NIH StrokeNet Coordinator Webinar

July 26, 2023

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New This Funding Cycle: Clinical Research Professional (CRP) Education and Training Core

- Education/training core dedicated to on-boarding, continuing education, and retention of CRPs that mirrors the ongoing Fellow Education Core and leverages resources of the CTSAs

- Their first activity will be to perform a detailed needs assessment and determine how to most effectively fill the needs.

- Fellow Education Core and the NCC created a checklist for training new coordinators and began to reorganize the StrokeNet website to improve CRP training accessibility

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New This Funding Cycle: Clinical Research Professional (CRP) Education and Training Core

- CALL FOR CHAIR APPLICANTS! Funding for two chair positions to lead this new core starts 12/1/2023
  - Open to RCC Managers and NCC Project Managers
- Contact Laura Benken osinsklr@ucmail.uc.edu with your resume and cover letter including experience in education and training in clinical research by 8/30/23
- Two Chairs will be selected in September 2023 and asked to present an initial plan (20 minutes) during the StrokeNet Meeting in Toronto on 10/9/2023

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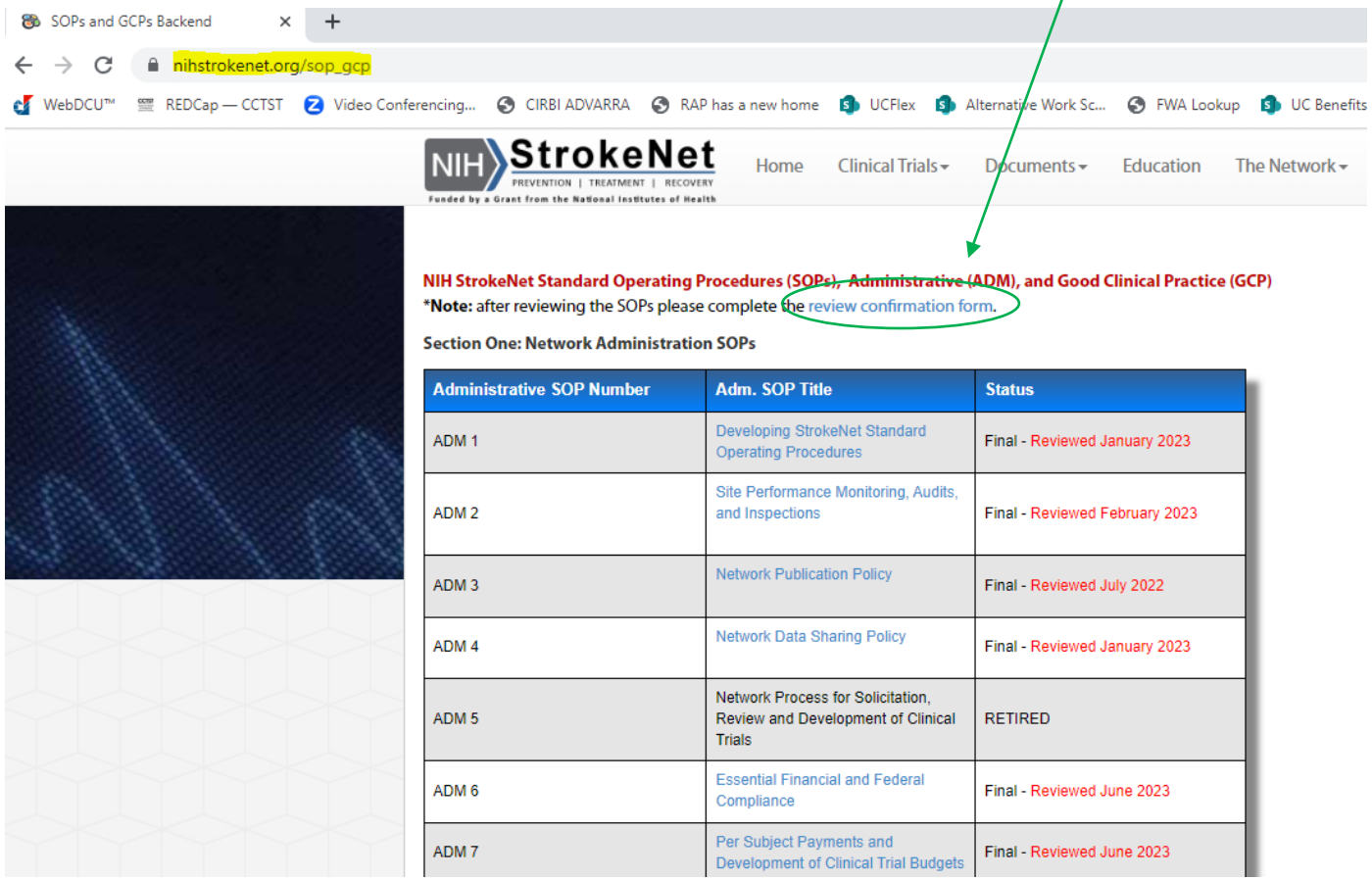
NIH StrokeNet Standard Operating Procedures (SOP) Series

