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# **STRENGTHENING SHARED DECISION MAKING BETWEEN nmCRPC PATIENTS AND THE HEALTHCARE TEAM**

## **GUIDE COMMUNICATION FRAMEWORK – PART 2**

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# A REMINDER OF GUIDE

**GUIDE'S five letters** each represent a crucial step in your conversations with patients with prostate cancer

**Gain insight into the goals of treatment and care** **G**

**Understand the gaps in the patient's knowledge** **U**

**Inform and educate** **I**

**Direct to additional support** **D**

**Empower the patient** **E**

Steps 1-2 and 4-5 of the GUIDE framework for **'Strengthening shared decision making between nmCRPC patients and the healthcare team'** can be found on:

[GU Nurses CONNECT](#)

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# PRINCIPLES AND USE OF THE **GUIDE** COMMUNICATION FRAMEWORK

## PRINCIPLES OF **GUIDE**

- ✓ **GUIDE** aims to support nurses in their role as a go-to figure for their patients
- ✓ The ultimate goal is to improve patient outcomes through enhanced patient engagement, understanding and outlook
- ✓ The framework may be delivered over several interactions and should be adapted to meet the patient's needs
- ✓ The role of the carer should also be considered, so they feel engaged appropriately

## HOW COULD YOU USE **GUIDE**?

- ✓ Include each step into your conversations with patients with nmCRPC
- ✓ Consider the need to incorporate the framework over a series of consultations
- ✓ Apply the principles to communication with family or carers
- ✓ Use **GUIDE** in conversations with patients with other types of cancers
- ✓ Encourage your team to complete this training and follow the steps consistently

# STEP 3

## THE GUIDE COMMUNICATION FRAMEWORK

**I** INFORM AND EDUCATE

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# THE RIGHT KNOWLEDGE

- As a nurse it is essential to have **up-to-date knowledge** on:
  1. The **disease** and common symptoms
  2. The **key studies** related to nmCRPC
  3. The **treatment aims and options**
  4. Potential **side effects and proactive management**
- Be aware of the type of information that is relevant for each individual patient, considering the patient's knowledge level and preferences

# THE RIGHT KNOWLEDGE

## DISEASE, SYMPTOMS AND DIAGNOSTICS

### Examples of resources for healthcare professionals



### Examples of resources for patients



- Its important to have a **detailed understanding of the pathophysiology, symptoms and key studies** related to nmCRPC
- There are many **high-quality information sources** available to help you gather this background knowledge, as well as to refer patients to

