

SCREENING EVALUATION (SE)

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>DATE OF EVALUATION</p>	<p>To collect information on medical history, current status of patient, and results of tests performed during the screening evaluation.</p> <p>Study Coordinator/study physician</p> <p>Patient, patient medical record and laboratories tests</p> <p>After a patient provides written informed consent to participate in the SyNCH Phase II study.</p> <p>GENERAL INSTRUCTIONS:</p> <p>This form is completed for all HCV patients screened for participation in the SyNCH Phase II study. The completed form is submitted to the Coordinating Center regardless of patient eligibility. If a patient is screened for the Phase II study and determined to be ineligible for participation, the form should still be completed and submitted to the Coordinating Center.</p> <p>SPECIFIC INSTRUCTIONS:</p> <p>Record the Patient ID number in the top left hand corner of each page.</p> <p>Record the date (month/day/year) that the screening evaluation is initiated, most likely the first screening visit. Provide year in four digit format.</p> <p>Check rescreen if the evaluation is being performed as part of the rescreen procedure.</p>
<p>SECTION I: DEMOGRAPHICS</p>	<p>GENERAL INSTRUCTION: Transcribe patient demographic information recorded on the Screening Demographic form.</p> <ol style="list-style-type: none"> 1. <u>Gender</u>: Check male or female to indicate patient gender. 2. <u>Date of birth</u>: Record the patient's date of birth. If any part of the birth date is unknown, record "Unk" in that field and complete the remaining fields. 3. <u>Is the patient Hispanic, Latino, or Latina?</u> Check "Yes" if the patient identifies himself/herself as Hispanic, Latino, or Latina. Hispanic is defined as a person of Cuban, Mexican, Puerto Rican, Central or South American, or other Spanish Culture or origin, regardless of race. Otherwise, check "No". 4. <u>With what race(s) does the patient identify?</u> Check the appropriate box(es) to indicate the race of the patient. If the patient identifies with more than one race, check all that apply. <ul style="list-style-type: none"> <u>White or Caucasian</u>: A person having origins in any of the original peoples of Europe, the Middle East, or North America. <u>Black or African-American</u>: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African-American". <u>Asian</u>: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the

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	<p>Philippine Islands, Thailand, and Vietnam.</p> <p><u>American Indian or Alaska Native:</u> A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.</p> <p><u>Native Hawaiian or Pacific Islander:</u> A person having origins in any of the original peoples of Hawaii, Guam, Samoa or other Pacific islands.</p> <p><u>Other:</u> Check this box if the patient’s racial background is not listed and specify in the space provided.</p> <p>NOTE: Some patients may identify their race with a specific country, such as indicating that they are “Scottish” or “Spanish” or “Swedish”. They are describing their ethnicity/origin, which should be correctly categorized as either “Hispanic, Latino, or Latina” , if applicable. They should identify race as one of the race categories listed.</p> <p>If a patient provides an ethnicity for the race, clarify the difference between race and ethnicity with the patient.</p> <p>“Ethnicity”, or origin, is defined as “The heritage, nationality group, lineage, or country of birth of the person or person’s parents or ancestors before their arrival in the United States.</p> <p>If after the clarification, the patient continues to insist the ethnicity is their race, record “Unk” (Unknown) for race.</p>
<p>SECTION II: PHYSICAL ASSESSMENT</p>	<p><u>Weight:</u> Record weight in kilograms (kg). Round up if the fraction of grams is at least 500, round down otherwise. (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>Height:</u> Record height in centimeters (cm). Round up if the fraction of millimeters is at least 5, round down otherwise. (1 inch = 2.54cm)</p> <ul style="list-style-type: none"> • Ask the patient to remove shoes. <p>If for any reason (e.g. wheelchair-bound, refusal, equipment failure, etc.) a standing 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. Use consistent measurement techniques across all visits (e.g. use the same arm).</p>

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	<p>If a blood pressure measurement is not obtained, record ND (Not Done).</p>
<p>SECTION III: MEDICAL HISTORY</p>	<ol style="list-style-type: none"> 1. <u>Does the patient have any known allergies to food or drug (including herbals)?</u> <p>Check "Yes" if the patient has a known allergy to any food or drug, including prescription, OTC, or herbal medications and record the food/drug and the type of reaction. Otherwise, check "No".</p> <p>If yes, specify food or drug and type of reaction. Refer to the codebook for the types of reactions and specify in the space provided if the type of reaction is not included in the listing.</p> 2. Has the patient used any milk thistle preparation for greater than 30 days duration in the past? <p>Check "Yes" if the patient has used a milk thistle preparation for greater than 30 days duration at any time in the past. Review the list of alternative names for milk thistle with the patient. Check "No" if the patient has used a milk thistle preparation for less than 30 days duration or never used them.</p> 3. <u>Has the patient been told by a doctor that he/she has diabetes:</u> <p>Check "Yes" if the patient has been told by a doctor that he/she has diabetes. If not, check "No".</p> <p>If yes,</p> <ol style="list-style-type: none"> a. <u>Is the patient's diabetes currently treated with oral medications?</u> <p>Check "Yes" if the patient currently uses oral medications to treat the diabetes. If not, check "No".</p> b. <u>Is the patient's diabetes currently treated with insulin?</u> <p>Check "Yes" if the patient's diabetes is currently treated with insulin. If not, check "No".</p> 4. <u>Has the patient been told by a doctor that he/she has high blood pressure or hypertension:</u> <p>Check "Yes" if the patient has been told by a doctor that he/she has high blood pressure or hypertension. If not, check "No".</p> <p>If yes, check all the current treatment(s) that apply.</p> <p><u>None:</u> No treatment regimen is currently being followed. <u>Diet:</u> Controlled by dietary management. <u>ACE inhibitors:</u> Agents that inhibit the circulating and tissue angiotensin-converting enzyme activity, thereby reducing angiotensin II formation. <u>Beta-blockers:</u> Agents that compete with epinephrine for beta-adrenergic receptor sites, reduce heart rate, and lower blood pressure. <u>Calcium channel blockers:</u> Agents that inhibit the transmembrane influx of calcium ions into cardiac muscle and smooth muscle. <u>Diuretics:</u> Agents that cause the body to excrete water and salt and increase urine output. <u>Vasodilators:</u> Agents that widen blood vessels. These are often used in combination with other antihypertensive medications.</p>

