Genomics of Drug Induced Renal Injury (DIRI): Adjudication Report

DR1 - CRF 15

Patient ID: ☐☐☐☐☐☐

Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

1. **Adjudicator ID:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

2. **Date of Review:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

3. a. **Phenotype and DIRI criteria that was used to determine patient's eligibility for enrollment with this study:**

○ AKI phenotype with AKIN stage 2 criteria based on rising serum creatinine
○ AKI phenotype with AKIN stage 2 criteria based on declining serum creatinine
(based on time course and magnitude of creatinine change)
○ Glomerular disorder phenotype *(based on biopsy)*

b. **Study Drugs:**

	NA	Drug ID	Drug Name	Met DIRI Criteria
Drug 1	☐	___		○ Y ○ N
Drug 2	☐	___		○ Y ○ N
Drug 3	☐	___		○ Y ○ N

4. **Assessment Tools**

a. **Naranjo Scores** (*Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin. Pharmacol. Ther. 1981;30:239-245.)*

Naranjo scores of 9 - 10 indicate that event was "definitely" an ADR; scores of 5 - 8 rate the likelihood as "probable"; scores of 1 - 4 are "possible"; and scores of less than 1 are "doubtful".

To assess the adverse drug reaction, please answer the following questions and give pertinent subscores for each drug.	**Question Points**			**Subscores**		
	Yes	**No**	**DoNot Know**	**Drug 1**	**Drug 2**	**Drug 3**
(1) Are there previous conclusive reports on this reaction?	+1	0	0	___	___	___
(2) Did the adverse event appear after the suspected drug was administered?	+2	-1	0	___	___	___
(3) Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	___	___	___
(4) Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0	___	___	___
(5) Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	___	___	___
(6) Did the reaction reappear when a placebo was given?	-1	+1	0	___	___	___
(7) Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	___	___	___
(8) Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	___	___	___
(9) Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	___	___	___
(10) Was the adverse event confirmed by any objective evidence?	+1	0	0	___	___	___
Add subscores from each column to calculate the Naranjo score for respective drug: (Score 0: Unlikely, Score 1-4: Possible, Score 5-8: Probable, Score 9-10: Definite)				___	___	___