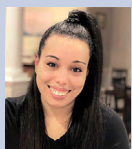


Breast Cancer: 2022 ASCO Annual Meeting Highlights for the Advanced Practitioner



Jacquelyn Lauria, RN, APN, AOCNP®, of Rutgers Cancer Institute, discusses results from the DESTINY-BREAST04

trial on HER2-low metastatic breast cancer, findings on sacituzumab govitecan in HR-positive, HER2-negative metastatic breast cancer, and options for disease progression after a CDK4/6 inhibitor. **Rose DiMarco, PharmD, BCPS, BCOP**, of Thomas Jefferson University Hospital, considers insights provided by a survey on participation in clinical trials among Black patients with metastatic breast cancer.

Abstract LBA3

DESTINY-Breast04 Trial: T-DXd Significantly Improves Survival in Patients With HER2-Low Metastatic Breast Cancer

By Alice Goodman

Visit https://ascopubs.org/doi/abs/10.1200/JCO.2022.40.17_suppl.LBA3 to read the full abstract and view author disclosures.

The antibody-drug conjugate fam-trastuzumab deruxtecan-nxki (T-DXd) doubled progression-free survival compared with chemotherapy alone in

patients with “HER2-low” metastatic breast cancer—ie, patients with low levels of HER2 expression. The agent also extended overall survival for patients with low levels of the HER2 receptor, regardless of hormone receptor status. These results could impact the way breast cancer is treated in about half of all breast cancers, for the first time incorporating patients with HER2-low disease as a subset that will benefit from a HER2-directed therapy such as T-DXd, experts predicted.

The study, DESTINY-Breast04, was presented during the Plenary Session at the 2022 ASCO Annual Meeting by lead author Shanu Modi, MD, a medical oncologist at Memorial Sloan Kettering Cancer Center, New York, who received a standing ovation.

“DESTINY-Breast04 is the first phase III trial of a HER2-directed therapy in patients with [HER2-low] metastatic breast cancer to show a statistically significant and clinically meaningful benefit in progression-free survival and overall survival compared to standard-of-care treatment, regardless of hormone receptor status. The results of DESTINY-Breast04 are practice-changing. The efficacy of trastuzumab deruxtecan—[which] links trastuzumab, a HER2-directed monoclonal antibody, to deruxtecan, a topoisomerase I inhibitor that interrupts DNA replication in cancer cells—supports the use of HER2-low as a new therapeutically targetable category for metastatic breast cancer,” stated Dr. Modi.

“This new standard of care can improve survival for about 50% of all patients diagnosed with

metastatic breast cancer today. These results mean that it is important for patients to know what level of HER2 their cancer expresses, not just whether it is HER2-positive or -negative, especially as HER2-low can be determined using commonly available tests," she added.

Trastuzumab, one component of the antibody-drug conjugate, is used to treat patients with breast cancer expressing high levels of HER2 (ie, HER2 3+ or HER2-positive) but not in those with low levels of HER2 expression (HER2 1+/2+ or HER2-low) or no HER2 expression (HER2 0+). T-DXd is approved in the United States for adults with unresectable or metastatic HER2-positive breast cancer who have been previously treated with prior anti-HER2-directed therapy, and the antibody-drug conjugate was recently granted Breakthrough Therapy designation for patients with HER2-low metastatic breast cancer.

Study Methodology

The randomized, double-blind, open-label, phase III DESTINY-Breast04 trial enrolled 557 patients in Asia, Europe, and North America with hormone receptor-negative or -positive metastatic breast cancer and centrally confirmed HER2-low expression. All patients had been previously treated with one or two prior lines of chemotherapy for metastatic breast cancer and were required to have endocrine therapy-refractory disease.

Patients were randomly assigned in a 2:1 ratio to receive either T-DXd at 5.4 mg/kg or physician's choice of standard chemotherapy (capecitabine, eribulin, gemcitabine, paclitaxel, or nab-paclitaxel). The primary endpoint was progression-free survival in patients with hormone receptor-positive disease. Key secondary endpoints were progression-free survival in patients with either hormone receptor-positive or -negative disease, as well as overall survival in all patients and in those with hormone receptor-positive disease.

Testing with immunohistochemistry (IHC) showed that 58% of patients were IHC 1+ and 42% were IHC 2+. "At baseline, the visceral burden of disease was high and similar across the two treatment arms," Dr. Modi said.

