

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Eleusis Health Solutions US, Inc.      Confirmation No.: 9172  
Serial No.: 17/910,452      Group No.:  
Filing or 371(c) Date: March 9, 2021      Examiner:  
Entitled: METHODS AND SYSTEMS FOR ENHANCING CLINICAL SAFETY OF  
PSYCHOACTIVE THERAPIES

**THIRD-PARTY PRE-ISSUANCE SUBMISSION**

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application:

1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)
2. CARHART-HARRIS (2016) “Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study” *The Lancet Psychiatry*, 3(7): 619-627
3. SLOSHOWER (2020) “Psilocybin-assisted therapy of major depressive disorder using Acceptance and Commitment Therapy as a therapeutic frame” *Journal of Contextual Behavioral Science*, 15:12-19

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 17/910,452 Pending Claims	Reference
<p><b>1.</b> A method of monitoring a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; and (ii) transferring the session data from the access module to a remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 34, line 20-24</b> “The invention features methods and systems involving a patient who is <b>undergoing treatment with a psychedelic agent</b> or who is a candidate for treatment with a psychedelic agent. In some embodiments, the invention involves <b>monitoring patients undergoing treatment with psychedelic agents</b>, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania.”</p> <p>From <b>patent document page 27, line 26-28</b> “The systems and methods of this invention can include or be implemented using <b>any suitable processing system(s)</b>. Suitable processing systems include a computer based server (e.g., a <b>remote server</b>)”</p>
<p><b>2.</b> The method of claim 1, further comprising: (iii) within the access module, processing the session data to derive a patient response metric.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 24 line 1-2</b> “In some embodiments, the invention provides methods and systems that utilize <b>automated behavioral analysis to determine a risk measure</b>”</p> <p>From <b>patent document page 19 line 38-39</b> “In some embodiments, the invention <b>provides methods and systems that utilize automated speech analysis to determine a risk measure.</b>”</p>
<p><b>3.</b> The method of claim 2, further comprising: (iv) transferring the patient response metric from the access module to the remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 28 line 19-22</b> “In some embodiments, the server database contains sufficient audio-video link information to establish audio and video communication between the candidate or patient and a clinician. For example, the server and database may contain both the internet address information for the practitioner,</p>

	<p>patient, and any third parties as needed, and also <b>act to relay the data packets between the parties</b>”</p> <p>From <b>patent document page 16 line 23-33</b> “The invention includes a software application delivered via computer, smartphone, or other device (e.g. mobile device), which is capable <b>of collecting patient data</b> through textual and/or audio recording of responses to automated and clinician administered structured interviews and surveys, audio recording of phone conversations, mobile sensors and other psychometric information gathered from a smartphone or other mobile device, and other prompted and unprompted voice, text, keypad, pushbutton, or other forms of computerized data captures. The invention is further capable of converting this data into a format capable of being rapidly analyzed in automated assessments in one or more validated quantitative frameworks capable of identifying prodromal or manifest symptoms of psychosis, hypomania, and mania. The invention is also capable of recording the results of these automated quantitative assessments and <b>making them available to supervisory clinicians</b> should they indicate a patient is in need of immediate attention”</p>
<p>4. A method of monitoring a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; and (ii) within the access module, processing the session data to derive a patient response metric indicative of a patient response to the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 23-33</b> “The invention includes a software application delivered via computer, smartphone, or other device (e.g. mobile device), which is capable <b>of collecting patient data</b> through textual and/or audio recording of responses to automated and clinician administered structured interviews and surveys, audio recording of phone conversations, mobile sensors and other psychometric information gathered from a smartphone or other mobile device, and other prompted and unprompted voice, text, keypad, pushbutton, or other forms of computerized data captures. The invention is further capable of <b>converting this data into a format capable of being rapidly analyzed in automated assessments in one or more validated quantitative frameworks</b> capable of identifying prodromal or manifest symptoms of psychosis, hypomania, and mania. The invention is also capable of recording the results of these automated quantitative assessments and <b>making them available to supervisory</b></p>

	<p><b>clinicians</b> should they indicate a patient is in need of immediate attention”</p>
<p><b>5.</b> The method of claim 4, further comprising: (iv) transferring unprocessed session data from the access module to the remote monitor; and/or (iii) transferring the patient response metric from the access module to a remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 40 line 33-36</b> “the patient would either be kept at the hospital for further observation by clinicians, or would agree to adhere to a <b>smartphone-based screening program that would allow clinicians to remotely assess the patient's risk</b> for developing psychosis, hypomania, or mania”</p>
<p><b>6.</b> The method of any one of claims 1-3 or 5, wherein the session data is transferred from the access module to the remote monitor in real-time.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 19 line 26</b> “In some embodiments, the language sample is <b>processed in real time</b>”</p>
<p><b>7.</b> The method of any one of claims 1-6, wherein the session data comprises digitally recorded data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 5 line 14-15</b> “In some embodiments, the language sample is a <b>text sample and/or an audio sample.</b>”</p> <p>From <b>patent document page 5 line 19-20</b> “In some embodiments, the <b>audio sample is transcribed into text.</b>”</p>
<p><b>8.</b> The method of claim 7, wherein the digitally recorded data comprises video and/or audio data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 28 line 25-27</b> “In general, in order to ensure quality and a consistent user interface, often the server will both present the telemedicine user interface (e.g. present one or more web pages for telemedicine applications) in addition to <b>relaying the audio and video data packets</b>”</p>

