



SAR-bisPSMA: A sensitive story

Drug & Device Conference

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Executive Chairperson

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For investor purposes only

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General

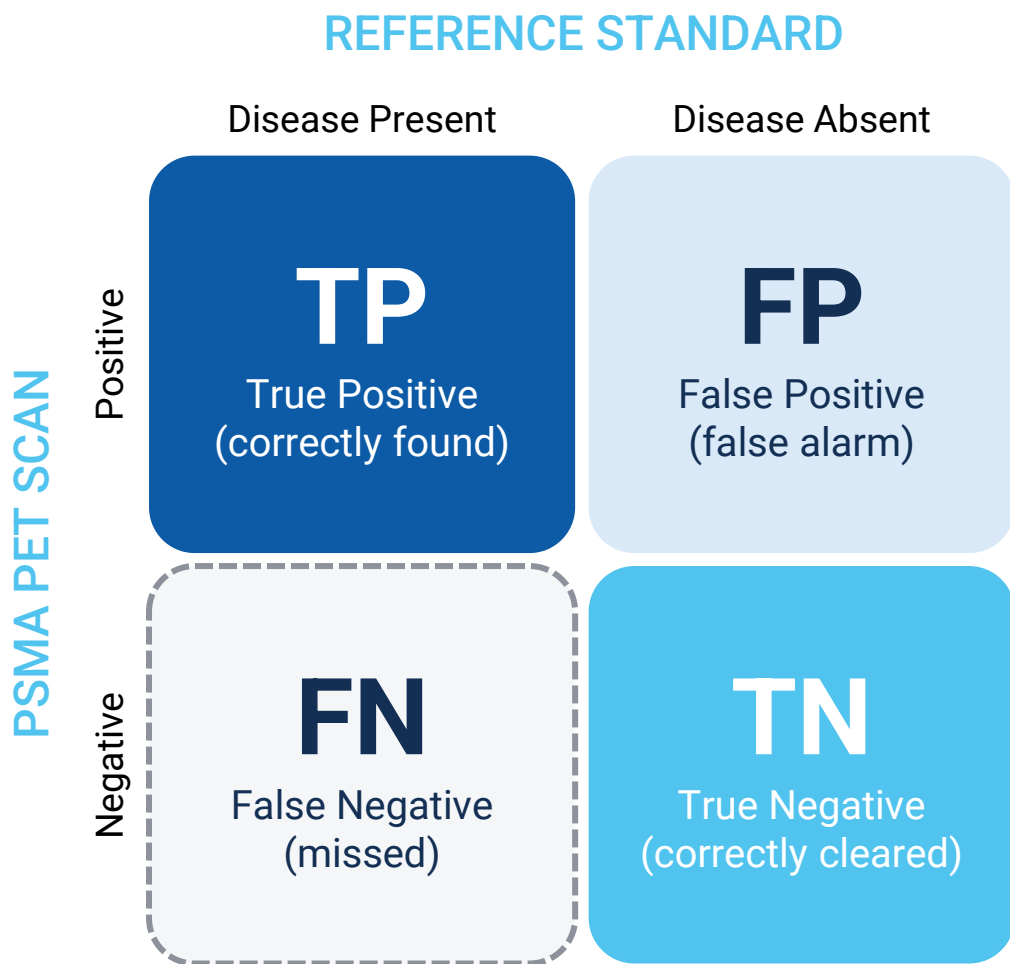
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Products

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Beyond positivity: measuring scan and product performance

Sensitivity, specificity and correct detection rate require a reference standard, detection rate does not



Sensitivity

If disease is present, is the scan positive?

Among patients with disease, the proportion with a positive scan

$$\text{TP} / (\text{TP} + \text{FN})$$

Specificity

If disease is absent, is the scan negative?

Among patients without disease, the proportion with a negative scan

$$\text{TN} / (\text{TN} + \text{FP})$$

Correct detection rate

How often is a scan a true positive across all patients?

Among all scanned patients, the proportion with a true-positive scan

$$\text{TP} / \text{all patients}$$

Detection rate

How often is the scan positive?

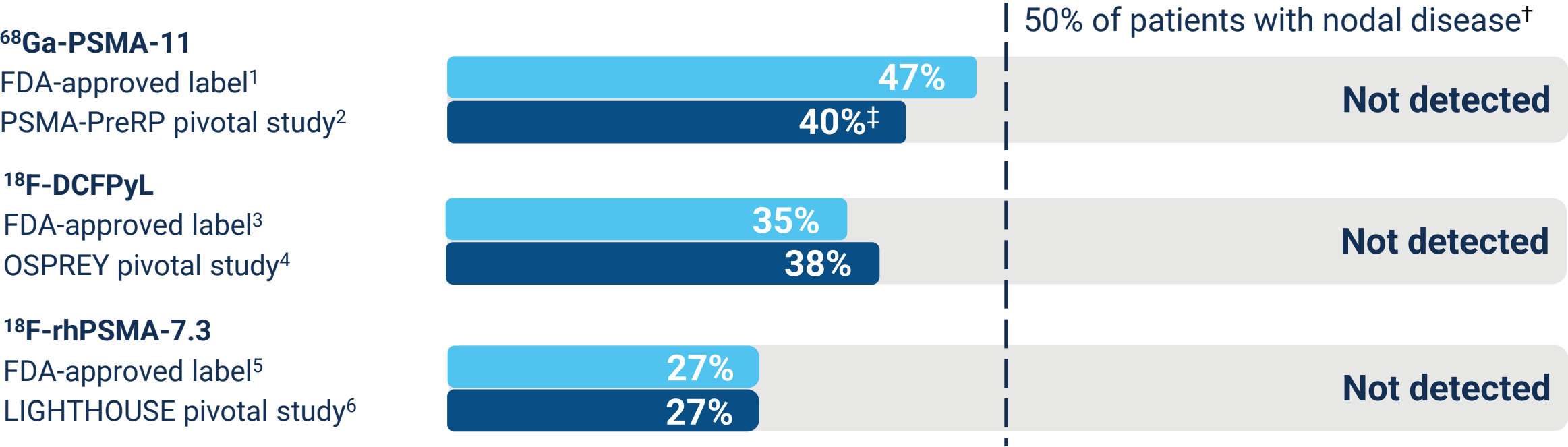
Among all scanned patients, the proportion with a positive scan

$$(\text{TP} + \text{FP}) / \text{all patients}$$

Approved PSMA PET agents did not detect pelvic nodal disease in most patients with nodal metastases, based on FDA labels/pivotal studies

No pivotal study of currently FDA-approved PSMA PET agents met their predefined sensitivity primary endpoint*

Sensitivity is determined by histopathology findings of the pelvic lymph nodes, which is essential for appropriate disease staging[#]



*Primary endpoints in the pre-prostatectomy setting based on each product's registrational trials and the corresponding FDA Center for Drug Evaluation and Research, Multi-Discipline Review. [#]Sensitivity values represent mean across the readers unless otherwise stated and as reported in the respective FDA label or published pivotal studies for each product. Not a head-to-head comparison. Cross-study comparisons are limited by differences in study design, patient populations, endpoints and methodology. [†]Reference line at 50% for illustration; not a predefined study threshold. [‡]Sensitivity value represents the majority read among the three readers.

1. Gallium Ga 68 gozetotide injection. Prescribing Information. UCLA Biomedical Cyclotron Facility; 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212642s002lbl.pdf. 2. Hope T, et al., JAMA Oncol. 2021;7;(11):1635-1642. 3. PYLARIFY TRUVU® (piflufolastat F 18) prescribing information. FDA; 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220089Orig1s000lbl.pdf. 4. Pienta KJ, et al. J Urol. 2021;206(1):52-61. 5. POSLUMA® (flotufolastat F 18) prescribing information. FDA; 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216023s000lbl.pdf. 6. Surasi DS, et al. Eur Urol 2023;84:361-370.

The sensitive topic of sensitivity

Detection rate and positivity rate are not the same as sensitivity

CLAIMED



Not All Prostate-Specific Membrane Antigen Imaging Agents Are Created Equal: Diagnostic Accuracy of Ga-68 PSMA-11 PET/CT for Initial and Recurrent Prostate Cancer

Andrei S. Purysko, MD,^{1,2}; Andre L. Abreu, MD,³; Daniel W. Lin, MD,⁴; and Sanoj Punnen, MD, MAS⁵
Applied Radiology March / April 2024

Sensitivity $\geq 80\%^1$

What was measured Includes intraprostatic lesions, not for staging. Heterogenous patients

Checked against Composite reference standards

Type of evidence Literature review

Funding & Oversight Sponsor-funded article

Journal impact factor 0.6

CONFIRMED BY HISTOPATHOLOGY

JAMA Oncology

Original Investigation

Diagnostic Accuracy of ⁶⁸Ga-PSMA-11 PET for Pelvic Nodal Metastasis Detection Prior to Radical Prostatectomy and Pelvic Lymph Node Dissection
A Multicenter Prospective Phase 3 Imaging Trial

Thomas A. Hope, MD^{1,2,3}; Matthias Eiber, MD^{4,5}; Wesley R. Armstrong⁴; et al

40%²

Pelvic lymph nodes, key to staging
Pre-prostatectomy patients only

Histopathology-verified (gold standard)

Phase III registrational trial, basis of FDA approval

Independent, academic-led study (UCLA and UCSF)