Key Findings

The median duration of treatment was 8.2 months with T-DXd and 3.5 months with physician's choice of chemotherapy. At a median follow-up of 18.4 months, a 49% reduction in the risk of progressive cancer and a 36% reduction in the risk of death were observed in patients with hormone receptor-positive, HER2-low expression in those treated with T-DXd vs standard chemotherapy. Median progression-free survival was 10.1 months for the T-DXd-treated patients vs 5.4 months for those treated with standard chemotherapy ($P < .0001$). Among all 557 patients enrolled in the study, median progression-free survival was 9.9 months vs 5.1 months, respectively ($P < .001$).

In the patients with hormone receptor-positive disease, median overall survival was 23.9 months vs 17.8 months, respectively. Median overall survival in the total study population was 23.4 months for T-DXd recipients vs 16.8 months for standard chemotherapy recipients—a significant gain of 6.6 months in survival favoring the antibody-drug conjugate ($P = .001$).

In an exploratory analysis of the hormone receptor-negative subgroup, median progression-free survival was 8.5 months with T-DXd vs 2.9 months with standard therapy. Also, in this group, median overall survival was 18.2 months vs 8.3 months, respectively. "This is a poor-prognosis group," Dr. Modi noted.

"We saw an unprecedented survival benefit in patients with hormone receptor-positive and hormone receptor-negative disease, regardless of IHC HER2 expression," Dr. Modi stated. "We have been relegated to treating these patients as HER2-negative. That's why these data are so significant. For the first time, we can extend HER2-targeted therapy to a broader range of patients."

The rates of grade 3 or higher treatment-related adverse events were somewhat lower with T-DXd: 52.6% vs 67.4% with standard chemotherapy. However, higher rates of interstitial pneumonitis (of any grade) were reported in the T-DXd arm: 12.1% vs 0.1%, respectively.

Lung Toxicity Concern

"Lung toxicity is an important safety concern that will need to be closely monitored," Dr. Modi said. "We want to be able to use this extremely

compelling and efficacious therapy for our patients as safely as we can. I think from my perspective, the way we do that is to select the right patients and know how to manage interstitial lung disease. There are guidelines out there for clinicians, and there has been a massive education campaign about how to manage lung toxicity. I do believe it has had an impact,” she said.

“Now we have a heightened awareness and guidelines and tools at our disposal, and the two

most recent studies in breast cancer show we have brought the high-grade event rate down through education. We should continue the campaign of awareness and giving clinicians the tools and the education they need to manage patients with lung toxicity appropriately,” she stated.

The next steps will be studies to explore the minimum threshold of HER2 expression that will respond to T-DXd.

The Advanced Practitioner Perspective

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DESTINY-Breast04 is a phase III trial that showed a doubling of progression-free survival (PFS) with the antibody-drug conjugate fam-trastuzumab deruxtecan (T-DXd; Enhertu) vs. chemotherapy alone in patients with HER2-low metastatic breast cancer.

It links the HER2-directed monoclonal antibody trastuzumab to deruxtecan, a potent topoisomerase I inhibitor. Until now, HER2-directed agents were only used if amplification was 3+ by immunohistochemistry (IHC) or fluorescence in situ hybridization (FISH) positive. In this study, HER2 low was defined as HER2 1+ or 2+ by IHC. Benefit was demonstrated regardless of hormone receptor status.

Of 557 patients enrolled, the median PFS was 9.9 months with T-DXd vs. 5.1 months with physician’s choice of chemotherapy. Median overall survival in the total study population was 23.4 months for the T-DXd arm vs. 16.8 months in the arm receiving standard chemotherapy.

This has the potential to improve survival for almost 50% of all patients diagnosed with metastatic breast cancer today.

These data should prompt advanced practitioners to:

- Understand that we can now extend HER2-targeted therapy to a broader range of patients.
- Review the more nuanced level of *HER2/neu* expression to determine if the tumor is now defined as HER2 low and recognize that this is a new subset of breast cancer.
- Educate patients with metastatic breast cancer about whether this option is appropriate for them.
- Be knowledgeable regarding potential grade 3 toxicities, especially interstitial lung disease, including pneumonitis. This includes recognizing signs or symptoms and management. A multidisciplinary approach including pulmonology should be considered.
- Be aware that importantly, the NCCN Guidelines have been updated to include this indication for T-DXd, which should facilitate payor approvals.

Disclosure: Ms. Lauria has served on the advisory board for Sanofi-Genzyme.

