

Appendix B: A full listing of the PROMIS Fatigue Item Bank with item content and an indication of the items included in each fixed-length form, submitted to FDA with Initial Briefing Package on August 11, 2017

PROMIS® Fatigue Item Bank

Variable Name	Item Stem	Reponse Choices	PROMIS "Universal" Bank	PROMIS Fatigue 7a	PROMIS Fatigue 4a	PROMIS Fatigue 6a	PROMIS Fatigue 8a	PROMIS Fatigue 10a	PROMIS Fatigue 13a
FATIMP1	To what degree did you have to push yourself to get things done because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP2	To what degree did your fatigue make you feel slowed down in your thinking?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP3	How often did you have to push yourself to get things done because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘				✘		
FATIMP4	How often did your fatigue interfere with your social activities?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP5	How often were you less effective at work due to your fatigue (include work at home)?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP6	How often did your fatigue make you feel slowed down in your thinking?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP8	How often were you too tired to watch television?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP9	How often did your fatigue make it difficult to plan activities ahead of time?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						

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FATIMP10	How often did your fatigue make it difficult to start anything new?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP11	How often did your fatigue make you more forgetful?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP13	How often were you too tired to do errands?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP14	How often did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP15	How often did your fatigue interfere with your ability to engage in recreational activities?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP16	How often did you have trouble finishing things because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X				X		
FATIMP17	How often did your fatigue make it difficult to make decisions?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP18	How often did you have to limit your social activities because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP19	How often were you too tired to do your household chores?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP20	How often did your fatigue make you feel less alert?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						

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FATIMP21	How often were you too tired to take a bath or shower?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘	✘					
FATIMP22	How often did your fatigue make it difficult to organize your thoughts when doing things at home?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP24	How often did you have trouble starting things because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP25	How often was it an effort to carry on a conversation because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP26	How often were you too tired to socialize with your family?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP27	To what degree did you have trouble starting things because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP28	How hard was it for you to carry on a conversation because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP29	How often were you too tired to leave the house?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATIMP30	How often were you too tired to think clearly?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘	✘					

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FATIMP33	How often did your fatigue limit you at work (include work at home)?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘	✘					
FATIMP34	To what degree did you have to limit your social activities because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP35	To what degree did your fatigue make it difficult to organize your thoughts when doing things at home?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP36	To what degree did your fatigue make it difficult to start anything new?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP37	Due to your fatigue were you less effective at work (include work at home)?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP38	To what degree did your fatigue make it difficult to make decisions?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATIMP40	How often did you have enough energy to exercise strenuously?	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always	✘	✘					

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FATIMP42	How often were you less effective at home due to your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP43	To what degree did your fatigue make it difficult to organize your thoughts when doing things at work (include work at home)?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP44	To what degree did your fatigue make you more forgetful?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP45	To what degree did your fatigue interfere with your ability to engage in recreational activities?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP47	To what degree did you have to force yourself to get up and do things because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP48	To what degree did your fatigue interfere with your social activities?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP49	To what degree did your fatigue interfere with your physical functioning?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X			X			

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FATIMP50	Did fatigue make you less effective at home?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP51	To what degree did you have trouble finishing things because of your fatigue?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP52	To what degree did your fatigue make you feel less alert?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATIMP53	How often were you too tired to take a short walk?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP55	How often did you have to force yourself to get up and do things because of your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATIMP56	How often were you too tired to socialize with your friends?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP2	How often did you feel run-down?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP5	How often did you experience extreme exhaustion?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X	X					

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FATEXP6	How often did you feel tired even when you hadn't done anything?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATEXP7	How often did you feel your fatigue was beyond your control?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATEXP12	To what degree did you feel tired even when you hadn't done anything?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP13	How bushed were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP16	How often were you sluggish?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATEXP18	How often did you run out of energy?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘	✘					
FATEXP19	How often were you physically drained?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘						
FATEXP20	How often did you feel tired?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	✘	✘					

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FATEXP21	How fatigued were you when your fatigue was at its worst?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATEXP22	How often were you bothered by your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP24	How often did you have enough energy to enjoy the things you do for fun?	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always	X						
FATEXP26	How often were you too tired to enjoy life?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP28	How often were you too tired to feel happy?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP29	How often did you feel totally drained?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP31	How often were you energetic?	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always	X						
FATEXP34	How tired did you feel on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						

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FATEXP35	How much were you bothered by your fatigue on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘			✘	✘		
FATEXP36	How exhausted were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP38	How fatigued were you on the day you felt most fatigued?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP40	How fatigued were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘		✘	✘	✘		
FATEXP41	How run-down did you feel on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘		✘	✘	✘		
FATEXP42	How much mental energy did you have on average?	5 = Not at all 4 = A little bit 3 = Somewhat 2 = Quite a bit 1 = Very much	✘						

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FATEXP43	How physically drained were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATEXP44	How energetic were you on average?	5 = Not at all 4 = A little bit 3 = Somewhat 2 = Quite a bit 1 = Very much	X						
FATEXP45	How sluggish were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						
FATEXP46	On how many days was your fatigue worse in the morning?	1 = None 2 = 1 day 3 = 2-3 days 4 = 4-5 days 5 = 6-7 days	X						
FATEXP48	How often did you find yourself getting tired easily?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X						
FATEXP49	How often did you think about your fatigue?	1 = Never 2 = Rarely 3 = Sometimes 4 = Often 5 = Always	X				X		
FATEXP50	How fatigued were you on the day you felt least fatigued?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						

Variable Name	Item Stem	Reponse Choices	PROMIS "Universal" Bank	PROMIS Fatigue 7a	PROMIS Fatigue 4a	PROMIS Fatigue 6a	PROMIS Fatigue 8a	PROMIS Fatigue 10a	PROMIS Fatigue 13a
FATEXP51	How easily did you find yourself getting tired on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP52	How wiped out were you on average?	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						
FATEXP54	How often did you have physical energy?	5 = Never 4 = Rarely 3 = Sometimes 2 = Often 1 = Always	✘						
FATEXP56	What was the level of your fatigue on most days?	1 = None 2 = Mild 3 = Moderate 4 = Severe 5 = Very Severe	✘						
HI7	I feel fatigued	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘		✘	✘	✘	✘	✘
HI12	I feel weak all over	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						✘
AN1	I feel listless ("washed out")	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	✘						✘

Variable Name	Item Stem	Reponse Choices	PROMIS "Universal" Bank	PROMIS Fatigue 7a	PROMIS Fatigue 4a	PROMIS Fatigue 6a	PROMIS Fatigue 8a	PROMIS Fatigue 10a	PROMIS Fatigue 13a
AN2	I feel tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X
AN3	I have trouble <u>starting</u> things because I am tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X		X	X	X	X	X
AN4	I have trouble <u>finishing</u> things because I am tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X
AN8	I need to sleep during the day	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X
AN12	I am too tired to eat	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X						X
AN14	I need help doing my usual activities	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X

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AN15	I am frustrated by being too tired to do the things I want to do	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X
AN16	I have to limit my social activity because I am tired	1 = Not at all 2 = A little bit 3 = Somewhat 4 = Quite a bit 5 = Very much	X					X	X
AN5	I have energy	5 = Not at all 4 = A little bit 3 = Somewhat 2 = Quite a bit 1 = Very much	X					X	X
AN7	I am able to do my usual activities	5 = Not at all 4 = A little bit 3 = Somewhat 2 = Quite a bit 1 = Very much	X					X	X