23.9

FDA PRESCRIBING INFORMATION

HIGHLIGHTS OF PRESCRIBING INFORMATION

GALLIUM GA-68 PSMA-11- gallium ga-68 gozetotide injection, solution

		Histopathology	
		Positive	Negative
PET scan	Positive	14	9
	Negative	16	84
Total		30	93
Diagnostic performance (95% CI)		Sensitivity 47% (29%, 65%)	Specificity 90% (84%, 96%)

47%³

Not applicable

Australian innovation challenging the PSMA PET standard

	⁶⁴ Cu-SAR-bisPSMA	⁶⁸ Ga-PSMA-11 ^{1-3*}	¹⁸ F-DCFPyL ^{4-6*}	¹⁸ F-rhPSMA-7.3 ^{7-9*}
Country of origin of the innovation	Australia 	Germany 	US 	Germany 
Innovator	University of Melbourne / Clarity collaboration	German Cancer Research Center (DKFZ), Heidelberg	Johns Hopkins University	Technical University of Munich (TUM)
Clinical development sponsor	Clarity	Academia	Progenics/Lantheus	Blue Earth Diagnostics
Patent	Active	No patent protection	Active	Active
Targeting moiety	Bivalent PSMA targeting	Monovalent PSMA targeting	Monovalent PSMA targeting	Monovalent PSMA targeting
Isotope half-life	⁶⁴ Cu (12.7 h)	⁶⁸ Ga (1.1 h)	¹⁸ F (1.8 h)	¹⁸ F (1.8 h)
Product shelf-life	Up to 48 h	6 h	10 h	10 h
Imaging window (post-administration)	1 to 30 hrs	50 to 100 min 	1 h 	1 h
Sensitivity		40% (prespecified endpoint not met)	38% (prespecified endpoint not met)	27% (prespecified endpoint not met)
Patient-level detection rate (biochemical recurrence)		Overall: 75% PSA <0.5 ng/mL: 38%	Overall: 59 – 66% PSA <0.5 ng/mL: 25 – 48%	Overall: 83% PSA <0.5 ng/mL: 64%

 Delayed imaging with ⁶⁸Ga-PSMA-11 beyond 100 minutes not approved by FDA²  Starting image acquisition more than 90 minutes after injection may adversely impact imaging performance⁵

Note: Not a head-to-head comparison. Cross-study comparisons are limited by differences in study design, patient populations, endpoints and methodology.

*Primary endpoints in the pre-prostatectomy and biochemical recurrence settings based on each product's registrational trials and the corresponding FDA Center for Drug Evaluation and Research, Multi-Discipline Review.

1. Hope T, et al. JAMA Oncol. 2021;7;(11):1635-1642. 2. Gallium Ga 68 gozetotide injection. Prescribing Information. UCLA Biomedical Cyclotron Facility; 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/212642s002lbl.pdf. 3. Fendler WP, Calais J, Eiber M, et al. JAMA Oncol. 2019;5(6):856-863. 4. Pienta KJ, et al. J Urol. 2021;206(1):52-61. 5. PYLARIFY TRUVU® (piflutofolastat F 18) prescribing information. FDA; 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/220089Orig1s000lbl.pdf. 6. Morris MJ, et al. Clin Cancer Res. 2021;27(13):3674-3682. 7. Surasi DS, et al. Eur Urol. 2023;84:361-370. 8. POSLUMA® (flotufolastat F 18) prescribing information. FDA; 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/216023s000lbl.pdf. 9. Jani AB, et al. J Urol. 2023;210(2):299-311.

⁶⁴Cu-SAR-bisPSMA data on file.

SAR-bisPSMA

- Proprietary SAR Technology
- Optimised targeting
- Same product for imaging & therapy
- Improved patient management
- First differentiated PSMA diagnostic
- Broad impact in patient care
- Manufacturing & supply advantages

Two Proprietary Positions

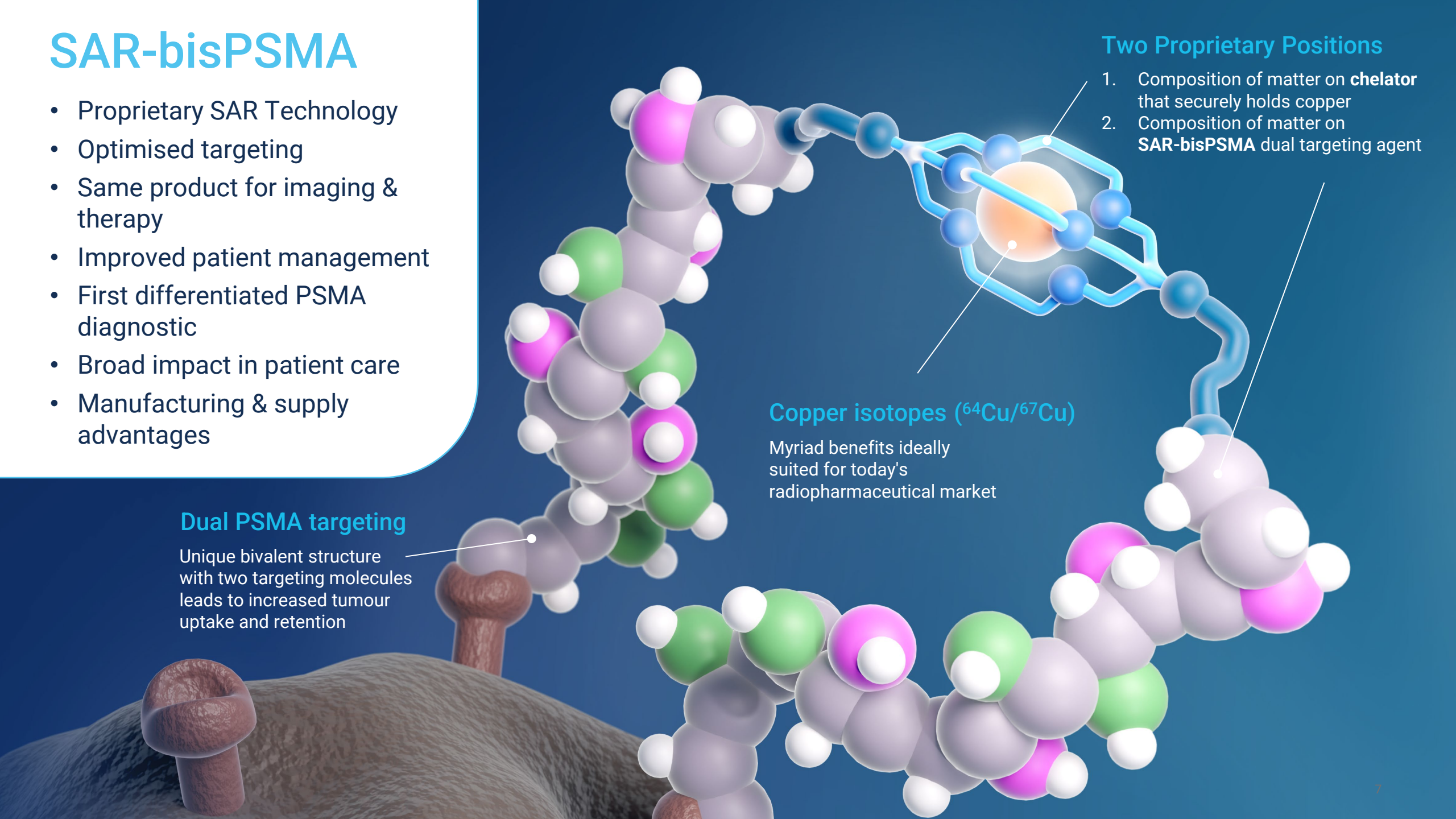
1. Composition of matter on **chelator** that securely holds copper
2. Composition of matter on **SAR-bisPSMA** dual targeting agent

Copper isotopes ($^{64}\text{Cu}/^{67}\text{Cu}$)

Myriad benefits ideally suited for today's radiopharmaceutical market

Dual PSMA targeting

Unique bivalent structure with two targeting molecules leads to increased tumour uptake and retention



Monovalent

^{177}Lu -PSMA-617*

^{18}F -DCFPyL*

^{18}F -rhPSMA-7.3*

^{68}Ga -PSMA-11*

^{64}Cu -PSMA-I&T

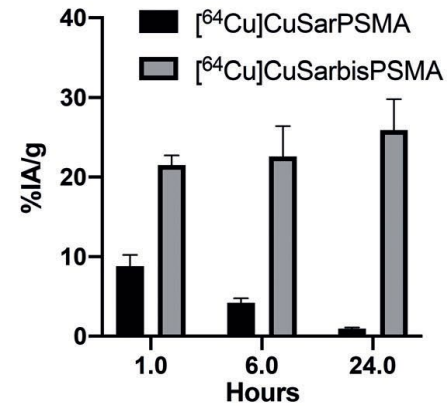
^{18}F -PSMA1007

SAR-PSMA vs. SAR-bisPSMA

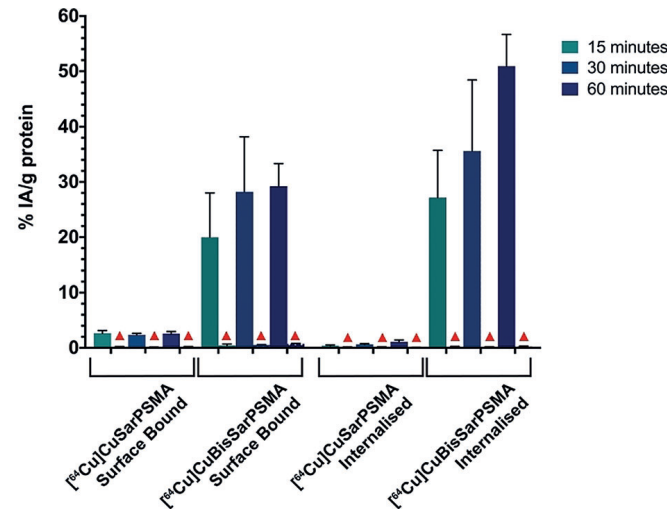
Monovalent

Bivalent

Higher uptake and prolonged retention



Considerably improved binding and internalisation



Bivalent

$^{64/67}\text{Cu}$ -SAR-bisPSMA

* FDA-approved products

SAR-bisPSMA: a body of evidence built for success



Patients

750+

across trials and
compassionate use
access



Scans performed

1,500+

⁶⁴Cu-SAR-bisPSMA same-
day and/or next-day
imaging



Trials

6

Phase I to
registrational Phase III
and investigator-
initiated trials



Countries

2

Australia and USA

SAR-bisPSMA clinical development program

Ongoing trials

CLARIFY - Phase III in pre-prostatectomy

- Registrational Phase III imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu -SAR-bisPSMA
- Recruitment ongoing