Abstract LBA1001**TROPiCS-02 Sacituzumab Govitecan Effective in Hormone Receptor-Positive, HER2-Negative Metastatic Breast Cancer**

By Caroline Helwick

Visit https://ascopubs.org/doi/abs/10.1200/JCO.2022.40.17_suppl.LBA1001 to read the full abstract and view author disclosures.

For advanced breast cancer that is hormone receptor-positive and HER2-negative, sacituzumab govitecan-hziy significantly reduced the risk of disease progression by 34% over physician's choice of treatment, based on the results of the phase III TROPiCS-02 trial. The heavily pretreated patients in the study had received a median of three prior therapies for metastatic disease. The primary progression-free survival analysis of TROPiCS-02 and the first of three planned overall survival analyses were presented at the 2022 ASCO Annual Meeting by Hope S. Rugo, MD, FASCO, Professor of Medicine at the University of California San Francisco.

"In the landmark analysis, three times more women were progression-free at the 1-year mark when treated with sacituzumab govitecan compared with treatment of physician's choice (21% vs 7%). Sacituzumab govitecan should be considered a potential treatment option for these patients," said Dr. Rugo.

Meeting the primary endpoint, the study showed a statistically significant improvement in progression-free survival by independent review. Median progression-free survival was 5.5 months with sacituzumab govitecan and 4.0 months with chemotherapy (hazard ratio [HR] = 0.66; $P = .0003$).

Difficult-to-Treat Population

Sacituzumab govitecan, an anti-Trop2 antibody-drug conjugate, is approved for patients with metastatic triple-negative breast cancer after at least two prior treatments (one or more for metastatic disease). The findings from TROPiCS-02 suggest the drug may be useful in women with hormone receptor-positive tumors as well.

As Dr. Rugo pointed out, hormone receptor-positive/HER2-negative tumors account for about

70% of metastatic disease. International guidelines recommend sequential endocrine therapy, starting with first-line endocrine therapy in combination with cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitors. When resistance to endocrine therapy develops, the next step is sequential single-agent chemotherapy.

"This is associated with declining efficacy and increased toxicity," Dr. Rugo noted. "With limited chemotherapy options in later-line settings, there remains a high unmet clinical need."

About TROPiCS-02

TROPiCS-02 is a global, open-label, randomized phase III study that enrolled 543 patients who had received a median of three prior regimens in the metastatic setting. Most of them had visceral metastases (95%) and had a median time from initial metastatic diagnosis to randomization of approximately 4 years.

Patients were required to have received at least one endocrine therapy and a CDK4/6 inhibitor and to have been treated with two to four lines of chemotherapy for metastatic disease. Baseline characteristics were balanced between the arms.

Investigators randomly assigned patients to receive sacituzumab govitecan (10 mg/kg on days 1 and 8 every 21 days) or treatment of physician's choice: capecitabine, eribulin, vinorelbine, or gemcitabine. The primary endpoint was progression-free survival by blinded independent review.

Landmark Analysis

Median progression-free survival was 5.5 months with sacituzumab govitecan vs 4.0 months with standard chemotherapy (HR = 0.66; $P = .0003$). The benefit was consistent across subgroups, including patients who had received at least three prior chemotherapy regimens in the metastatic setting (HR = 0.70), had visceral metastases (HR = 0.66), and were aged 65 or older (HR = 0.59).

Response rates were 21% with sacituzumab govitecan and 14% with chemotherapy (odds ratio [OR] = 1.63; $P = .03$), and the clinical benefit rates were 34% and 22%, respectively (OR = 1.84; $P = .002$). Overall survival data were immature, but a numerical trend for improvement was seen, with median overall survival of 13.9 months vs 12.3 months (HR = 0.84; $P = .14$), respectively.

Progression-free survival rates for sacituzumab govitecan vs chemotherapy were 46% vs 30% at 6 months and 21% vs 7% at 12 months, she reported.

“A subset of these heavily pretreated patients had rapid disease progression in the first 2 months on treatment; therefore, we analyzed progression-free survival at several key landmark time points,” Dr. Rugo said. “The Kaplan-Meier curves separated early and were consistent over time, with a higher proportion of patients on sacituzumab govitecan alive and progression-free at all landmark time points.”

Asked to explain the discordance between the 1.5-month benefit in progression-free survival and the more robust hazard ratio and *P* value (HR = 0.66; *P* = .0003), Dr. Rugo explained that patients with very resistant and aggressive disease have rapid disease progression, “even before they go to their first scan,” and she noted the proportion of such patients was parallel between the arms. This scenario has been observed in several trials in the metastatic setting. The result is a more modest progression-free survival that does not reflect the real benefit in patients able to complete treatment.

