

Follow-up Vital Status Form

DATA SECTION	COMPLETION INSTRUCTIONS
OUTCOME	<p>If the patient was not enrolled in the NAC trial a MedWatch form is not required.</p> <p>If the patient was enrolled in the NAC trial and has undergone liver transplantation since enrollment in the NAC trial, and the SAE is not considered to be related to study drug or unexpected, as determined by the clinical center investigator, a MedWatch form is not required.</p> <p>Refer to the Data Safety Monitoring Plan (DSMP) for SAE reporting guidelines and study definitions for serious, related, and unexpected events.</p> <p><u>Alive</u>: patient is alive without transplant at the time of the follow-up evaluation. Check “Yes” or “No” to indicate whether or not the patient was relisted for liver transplantation. If the patient was relisted, record the current UNOS status and MELD/PELD score.</p> <p><u>Died</u>: patient died during the follow-up interval. If “Yes”, complete the following: <u>Date of death</u>: Record the month, day and year the patient died. If any piece of the date is unknown, record “unk” in that field and complete the remaining fields. <u>Cause of death</u>: Specify the major underlying cause of death. Refer to the codebook on the project website for the most recent codes. <u>Autopsy performed</u>: Indicate whether or not an autopsy was performed.</p> <p>If the patient was enrolled in the NAC trial and died during the follow-up interval, complete a MedWatch form.</p>
FINAL DIAGNOSIS	<p><u>Change in final diagnosis since last evaluation</u>: Check “Yes” or “No” to indicate whether there is a change in the final diagnosis compared to the diagnosis recorded at the last evaluation, either hospital discharge or 6 month follow-up evaluation. The diagnosis should be determined based on all information available at the time of the current follow-up evaluation. If there has been no change in diagnosis since the previous evaluation, check “No”. If there has been a change in diagnosis since the previous evaluation, check “Yes”, and record the diagnosis. If more than one diagnosis applies, rank the diagnoses in order of primary=1, secondary=2, etc.</p> <p>SPECIFIC INSTRUCTIONS:</p> <p>The following diagnosis definitions are provided as guidelines. Tests and results listed are not required to confirm a diagnosis.</p> <p><u>Acetaminophen</u> History of acetaminophen ingestion (either suspected overdose or chronic ingestion, especially in combination with significant alcohol use). Toxic serum acetaminophen level or ALT > 3500 U/L with a history of acetaminophen ingestion >100mg/kg/day irrespective of the acetaminophen level.</p>

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	<p><u>ALF of Pregnancy</u> Acute Fatty Liver - ALF occurring between 26 weeks gestation and the immediate - postpartum period - liver biopsy c/w diagnosis (ie microsteatosis) HELLP syndrome - ALF occurring between 22 weeks gestation and immediate postpartum period (> 90% cases). - presence of hemolysis, elevated LFTs (transaminases) and low platelets (< 100,000) - often associated with hypertension/pre-eclampsia</p> <p><u>Budd-Chiari</u> Obstruction of blood flow of the centrilobular veins at any level as shown by: - doppler US - angiography Liver biopsy c/w diagnosis</p> <p><u>Shock/Ischemia</u> Development of ALF following documented hypotension. Development of ALF in association with a documented low flow state eg severe cardiac failure Exclusion of other causes</p> <p><u>Wilson's Disease</u> Serum ceruloplasmin < 20mg/dl Elevated serum free copper > 25µg/dl Urinary copper excretion > 100 µg/ 24 hours with or without Copper concentration in liver biopsy > 250 µg/g of dry weight</p> <p><u>Hepatitis A</u> Positive anti-HAV IgM</p> <p><u>Hepatitis B</u> Positive anti-HBc IgM Positive HBsAg</p> <p><u>Delta Hepatitis</u> Positive HBsAg Positive anti-HDV with or without Positive anti-HBc IgM</p> <p><u>Hepatitis C</u> Positive anti-HCV (may be absent early in the infection) Positive HCV RNA by PCR</p> <p><u>Hepatitis E</u> Positive anti-HEV IgM</p> <p><u>Autoimmune Hepatitis</u> Globulins elevated > 1.5X ULN ANA, ASMA or LKMA positive in titer of at least 1:80. Negative serology for viruses associated with acute or chronic hepatitis with or without - Liver biopsy showing CAH</p>

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COMMENTS	<p><u>Drug-Induced Hepatitis</u> Temporal relationship between exposure to suspected drug and onset of ALF Exclusion of other causes</p> <p><u>Mushroom Intoxication</u> Temporal relationship between mushroom ingestion and onset of ALF Exclusion of other causes</p> <p><u>Other Viral</u> HSV - anti-HSV IgM positive and anti-HSV IgG negative - four fold increase between acute and convalescent sera or - HSV seen in liver tissue EBV - anti-EBV IgM or - EBV seen in liver tissue CMV - anti-CMV IgM positive and anti-CMV IgG negative - four fold increase between acute and convalescent sera or - CMV seen in liver tissue</p> <p><u>Indeterminate</u> Exclusion of all the above diagnoses based on history, serology, and other laboratory tests.</p> <p>Record additional information not collected elsewhere on the form. When referring to a specific item on the form, record the section and question number.</p>