 CLARIFY

AMPLIFY – Phase III in BCR

- Registrational Phase III imaging trial with ^{64}Cu -SAR-bisPSMA in prostate cancer patients with biochemical recurrence (BCR)
- Recruitment completed, study ongoing

 AMPLIFY

SECURE - Phase I/IIa in mCRPC

- Theranostic trial for treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) with ^{67}Cu -SAR-bisPSMA
- Dose Escalation (Phase I) successfully completed recruitment
- Cohort Expansion (Phase II) main group at 8 GBq dose level achieved recruitment target
- Enzalutamide combination group recruitment ongoing

 SECURE

Completed trials

PROPELLER – Phase I in pre-prostatectomy

- First-in-human PET imaging trial of participants with confirmed prostate cancer using ^{64}Cu -SAR-bisPSMA in Australia
- Study completed, results released

 PROPELLER

COBRA – Phase I/II in BCR

- Phase I/II PET imaging trial of participants with BCR of prostate cancer following definitive therapy using ^{64}Cu -SAR-bisPSMA in the US
- Study completed, results released

 COBRA

Co-PSMA - Phase II Investigator-Initiated Trial in BCR

- Led by Prof Louise Emmett at St Vincent's Hospital Sydney
- Phase II head-to-head comparison of ^{64}Cu -SAR-bisPSMA vs. ^{68}Ga -PSMA-11 product for the detection of prostate cancer recurrence
- Study completed, results released

^{64}Cu -SAR-bisPSMA PET vs. SOC* PSMA PET

Performance of ^{64}Cu -SAR-bisPSMA PET vs. SOC PSMA PET assessed in all trials

PROPELLER ¹	CLARIFY ¹	COBRA ¹	Co-PSMA ²	AMPLIFY ¹
SOC PSMA PET	SOC PSMA PET	SOC PSMA PET	SOC PSMA PET	SOC PSMA PET
Median 20.5 days (2-50) between both scans	Within 60 days of Day 1	Within 60 days of Day 0, up to 180 days follow-up	Median 2 days (IQR 1-8) between SOC and ^{64}Cu PET ³	Within 60 days of Day 1, up to 180 days follow-up
^{64}Cu -SAR-bisPSMA PET	^{64}Cu -SAR-bisPSMA PET	^{64}Cu -SAR-bisPSMA PET	^{64}Cu -SAR-bisPSMA PET	^{64}Cu -SAR-bisPSMA PET
Exploratory endpoints • Number of lesions detected • Tracer uptake • Tumour-to-background ratio	Exploratory endpoints • Lesion detection	Post-hoc analysis • Lesion detection	Primary endpoint • Mean number of lesions detected per patient	Exploratory endpoint • Lesion detection
Intra-patient head-to-head comparison for confidence in decision making				

* Standard-of-care (SOC) PSMA PET includes ^{68}Ga -PSMA-11 and ^{18}F -DCFPyL; IQR: interquartile range. 1. Data on file. 2. Khan et al. Eur Urol. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001. 3. Interval between ^{68}Ga -PSMA-11 PET and ^{64}Cu -SAR-bisPSMA same-day PET.

PROPELLER Phase I trial: completed

PROPELLER

First-in-human, dose-ranging study evaluating safety and preliminary efficacy of ^{64}Cu -SAR-bisPSMA in participants with untreated, histopathology-confirmed prostate cancer

Key eligibility criteria (n=30)

- Participants with untreated, histologically confirmed adenocarcinoma of the prostate electing to undergo RP with PLND
- Intermediate- to high-risk PC characterised by:
 - Clinical Stage $\geq$ T2b or ISUP Grade Group $\geq$ 3 or prostate-specific antigen (PSA) $\geq$ 10 ng/mL

Screening Period

^{68}Ga -PSMA-11
PET/CT imaging
performed

^{64}Cu -SAR-bisPSMA
sequential administration
(100, 150 and 200 MBq:
1:1:3 ratio)

Same-day imaging
PET/CT acquisition at
 3 ± 1 h post-injection

Safety
assessments

RP with PLND/
histopathology

Verification of
 ^{64}Cu -SAR-bisPSMA
PET/CT findings

Day -35 to -1

Day 1

Day 5 to 28

Up to Week 11

- **Primary endpoints:** *safety* – incidence and severity of adverse events (AEs) and serious AEs following administration of ^{64}Cu -SAR-bisPSMA; *efficacy* – proportion of ^{64}Cu -SAR-bisPSMA PET/CT scans assessed as True Positive or False Negative for primary prostate cancer as confirmed by histopathology
- **Exploratory endpoints** include intra-patient head-to-head comparisons of the diagnostic performance of ^{64}Cu -SAR-bisPSMA vs. ^{68}Ga -PSMA-11

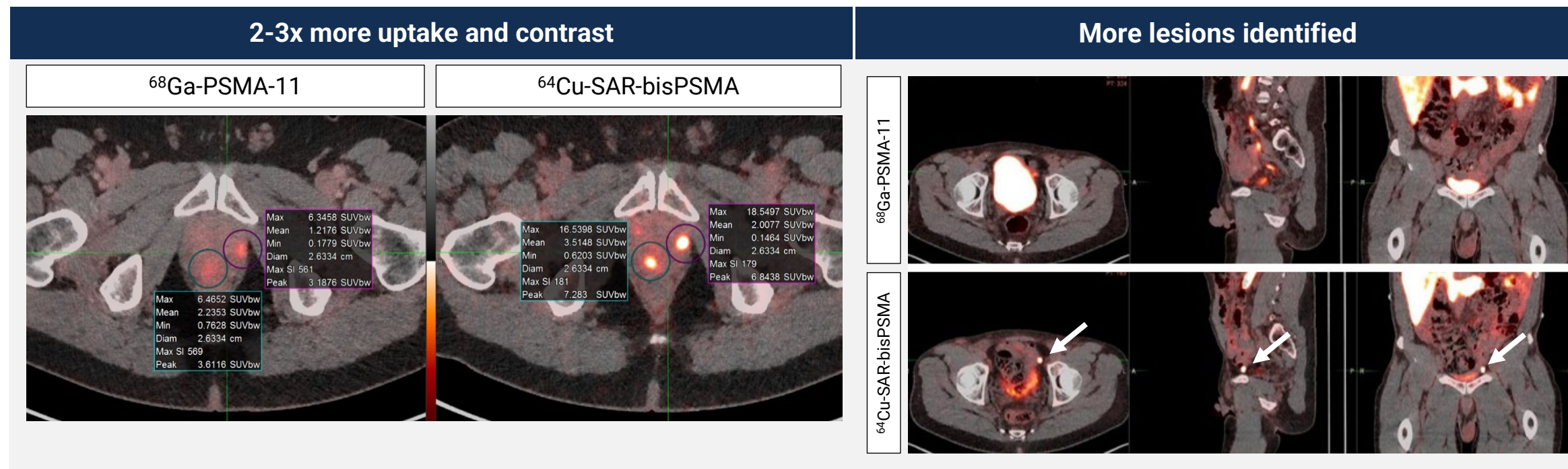
^{64}Cu -SAR-bisPSMA yielded higher tumour uptake and detected more lesions than ^{68}Ga -PSMA-11 on same-day imaging in first head-to-head trial

PROPELLER

Improved diagnostic performance of ^{64}Cu -SAR-bisPSMA compared to ^{68}Ga -PSMA-11 on same-day imaging

