Good Documentation Practices

Good Documentation Practices

Eligibility and Consent

Progress Note in Medical Record

- At a minimum, it should include:
  - the name of the study
  - documentation that the subject met all eligibility criteria
  - the name of the person consenting the subject
  - a statement that the study was explained to the subject or the subject's representative
  - a statement that the subject was given the opportunity to ask questions
  - documentation that consent was obtained before any subject procedures were performed

Best Practice:

Use a template in your medical record system to capture all of the elements identified above *(see example for SISTER)*

Good Documentation Practices

Eligibility and Consent

Use a template or dot phrase in your EMR

Example

CLINICAL RESEARCH TRIALS: SISTER IRB# XXXXXX

@NAME@ is a candidate for the SISTER clinical protocol (IRB#XXXXXX). SISTER (STRATEGY FOR IMPROVING STROKE TREATMENT RESPONSE (SISTER) TRIAL) is a Phase-2, prospective, randomized, placebo-controlled, blinded, dose-finding trial that aims to determine the safety and preliminary efficacy of TS23, a monoclonal antibody against the alpha-2 antiplasmin (a2-AP), in acute ischemic stroke. This study is being performed in coordination with the NIH StrokeNet to identify a dose of TS23 that is safe and more efficacious than placebo for the treatment of patients from 4.5 to 24 hours of ischemic stroke onset (or last known well) who have evidence of core-penumbra mismatch on perfusion imaging and are not a candidate for the standard of care reperfusion therapies. Randomized subjects will receive one of five doses of TS23 or placebo being evaluated in this study (placebo, 3.0 mg/kg TS23, 5.0 mg/kg TS23, 7.0 mg/kg TS23, or 10.0 mg/kg TS23). The study medication will be given as a one-time IV infusion over 15 minutes. Patients and bedside clinicians are blinded to the treatment assignment.

All acute ischemic stroke patients with a last known well time of 4.5 hours to 24 hours are considered for this protocol.

I have reviewed the inclusion/exclusion, and the patient is eligible for the study. The patient has no contraindications to receive TS23, such as a history of significant bleeding issues, history of stroke or penetrating head injury in the past 90 days, acute intracranial hemorrhage, subarachnoid hemorrhage, intracranial neoplasm, or arteriovenous malformation. Before the stroke, the patient had no prior significant disability and was able to perform basic activities of daily living (dressing, eating, walking, bathing, toileting) without assistance. Consideration for this protocol did not delay the standard of care management. No clinical trial procedures were performed before consent was obtained unless it was part of routine care.

After determining through my assessment of the patient on whether or not they had the capacity to provide informed consent, I reviewed the details of the protocol with the patient (or surrogate if appropriate) and discussed all relevant risks, benefits, and alternatives to this protocol. The patient (or surrogate) was given time to ask questions and have all questions answered by the investigator. Based on the discussion, the patient (or surrogate) reported that the patient would want to be enrolled into the clinical trial. If the patient was determined to have capacity, the patient completed the consent. If it was determined the patient did not have the capacity to provide consent, consent was obtained by a surrogate. The consent form was signed and dated by the consenter (patient or surrogate), and witnessed if required.

Per the protocol, the patient will receive one dose of TS23 or placebo. This will be given after the consent is signed, all required imaging is completed, and the patient is deemed eligible. All investigators and participants are blinded throughout the study, except the research pharmacist. Neither the patient nor the clinical team will know which group the patient was assigned to, and the team has no influence on this assignment.

In summary, the patient was enrolled in this clinical trial after obtaining informed consent. After determining the stroke onset time to be *** on ***, the patient was randomized at *** on ***. The study medication was administered at *** on ***. I was at the patient's bedside and oversaw the patient receiving the study medication.

