. at time of SAE:	Oxycodone, fluoxetine		
	Relationship to therapy (PI):	Not suspected		
	Event causality:	Not specified		
	Reason considered serious:	Resulted in death		
	Action taken:	no action taken		
	Did SAE lead to perm. disc.?	Yes		
	Outcome:	Death		
	Narrative: Patient 132-0001/JDM began receiving Clozaril on 29 Jul 1998. On 30 Sep 1998, she died. The autopsy revealed death to be suicide by acute intoxication with oxycodone (blood level at autopsy of 6.1 mg/L). The investigator did not suspect a relationship between the study drug and the SAE. Her last dose of study medication was apparently taken on 21 Sep 1998. The date of final visit given in the database was 30 Sep 1998.			

Study ABA 451 Subject No. 301-0002/M-K Treatment Group: Zyprexa		Narrative Classification: SAE/Death Depression, relapse of psychosis; suicide attempt
Age/sex/race of subject:	40/M/Black	
Diagnosis/age at diagnosis:	Schizophrenia/29	
Prior hosp. for psychosis/suicide prev.:	2/2	
Prior suicide attempts:	1	
Final study visit date:	23Jun1998	
S A E 1	SAE:	Depression, relapse of psychosis; suicide attempt
	Med/dose at time of SAE:	Zyprexa/15 mg
	Dates-SAE sympt. onset to res.:	29 May 1998 to 26 Jul 1998 (depression and psychosis); 7 Jul 1998 to 26 Jul 1998 (suicide attempt/death)
	Listed past medical history:	None listed
	Listed con. meds. At time of SAE:	Amitriptyline
	Relationship to therapy (PI):	Suspected
	Event causality:	Not applicable
	Reason considered serious:	Life threatening
	Action taken:	Hospitalization; trial drug permanently discontinued; concomitant medication taken
	Did SAE lead to perm. disc.?	Yes, 23 Jun 1998
Outcome:	Death	
<p>Narrative: Patient 301-0002 began receiving Zyprexa on 3 Apr 1998. On 29 May 1998, the patient became preoccupied with philosophical and supernatural ideas, and gradually became more and more depressed and psychotic with delusions of guilt. The patient fasted for 3 days, but denied any suicidal ideation. His study medication dosage was increased, and there was a slight improvement in the patient's condition. Over the next week the patient made 2 visits to emergency facilities on 23 Jun 1998 and 26 Jun 1998, but refused admission on both occasions. The patient was discontinued from the study due to the events of depression and relapse of psychosis; the patient received his last dose of study medication on 23 Jun 1998. On 30 Jun 1998, he was admitted as a voluntary patient to an acute psychiatric ward and placed under nursing observation. Amitriptyline treatment 50 mg daily was maintained, but the patient remained depressed and psychotic. No suicidal intent was shown. On the morning of 7 Jul 1998, he attempted to hang himself using his shoelaces. He was found unconscious and unresponsive and was referred to intensive care unit where he was ventilated and sedated. After a period of ventilation, he was breathing spontaneously but remained neurologically unresponsive (Glasgow coma scale 3/15). The patient did not tolerate nasogastric feeding. A magnetic resonance imaging scan showed swelling of brain stem and an electro encephalogram showed evidence of severe cortical damage. The patient was kept on intravenous fluids but there was no other assertive treatment. His respiratory condition deteriorated, and there was evidence of infection. The patient died on 26 July 1998. The investigator suspected a relationship between the study drug and the SAE, citing lack of efficacy. The patient's last study visit is given as 16 Jul 1998, though he was unconscious during this evaluation.</p>		

Study ABA 451		Narrative Classification: SAE/Death
Subject No. 302-0007/J-B		Acute subendocardial myocardial infarction
Treatment Group: Not applicable		
Age/sex/race of subject:	48/F/Caucasian	
Diagnosis/age at diagnosis:	Schizoaffective disorder/21	
Prior hosp. for psychosis/suicide prev.:	3/1	
Prior suicide attempts:	1	
Final study visit date:	15 Sep 1998	
S A E 1	SAE:	Acute subendocardial myocardial infarction
	Med/dose at time of SAE:	Zyprexa
	Dates-SAE sympt. onset to res.:	23 Sep 1998 to 24 Sep 1998
	Listed past medical history:	Right leg fracture, ankle edema, constipation
	Listed con. meds. at time of SAE:	Haloperidol, imipramine, risperidone