https://www.nihstrokenet.org/sop_gcp

- Series to review all StrokeNet SOPs
- All **RCC PIs** and **RCC Managers** will be required to review and attest they have reviewed all StrokeNet SOPs



Administrative SOP Number	Adm. SOP Title	Status
ADM 1	Developing StrokeNet Standard Operating Procedures	Final - Reviewed January 2023
ADM 2	Site Performance Monitoring, Audits, and Inspections	Final - Reviewed February 2023
ADM 3	Network Publication Policy	Final - Reviewed July 2022
ADM 4	Network Data Sharing Policy	Final - Reviewed January 2023
ADM 5	Network Process for Solicitation, Review and Development of Clinical Trials	RETIRED
ADM 6	Essential Financial and Federal Compliance	Final - Reviewed June 2023
ADM 7	Per Subject Payments and Development of Clinical Trial Budgets	Final - Reviewed June 2023

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StrokeNet SOP Review – Informed Consent

SOP #	SOP Title
GCP 03	Informed Consent and Stroke Trials
ADM 21	Regulatory Document Maintenance and Storage
ADM 26	Consenting Non-English Speaking or Literacy-Challenged Participants
GCP 13	Remote Informed Consent – Local Management
ADM 24	Central Electronic Informed Consent Process

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GCP 03 – Informed Consent and NIH StrokeNet Trials

- The informed consent process ensures that study participants understand the research study
- Happens prior to study-related procedures are performed (with the exception of emergency research or other waivers of consent are obtained)
- ICD includes the risks and potential benefits at a level that allows for clear understanding
- Allow enough time to read the ICD
- Answer initial questions
- Clearly state that initial and ongoing participation in the study is voluntary, and that a participant may discontinue participation at any time
- Obtain relevant signatures on the ICD
- Continue to provide information and answers to questions throughout study participation

GCP 03 – Informed Consent and NIH StrokeNet Trials

- Stroke population may include:
  - **Adults with impaired capacity to consent**
    - CIRB approved protocol will specify if the use of a LAR is allowed and specify appropriate methods to determine decision making capacity
  - **Non-English Speaking**
    - should be presented with a consent document written in a language understandable to them (more on this in ADM 26)
  - **Unable to read or sign ICD**
    - Provide an impartial third party to witness the informed consent process and to sign the ICD attesting the participant/LAR was read the ICD and agrees to study participation (more on this in ADM 26)
  - **Children**
    - If the child is able to understand the nature of participation in a study, the child may provide assent.
    - Parent/guardian would provide informed consent

