INDILI Proforma

(Indian Network for DILI)

(DILI: Drug Induced Liver Injury)

Centre Serial No.

Dear Colleagues,

The **INASL** (**Indian National Association for Study of the Liver**) in 2012 has decided to collect data on drug-induced liver injury (INDILI). The objectives were to study the different types of drugs causing DILI, including their pattern and outcome. This initial effort will provide us with a framework to plan and pursue further studies.

Towards this end the **INDILI** has been tasked by the INASL to coordinate efforts to capture as much data on DILI as possible. Your participation is important and on behalf of the INASL, I invite you to be part of this venture. The data you will provide will bridge the existing gap regarding pan-India cause for DILI. Your data will be acknowledged and the analysis will be mailed to those who contribute in significant numbers i.e., 20 or more complete cases. Contributing physicians may need to procure consent from patients or from the institutional review boards.

The proforma may be downloaded from the INASL website (www.inasl.org.in) and copies made as required. Alternatively, if necessary, forms will be mailed on request.

Instructions for filling the proforma:

- Enter as much data as possible.
- DILI is a disease of exclusion, and hence acute viral hepatitis needs to be excluded before a diagnosis of DILI is made.
- The RUCAM page need not be filled and will be completed at the time of analysis

On behalf of the INASL, we look forward to receiving your wholehearted participation and contribution, which is essential for the success of this endeavour.

Harshad Devarbhavi	**S P Singh**	**V A Saraswat**
Chair - INDILI	Secretary General, INASL	President, INASL

Drug Induced Liver Injury: Definition

AST or ALT > 5 times upper limit of normal (regardless of symptoms),

OR

Total bilirubin > 2 mg/dL and any rise in AST or ALT or alkaline phosphatase > 2 times upper limit of normal,

OR

AST or ALT > 3 times upper limit of normal, if symptomatic with nausea, vomiting, abdominal pain, anorexia, skin rashes etc.

And

Exclude competing causes such as viral hepatitis, bile duct obstruction or congestive heart failure.

INDILI Centre: _____

Name or initials: _____ Age: _____ Sex: _____

Hospital: _____

Hospital Landline no.: _____ Mobile no.: _____

Relative's mobile no.: _____

Seen in OPD: Yes ☐ No ☐ Admission Day DD MM YY Discharge Day DD MM YY

Height _____ Weight _____ BMI _____

Presentation	Duration
Jaundice	
Nausea	
Vomiting	
Anorexia	
Itching	
Fever	
Skin rashes	
Dark urine	
Abdominal pain	
Encephalopathy (Grade I / II / III / IV)	
Seizures	
Renal failure	
Skin rashes (Y/N) SJS (Y/N)	
Lymphadenopathy	
Encephalopathy	
JE (Jaundice-Encep) interval	
Hepatomegaly	
Ascites	
Alcohol intake (g/d), duration	
Smoking,(Y/N) No. of days/year	
Hypoglycemia	

Implicated Drug: _____ Start Date _____ Stop Date _____ Duration _____ Dose _____

Concomitant Drug(s): _____ Start Date _____ Stop Date _____ Duration _____ Dose _____

Is underlying liver disease present: Yes ☐ No ☐ If yes: Active ☐ Inactive ☐

CAM (Complementary and Alternative Medicine) Ayurvedic/Siddha/Herbals/Homeopathy/Indigenous
Name if possible: Duration _____ Dose _____

Primary Disease for which drug was given: _____

Were drugs discontinued with onset of symptoms: Yes ☐ No ☐

*SJS: Stevens-Johnson syndrome

Is primary disease convincingly proven (eg. TB) or was treatment empirical
TB site: Pulmonary/ Lymph node/ Abdominal/ CNS/Bone
Associated Diseases eg. DM, HTN, CRF, HIV, others(specify)

LFT / Others Variables	Lab Normal Range (Upper limit of normal)	Baseline	Initial	Follow up tests	Follow up tests	Follow up tests
Dates						
T. Proteins						
Albumin						
T. Bilirubin						
D. Bilirubin						
AST						
ALT						
ALP						
GGT						
PT / INR						
S. Creatinine						
FBS / RBS						
HB						
WBC (Total Count)						
Neutrophil/Lymphocyte/ Eosinophil (%)						
Platelet						
HBsAg/ IgManti-HBc						
IgM Anti-HEV						
IgM Anti-HAV						
HCV						
ANA/SMA						
HIV						
CD 4 Count						

USG (abdomen) _____

FHF: Yes ☐ No ☐

Recovery: Yes ☐ No ☐

Treatment given: Steroids ☐ UDCA ☐ SAME ☐ Others (name) _____

Sepsis: Yes ☐ No ☐ Site: Chest/ urine/blood/abdomen

Management: Antibiotics/ Inotropic support/ Ventilation/ Others (Mention)

Cause of death: ALF ☐ ACLF ☐ CLD ☐ Sepsis ☐ Others: _____

Liver biopsy (if done) Antemortem ☐ Post mortem ☐

Case narrative/brief description of case when possible _____

Date: _____

Name of Investigator _____ Signature _____

*ULN - upper limit of normal values to be mentioned for baseline LFT variables

RUCAM (Roussel Uclaf Causality Assessment Method) J Clinical Epidemiology 1993;46:1323-30

	Score
1. Temporal relationship of start of drug to start of illness	
a. Initial treatment 5-90 days; subsequent treatment course: 1-15 days	+2
b. Initial treatment <5 or >90 days; subsequent treatment course: >15 days	+1
c. From cessation of drug: within 15 days; or within 15 days after subsequent treatment	+1
d. Otherwise	0
2. Course	
a. ALT decreases ≥ 50% from peak within 8 days	+3
b. ALT decreases ≥ 50% from peak within 30 days	+2
c. If the drug is continued or decreased 50% from peak > 30 days, or inconclusive	0
d. Against causative role for drug	-2
3. Risk Factors	
a. Alcohol use, 1; No alcohol use,0	0 or 1
b. Age ≥ 55 years, +1; Age ≤ 55 years, 0	0 or 1
4. Concomitant drug	
a. No concomitant drug administered	0
b. Concomitant drug with suggestive or compatible time of onset	-1
c. Concomitant known hepatotoxin with suggestive or compatible time of onset	-2
d. Concomitant drug with positive rechallenge or validated diagnostic test	-3

5. Nondrug causes: Six are primary: Recent hepatitis A, B, or C, biliary obstruction, acute alcoholic hepatitis (AST ≥ 2 x ALT), recent hypotension (especially if heart disease). Secondary group: Underlying other disease; possible CMV, EBV or HSV infection

a. In this category, all primary and secondary causes reasonably ruled out	+2
b. All 6 primary causes ruled out	+1
c. 4 to 5 primary causes ruled out	0
d. Fewer than 4 primary causes ruled out (maximum negative score for items 4 and 5: -4)	-2
e. Non drug cause highly probable	-3
6. Previous information on hepatotoxicity of the drug in question	
a. Package insert or labeling mention	+2
b. Published case reports but not in label	+1
c. Reaction unknown	0
7. Rechallenge	
a. Positive (ALT doubles with drug in question alone)	+3
b. Compatible (ALT doubles with same drugs as given before initial reaction)	+1
c. Negative (Increase in ALT but ≤ 2 x ULN, same conditions as when reaction occurred)	-2
d. Not done, or indeterminate result	0

Total (range of algebraic sum: - 8 to + 14)
Score Interpretation: Highly probable >8; Probable 6-8; Possible 3-5; Unlikely 1-2; Excluded < 0