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Addressing Challenges and Barriers to Rural Veteran Participation in Clinical Research Within the Veterans Affairs Healthcare System

Presenters

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Relevant Financial Disclosures

The presenters have no relevant financial relationships to disclose.

Disclaimer

The views expressed in this presentation are those of the presenters and do not necessarily represent the views of the Department of Veterans Affairs or the government of the United States.

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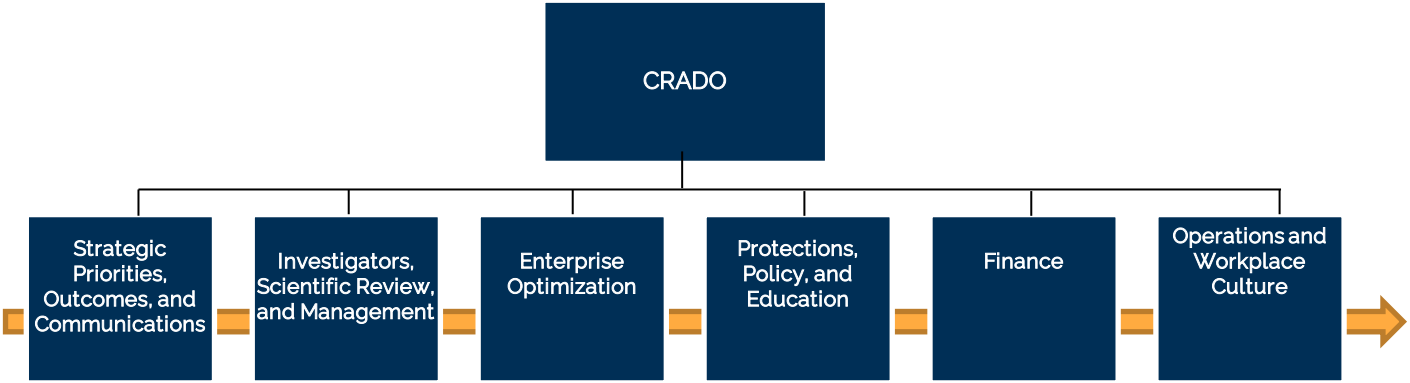
Bottom Line Up Front (BLUF)

The VA Cooperative Studies Program (CSP) ACCESS initiative was developed and implemented as a strategy to improve CSP's engagement with rural/lower complexity VA Medical Centers (VAMCs) and increase rural Veteran access to CSP and VA multi-site research more broadly.

Background/VA Research Overview



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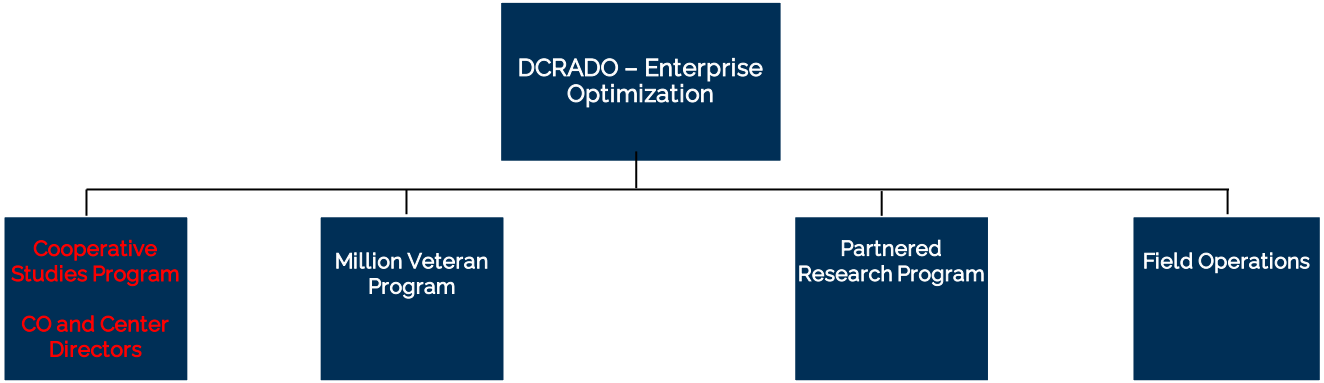

Background/CSP Overview

- ***CSP is a national infrastructure for sponsoring, developing, and executing:***
  - Multi-site clinical trials;
  - Epidemiological & Population Research; and
  - Genomic medicine research.

