

Implementation and Evaluation of a Self-Paced Diversity Training and Education (DTEACH[®]) Pilot Program for Clinical Trials Site Participants

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Abstract:

Training and educational programs tailored towards efforts to improve the diversity of patient populations in the clinical trials industry are much needed, however, still in development. To address this need, a self-paced diversity training (DTEACH[®]) was developed and implemented in partnership with a cohort of 40 sites engaged in neurology clinical trials throughout the United States. Between January and June 2023, one member assigned to the study from each of the sites completed the Diversity Site Assessment Tool (DSAT) and training modules made available via a web portal. These modules covered the importance of understanding diversity in clinical trials, standard operating procedures for becoming a diverse capable, and ready site, developing diversity recruitment and retention planning, and developing a continuum plan for diversity integration. Alongside the modules, participants had access to practical, clinical trial-specific diversity and inclusion resources that were designed to support everyday activities and build sustainable inclusive behaviors. After completing the training program and accessing the resources, participants completed a feedback survey that asked them to rate the extent to which they found the training program and its components to be of value, usefulness, and satisfaction. All data about the training and DSAT completion were collected and analyzed using the open-source statistical software, JASP. Results showed that the DSAT section 1 mean score was 51.03 ± 8.71 , the DSAT section 2 score was 47.65 ± 7.05 , the DSAT section 3 score was 28.61 ± 6.05 , and the total DSAT score was 127.29 ± 18.67 . Participant reactions related to value, usefulness, and satisfaction were high for each of the DTEACH[®] components and collectively (DSAT completion mean 84.14 ± 18.2 , training modules mean 84.25 ± 18.19 , portal mean 85.22 ± 17.94 and collective mean 84.27 ± 17.93). While there were no significant differences in DSAT scores and participant reactions by participant characteristics, there was a positive significant relationship ($r=0.42$, $p=0.02$) between DSAT scores and participant reactions. The findings of this study indicate that the DTEACH[®] diversity training and education program is an excellent resource for use by members of the clinical trials industry in their efforts to improve the diversity of patient populations in clinical trials conducted at research sites.

Background:

The clinical trials industry is increasingly focused on changing practices associated with the enrollment of underrepresented participants and how these practices engage members of the community in clinical trials. This increased focus emanates largely from the recognition within the pharmaceutical industry and regulatory world that the participants in clinical trials are not reflective of the actual population(s) that utilize these products. To address this issue, frameworks, guidance, incentives, white papers, programs, and materials¹⁻¹⁰ are being developed to help improve the diversity of participants in clinical trials.

One resource that is currently available for the clinical trials industry is the Diversity Site Assessment Tool (DSAT), authored by Dr. Diana Foster and supported by the Society for Clinical Research Sites, an organization representative of the needs of clinical research sites globally^{11,12}. The DSAT is a highly reliable and valid 25-item self-assessment tool considered to be an industry gold standard that can be completed by members of a clinical trial site to identify the extent to which diversity best practices are utilized at their site¹². It is composed of three sections scored on a 6-point scale (1-Hardly ever; 6-Always): a 10-item Site Overview section, a 9-item Site Recruitment and Outreach section, and a 6-item Patient Focused Services section. Upon completion, the DSAT provides its participants a comprehensive self-evaluation of the extent to which they are engaged in best practices associated with diversity in clinical trials and available within the industry for comparative analysis among and across sites, locally as well as globally. The DSAT has utility for continuous quality improvement and training purposes. It is believed that meeting the standards and guidelines issued by the FDA will require an integration of data-driven diversity and inclusion best practices across all levels of the clinical trial process, including sites, and that the DSAT can provide a valuable foundation for such purposes.

While prior published studies of DSAT have identified its robust psychometrics and utility in the identification of best practices in diversity recruitment and services within the clinical trials industry¹²⁻¹⁴, there have been no studies integrating DSAT into diversity training programs. Notably, there is a paucity of literature on diversity training programs within the clinical trials industry. This paper aims to address that gap and provide insights into a the diversity training program and education program DTEACH[®] which is a product of the organization, Total Diversity in Clinical Trials Management, a Clinical Research Organization (CRO) and diversity integration service provider. This program was designed using the DSAT and aimed towards facilitating sites to train their members in diversity best practices.

Methods:

Participants: Participants were members of 40 neurology sites selected by Teva Branded Pharmaceutical Products, Inc. (Teva) that were spread throughout the United States. These sites and members were identified by Teva and invited between January and June 2023 to participate in the pilot training program.