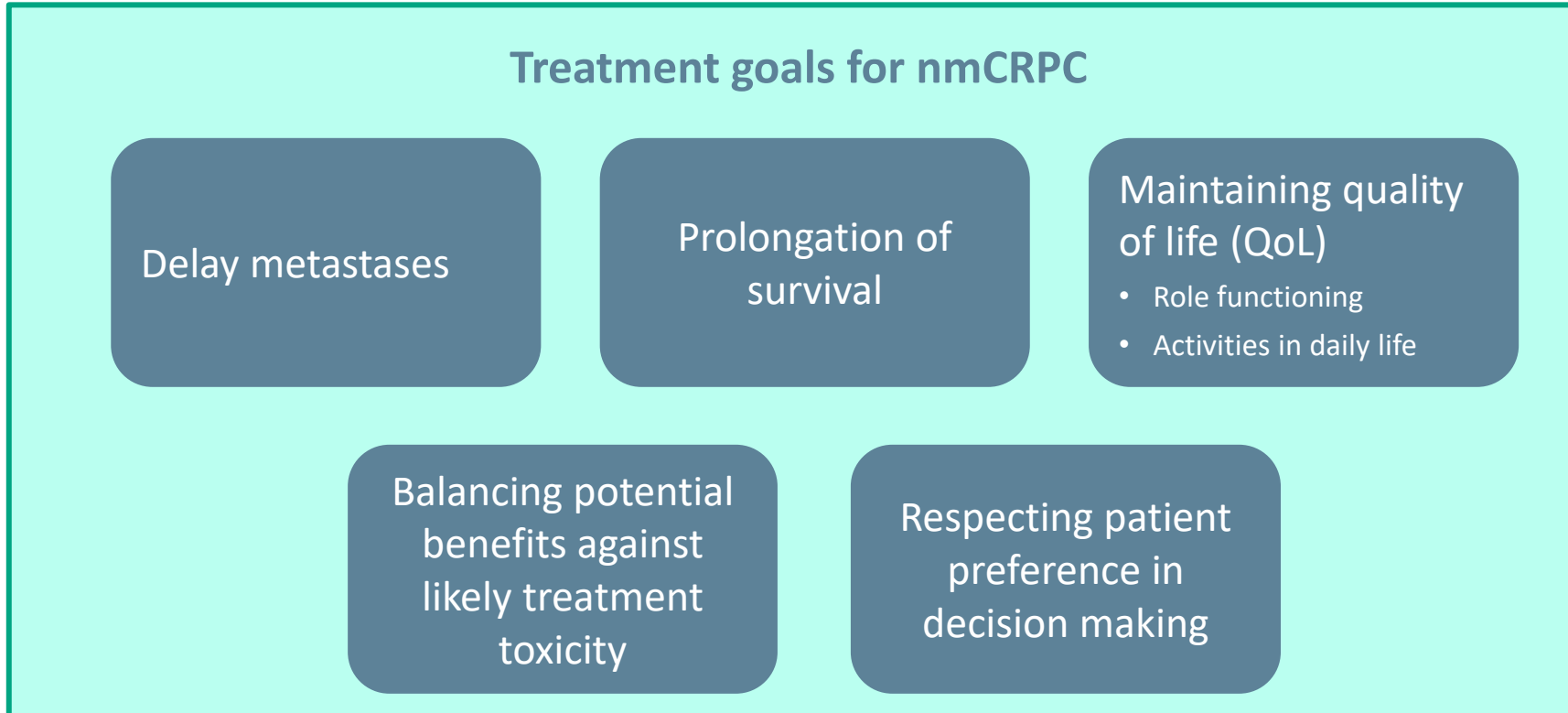


# THE RIGHT KNOWLEDGE

## THE DISEASE: WHAT IS nmCRPC

- **Patients with rising PSA with castrate levels of testosterone** ( $\leq 50$  ng/dL) despite ongoing ADT
- **No detectable metastases by conventional imaging** (bone scan and CT or MRI)
- **Generally asymptomatic** apart from symptoms from prior therapies
- nmCRPC patients with a PSADT  $< 10$  months are at significant risk for metastatic disease and prostate cancer-specific mortality
- The recent approvals of new-generation androgen-receptor pathway inhibitors address the gap in the management of nmCRPC

## TREATMENT AIMS AND OPTIONS



**Be aware that the patient's goals and preferences may change over time, as symptoms increase, side effects mount or QoL declines**

# THE RIGHT KNOWLEDGE

## WHAT DOES THE PATIENT WANT?

- Patients want to know that their treatment is intended to prolong their life. This means more time with family and friends
  - Meeting a new grandchild
  - Attending a wedding/graduation
  - Planning a vacation
- At this stage in their disease process, they should be educated that there is no cure for their disease and these treatments are meant to slow down the disease process to delay the development of metastases and prolong overall survival
- QoL means keeping their daily routine and being able to do the activities that they enjoy

## HOW DOES THE PSA LEVEL AFFECT PATIENT'S PSYCHOLOGICAL OUTCOME?

- Patients are focused on their PSA level
  - Patients want to know their PSA levels and when they start treatment, they expect to see their PSA levels decrease
- Patients may have anxiety and/or depression while waiting for their PSA results
- How can Oncology Nurses help?
  - Educate patients that PSA is just one tool used to measure progression. Other tools include:
    - Imaging
    - Patient-reported symptoms
  - Reassure patients that one PSA result is not as important as the trend, which is why several PSA levels over time are used to calculate their PSADT
  - Encourage patients to focus on their well-being and maintaining their quality of life
  - The goal for patients is to feel confident with their treatment

## EAU GUIDELINES: STRONG RECOMMENDATION

Recommendation	Strength rating
Offer apalutamide, darolutamide or enzalutamide to patients with M0 CRPC and a high risk of developing metastasis (PSADT <10 months) to prolong time metastases and overall survival.	Strong

# Level 1 Evidence of Benefit: Intensified Systemic Therapy

## NCCN GUIDELINES: CATEGORY 1 RECOMMENDATION

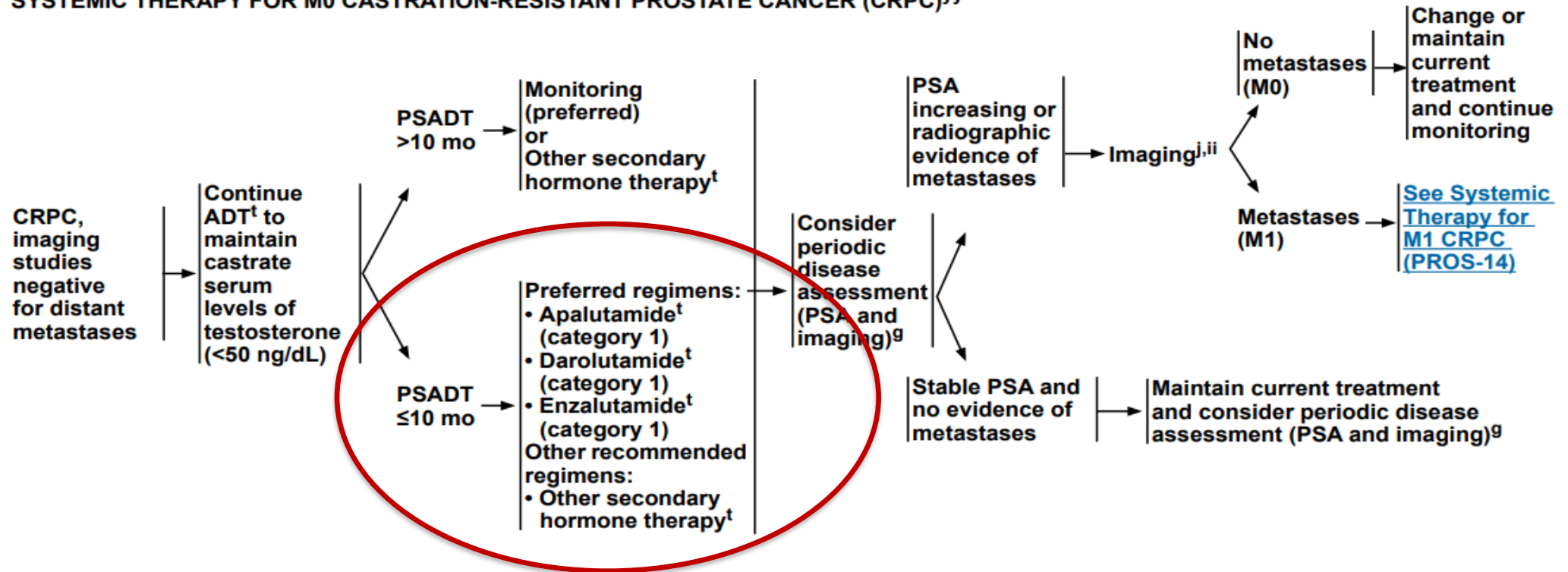


National  
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### NCCN Guidelines Version 1.2022 Prostate Cancer