“This is where the landmark analysis helps us. We can see three times as many patients are progression-free at 12 months with sacituzumab govitecan,” she added.

Safety and Quality of Life

The safety profile of sacituzumab govitecan in this study was consistent with that observed in previous trials. Grade ≥ 3 treatment-emergent adverse events were observed in 74% of that arm and in

60% of the chemotherapy arm. The most common toxicities associated with sacituzumab govitecan were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), and neutropenic colitis (2%). There were no events of interstitial lung disease with sacituzumab govitecan (vs 1% with chemotherapy) and no cases of cardiac failure or left-ventricular dysfunction in either arm. One death related to sacituzumab govitecan was reported, from septic shock due to neutropenic colitis.

“Sacituzumab govitecan also demonstrated an overall health-related quality-of-life benefit over chemotherapy, with delayed deterioration in fatigue and global health status/quality-of-life scales,” she further reported.

Explaining the Benefit in HR-Positive Tumors

Patients in TROPiCS-02 were required to have hormone receptor-positive tumors, although this was not centrally confirmed. Ideally, hormone receptor status would have been tested within a year of enrollment, but Dr. Rugo acknowledged that some testing could have occurred much earlier in the disease course.

In other words, hormone receptor status could have changed over time, so some patients' tumors now leaned toward negative. These “shifts” in subtypes are being observed more frequently now that sequential biopsies are performed more often. “As patients develop more visceral involvement and resistance to treatment, we do see falling estrogen receptor expression.... In those patients, we may be better able to overcome resistance by using these more effective drugs,” she said.

The Advanced Practitioner Perspective

Jacquelyn Lauria, RN, APN, AOCNP®
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Sacituzumab govitecan (Trodelyv) had until now only been approved for metastatic triple-negative breast cancer. However, about 70% of metastatic breast cancers are estrogen receptor positive and HER2 negative. We know that once these patients exhaust available hormonal therapies, their disease can be difficult to treat.

This newly reported phase III study of over 500 heavily pretreated women looked at hormone receptor-positive and HER2-negative

patients treated with sacituzumab govitecan vs. physician's choice of chemotherapy. With a primary endpoint of progression-free survival (PFS), sacituzumab showed a statistically significant improvement of 5.5 months vs. 4 months for standard chemotherapy (HR = 0.66; *p* = .0003).

The landmark analysis showed three times as many patients were progression free at 12 months with sacituzumab govitecan vs. the chemotherapy arm.

Eligible patients had at least one endocrine therapy and a CDK4/6 inhibitor, as well as two to four lines of chemotherapy for metastatic

disease. Median age was 56 years old, and 95% of patients had visceral metastases.

The overall health-related quality of life benefit was also noted, and no new safety issues were reported. Grade 3 adverse events were seen in 74% of patients in the sacituzumab arm compared with 60% in the chemotherapy arm. Fatigue, diarrhea, and neutropenia were the most common toxicities.

These study results challenge advanced practitioners to recognize this distinct set of

patients with tumors that are estrogen receptor positive and *HER2/neu* negative but who have become hormone refractory. In fact, these patients' tumors may have developed decreased estrogen receptor expression. We are also seeing this in clinical practice as we perform more sequential biopsies on tumors to identify new treatment targets (such as with next-generation sequencing).

Disclosure: Ms. Lauria has served on the advisory board for Sanofi-Genzyme.

Abstract LBA1004

Latest Findings on Fulvestrant or Exemestane With or Without Ribociclib in HR+, HER2- Metastatic Breast Cancer

By JADPRO Staff

Visit https://ascopubs.org/doi/abs/10.1200/JCO.2022.40.17_suppl.LBA1004 to read the full abstract and view author disclosures.

Phase II findings from the MAINTAIN trial showed a benefit in progression-free survival for patients with hormone receptor (HR)-positive/HER2-negative metastatic breast cancer when they switched to endocrine therapy and received ribociclib after disease progression on another CDK4/6 inhibitor.

CDK4/6 inhibitors have demonstrated benefit in progression-free survival (PFS) and overall survival (OS) in patients with HR-positive, HER2-negative MBC when combined with endocrine therapy (ET). While observational data demonstrate a potential benefit of continuing CDK4/6 inhibitors and switching ET at progression, no prospective trials have evaluated this approach. Investigators conducted a phase II, multicenter, randomized trial to evaluate the efficacy of fulvestrant or exemestane with or without ribociclib in patients with HR-positive, HER2-negative metastatic breast cancer whose cancer previously progressed on any CDK4/6 inhibitor plus any ET.