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	<p><u>Other</u>: If yes to other, record the category of the antihypertensive medication.</p>
<p>SECTION IV: SYMPTOMS</p>	<p><u>Does the patient currently have the following symptoms (within 48 hours):</u> Check “Yes” or “No” to indicate whether or not the symptom is currently present. Currently is defined as anytime within the 48 hours prior to the protocol visit.</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

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	<p>coldness.</p> <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>
<p>SECTION V: DEPRESSION MANAGEMENT</p>	<p>Ask the patient the following questions regarding any depressive symptoms the patient may have currently. Check “Yes” or “No” to indicate the patient’s response. If the patient responds “Yes” to any of the questions, notify the Principal Investigator.</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>
<p>SECTION VI: CONCOMITANT MEDICATIONS</p>	<p><u>Does the patient currently take any medications (prescription, OTC, herbals)?</u></p> <p>Check “Yes” if the patient currently takes any medication and then record each medication on the Concomitant Medication Log. Otherwise, check “No”.</p> <p>NOTE: All medications that the patient is currently taking or has taken within the last 30 days must be recorded on the Concomitant Medication Log. Information recorded on the Medication Log will be entered via a web-based form. The Medication Log must be kept up-to-date during the course of the study and may be reviewed in the event of an audit or if the patient experiences an adverse event or unexpected drug interaction with the study medication.</p>

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SECTION VII: HEALTH BEHAVIOR	<p>This section is to be administered to the patient. If the patient refuses to answer any of the questions or states that he/she does not know the answer, record "Ref" for Refused or "Unk" for Unknown.</p> <p>1. <u>During the past 12 months has the patient consumed an average of at least one alcoholic beverage per week:</u></p> <p>Check "Yes" if the patient has consumed an average of at least one alcoholic beverage per week during the past 12 months. If not, check "No".</p> <p>If yes, answer the following 3 questions to indicate the average number of alcoholic beverages the patient has consumed per week during the past 12 months.</p> <p><u>Beer:</u> Record the average number of 12 oz. bottles of beer the patient has consumed per week.</p> <p><u>Wine:</u> Record the average number of 4 oz. glasses of wine the patient has consumed per week.</p> <p><u>Liquor:</u> Record the average number of 1.5 oz. shots of hard liquor or mixed drinks the patient has consumed per week.</p> <p>2. <u>During the past 12 months has the patient ever consumed 7 or more alcoholic beverages within a 24-hour period:</u></p> <p>Check "Yes" if the patient has ever consumed 7 or more alcoholic beverages (mixed drinks, shots, beer and/or wine) in a 24 hour period during the past 12 months. If not, check "No".</p> <p>If yes, check the box that best indicates how often during the past 12 months the patient has had more than 7 alcoholic drinks in a 24 hour period.</p> <p>3. <u>Has the patient smoked at least 100 cigarettes in his/her entire life:</u></p> <p>Check "Yes" if the patient has smoked at least 100 cigarettes in his/her life. If not, check "No".</p> <p>If yes, check "Yes" or "No" to indicate whether the patient currently smokes cigarettes.</p> <p>If yes to currently smokes, check the box that best indicates how many packs the patient smokes per day. One pack is equal to 20 cigarettes.</p>
SECTION VIII: SEROLOGIES	<p>Check "Positive" or "Negative" for each serology test performed and record the date of the sample. If the test was not performed check "Not done".</p> <p>1. <u>HBsAg:</u> hepatitis B surface antigen within 5 years of the screening evaluation or during the screening evaluation</p> <p>2. <u>Anti-HIV:</u> antibodies to HIV within 5 years of the screening evaluation or during the screening evaluation</p>
SECTION IX: SCREENING LABS	<p>GENERAL INSTRUCTIONS:</p> <p>Record the laboratory result and the date of the sample. If the test was not done, check "Not Done". Note the time period in which the laboratory test is to be performed.</p> <p>HbA1c – as part of the screening evaluation in patients with diabetes. HbA1Ac is not required in patients who do not have diabetes.</p>

SyNCH Phase II

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	Urine drug screen – If the test was not performed check “Not done”. TIBC, Ferritin, Serum iron – at screening ANA – at any time prior to or during the screening evaluation HCV RNA quantitative – after the end of the most recent previous therapy for HCV or during the screening evaluation HCV genotype – at any time prior to or during the screening evaluation
SECTION X: COMMENTS	Check whether or not there are comments regarding the screening evaluation. If yes, record comments in the space provided. When referring to a specific item on the form, record the section and question number with the comment.