

A Patient Profile Using ODS RTF
PhilaSUG Spring 2004

Terek Peterson, MBA
tpeterso@cephalon.com

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Cephalon Today

Achieving The Right Balance

- Fully integrated, biotech-based pharmaceutical company
- Focus on research and development
- Major presence in the United States and Europe
- Three key products marketed in the United States
- Rapid growth
- Generating significant cash flow
- More than \$1 billion in cash available

Provigil

Creating The Wakefulness Market



Gabitril - Novel Mechanism of Action For Partial Seizures, a form of Epilepsy



Selectively Target GABA Reuptake

Hit your mark with Selective GABA Reuptake Inhibition (SGRI)

- Increases GABA levels *in vitro* by selectively binding to GAT-1, the predominant GABA uptake transporter^{1,2}
- Proven safety profile with a low potential for drug interactions
- Linear pharmacokinetics offer predictable systemic exposure
- The precise mechanism by which GABITRIL[®] exerts its effect in humans is unknown³

Adverse events were usually mild to moderate in intensity. The most common adverse events for GABITRIL in combination with other anticonvulsants⁴ were: dizziness/lightheadedness,⁵ asthenia/lack of energy, somnolence, nausea, nervousness/irritability, tremor,⁶ abdominal pain, and thinking abnormal/difficulty with concentration or attention.⁷

GABITRIL is indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures.

Please see brief summary of prescribing information on adjacent page.

¹Due to their development of specific enzyme-inhibiting anticonvulsants, ²pose or titration data related.

GABITRIL[®]
tiagabine HCl
Targeted action, GABA specific.

References:
1. GABITRIL, Ciba-Geigy Inc., Dugway, MO; 2. Rieder, LA, Miller DR, et al. Epilepsia 36:1000-1004 (1995); 3. Brackman TA, Brackman C, Tugade S, et al. Epilepsia 36:1000-1004 (1995); 4. GABA transporter GAT-1. *Acta Pharmacol* 1994;269:219-224.

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Actiq

For Breakthrough Cancer Pain



What is a Patient Profile?

Patient Information Tool

- A tool to review data from an individual patient/subject during a study
- The profile is made up of small macro programs or modules each with a unique purpose
- Modules can take advantage of features available when using the ODS output destination RTF
- Multiple modules can print to one page, allowing a mix of procedures on one page of output

Patient: 2000/Y-S Treatment: PLACEBO Age: 38 Sex: FEMALE Race: WHITE Med Start: 02SEP2003 Stop: 24NOV2003 Dur: 84
 Site : 1 (DUMMY INVESTIGATOR) Country: MN Baseline Hgt (cm): 172.72 Wgt (kg): 68.12 BMI: 22.83
 Randomized: YES Safety: YES Efficacy: YES Completed: YES Discontinued: NO Disc. Date: Reason:
 Schedule : STUDY STR | RANDOMIZE | MED START | MED STOP | DISC DATE | STUDY STP
 04AUG2003 | 01SEP2003 | 02SEP2003 | 24NOV2003 | . | 24NOV2003

Adverse Events

Study Day^		_Duration_		Description	Preferred Term	Body System	Serious	Severity	Action Taken		Outcome	Relation
Start	Stop	Hrs.	Min.						Study	Med		
-12	-10	.	.	HEADACHE	HEADACHE	NERV	NO	MILD	NONE		RESOLVED NO RESIDUAL EFFECT	POSSIBLE
30	33	.	.	HEADACHE	HEADACHE	NERV	NO	MODERATE	NONE		RESOLVED NO RESIDUAL EFFECT	POSSIBLE
51	58	.	.	PNEUMONIA	PNEUMONIA	INFEC	YES	MODERATE	NONE		RESOLVED NO RESIDUAL EFFECT	NOT RELATED

Physical Examination

VISIT LABEL	GENERAL APPEARANCE	HEENT	CHEST AND LUNGS	HEART	ABDOMEN	RECTAL / GENITALIA	MUSCULO-SKELETAL	SKIN	LYMPH NODES	NEUROLOGICAL
SCREENING A	NORMAL	NORMAL	NORMAL	NORMAL	NORMAL	NOT EXAMINED	NORMAL	ABNORMAL	NORMAL	NORMAL
WEEK 12	NORMAL	NORMAL	ABNORMAL	NORMAL	NORMAL	NOT EXAMINED	NORMAL	ABNORMAL	NORMAL	NORMAL