	Relationship to therapy (PI):	Not suspected
	Event causality:	Subendocardial myocardial infarction
	Reason considered serious:	Patient died
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	Yes; 23 Sep 1998
	Outcome:	Death
<p>Narrative: Patient 302-0007 had been screened, randomized to Zyprexa on 24 Sep 1998, but died prior to receiving medication. An autopsy done on 24 Sep 1998 showed that cause of death was acute subendocardial myocardial infarction. The patient also had an old myocardial infarction and triple coronary vascular disease. No action was taken. The investigator did not suspect a relationship between the study drug and the SAE.</p>		

Study ABA 451 Subject No. 302-0010/F-P Treatment Group: Clozaril		Narrative Classification: SAE/Death Pseudo-obstruction in bowel, sudden death	
Age/sex/race of subject:		35/M/Caucasian	
Diagnosis/age at diagnosis:		Schizoaffective disorder/14	
Prior hosp. for psychosis/suicide prev.:		5/1	
Prior suicide attempts:		7	
Final study visit date:		N/A	
S A E 1	SAE:	Pseudo-obstruction in bowel, sudden death	
	Med/dose at time of SAE:	Clozaril/450 mg	
	Dates-SAE sympt. onset to res.:	3 Mar 2000 to 6 Mar 2000	
	Listed past medical history:	Bilateral fractures tibia, fibula, pelvis - suicide trauma 1997	
	Listed con. meds. at time of SAE:	Omeprazole	
	Relationship to therapy (PI):	Suspected	
	Event causality:	Not applicable	
	Reason considered serious:	Patient died	
	Action taken:	Hospitalization, concomitant medications given, non-drug therapy	
	Did SAE lead to perm. Disc.?	Yes; 6 Mar 2000	
	Outcome:	Death	
<p>Narrative: Patient 302-0010 began receiving Clozaril on 28 Sep 1998. On 3 Mar 2000, Study Day 525, he was admitted to the hospital after suffering fecal vomiting and signs of acute bowel obstruction. The patient had a history of abdominal distension, pain, and vomiting. Enema was performed. The patient had an elevated WBC ($22.8 \times 10^9/L$). An abdominal X-ray revealed a grossly distended transverse colon, there was air entry into the small bowel, and distantly into the rectosigmoid. He had signs of renal impairment due to dehydration. He was treated with IV fluids and observed overnight. On 4 Mar 2000, he vomited a feculent material and on clinical review was diagnosed with paralytic ileus, most likely due to Clozapine, which was discontinued. The patient was treated with droperidol and lorazepam in the hospital. His urea and creatinine levels were increased. An ECG showed flat T waves in lateral leads V5 and inverted T waves in leads III and VF. A surgical review on 4 Mar 2000 was done and the patient was diagnosed with pseudo-obstruction and prerenal uremia. On 6 Mar 2000, the patient was still vomiting,; however his abdomen was softer and blood electrolytes were improving. Later that morning he had a cardiac arrest and could not be resuscitated. An ECG at this time showed asystole which then progressed to electromechanical disassociation, then to ventricular fibrillation. The post-mortem results were fully consistent with the diagnosis of pseudo-obstruction. Plasma Clozapine level was found to be within the normal therapeutic range. Lorazepam and droperidol were not detected, indicating that a drug reaction between these different drugs was unlikely. A metabolic cause for a cardiac arrest has not been identified. The coroner concluded that the most likely cause of death was a cardiac arrhythmia, which has arisen as a rare side effect of Clozapine and that plasma levels would have been declining following a cessation of treatment. However, post-mortem samples indicated that the arrhythmia appeared at therapeutic levels. The patient's last dose of study medication was 6 Mar 2000. The last study visit he attended was on 2 Mar 2000.</p>			

StudyABA 451		Narrative Classification: SAE and Death	
Subject No. 302-0012/DAS		Schizomanic relapse, delusions (1)	
Treatment Group: Zyprexa		Hypomania (2)	
		Hypomania (3)	
		Delusions; schizomanic relapse (4)	
		Esophageal carcinoma (5)	
Age/sex/race of subject:		58/M/Caucasian	
Diagnosis/age at diagnosis:		Schizoaffective disorder/14	
Prior hosp. For psychosis/suicide prev.:		14/3	
Prior suicide attempts:		4	
Final study visit date:		10 Feb 2000	
S A E 1	SAE:	Schizomanic relapse; delusions	