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[Discussion](#)

#### SYSTEMIC THERAPY FOR M0 CASTRATION-RESISTANT PROSTATE CANCER (CRPC)<sup>yy</sup>



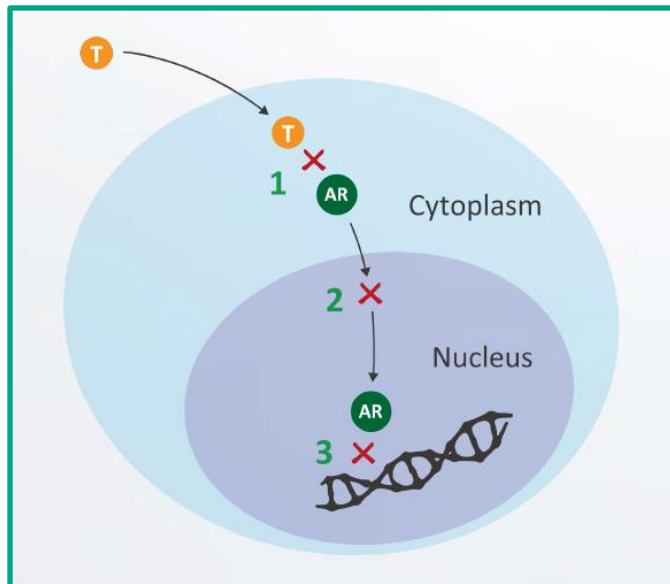
ADT, androgen deprivation therapy; CRPC, castration-resistant prostate cancer; M0, non-metastatic; NCCN, National Comprehensive Cancer Network; PSA, prostate-specific antigen; PSADT, prostate-specific antigen doubling time

NCCN Clinical Practice Guidelines in Oncology – Prostate Cancer, Version 1.2022. Accessed 14-Oct-2021

- APA, DARO, and ENZA are androgen receptor (AR)-signalling inhibitors

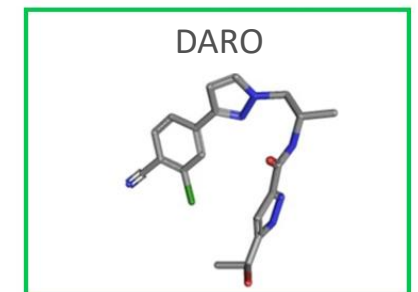
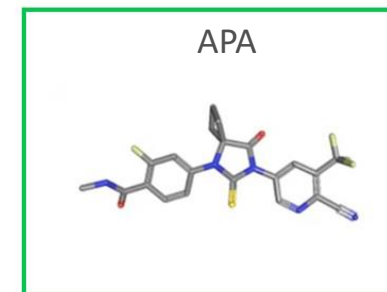
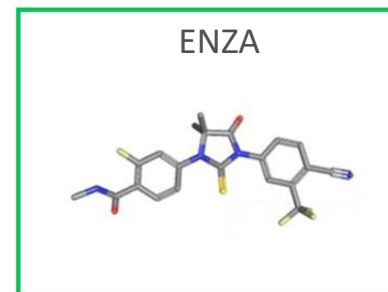
## MECHANISM OF ACTION<sup>1,2</sup>

1. Inhibit androgen binding to AR
2. Inhibit nuclear translocation of AR
3. Inhibit AR binding to DNA



## STRUCTURE

- DARO is structurally distinct from APA and ENZA, and is characterised by low blood–brain barrier penetration<sup>2,3,4</sup>
  - This could result in less central nervous system toxicity and improved tolerability



APA, apalutamide; AR, androgen receptor; DARO, darolutamide; ENZA, enzalutamide; T, testosterone

1. Tran C, et al. Science 2009;324:787-90; 2. Fizazi K, et al. Clin Genitourin Cancer. 2018;16(5):332-40; 3. Zurth C, et al. J Clin Oncol. 2018;36 suppl 6:345 (ASCO GU 2018 presentation); 4. Zurth C, et al. J Clin Oncol. 2019;37 suppl 7:156 (ASCO GU 2019 presentation); Images from PubChem database: <https://pubchem.ncbi.nlm.nih.gov/>

## nmCRPC TREATMENT OPTIONS

- The nmCRPC treatment landscape has been transformed by the approval of three next-generation oral androgen receptor inhibitors<sup>a</sup>
- **Apalutamide**
  - FDA approved for nmCRPC in 2018 based on the Phase 3 SPARTAN trial
- **Enzalutamide**
  - FDA approved for nmCRPC in 2018 based on the Phase 3 PROSPER trial
- **Darolutamide**
  - FDA approved for nmCRPC in 2019 based on the Phase 3 ARAMIS trial

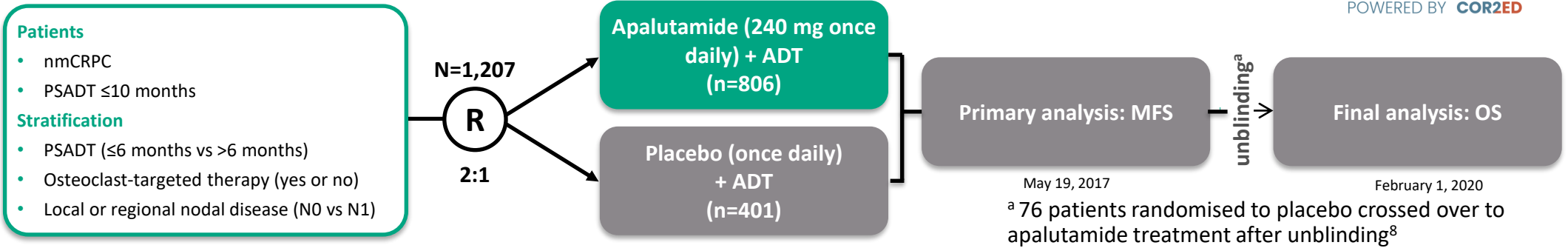
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<sup>a</sup> Androgen deprivation therapy (ADT) should be given in conjunction with next-generation androgen receptor inhibitors  
FDA, Food and Drug Administration; nmCRPC, non-metastatic castration resistant prostate cancer  
Olivier KM, et al. Int J Urol Nurs. 2021;15:47-58