Training Program: A comprehensive, evidence-based, clinical research-specific diversity and inclusion training program was designed for clinical research sites and industry professionals. The training program consisted of training modules addressing the importance of understanding diversity in clinical trials, standard operating procedures for becoming a diverse capable and ready site, developing diversity recruitment and retention plans, and developing a continuum plan for diversity integration. Each of these modules was made available via a web portal (<https://dteach.app/login>) where alongside these modules, participants had access to

practical, clinical trial-specific diversity and inclusion resources that were designed to support everyday activities and build sustainable inclusive behaviors.

From the perspective of theoretical design considerations for diversity training identified by Bezrukova and colleagues¹⁵, Table 1 presents the training inputs and outputs.

Training inputs included:

- a) an evaluation of the self-assessment of diversity best practices at their site (training context) using the 25-item, three-section-based DSAT instrument. One participant from each site completed the DSAT and DTEACH and was able to see the scores on each of the three sections and the total DSAT.
- b) instruction that used vital design considerations such as inclusive focus, moderate length, and consisting of knowledge as well as skills development content. The content of the training modules was designed by experts within the clinical trials industry who specialize in diverse perspectives.
- c) Each training module was followed by a quiz in which participants had to score 80% or more to receive a digital certificate. This ensured that trainee knowledge and motivational considerations were accounted for as discussed by Bezrukova and colleagues.
- d) Resources and supplementary materials designed to support everyday activities.

The training outputs included a measurement of participants' ratings in terms of the overall value, usefulness, and satisfaction with the different components of the training program. Ratings for each component and the collective training program were measured on a 100-point scale (no maximum possible).

Data Collection and Analysis: From a data analytics perspective, steps 1 (completion of DSAT) and 3 (Completion of Post Training Feedback Survey) yielded data related to DSAT and participant reactions. Given that each site was required to complete the program and thus had to pass the quizzes associated with the modules, data pertaining to participant quiz scores was not collected and analyzed. Data related to DSAT, and feedback survey was collected and exported into MS Excel and analyzed using JASP¹⁶. Individual section and composite total average scores for DSAT and average scores for value, usefulness, and satisfaction with each component and collective program were calculated and utilized for descriptive and bivariate analyses.

Results:

Characteristics of Participants:

A member from each of the 40 invited sites participated in the program. Most of the participants in the pilot program were from sites that had been conducting clinical trials for more than 5 years (95%) and acted as dedicated research centers (80%). Participants also reported having bilingual staff (85%) and diverse principal investigators (65%) at their sites. Twenty three percent of survey participants were of Hispanic ethnicity and 58% were from White racial background. Members represented geographic diversity with the largest representation being from the US-South region (36%) and the lowest from the US Northern region (5%).

DSAT Self-Assessment Scores and Reactions to DTEACH® Program Components:

Table 2 provides descriptive statistics for the data obtained from Steps 1 and 3 of the training programs. As can be observed, the mean DSAT scores for each of the sections indicate that the highest mean scores were in site recruitment and outreach (89%) and the lowest score for patient-focused services. Participants' reactions (rated value, usefulness, and satisfaction) were highly complementary of the individual components (DSAT self-assessment, DTEACH® modules, the DTEACH® portal) and the overall or collective training program. Results from the bivariate analysis about these data are discussed below.

DSAT Self-Assessment Scores and Relationship With Site Participant Characteristics

There were no statistically significant differences between mean total DSAT scores ($F(4,26) = 1.45, p = 0.25$), mean DSAT Section 1 score ($F(4,26) = 0.45, p = 0.77$), mean DSAT Section 2 score ($F(4,26) = 1.98, p = 0.13$) and mean DSAT Section 3 score ($F(4,26) = 0.78, p = 0.91$) of participants from different regions as determined by one-way ANOVA. Similarly, there were no statistically significant differences between mean total DSAT scores ($t = -1.81; df = 29, p = 0.08$), mean DSAT Section 1 score ($t = -1.34; df = 29, p = 0.19$), mean DSAT Section 2 score ($t = -1.59; df = 29, p = 0.12$) and mean DSAT Section 3 score ($t = -1.74; df = 29, p = 0.09$) of participants from Hispanic versus non-Hispanic ethnicity as determined by the T-test. Also, there were no statistically significant differences between total DSAT scores ($t = 0.98; df = 29, p = 0.34$), mean DSAT Section 1 score ($t = 0.77; df = 29, p = 0.45$), mean DSAT Section 2 scores ($t = 1.12; df = 29, p = 0.27$) and mean DSAT Section 3 scores ($t = 0.60; df = 29, p = 0.56$) of participants from White versus non-White race as determined by the T-test.