Patient Profile Header

Critical Patient Information

- The Patient Profile Header should contain critical information concerning a patient during the study (Demography, Important Dates, Termination, etc.)
- The Header layout should be created and agreed upon before the Patient Profile will work
- The Header will be the same on every page for a patient
- Use the Header to help validate other data across tables

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BFI

INDEX	PAGE	VISIT	NO	VISIT	NO	WIS	LABEL	VISIT	DT	NOT	DONE	IN	ITYN	SEQ	NO	Q	NUM	ITEM	FATIG	RESP	NUM
1	DB	11	2	BASELINE	01SEP2003	.	YES	1	1	PLEASE RATE YOUR FATIGUE (WEARINESS, TIREDNESS) BY CIRCLING THE ONE NUMBER THAT BEST DESCRIBES YOUR FATIGUE RIGHT NOW	YES	3									
2	DB	11	2	BASELINE	01SEP2003	.	YES	2	2	PLEASE RATE YOUR FATIGUE (WEARINESS, TIREDNESS) BY CIRCLING THE ONE NUMBER THAT BEST DESCRIBES YOUR FATIGUE DURING THE PAST 24 HOURS	YES	4									
3	DB	11	2	BASELINE	01SEP2003	.	YES	3	3	PLEASE RATE YOUR FATIGUE (WEARINESS, TIREDNESS) BY CIRCLING THE ONE NUMBER THAT BEST DESCRIBES YOUR WORST LEVEL OF FATIGUE DURING THE PAST 24 HOURS	YES	9									
4	DB	11	2	BASELINE	01SEP2003	.	YES	4	4A	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR GENERAL ACTIVITY	YES	8									
5	DB	11	2	BASELINE	01SEP2003	.	YES	5	4B	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR MOOD	YES	7									
6	DB	11	2	BASELINE	01SEP2003	.	YES	6	4C	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR WALKING ABILITY	YES	9									
7	DB	11	2	BASELINE	01SEP2003	.	YES	7	4D	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR NORMAL WORK (INCLUDES BOTH WORK OUTSIDE THE HOME AND DAILY CHORES)	YES	8									
8	DB	11	2	BASELINE	01SEP2003	.	YES	8	4E	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR RELATIONS WITH OTHER PEOPLE	YES	8									
9	DB	11	2	BASELINE	01SEP2003	.	YES	9	4F	CIRCLE THE ONE NUMBER THAT DESCRIBES HOW, DURING THE PAST 24 HOURS, FATIGUE HAS INTERFERED WITH YOUR ENJOYMENT OF LIFE	YES	8									
10	DB	20	3	WEEK 4	29SEP2003	.	YES	1	1	PLEASE RATE YOUR FATIGUE (WEARINESS, TIREDNESS) BY CIRCLING THE ONE NUMBER THAT BEST DESCRIBES YOUR FATIGUE RIGHT NOW	YES	4									
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Types of Modules

Small Specific Macro Programs

- Review all RAW or DERIVED data, as is
- Stack relevant datasets across visits
 - For example, stack Vitals, ECGs, and Labs
- Print specific data in a readable listing with important data bolded or italicized
- Create graphs with annotations that show data over time

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51	58	.	.	PNEUMONIA	PNEUMONIA	INFEC	YES	MODERATE	NONE		RESOLVED NO RESIDUAL EFFECT	NOT RELATED

