

**G.09.12.**  
**DAYTIME CONSEQUENCES OF SLEEP QUESTIONNAIRE (DCSQ) IPM**  
**[Option 1]**

**1. Purpose**

The Daytime Consequences of Sleep Questionnaire (DCSQ) is a measure to assess how an individual feels during the day. This questionnaire is not a validated or published instrument. Using a 7-day recall period, the questionnaire is a patient-reported instrument consisting of 10 items, which assess domains thought relevant to daytime functioning. A total score will be calculated as the average of the questionnaire items.

Permission to use the DCSQ must be obtained from the University of California-Los Angeles (UCLA). Pfizer has received permission from UCLA for unlimited use of the DCSQ company-wide. The DCSQ is available for use free of charge. Questions regarding the instrument can be addressed to the Outcomes Research (OR) representative for the compound under study. The OR representative will serve as a central contact and manager of operational interactions with the instrument developer, Ron D. Hays. Dr. Hays' address is:

Ron D. Hays, Ph.D.  
Professor of Medicine  
UCLA Division of GIM & Health Services Research  
UCLA AIDS Institute  
911 Broxton Plaza, Room 110  
Box 951736  
Los Angeles, CA 90095-1736

*[A date IPM (eg, A.3.6) should be used with this IPM.]*

*[A Language of Questionnaire IPM (ig, J.03.04 or J.03.05) MUST be used with this IPM.]*

## **2. Protocol**

### **2.1 Guidelines**

The protocol must define the time points at which these data will be collected.

### **2.2 Suggested Wording**

The Daytime Consequences of Sleep Questionnaire (DCSQ) will be administered *[insert desired time points or reference the study Timetable of Visits and Procedures; see Examples 1 and 2 below]*.

*Example 1: "...at each patient visit."*

*Example 2: "...as shown in the study Timetable of Visits and Procedures."*

The Daytime Consequences of Sleep Questionnaire (DCSQ) is a measure to assess how an individual feels during the day. Using a 7-day recall period, the questionnaire is a patient-reported instrument consisting of 10 items, which assess domains thought relevant to daytime functioning. A total score will be calculated as the average of the questionnaire items. The total score may range from 0 – 100; a higher total score indicating the patient has experienced better daytime functioning.

### 3. CRF Design

---

**Daytime Consequences of Sleep Questionnaire**

---

3 Not Done

*For each question, please ✓ the box that best indicates how you feel (✓ only one box per question).*

For how many of the last 7 days did you....

	All 7 days	5-6 days	3-4 days	1-2 days	0 days
1. wake up with aches and pains?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2. feel you might get sick because your sleep was poor?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3. feel tired during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4. have trouble concentrating and focusing during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
5. feel confused during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
6. feel clumsy and uncoordinated during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
7. accomplish less than you wanted to?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
8. wake up in a bad mood?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
9. wake up feeling grouchy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
10. feel depressed during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## 4. Database Design

### 4.1 Annotated CRFs

Daytime Consequences of Sleep Questionnaire						
<input type="checkbox"/> 3 Not Done <b>NOTDONE</b>						
For each question, please ✓ the box that best indicates how you feel (✓ only one box per question).						
For how many of the last 7 days did you....						
		All 7 days	5-6 days	3-4 days	1-2 days	0 days
<b>DCS01</b>	1. wake up with aches and pains?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS02</b>	2. feel you might get sick because your sleep was poor?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS03</b>	3. feel tired during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS04</b>	4. have trouble concentrating and focusing during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS05</b>	5. feel confused during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS06</b>	6. feel clumsy and uncoordinated during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS07</b>	7. accomplish less than you wanted to?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS08</b>	8. wake up in a bad mood?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS09</b>	9. wake up feeling grouchy?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b>DCS10</b>	10. feel depressed during the day?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## 4.2 Extract View Description

There should be only one record per patient per date.

FIELD NAME	FIELD DESCRIPTION	TYPE	DATA COLLECTION LENGTH	COMMENTS
NOTDONE	Not Done	C	8	Auxiliary Field
DCS01	Aches and Pain	N	1	Key Field
DCS02	Feels Sick	N	1	Key Field
DCS03	Feels Tired	N	1	Key Field
DCS04	Trouble Concentrating	N	1	Key Field
DCS05	Feels Confused	N	1	Key Field
DCS06	Feels Clumsy	N	1	Key Field
DCS07	Accomplish Less	N	1	Key Field
DCS08	Bad Mood	N	1	Key Field
DCS09	Feels Grouchy	N	1	Key Field
DCS10	Feels Depressed	N	1	Key Field

## 4.3 Field Calculations

FIELD NAME	DESCRIPTION	CALCULATION FORMULA	UNIT	BLANK ELEMENTS	EXPECTED RANGE, ROUNDING, SIGNIFICANT DIGITS
AVGSCR	DCS Average Score	$(DCS01 + DCS02 + DCS03 + DCS04 + DCS05 + DCS06 + DCS07 + DCS08 + DCS09 + DCS10) / 10$	--	Blank if any component is missing	1 - 5
TOTSCR	DCS Total Score	$(AVGSCR - 1) / 25$	--	Blank if AVGSCR is missing	0 - 100

*[The study day from the referenced IPM should be associated with these data.]*

## 5. Monitoring Guidelines

### 5.1 Source Document Verification

Not applicable as the CRF is the source document.

### 5.2 Internal Data Consistency Checks

As the CRF is a subject reported source document, it is impossible to retrieve missing information, so if the questionnaire is completed in a sleep lab, the site personnel must check that the questionnaire is appropriately completed before the subject leaves the sleep lab. If questionnaire is completed by a subject at home, it is not possible to retrieve missing data.