Reactions to DTEACH® Program Components and Relationship With Site Participant Characteristics

There were no statistically significant differences between mean DSAT reactions ($F(4,26) = 0.40, p = 0.81$), mean DTEACH® training module reactions ($F(4,26) = 0.35, p = 0.84$), mean DTEACH® Portal reactions ($F(4,26) = 0.43, p = 0.79$) and mean Collective Reactions ($F(4,26) = 0.63, p = 0.65$) of participants from different regions as determined by one-way ANOVA. There were no statistically significant differences between mean DSAT reactions ($t = 0.80; df = 29, p = 0.43$), mean DTEACH® training module reactions ($t = 0.42; df = 29, p = 0.68$), mean DTEACH® Portal reactions ($t = 0.59; df = 29, p = 0.56$) and mean Collective Reactions ($t = 0.47; df = 29, p = 0.64$) of participants from Hispanic versus non-Hispanic ethnicity as determined by the T-test. Similarly, there were no statistically significant differences between mean DSAT reactions ($t = 1.13; df = 29, p = 0.27$), mean DTEACH® training module reactions ($t = 1.46; df = 29, p = 0.16$), mean DTEACH® Portal reactions ($t = 1.42; df = 29, p = 0.17$) and mean Collective Reactions ($t = 1.43; df = 29, p = 0.16$) of participants from White versus non-White race as determined by the T-test.

Reactions to DTEACH® Program Components and Relationship With DSAT Scores

Table 3 provides results from the correlations between participant reactions (value, usefulness, and satisfaction) among the program components and with the DSAT scores. As can be observed from the table, there was a strong, positive, and significant relationship between the reactions to the program components and a collective and moderate positive significant relationship between participant reactions and DSAT scores.

Discussion:

Diversity of patient populations in clinical trials is a global concern currently receiving tremendous attention from regulators and stakeholders in pharmaceutical and biomedical product development and approval. Experts within the field have argued that the advancement of work associated with enhancing patient diversity in clinical trials will need a comprehensive strategy that includes a philosophy of continuous quality improvement using self-assessment, tailored education and training, and strategic investments in achieving patient diversity as a component of the organizational culture. In that regard, the development and psychometric testing of the Diversity Site Assessment Tool (DSAT) represents an improvement and provides a self-awareness for stakeholders to take meaningful actions toward addressing diversity issues on their own. The data on the three DSAT sections and the total DSAT scores of participants in this study are like those in prior published studies in that patient-focused services remain an area where the clinical trials industry can make significant improvements to patient diversity in clinical trials. Combined with the fact that participant characteristics were not significantly associated with the DSAT scores, the DSAT section scores indicate that the challenges and opportunities for improvements are both structural and procedural as they pertain to the experience of patients enrolled in clinical trials. Evidence-based and tailored solutions are much needed to help those involved in structural and procedural elements of diversity recruitment and outreach. The self-paced diversity training and education (DTEACH[®]) program, the first of its kind within the clinical trials industry, developed using key principles identified by Bezrukova and colleagues¹⁵ represents an important resource for the clinical trials industry. Participants in this study indicated high value, usefulness, and satisfaction with all the program components (teaching modules, portal, and resources) equally and without any influence by participant characteristics. This indicates that the training program had a universal appeal. The entire training program and its components were also significantly related to the DSAT scores, which suggests that those participants who engaged in self-assessment positively were also likely to indicate value, usefulness, and satisfaction with the training program. While it is important to acknowledge the limitations of the study that this was only conducted as a pilot and more extensive studies may be needed, the results of this study show that stakeholders within the clinical trials industry can strongly consider using the DTEACH[®] and its components to help support the advancement of efforts to enhancing diversity in clinical trials.

Conclusion:

This paper describes the implementation of a first-of-its-kind, clinical trials industry-specific self-paced diversity training and education program for site participants that was evaluated to be of high value, and usefulness and associated with high satisfaction and self-assessment using DSAT. Stakeholders in the clinical trials industry should strongly consider using the DTEACH[®] and its components as a component of their continuous quality improvement initiatives for improving the diversity of patient populations in clinical trials.

