Table VI. A. Inclusion/Exclusion Criteria for Completed Controlled Studies

Inclusion Criteria

1. Patients must be outpatients at least 18 years of age who are male, or if female, are practicing a medically acceptable method of contraception (e.g., oral contraceptive, barrier method, IUD, levonorgestrel implants), are surgically sterilized, or are at least 2 years post-menopausal.

2. Patients must fulfill DSM-III-R criteria for Post-traumatic Stress Disorder as determined by Part 1 of the Clinician Administered PTSD Scale (CAPS), with duration of symptoms > 6 months. The CAPS is to be administered by the investigator or a co-investigator who has been trained to administer the CAPS.

3. Patients must have a complete medical and psychiatric history and a physical examination at the time of entry into the study. The initial physical examination and laboratory values must be normal, or abnormalities must be clinically insignificant. These data will be recorded during the single-blind washout.

4. If the patient is a female of childbearing potential, she must have a negative serum beta-HCG pregnancy test at the time of study entry.

5. At baseline (end of washout), patients must continue to meet diagnostic criteria for current PTSD as determined by a score of 50 or above on Part 2 of the CAPS.

6. A urine drug screen on day 1 of washout must be negative. *(Studies 640 and 641 only)*

7. All other psychotropic medication (except chloral hydrate for sleep) must have been discontinued prior to entry into the study (see also Exclusion Criteria).

8. Patient must be literate in English and must be able to communicate intelligently with the investigative team.

9. Patients must be judged reliable for medication compliance and clearly motivated to obtain benefit from treatment. They must agree to keep appointments for study visits and all tests and examinations required by the protocol.

Exclusion Criteria

1. Pregnant women and women who are breast feeding. If a patient becomes pregnant during the study, she will be discontinued from the study immediately and followed appropriately.

2. Patients with Organic Mental Disorder (including post-concussion syndrome).

3. Patients who have a primary diagnosis meeting DSM-III-R criteria for:

   a. Major Depression, single episode or recurrent;

   b. Dysthymic Disorder;

   c. Personality Disorders from Clusters other than Cluster C (Avoidant, Dependent, Passive Aggressive *(640/641 only)*, and Obsessive-Compulsive Personality Disorders);

   d. Obsessive Compulsive Disorder, Generalized Anxiety Disorder, Panic Disorder, Simple Phobia, Social Phobia, Agoraphobia, or Anxiety Disorder NOS;

   e. Conversion Disorder *(671/682 only)*.

4. Patients who meet DSM-III-R criteria for Factitious Disorder or Malingering. *(671 and 682 only)*

5. Patients who meet DSM-III-R criteria for Bipolar Disorder (Depressed, Manic, Mixed or NOS), either currently or by history.

6. Patients with any current psychotic features or with a history of Schizophrenia, Delusional Disorder, Schizophreniform Disorder, or Psychotic Disorder NOS.

7. Patients with a Psychoactive Substance Abuse Disorder within the past 6 months.

8. Patients with medical contraindications to therapy with antidepressants as determined by past medical history, physical examination, or known allergy or hypersensitivity to antidepressants. *(671 and 682 only)*

9. Patients with a history or evidence of malignancy (other than excised basal cell carcinoma). Patients with significant hematological, endocrine, cardiovascular, renal, hepatic, neurological (including >1 childhood febrile seizure and all forms of epilepsy) or gastrointestinal disease. If there is a history of such disease, but the condition has been stable for more than 6 months *(671 and 682)* or 1 year *(640 and 641)* and is judged by the investigator not likely to interfere with the patient's participation in the study, the patient may be included if approved by the Pfizer Project Clinician.

10. Patients with any liver function test greater than twice the upper limit of the normal range at the screening visit (day 1 of washout); however *(for 671, 682 only)*, if any liver function test falls between 1.5 times and twice the upper limit of the normal range, the patient may be entered if approved by the Pfizer Project Clinician.

11. Patients on concomitant therapy with another investigational drug, or patients who have been in an investigational drug study within one month prior to entering this study, or who have ever been in a previous investigational study of sertraline.

12. Patients requiring concomitant psychotropic therapy of any type (with the exception of chloral hydrate) or drugs with a psychotropic component (Donnatal, metoclopramide HCl, sedating antihistamines, etc.). If there is any doubt regarding the choice of an acceptable concomitant medication (as noted in the concomitant medication table), the sponsor should be contacted.

13. Patients who have taken a monoamine oxidase inhibitor (MAOI) within two weeks prior to the first administration of double-blind study medication. (Patients will be instructed not to take MAOIs for 2 weeks after completing the study.)

14. Patients who have had therapy with any daily neuroleptic, antidepressant [(including lithium), anticonvulsant *(671/682 only)*], hypnotic or anxiolytic medication in the 2 weeks prior to the first administration of double-blind study medication; or any depot neuroleptic within 6 months of the first administration of double-blind study medication; or patients who have had regular therapy with fluoxetine (Prozac) in the 5 weeks prior to the first administration of double-blind study medication.

15. Patients with a history of non-response to adequate treatment (adequate dosage and duration) with sertraline or with at least two different classes of antidepressants (e.g., heterocyclics, MAOIs, atypicals/SSRIs).

16. Patients who will be receiving behavior therapy during the study. Psychotherapy is permitted but cannot be initiated or terminated during the study. If psychotherapy is ongoing, it must have been initiated at least 3 months prior to the screening visit. (Patients may attend support groups during the study.)

17. Patients who would pose a serious suicide risk during the course of the study.

18. Patients with current impulse control problems (i.e., who have committed an act of violence within the past 12 months) or who are judged to be potentially violent.

19. Patients who test positive for psychotropic drugs or drugs of abuse on the urine drug screen at the Screening visit.

20. Patients currently involved in criminal proceedings or in litigation for disability benefits or for damages related to their disorder.

21. Patients who, in the investigator's opinion, might not be suitable for the study.

APPEARS THIS WAY
ON ORIGINAL

TABLE VI. B. SCHEDULE OF ASSESSMENTS FOR COMPLETED CONTROLLED STUDIES

Assessment	Day 1 of Washout	Day 8[c] of Washout	Baseline	Double-Blind Treatment: End of Week*							
				1	2	3	4	6	8	10	12**
SCID-P	x										
Clinician Administered PTSD Scale (CAPS) - Part I	x										
CAPS - Part 2			x	a	x	a	x	x	x	x	x
Impact of Event Scale	a		x	x	x	x	x	x	x	x	x
Clinical Global Impressions (CGI)		b	x	x	x	x	x	x	x	x	x
Davidson Self-Rating PTSD Scale	a		x	x	x	x	x	x	x	x	x
Hamilton Depression Scale			x								x
Hamilton Anxiety Scale			a								a
Civilian Mississippi Scale			a								a
Pittsburgh Sleep Quality Index			a								a
Disorders of Extreme Stress			a								a
Quality of Life Scale			b								b
Health & Work Questionnaire		b									b
Physical Exam	x										x
BP/Pulse/Body Weight	x	b	x	x	x	x	x	x	x	x	x
Clinical Laboratory Work	x							x			x
Pregnancy Test	x							x			x
Thyroid Function Tests	x										a
Urine Drug Screen	x							a			
Electrocardiogram	x										x

* "End of Week" refers to "after 7 days of treatment."