- Nearly **200** clinical trials & observational studies.

- CSP Coordinating Centers (CSPCCs) provide study design, data management, statistical analysis & administrative support to VA Cooperative Studies.

Background/CSP Overview

- ***CSP infrastructure includes:***
  - CSP Coordinating Centers;
  - Pharmacy Coordinating Center;
  - Epidemiological Research Centers;
  - Network of Dedicated Enrollment Sites (NODES); and
  - DNA bank, biorepository and pharmacogenomics analysis laboratory.

VA CSP Locations

CSP Coordinating Centers are ISO 9001:2008 registered

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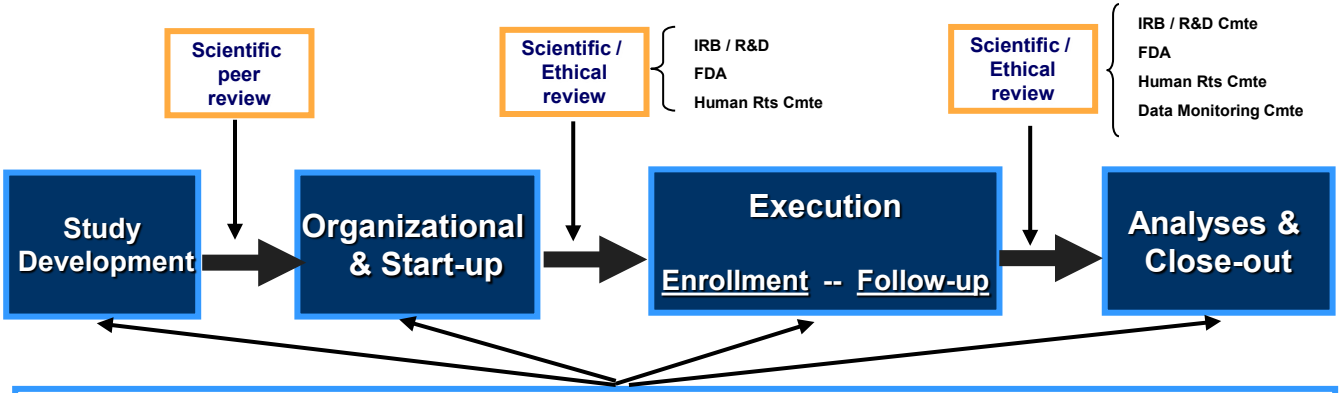
Background/CSP Overview



CSPCC Study Team

Biostatistician	Data Coordinators
Project Manager	Pharmacy/SMART
Database Programmer	QA
Statistical Programmer	NODES

What is NODES?

- CSP's Network of Dedicated Enrollment Sites (NODES) is a consortium of 23 VA Healthcare Systems with teams dedicated to conducting CSP studies to enhance the overall performance, compliance and local management of CSP multi-site research.

- NODES Primary goals are the following:
  - **Increase** study enrollment rates
  - Enhance participants **safety and experiences** in clinical research
  - Improve overall **efficiency** and **efficacy** of CSP research

NODES Key Contributions to Date

Study Enrollment

- ***Rapid Response Start-up and Enrollment support (Industry sponsored studies)***
  McClure, J., Asghar, A., Krajec, A., Johnson, M. R., Subramanian, S., Caroff, K., McBurney, C., Perusich, S., Garcia, A., Beck, D. J., & Huang, G. D. (2023). Clinical trial facilitators: A novel approach to support the execution of clinical research at the study site level. *Contemporary clinical trials communications*, 33, 101106. https://doi.org/10.1016/j.conctc.2023.101106