GCP 03 – Informed Consent and NIH StrokeNet Trials

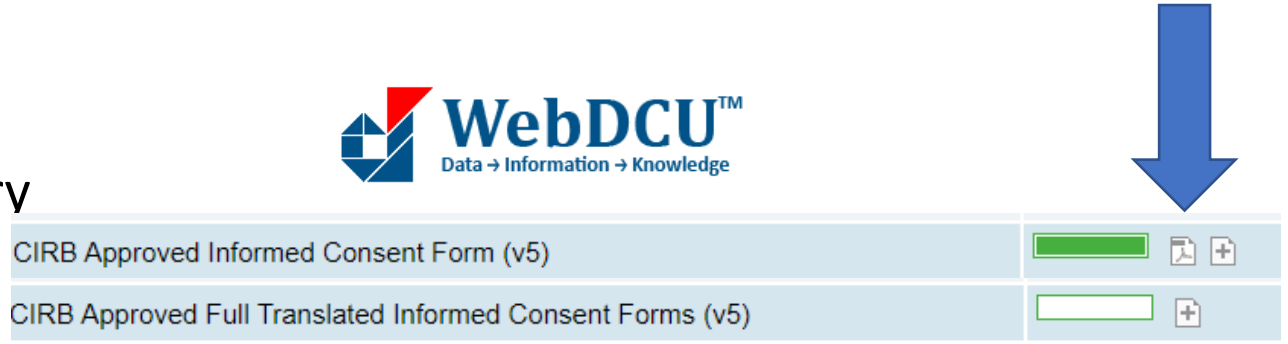
Documentation should be maintained in a note to file or a progress note in the participants research record

- **Documentation of Informed Consent Process:**
  - Verification that the ICD is the most recently approved version
  - The consent process that was followed prior to signing the ICD
  - Date informed consent was obtained
  - Who was present when the participant was consented
  - Verification of participant/family/legal representative comprehension of the ICD, if applicable
  - Verification that all questions posed by the potential participant were answered by designated study staff
  - Statement that the ICD was signed before any study assessments or procedures were performed (does not apply to EFIC studies)

ADM 21 – Regulatory Document Maintenance and Storage

- WebDCU is a large part of the **trial master file** of essential regulatory documents including the ICD.
- A PDF of every version of the ICD a site has been approved to use must be uploaded to WebDCU.
  - UC IRB studies – approved consent sent to site via email uploaded by site into WebDCU
  - Advarra IRB studies – approved consent uploaded by NCC regulatory from CIRBI portal into WebDCU

A **Trial Master File (TMF)** is a compilation of documents that prove that the clinical trial has been conducted following regulatory requirements (including Good Clinical Practice). The TMF plays a crucial role in ensuring that the trial has been managed successfully by the Investigator, Sponsor and Institution.



SOP ADM 21

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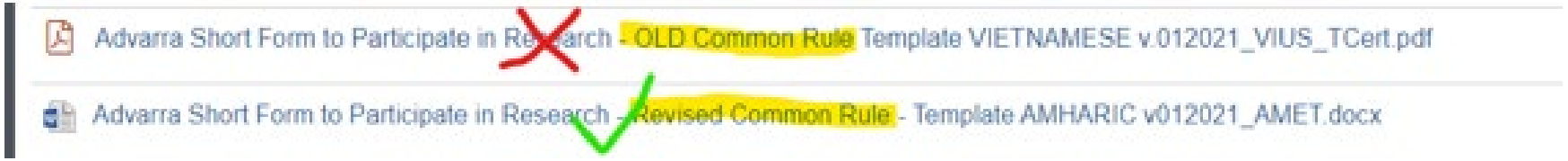
ADM 26 – Consenting Non-English or Literacy-Challenged Participants

- StrokeNet investigators are required to provide a fully translated ICD in a language understandable to the participants.
- The full version of the ICDs translated into Spanish will be made available to all sites, upon request, in each trial.
- NCC and Advarra provide translations of Short Form ICDs for use by request.
  - “bank” of Short Form ICDs in approximately 40 languages available, other languages may be added on case-by-case basis.
- The NCC and/or Advarra will provide fully translated ICDs in languages other than Spanish once the short form consent process is used for consenting in that specific language. Note: Sites need to submit their own request from Advarra via modification through CIRBI portal

Where is this “Bank” of Short Forms?