	Med/dose at time of SAE:	Zyprexa/20 mg	
	Dates-SAE sympt. onset to res.:	5 Nov 1998 to 30 Mar 1999	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	Valproate sodium, zolpidem tartrate	
	Relationship to therapy (PI):	Suspected	
	Event causality:	Not applicable	
	Reason considered serious:	Hospitalization	
	Action taken:	Hospitalization; concomitant medication taken	
	Did SAE lead to perm. disc.?	No	
	Outcome:	Completely recovered	
Narrative: Patient 302-0012 began receiving Zyprexa on 8 Oct 1998. On 5 Nov 1998, Study Day 31, the patient experienced delusions that he was receiving telepathic messages instructing him to kill terrorists and was hospitalized. On 6 Nov 1998, he absconded from the hospital and traveled to the airport where he requested to be flown to Dublin to meet his terrorist connections. The police returned the patient to the hospital. The patient was detained under the Mental Health Act and placed under constant supervision. Clonazepam was prescribed. The investigator stated that there was no risk of self-harm or harm to others. The investigator suspected a relationship between the study drug and the SAE, but also suggested that it could have been due to progression of underlying illness and lack of efficacy. The patient was completely recovered as of 30 Mar 1999 and continued in the study.			

Subject No. 302-0012/DAS		
S A E 2	SAE:	Hypomanic episode
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	14 Jun 1999 to 15 Jun 1999
	Listed past medical history:	Vasectomy
	Listed con. meds. at time of SAE:	Valproate sodium, clonazepam, lamotrigine
	Relationship to therapy (PI):	Not suspected
	Event causality:	Lack of efficacy; progression of underlying illness
	Reason considered serious:	Hospitalization
	Action taken:	Hospitalization; concomitant medication adjusted
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 302-0012 began receiving Zyprexa on 8 Oct 1998. On 14 Jun 1999, Study Day 252, the patient experienced hypomanic relapse with symptoms of increasingly elevated mood and gregarious behavior. The patient was admitted to the hospital overnight and given increased dosage of lamotrigine and clonazepam, which were tolerated. The investigator did not suspect a relationship between the study drug and the SAE, citing lack of efficacy and progression of underlying illness. The patient was completely recovered on 15 Jun 1999 and continued in the study.</p>		

Subject No. 302-0012/DAS		
S A E 3	SAE:	Hypomania
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	22 Jun 1999 to 26 Jul 1999
	Listed past medical history:	Vasectomy
	Listed con. meds. at time of SAE:	Sodium valproate, lamotrigine, clonazepam
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Hospitalization
	Action taken:	Concomitant medication taken; hospitalization
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 302-0012 began receiving Zyprexa on 8 Oct 1998. On 22 Jun 1999, Study Day 260. The patient was admitted to the hospital with hypomania which the investigator thought was related to non-compliance with sodium valproate. Sodium valproate was restarted. The investigator did not suspect a relationship between the study drug and the SAE. The patient was completely recovered as of 26 Jul 1999 and continued in the study.</p>		
S A E 4	SAE:	Delusions; schizomanic relapse
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	14 Aug 1999 to 18 Nov 1999
	Listed past medical history:	Vasectomy
	Listed con. meds. at time of SAE:	Sodium valproate, lamotrigine, clonazepam
	Relationship to therapy (PI):	Suspected
	Event causality:	Not applicable
	Reason considered serious:	Hospitalization
	Action taken:	Hospitalization; concomitant medication taken
	Did SAE lead to perm. disc.?	No
	Outcome:	Completely recovered
<p>Narrative: Patient 302-0012 began receiving Zyprexa on 8 Oct 1998. On 14 Aug 1999, Study Day 313, the patient was hospitalized due to schizomanic relapse. For 3 days prior to the admission the patient was refusing medication and rapidly became schizomanic. This was manifested by paranoia, anger, and a belief that he was fighting Armageddon, was hearing the voice of God discussing his life, and was seeing his mother crucified. The patient was admitted. The investigator suspected a relationship between the study drug and the SAE, citing lack of efficacy and progression of underlying illness. The patient was completely recovered as of 18 Nov 1999 and continued in the study.</p>		