<p>9. The method of claim 7 or 8, wherein the digitally recorded data comprises wearable sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or <b>smart wearable device</b>), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”</p>
<p>10. The method of any one of claims 7-9, wherein the digitally recorded data comprises EEG sensor data or infrared sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., <b>passive infrared sensors</b>, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device), or biosensors (e.g., <b>sensors that detect physiological characteristics</b>, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”</p>

<p><b>11.</b> The method of any one of claims 7-10, wherein the patient response metric comprises a measure of movement throughout the treatment setting derived from the digitally recorded data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 6 line 23-24</b> “In some embodiments, the measure of activity comprises a <b>measure of movement.</b>”</p>
<p><b>12.</b> The method of claim 11, wherein a high measure of movement throughout the treatment setting indicates an adverse patient response to the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 6 line 24-26</b> “In some embodiments, the <b>measure of movement is positively correlated with the risk of developing psychosis, hypomania, or mania</b>”</p>
<p><b>13.</b> The method of any one of claims 7-12, wherein the patient response metric comprises a measure of conversation between the patient and the attendant.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 18 line 6-7</b> “<b>Language samples</b> can be passively acquired (e.g., <b>recorded</b>, e.g., from <b>conversations that the candidate or patient has...</b>)”</p>
<p><b>14.</b> The method of claim 13, wherein a lengthy inaudible conversation between the patient and the attendant indicates a deviation from protocol.</p>	
<p><b>15.</b> The method of claim 12 or 14, further comprising alerting a clinical support staff member of the adverse patient response.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-35</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is <b>at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition</b>”</p>
<p><b>16.</b> The method of claim 15, wherein the clinical support staff member is the remote monitor, a non-certified staff</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p>

<p>member, a certified, clinician, or a physician.</p>	<p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)”</p>
<p><b>17.</b> The method of claim 15 or 16, wherein, after alerting the clinical support staff member of the adverse patient response, the clinical support staff member: (a) intervenes in the psychoactive therapy session; (b) alerts another clinical support staff member; and/or (c) escalates the alert to a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>18.</b> The method of claim 17, wherein part (b) further comprises escalating the alert to a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)”</p>
<p><b>19.</b> The method of claim 17 or 18, wherein the physician intervenes in the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis,</p>

	<p>hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention and/or discontinuation of the associated drug treatment.</b>”</p>
<p><b>20.</b> The method of claim 19, wherein the intervention is a remote intervention or a local intervention.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention and/or discontinuation of the associated drug treatment.</b>”</p>
<p><b>21.</b> The method of any one of claims 1-20, wherein the session data comprises manually recorded data provided by the attendant.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 12-14</b> “Passive acquisition can occur at predetermined time points and/or for predetermined durations. In other instances, <b>passive acquisition of behavioral samples can be initiated manually</b>”</p>
<p><b>22.</b> The method of claim 21, wherein the manually recorded data comprises a rating of unresponsiveness.</p>	
<p><b>23.</b> The method of claim 21 or 22, wherein the manually recorded data comprises a patient self-report.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 26 line 15-23</b> “In some embodiments, a candidate or patient identified as at risk of developing psychosis, hypomania, or mania can undergo additional testing for confirmation or comparison. Any suitable test known in the art may be used. For example... the <b>Altman Self-Rating Mania Scale...</b>”</p>



<p><b>24.</b> The method of claim 22 or 23, wherein the patient response metric comprises a measure of anxiety and/or paranoid ideation.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 2 line 17-20</b> “In some embodiments, any of the methods of the invention include screening the candidate for a likelihood of having or developing a <b>paranoid ideation</b> or propensity toward paranoid thinking, paranoid personality disorder, a personality disorder, an intellectual disability (e.g., intellectual developmental disorder), or bipolar disorder.”</p>
<p><b>25.</b> The method of claim 24, wherein a high measure of anxiety and/or paranoid ideation indicates an adverse patient response to the psychoactive therapy session.</p>	
<p><b>26.</b> The method of claim 25, further comprising alerting a clinical support staff member of the adverse patient response.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 27 line 41 – page 28 line 3</b> “A system of the invention may include a software application (e.g., a patient-interface application, e.g., a mobile-device application) that accesses such a database conditionally or automatically to <b>send one or more notifications, alerts, reports, or other information to a third party</b> (e.g., to a computing platform (e.g., a remote database) or a <b>clinical professional</b>) for storage or analysis.”</p>
<p><b>27.</b> The method of claim 26, wherein the clinical support staff member is the remote monitor, a non-certified staff member, a certified, clinician, or a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)”</p>
<p><b>28.</b> The method of claim 26 or 27, wherein, after alerting the clinical support staff member</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p>

<p>of the adverse patient response, the clinical support staff member: (a) intervenes in the psychoactive therapy session; (b) alerts another clinical support staff member; and/or (c) escalates the alert to a physician.</p>	<p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>29.</b> The method of claim 28, wherein part (b) further comprises escalating the alert to a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)”</p>
<p><b>30.</b> The method of claim 28 or 29, wherein the physician intervenes in the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>