Higher number of lesions identified

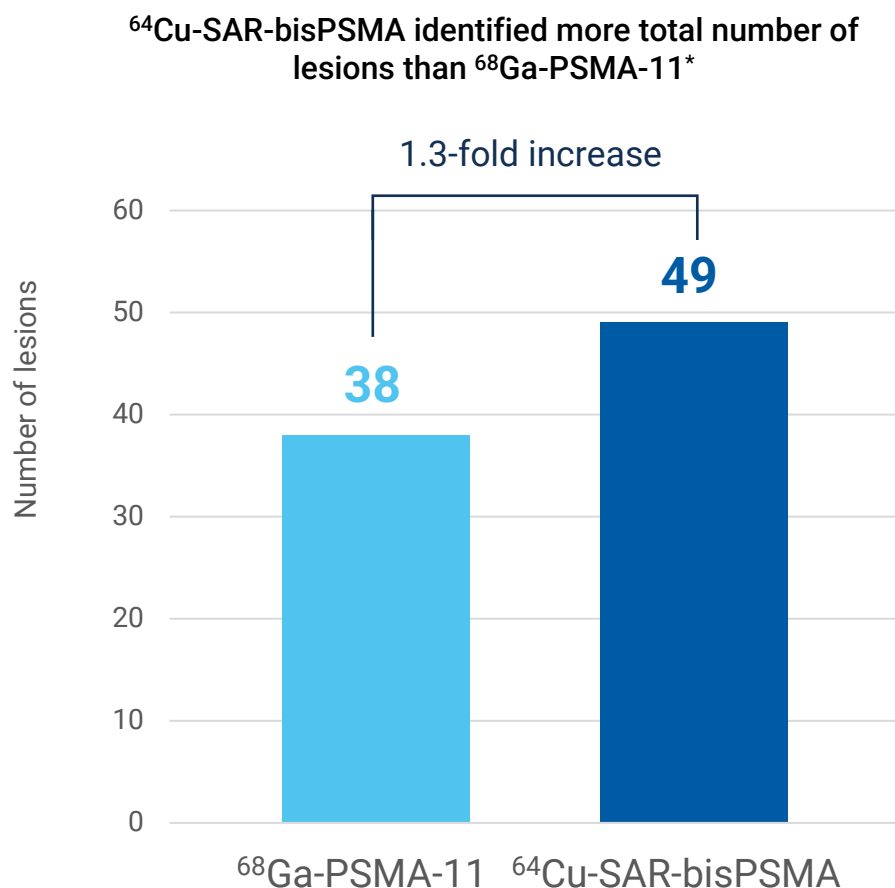
2-3 times higher uptake and tumour-to-background ratio



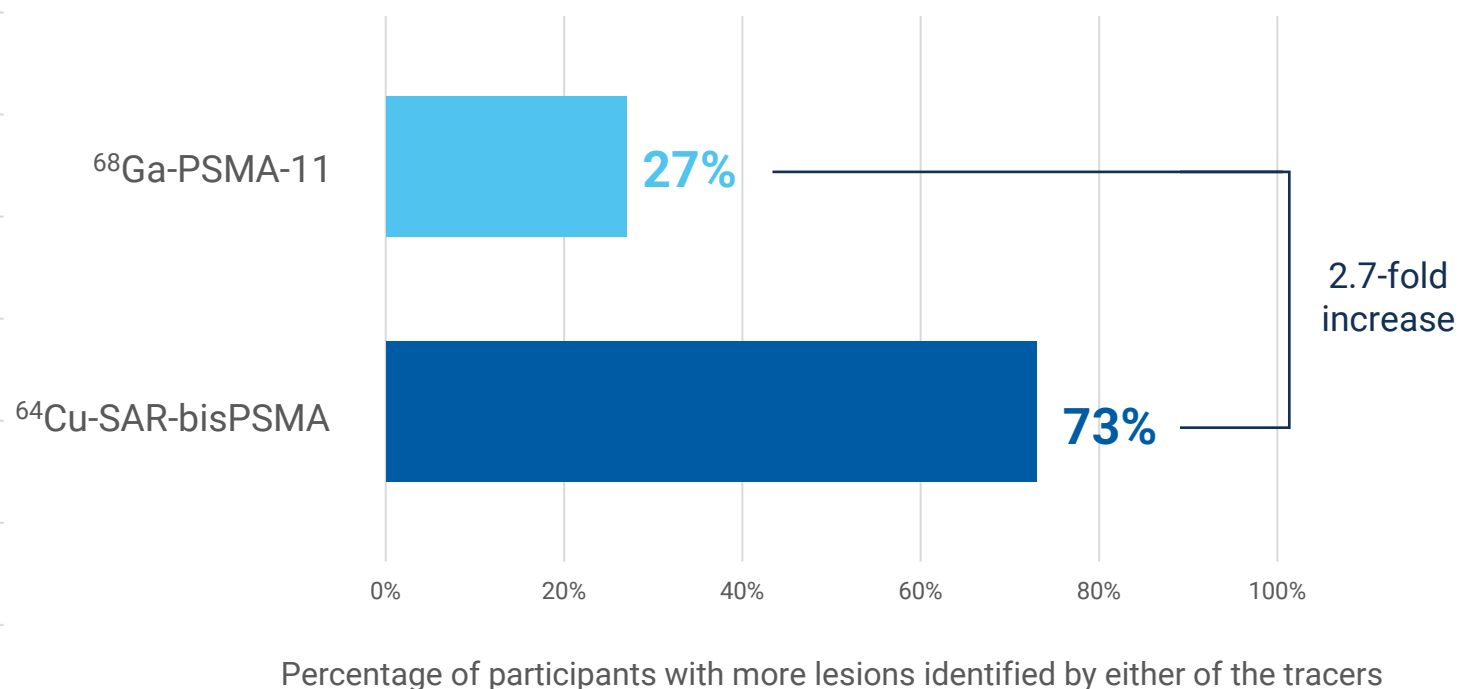
Left images: concordant lesions (same patient). Maximum standardised uptake value (SUVmax), mean standardised uptake value (SUVmean), tumour-to-background ratio (TBR): 2-3x increased values in ^{64}Cu -SAR-bisPSMA vs. ^{68}Ga -PSMA-11 PET ($p < 0.001$). Right images: pelvic lymph node identified by ^{64}Cu -SAR-bisPSMA but not by ^{68}Ga -PSMA-11 (prostate cancer confirmed by histopathology). Lengyelova & Emmett et al. PROPELLER study. ASCO, 2023. ClinicalTrials.gov identifier: NCT04839367.

^{64}Cu -SAR-bisPSMA identifies more lesions on same-day imaging vs. ^{68}Ga -PSMA-11

Prospective intra-patient comparison demonstrates that ^{64}Cu -SAR-bisPSMA same-day imaging detects more lesions than ^{68}Ga -PSMA-11 and outperforms it in most participants



Among participants with discordant lesion findings, ^{64}Cu -SAR-bisPSMA detected more lesions in more participants than ^{68}Ga -PSMA-11†



PROPELLER: First-in-human study

First study to demonstrate improved diagnostic performance of ^{64}Cu -SAR-bisPSMA PET over SOC PSMA PET in detecting primary prostate cancer prior to prostatectomy

^{64}Cu -SAR-bisPSMA PET outperformed ^{68}Ga -PSMA-11 PET in this head-to-head comparison in pre-prostatectomy patients based on:

-  **Higher lesion detection:** Greater total number of lesions and higher percentage of participants with more lesions
-  **Better image quality:** Higher tracer uptake and improved background contrast
-  **Favourable tolerability:** Well tolerated in all 30 participants with only a single related adverse event (AE) of Grade 1 dysgeusia (metallic taste) reported

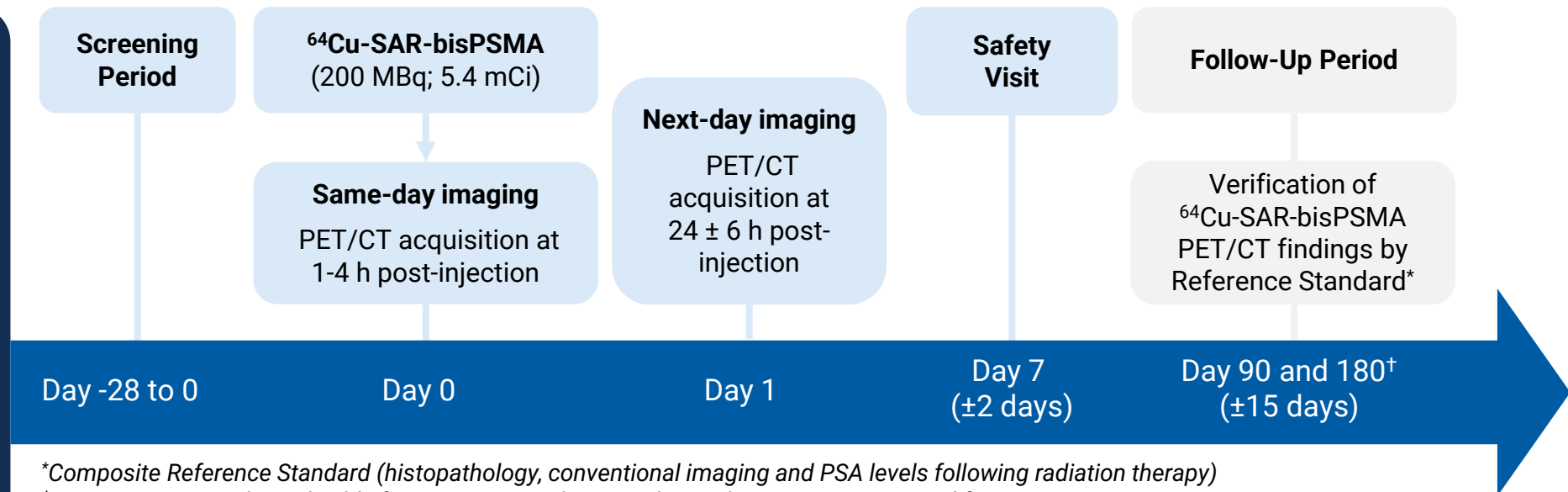
COBRA Phase I/II trial: completed



Phase I/II trial assessing the safety and efficacy of ^{64}Cu -SAR-bisPSMA in patients with BCR of prostate cancer and negative or equivocal SOC imaging