Subject No. 302-0012/DAS		
S A E 5	SAE:	Esophageal carcinoma
	Per FDA Request 05Nov2001:	RENAL FAILURE
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	27 Oct 1999 to 16 Feb 2000
	Listed past medical history:	Vasectomy
	Listed con. meds. at time of SAE:	Sodium valproate, zuclopenthixol, clonazepam, diamorphine
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Cancer
	Action taken:	Non drug therapy given; trial drug permanently discontinued; concomitant medication taken
	Did SAE lead to perm. disc.?	Yes; 16 Feb 2000
	Outcome:	Death 16 Feb 2000
<p>Narrative: Patient 302-0012 began receiving Zyprexa on 8 Oct 1998. In Sept 1999, the patient began experiencing dysphagia. An urgent endoscopy performed on 27 Oct 1999, Study Day 387, showed a malignant lesion at the lower end of the esophagus, extending into the stomach, histology inconclusive. A follow-up attempt at histological diagnosis on 10 Nov 1999 was also inconclusive. A whole body computed tomography scan performed on 6 Dec 1999, Study Month 12, showed metastatic carcinoma with lesions in the lung. A further endoscopy performed on 9 Dec 1999 showed a gross appearance of carcinoma located in the lower third of the esophagus. Histology showed deep cell atypia. A tube was inserted on 14 Dec 1999 to aid swallowing. Further investigation showed lung and liver metastases. Resection was not possible. Palliative care was planned and the patient was given dietary supplements. The patient gradually had more difficulties in swallowing, recurrent vomiting, and weight loss. The patient was treated palliatively and was admitted to a hospice on 8 Feb 2000. From 8 Feb 2000, the patient was treated with diamorphine administered via a syringe for pain relief. The patient died peacefully on 16 Feb 2000. The Death Certificate indicated that the cause of death was renal failure. The investigator did not suspect a relationship between the study drug and the SAE. The patient discontinued the study permanently due to this serious adverse event and took the last dose of study medication on 1 Feb 2000. The last study visit he attended was on 10 Feb 2000.</p>		

Study ABA 451		Narrative Classification: SAE/Death
Subject No. 303-0010/JCK		Overdose (intentional), potential suicide attempt/death,
Treatment Group: Clozaril		schizophrenia aggravated (1)
Age/sex/race of subject:	35/F/Caucasian	
Diagnosis/age at diagnosis:	Schizophrenia/23	
Prior hosp. for psychosis/suicide prev.:	3/2	
Prior suicide attempts:	6	
Final study visit date:	19 Oct 2000	
S A E 1	SAE:	Overdose (intentional), potential suicide attempt/death, schizophrenia aggravated
	Med/dose at time of SAE:	Clozaril/none (patient had completed study)
	Dates-SAE sympt. onset to res.:	22 Oct 2000 to unk Nov 2000
	Listed past medical history:	Drug hypersensitivity
	Listed con. meds. at time of SAE:	Lofepramine, clozapine
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying disease
	Reason considered serious:	Prolonged hospitalization; involved persistence of significant disability or incapacity; life-threatening; other significant medical event
	Action taken:	Prolonged hospitalization, concomitant medication discontinued
	Did SAE lead to perm. disc.?	No; patient had completed the study
Outcome:	Death	
Narrative: Patient 303-0010 began receiving Clozaril on 22 Oct 1998 and completed the study 2 years later, receiving her last dose of study medication on 18 Oct 2000 and attending her final study visit on 19 Oct 2000. She then began receiving off-study Clozaril. On 22 Oct 2000, the patient was admitted to the hospital following a drug overdose. She had taken 20 x 100 mg non-study Clozaril tablets. The patient's concomitant medication was discontinued and she was transferred to a psychiatric ward. On 24 Oct 2000, the patient set her clothing on fire and was subsequently taken to another hospital and then to a special burn unit. She died due to complications from the burns on an unspecified date in Nov 2000. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness.		

