
SmithKline Beecham Pharmaceuticals

Program: S329DEPR.SAS

Type: Table

By:

Date: 28-AUG-97

REDACTED

Description: Paroxetine 329 - GLM analyses for mean change from baseline
and creation of tables for ITT efficacy var
HAMD DEPRESSION ITEM

ACUTE PHASE

Files Included: SETUP329.INC
M_GLMPR.SAS

Tables Accessed:

Data Sets Accessed: HAMD329

Permanent Data Sets Created:

SAS Version: 6.08
Input Parameter: SYSPARM = 329
Output file: S329DEPA.LIS, S329DEPC.LIS
S329DEPR.PRT

Update:

```
*****;  
%include 'bio_code:stdinit.sas';  
%stdinit;  
*****  
* Initial set up commands to create libnames and macros for output data set, *  
* output file, protocol, table number, population type (ITT or per-protocol) *  
* and population title text *  
* Defines output file (.PRT) to print PROC GLM results *  
*****;
```

```
%let file=S329DEPR.SAS;  
%let protocol = %scan(&sysparm,1,'^');  
%let pop=ITT;  
%let num = %scan(&sysparm,2,'^');  
  
%include "bio_dev_proto:[code]SETUP&protocol..INC";  
  
%let subfile = %scan(&file,1,'.');  
%NEWPRINT(&subfile..PRT);  
  
%let report1 = %STR(S&protocol.DEPA.LIS);  
%let listdat = DATA.HAMD&protocol;  
  
%include "bio_dev_proto:[code]M_GLMPR.SAS";
```

```
%POPTITL;  
*****  
* ACUTE PHASE *  
*****  
*****  
* Defines data set for efficacy analysis. Screen and baseline visits excluded *  
* Baseline Analysis *  
*****;
```

```
DATA HAME; set &listdat(where=(week gt 0 and phase=1));  
by pid;  
if d_depr=. then delete;  
type='BAS';  
if first.pid;  
week = 0;
```

run;

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-----*

```

*****
- Call macros from M_GLMPR.SAS to create table for (Baseline visit)      *
* HAMD Total including sample sizes, lsmeans, standard errors, and treatment *
* p-values.                                                                *
*****;

%let rename= bl_depr=d_depr;
%BASE(HAME, d_depr);

%ANOVA(EFFBASE, d_depr, BHAMN, BHAMST, trx inv, trx inv, trx, BHAMMN,
      Analysis of Baseline HAMD DEPRESSION ITEM Mean, Reduced model);

*****
* Reduced model used without trx*inv interaction as determined by endpoint *
* model analysis in                                                         *
*****;

DATA HAMD; set alistdat(where=(week gt 0 and phase=1));
            by pid;
            if d_depr=. then delete;
            type='VIS';
run;

DATA ENDPOINT;
  set alistdat(where=(week gt 0 and phase=1));
  by pid;
  if d_depr=. then delete;
  if last.pid;
  type='VIS';
  week=99;
run;

DATA HAMD;
  set HAMD ENDPOINT;
  by pid;
run;

%ANOVA(HAMD, d_depr, DHAMN, DHAMST, trx inv, trx inv, trx, DHAMMN,
      Analysis of Mean change from Baseline in HAMD DEPRESSION ITEM by Week, Reduced
model);

%TRANS(DHAMST BHAMST, DHAMN BHAMN, d_depr, DHAMMN BHAMMN, HAM);

%NEWPRINT(&report1);
%let reportn = %STR(Table 13.35);
%RDMSHDR(stitle=&reportn, ltitle=Baseline Mean and Mean Change from Baseline at Weekly
Intervals--HAMD
Depressed Mood Item Acute Phase, cgrtype=TAB, out_ref=S329DEPA);

%F_PRINT( HAM, (week in(0,1,2,3,4,5,6,7,8,99)), Baseline Mean and Mean Change from Baseline
at Weekly Intervals--HAMD
Depressed Mood Item, Acute Phase, %STR(HAMD Depressed Mood Item is HAMD Item 1
) );

```

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Paroxetine - Protocol 329
Table 13.35
Baseline Mean and Mean Change from Baseline--HAMD Depressed Mood Item
Acute Phase
Intent to Treat Population

	PAROXETINE		IMIPRAMINE		PLACEBO		-- Pairwise Comparisons ---	
	n	mean (s.e.)	n	mean (s.e.)	n	mean (s.e.)	Par vs Pla	Imp vs Pla
Baseline	90	2.99 (0.08)	94	2.79 (0.08)	87	2.86 (0.08)	0.227	0.514
Week 1	88	-0.91 (0.11)	91	-0.61 (0.11)	84	-0.44 (0.12)	0.003 *	0.269
Week 2	81	-1.39 (0.13)	88	-0.90 (0.13)	80	-0.89 (0.13)	0.005 *	0.955
Week 3	76	-1.44 (0.15)	77	-1.12 (0.15)	75	-1.00 (0.14)	0.027 *	0.552
Week 4	76	-1.76 (0.14)	69	-1.45 (0.15)	73	-1.35 (0.14)	0.031 *	0.630
Week 5	72	-1.70 (0.15)	67	-1.54 (0.16)	70	-1.46 (0.16)	0.235	0.706
Week 6	72	-1.96 (0.15)	62	-1.61 (0.16)	66	-1.53 (0.15)	0.036 *	0.700
Week 7	67	-2.00 (0.16)	54	-1.76 (0.18)	63	-1.58 (0.17)	0.057	0.442
Week 8	67	-2.21 (0.17)	56	-1.76 (0.18)	66	-1.54 (0.17)	0.003 *	0.358
Endpoint	90	-2.00 (0.14)	94	-1.62 (0.14)	87	-1.33 (0.14)	0.001 *	0.135

Treatment differences and p-values are computed using analysis of variance with a model including effects for treatment and investigator.

* - significantly different from placebo for alpha = 0.05

HAMD Depressed Mood Item is HAMD Item 1

SET short_title "Table 13.35"

SET title "Baseline Mean and Mean Change from Baseline at Weekly Intervals--HAM-D Depressed Mood Item Acute Phase"

SET cgr_type "TABLE"

SET vax_filename "DISK\$STATS12:[BIO.DEV16.USPAT.SBBRL29060.329.LIST]S329DEPA.LIS;6"

SET vax_runtime "30OCT1997 15:17"

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