Supplementary Material

Supplemental Figure 1. Subject Usability and Satisfaction Scale (Ver 2.0)

<u>**Section A: Usability**</u>

1. **How easy or difficult was it for you to apply the patch on your body?**

Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
1	2	3	4	5	6	7

2. **How easy or difficult was it to pair the patch with the mobile phone application (app)?**

Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
1	2	3	4	5	6	7

3. **How easy or difficult was it for you to use the mobile phone application (app)?**

Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
1	2	3	4	5	6	7

4. **How easy or difficult was it for you to use the Digital Medicine System?**

Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
1	2	3	4	5	6	7

5. **How well do you agree with the following statement?**
   - **In general, I did not mind wearing the patch.**

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6	7

6. Since your last visit, did you receive assistance when changing and pairing the required patches? Yes   No

If yes,

	Never	**Once a month or less**	**A few times a month**	**Once a week**	**A few times a week**	**Daily**
How much assistance did you receive when applying the patches?						
How much assistance did you receive when syncing the technology?						

If you did receive any help or assistance, who helped or assisted you?
(please place a √ [check] to indicate who helped or assisted you)

Friend	**Hired Caregiver**	**Relative***	**Other****

*If a relative helped or assisted you, then please specify their relationship to you (such as wife, husband, father, mother, sister, brother, or whatever else you think is the most appropriate description of the relative who helped you): _____

**If you selected "Other", please specify your relationship to the person who helped you _____

Section B: Satisfaction

7. How easy or difficult was it for you to use the entire Digital Medicine System, which includes the patch, pills, and mobile phone application (app)?

Extremely Difficult	**Difficult**	**Somewhat Difficult**	**Neutral**	**Somewhat Easy**	**Easy**	**Extremely Easy**
1	**2**	**3**	**4**	**5**	**6**	**7**

8. **How helpful or unhelpful was the Digital Medicine System in the management of your condition?**

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

9. **How helpful or unhelpful was the Digital Medicine System for sharing information with your healthcare professionals to help you understand your treatment plan?**

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

10. **How helpful or unhelpful was the Digital Medicine System in improving your discussions with your doctor / treatment team?**

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

11. **Based on your experience, how would you rate your satisfaction with the Digital Medicine System?**

Extremely Dissatisfied	Dissatisfied	Somewhat Dissatisfied	Neutral	Somewhat Satisfied	Satisfied	Extremely Satisfied
1	2	3	4	5	6	7

12. **How likely would you be to use the Digital Medicine System in the future, if it were available and recommended by your doctor?**

Extremely Unlikely	Unlikely	Somewhat Unlikely	Neutral	Somewhat Likely	Likely	Extremely Likely
1	2	3	4	5	6	7

Supplemental Figure 2. Physician Utility Survey (Ver 2.0)

We ask the Principal Investigator, Physician Investigator, and Trial Coordinator(s) at a clinical site/trust to complete this survey for each patient enrolled. Please answer the below questions based on your overall experience using DMS.

1. **How easy or difficult was it for you and your patient to apply the patch on the patient's body?**

	Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
	1	2	3	4	5	6	7
For you							
For your patient							

2. **How easy or difficult was it for you and your patient to sync the patch with the mobile phone application (app)?**

	Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
	1	2	3	4	5	6	7
For you							
For your patient							

3. **How easy or difficult was it for you and your patient to complete the overall onboarding for the Digital Medicine System?**

	Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
	1	2	3	4	5	6	7
For you							
For your patient							

4. **Overall, how easy or difficult was it for you and your patient to use the mobile phone application (app)?**

	Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
	1	2	3	4	5	6	7
For you							
For your patient							

5. **Overall, how easy or difficult was it for you and your patient to use the entire Digital Medicine System, which includes the patch, pills, and mobile phone application (app)?**

	Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
	1	2	3	4	5	6	7
For you							
For your patient							

6. **How easy or difficult was it for you to use the HCP dashboard?**

Extremely Difficult	Difficult	Somewhat Difficult	Neutral	Somewhat Easy	Easy	Extremely Easy
1	2	3	4	5	6	7

7. **If you were in routine clinical practice (ie, in clinical practice without a study protocol), how helpful or unhelpful do you think the Digital Medicine System could be for the following elements of clinical management for this specific patient?**

	Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
	1	2	3	4	5	6	7
Assessment							
Clinical Advice/ Recommendations							
Treatment Decisions							

8. **How effective was the Digital Medicine System in aiding decision-making for medication adherence?**

Extremely Not Effective	Not Effective to Use	Somewhat Not Effective to Use	Neutral	Somewhat Effective to Use	Effective to Use	Extremely Effective to Use
1	2	3	4	5	6	7

9. **How helpful or unhelpful was the Digital Medicine System in providing a way to better engage your patients in self-management of their condition?**

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

10. **How helpful or unhelpful was the Digital Medicine System in improving quality of care for your patient?**

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

11. How helpful or unhelpful was the Digital Medicine System in improving your conversations with your patient about their treatment plan and progress?