Study ABA 451		Narrative Classification: SAE/Death
Subject No. 303-0022/EFW		Completed suicide
Treatment Group: Zyprexa		
Age/sex/race of subject:	21/M/Caucasian	
Diagnosis/age at diagnosis:	Schizophrenia/N/A	
Prior hosp. for psychosis/suicide prev.:	N/A	
Prior suicide attempts:	N/A	
S A E 2	SAE:	Completed suicide
	Med/dose at time of SAE:	None
	Dates-SAE sympt. onset to res.:	15 Jun 1999 to 15 Jun 1999
	Listed past medical history:	Asthma, drug abuse
	Listed con. meds. at time of SAE:	Amisulpride
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying disease
	Reason considered serious:	Patient died
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	No; patient had already discontinued
	Outcome:	Death
Narrative: Patient 303-0010 began receiving Zyprexa on 15 Jan 1999. The patient discontinued from the study on 3 Feb 1999, Study Day 19. On 15 Jun 1999, 4 months post-study, the patient was found hanged. The patient left a suicide note. The investigator did not suspect a relationship between the event and the study medication, indicating that the event was due to progression of the underlying illness. On 5 Oct 1999, the post mortem revealed that the cause of death was asphyxia due to hanging.		

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 401-0001/B-S		Suicide	
Treatment Group: Clozaril			
Age/sex/race of subject:		36/M/Caucasian	
Diagnosis/age at diagnosis:		Schizophrenia/22	
Prior hosp. for psychosis/suicide prev.:		9/1	
Prior suicide attempts:		10	
Final study visit date:		NA	
S A E 1	SAE:	Suicide	
	Med/dose at time of SAE:	Clozaril/200 mg	
	Dates-SAE sympt. onset to res.:	24 Aug 1998 to 24 Aug 1998	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	Zolpidem	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Progression of underlying illness; lack of efficacy	
	Reason considered serious:	Patient died	
	Action taken:	No action taken	
	Did SAE lead to perm. disc.?	Yes; 24 Aug 1998	
Outcome:	Death		
Narrative: Patient 401-0001 began receiving Clozaril on 30 Jul 1998. The patient was bisexual, and had split from his male partner the day before the event. He had a previous history of several violent suicide attempts. His mother committed suicide by hanging at age 32. The investigator described the patient as having a tempestuous lifestyle. Following the split from his partner, the patient wrote a letter that expressed his intention to die. The patient was subsequently hospitalized on 24 Aug 1998. On 24 Aug 1998, the patient committed suicide by hanging himself in his room. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness and lack of efficacy. The patient discontinued the study permanently due to this serious adverse event. The last study visit he attended was on 14 Aug 1998.			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 401-0022/C-W		Non-Hodgkin's lymphoma	
Treatment Group: Clozaril			
Age/sex/race of subject:		46/F/Caucasian	
Diagnosis/age at diagnosis:		Schizophrenia/19	
Prior hosp. for psychosis/suicide prev.:		19/3	
Prior suicide attempts:		4	
Final study visit date:		30 Dec 1998	
S A E 1	SAE:	Non-Hodgkin's lymphoma	
	Med/dose at time of SAE:	Clozaril/325 mg	
	Dates-SAE sympt. onset to res.:	Unk Nov 1998 to 18 Jan 1999	
	Listed past medical history:	Non Hodgkin's lymphoma	
	Listed con. meds. at time of SAE:	Levomepromazine, trimipramine, alprazolam	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Not specified	
	Reason considered serious:	Patient died, hospitalization, cancer	
	Action taken:	Concomitant medication taken, trial drug permanently discontinued, biopsy, hospitalization	
	Did SAE lead to perm. disc.?	Yes; 30 Dec 1998	
Outcome:	Death		
