DEVELOPMENT OF A DATA FACILITATION LOG FOR PERFORMANCE MONITORING AND EVALUATION IN A LARGE, **INTEGRATED HEALTHCARE SYSTEM CLINICAL RESEARCH CONSORTIUM**

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Problem

Performance monitoring and evaluation are critical tools that are used to demonstrate the value of employees, institutions and organizations.¹⁻² These tools can be somewhat arduous to develop, gain consensus on, and implement, particularly in multi-site entities such as clinical research consortiums.³⁻⁴

The Department of Veterans Affairs (VA) Cooperative Studies Program (CSP) established a consortium of nine VA medical centers (VAMCs) called the Network of Dedicated Enrollment Sites (NODES) that offer innovative approaches to address challenges to clinical trial execution.⁵⁻⁷

The challenges associated with the evaluation of a highly-matrixed clinical research program embedded within a large, integrated healthcare system are both numerous and constant.

Approach

Over the course of 5 months (March – July 2014), NODES successfully implemented a Data Facilitation Log (DFL) that relevant information could be populated into, including recruitment, staff time and effort, and data quality (Figure 1).

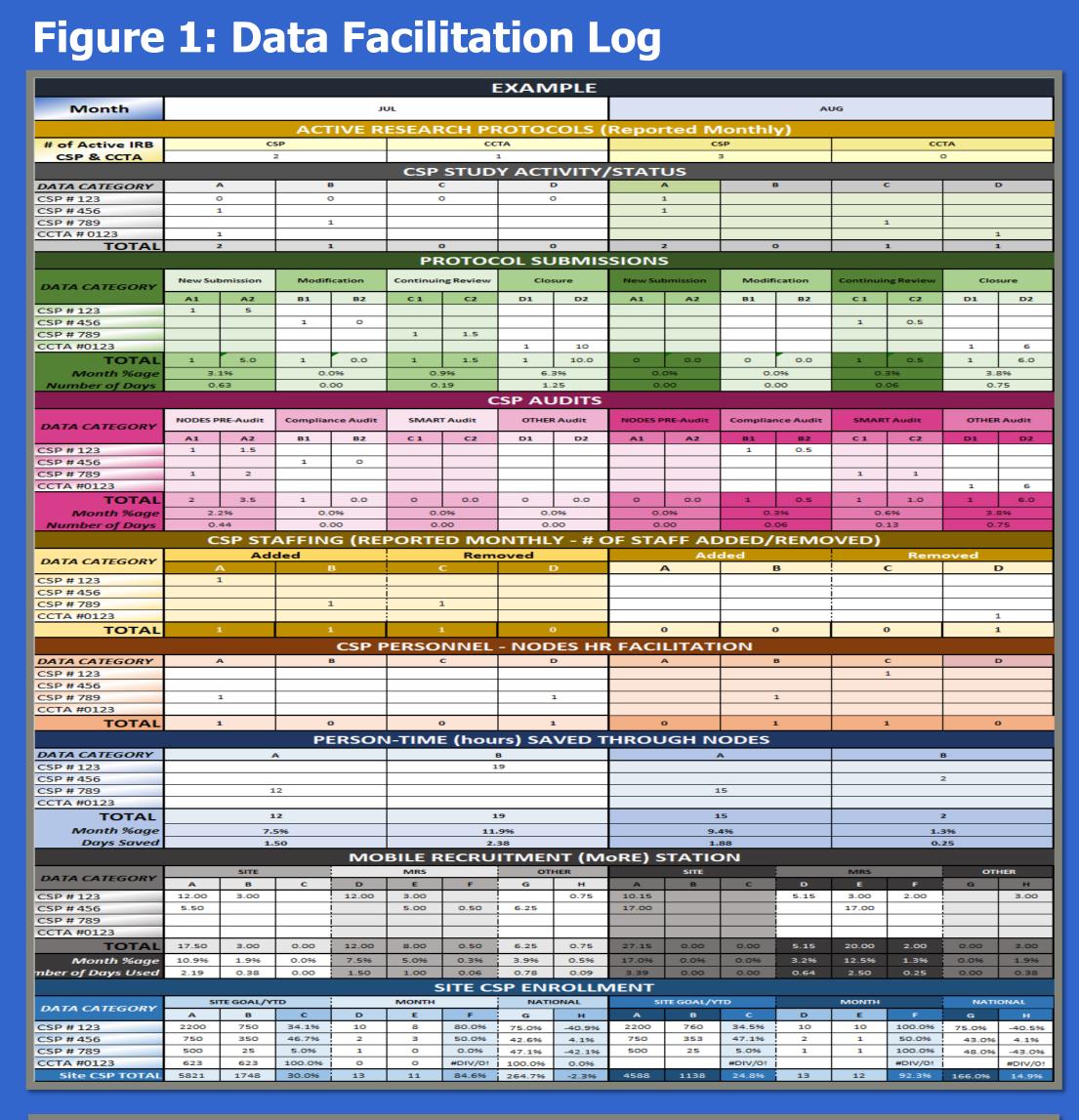
NODES collected data from all active CSP studies conducted at respective sites. The data was entered monthly, and included information such as staff turnover, staff coverage (time and fiscal cost), regulatory audits, administrative information, (e.g., meetings, local and national committee involvement, etc.), and novel recruitment strategies.