- ***Mobile Recruitment Strategy, Community-Based Outpatient Clinic (CBOC) Study Enrollment, Outreach Event Attendance***
  Beck, D., Asghar, A., Kenworthy-Heinige, T., Johnson, M. R., Willis, C., Kantorowicz, A. S., Condon, D. L., Huang, G. D., & VA Cooperative Studies Program (CSP) Network of Dedicated Enrollment Sites (NODES) (2020). Increasing access to clinical research using an innovative mobile recruitment approach: The (MoRe) concept. *Contemporary clinical trials communications*, 19, 100623. https://doi.org/10.1016/j.conctc.2020.100623

NODES Key Contributions to Date

Study Enrollment

- ***Research Site Mentorship***
  Johnson, M.R., Kenworthy-Heinige, T., Beck, D.J., Asghar, A., Broussard, E., Bratcher, K., Tommessilli, L., Antonelli M, Planeta B. "Research Site Mentoring: A Novel Approach to Improving Study Recruitment." *Contemporary Clinical Trials Communications* 2018 March; 9:172-177. https://doi.org/10.1016/j.conctc.2018.01.011

NODES Key Contributions to Date

Improve overall efficiency and efficacy of CSP research

- ***Performance Metric Development/Consortium Performance Evaluation***
  Johnson, M. R., Raitt, M., Asghar, A., Condon, D. L., Beck, D., & Huang, G. D. (2021). Development and implementation of standardized study performance metrics for a VA healthcare system clinical research consortium. *Contemporary clinical trials*, *108*, 106505. Advance online publication. https://doi.org/10.1016/j.cct.2021.106505

- ***Staff Engagement***
  Johnson, M. R., Asghar, A., Velarde, K., Donaire, M., Bratcher, K. (2021). Development and Implementation of Work Engagement Strategies in a Clinical Research Consortium During the Coronavirus Disease 2019 (COVID-19) Pandemic: A Reflective Inquiry. *Journal of Research Administration*, 52(2), 140-166. Fall 2021. https://www.srainternational.org/viewdocument/fall-2021

NODES Key Contributions to Date

Improve overall efficiency and efficacy of CSP research

- ***Hiring/Training CSP Personnel***

  Willis, C., Velarde, K.E., Bratcher, K., Condon, D., Johnson, M.R. Development of a Clinical Research Consortium Position Interview Panel within the Department of Veterans Affairs Health Care System. Journal of Research Administration, 52(1), 59-75. Spring 2021. https://files.eric.ed.gov/fulltext/EJ1292630.pdf

  Willis, C., Bratcher, K., Kenworthy-Heinige, T., McBurney, C., Asghar, A., Beck, D., Condon, D.L., Huang, G.D. The Anatomy of a Great Clinical Research Coordinator. *Clinical Researcher*, *32*(7), 5-14. August 2018. The Anatomy of a Great Clinical Research Coordinator - ACRP (acrpnet.org)

Problem

- Executing clinical research in medical facilities located in rural settings and/or with lower care complexity levels has been proven to be challenging. [1-6]

- Issues such as isolation and lack of organizational support and resources, difficulty with enrollment of patients in rural settings, and challenges with identifying and retaining experienced clinical research staff serve as barriers to developing the necessary infrastructure to conduct clinical research at these facilities.[1-6]

Solution

- The CSP "**A**dvancing **C**apacity for **C**linical Research through **E**ngagement with **S**trategic **S**ites **(ACCESS)**" initiative was initiated in 2020 as an approach for engaging rural/lower complexity VAHCs to participate in CSP clinical research.

- Rural/lower complexity VAHCs "strategic sites" receive guidance, education, and mentorship from assigned CSP Node sites, and CSP and ORD stakeholders that work with them to strengthen/improve their local research site enterprise to be able to effectively conduct multi-site clinical research.