<p><b>31.</b> The method of claim 30, wherein the intervention is a remote intervention or a local intervention.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>32.</b> A method of intervening in a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; (ii) transferring the session data from the access module to a remote monitor; (iii) identifying an aberrance in the session data; and (iv) summoning clinical support to the treatment setting, thereby intervening in the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 34, line 20-24</b> “The invention features methods and systems involving a patient who is <b>undergoing treatment with a psychedelic agent</b> or who is a candidate for treatment with a psychedelic agent. In some embodiments, the invention involves <b>monitoring patients undergoing treatment with psychedelic agents</b>, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania.”</p> <p>From <b>patent document page 27, line 26-28</b> “The systems and methods of this invention can include or be implemented using <b>any suitable processing system(s)</b>. Suitable processing systems include a computer based server (e.g., a <b>remote server</b>)”</p> <p>From <b>patent document page 24 line 1-2</b> “In some embodiments, the invention provides methods and systems that utilize <b>automated behavioral analysis</b> to <b>determine a risk measure</b>”</p> <p>From <b>patent document page 19 line 38-39</b> “In some embodiments, the invention <b>provides methods and systems that utilize automated speech analysis</b> to <b>determine a risk measure.</b>”</p>
<p><b>33.</b> The method of claim 32, wherein the aberrance is misconduct by the attendant.</p>	

<p><b>34.</b> The method of claim 32 or 33, further comprising: (v) within the access module, processing the session data to derive a patient response metric.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 24 line 1-2</b> “In some embodiments, the invention provides methods and systems that utilize <b>automated behavioral analysis to determine a risk measure</b>”</p>
<p><b>35.</b> The method of claim 34, further comprising: (iv) transferring the patient response metric from the access module to the remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 28 line 19-22</b> “In some embodiments, the server database contains sufficient audio-video link information to establish audio and video communication between the candidate or patient and a clinician. For example, the server and database may contain both the internet address information for the practitioner, patient, and any third parties as needed, and also <b>act to relay the data packets between the parties</b>”</p>
<p><b>36.</b> The method of any one of claims 32-35, wherein the aberrance is an adverse patient response to the psychoactive therapy session.</p>	<p>2. CARHART-HARRIS (2016) “Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study” <i>The Lancet Psychiatry</i>, 3(7): 619-627</p> <p>From <b>Summary – Methods</b> “Patients were monitored for adverse reactions during the dosing sessions and subsequent clinic and remote follow-up.”</p>
<p><b>37.</b> The method of any one of claims 1-36, wherein the access module and/or remote monitor receives session data from multiple treatment settings simultaneously.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 9 line 1-3</b> “In another aspect, the invention features a method of administering a psychedelic agent to a patient in need thereof, the method including: (i) <b>obtaining one or more measures of risk derived from one or more behavioral characteristics</b> of a behavioral sample obtained from the patient”</p>
<p><b>38.</b> The method of any one of claims 1-37, wherein the</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p>

<p>remote monitor is not a physician.</p>	<p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a physician, <b>pharmacist, administrative professional, nurse, support professional, or caretaker</b>).</p>
<p><b>39.</b> The method of claim 38, wherein the remote monitor is equipped with a secure connection to a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 28 line 29-31</b> “In any of the embodiments described above, the system can be configured to adhere to health-related privacy laws (e.g., HIPAA). For example, systems can be configured to privatize and/or anonymize individual data according to <b>encryption protocols.</b>”</p>
<p><b>40.</b> A method of intervening in a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; (ii) within the access module, processing the session data to derive a patient response metric indicative of a patient response to the psychoactive therapy session; (iii) identifying an aberrance based on the patient response metric; and (iv) summoning a clinical support staff member to the treatment setting, thereby</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 34, line 20-24</b> “The invention features methods and systems involving a patient who is <b>undergoing treatment with a psychedelic agent</b> or who is a candidate for treatment with a psychedelic agent. In some embodiments, the invention involves <b>monitoring patients undergoing treatment with psychedelic agents</b>, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania.”</p> <p>From <b>patent document page 27, line 26-28</b> “The systems and methods of this invention can include or be implemented using <b>any suitable processing system(s)</b>. Suitable processing systems include a computer based server (e.g., <b>a remote server</b>)”</p> <p>From <b>patent document page 24 line 1-2</b> “In some embodiments, the invention provides methods and systems that utilize <b>automated behavioral analysis to determine a risk measure</b>”</p> <p>From <b>patent document page 19 line 38-39</b> “In some embodiments, the invention <b>provides methods and systems that utilize automated speech analysis to determine a risk measure.</b>”</p>

<p>intervening in the psychoactive therapy session.</p>	<p>From <b>patent document page 28 line 19-22</b> “In some embodiments, the server database contains sufficient audio-video link information to establish audio and video communication between the candidate or patient and a clinician. For example, the server and database may contain both the internet address information for the practitioner, patient, and any third parties as needed, and also <b>act to relay the data packets between the parties</b>”</p> <p>From <b>patent document page 16 line 23-33</b> “The invention includes a software application delivered via computer, smartphone, or other device (e.g. mobile device), which is capable of <b>collecting patient data</b> through textual and/or audio recording of responses to automated and clinician administered structured interviews and surveys, audio recording of phone conversations, mobile sensors and other psychometric information gathered from a smartphone or other mobile device, and other prompted and unprompted voice, text, keypad, pushbutton, or other forms of computerized data captures. The invention is further capable of converting this data into a format capable of being rapidly analyzed in automated assessments in one or more validated quantitative frameworks capable of identifying prodromal or manifest symptoms of psychosis, hypomania, and mania. The invention is also capable of recording the results of these automated quantitative assessments and <b>making them available to supervisory clinicians</b> should they indicate a patient is in need of immediate attention”</p>
<p><b>41.</b> The method of claim 40, wherein the clinical support staff member is the remote monitor, a non-certified staff member, a certified, clinician, or a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)</p>
<p><b>42.</b> The method of claim 40 or 41, wherein, after alerting the clinical support staff member of the adverse patient response, the clinical support staff member: (a) intervenes in the psychoactive therapy session; (b) alerts another</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a</p>