Narrative: Patient 401-0022 began receiving Clozaril on 16 Dec 1998. Her medical history included non-Hodgkin's lymphoma, diagnosed in July 1995 and treated with radiotherapy and chemotherapy. A relapse on the scalp and in the mediastinal lymph nodes occurred in July 1996. She was again treated with radiotherapy and chemotherapy. After this treatment, the patient was considered to be in remission, and she was enrolled in the study. Prior to beginning study medication, a biopsy was performed, on 8 Dec 1998, and a relapse of the lymphoma was diagnosed. The patient did begin taking study medication, but several days later on 22 Dec 1998, was admitted to the hospital and was subsequently withdrawn from the study on 30 Dec 1998. The patient died in a psychiatric hospital on 18 Jan 1999. No autopsy was performed. The investigator did not suspect a relationship between the study drug and the SAE. The patient discontinued the study permanently due to this serious adverse event and took the last dose of study medication on 30 Dec 1998. The last study visit she attended was on 30 Dec 1998.			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 702-0010/M-O		Suicide	
Treatment Group: Clozaril			
Age/sex/race of subject:		38/M/Caucasian	
Diagnosis/age at diagnosis:		Schizophrenia/34	
Prior hosp. for psychosis/suicide prev.:		5/3	
Prior suicide attempts:		1	
Final study visit date:		11 Jan 1999	
S A E 1	SAE:	Suicide	
	Med/dose at time of SAE:	Clozaril/250 mg	
	Dates-SAE sympt. onset to res.:	13 Jan 1999 to 13 Jan 1999	
	Listed past medical history:	Duodenal ulcer, gastritis, insomnia	
	Listed con. meds. at time of SAE:	None listed	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Progression of underlying illness	
	Reason considered serious:	Patient died	
	Action taken:	None	
	Did SAE lead to perm. disc.?	Yes	
Outcome:	Death		
Narrative: Patient 702-0010 began receiving Clozaril on 26 Oct 1998. He had had a history of suicidal ideation since 1994. At his week 5 visit (30 Nov 1998), his dose of study medication was decreased to 100 mg because of sedation and dizziness. At his week 11 visit (11 Jan 1999), he was still experiencing suicidal ideation, and the dose of the trial medication was increased to 250 mg, and fluoxetine therapy was added. On 13 Jan 1999, the patient committed suicide by hanging and died. He did not appear to have taken any fluoxetine. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness. The patient discontinued the study permanently due to this serious adverse event. His last dose of study medication was taken on 12 Jan 1999. The last study visit he attended was on 11 Jan 1999.			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 802-0012/AR		Overdose (1)	
Treatment Group: Clozaril		Accidental trauma (2)	
Age/sex/race of subject:		37/M/Black	
Diagnosis/age at diagnosis:		Schizophrenia/NA	
Prior hosp. for psychosis/suicide prev.:		N/A	
Prior suicide attempts:		N/A	
Final study visit date:		8 Jun 1999	
S A E 1	SAE:	Overdose	
	Med/dose at time of SAE:	Clozaril/200 mg	
	Dates-SAE sympt. onset to res.:	10 Apr 1999 to 14 Apr 1999	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	None listed	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Progression of underlying illness	
	Reason considered serious:	Hospitalization	
	Action taken:	None	
	Did SAE lead to perm. disc.?	No	
Outcome:	Completely recovered		
Narrative: Patient 802-0012 began receiving Clozaril on 27 Oct 1998. On 9 Apr 1999 the patient felt anxious and tense. He took some of his trial medication to see if it would help him sleep and relieve his tension. On 10 Apr 1999 the patient was confused, drowsy and restless. He was admitted to the hospital. No treatment was given. Although the patient's condition improved, he was still anxious and tense, but expressed no suicidal ideation, stating that he was not trying to commit suicide, but trying to relieve his tension. The patient completely recovered on 14 Apr 1999. The investigator did not suspect a relationship between the event and the study medication, indicating that it was due to progression of underlying illness.			
