

SWOG PROMIS-29 PROFILE V2.1

Version Date: 07-21-2021

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____ (L, F M)	Date Questionnaire Completed		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

Page: PROMIS-29 Profile v2.1

Timepoint <i>(derived in Rave)</i>	<input type="radio"/> Baseline <input type="radio"/> Week 4 <input type="radio"/> Week 12 <input type="radio"/> Week 24 <input type="radio"/> Week 52
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Instructions: Please respond to each question or statement by marking one box per row.

	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
<u>Physical Function</u>					
1. Are you able to do chores such as vacuuming or yard work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Anxiety</u> In the past 7 days...	Never	Rarely	Some- times	Often	Always
5. I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Depression</u> In the past 7 days...	Never	Rarely	Some- times	Often	Always
9. I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Participant Identifier	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	Study Identifier	<input style="width: 20px; height: 20px;" type="text"/> S <input style="width: 20px; height: 20px;" type="text"/> 2 <input style="width: 20px; height: 20px;" type="text"/> 0 <input style="width: 20px; height: 20px;" type="text"/> 1 <input style="width: 20px; height: 20px;" type="text"/> 3	Registration Step	<input style="width: 20px; height: 20px;" type="text"/> 1
Participant Initials _____	(L, F M)	Date Questionnaire Completed	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>		

Page: PROMIS-29 Profile v2.1, continued

<u>Fatigue</u> During the past 7 days...	Not at all	A little bit	Some-what	Quite a bit	Very much
13. I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have trouble <u>starting</u> things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. How run-down did you feel on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. How fatigued were you on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Sleep Disturbance</u> In the past 7 days...	Very poor	Poor	Fair	Good	Very good
17. My sleep quality was	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the past 7 days...	Not at all	A little bit	Some-what	Quite a bit	Very much
18. My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Ability to Participate in Social Roles and Activities</u>	Never	Rarely	Some-times	Usually	Always
21. I have trouble doing all of my regular leisure activities with others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I have trouble doing all of the family activities that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I have trouble doing all of my usual work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I have trouble doing all of the activities with friends that I want to do	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Page: PROMIS-29 Profile v2.1, continued

	<u>Pain Interference</u> In the past 7 days...	Not at all	A little bit	Some-what	Quite a bit	Very much						
25.	How much did pain interfere with your day to day activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
26.	How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
27.	How much did pain interfere with your ability to participate in social activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
28.	How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>						
	<u>Pain Intensity</u> In the past 7 days...	No Pain								Worst pain imaginable		
29.	How would you rate your pain on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		0	1	2	3	4	5	6	7	8	9	10

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PROMIS COGNITIVE FUNCTION – SHORT FORM 4A

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____ (L, F M)	Date Questionnaire Completed <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>				

Page: PROMIS Cognitive Function - Short Form 4a

Timepoint (<i>derived in Rave</i>)	<input type="radio"/> Baseline <input type="radio"/> Week 4 <input type="radio"/> Week 12 <input type="radio"/> Week 24 <input type="radio"/> Week 52
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Instructions: Please respond to each question or statement by marking one box per row.

In the past 7 days...	Never	Rarely (Once)	Sometimes (Two or three times)	Often (About once a day)	Very often (Several times a day)
1. My thinking has been slow.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. It has seemed like my brain was not working as well as usual.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I have had to work harder than usual to keep track of what I was doing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I have had trouble shifting back and forth between different activities that require thinking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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SWOG FACT-G (Version 4)

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____	(L, F M)	Date Questionnaire Completed	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

Page: FACT-G (Version 4)

Timepoint *(derived in Rave)*

Baseline
 Week 4
 Week 12
 Week 24
 Week 52

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	Not at all	A little bit	Some-what	Quite a bit	Very much
I am bothered by side effects of treatment	1	2	3	4	5

English (Universal)
 Copyright 1987, 1997

SWOG S2013 PRO-CTCAE

Version Date: 07-21-2021

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____ (L, F M)	Date Questionnaire Completed		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

Page: PRO-CTCAE

Timepoint *(derived in Rave)*

- Baseline
- Week 4
- Week 12
- Week 24
- Weeks 52
- Suspected Grade 3 or higher irAE

Was the PRO-CTCAE completed for this timepoint?

- Yes No

Patient Instructions: As individuals go through treatment for their cancer they sometimes experience different symptoms and side effects. For each question, please check or mark an in the one box that best describes your experiences **over the past 7 days...**

1	In the last 7 days, how OFTEN did you have NAUSEA?	<input type="checkbox"/> Never <input type="checkbox"/> Rarely <input type="checkbox"/> Occasionally <input type="checkbox"/> Frequently <input type="checkbox"/> Almost constantly
2	In the last 7 days, what was the SEVERITY of your NAUSEA at its WORST?	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Very severe
3	In the last 7 days, how OFTEN did you LOSE CONTROL OF BOWEL MOVEMENTS?	<input type="checkbox"/> Never <input type="checkbox"/> Rarely <input type="checkbox"/> Occasionally <input type="checkbox"/> Frequently <input type="checkbox"/> Almost constantly
4	In the last 7 days, how much did LOSS OF CONTROL OF BOWEL MOVEMENTS INTERFERE with your usual or daily activities?	<input type="checkbox"/> Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Somewhat <input type="checkbox"/> Quite a bit <input type="checkbox"/> Very much

Item Library Version 1.0
English

The PRO-CTCAE™ items and information herein were developed by the NATIONAL CANCER INSTITUTE at the NATIONAL INSTITUTES OF HEALTH, in Bethesda, Maryland, U.S.A. Use of the PRO-CTCAE™ is subject to NCI's Terms of Use.

