

Enrollment Log

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	<p>The Enrollment Log captures basic demographic information on all patients eligible for participation in the Pediatric ALF registry, regardless of whether the patient is enrolled in the registry or NAC trial. One line of the log is completed for each potentially eligible patient.</p> <p>The Enrollment Log summarized eligibility criteria contained on the Registry Criteria (RC) and NAC Criteria (NC) forms.</p> <p>The Enrollment Log must be submitted to the Data Coordinating Center the first week of every month. The DCC will send an email reminder at the beginning of each month and the most recent version of the Enrollment log spreadsheet must be returned, via email, to the DCC.</p> <p>A Registry Criteria form must be completed for each patient recorded on the Enrollment log. The RC form captures the following registry inclusion and exclusion criteria.</p> <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Evidence of acute liver injury defined as clinical (jaundice, encephalopathy, bleeding tendency) or biochemical (elevated liver transaminases) evidence of liver disease 2. INR \geq 1.5 or protime \geq 15 with encephalopathy OR; INR \geq 2.0 or protime \geq 20 with or without encephalopathy 3. Patient < 18 years of age 4. Patient informed consent for participation in registry <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 5. Known underlying chronic liver disease 6. Coagulopathy corrected with Vitamin K 7. Other severe illness, condition, or other reason <p>The NAC Criteria form is to be completed for each patient enrolled in the PALF registry. The NC form captures the following NAC Trial inclusion and exclusion criteria.</p> <p>Inclusion criteria:</p> <ol style="list-style-type: none"> 1. Patient enrolled in the PALF registry 2. Patient informed consent for participation in the NAC Trial <p>Exclusion criteria:</p> <ol style="list-style-type: none"> 3. Acute acetaminophen toxicity 4. Patient already on N-acetylcysteine 5. Patient is pregnant 6. Patient has a known malignancy 7. Patient is on a liver support device 8. Sepsis 9. Signs of cerebral herniation 10. Intractable hypotension defined as systolic BP < 85 mm Hg or requires inotropic drugs other than renal dosing of dopamine 11. Other severe illness, condition, or other reason <p>Refer to the RC and NC Manuals of Operation for specific form completion instructions and study definitions.</p>

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DEMOGRAPHIC INFORMATION	SPECIFIC INSTRUCTIONS
	<p><u>Initial Diagnosis Code</u>: Record the liver failure code that best indicates the primary diagnosis at the time of screening. The initial diagnosis should be based on all information available at the time of screening. The initial diagnosis should not reflect information obtained after the screening date.</p> <p>Refer to the most recent diagnosis code list provided on the project website.</p> <p><u>Age at Screening</u>: Record the age of the patient, in both months and years at the time of screening.</p> <p>Record whole numbers for months and years, truncating when necessary.</p> <p>For example:</p> <ul style="list-style-type: none"> - Record '0 Months, 0 Years' for a child under 1 month of age at screening - Record '5 Months, 0 Years' for a child who is 5½ months at the time of screening - Record either '15 months' or '3 Months, 1 Year' for a child who is 1 year and 3 months at the time of screening - Record '6 Months, 3 Years' for a child who is 3½ years of age at the time of screening <p><u>Sex</u>: Enter M (male) or F (female) to indicate patient gender.</p> <p><u>Race</u>: Enter code 1 to 5 to indicate the race with which the patient most identifies. If the patient identifies with more than one race, enter other (6) and record the races with which the patient identifies.</p> <p><u>White or Caucasian (1)</u>: A person having origins in any of the original peoples of Europe, the Middle East, or North America.</p> <p><u>Black or African-American (2)</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".</p> <p><u>Asian (3)</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 Philippine Islands, Thailand, and Vietnam.</p> <p><u>American Indian or Alaska Native (4)</u>: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.</p> <p><u>Native Hawaiian or Pacific Islander (5)</u>: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p>

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<p>PALF REGISTRY ENROLLMENT</p>	<p><u>Other (6)</u>: Check this box if the patient’s racial background is not listed. Other may include multiracial or mixed interracial. If multiracial or mixed interracial, record the races with which the patient identifies.</p> <p><u>Hispanic</u>: Enter Y (yes) or N (no) to indicate whether or not the patient is of Hispanic origin. Hispanic is defined as a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term “Spanish origin” can also be used in addition to “Hispanic or Latino”.</p> <p>NOTE: Race must be provided regardless of ethnicity.</p> <p><u>Screening Month and Year</u>: Enter the month and year of the screening evaluation.</p> <p>All registry inclusion criteria must be met and none of the exclusion criteria met for the patient to be eligible for enrollment in the PALF registry. Refer to the RC form for eligibility criteria.</p> <p>Enter Y (yes) or N (no) to indicate whether or not the patient is enrolled in the PALF registry. If the patient is enrolled in the registry, assign a Patient ID, using the Patient ID Generator. <u>Do not</u> assign a Patient ID if the patient is not enrolled in the PALF registry.</p> <p>The Patient ID is comprised of a two digit site code, a three digit serial number, and a 3 character code.</p>
<p>NAC TRIAL ENROLLMENT</p>	<p>All NAC Trial inclusion criteria must be met and none of the exclusion criteria met for the patient to be eligible for enrollment in the NAC Trial. Refer to the NC form for eligibility criteria.</p> <p>Enter Y (yes) or N (no) to indicate whether or not the patient is enrolled in the NAC Trial. Enter N (no) if the patient is not enrolled in the PALF registry and therefore not eligible for the NAC Trial.</p> <p>If all criteria are not met for the PALF registry or NAC trial but you would like to enroll the patient regardless, follow the protocol exemption procedure to determine whether or not the patient may be enrolled.</p>