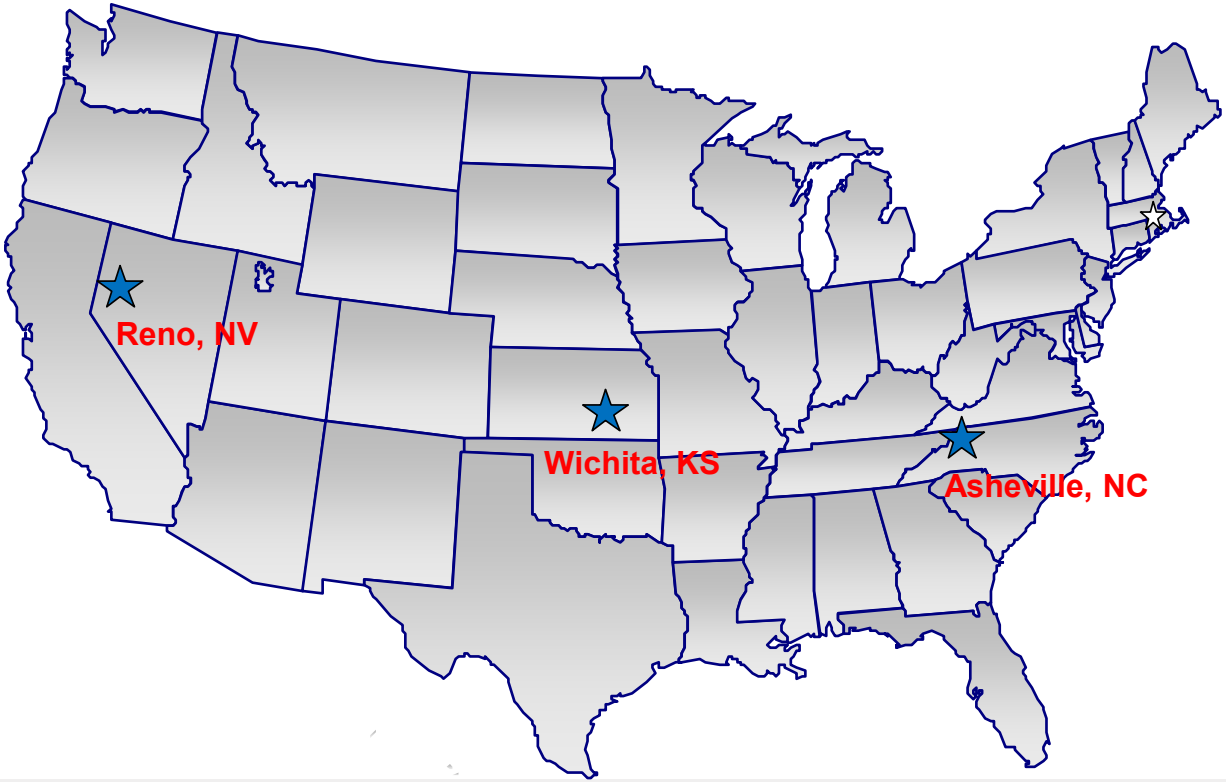
Solution

- ***Inclusion Criteria***
  - Facilities must meet at least "one" of the following two criteria to participate in the pilot:
    - Have a patient population that comprised of ≥ 40% rural Veterans; and/or
    - Is categorized as a "lower complexity/level 3 facility" per the VHA Complexity Model[7]

Solution

- The Asheville VA Healthcare System **(Asheville, NC)**, VA Wichita Healthcare System **(Wichita, KS)**, and VA Sierra Nevada Health Care System **(Reno, NV)** were selected as pilot sites.

CSP ACCESS Sites



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Solution

- ***CSP ACCESS Core Areas***
  - CSP Guidance, Education, and Mentorship
    - Improve site knowledge and awareness of CSP and its associated policies and processes for conducting VA multi-site clinical research
  - ORD Operations Guidance
    - Mentorship for site Research Leadership on ORD research execution/policy

Solution

- ***CSP ACCESS Core Areas***
  - Research Infrastructure
    - Business & strategic plan development
    - Focus on site improving/strengthening clinical research infrastructure

Results

CSP ACCESS Strategic Sites (Facility Demographics)