Study Design

Patients with measurable or non-measurable HR-positive, HER2-negative metastatic breast cancer

whose cancer progressed during CDK4/6 inhibitor therapy and ET were randomized 1:1 to fulvestrant or exemestane with or without ribociclib. Patients treated with prior fulvestrant received exemestane as ET in the randomization, and if they received prior exemestane, fulvestrant was the ET. If patients received neither, fulvestrant or exemestane was chosen at the investigator's discretion. Progression-free survival (PFS) was the primary endpoint, defined as time from randomization to progression of disease or death.

Results

Of the 120 randomized evaluable patients, 1 patient was removed due to not taking ET along with ribociclib/placebo. All but 1 patient was female, the median age was 57.0 years, 88 patients (74%) were white, and 21 (17.6%) were Hispanic. For ET, 99 patients received fulvestrant (83%) and 20 patients exemestane (17%). 100 patients previously received palbociclib (84%), 13 ribociclib (11%), 2 abemaciclib (2%), and 4 palbociclib and another CDK4/6 inhibitor (3%).

There was a statistically significant PFS improvement for patients randomized to fulvestrant or exemestane + ribociclib (median: 5.33 months) vs. placebo (median: 2.76 months). Similar results were seen in the subset of patients treated with fulvestrant, with a median PFS for those randomized to ribociclib (5.29 months) vs. placebo (2.76 months).

At 6 months, 42% were progression free on the ribociclib arm vs. 24% on placebo. At 12 months, 25% were progression-free on the ribociclib arm vs. 7% on placebo. Additional endpoints have yet to be reported, including overall response rate and safety.

The Advanced Practitioner Perspective
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The standard of care for first-line metastatic hormone receptor (HR)-positive, HER2-negative breast cancer is endocrine therapy plus a CDK4/6 inhibitor. However, we know from large phase III trials that the median progression-free survival (PFS) is only a little more than 2 years for these patients.

Previously, we did not have data for clinical guidance as to whether CDK4/6 inhibitors should be maintained after progression. This phase II study of 120 patients looked at the benefit of maintaining CDK4/6 inhibition with ribociclib (Kisqali) and switching endocrine therapy after progression on another CDK4/6 inhibitor.

Patients who had already received fulvestrant received exemestane. If they had prior exemestane, then they received fulvestrant. Eligibility required that patients have no more than one line of chemotherapy for metastatic breast cancer.

Results showed a statistically significant improvement in PFS for the fulvestrant or exemestane with ribociclib arm, with a median PFS of 5.33 months vs. 2.76 months for placebo with fulvestrant or exemestane. Most of the patients had previously received palbociclib (Ibrance). The most common side effects were neutropenia, anemia, and thrombocytopenia. No new safety concerns were identified.

This trial also did an exploratory analysis to look at circulating tumor DNA to see what role mutations, such as *ESR1*, may play in the development of resistance mechanisms to CDK4/6 inhibitors. This will require further study but is intriguing.

Advanced practitioners managing patients on CDK4/6 inhibitors should also continue to monitor for pneumonitis or QT prolongation. In addition, ongoing patient education regarding oral adherence is key, since two of the three CDK4/6 inhibitors are given on a 21-day-on/7-day-off cycle.

Disclosure: Ms. Lauria has served on the advisory board for Sanofi-Genzyme.

Abstract 1014

Nearly Half of Black Patients With Metastatic Breast Cancer Report Not Being Informed About Clinical Trials

By The ASCO Post Staff

Visit https://ascopubs.org/doi/abs/10.1200/JCO.2022.40.16_suppl.1014 to read the full abstract and view author disclosures.

A survey of patients with metastatic breast cancer found that 83% of Black respondents were somewhat or very likely to consider clinical trial participation; however, 40% of those respondents reported that they had not been informed by their care team about the opportunity to enroll in a trial. The research was presented by Walker et al at the 2022 ASCO Annual Meeting.

Among U.S. racial/ethnic groups, Black people with breast cancer have the highest death rate and shortest survival. Approximately 15% of patients with cancer in the United States are Black,

while only 4% to 6% of clinical trial participants are Black.

