

Adverse Drug Event Adjudication Form: Kidney Insufficiency

1. Subject Number:
2. Date event/symptom/abnormal lab first noted:
3. Describe symptoms noted at time ADE reported (fever, etc):
4. Serum creatinine levels:

	CRE (mg/dL)	Date
Baseline (from CIRT EDC Lab)		
Maximum		
Recovery (when discharge)		
Follow up (from CIRT EDC Lab)		

5. Was imaging performed at or around the time of the ADE: ☐ Yes ☐ No
- 5a. If yes, what is the result: ☐ Normal ☐ Abnormal
6. Pathology report: ☐ Yes ☐ No
- 6a. If yes, what is the result: _____
7. Dialysis: ☐ Yes ☐ No
8. Evidence of recovery: ☐ Full recovery ☐ Partial recovery ☐ No available Lab data
9. Presume cause of acute kidney injury: _____

No Likelihood codes and definitions for Kidney insufficiency related ADEs

Severity codes and definitions for Kidney insufficiency related ADEs (KDIGO guideline)*

- ☐ **Mild** (any elevation from baseline -1.9 times baseline of serum creatinine)
- ☐ **Moderate** (2.0-2.9 times baseline of serum creatinine)
- ☐ **Severe** (≥ 3 times baseline of serum creatinine)

**Kidney Disease: Improving Global Outcomes (KDIGO). Acute Kidney Injury Work Group. KDIGO clinical practice guidelines for acute kidney injury. Kidney Int Suppl 2012; 2:1.*