

# 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.<sup>1-2</sup> These tools can be somewhat arduous to develop, gain consensus on, and implement, particularly in multi-site entities such as clinical research consortiums.<sup>3-4</sup>

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.<sup>5-7</sup>

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.

## Figure 1: Data Facilitation Log

Month	JUL								AUG																							
<b>ACTIVE RESEARCH PROTOCOLS (Reported Monthly)</b>																																
# of Active IRB CSP & CCTA	CSP				CCTA				CSP				CCTA																			
	2				1				3				0																			
<b>CSP STUDY ACTIVITY/STATUS</b>																																
DATA CATEGORY	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D																
CSP # 123	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1																
CSP # 456	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0																
CSP # 789	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1																
CCTA #0123	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1																
<b>TOTAL</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>																
<b>PROTOCOL SUBMISSIONS</b>																																
DATA CATEGORY	New Submission		Modification		Closure		New Submission		Modification		Continuing Review		Closure																			
	A1	A2	B1	B2	C1	C2	D1	D2	A1	A2	B1	B2	C1	C2	D1	D2																
CSP # 123	1	5	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CSP # 456	1	1	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CSP # 789	1	1	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CCTA #0123	1	1	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
<b>TOTAL</b>	<b>4</b>	<b>8</b>	<b>4</b>	<b>0</b>	<b>4</b>	<b>6</b>	<b>4</b>	<b>40</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>4</b>	<b>2.0</b>	<b>4</b>	<b>24.0</b>																
Month %age	3.1%	6.3%	3.1%	0.0%	3.1%	4.7%	3.1%	30.0%	0.0%	0.0%	0.0%	0.0%	3.1%	1.0%	3.1%	18.0%																
Number of Days	0.63	1.25	0.63	0.00	0.63	0.94	0.63	6.25	0.00	0.00	0.00	0.00	0.63	0.25	0.63	3.75																
<b>CSP AUDITS</b>																																
DATA CATEGORY	NODES PRE-Audit		Compliance Audit		SMART Audit		OTHER Audit		NODES PRE-Audit		Compliance Audit		SMART Audit		OTHER Audit																	
	A1	A2	B1	B2	C1	C2	D1	D2	A1	A2	B1	B2	C1	C2	D1	D2																
CSP # 123	1	1.5	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CSP # 456	1	1.5	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CSP # 789	1	1.5	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
CCTA #0123	1	1.5	1	0	1	1.5	1	10	0	0.0	0	0.0	1	0.5	1	6.0																
<b>TOTAL</b>	<b>4</b>	<b>6</b>	<b>4</b>	<b>0</b>	<b>4</b>	<b>6</b>	<b>4</b>	<b>40</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0.0</b>	<b>4</b>	<b>2.0</b>	<b>4</b>	<b>24.0</b>																
Month %age	3.1%	4.7%	3.1%	0.0%	3.1%	4.7%	3.1%	30.0%	0.0%	0.0%	0.0%	0.0%	3.1%	1.0%	3.1%	18.0%																
Number of Days	0.63	0.94	0.63	0.00	0.63	0.94	0.63	6.25	0.00	0.00	0.00	0.00	0.63	0.25	0.63	3.75																
<b>CSP STAFFING (REPORTED MONTHLY - # OF STAFF ADDED/REMOVED)</b>																																
DATA CATEGORY	Added				Removed				Added				Removed																			
	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D																
CSP # 123	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CSP # 456	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CSP # 789	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CCTA #0123	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
<b>TOTAL</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>																
Month %age	3.1%	3.1%	3.1%	3.1%	0.0%	0.0%	0.0%	0.0%	3.1%	3.1%	3.1%	3.1%	0.0%	0.0%	0.0%	0.0%																
Number of Days	0.63	0.63	0.63	0.63	0.00	0.00	0.00	0.00	0.63	0.63	0.63	0.63	0.00	0.00	0.00	0.00																
<b>CSP PERSONNEL - NODES HR FACILITATION</b>																																
DATA CATEGORY	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D																
CSP # 123	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CSP # 456	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CSP # 789	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
CCTA #0123	1	1	1	1	0	0	0	0	1	1	1	1	0	0	0	0																
<b>TOTAL</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>																
Month %age	3.1%	3.1%	3.1%	3.1%	0.0%	0.0%	0.0%	0.0%	3.1%	3.1%	3.1%	3.1%	0.0%	0.0%	0.0%	0.0%																
Number of Days	0.63	0.63	0.63	0.63	0.00	0.00	0.00	0.00	0.63	0.63	0.63	0.63	0.00	0.00	0.00	0.00																
<b>PERSON-TIME (hours) SAVED THROUGH NODES</b>																																
DATA CATEGORY	A				B				A				B																			
	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D																
CSP # 123	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00																
CSP # 456	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50																
CSP # 789	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00																
CCTA #0123	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00																
<b>TOTAL</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>																
Month %age	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%																
Number of Days	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98																
<b>MOBILE RECRUITMENT (MOORE) STATION</b>																																
DATA CATEGORY	SITE				MRS				OTHER				SITE				MRS				OTHER											
	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
CSP # 123	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00	12.00	3.00		
CSP # 456	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50	5.50	3.50		
CSP # 789	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00		
CCTA #0123	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00	17.50	3.00		
<b>TOTAL</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>	<b>52.50</b>	<b>12.50</b>		
Month %age	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%	10.9%	1.9%				
Number of Days	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98	2.19	0.98				
<b>SITE CSP ENROLLMENT</b>																																
DATA CATEGORY	SITE GOAL/YTD				MONTH				NATIONAL				SITE GOAL/YTD				MONTH				NATIONAL											
	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H	A	B	C	D	E	F	G	H
CSP # 123	2500	750	34.3%	10	8	80.0%	75.0%	-40.9%	2200	750	34.5%	10	10	100.0%	75.0%	-40.5%	2500	750	30.0%	10	10	100.0%	75.0%	-40.5%	2500	750	30.0%	10	10	100.0%	75.0%	-40.5%
CSP # 456	750	350	46.7%	2	3	50.0%	43.0%	-4.1%	750	350	47.1%	2	1	50.0%	43.0%	-4.1%	750	350	46.7%	2	1	50.0%	43.0%	-4.1%	750	350	46.7%	2	1	50.0%	43.0%	-4.1%
CSP # 789	500	25	5.0%	1	0	0.0%	47.1%	-42.1%	500	25	5.0%	1	1	100.0%	48.0%	-43.0%	500	25	5.0%	1	1	100.0%	48.0%	-43.0%	500	25	5.0%	1	1	100.0%	48.0%	-43.0%
CCTA #0123	623	623	100.0%	0																												