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SWOG S2013 PRO-CTCAE

Version Date: 07-21-2021

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Participant Initials _____ (L, F M)		Date Questionnaire Completed <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>			

Page: PRO-CTCAE, continued

5	In the last 7 days, what was the SEVERITY of your SHORTNESS OF BREATH at its WORST?	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Very severe
6	In the last 7 days, how much did your SHORTNESS OF BREATH INTERFERE with your usual or daily activities?	<input type="checkbox"/> Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Somewhat <input type="checkbox"/> Quite a bit <input type="checkbox"/> Very much
7	In the last 7 days, did you have any RASH?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8	In the last 7 days, what was the SEVERITY of your ITCHY SKIN at its WORST?	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Very severe
9	In the last 7 days, what was the SEVERITY of your NUMBNESS OR TINGLING IN YOUR HANDS OR FEET at its WORST?	<input type="checkbox"/> None <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Very severe
10	In the last 7 days, how much did NUMBNESS OR TINGLING IN YOUR HANDS OR FEET INTERFERE with your usual or daily activities?	<input type="checkbox"/> Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Somewhat <input type="checkbox"/> Quite a bit <input type="checkbox"/> Very much
11	In the last 7 days, how much did FATIGUE, TIREDNESS, OR LACK OF ENERGY INTERFERE with your usual or daily activities?	<input type="checkbox"/> Not at all <input type="checkbox"/> A little bit <input type="checkbox"/> Somewhat <input type="checkbox"/> Quite a bit <input type="checkbox"/> Very much

Item Library Version 1.0
English

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SWOG
S2013 FEASIBILITY QUESTIONNAIRE

Version Date: 07-21-2021

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____	(L, F M)	Date Questionnaire Completed	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Page: Feasibility Questionnaire

Instructions: We would like to hear about your experience with the Medidata Patient Cloud application ("Patient Cloud app").

1. For how many years have you used a mobile device, such as a smartphone or tablet?

- Less than 1 year
- 1-3 years
- 3-5 years
- More than 5 years
- I do not use mobile devices like smartphones or tablets

2. Everyone completed questionnaires like the PROMIS-29 on paper at baseline. When you registered to this study, how did you choose to complete questionnaires like the PROMIS-29 at follow-up visits?

- Patient Cloud app
- On paper

*(If Patient Cloud app, please answer **questions 3 through 9** below.)*

If on paper, please select the main reason why you did not choose Patient Cloud:

- Data privacy concerns
- I do not have a smartphone or tablet
- Lack of knowledge or experience using a smartphone or tablet
- Lack of experience using apps
- Symptoms related to cancer prevent me from using apps like Patient Cloud

Questions 3-9 are to be completed only by those who planned to use the Patient Cloud app to complete follow-up questionnaires. Those who chose to complete follow-up forms on paper are finished with this form.

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SWOG S2013 FEASIBILITY QUESTIONNAIRE

Version Date: 07-21-2021

Participant Identifier	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Study Identifier	<input type="text" value="S"/> <input type="text" value="2"/> <input type="text" value="0"/> <input type="text" value="1"/> <input type="text" value="3"/>	Registration Step	<input type="text" value="1"/>
Participant Initials _____ (L, F M)		Date Questionnaire Completed			
		<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Page: Feasibility Questionnaire, continued

3. What device(s) did you use to complete questionnaires in the Patient Cloud app? *(Mark all that apply)*

- My personal smartphone
- My personal tablet
- A tablet provided to me by the clinic
- Someone else's smartphone or tablet
- Prefer not to answer
- I did not complete any questionnaires

4. Thinking about each time you completed or tried to complete the questionnaires, how easy or difficult did you find it to log into the Patient Cloud app?
(Please mark one answer for every time point.)

Time point	Very Easy	Easy	Difficult	Very Difficult	Did not get to app
Week 4 (1 month)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 12 (3 months)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 24 (6 months)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 52 (1 year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. Thinking about each time you completed or tried to complete the questionnaires, how easy or difficult did you find it to complete the questionnaires after logging into the Patient Cloud app?
(Please mark one answer for every time point.)

Time point	Very Easy	Easy	Difficult	Very Difficult	Did not get to app
Week 4 (1 month)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 12 (3 months)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 24 (6 months)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Week 52 (1 year)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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SWOG
S2013 FEASIBILITY QUESTIONNAIRE

Version Date:07-21-2021

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Participant Initials _____ (L, F M)	Date Questionnaire Completed		<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Page: Feasibility Questionnaire, continued

6. When using the Patient Cloud application, how much help did you need?

- None
- Some
- A lot
- I prefer not to answer

7. When using the Patient Cloud application, what kind of help did you need? *(Mark all that apply)*

- Help installing the application
- Help registering with the application the first time
- Help reading Questions
- Help reading Answers
- Help submitting Questionnaires
- Log in or Password Assistance
- I prefer not to answer
- I did not need any help

8. If you did not complete questionnaires at week 4, 12, 24, or 52 using the Patient Cloud app, please select the main reason why not:

- Data privacy concerns
- Lack of knowledge or experience using a smartphone or tablet
- Lack of experience using apps
- Symptoms related to cancer preventing Patient Cloud usage
- Difficult to make time to complete questionnaires
- I completed all of my questionnaires using the Patient Cloud app

9. Would you have preferred to complete the questionnaires on paper?

- Yes
- No
- Not sure

Thank you. You are finished with this form.