Both of these articles offer very helpful strategies in improving the clinical trial experience and application toward successful outcomes. However, NBCI National Clinical Trails Strategic Plan provides the glue to enhance the clinical trials outcomes by adding the main ingredient of diversity to ensuring at representative numbers of participation that has never been seem before. Here read more about it https://blackchurchclinicaltrials.com/pharma.php

Optimizing Patient Recruitment and Engagement Strategies

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Caroline Redeker, Donna Hanson

Five strategies to reduce risk and achieve deadlines.

Donna Hanson

Caroline Redeker

How long is too long? For decades, clinical trial sponsors and CROs have struggled with patient recruitment challenges as the number one reason for study delays and associated

budget increases. Year after year, at conference after conference, industry leaders have debated how best to address this familiar challenge. The COVID-19 pandemic has made the situation even worse, with a lingering effect on studies focused on other diseases.[1] In the early part of the pandemic, from February to May 2020, the number of trials launched in the United States amounted to only 57% of the number expected without the pandemic.[2]

On a positive note, our industry is making it easier for patients to participate in clinical trials in many ways. However, it is not a 'one-size-fits-all' approach and at times makes it more challenging for patients and sites as we introduce new technologies. Remote activities have changed the way trial Sponsors and CROs work with investigative site staff, and it often requires more of a burden on the sites to upload documents, rearrange their processes and address new budget issues from incorporating this approach.

The real issue remains: How do we efficiently reach a large sample of potential patients? As an industry, we have the obligation to complete trials in a timely manner. It took a pandemic to move us to a new form of patient interaction that allows participation without travel to the investigative site. With change already happening, it should be easier to innovate at a faster pace. Strategies need to incorporate a multi-faceted and customized solution for the best predictability and greatest success. It all starts with fully understanding the patient.

As trial design and management strategies are developed, five key strategies are recommended to deploy a thoughtful and proactive approach that meets study timelines and goals.