** or if a patient is discontinued prior to End of Week 12

a Protocols 640 and 641 only

b Protocols 671 and 682 only

c Protocols 640/641 had 1 week washout; 671/682 had 2 weeks washout

Table V.C.2. **Demographic Characteristics by Study for All Randomized Subjects**

	Protocol 640			Protocol 641			Protocol 671			Protocol 682		
	Sert n=100	Pbo n=108	P value	Sert n=86	Pbo n=83	P value	Sert n=94	Pbo n=93	P value	Sert n=96	Pbo n=97	P value
Sex												
Female	84	78		18	16		71	66		73	71	
Male	16	30	0.041	68	67	0.789	23	27	0.481	23	26	0.650
Race												
Asian	0	2		0	1		2	3		3	1	
Black	13	12		18	16		14	8		7	7	
White	83	91		58	62		76	82		84	88	
Other	4	3	0.523	10	4	0.287	2	0	0.255	2	1	0.701
Age (yrs)												
Mean ± SD	37.6±11.1	36.6±10.1	0.564	44.8±10.9	45.9±9.7	0.386	40.2±9.6	39.5±10.6	0.536	36.8±10.8	38.2±11.7	0.487
18 - 44	75	80		31	25		60	61		73	67	
45 - 64	23	28		51	54		34	31		23	28	
>= 65	2	0		4	4		0	1		0	2	
Weight (lb)												
Mean ± SD	167.2±49.1	169.1±39.3	0.751	190.0±45.8	191.6±47.5	0.789	181.2±52.4	168.5±45.6	0.088	162.8±38.5	172.8±48.0	0.128
Duration of Illness (yrs)												
Mean ± SD	11.7±11.1	12.8±12.4	0.505	17.4±12.3	19.2±12.1	0.245	13.1±11.8	11.2±12.7	0.295	11.0±11.1	10.2±10.8	0.504
Time from Traumatic Event (yrs)												
Mean ± SD	18.3±12.8	18.5±15.5	0.969	22.2±12.3	24.2±11.3	0.181	19.9±13.5	17.4±15.5	0.283	15.0±13.3	14.9±13.4	0.878
Comorbid Axis I Diagnoses												
Anxiety	23	16		17	10		17	11		25	29	
Depression	50	51	0.778	43	35	0.307	37	31	0.392	45	42	0.618
OCD	0	1		1	1		2	1		0	1	
Other	7	9		5	5		3	2		1	1	
None	40	46		40	45		50	55		43	41	

Differences between groups are based on the Pearson chi squared statistic for race and sex, and F test from two way ANOVA for mean age, weight, duration of illness, time from traumatic event, and Comorbid Axis I Diagnoses respectively.

a enrolled subjects at more than one location
b did not enroll any subjects in the trial

BEST POSSIBLE COPY

Table VII.A **Subject Completion Rates by Week for Completed Controlled Studies, and Combined**

Study Treatment Group	No. Rand	ITT Sample	Number (%) Patients Completing							
			Wk 1	Wk 2	Wk 3	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12
640 Sert	100	98	98 (100)	93 (94.9)	91 (92.9)	88 (89.8)	82 (83.7)	77 (78.6)	75 (76.5)	73 (74.5)
640 Pbo	105	104	104 (100)	102 (98.1)	99 (95.2)	95 (91.3)	88 (84.6)	81 (77.9)	77 (74.0)	74 (71.2)
641 Sert	86	84	84 (100)	81 (96.4)	75 (89.3)	71 (84.5)	68 (81.0)	65 (77.4)	63 (75.0)	62 (73.8)
641 Pbo	83	82	82 (100)	81 (98.8)	80 (97.6)	78 (95.1)	75 (91.5)	73 (89.0)	70 (85.4)	69 (84.1)
671 Sert	94	93	93 (100)	90 (96.8)	87 (93.5)	83 (89.2)	77 (82.8)	72 (77.4)	69 (74.2)	64 (68.8)
671 Pbo	93	90	90 (100)	87 (96.7)	83 (92.2)	81 (90.0)	74 (82.2)	70 (77.8)	69 (76.7)	67 (74.4)
682 Sert	96	94	94 (100)	89 (94.7)	83 (88.3)	81 (86.2)	79 (84.0)	75 (79.8)	72 (76.6)	72 (76.6)
682 Pbo	97	94	94 (100)	90 (95.7)	86 (91.5)	85 (90.4)	81 (86.2)	79 (84.0)	75 (79.8)	71 (75.5)
Total Sert	376	369	369 (100)	353 (95.7)	336 (91.1)	323 (87.5)	306 (82.9)	289 (78.3)	279 (75.6)	271 (73.4)
Total Pbo	381	370	370 (100)	360 (97.3)	348 (94.1)	339 (91.6)	318 (85.9)	303 (81.9)	291 (78.6)	281 (75.9)

BEST POSSIBLE COPY

APPEARS THIS WAY
ON ORIGINAL

a enrolled subjects at more than one location
b did not enroll any subjects in the trial

Efficacy Tables

Table VII.C.1.a Protocol 640: CAPS-2 Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	98	73.9	+/-	16.2	104	73.5	+/-	16.1	0.853
WEEK 1	95	-11.8	+/-	1.54	104	-7.6	+/-	1.48	0.052
WEEK 2	92	-15.9	+/-	1.65	100	-13.1	+/-	1.55	0.222
WEEK 3	90	-21.6	+/-	2.34	95	-21.2	+/-	2.24	0.882
WEEK 4	87	-23.7	+/-	2.29	95	-24.6	+/-	2.24	0.773
WEEK 6	82	-31.4	+/-	2.57	87	-28.0	+/-	2.69	0.357
WEEK 8	76	-31.5	+/-	2.79	81	-29.5	+/-	2.98	0.613
WEEK 10	74	-34.3	+/-	2.83	77	-30.2	+/-	2.99	0.323
WEEK 12	73	-38.2	+/-	2.86	74	-30.5	+/-	3.03	0.066
ENDPOINT	98	-33.0	+/-	2.41	104	-26.2	+/-	2.33	0.043

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.1.b: Protocol 640: CAPS-2 Change from Baseline by Visit - LOCF

Adjusted Mean Change From Baseline (1)
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE (2)	98	73.9	+/-	16.2	104	73.5	+/-	16.1	0.853
WEEK 1	98	-11.6	+/-	1.53	104	-7.6	+/-	1.48	0.062
WEEK 2	98	-15.7	+/-	1.58	104	-13.1	+/-	1.53	0.248
WEEK 3	98	-22.1	+/-	2.14	104	-20.6	+/-	2.07	0.621
WEEK 4	98	-23.2	+/-	2.09	104	-23.1	+/-	2.02	0.975
WEEK 6	98	-30.0	+/-	2.28	104	-25.3	+/-	2.20	0.137
WEEK 8	98	-30.1	+/-	2.38	104	-25.9	+/-	2.30	0.204
WEEK 10	98	-30.3	+/-	2.39	104	-26.7	+/-	2.31	0.272
WEEK 12	98	-33.0	+/-	2.41	104	-26.2	+/-	2.33	0.043

(1) Means are adjusted for treatment, site, treatment-by-site, and baseline values.
(2) Mean and standard deviation at baseline.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.1.c Protocol 640: IES Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	98	38.5	+/-	15.6	104	40.1	+/-	14.5	0.471
WEEK 1	94	-4.8	+/-	1.24	102	-4.1	+/-	1.20	0.685
WEEK 2	92	-6.9	+/-	1.34	100	-6.5	+/-	1.27	0.845
WEEK 3	90	-11.0	+/-	1.57	95	-11.4	+/-	1.50	0.854
WEEK 4	88	-13.8	+/-	1.54	95	-12.2	+/-	1.51	0.439
WEEK 6	82	-16.2	+/-	1.58	87	-14.9	+/-	1.64	0.568
WEEK 8	76	-17.2	+/-	1.81	80	-14.8	+/-	1.94	0.378
WEEK 10	73	-18.6	+/-	1.90	77	-17.9	+/-	1.97	0.796
WEEK 12	72	-21.1	+/-	1.77	74	-17.6	+/-	1.86	0.174
ENDPOINT	98	-19.2	+/-	1.53	104	-14.1	+/-	1.48	0.018

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

ON ORIGINAL

Table VII.C.1.d Protocol 640: IES Change from Baseline by Visit - LOCF

Adjusted Mean Change From Baseline (1)
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE (2)	98	38.5	+/-	15.6	104	40.1	+/-	14.5	0.471
WEEK 1	98	-4.6	+/-	1.20	104	-4.1	+/-	1.16	0.749
WEEK 2	98	-7.0	+/-	1.28	104	-6.5	+/-	1.24	0.762
WEEK 3	98	-11.3	+/-	1.45	104	-10.6	+/-	1.40	0.736
WEEK 4	98	-13.6	+/-	1.43	104	-11.9	+/-	1.38	0.402
WEEK 6	98	-16.1	+/-	1.46	104	-13.5	+/-	1.41	0.195
WEEK 8	98	-17.0	+/-	1.58	104	-13.2	+/-	1.53	0.090
WEEK 10	98	-18.2	+/-	1.58	104	-15.3	+/-	1.53	0.194
WEEK 12	98	-19.2	+/-	1.53	104	-14.1	+/-	1.48	0.018

(1) Means are adjusted for treatment, site, treatment-by-site, and baseline values.
(2) Mean and standard deviation at baseline.