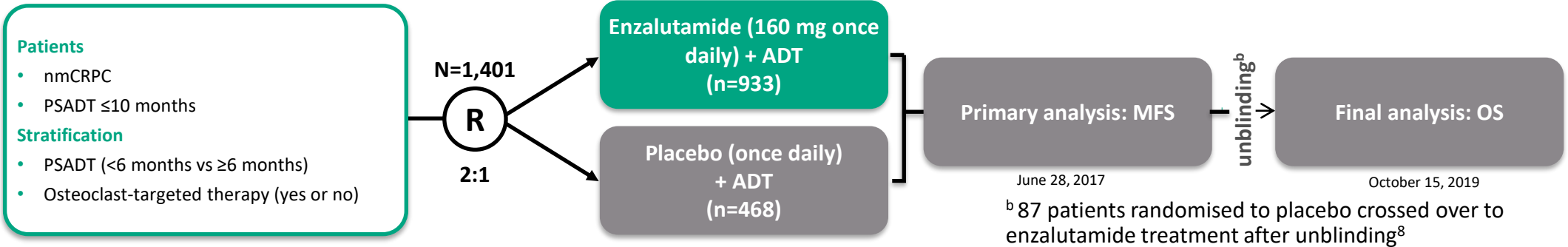


# STUDY DESIGNS: SPARTAN, PROSPER, ARAMIS

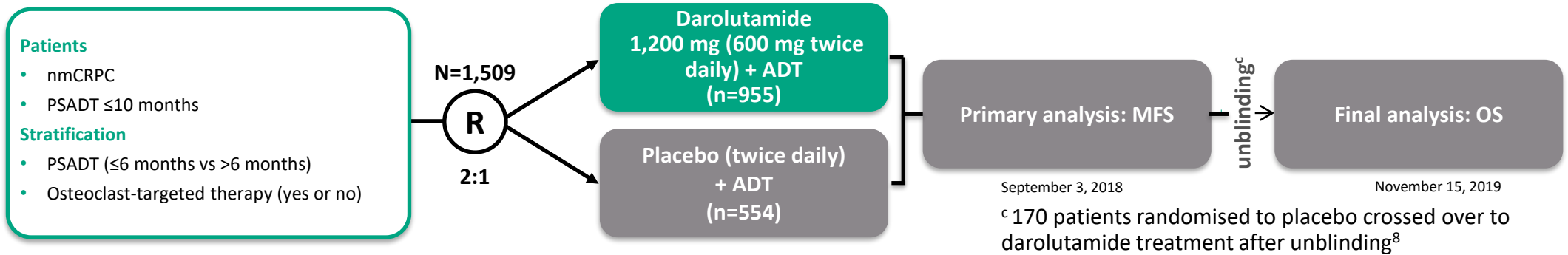
## SPARTAN: apalutamide vs placebo<sup>1,2</sup>



## PROSPER: enzalutamide vs placebo<sup>3,4</sup>



## ARAMIS: darolutamide vs placebo<sup>5-7</sup>



## EFFICACY: PRIMARY ANALYSIS (METASTASIS-FREE SURVIVAL)

	<b>SPARTAN (NCT01946204): Apalutamide (n=806) vs placebo (n=401)</b>	<b>PROSPER (NCT02003924): Enzalutamide (n=933) vs placebo (n=468)</b>	<b>ARAMIS (NCT02200614): Darolutamide (n=955) vs placebo (n=554)</b>
<b>Primary analysis</b>			
<b>Median follow-up</b>	20.3 months	Enzalutamide: 18.5 months; placebo 15.1 months	17.9 months
<b>Primary endpoint</b>	Median MFS: 40.5 vs 16.2 months; HR 0.28; 95% CI 0.23-0.35; p<0.001	Median MFS: 36.6 vs 14.7 months; HR 0.29; 95% CI 0.24-0.35; p<0.001	Median MFS: 40.4 vs 18.4 months; HR 0.41; 95% CI 0.34-0.50; p<0.001
<b>Secondary endpoints</b>	Median PFS: 40.5 vs 14.7 months; HR 0.29; 95% CI 0.24-0.36; p<0.001 Median time to symptomatic progression: NR vs NR; HR 0.45; 95% CI 0.32-0.63; p<0.001 Median OS: NR vs 39.0 months; HR 0.70; 95% CI 0.47-1.04; p=0.07 Median time to first cytotoxic chemotherapy: NR vs NR; HR 0.44; 95% CI 0.29-0.66	Median time to PSA progression: 37.2 vs 3.9 months; HR 0.07; 95% CI 0.05-0.08; p<0.001 Median time to first use of new antineoplastic therapy: 39.6 vs 17.7 months; HR 0.21; 95% CI 0.17-0.26; p<0.001 Median OS: NR vs NR; HR 0.80; 95% CI 0.58-1.09; p=0.15	Median OS: NR vs NR; HR 0.71; 95% CI 0.50-0.99; p=0.045 Median time to pain progression: 40.3 vs 25.4 months; HR 0.65; 95% CI 0.53-0.79; p<0.001 Median time to first use of cytotoxic chemotherapy: NR vs 38.2 months; HR 0.43; 95% CI 0.31-0.60; p<0.001 Median time to first SSE: NR vs NR; HR 0.43; 95% CI 0.22-0.84; p<0.01
<b>Exploratory endpoints</b>	Second PFS: NR vs 39.0 months; HR 0.49; 95% CI 0.36-0.66 Median time to PSA progression: NR vs 3.7 months; HR 0.06; 95% CI 0.05-0.08		Median PFS: 36.8 vs 14.8 months; HR 0.38; 95% CI 0.32-0.45; p<0.001 Median time to PSA progression: 33.2 vs 7.3 months; HR 0.13; 95% CI 0.11-0.16; p<0.001 Median time to first prostate cancer-related invasive procedure: NR vs NR; HR 0.39; 95% CI 0.25-0.61; p<0.001 Median time to initiation of subsequent anti-neoplastic therapy: NR vs NR; HR 0.33; 95% CI 0.23-0.47; p<0.001