If two responses are checked for a single question, the most severe data will be entered into the database. For all questions, the most severe data is the smaller numeric response.

## 6. Data Verification

When it is determined that data from this IPM will be CRITICAL to a study, the following checks should be performed.

*[Include the Data Verification checks specified in the referenced IPM.]*

#	PARAMETERS	DESCRIPTION
1.	NOTDONE ^= '' and (DCS01 ^= '' or DCS02 ^= '' or DCS03 ^= '' or DCS04 ^= '' or DCS05 ^= '' or DCS06 ^= '' or DCS07 ^= '' or DCS08 ^= '' or DCS09 ^= '' or DCS10 ^= '')	Not Done is indicated, but data are present on the CRF.
2.	NOTDONE = '' and (DCS01 = '' and DCS02 = '' and DCS03 = '' and DCS04 = '' and DCS05 = '' and DCS06 = '' and DCS07 = '' and DCS08 = '' and DCS09 = '' and DCS10 = '')	Not Done is blank and no data are present on the CRF.
3.	DCS01 = ''	Aches and Pain is blank.
4.	DCS02 = ''	Feels Sick is blank.
5.	DCS03 = ''	Feels Tired is blank.
6.	DCS04 = ''	Trouble Concentrating is blank.
7.	DCS05 = ''	Feels Confused is blank.

#	PARAMETERS	DESCRIPTION
8.	DCS06 = ‘	Feels Clumsy is blank.
9.	DCS07 = ‘	Accomplish Less is blank.
10.	DCS08 = ‘	Bad Mood is blank.
11.	DCS09 = ‘	Feels Grouchy is blank.
12.	DCS10 = ‘	Feels Depressed is blank.
13.	DCS01: 1, 5	Aches and Pain is out of the range 1-5.
14.	DCS02: 1, 5	Feels Sick is out of the range 1-5.
15.	DCS03: 1, 5	Feels Tired is out of the range 1-5.
16.	DCS04: 1, 5	Trouble Concentrating is out of the range 1-5.
17.	DCS05: 1, 5	Feels Confused is out of the range 1-5.
18.	DCS06: 1, 5	Feels Clumsy is out of the range 1-5.
19.	DCS07: 1, 5	Accomplish Less is out of the range 1-5.
20.	DCS08: 1, 5	Bad Mood is out of the range 1-5.
21.	DCS09: 1, 5	Feels Grouchy is out of the range 1-5.
22.	DCS10: 1, 5	Feels Depressed is out of the range 1-5.

## 7. Individual Patient Data Display Requirements

### 7.1 CRF Tabulation Requirements

Appendix #  
Patient Data Tabulation

Study Title Line 1  
Study Title Line 2

Protocol:  
Patient ID:  
Treatment Group:

Age (yr):  
Race:  
Sex:

[Optional 1]:  
[Optional 2]:  
[Optional 3]:

#### Restorative Sleep Questionnaire

Study Day	Aches and Pain <i>DCS01</i>	Feels Sick <i>DCS02</i>	Feels Tired <i>DCS03</i>	Trouble Concentrating <i>DCS04</i>	Feels Confused <i>DCS05</i>	Feels Clumsy <i>DCS06</i>	Accomplish Less <i>DCS07</i>	Bad Mood <i>DCS08</i>	Feels Grouchy <i>DCS09</i>	Feels Depressed <i>DCS10</i>	Total Score <i>TOTSCR</i>
1	2	2	2	2	2	2	2	2	2	2	25

(Page X of Y)

## 7.2 Listing Table Requirements

[optional: HH:MM dd-mon-yyyy]

Appendix #  
Daytime Consequences of Sleep Questionnaire  
Title of Study (Line 1)  
Title of Study (Line 2)  
[optional: third title]

Protocol xxxx-xxx-xxx [optional: subset information]

Treatment Group	Patient ID	Study Day	Total Score
Study Med 1	1		<b>TOTSCR</b>
		1	25
		2	56.3
...			
Study Med 2	2		<b>TOTSCR</b>
		1	75
		2	62.6
...			

---

(Page X of Y)

## 8. Summary Data Display Requirements

### 8.1 Summary Table Requirements

Appendix #  
[Title of Summary]

[Study Title]

Protocol xxxx-xxx-xxx

Total Score	Rxgrp 1 (N=xx) <sup>a</sup>	Rxgrp 2 (N=xx)	Rxgrp 3 (N=xx)
Time (Baseline)			
N <sup>b</sup>	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median (Min, Max)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)
Time (Timepoint X)			
N <sup>b</sup>	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median (Min, Max)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)
Time (Change from Baseline to Timepoint X)			
N <sup>c</sup>	23	23	23
Mean, SD	69.5, 4.55	69.5, 4.55	69.5, 4.55
Median (Min, Max)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)	65.3 (33.4, 96.7)

<sup>a</sup> [This is the total number of patients in that treatment group]

<sup>b</sup> [This is the total number of subjects in that treatment group that answered the questionnaire]

<sup>c</sup> [This is the total number of subjects with data at both time points]

### 8.2 Summary Graphical Display Requirements

Not Applicable

## 9. Statistical Information

The relationship between Total Score (or the change from baseline, or the percent change from baseline) and the doses or the pharmacokinetic parameters (plasma concentrations, AUC's or Cmax's) may be analyzed with a linear model. Additional predictor variables such as subject effects or time post dose, or covariates such as age or gender, may be included in the linear model as deemed appropriate. For each effect, point estimates, standard errors, 95% confidence intervals and p-values for  $H_0$ : effect = 0 should be reported. For comparisons of interest among the effects, the same statistics should be reported.

IPM Appendices	
Appendix 1	
Appendix 2	
Appendix 3	
Appendix 4	
Appendix 5	
Appendix 6	Comment Document