APPEARS THIS WAY
ON ORIGINAL

ON ORIGINAL

Table VII.C.1.e Protocol 640: CGI-S Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	98	4.6	+/-	0.96	104	4.6	+/-	0.93	0.429
WEEK 1	94	-0.2	+/-	0.06	104	-0.2	+/-	0.06	0.782
WEEK 2	92	-0.3	+/-	0.07	100	-0.3	+/-	0.06	0.479
WEEK 3	90	-0.7	+/-	0.09	95	-0.6	+/-	0.09	0.489
WEEK 4	88	-0.9	+/-	0.10	95	-0.8	+/-	0.10	0.571
WEEK 6	81	-1.1	+/-	0.12	88	-0.8	+/-	0.12	0.101
WEEK 8	76	-1.2	+/-	0.12	81	-1.0	+/-	0.13	0.246
WEEK 10	74	-1.4	+/-	0.13	77	-1.2	+/-	0.13	0.201
WEEK 12	73	-1.6	+/-	0.14	74	-1.2	+/-	0.15	0.123
ENDPOINT	98	-1.3	+/-	0.12	104	-1.0	+/-	0.12	0.037

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Adjusted Mean Change From Baseline (1)
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE (2)	98	4.6	+/-	0.96	104	4.6	+/-	0.93	0.429
WEEK 1	98	-0.2	+/-	0.06	104	-0.2	+/-	0.06	0.843
WEEK 2	98	-0.3	+/-	0.06	104	-0.3	+/-	0.06	0.692
WEEK 3	98	-0.7	+/-	0.08	104	-0.6	+/-	0.08	0.361
WEEK 4	98	-0.8	+/-	0.09	104	-0.7	+/-	0.09	0.454
WEEK 6	98	-1.0	+/-	0.10	104	-0.8	+/-	0.10	0.078
WEEK 8	98	-1.1	+/-	0.10	104	-0.9	+/-	0.10	0.055
WEEK 10	98	-1.2	+/-	0.11	104	-0.9	+/-	0.11	0.066
WEEK 12	98	-1.3	+/-	0.12	104	-1.0	+/-	0.12	0.037

(1) Means are adjusted for treatment, site, treatment-by-site, and baseline values.
(2) Mean and standard deviation at baseline.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.1.g Protocol 640: CGI-I Score by Visit - Observed Cases

Adjusted Mean +/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
WEEK 1	94	3.6	+/-	0.08	104	3.6	+/-	0.08	0.771
WEEK 2	92	3.2	+/-	0.10	100	3.4	+/-	0.09	0.218
WEEK 3	90	2.8	+/-	0.11	95	3.0	+/-	0.11	0.209
WEEK 4	88	2.7	+/-	0.12	95	2.9	+/-	0.12	0.177
WEEK 6	81	2.4	+/-	0.12	88	2.5	+/-	0.12	0.536
WEEK 8	76	2.4	+/-	0.15	81	2.6	+/-	0.16	0.349
WEEK 10	74	2.3	+/-	0.14	77	2.6	+/-	0.15	0.191
WEEK 12	73	2.0	+/-	0.14	74	2.4	+/-	0.14	0.065
ENDPOINT	98	2.3	+/-	0.13	104	2.8	+/-	0.12	0.014

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.1.h Protocol 640: CGI-I Score by Visit - LOCF

Adjusted Mean +/- Standard Deviation

	Sertraline					Placebo				
	N	Mean	+/-	SD		N	Mean	+/-	SD	p-value
WEEK 1	98	3.5	+/-	0.84		104	3.6	+/-	0.80	0.815
WEEK 2	98	3.2	+/-	0.93		104	3.4	+/-	0.87	0.372
WEEK 3	98	2.9	+/-	0.86		104	3.1	+/-	1.07	0.094
WEEK 4	98	2.8	+/-	0.99		104	3.1	+/-	1.06	0.075
WEEK 6	98	2.6	+/-	1.00		104	2.8	+/-	1.13	0.182
WEEK 8	98	2.5	+/-	1.17		104	2.9	+/-	1.20	0.041
WEEK 10	98	2.4	+/-	1.09		104	2.8	+/-	1.25	0.031
WEEK 12	98	2.2	+/-	1.16		104	2.8	+/-	1.21	0.001

Means are adjusted for treatment, site, treatment-by-site.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.2.a Protocol 671: CAPS-2 Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	93	76.6	+/-	17.5	90	75.1	+/-	17.7	0.684
WEEK 1									
WEEK 2	87	-19.5	+/-	1.94	86	-13.9	+/-	1.94	0.041
WEEK 3									
WEEK 4	81	-27.6	+/-	2.39	81	-17.1	+/-	2.24	0.002
WEEK 6	77	-31.3	+/-	2.61	74	-21.8	+/-	2.61	0.011
WEEK 8	72	-37.2	+/-	3.12	70	-25.4	+/-	2.84	0.006
WEEK 10	68	-40.3	+/-	3.50	69	-26.5	+/-	3.06	0.004
WEEK 12	64	-39.3	+/-	3.89	67	-27.3	+/-	3.42	0.023
ENDPOINT	93	-33.0	+/-	2.82	90	-23.2	+/-	2.86	0.016

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

CAPS-2 was not administered during visits at the end of weeks 1 and 3 in Protocol 671.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.2.b Protocol 671: CAPS-2 Change from Baseline by Visit - LOCF

Adjusted Mean Change From Baseline (1)
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE (2)	93	76.6	+/-	17.5	90	75.1	+/-	17.7	0.684
WEEK 2	93	-18.2	+/-	1.86	90	-13.4	+/-	1.89	0.072
WEEK 4	93	-24.3	+/-	2.16	90	-15.9	+/-	2.20	0.007
WEEK 6	93	-28.8	+/-	2.42	90	-20.1	+/-	2.45	0.012
WEEK 8	93	-30.9	+/-	2.49	90	-22.6	+/-	2.53	0.021
WEEK 10	93	-32.8	+/-	2.65	90	-23.1	+/-	2.69	0.012
WEEK 12	93	-33.0	+/-	2.82	90	-23.2	+/-	2.86	0.016

(1) Means are adjusted for treatment, site, treatment-by-site, and baseline values.
Mean and standard deviation at baseline.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.2.c Protocol 671: IES Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	93	37.7	+/-	15.7	90	36.7	+/-	15.4	0.687
WEEK 1	90	-4.3	+/-	1.18	90	-3.5	+/-	1.18	0.642
WEEK 2	87	-7.8	+/-	1.37	87	-7.9	+/-	1.36	0.981
WEEK 3	83	-11.7	+/-	1.42	79	-11.1	+/-	1.43	0.746
WEEK 4	81	-14.1	+/-	1.52	81	-10.0	+/-	1.43	0.053
WEEK 6	77	-15.5	+/-	1.58	74	-13.8	+/-	1.58	0.438
WEEK 8	72	-19.4	+/-	1.86	70	-14.5	+/-	1.68	0.052
WEEK 10	68	-20.4	+/-	2.11	69	-14.6	+/-	1.83	0.041
WEEK 12	64	-19.9	+/-	2.19	67	-14.0	+/-	1.90	0.049
ENDPOINT	93	-16.2	+/-	1.60	90	-12.1	+/-	1.63	0.071

