

Adverse Event Reporting

Catherine Dillon, MS



Adverse Events

- Adverse Events (AEs) are “. . . any **untoward** medical occurrence in a subject that was not previously identified which does not necessarily have a causal relationship to the study drug...”
- Events existing prior to randomization should not be reported as AEs, unless there is a change in severity.
- Pre-existing conditions that are discovered after randomization are not adverse events. These should be documented as medical history.
- Abnormal lab values collected after randomization that are considered to be clinically significant by the site investigator are adverse events.



Serious Adverse Events

Serious Adverse Events (SAEs):

- Are Fatal
- Are Life-threatening
- Result in hospitalization/prolonging of hospitalization – excluding optional, pre-planned surgery
- Result in disability/congenital anomaly
- Require intervention to prevent permanent impairment or damage



Reporting AEs

- Reported on Form 104 – Adverse Event Case Report Form (CRF)
- One AE per CRF
- Report diagnosis, not symptoms
 - Fever, cough, chest pain, crackles = pneumonia
- Avoid abbreviations/colloquialisms



Reporting AEs

- Death, surgery, intubation, etc. are NOT adverse events. They are outcomes of adverse events.
- All AEs will be coded using MedDRA.
- A new feature of WebDCU™ will auto-populate the Lowest Level Term when 3 or more letters are entered into the name field .



Reporting Requirements for AEs

- AE reporting – must be submitted through the StrokeNet WebDCU™ as described and within the timeframes described in NIH StrokeNet Network Standard Operating Procedure ADM 12 Central Institutional Review Board (CIRB) Reporting.
- SAE reporting – reported in WebDCU™ within 24 hours of the study site being made aware of the occurrence of the SAE.



Data Entry Timelines for AEs

- Non-serious AEs must be entered and **submitted** into WebDCU™ within 5 days of data collection.
- SAEs must be entered and **submitted** into WebDCU™ within **24 hours** of discovery.



Reporting SAEs

SAEs require additional information to be submitted on the AE CRF:

- Detailed description of the event
- Relevant tests/laboratory data
- Relevant history and pre-existing conditions
- Concomitant medications



SAE Narratives

- Narratives assist the Independent Medical Safety Monitor (IMSM) in reviewing the event.
- Remove any protected health information (PHI) from the narrative
 - i.e., subject, physician or institution name



IMSM Review Process

- Site enters data and submits AE CRF into WebDCU™
- Automatic e-mail notifications to Site Manager (SM).
- If SAE and data is sufficient, automatic e-mail notification sent to the IMSM
- IMSM blindly reviews the event and indicates whether it is serious, unexpected and study intervention-related
- SM closes review process and reports to cIRB if required.

