CASE STUDY HIGHLIGHTS: Data-driven Diversity Assessments at a Medical Device Company

How Boston Scientific utilizes data to prioritize racial and ethnic diversity in clinical trials systematically

BACKGROUND

Boston Scientific's health equity initiative, Close the Gap, was created to eliminate disparities in care across the United States. The initiative was established in 2004, at a time when cardiovascular disease in women was gaining widespread attention.

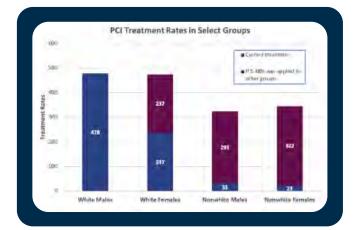
Although implantable cardioverter defibrillators (ICDs) were approved for prevention of sudden cardiac death (SCD) in high risk heart "The disconnect between the burden of illness observed in the community and who is actually being treated in the hospital makes obvious that some of the people needing treatment are being missed."

- Dr. Paul Underwood, Boston Scientific Interventional Cardiology Medical Director

failure patients, women and ethnic minorities at-risk for SCD were 60% less likely to receive ICDs than White males. While *Close the Gap* was initiated to address this disparity, it has expanded to other areas such as coronary artery disease, atrial fibrillation, and colon cancer.

APPROACH

The *Close the Gap* initiative connects client hospitals with community partners and professional/patient advocacy organizations to increase awareness regarding demographic disparities in cardiovascular care. The initiative also links the providers' understanding of disparities with the provider's experience and provides helpful quantitative assessments to guide these processes.



REAL AND WOMEN'S HOSPITAL and HARVARD

Quantifying treatment inequities: Disparity Index mobile application

The Disparity Index mobile application facilitates conversations around health disparities between Boston Scientific's local sales teams and partner hospitals. The application permits hospitals to view a visual analysis of coverage and treatment access for patients within their service area.

How it works:



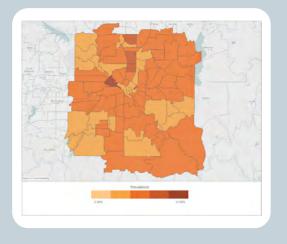
Claims data from partnering hospitals are collected to calculate treatment rates by demographic group in a given therapeutic area.



These data are matched to census data at the zip code-level to project disease prevalence by demographic subgroup.



A customizable hospital service area map is created using zip codes derived from the hospital's community health needs assessment (CHNA).



These visualizations help hospitals understand their patients' demographics and the quantitative impact on disease burden. This facilitates the establishment of long-term goals and monitoring metrics. These matched data also enable hospitals to quantify the treatment disparities in a given disease.

Monitoring diverse enrollment: Clinical Site Scorecard

Boston Scientific also uses demographic data to promote diverse enrollment in their clinical studies.

By utilizing real time enrollment demographic data from all clinical sites, project teams can develop a 'Clinical Site Scorecard' for each investigative site that displays demographic data by gender and race.

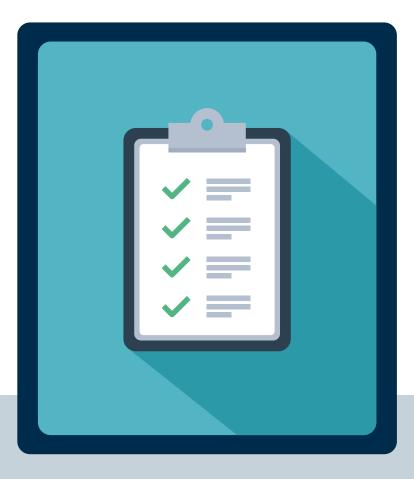
Site Scorecard						Definit	ions	↓ Export	
Project	PLA	TINUM DIV	ERSITY V			Performa	nce Demogra	Demographics	
SITE		CENTER CODE	INVESTIGATOR	LOCATION	ACTIVATION DATE		FEMALE SHARE OF ENROLLMENT	NON-WHITE SHARE OF ENROLLMENT	
Baptist Health Medical Center		0111	Brown, Roxanne	United States	17-Nov-2014	101	86.1%	23.89	
Memorial Regional Hospital		0222	Blue, Fredrick	United States	14-Oct-2014	95	37.6%	91.59	
Mount Sinai Medical Center		0333	Grey, Luis	United States	10-Oct-2014	81	48.5%	50.49	
Union Memorial Hospital		0444	White, John	United States	06-Nov-2014	83	74.2%	62.29	
Wake Medical Center		0555	Red, Maria	United States	01-Dec-2014	75	54.3%	12.89	
Bay Medical Center		0666	Black, Mary	United States	27-Oct-2014	48	81.7%	50.79	

By collecting the data in real-time, enrollment of diverse populations can be actively monitored in conjunction with other trial performance indicators.

RESULTS

The Disparity Index app allows hospitals to identify treatment disparities in a given disease by demographic subgroup – thereby showing facility-level 'gaps' in treatment. As a result, demographic subgroups such as Blacks, who carry a higher baseline burden of heart failure, are receiving the care they needed.

Real-time monitoring of clinical trial enrollment and utilization of clinical trial scorecards enabled clinical sites to evaluate whether enrolled patients are reflective of disease prevalence in the hospital's patient community.



CONCLUSION

Through their health equity initiative, *Close the Gap*, Boston Scientific developed quantitative tools to call attention to demographic disparities in cardiovascular treatment and clinical research. At partner hospitals, the company used a novel application platform to highlight demographic subgroups being missed in cardiovascular treatment.

At selected clinical study sites, the initiative collected demographic data, actively monitoring disparities in study enrollment on their 'Clinical Trial Scorecard.' This helped ensure that the intended distribution of enrolled populations were representative of the disease prevalence and that trial data are generalizable to the entire population.

Boston Scientific's data-based tools for identifying disparities demonstrate a tangible approach for sponsor companies to contribute to diverse representation in clinical research and care.