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.2.g Protocol 671: CGI-I Score by Visit - Observed Cases

Adjusted Mean +/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
WEEK 1	91	3.6	+/-	0.06	90	3.9	+/-	0.06	0.000
WEEK 2	87	3.1	+/-	0.09	87	3.3	+/-	0.09	0.081
WEEK 3	83	3.1	+/-	0.10	78	3.3	+/-	0.10	0.181
WEEK 4	81	2.7	+/-	0.10	81	3.3	+/-	0.10	0.000
WEEK 6	77	2.7	+/-	0.12	74	3.0	+/-	0.11	0.032
WEEK 8	72	2.3	+/-	0.13	70	2.7	+/-	0.12	0.066
WEEK 10	67	2.2	+/-	0.17	68	2.8	+/-	0.15	0.008
WEEK 12	64	2.3	+/-	0.18	67	2.7	+/-	0.16	0.062
ENDPOINT	93	2.5	+/-	0.13	90	3.0	+/-	0.14	0.016

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VII.C.2.h Protocol 671: CGI-I Score by Visit - LOCF

Adjusted Mean +/- Standard Deviation

	Sertraline				Placebo				
	N	Mean	+/-	SD	N	Mean	+/-	SD	p-value
WEEK 1	93	3.6	+/-	0.61	90	3.9	+/-	0.63	0.001
WEEK 2	93	3.2	+/-	0.94	90	3.4	+/-	0.77	0.142
WEEK 3	93	3.2	+/-	0.87	90	3.3	+/-	0.83	0.180
WEEK 4	93	2.9	+/-	0.92	90	3.3	+/-	0.92	0.004
WEEK 6	93	2.8	+/-	0.98	90	3.1	+/-	0.97	0.026
WEEK 8	93	2.6	+/-	1.00	90	2.9	+/-	1.01	0.030
WEEK 10	93	2.5	+/-	1.10	90	3.0	+/-	1.20	0.004
WEEK 12	93	2.5	+/-	1.22	90	3.0	+/-	1.20	0.017

Means are adjusted for treatment, site, treatment-by-site.

APPEARS THIS WAY
ON ORIGINAL

able VII.D.1 Protocol 640: Davidson Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	97	74.5	+/-	26.9	104	73.8	+/-	26.2	0.789
WEEK 1	94	-10.1	+/-	2.08	102	-4.4	+/-	2.02	0.054
WEEK 2	92	-16.0	+/-	2.13	100	-9.2	+/-	2.01	0.021
WEEK 3	90	-20.6	+/-	2.89	95	-16.0	+/-	2.77	0.249
WEEK 4	88	-22.4	+/-	2.81	95	-18.3	+/-	2.76	0.295
WEEK 6	83	-28.9	+/-	2.92	87	-23.3	+/-	3.08	0.195
WEEK 8	76	-30.2	+/-	3.46	80	-22.6	+/-	3.72	0.137
WEEK 10	74	-32.9	+/-	3.33	77	-26.2	+/-	3.51	0.168
WEEK 12	73	-35.8	+/-	3.29	74	-25.3	+/-	3.47	0.029
ENDPOINT	97	-32.3	+/-	2.81	104	-20.0	+/-	2.70	0.002

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VII.D.2 Protocol 671: Davidson Change from Baseline by Visit - Observed Cases

Adjusted Mean Change From Baseline
+/- Standard Error

	Sertraline				Placebo				
	N	Mean	+/-	SE	N	Mean	+/-	SE	p-value
BASELINE	90	71.9	+/-	24.1	88	68.5	+/-	27.8	0.481
WEEK 1	88	-8.0	+/-	1.81	88	-2.8	+/-	1.85	0.048
WEEK 2	84	-15.2	+/-	2.31	85	-12.6	+/-	2.32	0.431
WEEK 3	82	-20.5	+/-	2.60	77	-15.4	+/-	2.68	0.177
WEEK 4	79	-23.8	+/-	2.87	79	-13.1	+/-	2.75	0.008
WEEK 6	76	-25.3	+/-	2.87	72	-18.0	+/-	2.93	0.077
WEEK 8	70	-32.1	+/-	3.33	68	-18.4	+/-	3.09	0.003
WEEK 10	66	-36.2	+/-	3.63	67	-17.3	+/-	3.21	0.000
WEEK 12	63	-35.6	+/-	3.63	65	-19.2	+/-	3.24	0.001
ENDPOINT	90	-28.1	+/-	2.77	88	-16.1	+/-	2.85	0.003

Individual study means are adjusted for treatment, site, treatment-by-site, and baseline values.

APPEARS THIS WAY
ON ORIGINAL

Table VIII.L.1 Concomitant Medications Allowed and Not Allowed in Completed Controlled Studies

	P.R.N.	Chronic
Allopurinol (specified in 640/641 only)	Y	Y
Analgesics (non-narcotic); (chronic use not permitted in 640/641)	Y	Y
Anesthetics (specified in 671/682 only)		
General	N	N
Local	Y	N
Anorexics	N	N
Antacids (except cisapride in 671/682); (chronic use not permitted in 640/641)	Y	Y
Anti-inflammatory drugs (except Indocin and systemic corticosteroids); (sulindac not permitted in 640/641)	Y	Y*
Antianginal agents (permitted in 640/641 if taken for 6 mos at stable dose)	N	N
Antiarrhythmics	N	N
Antiasthma agents	Y	Y
Antibiotics	Y	Y[a]
Anticoagulants (only aspirin max. 5 gr/day for chronic use)	Y	Y
Anxiolytics	N	N
Anticonvulsants	N	N
Antidepressants	N	N
Antidiarrheal agents (only loperamide HCl, Kaolin preparations and Pepto-Bismol in 671/682)	Y	N
Antifungal Agents (only specified in 671/682)		
Systemic	N	N
Topical	Y	Y
Antihistamines (only cetirizine and loratidine in 671/682); (only terfenadine and astemizole in 640/641, and no chronic dosing)	Y	Y[a]
Antihypertensives	N	Y[b]**
Antinauseants	Y[c]	N
Antipsychotics	N	N
Antiviral agents (only acyclovir; specified in 671/682 only)	Y	Y*
Colchicine (specified in 640/641 only)	Y	Y
Cough/Cold preparations: 640/641: only products without pseudoephedrine, phenylpropanolamine, or narcotic decongestants were permitted, and for episodic use only. 671/682: cetirizine and loratidine were permitted for episodic use. Narcotic decongestants were not permitted. Other cough and cold preparations were restricted to use 3 days per week. The Pfizer clinician was to be called regarding chronic use.	see text	see text
Diuretics	Y[e]*	Y*
H2 Blockers (640/641: ranitidine only, and no episodic use; 671/682: cimetidine not permitted)	Y	Y**
Hormones	N	Y[f]**
Hormone Suppressants (specified in 671/682 only; only finasteride allowed)	N	Y**
Hypoglycemic agents (oral hypoglycemic agents only)	N	Y**
Hypolipidemics (specified in 671/682 only: only statins allowed)	N	Y**
Insulin	N	N
Laxatives (only fiber products and Colace)	Y	Y*
Muscle Relaxants (specified in 671/682 only)	N	N

Table VIII.L.1 (cont.)