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

12. How helpful or unhelpful was the Digital Medicine System in the identification of potential lifestyle changes for your patient (eg sleep and exercise)?

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful
1	2	3	4	5	6	7

13. Other than during the patient visit(s), did you look at the HCP dashboard at other times? Please select all that apply

	Place a √ (check) next to the time you referred to the HCP dashboard
No, only during the patient visit	
Prior to patient visit (same day as visit)	
In between visits	
Other: *Please Specify:* _____	

14. What features did you find helpful?   Please select all that apply

	Place a √ (check) next to the features you found helpful	For the features you have selected, please rank these features from 1 (most helpful) to 7 (least helpful) in order of helpfulness
Pill ingestion data		
Patient reported reason code for missed doses		
Multiple dose alerts		
Missed dose alerts		
Activity		
Rest		
Patient reported rest quality rating		
Other: *Please Specify:* _____		

15. Did you set up alerts to be notified of missed doses? Yes/no

   a. If yes, based on your overall experience, how helpful were the missed dose alerts?

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful	Not Applicable – No alerts received
1	2	3	4	5	6	7	

   15a. If you received a missed dose alert what action did you take, if any? (If none, please write N/A) _____

16. Did you set up alerts to be notified of multiple doses? Yes/no

   a. If yes, based on your overall experience, how helpful were the multiple dose alerts?

Extremely Unhelpful	Unhelpful	Somewhat Unhelpful	Neutral	Somewhat Helpful	Helpful	Extremely Helpful	Not Applicable – No alerts received
1	2	3	4	5	6	7	

16a. If you received a multiple dose alert what action did you take, if any? (If none, please write N/A _____

17. How well do you agree with the following statement?

   a. Overall, the Digital Medicine System adds value to my practice.

Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
1	2	3	4	5	6	7

18. Based on your overall experience with this patient, how would you rate your satisfaction with the Digital Medicine System?

Extremely Dissatisfied	Dissatisfied	Somewhat Dissatisfied	Neutral	Somewhat Satisfied	Satisfied	Extremely Satisfied
1	2	3	4	5	6	7

Supplemental Figure 3. Caregiver/Support Person Involvement Scale (Ver 2.0)

DMS Caregiver/Support Person Involvement Scale

1. **Are you aware that the study participant/patient is currently participating in the Digital Medicine study (check one)?**

Yes	No*

*If no, stop here and do not answer the rest of the questions on this form.

2. **Indicate your relationship to the study participant/patient by placing a √ (check).**

Friend	Hired Caregiver	Relative*	Other**

*If you are a relative, please specify relationship to the study participant/patient, e.g., wife, father:

**If you selected "Other", please specify your relationship to the study participant/patient:

_____

3. **How much involvement did you provide the subject with regard to taking medication, pairing the patch, applying the patch, and using the app during the course of the study?**

	Never	Once a month or less	A few times a month	Once a week	A few times a week	Daily
How much overall assistance did you provide the subject during the course of the study?						
How much assistance did you provide with patch application?						
How much assistance did you provide with syncing the technology?						
How much assistance did you provide with using the app?						
	Never	Once a week	A few times a week	Nearly every day	Daily	More than once/day
How much overall assistance did you provide during the past week of the study?						

Clinical Global Impression Scale

Clinical Global Impression – Severity Scale (CGI-S)

Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

0 = Not assessed   4 = Moderately ill

1 = Normal, not at all ill   5 = Markedly ill

2 = Borderline mentally ill   6 = Severely ill

3 = Mildly ill   7 = Among the most extremely ill subjects

Supplemental Figure 4. Personal and Social Performance Scale

Original version: Morosini PL, Magliano L, Brambilla L, et al. Development, reliability and acceptability of a new version of the DSM-IV Social and Occupational Functioning Assessment Scale (SOFAS) to assess routine social functioning. *Acta Psychiatr Scand* 2000;101(4):323-9 Copyright © 2000 John Wiley & Sons, Inc. Reproduced with permission of Blackwell Publishing Ltd.

Personal and Social Performance Scale (PSP)

The rating is based on four main areas: (a) socially useful activities, including work and study; (b) personal and social relationships; (c) self-care; and (d) disturbing and aggressive behaviors.