Key eligibility criteria (n=50)

- Confirmed adenocarcinoma of the prostate with subsequent definitive therapy
- Suspected recurrence of PC based on rising or detectable PSA
- Negative or equivocal findings for PC on conventional imaging per SOC within 60 days prior to Day 0



Key primary endpoints

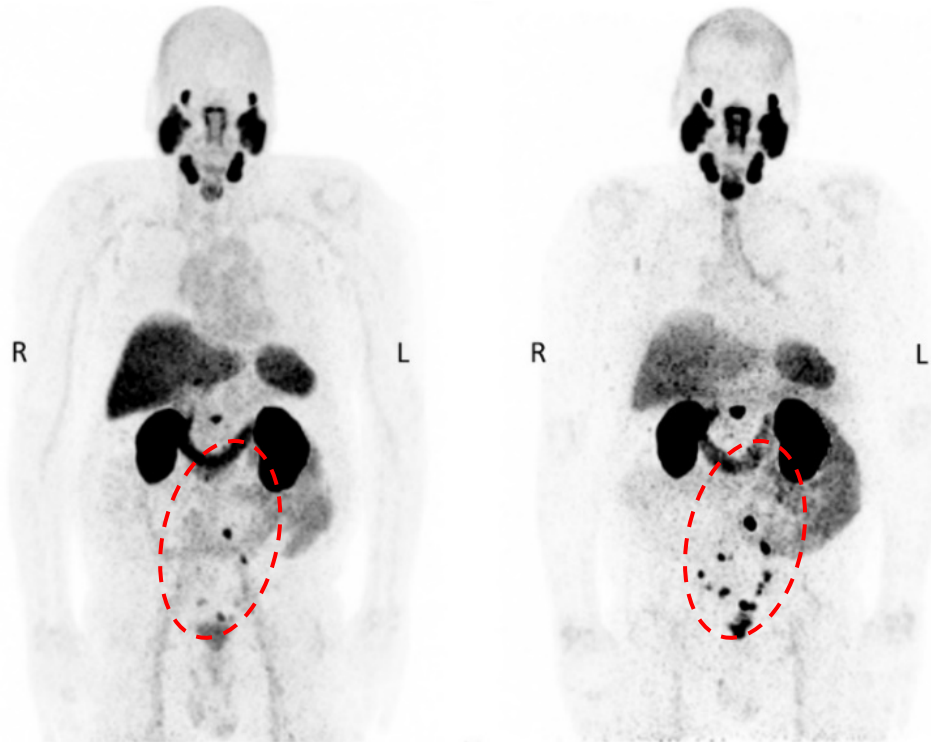
- Incidence and severity of treatment-emergent AEs and Serious AEs following the administration of ^{64}Cu -SAR-bisPSMA
- Assessed independently for same-day and next-day imaging: Correct detection rate (CDR) defined as the proportion of true-positive participants out of all scanned participants who had at least one evaluable reference standard datapoint

More lesions and patients with a positive scan identified by ^{64}Cu -SAR-bisPSMA on next-day imaging

^{64}Cu -SAR-bisPSMA

Same-day imaging

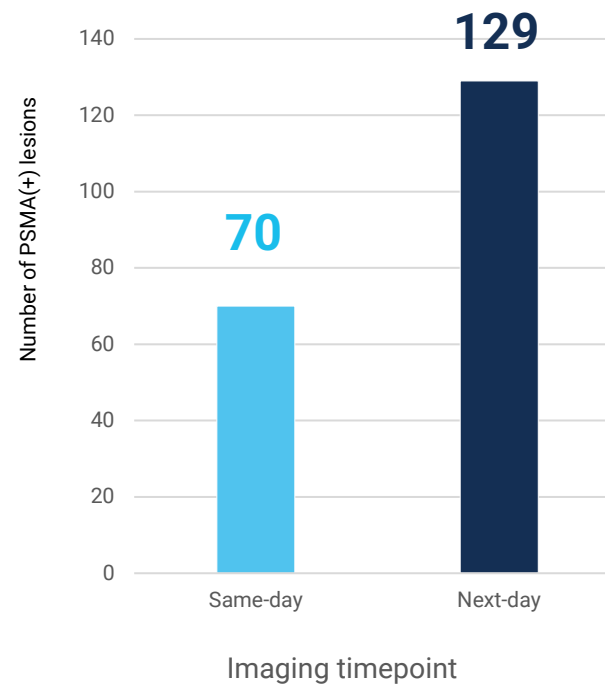
Nex-day imaging



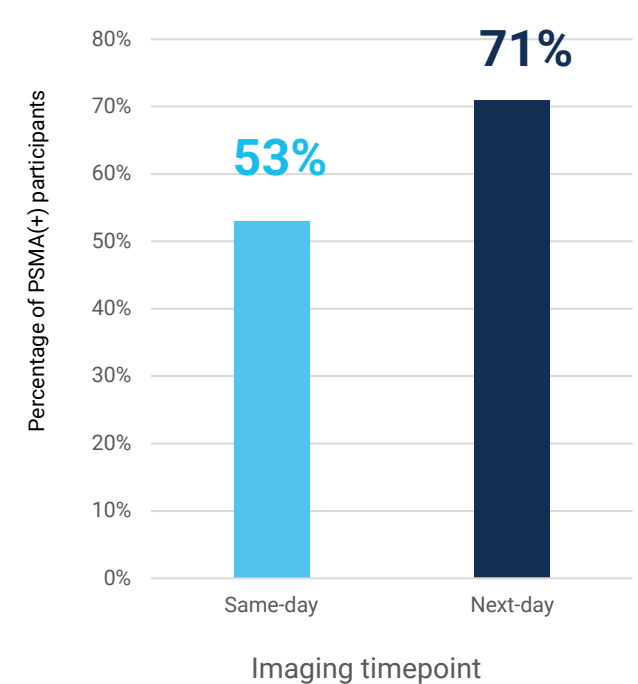
^{64}Cu -SAR-bisPSMA PET showing positive lymph nodes in the pelvic, extra-pelvic (retroperitoneal) and lesions in the prostatic bed regions

Next-day imaging identified additional lesions compared to same-day imaging

The number of lesions identified by ^{64}Cu -SAR-bisPSMA **increased by 82%***



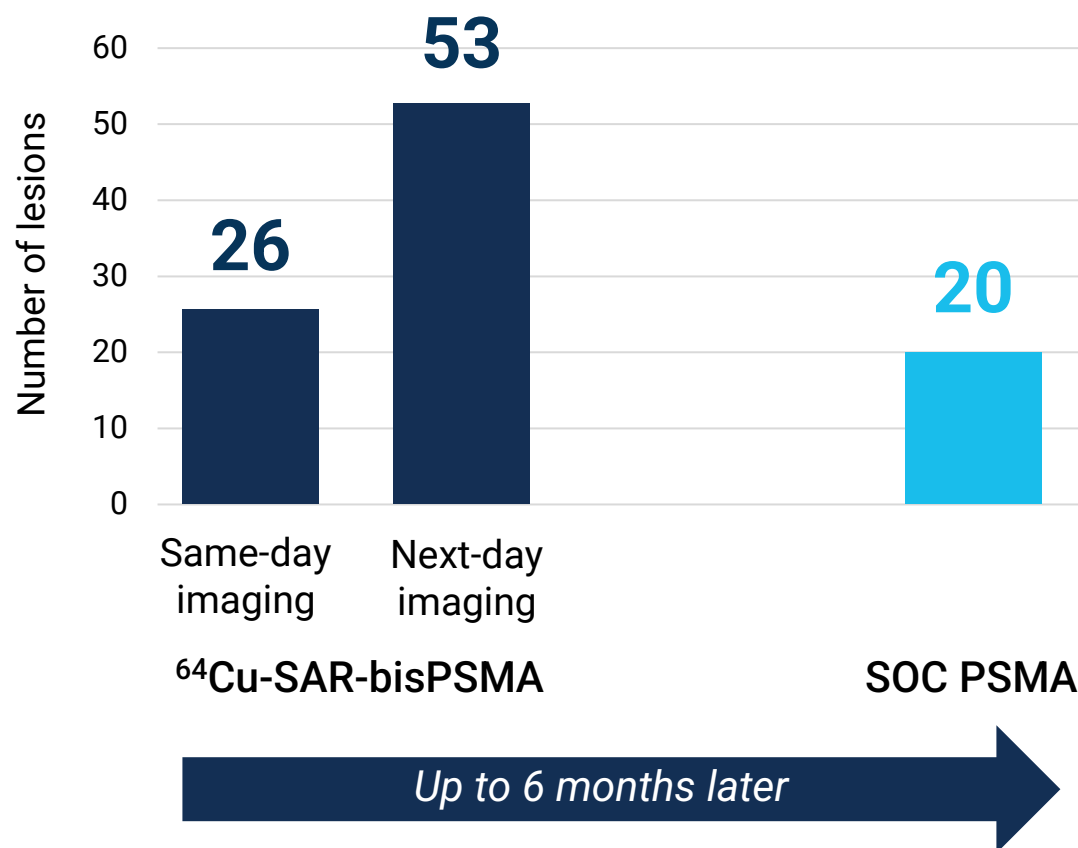
% of ^{64}Cu -SAR-bisPSMA PET-positive participants **increased by 34%†**