Psychotropic drugs not otherwise specified	N	N
Sedatives/hypnotics	N[9]	N
Steroids (for 671/682 only; no steriods allowed in 640/641)		
Systemic	N	N
Topical	Y	Y
Inhalant	Y	N
Tryptophan (640/641 expressly not allowed)	N	N
Vaccines (specified in 671/682 only)	Y	N/A

APPEARS THIS WAY
ON ORIGINAL

Table VII.F.1 Summary of Analysis of Treatment by Sex Interaction Effect for Studies 640 and 671. The table contains the least-square changes from baseline to endpoint, the p-values for the treatment effect in men and women and the p value for the treatment x sex interaction effect.

Variable	Women			Men			
	Sertraline (N=152)	Placebo (N=139)	p[1]	Sertraline (N=39)	Placebo (N=55)	p[1]	p[2]
CAPS-2 Total	-34.34	-22.50	0.0001	-29.04	-29.13	0.99	0.041
CAPS-B	-7.67	-5.52	0.005	-5.92	-7.09	0.39	0.033
CAPS-C	-15.32	-9.13	0.0001	-12.81	-12.08	0.76	0.052
CAPS-D	-11.26	-7.69	0.0007	-10.38	-10.50	0.95	0.088
CAPS-AF	-10.45	-6.91	0.002	-11.58	-8.36	0.12	0.89
Davidson Total	-32.16	-16.40	0.0001	-24.45	-24.63	0.97	0.009
DAV-B	-6.27	-3.53	0.0009	-4.76	-5.26	0.74	0.056
DAV-C	-13.74	-6.33	0.0001	-10.72	-10.51	0.93	0.013
DAV-D	-12.24	-6.35	0.0001	-8.79	-9.82	0.62	0.004
IES Total	-18.46	-12.85	0.001	-16.05	-15.30	0.80	0.16
IES-B	-8.82	-6.05	0.003	-7.00	-7.81	0.62	0.059
IES-C	-9.65	-6.69	0.003	-8.98	-7.80	0.51	0.38
CGI Improvement	2.36	2.96	0.0001	2.49	2.73	0.34	0.22
HAM-D Total[3]	-8.24	-4.95	0.005	-6.49	-7.34	0.69	0.088
	(N=121)	(N=111)		(N=28)	(N=46)		

1. p value for treatment effect within men and women.
2. p value for treatment x sex interaction
3. N's = no. of subjects with baseline and endpoint HAM-D.

APPEARS THIS WAY
ON ORIGINAL

SAFETY TABLES

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682

ALL SAFETY ANALYZABLE SUBJECTS

TABLE VIII.F **INCIDENCE OF CLINICALLY SIGNIFICANT LABORATORY ABNORMALITIES**

Sertraline		Placebo					
ABN	%	ALL	ABN	%			ALL
		GROUP			PARAMETER	UNITS	CRITERIA
		HEMATOLOGY					
					HCT(HEMATOCRIT)	%	<= 32(F) 37(M)
3	0.9	327	3	0.9			318
					HGB(HEMOGLOBIN)	g/dl	<= 9.5(F) 11.5(M)
1	0.3	327	1	0.3			319
					WBC (WHITE BLOOD COUNT)	X 10 3	<= 2.8
1	0.3	327	0	0.0			319
							>= 16
2	0.6	327	0	0.0			319
					RBC (RED BLOOD CELLS)	X 10 6	<= 3
0	0.0	327	0	0.0			319
							>= 6
1	0.3	327	2	0.6			319
					NEUTROPHILS	%	<= 15
0	0.0	327	0	0.0			319
					EOSINOPHILS	%	>= 10
2	0.6	327	1	0.3			319
					PLATELETS	X 10 3	<= 75
0	0.0	327	0	0.0			320
							>= 700
0	0.0	327	0	0.0			320
		SERUM CHEMISTRY					
					SGOT UNITS	U/L	>= 3.0 X ULN
2	0.6	328	1	0.3			320
					SGPT UNITS	U/L	>= 3.0 X ULN
4	1.3	328	2	0.6			320
					ALK PHOSPHATASE	U/L	>= 3.0 X ULN
0	0.0	328	0	0.0			321
					T/PROTEIN	g/dl	<= 4.5
0	0.0	328	0	0.0			321

						>=	9	321
0	0.0	328	0	0.0				
		ALBUMIN			g/dl	<=	3.5	320
15	4.7	328	22	6.7				
						>=	6.5	320
0	0.0	328	0	0.0				
		RANDOM GLUCOSE			mg/dl	>=	140	320
16	5.0	328	21	6.4				
		T/BILIRUBIN			mg/dl	>=	2	320
1	0.3	328	2	0.6				
		BUN			mg/dl	>=	30	321
0	0.0	328	1	0.3				
		CREATININE			mg/dl	>=	2	321
0	0.0	328	0	0.0				
		CHOLESTEROL			mg/dl	>=	330	321
3	0.9	328	2	0.6				
		URIC ACID			mg/dl	>=	8.5(F) 10.5(M)	321
1	0.3	328	1	0.3				
		URINALYSIS						
		GLUCOSE:URINE				>=	2	320
1	0.3	328	3	0.9				
		PROTEIN:URINE				>=	2	319
4	1.3	328	4	1.2				

PROGRAM NAME: T90101 BY DEG

DATE AND TIME THE PROGRAM EXECUTED:12MAY98 13:26

PAGE: 1

gmf v.1 02/27/99

APPEARS THIS WAY
ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
ALL SAFETY ANALYZABLE SUBJECTS

TABLE VIII.G **INCIDENCE OF CLINICALLY SIGNIFICANT CHANGES IN VITAL SIGNS**

PARAMETER	NUMBER AND % OF SUBJECTS SPECIFIED CHANGE(2) SERTRALINE		PLACEBO		CRITERION VALUE	P-VALUE(3)	CHANGE RELATIVE TO BASELINE	NUMBER TESTED(1) SERTRALINE	PLACEBO	WITH
SITTING SYSTOLIC BP	0.5%	2	0.5%	1.000	>=180 MMHG		INCREASE >=20	370	368	2
	3.2%	4	1.0%	0.074	<= 90 MMHG		DECREASE >=20	370	368	12
SITTING DIASTOLIC BP	0.5%	4	1.0%	0.450	>=105 MMHG		INCREASE >=15	370	368	2
	0.5%	4	1.0%	0.450	<= 50 MMHG		DECREASE >=15	370	368	2
SITTING HEART RATE	0.0%	1	0.2%	0.499	>=120 BPM		INCREASE >=15	370	368	0
	0.5%	2	0.5%	1.000	<= 50 BPM		DECREASE >=15	370	368	2

(1) TOTAL NUMBER OF SUBJECTS FOR WHOM EACH VITAL SIGN ASSESSMENT WAS AVAILABLE AT BASELINE AND AT LEAST ONE FOLLOW-UP TIME.
(2) NUMBER AND % OF SUBJECTS FOR WHOM ONE OR MORE FOLLOW-UP VALUE MEETS THE CRITERION.
(3) COMPARISON OF INCIDENCE RATES USING THE FISHER'S EXACT TEST (TWO-TAILED).

NOTE: IN ORDER TO BE IDENTIFIED, A VALUE MUST MEET THE CRITERION VALUE AND ALSO REPRESENT A CHANGE OF AT LEAST
THE MAGNITUDE NOTED IN THE CHANGE COLUMN.

PROGRAM: T:\HOME\JEANMLAY\PC\SERT\PTSD\SPTSVITL.SAS
DATE : 29JUN98 TIME: 9:36
gmf v.1 02/27/99

APPEARS THIS WAY
ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
ALL SAFETY ANALYZABLE SUBJECTS

TABLE VIII.H **INCIDENCE OF CLINICALLY SIGNIFICANT CHANGES IN BODY WEIGHT**

CHANGE	NUMBER AND % OF SUBJECTS WITH SPECIFIED CHANGE			
	SERTRALINE		PLACEBO	
P-VALUE**	N=(370)*		N=(367)*	
INCREASE (>=7% ABOVE BASELINE)	2	0.5%	7	1.9%
0.1060				
DECREASE (>=7% BELOW BASELINE)	13	3.5%	9	2.4%
0.5170				

* TOTAL NUMBER OF SUBJECTS FOR WHOM BODY WEIGHT DATA WAS AVAILABLE AT BASELINE AND AT LEAST ONE FOLLOW-UP TIME.
** COMPARISON OF INCIDENCE RATES USING THE FISHER'S EXACT TEST (TWO-TAILED).