**Note:** these data do not represent a head-to-head comparison of SPARTAN, PROPSER and ARAMIS

CI, confidence interval; HR, hazard ratio, MFS, metastasis-free survival; NR, not reached; OS, overall survival; PFS, progression-free survival; PSA, prostate-specific antigen; SSE, symptomatic skeletal event

Olivier KM, et al. Int J Urol Nurs. 2021;15:47-58

## EFFICACY: FINAL ANALYSIS (OVERALL SURVIVAL)

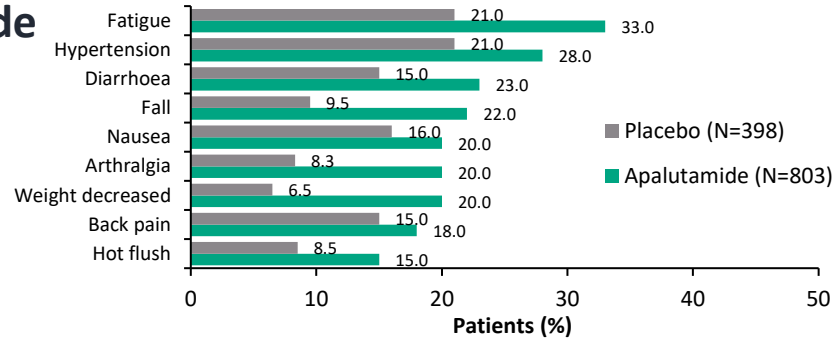
	<b>SPARTAN (NCT01946204): Apalutamide (n=806) vs placebo (n=401)</b>	<b>PROSPER (NCT02003924): Enzalutamide (n=933) vs placebo (n=468)</b>	<b>ARAMIS (NCT02200614): Darolutamide (n=955) vs placebo (n=554)</b>
<b>Final analysis</b>			
<b>Median follow-up</b>	52.0 months	48.0 months	29.1 months
<b>Secondary endpoints</b>	Median OS: 73.9 vs 59.9 months; HR 0.78; 95% CI 0.64-0.96; p=0.016 Median time to cytotoxic chemotherapy: NR vs NR; HR 0.63; 95% CI 0.49-0.81; p=0.0002 Median time to symptomatic progression: NR vs NR; HR 0.57; 95% CI 0.44-0.73; p<0.0001 <sup>a</sup>	Median OS: 67.0 vs 56.3 months; HR 0.73; 95% CI 0.61-0.89; p=0.001 Median time to use of cytotoxic chemotherapy: NR vs NR; HR 0.54; 95% CI 0.44-0.67 Median time to first use of new subsequent antineoplastic therapy: 66.7 vs 19.1 months; HR 0.29; 95% CI 0.25-0.34 Chemotherapy-free survival: 58.3 vs 41.6 months; HR 0.62; 95% CI 0.52-0.72	Median OS: NR vs NR; HR 0.69; 95% CI 0.53-0.88; p=0.003 Median time to first cytotoxic chemotherapy: NR vs NR; HR 0.58; 95% CI 0.44-0.76; p<0.001 Median time to pain progression: 40.3 vs 25.4 months; HR 0.65; 95% CI 0.53-0.79; p<0.001 Median time to first SSE: NR vs NR; HR 0.48; 95% CI 0.29-0.82; P=0.005
<b>Exploratory endpoints</b>	Median time to PSA progression: 40.5 vs 3.7 months; HR 0.07; 95% CI 0.06-0.09; p<0.0001 <sup>a</sup> Median time to second PFS2: 55.6 vs 41.2 months; HR 0.55; 95% CI 0.46-0.66; p<0.0001 <sup>a</sup>		