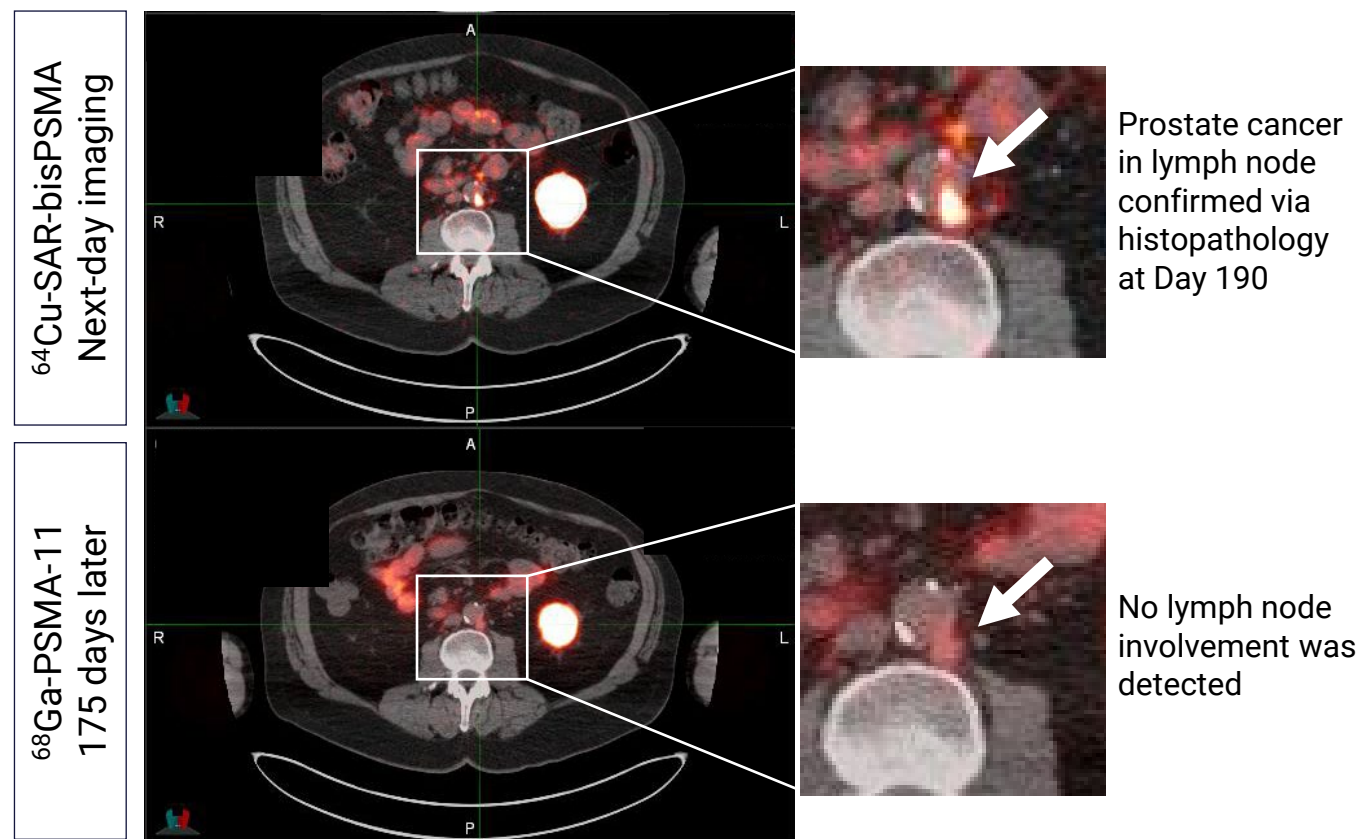
*Average increase across readers of 82% (from same to next-day imaging). Ranges across the readers for the total number of lesions detected: 53–80 on same-day vs. 82–153 on next-day imaging. Full Analysis Set: 42 patients. †Average increase across readers of 34% (from same to next-day imaging). Detection rate (DR) range across the readers on same-day imaging was 44–58% (95% confidence interval [CI] 30–71.8), increasing on next-day imaging to 58–80% (95% CI 43.2–90). AEs: One related AE reported across the trial population (grade 2 worsening of type II diabetes, resolved). Images are displayed at maximum intensity projection. Nordquist et al. COBRA. EANM, 2024. ClinicalTrials.gov identifier: NCT05249127. Data on file.

^{64}Cu -SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents

Number of lesions identified by
 ^{64}Cu -SAR-bisPSMA and SOC PSMA agents



^{64}Cu -SAR-bisPSMA detects lymph node missed by
 ^{68}Ga -PSMA-11 (SOC PET performed ~6 months later)



Graph: Average number of lesions identified by the readers on same-day, next-day imaging (^{64}Cu -SAR-bisPSMA) or SOC PSMA PET (^{68}Ga -PSMA-11 or ^{18}F -DCFPyL) in a subset of 20 participants with follow-up SOC PSMA PET: 26.3, 52.7 and 20, respectively. Median number of days between Day 0 and the follow-up SOC scan: 73.5 (range 29-180). Images: retroperitoneal lesion detected by ^{64}Cu -SAR-bisPSMA on next-day imaging (confirmed by all 3 readers). ^{68}Ga -PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show uptake of tracer. Nordquist et al. COBRA. EANM, 2024. ClinicalTrials.gov identifier: NCT05249127. Data on file.

⁶⁴Cu-SAR-bisPSMA: closing the diagnostic gap in prostate cancer recurrence

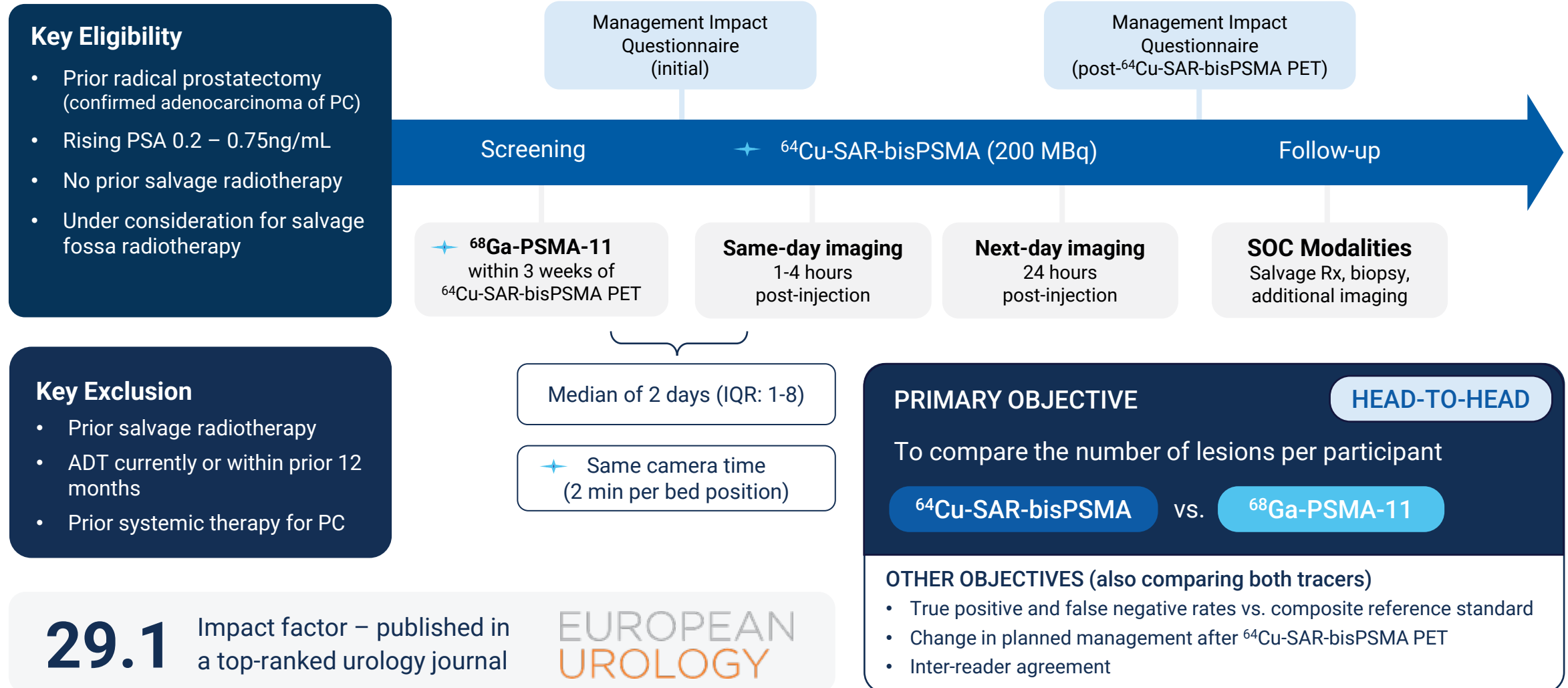


BCR patients with a negative/equivocal SOC scan at study entry

- ✔ **Next-day imaging increased lesion detection by 82%**, with the total number of identified lesions increasing from 70 to 129 (average across readers)
- ✔ **More participants were identified as PSMA-positive on next-day imaging, increasing from 53% to 71%**, representing a 34% increase versus same-day imaging (average across readers)
- ✔ **Over 80% higher tracer uptake in lesions and >5x higher contrast on next-day imaging enabled the detection of small lesions**, including lesions in the 2 mm range
- ✔ **In a subset of participants, ⁶⁴Cu-SAR-bisPSMA identified 53 lesions on next-day imaging versus 20 lesions detected by SOC PSMA PET performed up to 6 months later**, demonstrating the ability to detect recurrent disease earlier