- UC StrokeNet CIRB – Request one from the trial PM or Regulatory Specialist
- Advarra – In CIRBI > Referenced Materials > Advarra IRB Reference Materials > Scroll/next page until you see “Advarra Short Form to Participate in Research – *Revised Common Rule* – Template *LANGUAGE*
  - *Request CIRBI Short Form Navigation Guide*



SOP ADM 26

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Using an Interpreter:

- Site investigators must provide the CIRB with a description of how interpreters for oral communication will be made available to participants that do not understand English during the consent process and while participating in follow-up for the study.
- Sites should also describe if interpreters are utilized **in person** or **remotely** during the informed consent process.
- This information should be documented on the StrokeNet CIRB Local Context Form or on the Advarra IRB CIRBI application.

SOP ADM 26

Who can be my witness?

- **Impartial Witness** - A person who is independent of the trial, cannot be unduly influenced by the people involved with the trial, who is present during the entire informed consent process and who attests to the adequacy of the consent process and to the participant's voluntary consent.
- A **non-research staff member** or the **participant's adult relative** if there is no reasonable concern that the proposed witness is not acting in the best interest of the individual.
  - Sites may has different policy on who can be a witness. Sites should follow any local policy.

How do I know if I need a witness?

Ask yourself: Can the participant/LAR **read** and **sign** the ICD?

Yes – no witness needed

No – witness needed

Reasons a participant/LAR can not read or sign the ICD:

1. They are non-English speaking therefore can not read an English ICD
2. They are illiterate therefore can not read or sign the ICD
3. They are visually impaired therefore can not read the ICD
4. They are physically unable to sign the consent form

StrokeNet Signature Blocks for the Witness:

- Best practice is to document the use of an interpreter and/or witness along with the informed consent process (GCP 03)
  - Note to file or process note in the participants research record
  - Add a general comment on Informed Consent CRF

WITNESS STATEMENT:

The participant or LAR was unable to read or sign this consent document because of the following reason:

___ The participant or LAR is non-English speaking
___ The participant or LAR is illiterate
___ The participant or LAR is visually impaired
___ The participant or LAR is physically unable to sign the consent document
Please describe: _____
___ Other
Please specify: _____

_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant or LAR named above was read the information in the consent document and that the participant or LAR has agreed to take part in the research study.

_____
Signature of Witness Date

_____
Print Name

SOP ADM 26

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Informed Consent Procedures for Participant/LAR Who Do Not Understand English is **EXPECTED** and a Fully Translated ICD is Used:

	Person Obtaining Consent	Interpreter	Impartial Witness	Participant / LAR
Performs the oral presentation of informed consent process	X	X		
Present during the oral presentation of informed consent process	X	X	X^ must be fluent in the language of oral presentation	X
Signs/Dates Fully Translated ICD	X		X*^	X

*interpreter may serve as the witness
^only if participant/LAR can not read or sign ICD

Short Form Process:

- Investigator + Interpreter perform the informed consent process and provides an oral translation of the CIRB-approved English ICD.
  - The oral presentation must be in a language understandable to the participant.
- Investigator + Interpreter answers any questions from the prospective participant/LAR.
- Participant/LAR given the CIRB-approved translated short form and a copy of the CIRB-approved English version of ICD, which serves as the written summary.
- Witness (may be Interpreter) must be present and attest to the consent process.

Short Form Process:

- Once the participant/LAR has consented and eligibility is confirmed, the English version of the CIRB-approved ICD is translated into the participant's native language (coordinated by the NCC or Advarra) and CIRB approves for use.
- The translated ICD must be provided to the participant within 30 days for the UC CIRB from initial consent with the short form process and the date of provision should be documented.

