Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Adverse Event Reporting

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Reporting 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
- AEs (both serious and non-serious) are reported on the Adverse Event CRF

Reporting Adverse Events

- Report the diagnosis, not the symptoms:
  Fever, cough, chest pain, crackles = pneumonia

- Death, surgery, intubation, etc. are not adverse events. They are outcomes of adverse events

Reporting Adverse Events

- All AEs will be coded centrally using MedDRA
- 1 AE per CRF
- Avoid abbreviations/colloquialisms
- AEs that can’t be coded will be queried

Reporting Adverse Events

- All AEs must be reported through completion of study treatment.

- All SAEs must be reported through End of Study.

Serious Adverse Events

- fatal
- life-threatening
- result in hospitalization/prolongation of hospitalization
- result in disability/congenital anomaly OR
- require intervention to prevent permanent impairment or damage

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

Reporting SAEs

SAEs require additional information:

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

Reporting SAEs

- These narratives assist the Medical Safety Monitor in reviewing the event
- Do not identify any subject, physician, or institution by name.

Reporting SAEs

- Site data enters and submits AE CRF into WebDCU™
- Automatic e-mail notification to Project Manager (PM- Ms. Allie Kade)
- PM reviews narrative - If CRF is sufficient, an automatic email notification will be sent to the Internal Medical Monitor (IMM- Dr. Lewis Morgenstern)

Reporting SAEs

- IMM reviews narrative - If AE data is sufficient, an automatic email notification will be sent to the external Medical Safety Monitor (MSM- Dr. Tom Bleck)
- MSM reviews the event and indicates whether the event is serious and unexpected
- PM closes review process

SAE Reporting

- DSMB requires expedited reporting of all SAEs
- Site PIs are responsible for reporting the SAE to their IRB according to local requirements
- Site PIs responsible for submitting follow-up information into WebDCU™ , as it becomes available.

Hypoglycemia Reporting

- Site PI must report to MSM if a subject has 3 or more episodes of hypoglycemia within a 24 hour period.
- Call the SHINE study hotline
- MSM will determine if the level of sliding scale insulin should be adjusted or if insulin drip protocol should discontinued

Questions?