PROGRAM: T:\HOME\JEANMLAY\PC\SERT\PTSD\SPTSVITL.SAS
DATE : 29JUN98 TIME: 9:36
gmf v.1 02/27/99

APPEARS THIS WAY
ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
ALL SAFETY ANALYZABLE SUBJECTS

TABLE VIII.I **INCIDENCE OF CHANGES FROM BASELINE IN ECG**

BASELINE/FOLLOW-UP P-VALUE*	NUMBER OF SUBJECTS (%) SERTRALINE		PLACEBO	
	(N=307)		(N=306)	
NORMAL /NORMAL	202	(65.8%)	204	(66.7%)
NORMAL /ABNORMAL 0.888	29	(9.4%)	28	(9.2%)
ABNORMAL/NORMAL	21	(6.8%)	25	(8.2%)
ABNORMAL/ABNORMAL	55	(17.9%)	49	(16.0%)

NOTE: INCIDENCES FOR ALL VISITS WERE SUMMARIZED.
SUBJECT REQUIRED A BASELINE ECG AND AT LEAST ONE ADDITIONAL ECG IN ORDER TO BE INCLUDED IN THE SUMMARY.

* FISHER'S EXACT TEST (TWO-TAILED) WAS USED TO COMPARE THE PROPORTION OF SUBJECTS IN EACH GROUP WHO HAD
A NORMAL BASELINE ECG AND AT LEAST ONE ABNORMAL FOLLOW-UP ECG.

APPEARS THIS WAY
ON ORIGINAL

TABLE 9.2: PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

LABORATORY TEST CHANGES FROM BASELINE TO FINAL VALUE

LABORATORY TEST	SERTRALINE BASELINE N	SERTRALINE BASELINE MEAN	SERTRALINE CHANGE FROM BASELINE MEAN	SERTRALINE CHANGE FROM BASELINE S.E.	PLACEBO BASELINE N	PLACEBO BASELINE MEAN	PLACEBO CHANGE FROM BASELINE MEAN	PLACEBO CHANGE FROM BASELINE S.E.	GROUP COMPARISON P-VALUE
HEMATOLOGY									
HCT(HEMATOCRIT)	317	42.11	-0.15	0.15	323	42.85	-0.47	0.16	0.141
HGB(HEMOGLOBIN)	318	14.12	-0.06	0.04	324	14.34	-0.09	0.04	0.623
WBC (WHITE BLOOD COUNT)	318	7.37	0.14	0.09	324	7.29	-0.22	0.09	0.006
RBC (RED BLOOD CELLS)	318	4.67	-0.01	0.01	324	4.72	-0.05	0.01	0.043
NEUTROPHILS	318	60.22	1.72	0.47	323	60.22	-0.70	0.51	0.001
EOSINOPHILS	318	2.17	0.19	0.09	323	2.06	0.23	0.09	0.714
PLATELETS	319	262.31	-5.66	2.21	324	255.75	-1.84	1.97	0.197
SERUM CHEMISTRY									
SGOT UNITS	320	20.75	3.11	0.63	327	20.53	-0.13	0.37	0.000
SGPT UNITS	320	30.39	4.50	1.30	327	29.60	0.67	0.67	0.009
ALK PHOSPHATASE	321	72.68	5.10	0.79	327	75.29	-1.43	0.59	0.000
T/PROTEIN	321	7.33	-0.02	0.02	327	7.34	-0.10	0.02	0.026
ALBUMIN	320	4.14	-0.02	0.01	327	4.16	-0.08	0.01	0.002
RANDOM GLUCOSE	320	92.33	1.44	1.44	327	91.97	2.94	1.18	0.420
T/BILIRUBIN	315	0.52	-0.04	0.01	326	0.54	-0.02	0.01	0.150
BUN	321	12.38	0.22	0.19	327	12.58	0.20	0.17	0.920
CREATININE	321	0.81	-0.00	0.01	327	0.82	0.00	0.01	0.719
CHOLESTEROL	321	200.35	13.31	1.49	327	199.01	-2.90	1.43	0.000
URIC ACID	321	4.61	-0.42	0.04	327	4.82	-0.02	0.04	0.000

THE CHANGE FROM BASELINE MEAN WAS COMPUTED ON THE CHANGE FROM BASELINE TO FINAL VISIT VALUE FOR EACH SUBJECT.

PROGRAM: T0902 SAS by DEG
DATE : 12MAY98 TIME: 17:00

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

TABLE 11.1: INCIDENCE OF CHANGES FROM BASELINE IN ECG

BASELINE/FOLLOW-UP	NUMBER OF SUBJECTS (%) SERTRALINE (N=307)		PLACEBO (N=306)		P-VALUE*
NORMAL /NORMAL	202	(65.8%)	204	(66.7%)	
NORMAL /ABNORMAL	29	(9.4%)	28	(9.2%)	0.888
ABNORMAL/NORMAL	21	(6.8%)	25	(8.2%)	
ABNORMAL/ABNORMAL	55	(17.9%)	49	(16.0%)	

NOTE: INCIDENCES FOR ALL VISITS WERE SUMMARIZED.
SUBJECT REQUIRED A BASELINE ECG AND AT LEAST ONE ADDITIONAL ECG IN ORDER TO BE INCLUDED IN THE SUMMARY.

* FISHER'S EXACT TEST (TWO-TAILED) WAS USED TO COMPARE THE PROPORTION OF SUBJECTS IN EACH GROUP WHO HAD A NORMAL BASELINE ECG AND AT LEAST ONE ABNORMAL FOLLOW-UP ECG.

PROGRAM: T:\HOME\JEANMLAY\PC\SERT\PTSD\SPTSEKG.SAS
DATE : 29JUN98 TIME: 9:27

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

TABLE 10.3: VITAL SIGNS AND BODY WEIGHT CHANGES FROM BASELINE TO FINAL VALUE

	SERTRALINE						PLACEBO							
		MEAN BASELINE	CHANGE FROM BASELINE					MEAN BASELINE	CHANGE FROM BASELINE				P-VALUE** OF MEAN BASELINE	P-VALUE** OF MEAN CHANGES
VITAL SIGN	N*	VALUE	MEAN	S.D.	MIN	MAX	N*	VALUE	MEAN	S.D.	MIN	MAX		
SITTING SYSTOLIC BP MMHG	370	118.47	-0.06	11.76	-48.0	40.0	368	118.72	-1.19	11.19	-40.0	34.0	0.7749	0.2875
SITTING DIASTOLIC BP MMHG	370	76.87	-0.94	8.96	-24.0	30.0	368	77.14	-0.86	7.88	-21.0	20.0	0.6385	0.8011
SITTING HEART RATE BPM	370	73.29	-0.99	10.72	-35.0	36.0	368	72.43	1.31	10.41	-30.0	40.0	0.3883	0.0083
BODY WEIGHT LB.(1)	370	175.92	-1.87	5.57	-27.0	18.5	367	176.23	0.04	5.52	-41.0	20.6	0.7430	0.0001

* TOTAL NUMBER OF SUBJECTS FOR WHOM EACH VITAL SIGN ASSESSMENT WAS AVAILABLE AT BASELINE AND AT LEAST ONE FOLLOW-UP TIME.
** COMPARISONS OF BASELINE VALUES AND CHANGE FROM BASELINE USING THE WILCOXON RANK SUM TEST.
(1) ALL BODY WEIGHT DATA ENTERED IN KG WAS CONVERTED TO LB.

