

VISIT EVALUATION (VE)

DATA SECTION	COMPLETION INSTRUCTIONS
<p>PURPOSE</p> <p>PERSON(S) RESPONSIBLE</p> <p>SOURCE(S) OF INFORMATION</p> <p>WHEN TO ADMINISTER FORM:</p> <p>PATIENT ID</p> <p>TIME POINT</p> <p>DATE OF EVALUATION</p>	<p>To collect information on the status of a patient during the treatment and follow-up intervals, at the time of each protocol visit.</p> <p>Study Coordinator/study physician</p> <p>Patient and patient records</p> <p>Treatment Weeks 2, 4, 8, 12, 20 and 24 Follow-up Weeks 4 and 12 At the time of premature discontinuation of study</p> <p>SPECIFIC INSTRUCTIONS:</p> <p>Record the Patient ID number in the top left hand corner of the page.</p> <p>Record the protocol time point for the evaluation.</p> <p>Record the date (month/day/year) of the patient evaluation.</p>
<p>SECTION I: PHYSICAL ASSESSMENT</p>	<p><u>Weight:</u> Record weight in kilograms (kg). Round up if the fraction of grams if at least 500, otherwise, round down. (1lb. = 0.45kg)</p> <ul style="list-style-type: none"> • When appropriate, ask the patient to remove shoes and bulky clothing and to empty their pockets of all items. • Use consistent measurement technique across all protocol visits (e.g., same time of day). <p>If for any reason (e.g. wheelchair-bound, refusal, equipment failure, etc.) a measurement is not obtained, record “ND” (Not Done).</p> <p><u>Temperature:</u> Record the patient’s temperature in degrees Fahrenheit.</p> <p style="text-align: center;">Fahrenheit = (9/5) * Celsius +32</p> <p>If the patient’s temperature is not obtained, record “ND” (Not Done).</p> <p><u>Heart rate:</u> Record the patient’s heart rate in beats per minute (beats/min).</p> <p>If the patient’s heart rate is not obtained, record “ND” (Not Done).</p> <p><u>Blood pressure:</u> Measure the patient’s systolic and diastolic blood pressure in mmHg. Blood pressure should be obtained after the patient has been seated with both feet flat on the floor for at least 5 minutes.</p> <ul style="list-style-type: none"> • Use consistent measurement techniques across all visits (e.g. use the same arm). <p>If a blood pressure measurement is not obtained, record ND (Not Done).</p>
<p>SECTION II: ADVERSE EVENTS</p>	<p>1. <u>Since the previous evaluation has the patient had an adverse event?</u></p> <p>Check “Yes” or “No” to indicate whether or not the patient experienced an adverse event since the previous evaluation. If “Yes”, complete the Adverse Event (AE) form.</p>

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SECTION III: SYMPTOMS	<p><u>Since the previous evaluation has the patient had any of the following symptoms:</u></p> <p>Check “Yes” or “No” to indicate whether or not the patient experienced the symptom between this protocol evaluation and the previous in-person protocol evaluation.</p> <ol style="list-style-type: none"> 1. <u>Fatigue</u>: Defined as a lack of energy or weariness or chronically tired. Characterized as prolonged weakness or tiredness that is not relieved by adequate rest, sleep or by the removal of other stressful factors. The patient may feel rested but with daily activity feel tired or feel tired after awakening and throughout the day. 2. <u>Weakness</u>: Defined as a reduction in the strength or the feeling of the loss of strength of one or more muscles. The patient may feel that extra effort is required to move the muscles of the body. 3. <u>Nausea</u>: Defined as the sensation leading to the urge to vomit. 4. <u>Vomiting</u>: Defined as forcing the contents of the stomach through the esophagus and out of the mouth. 5. <u>Poor appetite</u>: Defined as a lack of appetite although there is a physical need for food. This may lead to unintentional weight loss. 6. <u>Weight loss</u>: Defined as any unintentional loss in weight. 7. <u>Muscle aches</u>: Defined as any pain in the muscles. Do not include pain that is due to recent overuse or exercise. 8. <u>Joint aches</u>: Characterized as pain or stiffness in one or more joints. 9. <u>Headache</u>: Defined as pain in the head from any cause. 10. <u>Pain over liver</u>: Pain in the upper right section of the abdomen. 11. <u>Other abdominal pain</u>: Defined as pain in the abdominal area, stomach region, or belly. May also be referred to as stomach pain, belly ache, or abdominal cramps. 12. <u>Rash</u>: Defined as an eruption or change in color or texture of the skin. Symptoms are skin redness or inflammation and skin lesions. 13. <u>Itching</u>: Defined as a peculiar tingling or uneasy irritation of the skin which causes a desire to scratch the affected part. 14. <u>Hair loss</u>: Defined as partial or complete loss of hair. Do not include hair loss due to pattern baldness, heredity, or aging. 15. <u>Fever</u>: Defined as a body temperature of 100 degrees Fahrenheit or above. 16. <u>Chills</u>: Defined as the sensation of cold from exposure to a cold environment, or an episode of shivering with paleness and a feeling of coldness.

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	<p>17. <u>Night sweats</u>: Defined as periodic sweating at night while sleeping without an obvious cause.</p> <p>18. <u>Cough</u>: Defined as the sudden forceful release of air from the lungs.</p> <p>19. <u>Shortness of breath</u>: Defined as difficult or uncomfortable breathing or a feeling of not getting enough air.</p> <p>20. <u>Irritability</u>: Defined as abnormal or excessive response to slight or harmless stimuli.</p> <p>21. <u>Trouble sleeping</u>: Defined as the inability to sleep, remain asleep throughout the night or feel refreshed by sleep.</p> <p>22. <u>Difficulty concentrating</u>: Defined as a lack of focus, ability to maintain attention on tasks, or a feeling of being easily distracted.</p> <p>23. <u>Depression</u>: Defined as having extreme feelings of sadness, dejection, lack of worth, and emptiness. There may be a loss of sense of pleasure in normal activities, decreased energy, change in sleeping habits, and feelings of hopelessness. Clinical definition of depression is the presence of these symptoms for at least a two week period.</p> <p>24. <u>Diarrhea</u>: Defined as frequent or loose bowel movements of unformed, watery stools.</p> <p>25. <u>Constipation</u>: Defined as infrequent or hard stools, or difficulty passing stools.</p> <p>26. <u>Other</u>: Any symptom that is not already listed. If yes, record the symptom in the space provided.</p>
SECTION IV: DEPRESSION MANAGEMENT	<p>Ask each of these questions of the patient, as written, to assess symptoms of depression and then check “Yes” or “No” to indicate their response. Notify the investigator if the patient responds “Yes” to any of the questions.</p> <ol style="list-style-type: none"> 1. <u>Have you felt depressed, sad, or blue most of the time?</u> 2. <u>Have you often felt helpless about the future?</u> 3. <u>Have you had thoughts about harming or killing yourself or others?</u>
SECTION V: CONCOMITANT MEDICATIONS	<ol style="list-style-type: none"> 1. <u>Since the previous evaluation has there been a change in concomitant medications taken?</u> <p>Check “Yes” or “No” to indicate whether or not there has been a change in concomitant medications taken since the previous evaluation. If “Yes”, update the Concomitant Medication Log and enter the information via the web-based entry form.</p> <p>Change refers to the start of a new medication or discontinuation of a medication. A change in dose for a medication already recorded on the Medication Log is not considered a change in medications.</p>
SECTION VI: COMMENTS	<p>Check whether there are comments regarding the evaluation. If yes, record the comments in the space provided. When referring to a specific item on the form, record the section and question number with the comment.</p>