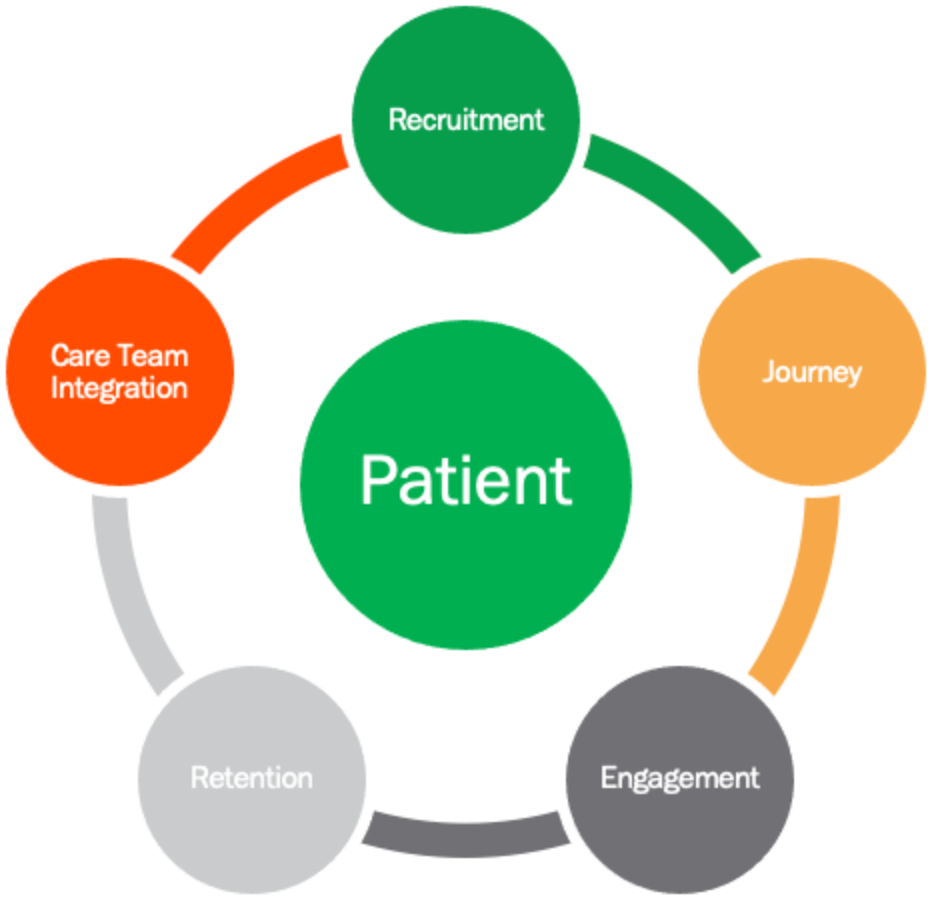

Figure 1. *Optimizing interactions with clinical trial participants*

Strategy 1: Trial design and location

Once a clinical trial is designed, many logistical planning efforts must follow to successfully implement and manage the trial. One key factor is how and where the investigational product will be shipped once ready—to the site or directly to the patient. Once engaged, the patient experience is key to their willingness to participate over the required timeframe. Factors such as in-person office visit frequency and the requirements of each visit will affect continued participation. Input from care teams *and* directly with patients is critical to understanding the journey and perspectives affecting protocol design—elements that may change sharply between countries based on varying healthcare options, cultural norms, therapeutic indications, and other geographic considerations. These factors can shape the trial design and willingness of both sites and patients to participate in certain activities within a protocol. Trial design and location is the most important early planning activity to ensure success.

Strategy 2: Global feasibility

The most successful companies invest significant time into thoroughly understanding the feasibility of the trial and its associated costs and timelines. This exploration should occur very early and is more than feasibility at the time of RFP sent to a provider. The best results are produced when feasibility activity occurs both at the time of trial design and after the protocol is written. The most appropriate type of feasibility will include analyzing the therapeutic indication, epidemiology, geographical standard-of-care differences, site feedback, patient feedback, utilization of historic and current data, as well as operational considerations with recommended risk mitigation strategies. Specific items detailed in the protocol may change how a site or patient will feel about participation. Investigators may have perspectives on patient needs that differ from the patients' own perspectives. Reaching out directly to the patient population requires a change of mindset for most trial sponsors, which has traditionally relied primarily on Principal Investigators to provide insights on patients. A comprehensive feasibility exercise helps develop a strategy that is accurate in predicting costs and timelines and identifies key risks to consider in the study plan.

Strategy 3: Reducing risk

With any study comes risk, but some involve more risk than others. Each study should have its own risk management plan, accounting for patient enrollment and retention risks. Even with the best feasibility and alignment with management, everything may not go according to plan. Defining the key leading or risk indicators that will continually measure success is important, as well as setting specific timepoints to measure those indicators. In addition, it is important to have a 'plan B' in place, ready to implement if needed. The plan B decision criteria should be defined up front and align with all stakeholders to best manage and overcome risks.

Strategy 4: Alignment and managing expectations

Alignment is needed among the study team (including the trial sponsor, CRO, other providers and sites) on the plan, timelines, and costs associated with the study; however, this is not always easy to accomplish. Once aligned, each team member should communicate the plan with their respective management teams—including the risks, risk management plans, and costs associated with those plans. Implementing these key strategies helps ensure that there are no surprises to any team members, and thus no need for unexpected requests for more time and money. Keep in mind, robust feasibility assessments are a starting point and will evolve with a study; expectations should be clear, fluid, flexible and continually communicated.

Strategy 5: Recruiting, engaging, and retaining patients

Recruiting, engaging, and retaining patients should each have a separate strategy, and these should be integrated with one another to ensure a consistent patient experience through to study completion. This optimizes the chance of retention and minimizes the risk to study timelines.

Unfortunately, there is no one-size-fits-all solution to tackling the challenges brought on by patient recruitment. New data platforms and EMR technologies are slowly providing information about doctors that see specific patient populations. At best, these technologies and data systems are providing small pictures into the patient population or Principal Investigator experiences. Each study has its own unique patient population and study challenges. Some studies may lend themselves to incorporating DCT components and technologies while others may not. If the Sponsor/CRO has listened to the voice of the patient, understands their journey and has designed the study accordingly, followed by performing global feasibility and risk planning, then study management projections and success should follow.