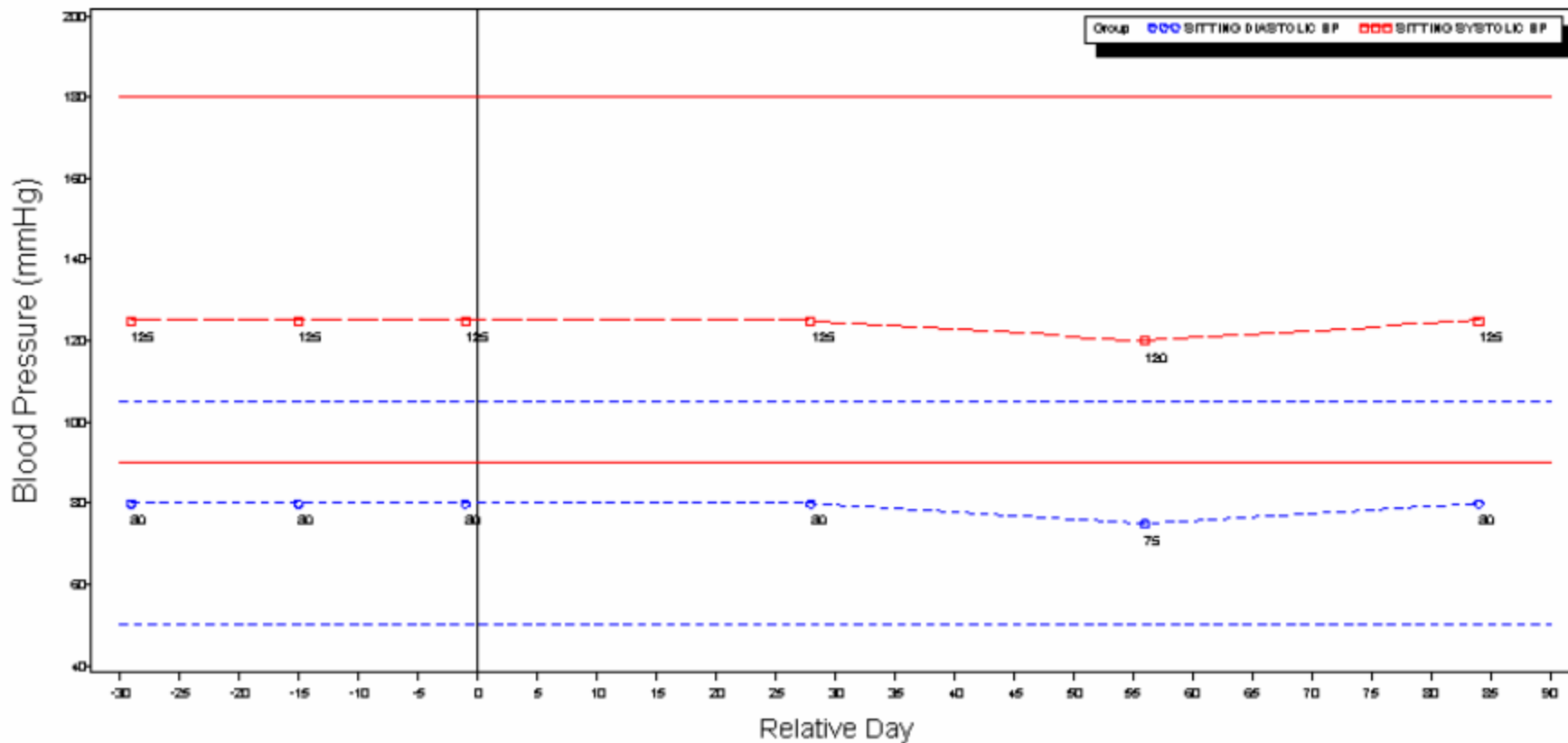
Physical Examination

VISIT LABEL	GENERAL APPEARANCE	HEENT	CHEST AND LUNGS	HEART	ABDOMEN	RECTAL / GENITALIA	MUSCULO-SKELETAL	SKIN	LYMPH NODES	NEUROLOGICAL
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WEEK 12	NORMAL	NORMAL	ABNORMAL	NORMAL	NORMAL	NOT EXAMINED	NORMAL	ABNORMAL	NORMAL	NORMAL

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Age: 38 Sex: FEMALE Race: WHITE
Completed: YES Discontinued: NO
Disc. Date: . Reason:

Med Start: 02SEP2003 Stop: 24NOV2003 Dur: 84
Baseline Hgt (cm): 172.72 Wgt (kg): 68.12 BMI: 22.83



How does the Patient Profile Work?