<p>clinical support staff member; and/or (c) escalates the alert to a physician.</p>	<p>psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>43.</b> The method of claim 42, wherein part (b) further comprises escalating the alert to a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)</p>
<p><b>44.</b> The method of claim 42 or 43, wherein the physician intervenes in the psychoactive therapy session.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis, hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>45.</b> The method of claim 44, wherein the intervention is a remote intervention or a local intervention.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 16 line 33-37</b> “The invention is also capable of <b>alerting clinicians</b> should these results indicate a patient is at risk of developing psychosis,</p>

	<p>hypomania, or mania, or is currently experiencing a psychotic or manic condition, enabling a retest of the patient to avoid possible false-positive result, excluding the patient if they have not yet commenced a drug treatment, and if warranted, <b>emergency medical intervention</b> and/or discontinuation of the associated drug treatment.”</p>
<p><b>46.</b> The methods of any one of claims 40-45, further comprising transferring the patient response metric from the access module to a remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 40 line 33-36</b> “the patient would either be kept at the hospital for further observation by clinicians, or would agree to adhere to a <b>smartphone-based screening program that would allow clinicians to remotely assess the patient's risk</b> for developing psychosis, hypomania, or mania”</p>
<p><b>47.</b> The method of any one of claims 40-46, further comprising transferring unprocessed session data from the access module to the remote monitor.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 40 line 33-36</b> “the patient would either be kept at the hospital for further observation by clinicians, or would agree to adhere to a <b>smartphone-based screening program that would allow clinicians to remotely assess the patient's risk</b> for developing psychosis, hypomania, or mania”</p>
<p><b>48.</b> The method of any one of claims 32-47, wherein the session data comprises digitally recorded data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 5 line 14-15</b> “In some embodiments, the language sample is a <b>text sample and/or an audio sample.</b>”</p> <p>From <b>patent document page 5 line 19-20</b> “In some embodiments, the <b>audio sample is transcribed into text.</b>”</p>
<p><b>49.</b> The method of claim 48, wherein the digitally recorded data comprises video and/or audio data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 28 line 25-27</b> “In general, in order to ensure quality and a consistent user interface, often</p>



	<p>the server will both present the telemedicine user interface (e.g. present one or more web pages for telemedicine applications) in addition to <b>relaying the audio and video data packets</b>”</p>
<p><b>50.</b> The method of claim 48 or 49, wherein the digitally recorded data comprises wearable sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a <b>sensor</b>. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or <b>smart wearable device</b>), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”</p>
<p><b>51.</b> The method of any one of claims 48-50, wherein the digitally recorded data comprises EEG sensor data or infrared sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., <b>passive infrared sensors</b>, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device), or biosensors (e.g., <b>sensors that detect physiological characteristics</b>, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood</p>

	glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”
<b>52.</b> The method of any one of claims 48-51, wherein the patient response metric comprises a measure of movement throughout the treatment setting derived from the digitally recorded data.	1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)  From <b>patent document page 6 line 23-24</b> “In some embodiments, the measure of activity comprises a <b>measure of movement.</b> ”
<b>53.</b> The method of claim 52, wherein the aberrance is an adverse patient response to the psychoactive therapy session indicated by a high measure of movement throughout the treatment setting.	1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)  From <b>patent document page 6 line 24-26</b> “In some embodiments, the <b>measure of movement is positively correlated with the risk of developing psychosis, hypomania, or mania</b> ”
<b>54.</b> The method of any one of claims 48-53, wherein the patient response metric comprises a measure of conversation between the patient and the attendant.	1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)  From <b>patent document page 18 line 6-7</b> “ <b>Language samples</b> can be passively acquired (e.g., <b>recorded</b> , e.g., from <b>conversations that the candidate or patient has...</b> )”
<b>56.</b> The method of any one of claims 32-55, wherein the session data comprises manually recorded data provided by the attendant.	1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)  From <b>patent document page 22 line 12-14</b> “Passive acquisition can occur at predetermined time points and/or for predetermined durations. In other instances, <b>passive acquisition of behavioral samples can be initiated manually</b> ”
<b>57.</b> The method of claim 56, wherein the manually recorded data comprises a rating of unresponsiveness.	
<b>58.</b> The method of claim 56 or 57, wherein the manually	1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)