PROGRAM: T:\HOME\JEANMLAY\PC\SERT\PTSD\SPTSVITL.SAS
DATE : 29JUN98 TIME: 9:36

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

TABLE 10.3: VITAL SIGNS AND BODY WEIGHT CHANGES FROM BASELINE TO FINAL VALUE

	SERTRALINE						PLACEBO							
		MEAN	CHANGE FROM BASELINE					MEAN	CHANGE FROM BASELINE					
VITAL SIGN	N*	BASELINE VALUE	MEAN	S.D.	MIN	MAX	N*	BASELINE VALUE	MEAN	S.D.	MIN	MAX	P-VALUE** OF MEAN BASELINE	P-VALUE** OF MEAN CHANGES
SITTING SYSTOLIC BP MMHG	370	118.47	-0.06	11.76	-48.0	40.0	368	118.72	-1.19	11.19	-40.0	34.0	0.7749	0.2875
SITTING DIASTOLIC BP MMHG	370	76.87	-0.94	8.96	-24.0	30.0	368	77.14	-0.86	7.88	-21.0	20.0	0.6385	0.8011
SITTING HEART RATE BPM	370	73.29	-0.99	10.72	-35.0	36.0	368	72.43	1.31	10.41	-30.0	40.0	0.3883	0.0083
BODY WEIGHT LB.(1)	370	175.92	-1.87	5.57	-27.0	18.5	367	176.23	0.04	5.52	-41.0	20.6	0.7430	0.0001

* TOTAL NUMBER OF SUBJECTS FOR WHOM EACH VITAL SIGN ASSESSMENT WAS AVAILABLE AT BASELINE AND AT LEAST ONE FOLLOW-UP TIME.
** COMPARISONS OF BASELINE VALUES AND CHANGE FROM BASELINE USING THE WILCOXON RANK SUM TEST.
(1) ALL BODY WEIGHT DATA ENTERED IN KG WAS CONVERTED TO LB.

PROGRAM: T:\HOME\JEANMLAY\PC\SERT\PTSD\SPTSVITL.SAS
DATE : 29JUN98 TIME: 9:36

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Sertraline Hydrochloride												
PHARMACEUTICALS												
9500811 N-0640 061 93-N-0169	US	F	39	W	77.0	50.00 MG	57	53	DELIRIUM; ATAXIC	DOSE PERMANENTLY STOPPED	OTHER ILLNESS (Multiple sclerosis.)	UNKNOWN HOSPITALIZATION
9511820 N-0640 176 94-N-0177	US	F	39	W	72.5	425.00 MG	4	4	AGITATION	DOSE PERMANENTLY STOPPED	DISEASE UNDER STUDY	RESOLVED HOSPITALIZATION
9407747 N-0641 510 93-N-0173	US	M	44	O	71.0	200.00 MG	58	78	HOMICIDAL IDEATION	NO ACTION TAKEN	OTHER (Social stressor)	RESOLVED HOSPITALIZATION
9410385 N-0641 565 93-N-0180	US	M	46	W	92.0	25.00 MG	6	5	SUICIDAL IDEATION	DOSE PERMANENTLY STOPPED	OTHER (Stressors in patient's life)	RESOLVED HOSPITALIZATION
9510882 N-0641 588 93-N-0177	US	M	51	W	84.8	25.00 MG	3	2	RIGHT RADIAL HEAD FRACTURE; LOSS OF CONSCIOUSNESS	DOSE PERMANENTLY STOPPED	OTHER ILLNESS (Probable vasovagal episode)	DISABILITY HOSPITALIZATION

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) Inpatient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Sertraline Hydrochloride												
PHARMACEUTICALS												
9705197 N-0671 0183 95-N-0074	US	F	38	W	70.8	50.00 MG	32	13	SUICIDE ATTEMPT	POST THERAPY EVENT - DRUG PREVIOUSLY DISCONTINUED	OTHER ILLNESS (Alcohol abuse)	RESOLVED HOSPITALI-ZATION
9704544 N-0672 7025 95-N-0087	US	F	48	W	105.2	200.00 MG	174	N/A	INCISIONAL HERNIA	NO ACTION TAKEN	OTHER (HERNIA)	RESOLVED HOSPITALI-ZATION
9703602 N-0672 8012 96-N-0058	US	F	32	B	169.2	50.00 MG	7	N/A	SHORTNESS OF BREATH; CHEST PAIN	NO ACTION TAKEN	DISEASE UNDER STUDY	RESOLVED HOSPITALI-ZATION
9716299 N-0672 8012 96-N-0058	US	F	32	B	139.3	50.00 MG	166	165	NEW ONSET OF ASTHMA; ANGIOEDEMA; PHARYNGEAL CONSTRICTION	DOSE PERMANENTLY STOPPED	CONCOMITANT TREATMENT (LOTENSIN)	RESOLVED HOSPITALI-ZATION
9713924 N-0672 8020 96-N-0054	US	F	25	W	107.9	200.00 MG	44	N/A	RIGHT OVARIAN CYST	DOSE TEMPORARILY STOPPED	OTHER ILLNESS (RECURRENT OVARIAN CYST)	RESOLVED HOSPITALI-ZATION

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) Inpatient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Sertraline Hydrochloride												
PHARMACEUTICALS												
9709099 N-0672 8041 96-N-0061	US	F	30	B	88.0	100.00 MG	115	N/A	BREAST REDUCTION SURGERY	NO ACTION TAKEN	OTHER (Large breast)	RESOLVED HOSPITALI-ZATION
9717764 N-0672 8123 96-N-0057	US	F	40	W	89.4	50.00 MG	7	N/A	BASAL CELL CARCINOMA OF THE RIGHT LOWER EYELID	NO ACTION TAKEN	OTHER ILLNESS (basal cell carcinoma)	EVENT STILL PRESENT, BETTER THAN ONSET
9728606 N-0672 8123 96-N-0057	US	F	41	W	90.7	100.00 MG	136	N/A	BONE GRAFT OF THE LEFT HUMERUS; REMOVAL AND REPLACEMENT INTRAMEDULLARY ROD	NO ACTION TAKEN	OTHER (MOTOR VEHICLE ACCIDENT)	RESOLVED HOSPITALI-ZATION
9718413 N-0682 151 96-N-0040	US	F	24	W	53.2	200.00 MG	95	84	SUICIDAL IDEATION	POST THERAPY EVENT - TREATMENT PERIOD COMPLETED	DISEASE UNDER STUDY	RESOLVED HOSPITALI-ZATION

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) Inpatient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Sertraline Hydrochloride												
PHARMACEUTICALS												
9724689 N-0682 207 97-N-0053	US	F	58	W	73.9	150.00 MG	62	88	CHOLECYSTITIS	NO ACTION TAKEN	OTHER ILLNESS (CHOLECYSTOLITHIASIS)	RESOLVED HOSPITALIZATION
TREATMENT: Blinded Therapy												
PHARMACEUTICALS												
9615371 STL-AUS-94-001 008 00127	AUSTRALIA	M	48	W	93.0	N/A	24	23	ATRIAL FIBRILLATION; PALPITATIONS	DOSE TEMPORARILY STOPPED	OTHER (unknown-possibly cardiac problem)	RESOLVED HOSPITALIZATION
9706158 STL-AUS-94-001 029 00545	AUSTRALIA	F	29	W	65.0	N/A	N/A	N/A	OVARIAN CYST	DOSE TEMPORARILY STOPPED	OTHER ILLNESS (Ovarian Cyst)	RESOLVED HOSPITALIZATION
9616277 STL-AUS-94-001 145 00128	AUSTRALIA	F	33	W	ND	N/A	6	7	SUICIDAL IDEATION, PROGRESSION OF; FEELINGS OF HOPELESSNESS; FEELINGS OF HELPLESSNESS	DOSE PERMANENTLY STOPPED	DISEASE UNDER STUDY	EVENT STILL PRESENT, BETTER THAN ONSET HOSPITALIZATION

