

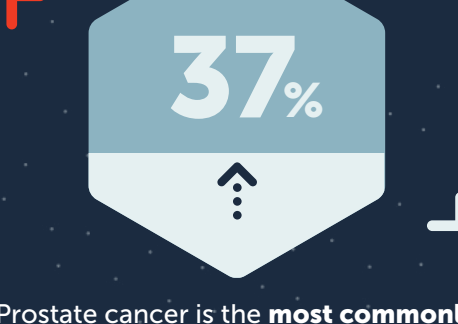
# African Americans and prostate cancer

Overcoming barriers to improve detection and care



## Key facts: high prevalence, poor outcomes

### INCREASED PREVALENCE



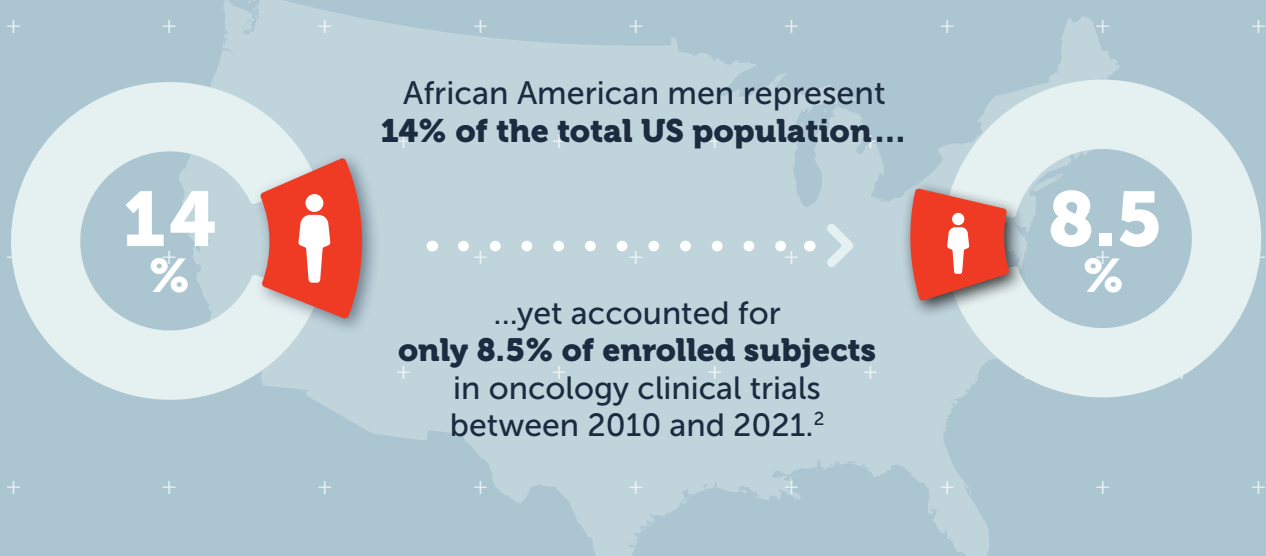
Prostate cancer is the **most commonly diagnosed cancer** among African American men (37% of all new diagnoses in 2022).<sup>1</sup>

### POOR PROGNOSIS



African American patients have the **lowest survival rate of any racial or ethnic group** for most cancers. African American men are >2x more likely to die from prostate cancer than White men.<sup>1</sup>

## Disparity in clinical trials



**The US Food and Drug Administration (FDA) has issued draft guidance on clinical trial diversity, and organizations such as the American Society of Clinical Oncology (ASCO) have called out the need for enriched diversity in oncology clinical trial participation.**<sup>3,4</sup>

## Bridging the gap: Our commitment to minimizing disparities

Blue Earth Diagnostics is dedicated to promoting inclusive participation in our clinical trials, particularly within the African American community, to reduce health disparities and improve detection and care. Encouraging diversity in clinical trials is essential for understanding potential differences in efficacy while also helping to reduce stigma and address concerns about participation.<sup>3,4</sup>



The Phase 3 SPOTLIGHT study assessed the performance and safety of POSLUMA® (flotufolostat F 18), an FDA-approved positron emission tomography (PET) diagnostic imaging radiopharmaceutical for use in men with biochemical recurrence of prostate cancer.<sup>5,6</sup> Given the high prevalence and high mortality of prostate cancer in African American men, a sub-analysis of SPOTLIGHT data was conducted to evaluate the performance of POSLUMA in African American patients enrolled in the trial.<sup>2</sup>

### INDICATION

POSLUMA® (flotufolostat F 18) injection is indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer

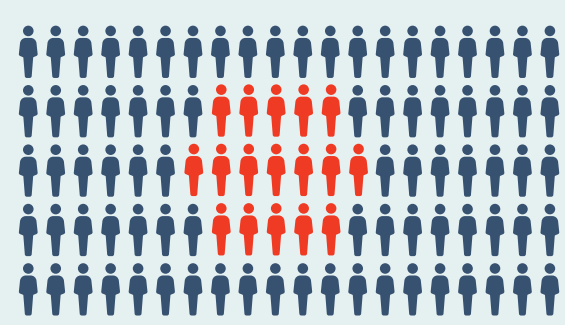
- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

### IMPORTANT SAFETY INFORMATION

• Image interpretation errors can occur with POSLUMA PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of POSLUMA for imaging metastatic pelvic lymph nodes in patients prior to initial definitive therapy seems to be affected by serum PSA levels and risk grouping. The performance of POSLUMA for imaging patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. Flotufolostat F 18 uptake is not specific for prostate cancer and may occur in other types of cancer, in non-malignant processes, and in normal tissues. Clinical correlation, which may include histopathological evaluation, is recommended.