Outcomes

The DFL provided data for analysis of performance rank (e.g., study participant enrollment), fiscal savings (e.g., salary support through cross coverage), captured time and effort NODES personnel contributed to program meetings and committees.

This data collection produced information that justified the NODES initiative as a valuable national and local resource of support, expertise, and stewardship to CSP. It also provided a platform for further development of quality performance metrics, program improvements, increased technology, and the enhancement of institutional memory and best practices translatable to all VA clinical research efforts.

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Next Steps

NODES will continue efforts to streamline and increase the data facilitation log's usability and staff satisfaction with the tool, as well as align its data points with the program's current (FY19-20) strategic goals and objectives.

These program goals and objectives focus primarily on activities that that the NODES staff are responsible for achieving such as establishing regular meetings with facility stakeholders to advocate for support and resources, hosting meetings with local site study teams that focus on sharing research management best practices, and education and training related to research good clinical practice.

Data related to study recruitment/retention has recently been transitioned into a separate "Enrollment Tracking Database" so that it be more easily managed and retrieved. There are plans to follow a similar approach for study quality data.

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References

1. Fauth R, Bevan S, Mills P. Employee Performance in the Knowledge Economy: Capturing Keys to Success. Psychology Research and Behavior Management, 2: 1-12.

2. Draghici A, Popescu, AD, Gogan LM. A Proposed Model for Monitoring Organizational Performance. Procedia – Social and Behavioral Sciences. 2014 March; 124:544-551. 3. Rouhana RE, Van Caillie D.The Design of Performance Monitoring Systems in Healthcare Organizations: A Stakeholder Perspective. Le Journal Medical Libanais. 2016 Jan-Mar;64(1): 33-39.

Walker KF, Turzanski J, Whitham D, Montgomery A, Duley L. "Monitoring Performance of Sites Within MultiCentre Randomised Trials: A Systematic Review of Performance Metrics." Trials 2018; 19:562. Published online 2018 Oct 16. doi: 10.1186/s13063-018-2941-8

5. Condon D, Beck DJ, Kenworthy-Heinige T, Bratcher K, O'Leary M, Asghar A, Willis C, Johnson MR, Huang GD. "A Cross-Cutting Approach to Enhancing Clinical Trial Site Success: The Department of Veterans Affairs' Network of Dedicated Enrollment Sites (NODES) Model." Contemporary Clinical Trials Communications 2017 June; 6:78-84. Epub 2017 Mar 29.

6. Johnson MR, Kenworthy-Heinige T, Beck DJ, Asghar A, Broussard E, Bratcher K, Tom messilli L, Antonelli M, Planeta B. "Research Site Mentoring: A Novel Approach to Improving Study Recruitment." Contemporary Clinical Trials Communications 2018 March; <u>9</u>:172-177. <u>https://doi.org/10.1016/j.conctc.2018.01.011</u>

7. Velarde K, Romesser J, Johnson MR, Clegg DO, Efimova OV, Oostema SJ, Scehnet J, Duvall SL, Huang GD. "An Initiative Using Informatics to Facilitate Clinical Research Planning and Recruitment in the VA Health Care System." Contemporary Clinical Trials Communications 2018 September; 11: 107https://doi.org/10.1016/j.conctc.2018.07.001

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