The above steps, when done thoroughly and early, will demonstrate success in today's environment. The challenge for our industry remains the same: How do we make sure more potential patients know about opportunities for clinical trial participation? We know that many doctors do not present clinical trial opportunities to their patients. Referrals of patients have always been a challenge as doctors do not like to lose patient revenue to other physicians. Trial participation isn't something that enters into everyday life in the way other information is presented to consumers and potential trial patients. There are online and traditional recruitment approaches, thought leader involvement in rare diseases and other recruitment activities that make a difference. However, if we only integrate these strategies into mitigation plans and not proactively into every single trial plan, history will keep repeating itself and recruitment will remain the number one hurdle our industry faces.

How will we innovate to the next level? We have made great progress in our ability to engage patients, but how will we connect with more patients faster? After all, we are here to benefit the patient community and to provide treatments, support and hope to them. Who are the innovators out there? Are we all up for the assignment? If so, let's get those together who get it and make a difference!

***Caroline Redeker**, Senior Vice President of Corporate Development at Advanced Clinical, and **Donna Hanson**, Senior Director of Strategy and Optimization at Advanced Clinical*

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Getting to Clinical Trial Diversity

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Michael J. Howley, PA-C, MBA, PhD , Jai Seth, Stella Sechopoulos, Peter Malamis, MBA
Differing levels of trust in clinical trials information channels across diverse populations is examined in this research.

The clinical and commercial success of clinical trials depends on having a diverse pool of study participants.[1,2,3] But despite considerable effort and investment from industry and encouragement from FDA, we have not yet achieved adequate diversity of trial participants.[4,5] This suggests that we do not understand the mechanisms which motivate patients from diverse backgrounds to participate in clinical trials.

A variety of tactics have been suggested to increase diversity in clinical trials, including proactively recruiting diverse participants, addressing language and cultural barriers, creating inclusive eligibility criteria, and employing a diverse research workforce.[6,7] All these tactics work by increasing *trust* in the clinical trial, which increases under-represented patients willingness to participate in clinical trials.[8,9] But if we are using trust-based recruiting, and we still don't have diverse trials, then we should re-consider how we should improve diversity in clinical trials.

To address these questions, this research will examine the role of trust in clinical trials. Specifically, we model how trust in information from different channels is associated with willingness to participate in clinical trials and how this trust varies across ethnicity and race. The results of this study suggest a more modest role for trust than was previously thought, shows how trusted information about clinical trials comes from a variety of channels, and illustrates the differing trust sources work across racial and ethnic boundaries.

Methods

To understand how trust works in clinical trial recruitment, we randomly surveyed patients using the Phreesia digital intake software used by medical practices to sign patients in when they arrive for an appointment. The practices were mostly primary care practices but also included a wide variety of specialties. During the digital intake process, patients were asked to participate in a survey. Patients who agreed were presented with a digital questionnaire. Most of the patients responded on a mobile device and the other respondents used home desktop computers or tablets. The data was collected in July 2022.

Since few patients have ever been approached about a clinical trial,[10] we asked about their willingness to participate in a clinical trial: "How likely would you be to apply to participate in a clinical trial that is relevant to you?" Trust was assessed by asking how much the respondent trusted various sources of clinical trial information. We included items on how much the respondent trusted doctors, nurses, family, digital intake software, the medical

internet, and social media for information about clinical trials. The trust questions were presented as a block and coded on a scale of 1 through 10. As a control, we asked respondents about their familiarity with clinical trials on a 1 to 5 scale. The items for covariates were age, gender, race, and ethnicity, and whether they used a mobile device. Ethnicity was coded as 1 = Hispanic and 0 = non-Hispanic. Race was coded as 1 = Black and 0 = non-black – collapsing multiple racial categories including White, Asian, bi-racial, etc. Only 16 respondents categorized themselves as both Black and Hispanic. The covariates were mostly categorical variables with the exception of age.

Since the goal of this research is to isolate the effects of trust in various trial information channels, we used regression analysis, which parses out the unique effects of each predictor from the effects of other predictors and covariates. All the continuous variables are centered, so coefficients can be interpreted at the average levels of the other predictors and covariates. The Base Model estimates the model described above across the entire sample, accounting for the effects of ethnicity and race in the model. Given the significance of the findings, we re-ran the models estimating the coefficients just in the Hispanic and Black samples, comparing them to the non-Hispanic and non-Black samples.

Results

The regression model included 2,587 respondents, of which 61% were female, 18% were Black, 14% were Hispanic, and 61% responded on a mobile device. The means, standard deviations, and correlations are presented in Table 1. Trust in doctors (μ= 7.5) and nurses (μ= 7.0) was much higher than for social media (μ= 3.3), which we found unsurprising.

