SWOG
S2209 COVER SHEET FOR PARTICIPANT-COMPLETED QUESTIONNAIRES

Participant Identifier | | | | | | | **Study Identifier** | S | 2 | 2 | 0 | 9 | **Registration Step** |

Participant Initials _____ (L, F M)

Page: Cover Sheet for Participant-Completed Questionnaires

Instructions: Please complete form at the time points listed below.

Time Point

- ◯ Baseline
- ◯ Month 1
- ◯ Month 3
- ◯ Month 9
- ◯ Month 18

PARTICIPANT-COMPLETED QUESTIONNAIRES

Was the EORTC QLQ-C30 completed?

- ◯ Yes
- ◯ No

If the participant-completed questionnaire was completed

Did the participant require assistance? ◯ Yes ◯ No

If yes, who provided assistance?

- ◯ Caregiver
- ◯ Clinical Research Associate
- ◯ Clinical Research Coordinator
- ◯ Domestic Partner
- ◯ Family member
- ◯ Friend
- ◯ Guardian
- ◯ Healthcare Professional
- ◯ Investigator
- ◯ Parent
- ◯ Proxy
- ◯ Sibling
- ◯ Significant Other
- ◯ Spouse
- ◯ Other, specify:_____

How was the questionnaire completed?

- ◯ In the clinic
- ◯ By telephone
- ◯ Completed at home and returned
- ◯ Other, specify:_____

If the participant-completed questionnaire was <u>not</u> completed

What was the primary reason?

- ◯ Illness/deteriorating health
- ◯ Not illness related
- ◯ Institution error
- ◯ Death
- ◯ Other, specify:_____

Comments

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

SWOG
S2209 PRO-CTCAE

Participant Identifier | | | | | | | **Study Identifier** | S | 2 | 2 | 0 | 9 | **Registration Step** | 1 |

Participant Initials _____ (L, F M) **Cycle Number** | | |

Date Questionnaire Completed | | | | | | | | | |

Page: PRO-CTCAE

Instructions: Submit the baseline form within 15 days after registration and subsequent forms within 15 days after the end of each cycle up to Cycle 18. Explain any blank fields or dates in the **Comments** section. All dates are **DD MON YYYY**.

Was the PRO-CTCAE completed for this cycle? ◯ Yes ◯ No

Patient Instructions: As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, select the answer that best describes your experiences **over the past 7 days…**

1a	In the last 7 days, what was the SEVERITY of your FATIGUE, TIREDNESS, OR LACK OF ENERGY at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe
1b	In the last 7 days, how much did FATIGUE, TIREDNESS, OR LACK OF ENERGY INTERFERE with your usual or daily activities?	☐ Not At All ☐ A Little Bit ☐ Somewhat ☐ Quite A Bit ☐ Very Much
2a	In the last 7 days, how OFTEN did you have PAIN?	☐ Never ☐ Rarely ☐ Occasionally ☐ Frequently ☐ Almost constantly
2b	In the last 7 days, what was the SEVERITY of your PAIN at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe
2c	In the last 7 days, how much did PAIN INTERFERE with your usual or daily activities?	☐ Not At All ☐ A Little Bit ☐ Somewhat ☐ Quite A Bit ☐ Very Much

(continued on next page)

Item Library Version 1.0
English

Participant Identifier | | | | | | | **Study Identifier** | S | 2 | 2 | 0 | 9 | **Registration Step** | 1 |

Participant Initials _____ (L, F M) **Cycle Number** | | |

Date Questionnaire Completed | | | | | | | | | |

Page: PRO-CTCAE, continued

3a	In the last 7 days, what was the SEVERITY of your NUMBNESS OR TINGLING IN YOUR HANDS OR FEET at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
3b	In the last 7 days, how much did NUMBNESS OR TINGLING IN YOUR HANDS OR FEET INTERFERE with your usual or daily activities?	☐ Not at all ☐ A little bit ☐ Somewhat ☐ Quite a bit ☐ Very much

(continued on next page)

SWOG
S2209 PRO-CTCAE

Participant Identifier | | | | | | | **Study Identifier** | S | 2 | 2 | 0 | 9 | **Registration Step** | 1 |

Participant Initials _____ (L, F M)

Cycle Number | | |

Date Questionnaire Completed | | | | | | | | | | |

Page: PRO-CTCAE, continued

OTHER SYMPTOMS

Do you have any other symptoms that you wish to report? ◯ Yes ◯ No

If yes, please list any other symptoms:

1 _____	In the last 7 days, what was the SEVERITY of this symptom at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
2 _____	In the last 7 days, what was the SEVERITY of this symptom at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
3 _____	In the last 7 days, what was the SEVERITY of this symptom at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
4 _____	In the last 7 days, what was the SEVERITY of this symptom at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
5 _____	In the last 7 days, what was the SEVERITY of this symptom at its WORST?	☐ None ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe

Item Library Version 1.0
English