Subset Data, Setup Template, Create Header

- Set all data from RAW and/or DERIVED to WORK, sub-setting all data by one patient's number
- Use PROC TEMPLATE to setup the style used by ODS or pick a SAS provided ODS template
- Create the Header that will be used on every page, every title and footnote will become a Header or a Footer in the Word document

Creating the Header

Create Macro Variables, Create Titles

```
proc sql noprint;
    select patid into : admnpid from d_admn;
    select site_inv into : admnsite from d_admn;
    select treat into : admntgrp from d_admn; ...

data _null_;
    set d_admn;
    call symput("tit4a","Patient: &admnpid"||byte(160)||byte(160)||
                "Treatment: &admntgrp"); ...

title4    j=l bold "&tit4a" j=c bold "&tit4b" j=r bold "&tit4c"; ...
```

How does the Patient Profile Work?

Start ODS, Call Modules, Close ODS

- Start ODS RTF. The output destination could be `..\Profiles\Patient Number.RTF`
- Call Modules. Modules must not have any Titles or Footnotes. It should be OK to use any SAS procedure.
- Between Modules the ODS option STARTPAGE must equal NO or NEVER
- Close ODS RTF

Basic Syntax of ODS Section

Start ODS, Call Modules, Close ODS

```
ods rtf file="..\profiles\&patient..rtf" style=newrtf;  
ods ESCAPECHAR='~';
```

```
%pp_raw;
```

```
ods rtf startpage=NO;  
%pp_ae(pref=aepref, body=bodysys, bystring=tgrp treat, space=2);
```

```
ods rtf startpage=never;  
%pp_gv2;
```

```
ods rtf startpage=YES;  
ods rtf close;
```

RAW Data Module

Print All RAW Data from One Patient

```
%macro pp_raw(dropvar=protocol site patno patinits scrno,  
              rawdata=ae demog elig labs vitals ecgs term madrs cgis);  
  %let k=1;  
  %do while (%scan(%quote(&rawdata), &k, ' ') ^= %str());  
  
    proc print data=%upcase(%scan(%quote(&rawdata,&k, ' '))  
      (drop=&dropvar) width=min  
      obs="~S={font_style=italic font_weight=bold font_size=8pt}  
        %upcase(%scan(%quote(&rawdata),&k, ' '))  
        ~S={}~n~n";  
  
      run;  
      %let k=%eval(&k+1);  
  %end;  
%mend;
```

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VITALS

INDEX	PAGENO	VISITNO	VISLABEL	VISIT_DT	NOTDONE	TIMEPT	SEQNO	CATEGORY	RESULT	UNIT
1	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	1	SITTING PULSE	68.0	BPM
2	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	2	SITTING SYSTOLIC BP	125.0	MMHG
3	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	3	SITTING DIASTOLIC BP	80.0	MMHG
4	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	5	HEIGHT	68.0	IN
5	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	6	WEIGHT	150.2	LB
6	DB	4.0	1 SCREENING A	04AUG2003	.	MORNING	8	BODY TEMPERATURE	98.6	F
7	DB	9.0	1.5 SCREENING B	18AUG2003	.	MORNING	1	SITTING PULSE	69.0	BPM
8	DB	9.0	1.5 SCREENING B	18AUG2003	.	MORNING	2	SITTING SYSTOLIC BP	125.0	MMHG
9	DB	9.0	1.5 SCREENING B	18AUG2003	.	MORNING	3	SITTING DIASTOLIC BP	80.0	MMHG
10	DB	13.0	2 BASELINE	01SEP2003	.	EVENING	1	SITTING PULSE	68.0	BPM
11	DB	13.0	2 BASELINE	01SEP2003	.	EVENING	2	SITTING SYSTOLIC BP	125.0	MMHG
12	DB	13.0	2 BASELINE	01SEP2003	.	EVENING	3	SITTING DIASTOLIC BP	80.0	MMHG
13	DB	10.0	2 BASELINE	01SEP2003	.	MORNING	1	SITTING PULSE	68.0	BPM
14	DB	10.0	2 BASELINE	01SEP2003	.	MORNING	2	SITTING SYSTOLIC BP	125.0	MMHG
15	DB	10.0	2 BASELINE	01SEP2003	.	MORNING	3	SITTING DIASTOLIC BP	80.0	MMHG
16	DB	13.0	2 BASELINE	01SEP2003	.	MORNING POST-NPSG	1	SITTING PULSE	67.0	BPM
17	DB	13.0	2 BASELINE	01SEP2003	.	MORNING POST-NPSG	2	SITTING SYSTOLIC BP	120.0	MMHG
18	DB	13.0	2 BASELINE	01SEP2003	.	MORNING POST-NPSG	3	SITTING DIASTOLIC BP	75.0	MMHG
19	DB	23.0	3 WEEK 4	29SEP2003	NOT DONE	
20	DB	18.0	3 WEEK 4	29SEP2003	.	MORNING	1	SITTING PULSE	68.0	BPM
21	DB	18.0	3 WEEK 4	29SEP2003	.	MORNING	2	SITTING SYSTOLIC BP	125.0	MMHG
22	DB	18.0	3 WEEK 4	29SEP2003	.	MORNING	3	SITTING DIASTOLIC BP	80.0	MMHG
23	DB	99.1	3.1 UNSCHEDULED	06OCT2003	.	EVENING	1	SITTING PULSE	70.0	BPM
24	DB	99.1	3.1 UNSCHEDULED	06OCT2003	.	EVENING	2	SITTING SYSTOLIC BP	125.0	MMHG
25	DB	99.1	3.1 UNSCHEDULED	06OCT2003	.	EVENING	3	SITTING DIASTOLIC BP	80.0	MMHG
26	DB	99.1	3.1 UNSCHEDULED	06OCT2003	NOT DONE	MORNING POST-NPSG