<p>recorded data comprises a patient self-report.</p>	<p>From <b>patent document page 26 line 15-23</b> “In some embodiments, a candidate or patient identified as at risk of developing psychosis, hypomania, or mania can undergo additional testing for confirmation or comparison. Any suitable test known in the art may be used. For example... the <b>Altman Self-Rating Mania Scale...</b>”</p>
<p><b>59.</b> The method of any one of claims 56-58, wherein the patient response metric comprises a measure of anxiety and/or paranoid ideation.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 2 line 17-20</b> “In some embodiments, any of the methods of the invention include screening the candidate for a likelihood of having or developing a <b>paranoid ideation</b> or propensity toward paranoid thinking, paranoid personality disorder, a personality disorder, an intellectual disability (e.g., intellectual developmental disorder), or bipolar disorder.”</p>
<p><b>60.</b> The method of claim 59, wherein the aberrance is an adverse patient response to the psychoactive therapy session indicated by a high measure of anxiety and/or paranoid ideation.</p>	<p>2. CARHART-HARRIS (2016) “Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study” <i>The Lancet Psychiatry</i>, 3(7): 619-627</p> <p>From <b>page 625</b> “The <b>most common adverse events were transient anxiety</b> (mostly mild) during drug onset (n=12), transient confusion or thought disorder (n=9), mild and transient nausea (n=4), and transient headache (n=4; table 2) <b>These adverse events were expected psychological effects of psilocybin.</b>”</p>
<p><b>61.</b> A method of training clinical staff for monitoring a psychoactive therapy session, the method comprising:  (i) performing a method of any one of claims 1-60;  (ii) providing one or more trainees;  (iii) presenting session data to the one or more trainees; and  (iv) providing a characterization of the session data to the one or more</p>	<p>3. SLOSHOWER (2020) “Psilocybin-assisted therapy of major depressive disorder using Acceptance and Commitment Therapy as a therapeutic frame” <i>Journal of Contextual Behavioral Science</i>, 15:12-19</p> <p>From <b>page 17</b> “6. Therapist training  Once the therapy manual was completed, we devised a <b>training program for study therapists</b>. All therapists recruited for the study are <b>licensed clinicians</b> with extensive clinical experience treating patients with depression.”</p>

<p>trainees, thereby training clinical staff.</p>	
<p><b>62.</b> The method of claim 61, wherein the clinical staff is an attendant, a remote monitor, a clinical professional, or a physician.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 1 line 42 – page 2 line 2</b> “The third party can be, for example, a <b>clinical professional</b> (e.g., a <b>physician</b>, pharmacist, administrative professional, nurse, support professional, or caretaker)</p>
<p><b>63.</b> A method of conducting a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; (ii) within the access module: (a) processing the session data to derive a first patient response metric indicative of a psychoactive drug effect; and (b) processing the session data to derive a subsequent patient response metric indicative of the psychoactive drug effect; and (iii) comparing the first patient response metric with the subsequent patient response metric; and (iv) based on the comparison of (iii), determining whether to dismiss the patient from the treatment setting.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 34, line 20-24</b> “The invention features methods and systems involving a patient who is <b>undergoing treatment with a psychedelic agent</b> or who is a candidate for treatment with a psychedelic agent. In some embodiments, the invention involves <b>monitoring patients undergoing treatment with psychedelic agents</b>, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania.”</p> <p>From <b>patent document page 27, line 26-28</b> “The systems and methods of this invention can include or be implemented using <b>any suitable processing system(s)</b>. Suitable processing systems include a computer based server (e.g., a <b>remote server</b>)”</p> <p>From <b>patent document page 24 line 1-2</b> “In some embodiments, the invention provides methods and systems that utilize <b>automated behavioral analysis to determine a risk measure</b>”</p> <p>From <b>patent document page 19 line 38-39</b> “In some embodiments, the invention <b>provides methods and systems that utilize automated speech analysis to determine a risk measure.</b>”</p> <p>From <b>patent document page 40 line 29-34</b> “Ketamine and esketamine are used as anti-depressant therapies for use in severe major depression. Use of the invention in the context of using ketamine or esketamine for the treatment of depression involves application as both a screening tool, to exclude patients at risk for psychosis, hypomania, or mania,</p>

	<p>as well as in the release interview for the patient, <b>enabling clinicians to confirm the drug effects have subsided</b> and the absence of lingering psychotic or manic symptoms.”</p>
<p><b>64.</b> The method of claim 63, wherein the access module comprises a processor, and wherein the processor performs the comparison of (iii).</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 7-18</b> “In another aspect, the invention features a <b>computer system for assessing a risk</b> of precipitating or exacerbating psychosis, hypomania, or mania in a patient undergoing treatment with a psychedelic agent or a candidate for treatment with a psychedelic agent, the computer system including: (i) a mobile device comprising one or more input mechanisms, a <b>processor</b>, and one or more output mechanisms; and (ii) a software program readable by the processor, the software program featuring instructions for: (a) using the <b>one or more input mechanisms</b>, obtaining one or more language and/or behavioral samples from the user; (b) using the processor, deriving <b>one or more language characteristics</b> from the one or more language samples and/or <b>one or more behavioral characteristics</b> from the one or more behavioral samples; and based on the one or more language and/or behavioral characteristics, <b>determining a measure of risk</b>, wherein the measure of risk correlates with a risk of precipitating or exacerbating psychosis, hypomania, or mania in the candidate; and (c) using the one or more output mechanisms, reporting the measure of risk to the user and/or a third party.”</p>
<p><b>65.</b> A method of editing session data from a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session; and (ii) within the access module: (a) processing the session data comprising a pertinent dataset and an extraneous dataset to derive a patient response metric indicative of a patient</p>	