**Note:** these data do not represent a head-to-head comparison of SPARTAN, PROPSER and ARAMIS

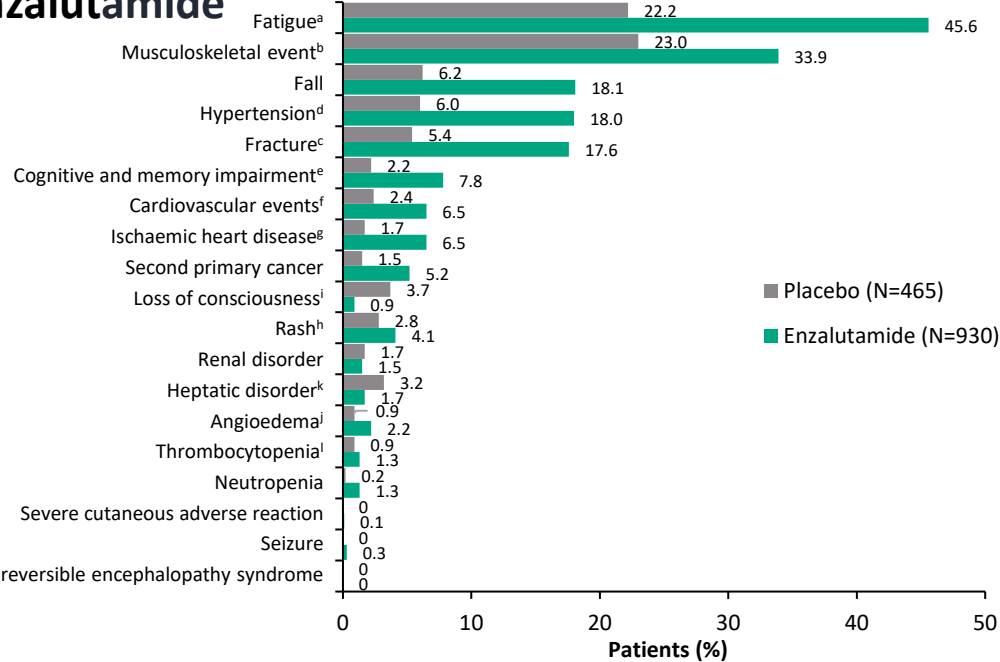
<sup>a</sup> Nominal P value

# INCIDENCE OF ADVERSE EVENTS ASSOCIATED WITH ARIs

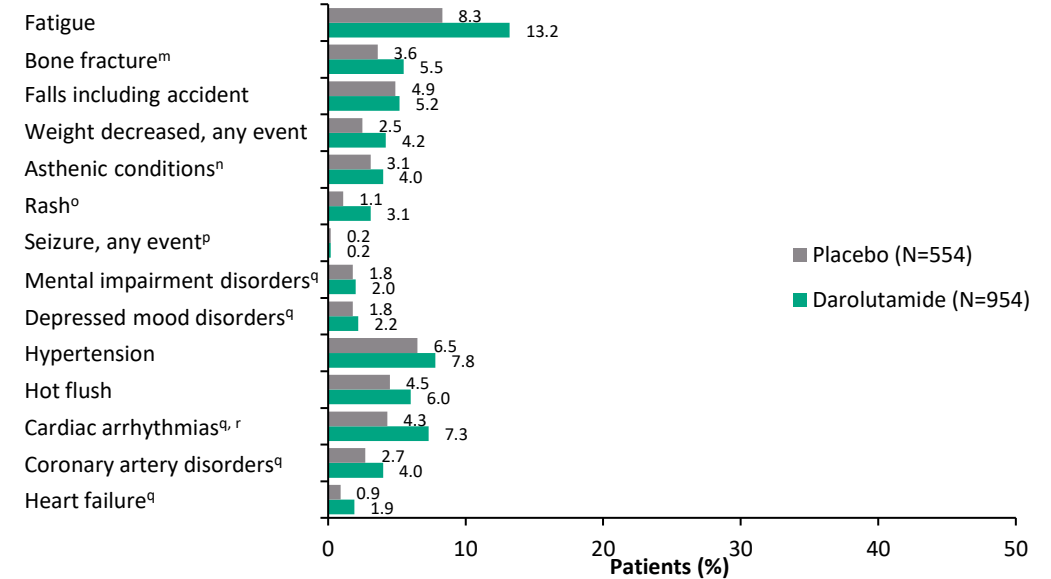
## SPARTAN:<sup>1,2</sup> apalutamide



## PROSPER:<sup>3</sup> enzalutamide



## ARAMIS:<sup>4</sup> darolutamide



### Incidence of adverse events associated with ARIs reported in the final analyses of the SPARTAN, PROSPER, and ARAMIS clinical trials.

**SPARTAN:** at final analysis, median follow-up was 52.0 months; median treatment duration in apalutamide arm was 32.9 months and in the placebo arm was 11.5 months.

**PROSPER:** at final analysis, median follow-up was 48.0 months; median treatment duration in enzalutamide arm was 33.9 months (95% CI 0.2–68.8) and in the placebo arm was 14.2 months (95% CI 0.1–51.3). <sup>a</sup>Fatigue events included asthenia. <sup>b</sup>Musculoskeletal events included back pain, arthralgia, myalgia, musculoskeletal pain, pain in extremity, musculoskeletal stiffness, muscular weakness, and muscle spasms. <sup>c</sup>Fracture events included bone and joint injuries.

<sup>d</sup>Hypertension events included hypertensive retinopathy, increased blood pressure, systolic hypertension, and hypertensive crisis. <sup>e</sup>Events of cognitive and memory impairment included disturbance in attention, cognitive disorders, amnesia, Alzheimer's disease, dementia, senile dementia, mental impairment, and vascular dementia. <sup>f</sup>Cardiovascular events included haemorrhagic central nervous system vascular conditions, ischaemic central nervous system vascular conditions, and cardiac failure. <sup>g</sup>Events of ischaemic heart disease included myocardial infarction and other ischaemic heart disease. <sup>h</sup>Rash events included maculopapular rash, generalised rash, macular rash, papular rash, and pruritic rash. <sup>i</sup>Loss-of-consciousness events included syncope and presyncope. <sup>j</sup>Angio-oedema events included urticaria, eyelid oedema, periorbital oedema, swollen tongue, swollen lip, face oedema, laryngeal oedema, and pharyngeal oedema. <sup>k</sup>Hepatic disorders included hepatic failure, fibrosis, cirrhosis, and other liver damage-related conditions, and hepatitis and liver-related investigations, signs, and symptoms. <sup>l</sup>Thrombocytopenia events included decreases in platelet count.