Possible Uses

QC Data, Edit Checks, Communication Tool

- QC of Raw or Derived Data, quick printout of all data for an individual patient
- Edit Checks for troublesome data or important analysis sets
- Discovery of Anomalies across time and between data sets
- Communication Tool

Patient: 2000/Y-S Treatment: PLACEBO Age: 38 Sex: FEMALE Race: WHITE Med Start: 02SEP2003 Stop: 24NOV2003 Dur: 84
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MED

INDEX	PAGENO	NAME	SEQNO	DRUGNAME	DOSE	UNITS	CMON_MM	CMON_DD	CMON_YY	CMON_DT	CMRS_MM	CMRS_DD	CMRS_YY	CMRS_DT	CONTINUE
1	DB	39.01	.	2 ORTHONOVUM	1	TAB	.	.	1975	YES
2	DB	39.01	.	5 ADVIL	400	MG	10	28	2003	28OCT2003	10	31	2003	31OCT2003	.
3	DB	39.01	.	3 ACETAMINOPHEN	300	MG	9	17	2003	17SEP2003	9	19	2003	19SEP2003	.
4	DB	39.01	.	6 BIAXIN	500	MG	11	22	2003	22NOV2003	11	28	2003	28NOV2003	.
5	DB	39.01	.	1 MULTI-VITAMIN	1	TAB	.	.	1975	YES
6	DB	39.01	.	4 CLARITIN	200	MG	8	.	1985	YES

MED

INDICAT	PREF	ATCCODE	ATCTEXT	ATC_SUM
1 BIRTH CONTROL	ORTHO-NOVUM	503	SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	
2 HEADACHE	IBUPROFEN	502	OTHER GYNECOLOGICALS	
3 HEADACHE	PARACETAMOL	N02	ANALGESICS	Non-opioid analgesics/anti inflammatory
4 PNEUMONIA	CLARITHROMYCIN	J01	ANTIBACTERIALS FOR SYSTEMIC USE	Antibacterives
5 PROPHYLAXIS	MULTI-VITAMINS	A11	VITAMINS	Vitamins/Nutritional Supplement
6 SEASONAL ALLERGIES	LORATADINE	R06	ANTIHISTAMINES FOR SYSTEMIC USE	Antihistamines

Comment: Missing ATC_SUM

Conclusion

Patient Profile using ODS RTF is Flexible

- ODS RTF allows extreme flexibility to fit your company's presentation style
- Fairly easy to implement and output can improve as new modules are created
- Can provide a solution if the FDA requires Patient Profiles for patients in your study

Comments/Questions?

PhilaSUG Spring 2004
June 17, 2004