About the Study

Researchers did a literature review of 34 articles related to Black patient participation in clinical trials. They also conducted 31 virtual interviews, including patients living with metastatic breast cancer, clinicians involved in breast cancer treatment, hospital administrators, and others, to identify relevant issues, concerns, motivations, barriers, and experiences in dealing with the disease. The messages from the literature review and the informant interviews were then used to inform the survey questions.

Key Findings

This survey of patients with metastatic breast cancer, which is part of the BECOME (Black Experience of Clinical Trial and Opportunities for Meaningful Engagement) initiative, showed that:

- Black respondent trust and satisfaction with their oncology care team was over 90%, while 83% were somewhat or very likely to

consider trial participation.

- 40% of Black respondents said that their care team had not discussed trial enrollment compared to 33% of non-Black respondents.
- One of the reasons Black respondents declined to participate in a trial was concerns about side effects (73%).
- Black respondents were more likely than non-Black respondents to be concerned that unstudied treatments may be harmful (57% vs 31%).
- Black respondents were less likely than non-Black respondents to indicate they trust trials (73% vs 91%) and trust that people of all races/ethnicities get fair treatment in trials (32% vs 56%).
- Black respondents were more likely than non-Black respondents to value receiving trial information from someone of the same racial/ethnic identity (67% vs 10%), who has had breast cancer (73% vs 44%) or metastatic breast cancer (73% vs 51%), or who has participated in a clinical trial (72% vs 48%).
- Black respondents were more likely than non-Black respondents to be motivated to participate in clinical trials to ensure people with their racial or ethnic identity would benefit (83% vs 51%).

“This study was initiated in 2019 and led by a very special and ardent advocate of inclusivity in breast cancer trial enrollment. Sadly, she passed away from metastatic breast cancer, but we all strive to continue her efforts by bringing the patient voice and authenticity of advocacy to our work so that we can demonstrate the impact that patients can have on the clinical trials process,” said lead study author Stephanie Walker, RN,

The Advanced Practitioner Perspective

Rose DiMarco, PharmD, BCPS, BCOP

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Thomas Jefferson University Hospital

It is no secret that many oncology clinical trials have low rates of minority patient enrollment. The Metastatic Breast Cancer Alliance presented this much-needed look at the experiences of Black patients with metastatic breast cancer (MBC), where 40% of Black respondents reported that clinical trials were

project lead on the BECOME initiative for the Metastatic Breast Cancer Alliance, a collective of cancer nonprofits, pharmaceutical and biotech industry members, and individual patient advocates, many of whom are living with metastatic breast cancer.

Next Steps

The survey respondents tended to be highly educated (over 80% of respondents held an advanced degree) with high socioeconomic status (about half of respondents had annual household incomes of \$50,000 or higher) and access to social media. Patients not connected to social media, or those who received their care in community cancer centers, were not well represented in the survey, factors which the investigators hope to address in future studies.

Members of the BECOME initiative will meet with other groups who have recently performed surveys focused on Black patients with metastatic breast cancer to share results and identify strategies for improved care.

The investigators hope to incorporate steps into the clinical trial enrollment processes to increase Black patient participation, including:

- Enhancing clinical trial awareness by informing patients, increasing education, training health-care providers to deliver patient-friendly information in an unbiased manner, and providing messaging from people of shared racial/ethnic identities and health experiences.
- Building trust through clear communication.
- Addressing concerns about side effects, effectiveness, harm, and fair treatment.
- Helping patients find and access trials.

not discussed compared with 33% of non-Black respondents.

There is no simple answer to the questions of why fewer Black patients are being offered clinical trials and why more Black respondents reported being concerned about the safety of clinical trials. The United States has a history of conducting unethical experimental medications and procedures on minority patients. The trauma inflicted upon these patients has led to generations of mistrust of the health-care sys-

tem. In addition, unconscious (or implicit) bias can often lead to disparities in the care that is provided to different patients. The authors note that building trust and providing clear unbiased education may help increase minority enrollment in clinical trials.

As an advanced practitioner, it is imperative to assess our own implicit biases. The Implicit Association Tests are available at <https://implicit.harvard.edu/implicit/takeatest.html> and can give an eye-opening look at internalized stereotypes, which will allow us to

change our perspectives and provide better patient-centered care.

It is also important to educate ourselves on not just clinical trial availability, but also the safety measures that are put in place to protect patients, such as informed consent and Institutional Review Boards. These steps will aid in better educating our patients and gaining their trust when discussing clinical trial participation.

Disclosure: Dr. DiMarco has served on an advisory board for Bristol Myers Squibb.



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