**ARAMIS:** at final analysis, median follow-up was 29.0 months; median exposure in darolutamide arm was 18.5 months and in the placebo arm was 11.6 months. <sup>m</sup>Combined term comprising MedDRA terms of any fractures and dislocations, limb fractures and dislocations, skull fractures, facial bone fractures and dislocations, spinal fractures and dislocations, and thoracic cage fractures and dislocations. <sup>n</sup>Combined term comprising MedDRA terms of asthenic conditions, disturbances in consciousness, decreased strength and energy, malaise, lethargy, and asthenia. <sup>o</sup>Combined term comprising MedDRA terms of rash, macular rash, maculopapular rash, papular rash, and pustular rash. <sup>p</sup>One additional incidence of seizure occurred in the darolutamide group during the open-label period, in a patient with a history of epilepsy. <sup>q</sup>MedDRA High Level Group term. <sup>r</sup>Although the incidence of cardiac arrhythmia was higher with darolutamide than with placebo, both a history of cardiac arrhythmia and electrocardiogram abnormalities were present to a greater extent in the darolutamide group at baseline, as observed at primary analysis.

ARI, androgen receptor inhibitor; CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities

1. Smith MR, et al. N Engl J Med. 2018;378:1408-18; 2. Smith MR, et al. Eur Urol. 2021;79:150-8; 3. Sternberg CN, et al. N Engl J Med. 2020;382:2197-206;

4. Fizazi K, et al. N Engl J Med. 2020;383:1040-9; Figure adapted from: Saad F, et al. Prostate Cancer Prostatic Dis. 2021;24(2):323-34

# THE RIGHT KNOWLEDGE

## MANAGING TREATMENT-EMERGENT ADVERSE EVENTS

### Fatigue:

- Nurses should encourage regular exercise and eating a healthy diet
- If severe or unmanageable then nurses should encourage prescribers to modify treatment strategy, including dose interruptions or reductions

### Bone health:

- Evaluate bone health and fracture risk prior to ADT and throughout treatment (DEXA, FRAX tool)
- Vitamin D and calcium supplementation and when applicable receive bisphosphonate or denosumab
- Nurses should encourage weight-bearing exercise and implement lifestyle changes to prevent falls

# THE RIGHT KNOWLEDGE

## MANAGING TREATMENT-EMERGENT ADVERSE EVENTS

### Cognitive impairment:

- Screen for cognitive function at baseline and periodically throughout treatment
- Nurses should elicit observations of cognitive changes from caregivers or responsible family members

### Rash:

- Nurses should educate patients of the risk of developing a rash
- If rash is detected on physical exam nurses should encourage prescribers to consider management with oral antihistamines and/or systemic corticosteroids (for grade 3-4 rash) as well as topical corticosteroids or dose interruption
- Early intervention may lessen severity and recurrence of rash and may prevent dose interruptions

# THE RIGHT KNOWLEDGE

## MANAGING TREATMENT-EMERGENT ADVERSE EVENTS

### Metabolic changes:

- Monitor fasting glucose and LFTs at baseline and throughout treatment
- Nurses should educate on regular exercise and dietary modifications

### Cardiovascular AEs:

- Monitor at baseline and throughout treatment
- Nurses should educate on heart-healthy diet
- Nurses should educate on how to recognise, control and prevent hypertension, DVT and PE

# THE RIGHT KNOWLEDGE

## MANAGING TREATMENT-EMERGENT ADVERSE EVENTS

### Hot Flashes:

- Consider venlafaxine, gabapentin, and medroxyprogesterone acetate

### Sexual Health:

- Nurses can foster open communication between patients and their partners and provide counseling on pharmacologic and nonpharmacologic options to reduce the burden of erectile dysfunction



# THE RIGHT KNOWLEDGE

## QUALITY OF LIFE

- The results of SPARTAN, PROSPER, and ARAMIS demonstrate that apalutamide, enzalutamide, and darolutamide have all been proven to delay disease progression and prolong overall survival
- In addition, in SPARTAN, PROSPER, and ARAMIS no treatment-induced deterioration in patient-reported quality of life occurred
  - Patients treated with enzalutamide or darolutamide also demonstrated delayed time to pain progression and delayed deterioration in urinary and bowel symptoms vs placebo

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AR, androgen receptor; nmCRPC, non-metastatic castration-resistant prostate cancer

Olivier KM, et al. *Int J Urol Nurs.* 2021;15:47-58; Saad F, et al. *Prostate Cancer Prostatic Dis.* 2021;24(2):323-34; Saad F, et al. *Lancet Oncol.* 2018; 19:1404–16; Tombal B, et al. *Lancet Oncol.* 2019; 20:556–69; Fizazi K, et al. *J Clin Oncol.* 2019;37 (15\_Suppl):5000; Fizazi K, et al. *N Engl J Med.* 2019;380:1235-1246; Smith M, et al. *European Journal of Cancer* 2021; 154: 138-146

# WHAT NEEDS TO BE EXPLAINED TO THE PATIENT

## TAILORING TREATMENT TO PATIENTS

- Oncology nurses can offer education to patients throughout the therapeutic course by providing reliable, factual information on what to expect from their prescribed treatment regimen
  - Dosing
  - Treatment-emergent adverse events
  - Life expectancy
- When considering the most appropriate treatment for a patient, the risks reported for different treatment should be considered

# WHAT NEEDS TO BE EXPLAINED TO THE PATIENT

## HOW TO FILL THE GAPS IN THE PATIENT'S KNOWLEDGE

- Knowing your audience is key when having treatment discussions
    - Patient's knowledge
    - Patient's support system
  - Clinical trial data can be shared with patients and the emphasis should be that the studies have shown that these drugs prolong overall survival
  - Provide patients with educational materials about their disease state and treatments for them to take home and review
-

# WHAT NEEDS TO BE EXPLAINED TO THE PATIENT

## FILL THE GAPS IN THE PATIENT'S KNOWLEDGE

For more information on the **Ask, Tell, Ask** model, please refer to:

- The paper “If We Don’t Ask, Our Patients Might Never Tell: The Impact of the Routine Use of a Patient Values Assessment” by J. Russell Hoverman et al.



