

Drug #1: \_\_\_\_\_  
please print name

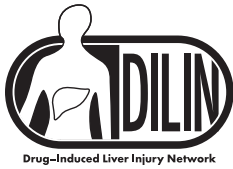
# Prospective Study RUCAM

Site Number: \_\_\_\_\_ Participant ID Number: \_\_\_\_\_

Date completed: \_\_\_\_/\_\_\_\_/\_\_\_\_  
day month year

Reviewer Code: \_\_\_\_\_  Site investigator  Reviewer A  Reviewer B

<b>RUCAM</b> Causality Assessment of a Drug in a Case of Acute Liver Injury					
	Hepatocellular Type		Cholestatic or Mixed Type		Assessment
<b>1 Time to onset:</b>					
Incompatible	Reaction occurred before starting the drug or more than 15 days after stopping the drug (except for slowly metabolized drugs)		Reaction occurred before starting the drug or more than 30 days after stopping the drug (except for slowly metabolized drugs)		<b>Unrelated</b>
Unknown	When information is not available to calculate time to onset, then case is:				<b>Insufficiently documented</b>
	<b>INITIAL TREATMENT</b>	<b>SUBSEQUENT TREATMENT</b>	<b>INITIAL TREATMENT</b>	<b>SUBSEQUENT TREATMENT</b>	<b>Score</b> <small>(check the results)</small>
<b>1a From the beginning of the drug:</b>					
Suggestive	5-90 days	1-15 days	5-90 days	1-90 days	<input type="checkbox"/> +2
Compatible	< 5 or > 90 days	> 15 days	< 5 or > 90 days	> 90 days	<input type="checkbox"/> +1
<b>1b From the cessation of the drug:</b>					
Compatible	≤ 15 days	≤ 15 days	≤ 30 days	≤ 30 days	<input type="checkbox"/> +1
<b>2 Course:</b>	<b>DIFFERENCE BETWEEN THE PEAK OF ALT (SGPT) AND UPPER LIMIT OF NORMAL VALUES</b>		<b>DIFFERENCE BETWEEN THE PEAK OF A.P. (OR TB) AND UPPER LIMIT OF NORMAL VALUES</b>		
<b>2a After cessation of the drug:</b>					
Highly suggestive	Decrease ≥ 50% within 8 days		Not applicable		<input type="checkbox"/> +3
Suggestive	Decrease ≥ 50% within 30 days		Decrease ≥ 50% within 180 days		<input type="checkbox"/> +2
Compatible	Not applicable		Decrease < 50% within 180 days		<input type="checkbox"/> +1
Inconclusive	No information <b>OR</b> Decrease ≥ 50%, after the 30 <sup>th</sup> day		Persistence or increase or no information No situation		<input type="checkbox"/> 0
Against the role of the drug	Decrease < 50%, after the 30 <sup>th</sup> day <b>OR</b> Recurrent increase		Not applicable		<input type="checkbox"/> -2
<b>OR</b>					
<b>2b If the drug is continued:</b>					
Inconclusive	All situations		All situations		<input type="checkbox"/> 0
<b>3 Risk factors:</b>	<b>ETHANOL</b>		<b>ETHANOL OR PREGNANCY</b>		
Presence					<input type="checkbox"/> +1
Absence					<input type="checkbox"/> 0
Age of the patient ≥ 55 years					<input type="checkbox"/> +1
Age of the patient < 55 years					<input type="checkbox"/> 0



**Fax completed form to  
Duke Clinical Research Institute  
(919) 668-7100**

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## RUCAM Causality Assessment of a Drug in a Case of Acute Liver Injury (continued)

	<b>Score</b>
<b>4 Concomitant drug(s):</b>	
None or no information or concomitant drug with incompatible time to onset	<input type="checkbox"/> 0
Concomitant drug with compatible or suggestive time to onset	<input type="checkbox"/> -1
Concomitant drug known as hepatotoxin and with compatible or suggestive time to onset	<input type="checkbox"/> -2
Concomitant drug with evidence for its role in this case ( <i>positive rechallenge or validated test</i> )	<input type="checkbox"/> -3
<b>5 Search for nondrug causes:</b>	
<p><b>Group I (6 causes):</b>  <b>RECENT VIRAL INFECTION WITH HAV</b> (IgM anti-HAV antibody) or <b>HBV</b> (IgM anti-HBc antibody) or <b>HCV</b> (anti-HCV antibody and circumstantial arguments for non-A, non-B hepatitis); <b>BILIARY OBSTRUCTION</b> (ultrasonography); <b>ALCOHOLISM</b> (AST/ALT ≥2); <b>ACUTE RECENT HYPOTENSION HISTORY</b> (particularly if underlying heart disease).  <b>Group II:</b>                      Complications of underlying disease(s); clinical and/or biological context suggesting CMV, EBV or herpes virus infection.</p>	<ul style="list-style-type: none"> <li>• All causes—groups I and II—reasonably ruled out <input type="checkbox"/> +2</li> <li>• The 6 causes of group I ruled out <input type="checkbox"/> +1</li> <li>• Five or 4 causes of group I ruled out <input type="checkbox"/> 0</li> <li>• Less than 4 causes of group I ruled out <input type="checkbox"/> -2</li> <li>• Non drug cause highly probable <input type="checkbox"/> -3</li> </ul>
<b>6 Previous information on hepatotoxicity of the drug:</b>	
Reaction labeled in the product characteristics	<input type="checkbox"/> +2
Reaction published but unlabeled	<input type="checkbox"/> +1
Reaction unknown	<input type="checkbox"/> 0
<b>7 Response to readministration:</b>	
Positive	<input type="checkbox"/> +3
Compatible	<input type="checkbox"/> +1
Negative	<input type="checkbox"/> -2
Not done or not interpretable	<input type="checkbox"/> 0

**Investigator Signature**

Investigator's signature: \_\_\_\_\_ Date signed: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
day month year