Willingness to participate in clinical trials was μ= 3.7 on a 6-point scale and familiarity with clinical trials was 2.6 on a 5-point scale. These middling scores on willingness to participate and familiarity with clinical trials are concerning for the industry. The regression model included 2,587 respondents, of which 61% were female, 18% were Black, 14% were Hispanic, and 61% responded on a mobile device. The means, standard deviations, and correlations are presented in Table 1. Trust in doctors (μ= 7.5) and nurses (μ= 7.0) was much higher than for social media (μ= 3.3), which we found unsurprising. Willingness to participate in clinical trials was μ= 3.7 on a 6-point scale and familiarity with clinical trials was 2.6 on a 5-point scale. These middling scores on willingness to participate and familiarity with clinical trials are concerning for the industry.

	Scale	Mean	Std. Dev.	Doctor Trust	Nurse Trust	Digital Intake Trust	Family Trust	Med Web Trust	Social Media Trust	Familiar	Age	Trial Willing.
Doctor Trust	1-10	7.5	2.6	1								
Nurse Trust	1-10	7.0	2.5	.82	1							
Digital Intake Trust	1-10	6.1	2.8	.49	.58	1						
Family Trust	1-10	5.7	2.7	.44	.48	.47	1					
Medical Web Trust	1-10	5.5	2.5	.39	.44	.48	.33	1				
Social Media Trust	1-10	3.3	2.5	.07	.17	.37	.33	.42	1			
Familiarity	1-5	2.6	1.2	.13	.15	.11	.08	.16	.09	1		
Age	18-85	48.8	19.7	.08	.05	.01	.01	.00	-.07	.06	1	
Clinical Trial Willingness	1-6	3.7	1.4	.27	.26	.21	.18	.20	.12	.30	.04	1

Table 1. *Descriptive statistics & correlations for variables used in the models*

Source: *Phreesia data, July 2022*

The Base Model

The Base Model runs the regression across the entire sample, accounting for the variance due to ethnicity and race. The Base Model predicted a significant ($F_{12, 2,317}$= 35.91, p< .0001) amount of the respondent's intent to participate in relevant clinical trials with an R^2 that only explained 16% of the variance, as shown in Table 2. The significant predictors of clinical trial participation were Familiarity (b= .30, t= 13.13, p< .0001), Trust in Doctors (b= .08, t= 4.17, p< .0001), and Trust in Social Media (b= .03, t= 2.54, p= .01). It is notable that the Familiarity with Clinical Trials was more than three-times the magnitude to the next most impactful coefficient for Trust in Doctors. That Trust in Social Media was significant was surprising to us, given the low levels of trust we found in the descriptives (μ= 3.3 on a 1-10 scale). Even though people have low levels of trust in social media information, improving that trust will significantly improve clinical trial participation. We also found that Ethnicity (b= -.14, t= -1.80, p= .07), Race (b= -.14, t= -1.83, p= .07) and Trust in Digital Intake (b= .02, t= 1.68, p= .09) were marginally significant. Notice that with the Ethnicity and Race estimates, the magnitude of these coefficients were greater than any of the Trust variables, but noise in the standard error dragged down the significance. We explore the details of the negative impacts of ethnicity and race in the next models.

	Estimate	Std Err	t	p
Intercept	3.74	.05	75.99	<.0001
Trust Digital Intake	.02	.01	1.68	.09
Trust Doctor	.08	.02	4.17	<.0001
Trust Family	.01	.01	1.1	.27
Trust Medical Web	.02	.01	1.36	.17
Trust Nurses	.02	.02	1.19	.24
Trust Social Media	.03	.01	2.54	.01
Patient Age	.00	.00	0.9	.37
Gender	-.03	.05	-0.58	.56
Race (0=Non-Black,1=Black)	-.14	.08	-1.83	.07
Ethnicity (0=Non-Hisp,1=Hispanic)	-.17	.10	-1.8	.07
Device(0=Mobile;1=Non-Mobile)	-.06	.06	-1.02	.31
Familiar Clin. Trials	.30	.02	13.13	<.0001

Table 2. *Estimates for the Base Model*

Source: *Authors' analysis, Phreesia data, July 2022*

Race & Ethnicity Models

To examine the role of race and ethnicity in clinical trial recruitment, we ran separate regression models for each of the ethnicity and race categories. The results of the regressions comparing the Non-Hispanic and Hispanic models (i.e. Ethnicity) are shown in Table 3. The Hispanic model is significant ($F_{11,195}= 4.40$, $p< .0001$) and the explained variance increased to 20%.

