

**DATAFORM 5**  
**ADE and Near Miss Incident Classification Form**

1. Study ID Number: \_\_\_\_\_
1. Rx ID Number: \_\_\_\_\_
2. Case Number: \_\_\_\_\_
3. Reviewer Initials: \_\_\_\_\_
4. Classification of incident  
(Choose only one) \_\_\_\_\_
- 1. ADE
  - 2. Near Miss
  - 3. Medication Error
  - 4. Exclusion
5. Confidence regarding above judgement? \_\_\_\_\_
- 1. Little or no evidence
  - 2. Modest confidence
  - 3. Medium confidence
  - 4. Strong confidence
  - 5. Very certain confidence
6. Severity of ADE or PADE  
(Choose only one) \_\_\_\_\_
- 1. Fatal
  - 2. Life-threatening
  - 3. Serious
  - 4. Significant
  - 5. Not an ADE or Near Miss
7. Preventability—Implicit  
(choose only one) \_\_\_\_\_
- 1. Error intercepted
  - 2. Definitely preventable
  - 3. Probably preventable
  - 4. Probably not preventable
  - 5. Definitely not preventable

8. Could this event have been prevented by any of the following checks?  
(Choose all that apply)

\_\_\_\_\_

1. Computerized physician order entry (basic design which ensure complete field legibility and signature)
2. CPOE with drug decision support
  - 2a. Drug-weight or drug dose check (guided dose algorithms)
  - 2b. Drug-allergy check
  - 2c. Drug-drug check
  - 2d. Drug-lab check
  - 2e. Drug frequency check
  - 2f. Drug-route check
  - 2g. Drug-pt. characteristic check: renal function
  - 2h. Drug-pt. characteristic check: age
  - 2i. Drug-pt. characteristic check: pregnancy
  - 2j. Drug-pt. characteristic check: other, specify: \_\_\_\_\_
  - 2k. Drug duration
3. Electronic transmission of prescription
4. Clinical pharmacist
  - 4a. Discussing ordering
  - 4b. Discussing administration/monitoring
  - 4c. Monitoring/dispensing
5. Changes in staffing for:
  - 5a. Physicians
  - 5b. Nurses
  - 5c. Pharmacists
  - 5d. Other, specify: \_\_\_\_\_
6. Changes in training for:
  - 6a. Physicians
  - 6b. Nurses
  - 6c. Pharmacists
  - 6d. Other, specify: \_\_\_\_\_
7. Changes in hours for:
  - 7a. Physicians
  - 7b. Nurses
  - 7c. Pharmacists
  - 7d. Other, specify: \_\_\_\_\_
8. Changes in communication between:
  - 8a. Physicians and patients
  - 8b. Nurses and patients
  - 8c. Physicians and pharmacists
  - 8d. Physicians and RNs, PAs, NPs, etc.
  - 8e. Parents and other caregivers (babysitter, school)
  - 8f. Other, specify: \_\_\_\_\_
  - 8g. Pharmacists and patients
9. Other, specify:  
\_\_\_\_\_
10. None
11. Drug specific guidelines
12. Pre printed template

9. Complete the following table

	<b>Yes</b>	<b>No</b>	<b>Unsure</b>
9.1 Are there any previous reports of this reaction in the Literature to your knowledge?	<b>Y</b>	<b>N</b>	<b>U</b>
9.2 Was the condition present before the administration of the drug in question?	<b>Y</b>	<b>N</b>	<b>U</b>
9.3 Could a non-pharmalogical clinical condition explain the change noted?	<b>Y</b>	<b>N</b>	<b>U</b>
9.4 Was the amount of the drug used too much for this patient?	<b>Y</b>	<b>N</b>	<b>U</b>
9.5 Is there objective evidence of toxicity (eg. from body fluids, biopsy, blood levels, but NOT rash or vital signs)?	<b>Y</b>	<b>N</b>	<b>U</b>
9.6 Did the patient receive an antagonist to the drug?	<b>Y</b>	<b>N</b>	<b>U</b>
9.7 Was the antagonist effective?	<b>Y</b>	<b>N</b>	<b>U</b>
9.8 Did the patient undergo therapy other than the antagonist directed at the condition in question?	<b>Y</b>	<b>N</b>	<b>U</b>
9.9 Was the therapy effective?	<b>Y</b>	<b>N</b>	<b>U</b>
9.10 Does the patient have a known allergy or intolerance to the drug?	<b>Y</b>	<b>N</b>	<b>U</b>
9.11 Was this reaction a rash, hives, itching, or anaphylaxis?	<b>Y</b>	<b>N</b>	<b>U</b>
9.12 Was this reaction a commonly reported sensitivity to this medication (eg. Nausea to opiates)?	<b>Y</b>	<b>N</b>	<b>U</b>

10. Was the event ameliorable?

- \_\_\_\_\_ 1. Yes  
 \_\_\_\_\_ 2. No