Informed Consent Procedures for Participant/LAR Who Do Not Understand English is **UNEXPECTED** and a Fully Translated ICD is NOT Available -> Use a Short Form (IRB approval needed to use a short form for UC CIRB)

	Person Obtaining Consent	Interpreter	Impartial Witness	Participant / LAR
Performs the oral presentation of informed consent process	X	X		
Present during the oral presentation of informed consent process	X	X	X must be fluent in the language of oral presentation	X
Signs Short Form			X*	X
Signs English Version of ICD	X		X*	
Signs Fully Translated ICD within 30 days of Short Form Signature	X		X*^	X

*interpreter may serve as the witness
^only if participant/LAR can not read or sign ICD

SOP ADM 26

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Low Literacy

Participants who cannot read or write or have apparent low literacy skills may have the ICD presented to them orally and can indicate their consent by "making their mark" on the ICD, when consistent with applicable state law. In this situation a progress note in the participant's case history and research record should indicate the reason for oral presentation and the lack of a signature.

	Person Obtaining Consent	Impartial Witness	Participant / LAR
Performs the oral presentation of informed consent process	X		
Present during the informed consent process	X	X	X
Signs/Dates English ICD	X	X	X "makes their mark" and process note

Consent Scenario Questions

- A Spanish-speaking study team member obtains consent from a Spanish-speaking participant. The participant is literate and has no physical impairments. The ICD used was fully translated into Spanish.

Is a witness required?

a. Yes, a witness is required.

b. No, a witness is not required.

c. Unsure.

A witness is not required when the ICD is fully translated into the participant's native language and they are able to read and sign the ICD.

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Consent Scenario Questions

- An English-speaking study team member obtains consent from a Spanish-speaking participant through the use of an interpreter. The participant is literate and has no physical impairments. The ICD used was fully translated into Spanish.

Is a witness required?

a. Yes, a witness is required.

b. No, a witness is not required.

c. Unsure.

A witness is not required when the ICD is fully translated into the participant's native language and they are able to read and sign the ICD. Best practice is to document the use of an interpreter in the participant's research record.

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Consent Scenario Questions

- An English-speaking study team member obtains consent from a Vietnamese-speaking participant through the use of an interpreter. A Vietnamese short form consent process was used.

Is a witness required?

a. Yes, a witness is required.

b. No, a witness is not required.

c. Unsure.

A witness is always required if a participant is consented using a short form when a fully translated ICD is not available.

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GCP 13 – Remote Informed Consent Process

- Step-by step procedure on how to perform informed consent when the participant or LAR and the person obtaining informed consent are NOT in the same physical location
- The ICD (and any stand-alone HIPAA or stand-alone Bill of Rights if applicable) must be presented to the subject and/or LAR during the consent process. Transmission of these documents must use one of the following **21 CFR part 11** compliant methods:
  - online survey (via REDCap or other secure software)
  - E-consent module in EMR
  - Fax
  - Postal mail
  - email

Acceptable Signatures

- The participant/LAR must document consent with a **handwritten signature** via wet signature, signing using a signature pad, touchscreen on a tablet or cell phone with a stylus, mouse, or their finger.
- NIH StrokeNet determined that **only handwritten signatures will be accepted on eICD's signed remotely** for StrokeNet studies.

Acceptable

NOT Acceptable

SOP GCP 13

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If a witness is required, then remote consent will **not** be used.

- StrokeNet does not allow the use of an impartial witness during the remote consent process due to feasibility and compliance issues.
- In some situations, a witness does not need to be impartial. For example, some institutions require two study team members to witness the consent conversation if consent is obtained remotely. In this situation, witness documentation should be maintained at the site level according to local policies.

ADM 24 – StrokeNet Central Electronic Informed Consent Process

- StrokeNet uses the University of Cincinnati and Cincinnati Children's Hospital Medical Center's REDCap platform for eConsent.
- REDCap is a mature, secure web application for building and managing online surveys and databases.
- The StrokeNet centrally managed eConsent process meets the requirements of 21 CFR Part 11 by combining the technical features of REDCap with StrokeNet policies, procedures, training, validation, and documentation.
- The centrally managed REDCap eConsent is the preferred method of obtaining consent in-person and remotely as it minimizes common documentation errors and administrative burdens.

SOP ADM 24

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ADM 24 – StrokeNet Central Electronic Informed Consent Process

https://redcap.link/StrokeNet_eConsent_Training

Access REDCap eConsent training here!

