
UPDATED: Manual for Expedited Reporting of Adverse Events to DAIDS

**What are the major changes?
How does this affect VOICE?**

Old vs. New: EAE Reporting Categories

Old

Standard

Intensive

Targeted

New

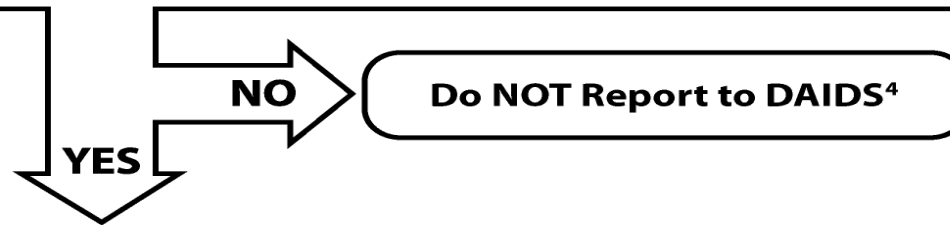
All SAE – VOICE will be using this reporting category

SUSAR

New: All SAE Reporting Category

Does the AE, following study agent exposure, meet any of the following criteria?

1. Results in death
2. Is life-threatening¹
3. Requires inpatient hospitalization or prolongation of hospitalization²
4. Results in persistent or significant disability/incapacity
5. Is a congenital anomaly/birth defect³
6. Is an important medical event (may jeopardize the patient or may require intervention to prevent one of the other outcomes above)



Report to DAIDS within three (3) reporting days:

- A Reporting day starts at 12:00 AM (Midnight) and ends at 11:59 PM Monday through Friday local time. (For more information consult the EAE Manual)
- Any holiday (U.S. or in country/local) that falls on a Monday through Friday count **as reporting days**.

Contact Information for the DAIDS Safety Office:

Website: <http://rcc.tech-res.com> • **E-mail:** RCCSafetyOffice@tech-res.com

Office Phone: 1-800-537-9979 (U.S. only) or +1-301-897-1709 • **Fax:** 1-800-275-7619 (U.S. only) or +1-301-897-1710
(Office Phone and Fax are accessible 24 hours per day)

Mailing Address: DAIDS Safety Office 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817

Old vs. New:

Relationship to a Study Agent

Old

Definitely Related

Probably Related

Possibly Related

Probably Not Related

Not Related

Pending

New

Related - There is a reasonable possibility that the AE may be related to the study agent(s)

Not Related – There is not a reasonable possibility that the AE may be related to the study agent(s)

NA

Old vs. New:

Submitting Updated EAE reports

Old

No guidance was given in the manual

New

Submit an **updated report** to DAIDS for each AE when significant additional information is available

Updating EAE Reports

- When to update an EAE report:
 - AE is stable or has resolved,
 - Change in the severity,
 - Change in the relationship between the AE and the study agent,
 - Additional significant information on a previously reported AE

 - **NOTE:** Change in the severity of an AE will still require a new AE Log form to be completed and datafaxed to SCHARP per the VOICE SSP Manual
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Old vs. New: Timeframe for reporting

Old

3 business days

Business day – Monday through Friday, not including holidays or weekends

New

3 **reporting** days

Reporting day – Monday through Friday, **including holidays**, not including weekends

NOTE: Reporting day ends at 11:59 pm local time

New:

Site Investigator Assessment and Signature

- The IoR must designate at least one other physician at the site who can perform AE assessments and sign the appropriate forms
 - VOICE sites must have the second physician who can perform AE assessments listed as sub-investigator on 1572
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Clarification: Life-Threatening

- “Life-threatening” refers to an event in which the patient was at risk of death at the time of the event.

It does NOT refer to an event that might have caused death if it were more severe.

- A grade 4 severity does not automatically qualify as “life-threatening”.
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Clarification: Hospitalization

- Hospitalization is NOT an adverse event (AE), but is an outcome of the event.
 - Do not report:
 - Admissions unrelated to an AE;
 - Admission for diagnosis or therapy of a condition that existed before receipt of study agent(s) **and** has not increased in severity or frequency as judged by the clinical investigator.
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Clarification: Birth defect

- Clinically insignificant physical findings at births including those regarded as normal variants should NOT be reported.
 - When a clinically significant anomaly is reported, all findings (including those of no individual significance) should be included in the same report.
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Questions?