Co-PSMA Phase II investigator-initiated trial: completed

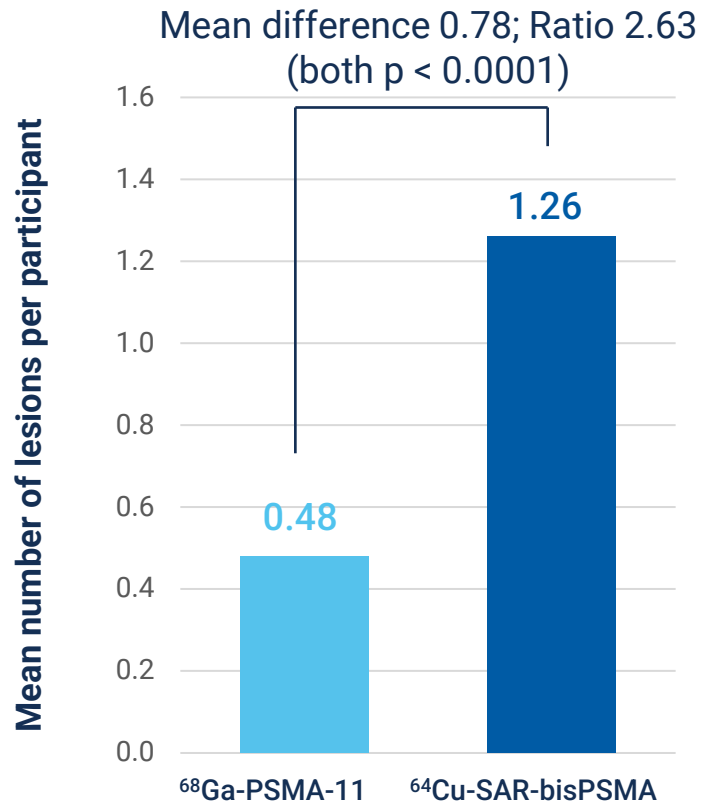
This prospective single-arm imaging trial enrolled 50 participants and evaluated the comparative performance of ^{64}Cu -SAR-bisPSMA vs. ^{68}Ga -PSMA-11



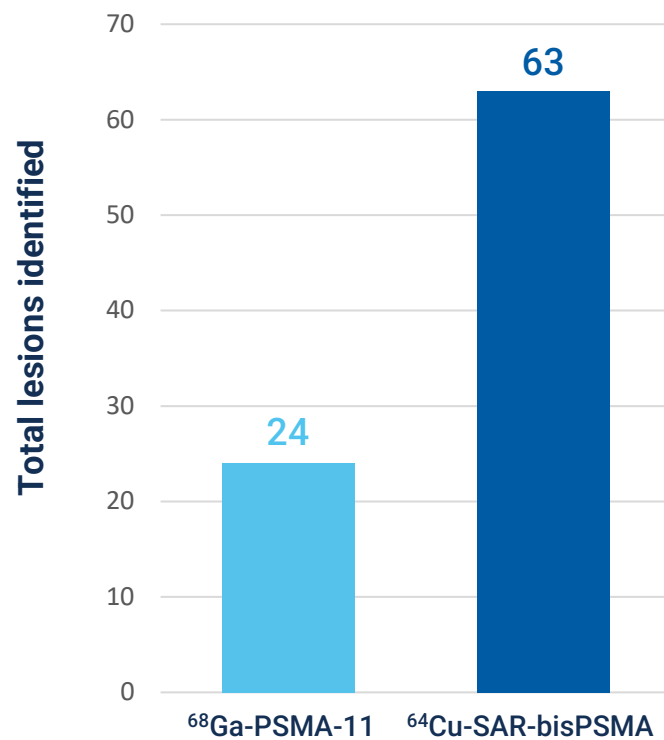
Co-PSMA: Improved diagnostic performance with next-day ^{64}Cu -SAR-bisPSMA PET vs. ^{68}Ga -PSMA-11 in early BCR*

Primary endpoint met: next-day ^{64}Cu -SAR-bisPSMA PET detected **2.6x more lesions per participant** than ^{68}Ga -PSMA-11 ($p < 0.0001$)

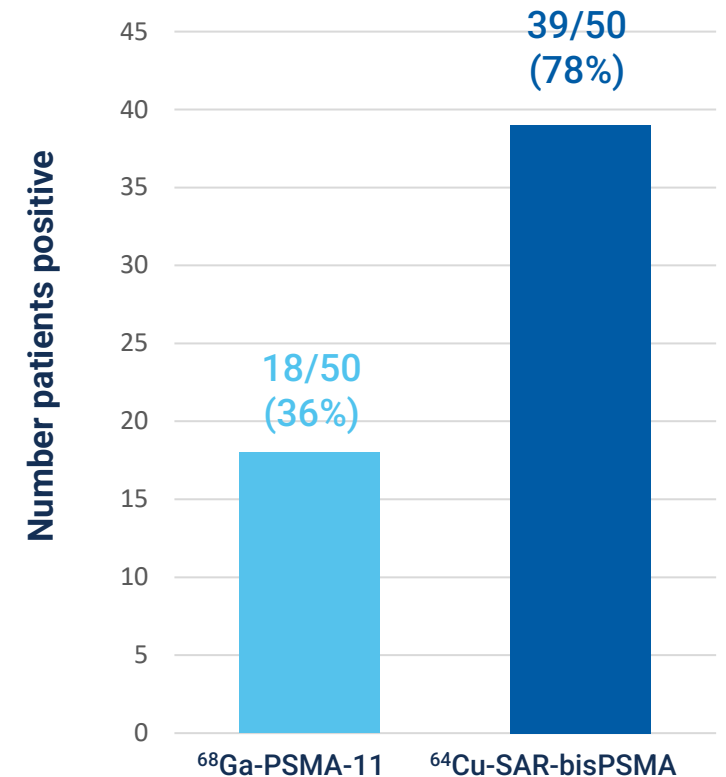
Number of lesions per participant



Total number of lesions



Participants with a positive scan



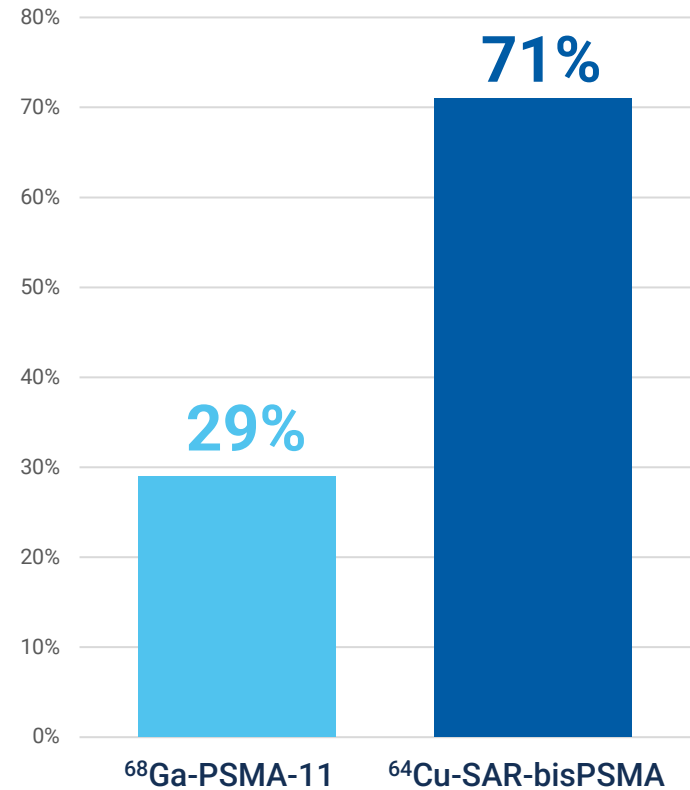
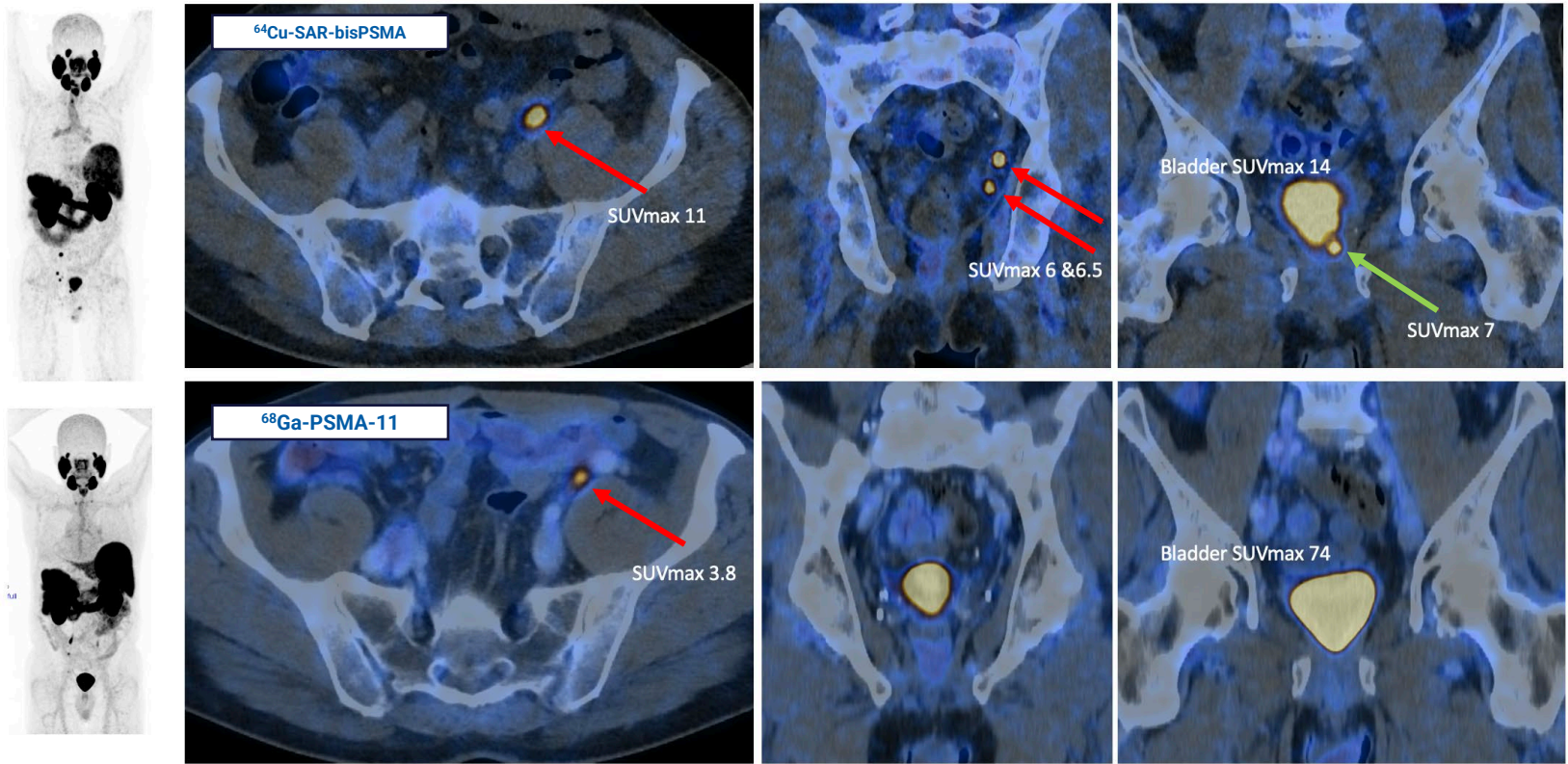
* Patients with confirmed BCR following radical prostatectomy with a PSA 0.2-0.75 ng/mL; Khan S, et al. Co-PSMA trial. Eur Urol. 2026; <https://doi.org/10.1016/j.eururo.2026.03.001>
Khan et al. Eur Urol. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001