Table 1. Components of the Pilot Training Program

Pilot Training Program Components		Completion Time
Inputs	Step 1: Diversity Site Assessment Tool (DSAT)	15 minutes
	Step 2: 2a. Completion of Diversity Training and Education (DTEACH®) Training Modules <ul style="list-style-type: none"> ● Module 1: Becoming a Diverse Capable and Ready Site: Standard Operating Procedures for Sites <ul style="list-style-type: none"> ○ Steps to develop a site diversity plan ○ Quiz (Digital certificate if >80% score) ● Module 2: Developing a Diversity Recruitment and Retention Plan <ul style="list-style-type: none"> ○ Community outreach and engagement ○ Quiz (Digital certificate if >80% score) ● Module 3: Creating a Plan for Diversity Integration Across the Site Continuum <ul style="list-style-type: none"> ○ Processes to improve inclusion ○ Quiz (Digital certificate if >80% score) 	20 minutes each (60 minutes total)
	2b. Access to Web Portal Resources for Enhancing Diversity Integration	Infinite access
Outputs	Step 3: Post Training Feedback Survey <ul style="list-style-type: none"> ● Section 1: Utility of DSAT <ul style="list-style-type: none"> ○ Site perception of utility of <u>DSAT</u> tool in highlighting site’s current diversity and inclusion knowledge, practices, and growth areas. ● Section 2: Quality and Value of DTEACH® Training Modules <ul style="list-style-type: none"> ○ Site perception of the quality and value of the content provided in the <u>DTEACH® Training Modules</u> in providing the necessary framework to begin enhancing diversity and inclusion practices at site ● Section 3: Satisfaction with the Pilot Program <ul style="list-style-type: none"> ○ Site satisfaction with the collective components of the pilot program in enhancing diversity and inclusion practices at site 	5 minutes

Table 2. Descriptive Statistics of Program Elements and Participant Reactions

	Item	Mean	Std. Deviation
DSAT Self-Assessment	DSAT Section 1 Score (Out of 60)	51.03	8.71
	DSAT Section 2 Score (Out of 54)	47.65	7.05
	DSAT Section 3 Score (Out of 36)	28.61	6.05
	DSAT Total (Out of 150)	127.29	18.67
<u>Value, Utility and Satisfaction With DSAT</u>	<u>Value</u> of the DSAT in highlighting site's current diversity and inclusion knowledge and practices	84.35	18.74
	<u>Usefulness</u> of the DSAT in highlighting site's current diversity and inclusion knowledge and practices	82.9	19.53
	<u>Satisfaction with</u> the DSAT in highlighting site's current diversity and inclusion knowledge and practices	85.16	17.49
	Average DSAT Reaction	84.14	18.2
<u>Value, Utility and Satisfaction With DTEACH© Modules</u>	<u>Value</u> of the DTEACH© modules content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	85.16	18.95
	<u>Usefulness</u> of the DTEACH© modules content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	81.94	20.48
	<u>Satisfaction with</u> the DTEACH© modules content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	85.65	17.16
	Average DTEACH© Modules reaction	84.25	18.19
<u>Value, Utility and Satisfaction With DTEACH© Portal</u>	<u>Value</u> of the DTEACH© Portal and its content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	85.16	17.91
	<u>Usefulness</u> of the DTEACH© Portal and its content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	84.68	20.37
	<u>Satisfaction with</u> the DTEACH© Portal and its content in providing the necessary framework to begin enhancing diversity and inclusion practices at site	85.81	16.64
	Average Portal Materials Reaction	85.22	17.94
<u>Utility and Satisfaction With DTEACH© Training Program</u>	<u>Usefulness</u> of the DTEACH© Program to enhance diversity and inclusion practices at site	83.71	19.58
	<u>Satisfaction with</u> the DTEACH© Program to enhance diversity and inclusion practices at site	84.84	16.86
	Average Collective Reaction	84.27	17.93

Table 3. Relationship Between DSAT Score and Participant Reactions

Variable	Statistics and Significance	Average DSAT Reaction	Average DTEACH[®] Portal Materials Reaction	Average DTEACH[®] Collective Reaction	DSAT Total
Average DTEACH [®] training modules reaction	Correlation	0.98	0.98	0.97	0.45
	p-value	<0.001	<0.001	<0.001	0.01
Average DTEACH [®] Portal Materials Reaction	Correlation	0.99			
	p-value	<0.001			
Average DTEACH [®] Collective Reaction	Correlation	0.97	0.98		
	p-value	<0.001	<0.001		
DSAT Total	Correlation	0.42	0.44	0.42	
	p-value	0.02	0.01	0.02	

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