S A E 2	SAE:	Accidental trauma	
	Med/dose at time of SAE:	Clozaril/200 mg	
	Dates-SAE sympt. onset to res.:	26 Oct 1999 to 26 Oct 1999	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	None listed	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Accident	
	Reason considered serious:	Patient died	
	Action taken:	None	
	Did SAE lead to perm. disc.?	No	
Outcome:	Death		
Narrative: Patient 802-0012 began receiving Clozaril on 27 Oct 1998. The patient had discontinued the study medication on 8 Jun 1999 due to substance abuse and poor compliance. On 26 Oct 1999, 4 months after the patient discontinued from the study, he was involved in a traffic accident as a pedestrian. He died from multiple injuries. The patient was not thought to be suicidal. On 14 Oct 1999, at a hospital appointment, he had not expressed any active plans to commit suicide. The investigator did not suspect a relationship between the event and the study medication, stating that it seemed to be an accident.			

Study ABA 451		Narrative Classification: SAE/Death	
Subject No. 902-0002/J-J		Suicide	
Treatment Group: Clozaril			
Age/sex/race of subject:		42/M/Caucasian	
Diagnosis/age at diagnosis:		Schizoaffective disorder/39	
Prior hosp. for psychosis/suicide prev.:		3/3	
Prior suicide attempts:		3	
Final study visit date:		14 Dec 1999	
S A E 1	SAE:	Suicide	
	Med/dose at time of SAE:	Clozaril/150 mg	
	Dates-SAE sympt. onset to res.:	12 Dec 1999 to 12 Dec 1999	
	Listed past medical history:	None listed	
	Listed con. meds. at time of SAE:	None listed	
	Relationship to therapy (PI):	Not suspected	
	Event causality:	Not specified	
	Reason considered serious:	Patient died	
	Action taken:	No action taken	
	Did SAE lead to perm. disc.?	Yes; 12 Dec 1999	
	Outcome:	Death	
Narrative: Patient 902-0002 began receiving Clozaril on 20 Oct 1998. On 12 Dec 1999, Study Day 58, after lunch the patient told his common-law wife that he was going for a walk. At 14:00, the patient jumped in front of a train. At 14:20 at the place of the accident, air rescue and a medical doctor were present. The patient was pronounced dead at the scene and an autopsy was not ordered. The patient did not leave a suicide note. He had not shown signs of psychosis or depression in the previous month. The investigator did not suspect a relationship between the study drug and the SAE. The patient had taken his last dose of study medication on 11 Dec 1999.			

Study ABA 451		Narrative Classification:SAE/Death
Subject No. 953-0007/BEO		Suicide attempt (1)
Treatment Group: Zyprexa		Cardiorespiratory arrest (2)
Age/sex/race of subject:	60/F/Caucasian	
Diagnosis/age at diagnosis:	Schizophrenia/30	
Prior hosp. for psychosis/suicide prev.:	0/1	
Prior suicide attempts:	3	
Final study visit date:	17 Nov 2000	
S A E 1	SAE:	Suicide attempt
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	17 Apr 1999 to 17 Apr 1999
	Listed past medical history:	None listed
	Listed con. meds. at time of SAE:	Clonazepam
	Relationship to therapy (PI):	Not suspected
	Event causality:	Progression of underlying illness
	Reason considered serious:	Life-threatening
	Action taken:	No action taken
	Did SAE lead to perm. disc.?	No
Outcome:	Completely recovered	
Narrative: Patient 953-0007 began receiving Zyprexa on 15 Jan 1999. On 17 Apr 1999, the patient was at home with her mother (weekend leave). When her mother was sleeping, the patient closed the doors and windows of the kitchen and then opened the gas taps. After a few minutes her mother discovered the patient and opened the windows, and the patient recovered immediately. The patient stated that "I had no plan, I simply wanted to end my life." The site increased surveillance of the patient and her intake of medication was monitored. No more weekend leaves were allowed and she lost ward privileges. The investigator did not suspect a relationship between the study drug and the SAE, citing progression of underlying illness. The patient was completely recovered as of 17 Apr 1999 and continued in the study.		