Co-PSMA: ⁶⁴Cu-SAR-bisPSMA detected more lesions per patient and a higher true positive rate than ⁶⁸Ga-PSMA-11

Near-perfect inter-reader agreement: very high level of reliability in scan interpretation between different nuclear medicine specialists
Kappa score of 0.94 (95% CI: 0.83-1.00) for ⁶⁴Cu-SAR-bisPSMA vs. 0.75 (95% CI: 0.56-0.94) for ⁶⁸Ga-PSMA-11

Next-day ⁶⁴Cu-SAR-bisPSMA PET scan identified 4 lesions vs. 1 lesion with ⁶⁸Ga-PSMA-11

True positive rate*

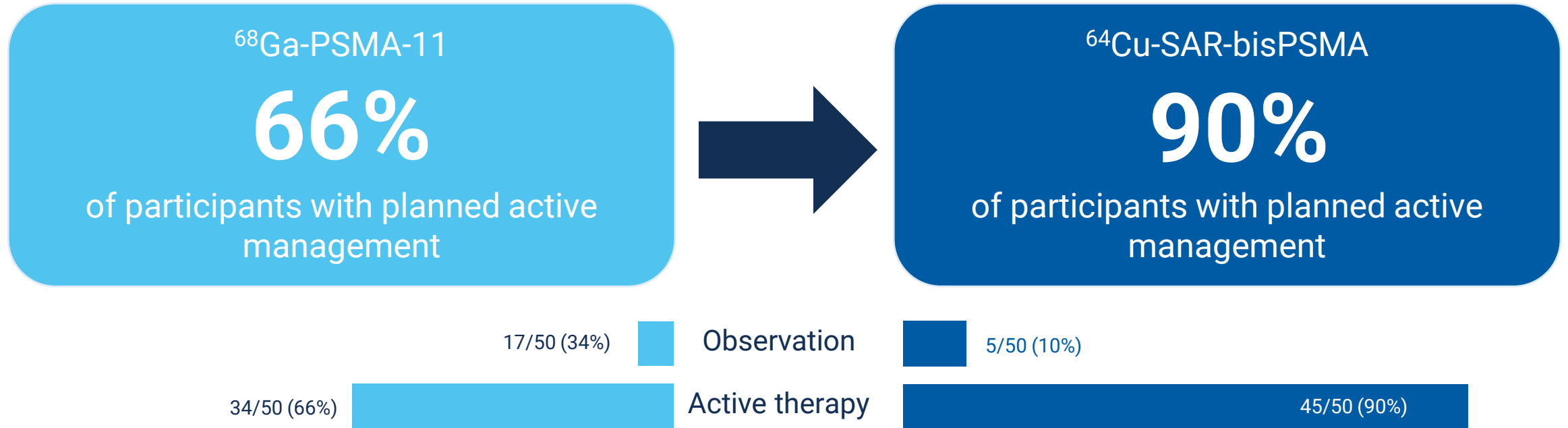


Adapted from Khan et al., European Urology 2026

→ Nodal lesion → Local recurrent lesion

* True positive rate was derived from a composite reference standard as defined in Khan et al., European Urology. 2026;89:512-520. doi: 10.1016/j.eururo.2026.03.001

Co-PSMA: Next-day ^{64}Cu -SAR-bisPSMA PET drove treatment change in more participants with early BCR* in comparison to ^{68}Ga -PSMA-11



44%

of patients (22/50) underwent a treatment change based on the ^{64}Cu -SAR-bisPSMA scans

55% (12/22) changed from observation to targeted radiation therapy

40% (9/22) changed radiation fields

14% (3/22) added SBRT

18% (4/22) added ADT

Co-PSMA builds on head-to-head evidence, helping bridge the diagnostic gap

Next-day ^{64}Cu -SAR-bisPSMA PET outperforms ^{68}Ga -PSMA-11

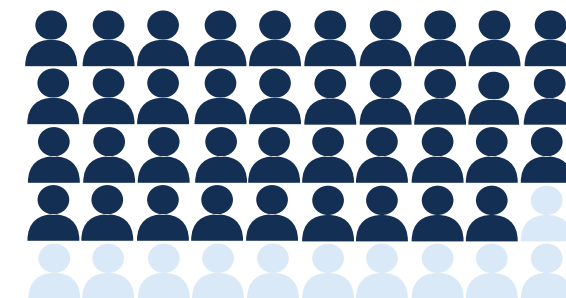
- Higher number of patients with a positive scan (78% vs. 36%)
- Higher true positive rate (71% vs. 29%)
- Higher number of lesions (2.6x more lesions per participant)
- Higher number of anatomical regions with tracer uptake
- Higher rate of change in treatment plan (90% vs 66%)
- Same scanning times (approximately 2 min/bed position)
 - *Median time between ^{68}Ga and ^{64}Cu scans: 2 days (IQR 1-8)*

“(...) whenever we can detect more lesions in the lower PSA ranges, we can eventually, as the Co-PSMA study shows, change the way we manage prostate cancer, (...)”

Dr Alberto Briganti, Editor-in-Chief, European Urology journal,
European Urology Podcast*

Participant-level detection of prostate cancer by tracer

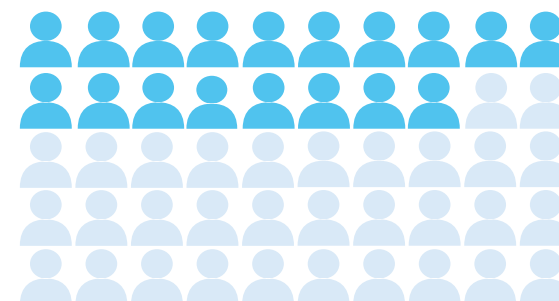
^{64}Cu -SAR-bisPSMA



^{64}Cu -pos. (78%)

^{64}Cu -neg. (22%)

^{68}Ga -PSMA-11



^{68}Ga -pos. (36%)

^{68}Ga -neg. (64%)

CLARIFY and AMPLIFY: registrational Phase III trials designed to measure diagnostic performance against defined reference standards

 CLARIFY

Topline data 1HCY2027

Pre-prostatectomy, high-risk prostate cancer (n=383)

REFERENCE STANDARD

Histopathology of surgically removed pelvic lymph nodes to verify ^{64}Cu -SAR-bisPSMA PET/CT findings

CO-PRIMARY ENDPOINTS

Sensitivity

Specificity

Same-day and next-day imaging assessed independently

 AMPLIFY

Topline data 1HCY2027

Biochemical recurrence (n=232)

REFERENCE STANDARD

Composite reference standard: histopathology, PSA levels after loco-regional therapy or follow-up conventional scans

CO-PRIMARY ENDPOINTS

Participant-level correct detection rate

Region-level positive predictive value

Same-day and next-day imaging assessed independently

Exploratory endpoints include intra-patient, head-to-head comparisons of the diagnostic performance of ^{64}Cu -SAR-bisPSMA vs. SOC PSMA PET agents

Thank you