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) Inpatient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Double Blind Study Drug												
PHARMACEUTICALS												
9716632 N-0703 1049 96-N-0192	US	F	32	W	60.8	N/A	60	29	FETAL DEATH	POST THERAPY EVENT - DRUG PREVIOUSLY DISCONTINUED	OTHER (Unknown, not study drug related.)	RESOLVED
9802075 N-0703 1054 96-N-0199	US	M	48	W	97.1	N/A	199	N/A	POWER SAW INJURY TO LEFT DORSAL HAND	NO ACTION TAKEN	OTHER (Accidental trauma)	RESOLVED HOSPITALI-ZATION
TREATMENT: Placebo												
PHARMACEUTICALS												
9405385 N-0641 557 93-N-0179	US	M	47	W	104.0	0.00 MG	43	84	SUICIDAL IDEATION	NO ACTION TAKEN	DISEASE UNDER STUDY	RESOLVED HOSPITALI-ZATION
9606407 N-0641 594 93-N-0175	US	M	25	W	73.5	0.00 MG	22	21	ADJUSTMENT REACTION	POST THERAPY EVENT - DRUG PREVIOUSLY DISCONTINUED	DISEASE UNDER STUDY	RESOLVED HOSPITALI-ZATION

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) Inpatient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

SERIOUS ADVERSE EVENTS

TABLE 6
SERTRALINE PTSD SUBMISSION
ALL CAUSALITIES
REPORTING PERIOD: CUMULATIVE THROUGH 26FEB98

AEM CASE NO./ (a) PATIENT IDENTIFIER	COUNTRY	SEX	AGE	RACE	WEIGHT (KG)	TOTAL DAILY DOSE (b)	EVENT ONSET DAY (c)	THERAPY STOP DAY	EVENT TERM	ACTION TAKEN	INVESTIGATOR CAUSALITY	OUTCOME(d)
TREATMENT: Placebo												
PHARMACEUTICALS												
9607452 N-0641 698 93-N-0174	US	F	34	W	91.6	0.00 MG	45	50	EXACERBATION OF BRONCHIAL ASTHMA	DOSE PERMANENTLY STOPPED	OTHER ILLNESS (Pre-existing bronchial asthma)	RESOLVED HOSPITALIZATION
9617762 N-0671 014 95-N-0064	US	F	32	W	108.9	0.00 MG	35	32	HIVES	DOSE PERMANENTLY STOPPED	OTHER (Xylocaine)	RESOLVED HOSPITALIZATION
9701420 N-0682 0042 96-N-0047	US	F	39	W	101.6	0.00 MG	25	25	GANGRENE, LEFT HAND; HEMORRHAGE	DOSE PERMANENTLY STOPPED	OTHER (Impaired blood flow in left hand 2nd to smoking)	EVENT STILL PRESENT, BETTER THAN ONSET HOSPITALIZATION

APPEARS THIS WAY
ON ORIGINAL

(a) PROTOCOL/PATIENT ID/GRANT NO./LOCAL COUNTRY NO. - Blank fields suppressed
(b) Closest to onset of event
(c) Days are relative to the day of starting double blind/active therapy (Day 1)
(d) An outcome of "Hospitalization" means the event being reported resulted in either of the following:
(i) In-patient hospitalization or (ii) Prolongation of hospital stay

ND = NOT DONE
N/A = NOT AVAILABLE

RACE KEY: W = WHITE A = ASIAN
B = BLACK O = OTHER

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

TABLE 5.2.1 : LIST OF SERTRALINE SAFETY ANALYZABLE SUBJECTS WHO DISCONTINUED DUE TO MEDICAL REASONS*

TREATMENT GROUP: SERTRALINE

SITE	SUBJECT	SEX	AGE (YRS)	DOSE AT TIME OF WITHDRAWAL (MG/DAY)	DURATION OF THERAPY(DAYS)	REASON
PROTOCOL: 0640						
93N0165	29	F	26	100	46	ADVERSE EVENT
93N0168	122	F	52	25	5	ADVERSE EVENT
93N0169	61	F	39	50	53	ADVERSE EVENT
93N0170	118	F	34	25	8	ADVERSE EVENT
93N0171	77	F	42	50	27	ADVERSE EVENT
93N0185	11	F	43	25	13	ADVERSE EVENT
94N0157	100	M	62	50	41	ADVERSE EVENT
94N0158	109	F	40	50	29	ADVERSE EVENT
94N0177	176	F	39	425	4	ADVERSE EVENT
PROTOCOL: 0641						
93N0172	507	F	29	50	25	ADVERSE EVENT
93N0172	655	M	25	25	12	ADVERSE EVENT
93N0172	657	F	39	25	14	ADVERSE EVENT
93N0172	670	M	42	100	42	ADVERSE EVENT
93N0172	671	F	29	25	7	ADVERSE EVENT
93N0173	666	M	51	25	11	ADVERSE EVENT
93N0176	540	M	52	150	49	ADVERSE EVENT
93N0177	575	M	58	150	31	ADVERSE EVENT
93N0177	588	M	51	25	2	ADVERSE EVENT
93N0180	565	M	46	25	5	ADVERSE EVENT
94N0175	608	M	49	100	21	ADVERSE EVENT
PROTOCOL: 0671						
95N0061	78	F	49	50	20	ADVERSE EVENT
95N0065	125	F	51	150	57	ADVERSE EVENT
95N0074	48	F	40	50	43	ADVERSE EVENT
95N0075	51	F	53	25	8	ADVERSE EVENT

*MEDICAL REASONS: ADVERSE EVENT,LABORATORY ABNORMALITY,OTHER:PREGNANCY

FILE: T:\HOME\LIN\SPTS\T52.SAS
DATE: 08/11/98 13:36:03

PAGE : 1

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

PROTOCOL: PROTOCOLS 0640, 0641, 0671, 0682
STUDY: ALL COMPLETED STUDIES

TABLE 5.2.1 : LIST OF SERTRALINE SAFETY ANALYZABLE SUBJECTS WHO DISCONTINUED DUE TO MEDICAL REASONS*

TREATMENT GROUP: SERTRALINE

SITE	SUBJECT	SEX	AGE (YRS)	DOSE AT TIME OF WITHDRAWAL (MG/DAY)	DURATION OF THERAPY(DAYS)	REASON
95N0033	53	F	30	150	31	ADVERSE EVENT
PROTOCOL: 0682						
96N0040	22	M	30	50	42	ADVERSE EVENT
96N0041	112	F	35	50	12	ADVERSE EVENT
96N0042	101	F	29	50	11	ADVERSE EVENT
96N0043	124	F	38	150	58	ADVERSE EVENT
96N0047	46	F	50	50	19	ADVERSE EVENT
96N0049	81	F	35	50	14	ADVERSE EVENT
97N0052	195	F	23	100	20	ADVERSE EVENT
PROTOCOL: 0640						
93N0165	27	F	36	150	47	LABORATORY ABNORMALITY
93N0184	230	M	48	200	47	LABORATORY ABNORMALITY
PROTOCOL: 0671						
95N0062	69	F	32	150	51	LABORATORY ABNORMALITY
95N0065	124	F	37	150	44	LABORATORY ABNORMALITY
95N0074	183	F	37	50	13	LABORATORY ABNORMALITY
PROTOCOL: 0640						
93N0168	52	F	20	25	2	OTHER:PREGNANCY

*MEDICAL REASONS: ADVERSE EVENT,LABORATORY ABNORMALITY,OTHER:PREGNANCY

FILE: T:\HOME\LIN\SPTS\T52.SAS
DATE: 08/11/98 13:36:03

APPEARS THIS WAY ON ORIGINAL

APPEARS THIS WAY ON ORIGINAL