

CRP Training and Education Core Updates

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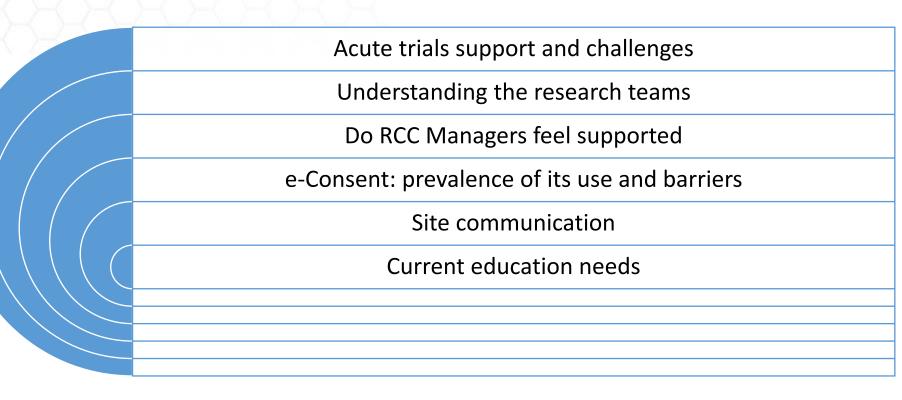
Kristine Konsulis



Summary of activities



- Nov 2023- Jan 2024: baseline assessments, RCC one-on-one meetings
 - Data collected from 25 RCC (1 RCC didn't have a manager, 1 new RCC that wasn't set up)
- Continued new RCC manager mentoring



Acute trials support and challenges

9 RCC without 24/7 after hours coverage

- Not a dedicated 24/7 coordinator
- Not expected to come in over nights/weekend.
- No additional pay. Comp time is offered if the coordinator happens to stay after hours
- IDS Pharmacy is expensive after business hours
- Limited pharmacy hours
- Small team, no back-up coordinators

16 RCCs with 24/7 or limited after hours coverage (7am-11pm or similar)

- Few sites have an actual call schedule for coordinators
- Higher salaries to compensate for on call
- Acute stroke recruitment is done remotely (clinicians are boots on the ground)
- Hard work/life balance for the 24/7 coordinators, lots of turn over
- Research pharmacy is 24/7
- The coordinator is on call 24/7 by their choice. No back up coordinator coverage



Understanding the research teams

- Have mix of RNs, CCRPs, non-licensed or certified research assistants, International medical graduates, post bac interns, etc.
- Clear career path- 3 levels of coordinators: 1. Entry level (e.g. RA1), 2. Experienced coordinators(e.g. RA2), 3.Research nurse coordinators
- Some of the research coordinators do not have reliable clinical knowledge
- Most RCCs have CTSAs
- Optional training opportunities exist at most sites



Do RCC Managers feel supported?

Yes

- Engaged PIs who have great working relationships with Manager and team
- Supportive department that recognizes the hard work and prestige
- Weekly meetings with stroke attendings
- Ability to work in a hybrid model has been helpful for work life balance

No

- Feels lost, did not get much education when transitioning to manager role
- Concepts are a bit abstract
- Past year has been hard
- StrokeNet coordinator for a long time, regulatory duties are new and challenging
- Being understaffed



eConsent: usage and barriers

Positives:

- Most RCCs and satellites have some version of <u>eConsent</u> currently approved for use
- Most sites are comfortable with remote consent and <u>eConsent</u> in the acute setting
- A few sites have dedicated tablets and are trying to use mostly <u>eConsent</u>
- Only 4 RCCs are paper only

Negatives:

- Challenging to use, especially in person, for older patients
- Some institutions strongly prefer paper for in person interactions
- Lack of dedicated tablet for research purposes