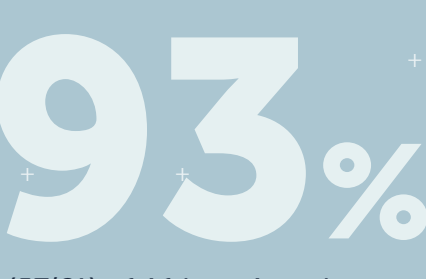
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## MEANINGFUL PARTICIPATION



The enrollment rate of **17%** African American patients in SPOTLIGHT demonstrated that appropriate demographic representation of this population in oncology clinical trials is achievable.<sup>2</sup>

## CONSISTENT RESULTS



(57/61) of African American patients enrolled in SPOTLIGHT were found to have a **positive POSLUMA PET scan**, consistent with the 87% (264/305) detection rate for all other patients enrolled in the study.<sup>2</sup>



## Takeaways for future oncology clinical trials



Target geographic regions and clinical trial sites with populations high in African Americans.<sup>2</sup>



Educate potential trial participants about the process and availability.<sup>2</sup>



Partner with community-based organizations to support trial participants.<sup>2</sup>

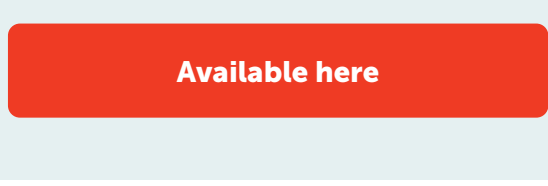


**Encouraging inclusive participation in oncology clinical trials is crucial** to understand potential differences in efficacy and safety across diverse populations and to mitigate ethnic disparities in cancer care and outcomes.<sup>3,4</sup>

Findings from this Blue Earth Diagnostics post hoc analysis provide considerations for future decision-making in encouraging higher enrollment and achieving clinical trial diversity.<sup>2</sup>

### Read the analysis

**"<sup>18</sup>F-Flotufolostat Positron Emission Tomography in African American Patients With Suspected Prostate Cancer Recurrence: Findings From the Phase 3 SPOTLIGHT Study."**



### IMPORTANT SAFETY INFORMATION (Continued)

- Risk of Image Misinterpretation in Patients with Suspected Prostate Cancer Recurrence: The interpretation of POSLUMA PET may differ depending on imaging readers, particularly in the prostate/prostate bed region. Because of the associated risk of false positive interpretation, consider multidisciplinary consultation and histopathological confirmation when clinical decision-making hinges on flotufolostat F 18 uptake only in the prostate/prostate bed region or only on uptake interpreted as borderline.
- POSLUMA use contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Advise patients to hydrate before and after administration and to void frequently after administration. Ensure safe handling to minimize radiation exposure to the patient and health care providers.
- The adverse reactions reported in ≥0.4% of patients in clinical studies were diarrhea, blood pressure increase and injection site pain.
- Drug Interactions: androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of flotufolostat F 18 in prostate cancer. The effect of these therapies on performance of POSLUMA PET has not been established.

To report suspected adverse reactions to POSLUMA, call 1-844-POSLUMA (1-844-767-5862) or contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Please see full Prescribing Information at [www.posluma.com/prescribing-information.pdf](http://www.posluma.com/prescribing-information.pdf).**

### References

1. Giaquinto AN, Miller KD, Tossas KY, et al. Cancer statistics for African American/Black people 2022. *CA Cancer J Clin.* 2022;72(3):202-229. doi:10.3322/caac.21718
2. Rais-Bahrami S, Fleming M, Gartrell B, et al. <sup>18</sup>F-flotufolostat positron emission tomography in African American patients with suspected prostate cancer recurrence: findings from the phase 3 SPOTLIGHT Study. *Adv Radiat Oncol.* 2024;9(9):101571. doi:10.1016/j.adro.2024.101571
3. Diversity action plans to improve enrollment of participants from underrepresented populations in clinical studies guidance for industry. US Department of Health and Human Services. Food and Drug Administration. June 2024. Accessed December 17, 2024. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies>
4. Oyer RA, Hurley P, Boehmer L, et al. Increasing racial and ethnic diversity in cancer clinical trials: an American Society of Clinical Oncology and Association of Community Cancer Centers joint research statement. *J Clin Oncol.* 2022;40(19):2163-2171. doi:10.1200/JCO.22.00754
5. POSLUMA. Package insert. Blue Earth Diagnostics Ltd; 2023.
6. Jani AB, Ravizzini G, Gartrell BA, et al. Diagnostic performance and safety of <sup>18</sup>F-<sup>18</sup>F-PSMA-7.3 positron emission tomography in men with suspected prostate cancer recurrence: results from a phase 3, prospective, multicenter study (SPOTLIGHT). *J Urol.* 2023;210(3):411-412. doi:10.1097/JU.0000000000003598