		VA Asheville HCS	VA Wichita HCS	VA Sierra Nevada HCS
CL	Complexity Level	1c-High Complexity	2-Medium Complexity	2-Medium Complexity
Rurality	Highly Rural	7.69%	10.30%	3.70%
	Rural	43.91%	45.83%	37.13%
	Insular Islands	0.00%	0.01%	0.00%
	Urban	48.02%	43.48%	57.26%
	Unknown	0.37%	0.39%	1.91%
Race	AMERICAN INDIAN OR ALASKAN NATIVE	0.65%	0.95%	1.09%
	ASIAN	0.22%	0.44%	1.25%
	BLACK OR AFRICAN AMERICAN	7.03%	6.87%	2.81%
	DECLINED TO ANSWER	1.72%	2.96%	3.02%
	MULTIPLE	0.56%	1.08%	1.39%
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0.31%	0.35%	1.03%
	UNKNOWN	3.15%	6.45%	6.32%
	WHITE	86.35%	80.91%	83.09%
Ethnicity	Hispanic or Latino	1.05%	3.65%	4.92%
	Not Hispanic or Latino	94.79%	88.95%	88.31%
	Declined to Answer	1.19%	2.21%	1.95%
	UNKNOWN	2.97%	5.19%	4.82%
Gender	Female	8.34%	9.43%	10.03%
	Male	91.63%	90.55%	89.93%
	Unknown	0.02%	0.02%	0.04%

Results

CSP Study Feasibility and Selection Data (ACCESS Strategic Sites)

Site/CSP Study Data	FY17 to FY21	FY22 to Present	% Change
Reno			
Number of CSP Study Feasibility Surveys Received (Pre-CSSEC Review)	1	3	200%
Number of CSP Study Selection Surveys Received (Post-CSSEC Review; Study is Approved for Funding)	0	4	400%
Number of New CSP Studies Site Selected For	0	1	100%
Wichita			
Number of CSP Study Feasibility Surveys Received (Pre-CSSEC Review)	0	3	300%
Number of CSP Study Selection Surveys Received (Post-CSSEC Review; Study is Approved for Funding)	0	3	300%
Number of New CSP Studies Site Selected For	0	1	100%
Asheville			
Number of CSP Study Feasibility Surveys Received (Pre-CSSEC Review)	-	5	-
Number of CSP Study Selection Surveys Received (Post-CSSEC Review; Study is Approved for Funding)	-	6	-
Number of New CSP Studies Site Selected For	3	8	500%

Results

Investigator Survey (ACCESS Strategic Sites)

CSP Investigator Survey	Does Not Apply	Strongly Disagree	Disagree	Neither Disagree or Agree	Agree	Strongly Agree
n=9						
Overall, I am satisfied with these training sessions to date.	-	-	-	1 (11%)	3 (33%)	5 (56%)
I would recommend these training sessions to others.	-	-	-	-	2 (22%)	7 (78%)
I learned new knowledge and skills from the training sessions that I've attended to date.	-	-	-	1 (11%)	2 (22%)	6 (67%)
How much have you learned about the various CSP study phases, as a result of these training sessions?	-	-	-	1 (11%)	3 (33%)	5 (56%)
These training sessions increased my interest in either submitting a Letter of Intent (LOI) or participating as a Local Site Investigator (LSI) for a future CSP study.	1 (11%)	-	-	3 (33%)	1 (11%)	4 (44%)
These training sessions improved my knowledge/understanding of clinical research in general.	-	-	2 (22%)	-	4 (44%)	3 (33%)
The scope of these learning sessions were appropriate to my professional needs.	-	-	1 (11%)	-	4 (44%)	4 (44%)
I will be able to apply the knowledge and skills learned to improve my job performance.	-	-	-	2 (22%)	4 (44%)	3 (33%)
The training environment (video conference/MS Teams) was effective for my learning.				1 (11%)	4 (44%)	4 (44%)
		Not Useful	Little Useful	Neutral	Useful	Extremely Useful
How useful was the content of these training sessions for your practice or other professional development?	-	-	-	2 (22%)	3 (33%)	4 (44%)

Lessons Learned (Strategic Site Perspective)

Successes

- Mentor Site
  - Walked RJDVA through 1st CSP site selection survey. This effort was successful and RJDVA was selected as participating site for this study.
  - Discussion re: Long-term benefits of research to the facility and the resources that will be necessary to achieve these benefits, including space.