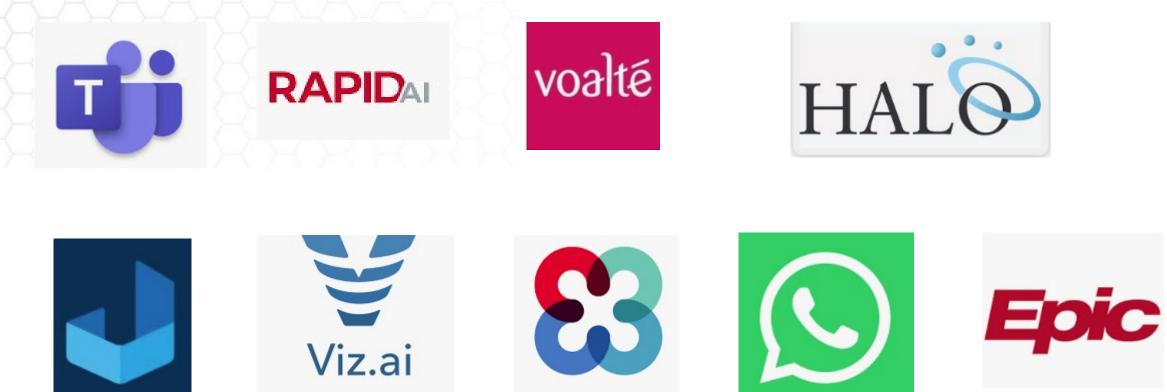


- Clear top to bottom expectation coming from StrokeNet
- Possibly providing a tablet to use for consent with future trials
- Educational session to increase comfort



Site communication

Mostly direct communication: in person, email, phone, text





Current education needs

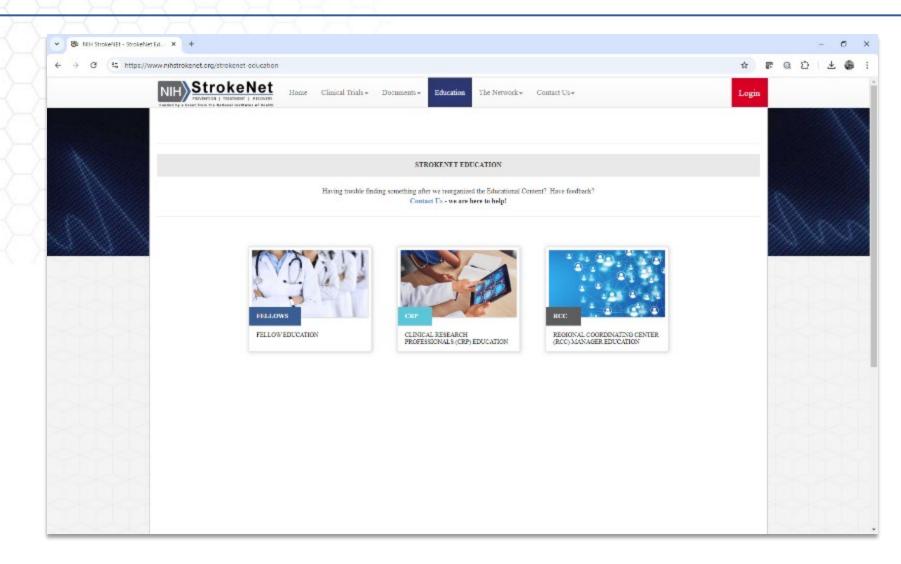
- Short, pragmatic how-to videos and slides on basics (source documentation, how to make a correction, AE/SAE reporting, checklists)
- Reorganization of the existing resources and WebDCU Toolbox
- Re-naming of webinars, abstracting the education to a separate slide deck, # system to make it searchable by keywords
- One on one mentorship is helpful, should be consistent for all new RCC managers
- Strengthening stroke knowledge, SOC vs research, imaging, etc.
- Lunch and Learns, in person boot camps for coordinators/ managers where cases are discussed on a peer-to-peer basis
- Clear definition of roles and responsibilities between study team members (PI/Sub-I/fellow/manager/coordinators/trial specific central PM)