Subject No. 953-0007/BEO	
	SAE: Cardiorespiratory arrest
	Med/dose at time of SAE: Zyprexa/10 mg
	Dates-SAE sympt. Onset to res.: 11 Dec 2000 to 11 Dec 2000
	Listed past medical history: Chronic bronchitis, nicotine addiction
S	Listed con. meds. at time of SAE: None listed
A	Relationship to therapy (PI): Not suspected
E	Event causality: Respiratory arrest
	Reason considered serious: Patient died; other significant medical event
2	Action taken: Resuscitation procedures
	Did SAE lead to perm. disc.?: Yes; 11 Dec 2000
	Outcome: Death
<p>Narrative: Patient 953-0007 began receiving Zyprexa on 15 Jan 1999. The patient, who had chronic bronchitis treated with a nebulizer, developed diarrhea on 9 Dec 2000 and became dehydrated. She was noted to be hypotensive (blood pressure 80/60 mmHg) and had a fast pulse (120 beats per minute). She was given loperamide for the diarrhea and parenteral fluids for rehydration. On 11 Dec 2000, the patient suddenly collapsed and became unconscious while walking by the nurses' office. She was cyanotic and her systolic blood pressure was 50 mmHg. She was cold and sweating. The emergency unit doctors put up a saline drip and performed a blood glucose test, which gave a reading of 40 to 80 mg%. The patient developed respiratory arrest from which she could not be resuscitated. After 20 minutes she was pronounced dead at 18.00 on 11 Dec 2000. A thoracic X-ray plate was sent to the emergency department after the patient's death. The radiologist had reported "blurring of the lower right field (acute pulmonary disease/embolism?) – vertices (apices) and costophrenic sinuses (angles) free." The investigator therefore states that the cause of death may have been an acute pulmonary disease. No autopsy was performed. The investigator and the sponsor medical expert did not suspect a relationship between the study drug and the SAE, citing progression of a concomitant condition. The patient discontinued the study permanently due to this serious adverse event. The last study visit she attended was on 17 Nov 2000.</p>	

Study ABA 451		Narrative Classification: SAE/Death
Subject No. 953-0011/AMS		Cardio-respiratory arrest
Treatment Group: Zyprexa		
Age/sex/race of subject:	54/F/Caucasian	
Diagnosis/age at diagnosis:	Schizophrenia/17	
Prior hosp. for psychosis/suicide prev.:	0/0	
Prior suicide attempts:	3	
Final study visit date:	30 Mar 1999	
S A E 1	SAE:	Cardiorespiratory arrest/death
	Med/dose at time of SAE:	Zyprexa/20 mg
	Dates-SAE sympt. onset to res.:	31 Mar 1999 to 31 Mar 1999
	Listed past medical history:	Urinary tract infection
	Listed con. meds. at time of SAE:	Trimethoprim, sulfamethoxazole
	Relationship to therapy (PI):	Not suspected
	Event causality:	Not specified
	Reason considered serious:	Patient died
	Action taken:	Hospitalization
	Did SAE lead to perm. disc.?	Yes; 31 Mar 1999
	Outcome:	Death
<p>Narrative: Patient 953-0011 began receiving Zyprexa on 25 Jan 1999. On 31 Mar 1999, at which time the patient was inpatient in a psychiatric hospital, she suddenly presented with dyspnea, stupor, loss of urinary sphincter control, no pupillary reflex, no response to pain stimuli, vomiting, and positive bilateral Babinski reflexes. The patient's blood pressure was 80/40 mmHg, and her pulse was regular (60 bpm). No concomitant medication was given to the patient because the physicians on duty decided to transfer her to another hospital. The patient died the same day, due to cardio-respiratory arrest. The investigator suspected that the patient had had a stroke. The patient never had a fever and only had a moderate rise in her blood pressure (maximum 150/90 mmHg). There was no obvious relationship between her urinary tract infection (listed in medical history) and cause of death. The investigator did not suspect a relationship between the study drug and the SAE. The patient discontinued the study permanently due to this serious adverse event. The last study visit she attended was on 30 Mar 1999.</p>		