# THE RIGHT WAY TO DELIVER THE MESSAGES

- Continue to use the **Ask, Tell, Ask model** to discover knowledge gaps and efficiently educate patients
  - Acknowledge the patient's **emotions**
  - Ask if they **wish and are ready to hear and understand** more information before you continue
  - **Repeat** information as often as needed
  - Listen actively
  - Continue to involve the carer
  - Use patient-friendly language
- Use **printed and/or written materials** to embed knowledge



## Practical tips:

- When printed materials are not available, consider simply **writing** a brief summary or **drawing** a quick diagram supporting your explanation for patients to take with them
- Remember to educate the patient with **reassurance and confidence**

# SUMMARY

## THE GUIDE COMMUNICATION FRAMEWORK

### WHAT

#### THE GUIDE COMMUNICATION FRAMEWORK

- Is a 5-step communication framework to improve the benefit of nurse-patient interactions
- Supports nurses in their role as a knowledgeable go-to person for patients with nmCRPC strengthening shared decision making and delivering the best possible care
- Includes a memory aid – GUIDE
- May be delivered over several interactions and should be adapted depending on patient needs

### WHY

#### IS THE COMMUNICATION FRAMEWORK NEEDED

- Nurses are to be regarded as a go-to person for their patients with nmCRPC and therefore must
  - empower patients through guidance and support throughout the treatment journey
  - be an active member of the MDT in delivering shared decision makingso they can provide patients with the greatest chance of success

GUIDE, a communication framework that will help you have even better conversations with your patients, to educate and guide them throughout their cancer treatment journey. GUIDE's five letters each represent a crucial step in your conversations with patients with nmCRPC.

nmCRPC, non-metastatic castration-resistant prostate cancer; MDT, multidisciplinary team

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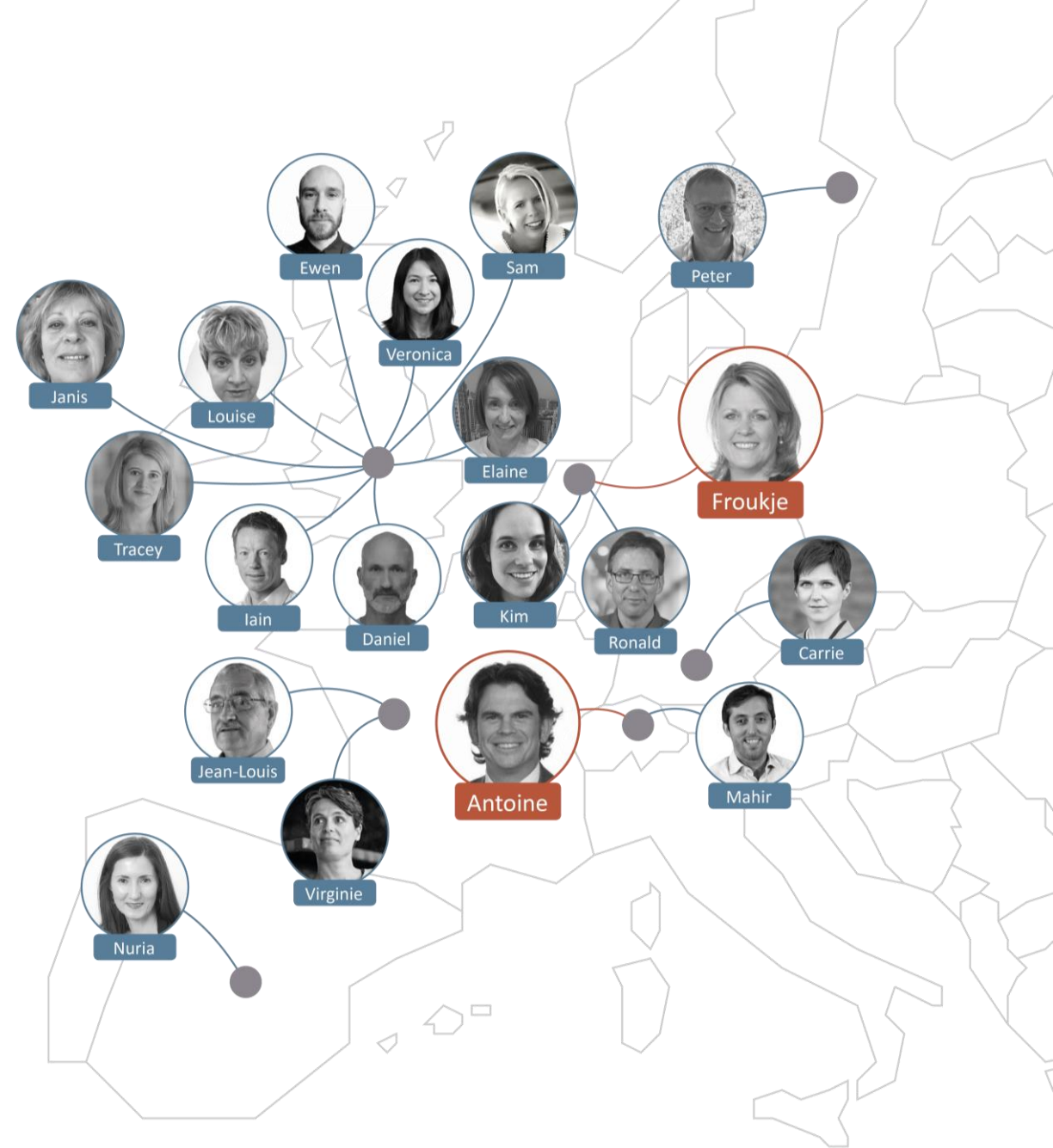
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