<p>response to the psychoactive therapy session, wherein the patient response metric is preferentially based on the pertinent dataset; and (b) producing an edited dataset by isolating the pertinent dataset from the extraneous dataset.</p>	
<p><b>66.</b> A method of generating a patient response database, the method comprising: (i) via an access module, receiving session data from a first psychoactive therapy session and session data from a second psychoactive therapy session, wherein the first and second psychoactive therapy sessions are each conducted in a treatment setting comprising a patient and an attendant, wherein no physician is present in the treatment setting during either of the first and second psychoactive therapy sessions; (ii) within the access module: (a) processing the session data from the first psychoactive therapy session to derive a first patient response metric indicative of a first patient response to the psychoactive therapy session; and (b) processing the session data from the second psychoactive therapy session to derive a second patient response metric indicative of a second patient response to the psychoactive therapy session; (iii) recording the first patient response metric and the second patient response metric to a computer-readable</p>	

<p>medium, thereby generating a patient response database.</p>	
<p>67. The method of claim 66, further comprising deriving an average patient response from the first patient response and the second patient response.</p>	
<p>68. A method of monitoring a psychoactive therapy session, the method comprising: (i) receiving session data via an access module, wherein the session data is transmitted to the access module from the psychoactive therapy session, wherein the psychoactive therapy session is conducted in a treatment setting comprising a patient and an attendant, and wherein no physician is present in the treatment setting; and (ii) within the access module, processing the session data to derive a patient response metric indicative of a patient response to the psychoactive therapy session, wherein the processing draws reference data from a patient response database generated by the method of claim 66 or 67.</p>	
<p>69. The method of any one of claims 1-68, wherein the psychoactive therapy session is for treatment of a psychological condition.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 37 – page 14 line 5</b> “As used herein, "well-being" refers to a positive state of health or comfort, e.g., relative to a reference population. As used herein "mental well-being" refers to a positive mental state, relative to a reference population. For example, in an individual having <b>depression, low self-esteem, addiction, compulsion, or anxiety</b> may experience an improvement in</p>

	<p>mental well-being in response to therapy aimed at improving mood, self-esteem, addiction, compulsion, or anxiety, respectively. As used herein, "physical well-being" refers to one or more positive aspects of an individual's physical health. For example, an improvement of physical well-being includes alleviation of somatic symptoms associated with a <b>psychological disorder, depression, addiction, compulsion, anxiety, or sexual dysfunction</b>. Such symptoms include, for example, chronic pain, pain disorder, relational disorder, body dysmorphia, conversion (e.g., loss of bodily function due to anxiety), hysteria, neurological conditions without identifiable cause, or psychosomatic illness).”</p>
<p><b>70.</b> The method of claim 69, wherein the psychological condition is depression, anxiety, PTSD, or substance abuse, alcoholism, anorexia nervosa, bulimia, obesity, eating disorders, or obsessive-compulsive disorder.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 37 – page 14 line 5</b> “As used herein, "well-being" refers to a positive state of health or comfort, e.g., relative to a reference population. As used herein "mental well-being" refers to a positive mental state, relative to a reference population. For example, in an individual having depression, low self-esteem, addiction, compulsion, or anxiety may experience an improvement in mental well-being in response to therapy aimed at improving mood, self-esteem, addiction, compulsion, or anxiety, respectively. As used herein, "physical well-being" refers to one or more positive aspects of an individual's physical health. For example, an improvement of physical well-being includes alleviation of somatic symptoms associated with a psychological disorder, <b>depression, addiction, compulsion, anxiety, or sexual dysfunction</b>. Such symptoms include, for example, chronic pain, pain disorder, relational disorder, body dysmorphia, conversion (e.g., loss of bodily function due to anxiety), hysteria, neurological conditions without identifiable cause, or psychosomatic illness).”</p>
<p><b>71.</b> The method of any one of claims 1-68, wherein the psychoactive therapy session is for treatment of a non-psychological condition.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 37 – page 14 line 5</b> “As used herein, "well-being" refers to a positive state of health or comfort, e.g., relative to a reference population. As used herein "mental well-being" refers to a positive mental</p>



	<p>state, relative to a reference population. For example, in an individual having depression, low self-esteem, addiction, compulsion, or anxiety may experience an improvement in mental well-being in response to therapy aimed at improving mood, self-esteem, addiction, compulsion, or anxiety, respectively. As used herein, "physical well-being" refers to one or more positive aspects of an individual's physical health. For example, an improvement of physical well-being includes alleviation of somatic symptoms associated with a psychological disorder, depression, addiction, compulsion, anxiety, or sexual dysfunction. Such symptoms include, for example, <b>chronic pain, pain disorder</b>, relational disorder, body dysmorphia, conversion (e.g., loss of bodily function due to anxiety), hysteria, neurological conditions without identifiable cause, or psychosomatic illness).”</p>
<p>72. The method of claim 71, wherein the non-psychological condition is an autoimmune condition or a pain.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 37 – page 14 line 5</b> “As used herein, "well-being" refers to a positive state of health or comfort, e.g., relative to a reference population. As used herein "mental well-being" refers to a positive mental state, relative to a reference population. For example, in an individual having depression, low self-esteem, addiction, compulsion, or anxiety may experience an improvement in mental well-being in response to therapy aimed at improving mood, self-esteem, addiction, compulsion, or anxiety, respectively. As used herein, "physical well-being" refers to one or more positive aspects of an individual's physical health. For example, an improvement of physical well-being includes alleviation of somatic symptoms associated with a psychological disorder, depression, addiction, compulsion, anxiety, or sexual dysfunction. Such symptoms include, for example, <b>chronic pain, pain disorder</b>, relational disorder, body dysmorphia, conversion (e.g., loss of bodily function due to anxiety), hysteria, neurological conditions without identifiable cause, or psychosomatic illness).”</p>
<p>74. The method of any one of claims 1-68, wherein the psychoactive therapy session is for enhancing well-being.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 13 line 37 – page 14 line 5</b> “As used herein, "<b>well-being</b>" refers to a positive state of</p>