Data will be captured in the following format using the PSP descriptions provided below:

	Absent	Mild	Manifest	Marked	Severe	Very Severe
a. Socially useful activities, including work and study	☐	☐	☐	☐	☐	☐
b. Personal and social relationships	☐	☐	☐	☐	☐	☐
c. Self-care	☐	☐	☐	☐	☐	☐
d. Disturbing and aggressive behaviors	☐	☐	☐	☐	☐	☐

The levels of functioning in other areas should be taken into account to adjust the rating inside the decimal level (for instance, from 31 to 40). Suicidal risk is not included in the scale.

10-point intervals	PSP descriptions
100–91	Excellent functioning in all four main areas*. He/she is held in high consideration for his/her good qualities, copes adequately with life problems, is involved in a wide range of interests and activities.
90–81	Good functioning in all four main areas, presence of only common problems or difficulties.
80–71	Mild difficulties in 1 or more of areas a–c.
70–61	Manifest, but not marked difficulties in 1 or more areas a–c, or mild difficulties in d.
60–51	Marked difficulties in 1 of areas a–c, or manifest difficulties in d.
50–41	Marked difficulties in 2 or more, or severe difficulties in 1 of areas a–c, with or without manifest difficulties in d.
40–31	Severe difficulties in 1 and marked difficulties in at least 1 of areas a–c, or marked difficulties in d.
30–21	Severe difficulties in 2 of areas a–c, or severe difficulties in d, with or without impairment in areas a–c.
20–11	Severe difficulties in all areas a–d, or very severe in d with or without impairment in general areas a–c. If the person reacts to external prompts the suggested scores are 20–16, if not, the suggested scores are 15–11.
10–1	Lack of autonomy in basic functioning with extreme behaviors but without survival risk (ratings 6–10) or with survival risk, eg, death risk due to malnutrition, dehydration, infections, inability to recognize situation of manifest danger (ratings 5–1).

For main areas a–c, the degrees of severity are:

Absent	
Mild	Not manifest difficulties, known only to someone who is very familiar with the person.
Manifest, but not marked	Difficulties clearly noticeable by everyone, but not interfering substantially with the person's ability to perform his/her role in that area, given the person's socio-cultural context, age, sex and educational levels.
Marked	Difficulties heavily interfering with role performance in that area; however, the person is still able to do something without professional or social help, although inadequately and/or occasionally; if helped by someone, he/she may be able reach the previous level of functioning.
Severe	Difficulties that make the person unable to perform any role in that area, if not professionally helped, or lead the person to a destructive role; however, there are no survival risks.
Very severe	Impairments and difficulties of such intensity to endanger person's survival.

For general area d, the degrees of severity are:

Absent	
Mild	Mild rudeness, unsociability or whingeing.
Manifest, but not marked	Speaking too loudly or speaking to others in a too-familiar manner, or eating in a socially unacceptable manner.
Marked	Insulting other in public, breaking or wrecking objects, acting frequently in a socially inappropriate but not dangerous way (eg, stripping in public or urinating in public).
Severe	Frequent verbal threats or frequent physical assaults, without intention or possibility of severe injuries.
Very severe	Frequent aggressive acts, aimed at or likely to cause severe injuries.

Occasional is defined as occurring three or more times in the reference period or occurring even less than three times but in circumstances and/or with such a previous history to convince the rater that there is a risk of recurrence in the near future. If the aggressive behavior has been present occasionally, the rating may be decreased by one degree, eg, from severe to marked.

* Main areas: a = socially useful activities, including work and study; b = personal and social relationships; c = self-care; d = disturbing and aggressive behaviors.

Guidelines for PSP Total Score

Ratings from 71–100 reflect only mild difficulties.
Ratings from 31–70 reflect manifest disabilities of various degrees.
Ratings from 1–30 reflect functioning so poor that intensive support or supervision is needed.

Supplemental Figure 5. Patient Activation Measure-Mental Health Scale

The following questions ask about your feelings regarding your mental healthcare. When you think about mental health and mental health care, how much do you agree or disagree with the following statements? Please circle the answer that you most agree with:

1. When all is said and done, I am the person who is responsible for managing my mental health.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

2. Taking an active role in my own mental health is the most important factor in determining my mental health and ability to function.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my mental health condition.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

4. I know what each of my prescribed mental health medications does.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

5. I am confident that I can tell when I need to go get mental health care, and when I can handle a mental health problem myself.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

6. I am confident I can tell my mental health clinician about concerns I have, even when he or she does not ask.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

7. I am confident that I can follow through on mental health treatments I need to do at home.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

8. I understand the nature and causes of my mental health condition(s).

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

9. I know the different treatment options available for my mental health condition(s).

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

10. I am able to maintain the lifestyle changes I have made for my mental health.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

11. I know how to prevent further mental health problems.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

12. I am confident I can figure out solutions when new situations or problems arise with my mental health.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree

13. I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.

1	2	3	4
Strongly Disagree	Disagree	Agree	Strongly Agree