	Non-Hispanic Sample				*Hispanic Sample*			
	Estimate	SE	t	p	Estimate	SE	t	p
Intercept	3.76	.05	74.74	<.0001	3.41	.18	18.75	<.0001
Trust Digital Intake	.02	.01	1.75	.08	.00	.05	.09	.93
Trust Doctor	.08	.02	3.98	<.0001	.07	.07	1.12	.26
Trust Family	.01	.01	.41	.68	.10	.05	2.26	.02
Trust Medical Web	.02	.01	1.58	.11	-.02	.05	-.40	.69
Trust Nurses	.03	.02	1.26	.21	.02	.08	.21	.83
Trust Social Media	.03	.01	2.30	.02	.03	.05	.63	.53
Patient Age	.00	.00	.58	.56	.01	.01	1.09	.28
Gender	-.05	.06	-.88	.38	.17	.20	.84	.40
Race (0=Non-Black,1=Black)	-.15	.08	-1.92	.06	.12	.43	.27	.79
Device(0=Mobile;1=Non-Mobile)	-.08	.06	-1.41	.16	.25	.21	1.19	.23
Familiar Clin. Trials	.30	.02	12.51	<.0001	.27	.08	3.46	.00

Table 3. *Estimates for the Ethnicity Model*

Source: *Authors' analysis, Phreesia data, July 2022*

In the Ethnicity Model, we-ran the model comparing the estimates for the Hispanic sample to the non-Hispanic sample, shown in Table 3. Overall, we see a shift away from trusting doctors and a significant and positive increase in trust in family members for information about clinical trials. Family trust 10-fold from the Non-Hispanic Model (b= .01, t= .41, p= .68) to the Hispanic Model (b= .10, t= 2.26, p= .02) and became significant. At the same time, Trust in Doctors for trial information moved from highly significant in the Non-Hispanic Model (b= .08, t= 3.98, p< .0001) to insignificant in the Hispanic Model (b= .07, t= 1.12, p = .26). Similarly, Trust in Social Media moved from significance in the Non-Hispanic Model (b= .03, t= 2.30, p= .02) to insignificance in the Hispanic Model (b= .03, t= .63, p= .53). Notice that in the Trust in Doctors and Trust in Social Media, the coefficients did not change much but they both moved to insignificance. This means that there is a similar average effect across the sample but wider variation or noise in the Trust in Doctors and Social Media for these Hispanic respondents, suggesting more variation in this sample.

In the Race Model, we compared the estimates with those respondents who identified as Black with the non-Black respondents, shown in Table 4. The model for the Black sample was again significant F11,353= 7.31, p< .0001) and the R2 again increased, this time to 19%. Overall, we saw little effect of trust in the Black sample although the effects of Familiarity remain similar in the Black sample (b= .29, t= 5.20, p< .0001) compared to the Non-Black sample (b= .30, t= 11.98, p< .0001). The most important change was that the magnitude of the Social Media coefficient doubled in the Black sample (b= .06, t 1.84, p= .07) compared to the non-Black sample (b= .03, t= 1.81, p= .07) although both estimates remained marginally significant. This was offset by a decrease in Trust in Doctors in the Non-Black sample (b= .08, t= 4.03, p< .0001) to insignificance in the Black sample (b= .06, t= 1.18, p= .24) without a concomitant increase in Trust in Family (b= .01, t=.16, p= .87) in the Black sample.