	<p>health or comfort, e.g., relative to a reference population. As used herein "<b>mental well-being</b>" refers to a positive mental state, relative to a reference population. For example, in an individual having depression, low self-esteem, addiction, compulsion, or anxiety may experience an improvement in mental well-being in response to therapy aimed at improving mood, self-esteem, addiction, compulsion, or anxiety, respectively. As used herein, "physical well-being" refers to one or more positive aspects of an individual's physical health. For example, an improvement of physical well-being includes alleviation of somatic symptoms associated with a psychological disorder, depression, addiction, compulsion, anxiety, or sexual dysfunction. Such symptoms include, for example, <b>chronic pain, pain disorder</b>, relational disorder, body dysmorphia, conversion (e.g., loss of bodily function due to anxiety), hysteria, neurological conditions without identifiable cause, or psychosomatic illness).”</p>
<p>75. The method of any one of claims 1-70, wherein the psychoactive therapy session is conducted in the presence of one and only one attendant.</p>	
<p>76. The method of any one of claims 1-75, wherein the patient and the attendant are the only people in the treatment setting during the psychoactive therapy session.</p>	
<p>77. The method of any one of claims 1-76, wherein the psychedelic therapy session comprises a perceptual dose of a psychoactive agent.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 29 line 4-17</b> “For example, the patient may be determined as likely to benefit from a <b>perceptible dose</b> (e.g., a medium to high dose) of the psychedelic therapy. <b>In some embodiments, a perceptible dose of a psychedelic therapy is administered</b> (e.g., a dose of greater than about 0.1 µg/kg, greater than about 0.5 µg/kg, greater than about 1 .0 µg/kg, greater than about 5.0 µg/kg, greater than about 10 µg/kg, greater than about 20 µg/kg, greater than about 50 µg/kg, greater than about 100 µg/kg, greater than about 200 µg/kg, greater than about 500 µg/kg, greater than about 1 .0 mg/kg, greater than about 5.0 mg/kg,</p>

	<p>greater than about 10 mg/kg, greater than about 50 mg/kg, or greater than about 100 mg/kg body weight, e.g., from about 0.1 µg/kg to about 0.5 µg/kg, from about 0.5 µg/kg to about 10 µg/kg, from about 1 .0 µg/kg to about 5.0 µg/kg, from about 5.0 µg/kg to about 10 µg/kg, from about 10 µg/kg to about 50 µg/kg, from about 50 µg/kg to about 100 µg/kg, from about 100 µg/kg to about 500 µg/kg, from about 500 µg/kg to about 1 .0 mg/kg, from about 1 .0 mg/kg to about 10 mg/kg, from about 10 mg/kg to about 50 mg/kg, from about 50 mg/kg to about 1 00 mg/kg, or from about 100 mg/kg to about 500 mg/kg).”</p>
<p><b>78.</b> The method of any one of claims 1-77, wherein the psychoactive therapy session comprises administration of an agent selected from the group consisting of a 5-HT.sub.2A receptor agonist, an empathogenic agent, and a dissociative agent.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include <b>5-HT2A agonists</b> (e.g., lysergic acid diethylamide (LSD)), <b>empathogenic agents</b> (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and <b>dissociative agents</b> (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p>
<p><b>79.</b> The method of claim 78, wherein the psychoactive therapy session comprises administration of a 5-HT.sub.2A receptor agonist.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety</p>

	<p>of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include <b>5-HT2A agonists</b> (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p>
<p><b>80.</b> The method of claim 79, wherein the 5-HT.sub.2A receptor agonist is selected from lysergic acid diethylamide (LSD), psilocybin, DOI (±)-1-(2,5-dimethoxyphenyl)-2-aminopropane hydrochloride; (R)-DOI ((R)-1-(2,5-dimethoxy-4-iodophenyl)-2-aminopropane); LA-SS-Az (2'S,4'S)-(+)-9,10-Didehydro-6-methylergoline-8β-(trans-2,4-dimethylazetidide); 2C-BCB (4-Bromo-3,6-dimethoxybenzocyclobuten-1-yl)methylamine) ayahuasca; 3,4,5-trimethoxyphenethylamine (mescaline); 5-methoxy-N,N-dimethyltryptamine (5-meo-DMT); ibogaine; voacangine; noribogaine; coronaridine; 18-methoxycoronaridine (18-mc); methoxyethyl 18-MC; 18-methylaminocoronaridine (18-MAC); 2-methoxyethyl-18-methoxycoronaridinate; a compound of ##STR00006## or a pharmaceutically acceptable salt thereof.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include <b>5-HT2A agonists</b> (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p> <p>From <b>patent document page 15 line 1-7</b> “As used herein, a "5-HT2A agonist" refers to a compound that increases the activity of a 5-hydroxytryptamine 2A receptor. Examples of such agonists include psilocybin, <b>LSD, DOI (±)-1 -(2,5-dimethoxyphenyl)-2-aminopropane hydrochloride; (R)-DOI ((R)-1 -(2,5-dimethoxy-4-iodophenyl)-2-aminopropane) (greater than 95% R enantiomer); LA-SS-Az (2'S,4'S)-(+)-9,10-Didehydro-6-methylergoline-8p-(trans-2,4-dimethylazetidide); 2C-BCB (4-Bromo-3,6-dimethoxybenzocyclobuten-1 -yl) methylamine; ayahuasca; 3,4,5-trimethoxyphenethylamine (mescaline); 5-methoxy-N,N-dimethyltryptamine (5-meo-DMT); ibogaine”</b></p>