Lessons Learned (Strategic Site Perspective)

Successes

- Met with RDJVA Executive Leadership Team (ELT).
  - Discussion re: Long-term benefits of research to the facility and the resources that will be necessary to see these benefits, including space.
- Facility Research Strategic Plan completed.
- Completion of the Facility Research Business plan is pending.

Metaphor—Intangible Benefit of CSP ACCESS Mentorship

Metaphor—Intangible Benefit of CSP ACCESS Mentorship

Lessons Learned (Strategic Site Perspective)

Challenges

- Training was built into the program to aid investigators in the process of developing a study which could be performed as a CSP trial.
  - Our investigators are not yet seasoned enough to be able to benefit from that potentially helpful training.

ACCESS Relevance/Impact (NODES/Strategic Sites)

- ***Project Action Plan–Guidance, Education, and Mentorship***
  - Increase awareness of CSP across ACCESS strategic sites to increase the likelihood of their participation in CSP trials.
    - CSPCCs and NODES co-lead education/training series
  - Provide CSP guidance, education, and mentorship to VHA strategic sites that are interested in improving their capacity to conduct CSP multi-site studies.
    - NODES provides direct mentorship to strategic sites
    - Bi-directional communication pathways created

ACCESS Relevance/Impact (NODES/Strategic Sites)

- ***Project Action Plan – Research Infrastructure***
  - Establish an infrastructure to enable the hub (existing CSP Node sites) and spoke (strategic sites) model:
    - Spoke sites signed a Memorandum of Understanding to participate as a spoke (e.g., provide the appropriate levels of protected time for investigators)
    - Three strategic sites were paired with three CSP Node sites in a 1:1 ratio for research site mentorship
    - 12-month mentorship including in-person site visits with facility partners (NODES, R&D Offices)

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ACCESS Relevance/Impact (NODES/Study Sites)

- ***Project Action Plan – Research Infrastructure***
  - Developing Strategic and Business Plans to guide growth
  - Creating pathways to recruit and retain experienced clinical research staff
  - Partnering facility/clinical leadership teams to create shared strategic priority areas and growth plans

Lessons Learned (NODES Perspective)

Successes

- Established upfront expectations and goals (MOU)
- Offered open forum for discussing sensitive/difficult topics
- Questions/issues addressed in a timely manner
- Provided demonstrated/practical solutions to issues
- Shared motivation between partners to advance clinical research

Lessons Learned (NODES Perspective)

Challenges

- Established vs. emerging research operations
- Leadership transitions
- Geographical distance between sites
- Unpredictable issues to address (no clear roadmap)
- Unutilized resources and unidentified facility support

ACCESS Relevance/Impact (CSP/Clinical Research)

- ***Site Engagement and Participation in CSP projects***
  - Contribution to CSP and other research projects
    - Diverse population demographics
    - Equal access to ORD Research
    - Novel ways of engaging Veterans
  - Incorporating support mechanisms for new research ideas from site investigators

Lessons Learned (CSPCC Perspective)

Successes

- Participation of ACCESS sites in new CSP studies
- Site personnel engagement and interaction
- Revision/re-initiation of CSP research training material

Lessons Learned (CSPCC Perspective)

Challenges

- Site adjustment to larger research infrastructure
- Research training of clinical investigators
- Local support for dedicated clinician effort for research
- Accurate site assessment of ‘best-fit’ CSP studies
- Fiscal environment

Summary/Next Steps

- The CSP ACCESS pilot will continue through the end of VA FY24 (9/30/24)
- Will continue to evaluate impact through criteria such as:
  - Number of CSP studies launched at strategic sites;
  - Number of feasibility/site selection surveys received by strategic sites; and
  - Investigator satisfaction surveys with training program, etc.

Summary/Next Steps

- Findings from pilot will help inform the next phase of the initiative.

- Explore the feasibility of scaling the model to additional sites starting in VA FY25 (10/1/24).

- A proposed CSP ACCESS site expansion will continue to focus on rural Veterans, but will also place an additional focus on other VA subpopulations that have been traditionally underrepresented (race/ethnicity, gender) in clinical research, e.g., minorities, women, etc.

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QUESTIONS?