	Non-Black Sample				*Black Sample*			
	Estimate	SE	t	p	Estimate	SE	t	p
Intercept	3.76	.05	72.94	<.0001	3.48	.15	23.68	<.0001
Trust Digital Intake	.02	.01	1.60	.11	.02	.04	.57	.57
Trust Doctor	.08	.02	4.03	<.0001	.06	.05	1.18	.24
Trust Family	.01	.01	1.12	.26	.01	.03	.16	.87
Trust Medical Web	.02	.01	1.20	.23	.03	.04	.82	.41
Trust Nurses	.02	.02	.94	.35	.03	.05	.67	.50
Trust Social Media	.03	.01	1.81	.07	.06	.03	1.84	.07
Patient Age	.00	.00	.96	.34	.00	.00	.20	.84
Gender	-.04	.06	-.66	.51	.01	.16	.07	.94
Ethnicity (0=Non-Hisp,1=Hispanic)	-.17	.10	-1.78	.08	.05	.41	.13	.90
Device(0=Mobile;1=Non-Mobile)	-.09	.06	-1.46	.14	.12	.15	.76	.45
Familiar Clin. Trials	.30	.03	11.98	<.0001	.29	.06	5.20	<.0001

Table 4. *Estimates for the Race Model*

Source: *Authors' analysis, Phreesia data, July 2022*

Discussion

In this research, we examined the effectiveness of different information channels in building trust in clinical trials in a way that leads to diverse clinical trials participation. Although trust is widely considered to be the key to clinical trial participation, we found a relatively small effect of trust and greater effects of familiarity in predicting clinical trial participation. We see familiarity as being more than just awareness.[9] Familiarity includes awareness but also implies that the prospect has some knowledge of what clinical trials involve (i.e. knowledge) and they also believe that it is a good thing to participate in clinical trials (i.e. affective commitment). The middling levels of familiarity (average of 2.6 on a scale of 1 to 5) suggest an opportunity for more familiarity with clinical trials. Familiarity takes time, so clinical trial recruiting should be thought of as a process to manage over time. In this, it might be useful to think of clinical trial recruiting as analogous to a sales process or a recruit relationship management process instead of a one-time request to participate in a trial.

We found that there was a variety of information channels that built trust and that these channels shifted across ethnic and racial groups. This suggests that clinical trial recruiters need an omnichannel marketing capability to build both trust and familiarity. Rather than focus on one information channel (doctors, social media, or digital intake), recruiters should raise awareness about trials and educate patients across a variety of touchpoints that will echo across channels. Future research can develop the details of these synergies across information channels.

The details of the Hispanic and Black Models offer specific recommendations as to how to approach these groups. First, it is interesting to see that the R2 jumped in both groups by about 5%, suggesting a greater role for trust in these samples. In the Hispanic sample,

Trust in Digital Intake, Doctors, and Social Media decreased to non-significance where Trust in Family increased 10-fold to significance. This suggests, for example, that it may be more effective when recruiting to Hispanic segments to target information to younger generations and count on them to communicate to their older grandparents. This was the approach US Surgeon General Jerome Adams used to encourage Hispanic elderly to get COVID vaccines in 2020 (i.e. 'Tell your abuela to get the shot').[11] We saw a similar shift in the Black sample except the trusted channels shifted to social media.

An important limitation of this research can be seen in our findings from the Ethnicity and Race Models. We found that some coefficients were essentially the same magnitude but lost significance in the Hispanic or Black samples. (e.g. Trust in Doctors and Social Media in the Hispanic sample and Trust in Doctors in the Race Model). The statistical issue here is that there was an increase in the variation or noise in the Hispanic and Black samples, which inflated the standard error, leading to a loss of significance. Since a significance test is a signal-to-noise ratio, increasing the noise in the sample can lead to a loss of significance. The implication in all this is that simple demographic segmentation (identification as Hispanic or Black) is not adequate.Within these ethnic and racial categories, there is diversity which leads to variations in our survey items. These findings suggest that clinical trial recruiters need a more developed segmentation approach than simple ethnic or racial categories.

Conclusion

In this study, we examined how trust in various information channels leads to willingness to participate in clinical trials. We found a variety of information channels that led to willingness to participate in clinical trials (e.g. Doctors, Social Media, Digital Intake) but these channels have complex effects which change across ethnic and racial categories. In our Hispanic and Black samples, for example, patients had less trust in doctors but that Hispanic respondents trusted family more and Black respondents had greater trust in social media. Finally, our findings suggest that clinical trial recruiters should develop more sophisticated segment profiles that go beyond race or ethnic categories.

***Michael J Howley**, PA-C, MBA, PhD, Clinical Professor, LeBow College of Business, Drexel University, Philadelphia PA, **Jai Seth**, Senior Research Manager, Phreesia, **Stella Sechopoulos**, Research Associate, Phreesia, and **Peter Malamis**, Senior Director, Market Development, Phreesia*

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