<p><b>81.</b> The method of claim 78, wherein the psychoactive therapy session comprises administration of an empathogenic agent.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include 5-HT2A agonists (e.g., lysergic acid diethylamide (LSD), <b>empathogenic agents</b> (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p>
<p><b>82.</b> The method of claim 81, wherein the empathogenic agent is MDMA.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include 5-HT2A agonists (e.g., lysergic acid diethylamide (LSD), <b>empathogenic agents</b> (i.e., serotonin (5-HT) releasing agents; e.g., <b>MDMA</b>), and dissociative agents (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p>

<p><b>83.</b> The method of claim 78, wherein the psychoactive therapy session comprises administration of a dissociative agent.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include 5-HT2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and <b>dissociative agents</b> (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., ketamine).”</p>
<p><b>84.</b> The method of claim 83, wherein the dissociative agent is ketamine, esketamine, or arketamine.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 14 line 33-41</b> “As used herein, a "psychedelic agent" refers to a compound capable of inducing an altered state of consciousness, i.e., a marked deviation in the subjective experience or psychological functioning of a normal individual from his or her usual waking consciousness. Altered states of consciousness can be monitored, evaluated, and/or quantified using any of a variety of methods known in the art including, without limitation, Dittrich's APZ (Abnormal Mental States) questionnaire, and its revised versions, OAV and 5D-ASC (see, for example, Dittrich et al., A Pharmacopsychiatry 1998, 31 :80; Studerus et al., PLoS ONE 2010, 5). Psychedelic agents include 5-HT2A agonists (e.g., lysergic acid diethylamide (LSD), empathogenic agents (i.e., serotonin (5-HT) releasing agents; e.g., MDMA), and <b>dissociative agents</b> (i.e., N-Methyl-D-aspartate (NMDA) receptor agonists; e.g., <b>ketamine</b>).”</p>
<p><b>85.</b> A system comprising an access module configured to</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p>

<p>perform the method of any one of claims 1-84.</p>	<p>From <b>patent document page 34, line 20-24</b> “The invention features methods and systems involving a patient who is <b>undergoing treatment with a psychedelic agent</b> or who is a candidate for treatment with a psychedelic agent. In some embodiments, the invention involves <b>monitoring patients undergoing treatment with psychedelic agents</b>, e.g., for risk of precipitation or exacerbation of prodromal or symptomatic psychosis, mania, or hypomania.”</p> <p>From <b>patent document page 27, line 26-28</b> “The systems and methods of this invention can include or be implemented using <b>any suitable processing system(s)</b>. Suitable processing systems include a computer based server (e.g., a remote server)”</p>
<p><b>86.</b> The method of any one of claims 61-85, wherein the session data comprises wearable sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., passive infrared sensors, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or <b>smart wearable device</b>), or biosensors (e.g., sensors that detect physiological characteristics, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”</p>
<p><b>87.</b> The method of claim 86, wherein the sensor data comprises EEG sensor data or infrared sensor data.</p>	<p>1. Intl. Pat. Doc. No. WO2019079742 “Methods and systems for enhancing safety of psychedelic drug therapies” (Published April 25, 2019)</p> <p>From <b>patent document page 22 line 30-38</b> “In other instances, a behavioral sample detected by a sensor. For example, physical activity of an individual may be detected or monitored by a sensor. For example, physical sensors include any device able to detect physical activity or</p>

	<p>characteristics (e.g., mobility, physiology, and/or motion, e.g., psychomotor activity), including video sensors (e.g., video cameras), motion sensors (e.g., <b>passive infrared sensors</b>, ultrasonic sensors, microwave sensors, or tomographic sensors), GPS, accelerometers (e.g., as part of a mobile device, such as a smartphone or smart wearable device), or biosensors (e.g., <b>sensors that detect physiological characteristics</b>, such as body mass, body temperature, heart rate, breathing characteristics (e.g., rate or depth), or blood characteristics (e.g., blood pressure, blood glucose levels, blood-drug concentration (e.g., blood-alcohol concentration))).”</p>
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## Electronic Acknowledgement Receipt

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<b>Confirmation Number:</b>	9172
<b>Title of Invention:</b>	METHODS AND SYSTEMS FOR ENHANCING CLINICAL SAFETY OF PSYCHOACTIVE THERAPIES
<b>First Named Inventor/Applicant Name:</b>	Neiloufar FAMILY
<b>Customer Number:</b>	21559
<b>Filer:</b>	Sisi Li
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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	57340 ac6ea6bacad7fedd4aa1134581ea54cd724ea870	no	3
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3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23614 41e765fa17178263934804b80ecd33ef4c9fe15e	no	1
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7	Concise Description of Relevance	Claims_Chart.pdf	427431	no	32
			1b021274b59052eb6174b91841230ca9e7dd0ff5		

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8	Fee Worksheet (SB06)	fee-info.pdf	37312	no	2
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