- Using the REDCap platform, the delegated study personnel obtaining consent will share the eICD via emailing or texting the site-specific URL link to the participant or LAR.
- The study team member obtaining consent will give instructions about completing the information fields on the eICD, where to sign and date and how to transmit the entire signed and dated form back to the study team using the REDCap platform.
- A copy of the signed eICD will be automatically saved in the REDCap database and should be immediately accessible to the research team for review. A printed copy of the eICD should be provided to the participant/LAR if the participant/LAR does not request an electronic copy be emailed to the address provided during the online survey.

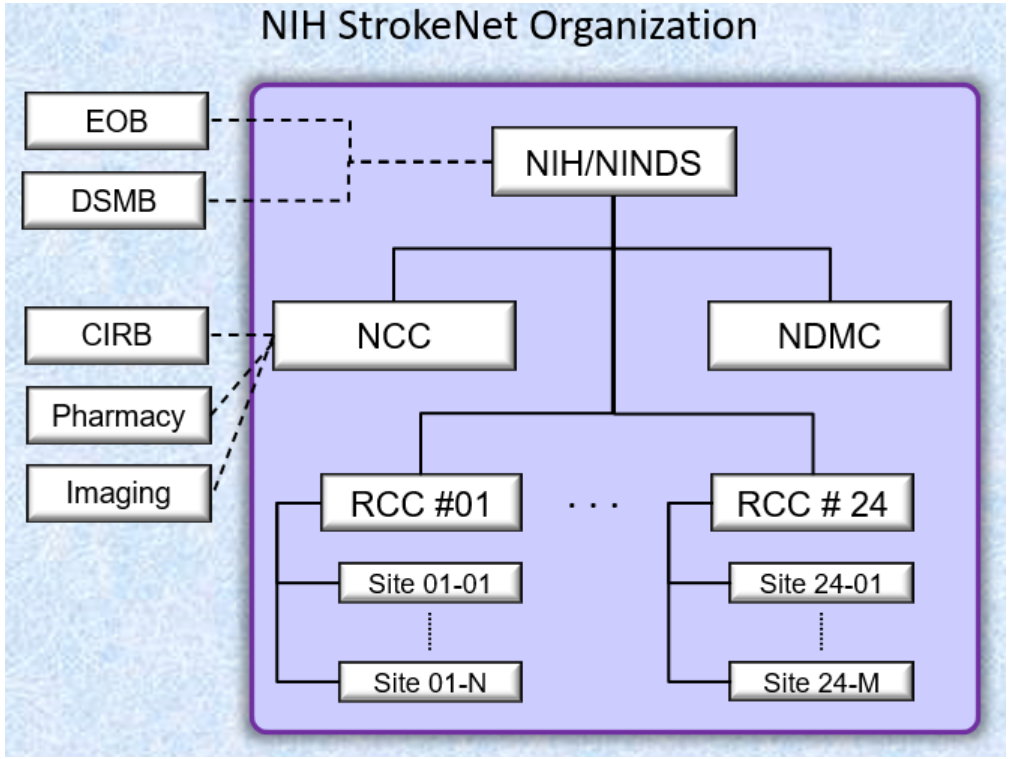
CIRB approval to use remote consent procedures

- **UC CIRB** – Sites must obtain site-specific CIRB approval to use the remote consent procedures described in SOP GCP 13 and ADM 24.
  - Each trial has a specific Remote Consent Implementation Form that captures the site's election to use these procedures.
  - The Remote Consent Implementation Form is submitted to and approved by the UC CIRB.
- **Advarra CIRB** – Sites do not need site-specific CIRB approval to utilize a method of remote consent that is approved at the sponsor/study level.
  - Sites may elect to use centrally managed eConsent by completing a REDCap survey that is managed at the trial-level.

SOP GCP 13 and ADM 24

Next Time On – StrokeNet SOP Series

- How StrokeNet is Structured (ADM 17)
- RCC Performance, Management of Satellite Sites (SS) and Performance Sites (PS), Adding new SS and PS (ADM 8, 9, 10)
- Network Communications (ADM 15)



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