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Example

SISTER (IRB #XXXXXX)
Did the patient have capacity to provide consent?
YES – No surrogate needed
NO – Surrogate needed for consent

Did the patient and/or surrogate indicate, either verbally or non-verbally, any hesitation or unwillingness to participate?
NO

Does the patient meet all eligibility criteria?
YES

Were all study procedures, the consequences of participating, and the option not to participate explained to the patient and/or surrogate?
YES

Was the patient or surrogate given the opportunity to ask questions?
YES

Did the patient/surrogate sign the consent form?
YES

Was consent obtained before any study specific procedure?
YES

Investigator Obtaining Consent @MEWITHCREDENTIAL@
Date of consent ***
Time of consent ***

Was a copy of the form given to the person providing consent?
YES

Was the decision re-reviewed after a "time out?"
YES

Note Author: @MEWITHCREDENTIAL@

Good Documentation Practices

Daily Progress Note

Use a template or dot phrase in your EMR

Example

DAILY CLINICAL TRIAL RESEARCH NOTE – SISTER (IRB#809375):

Demographics
Date: @FDATE@
Age: @AGE@
Sex: @SEX@
DOA: @ADMITDT@

@NAME@ was consented and enrolled into the SISTER clinical trial protocol which is a Phase-2, prospective, randomized, placebo-controlled, blinded, dose finding trial that aims to determine the safety and preliminary efficacy of TS23, a monoclonal antibody against the alpha-2 antiplasmin (a2-AP), in acute ischemic stroke. This clinical trial is being performed in coordination with the NIH StrokeNet to identify a dose of TS23 that is safe and more efficacious than placebo for the treatment of patients from 4.5 to 24 hours of ischemic stroke onset (or last known well), who have evidence of core-penumbra mismatch on perfusion imaging, and are not a candidate for standard of care reperfusion therapies. In summary, this patient has received a treatment of one infusion of either TS23 or placebo.

Interval events since last research note (including significant laboratory or imaging results):
***

Summary of study medication administration:
The study medication was administered at *** on ***.

Summary of adverse events since last research note (write "N/A" if no adverse events since last research note)**:**
***

Vitals:
@VS@

Neurological Examination:
***

Overview of NIHSS
Randomization NIHSS:***
Last NIHSS: *** (provide date/time and total score)

Today's NIHSS Breakdown (insert NIHSS template score entered
Item Q1a. LOC Code (X/3): ***
Item Q1b. LOCQ (X/2): ***
Item Q1c. LOCC (X/2): ***
Item Q2. Best Gaze (X/2): ***
Item Q3. Visual Fields (X/3): ***
Item Q4. Facial Palsy (X/3): ***
Item Q5a. Left Arm Code (X/4): ***
Item Q5b. Right Arm Code (X/4): ***
Item Q6a. Left Leg Code (X/4): ***
Item Q6b. Right Leg Code (X/4): ***
Item Q7. Limb Ataxia (X/2): ***
Item Q8. Sensory Loss (X/2): ***
Item Q9. Aphasia (X/3): ***
Item Q10. Dysarthria (X/2): ***
Item Q11. Extinction/ Neglect (X/2):***
NIHSS Total Score (Date): ***
Time NIHSS Score Performed:***
Study Investigator Name Performing NIHSS:***

Total Change in NIHSS since Randomization:***
Total Change in NIHSS since last assessment:***
If neuroworsening noted (>= 4pts), presumed cause (write "N/A" if no neuroworsening): ***

Today's Clinical Assessment and Plan:
***

Note Author:
@SIGNATURE@, @TITLE@

Good Documentation Practices

Daily Progress Note

Use a template or dot phrase in your EMR

Example

DAILY CLINICAL TRIAL RESEARCH NOTE – SISTER (IRB#809375):