Updated website: https://nihstrokenet.org/strokenet-education





Updated website

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Updated website



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① Screening Tools			Good Documentation Practice	
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Updated website: https://dcu.musc.edu/campus/

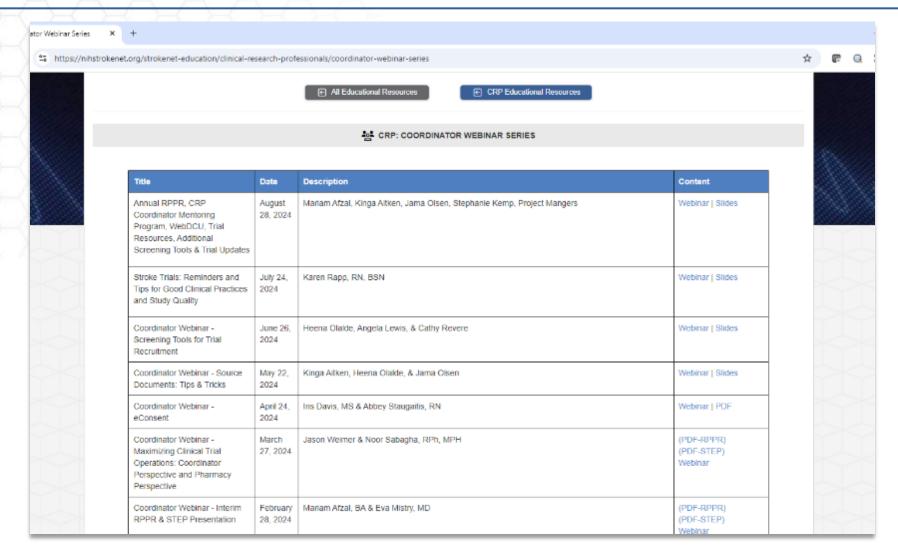
WebDCU™ CTMS Training

- Logging In and Changing Password <u>MP4</u>
- WebDCU™ Setup <u>MP4</u>
- Regulatory Management <u>MP4</u>
- Lab Kit Tracking <u>MP4</u>
- Editing Your DOA <u>MP4</u>
- Adding Study Team Members <u>MP4</u>
- Adding Screen Failures <u>MP4</u>
- Study Design and CRF Collection Schedule <u>MP4</u>
- Subject CRF Binder <u>MP4</u>
- Data Entry <u>MP4</u>
- F104 Adverse Event <u>MP4</u>
- Rule Violations <u>MP4</u>
- Data Clarification Requests <u>MP4</u>
- Helpful Tools <u>MP4</u>
- Finding Help <u>MP4</u>

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Coordinator Webinars





- October 2024 Career advancement: Abby Staugaitis, Dave Haney and Mariam Afzal
- Integration of clinical care & research: PI and coordinator perspective
- Grant management 101, everything an RCC manage must know (Mariam Afzal)
- WebDCU navigation
- Roles and responsibilities for PI, Sub-I, RCC Manager, Trial Coordinators
- Collaboration with DEI Core



NEW CRP Mentoring Program

- Open to any CRC participating in at least 1 SN trial
- Small group, interactive learning sessions w/ mentor – Max 5 mentees/ mentor
- Certificate of completion offered
 - can be used towards professional clinical research certification/recertification
- Mentors: subject matter experts vetted by the CRP Core
- Go live: January 1, 2025



Topics

Topics from 4 sections:

- StrokeNet policy
- Consenting (e.g. role play, eConsent, tech back method)
- Regulatory and Data Management (GCP, documentation best practices, start-ups, cIRB reliance Cincinnati vs Advarra, Monitoring)
- Communication and professionalism (e.g. how to communicate with clinicians/pts/families)



Additional Education Topics?

What other educational topics would you like to see the StrokeNet CRP core address in the coming months?

Please contact co-chairs:

- Heena Olalde at <u>heena-olalde@uiowa.edu</u>
- Kinga Aitken at kinga.aitken@hsc.utah.edu





Questions?



