ADVERSE EVENT REPORTING

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Reporting Adverse Events

- The Adverse Event that is being reported must meet at least one of the following criteria below:

1. Is likely related to study procedures (reasonable possibility or definitely), or
2. Is serious, or
3. Changes the function in the subject's affected arm

- If AE does not meet any of the three options, the AE form should not be filled out.

Reporting Adverse Events

- 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.

Reporting Adverse Events

- Adverse Events are reported on Form 104
- Only 1 AE should be reported, per CRF
- Report AEs from end of week 1 visit to 30 day follow up visit
- Report the diagnosis, not the symptoms:

  Fever, cough, chest pain, crackles = pneumonia
- Death, surgery, intubation, etc. are not names of adverse events. They are outcomes of adverse events
- Avoid abbreviations/colloquialisms

Reporting Adverse Events

Serious Adverse Events are:

- Fatal,
- Life-Threatening,
- Result in hospitalization
- Result in disability/congenital anomaly, or
- Require intervention to prevent permanent impairment or damage

Reporting SAEs

SAEs require additional information

to be submitted on the AE CRF:

1. Detailed description of the event
2. Relevant tests/laboratory data
3. Relevant history and pre-existing conditions
4. Concomitant meds

SAE Narrative

- Do not identify any subject, physician, or institution by name.
- Please provide a comprehensive SAE narrative:

❖"A [age] year old [male/female] presented on [mm/dd/yy] with _____ with initial NIHSS [score]. Patient was enrolled in TeleRehab, and randomized at _____ [mm/dd/yy]. On [mm/dd/yy], at _____ [days post treatment] the patient _____ [start of event, description of initial symptoms, course]. [Treatment course description in detail] _____. The patient developed _____ during hospitalization and was treated with _____. Patient was _____ [discharged/transferred/other course] on _____ [mm/dd/yy]. _____ [days] after discharge, the patient continued to decline cognitively. _____[further description]"

- This example narrative can also be found in WebDCU → Toolbox → Project Documents → Data Collection Guidelines

Data Entry Time Lines 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