Demographics
Date: @FDATE@
Age: @AGE@
Sex: @SEX@
DOA: @ADMITDT@

@NAME@ was consented and enrolled into the SISTER clinical trial protocol which is a Phase-2, prospective, randomized, placebo-controlled, blinded, dose finding trial that aims to determine the safety and preliminary efficacy of TS23, a monoclonal antibody against the alpha-2 antiplasmin (a2-AP), in acute ischemic stroke. This clinical trial is being performed in coordination with the NIH StrokeNet to identify a dose of TS23 that is safe and more efficacious than placebo for the treatment of patients from 4.5 to 24 hours of ischemic stroke onset (or last known well), who have evidence of core-penumbra mismatch on perfusion imaging, and are not a candidate for standard of care reperfusion therapies. In summary, this patient has received a treatment of one infusion of either TS23 or placebo.

Interval events since last research note (including significant laboratory or imaging results):
***

Summary of study medication administration:
The study medication was administered at *** on ***.

Summary of adverse events since last research note (write "N/A" if no adverse events since last research note)**:**
***

Vitals:
@VS@

Neurological Examination:
***

Overview of NIHSS
Randomization NIHSS:***
Last NIHSS: *** (provide date/time and total score)

Today's NIHSS Breakdown (insert NIHSS template score entered
Item Q1a. LOC Code (X/3): ***
Item Q1b. LOCQ (X/2): ***
Item Q1c. LOCC (X/2): ***
Item Q2. Best Gaze (X/2): ***
Item Q3. Visual Fields (X/3): ***
Item Q4. Facial Palsy (X/3): ***
Item Q5a. Left Arm Code (X/4): ***
Item Q5b. Right Arm Code (X/4): ***
Item Q6a. Left Leg Code (X/4): ***
Item Q6b. Right Leg Code (X/4): ***
Item Q7. Limb Ataxia (X/2): ***
Item Q8. Sensory Loss (X/2): ***
Item Q9. Aphasia (X/3): ***
Item Q10. Dysarthria (X/2): ***
Item Q11. Extinction/ Neglect (X/2):***
NIHSS Total Score (Date): ***
Time NIHSS Score Performed:***
Study Investigator Name Performing NIHSS:***

Total Change in NIHSS since Randomization:***
Total Change in NIHSS since last assessment:***
If neuroworsening noted (>= 4pts), presumed cause (write "N/A" if no neuroworsening): ***

Today's Clinical Assessment and Plan:
***

Note Author:
@SIGNATURE@, @TITLE@

Daily Research Note: This is often a secondary note to the clinical progress note. It should include a summary of interval events, dosing, toleration, adverse events, assessment of neuroworsening, and plan as it relates to research (eg. reassess capacity for consent).

Good Documentation Practices

ALCOA - C

Remember –
"If isn't documented, it didn't happen"

Good Documentation Practices:

Attributable – It should be obvious who documented or did what; traceable to a person, date, and subject visit

Legible – the record should be easy to read and signatures identifiable

Contemporaneous – The info should be documented as it happens. If a clinical observation cannot be entered when made, chronology should be recorded. All signatures or initials should be attached to a date indicating when the signature was added to the document.

Original – First record of the information or certified copy. The investigator should have the original source document.

Accurate – Accurate, consistent, and real representation of facts.

Complete - The information should be complete (e.g., to answer who, what, when, where, why, and how).

Good Documentation Practices

Reminders and Tips

ALCOA - C

- Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (ICH 4.9.3)
- The completer must sign ALL source documents. FDA guidance specifies that data should be "attributable".

Good Documentation Practices

Reminders and Tips

ALCOA - C

- Review the following CRF data and select the most appropriate method to correct the date to 01/10/2024. Identify the mistake in each of the others.

A.

CXR Findings

01/10/24

Date of Report: ~~01/10/23~~

07/22/24 KR

B.

CXR Findings

01/10/24

Date of Report: [redacted]

07/22/2024 KR

C.

CXR Findings

01/10/24

Date of Report: ~~01/10/23~~ KR

D.

CXR Findings

01/10/24

Date of Report: ~~01/10/23~~

07/22/2024 KR