

# Treatment patterns and survival outcomes for metastatic castration sensitive prostate cancer: real world evidence from four different European countries

**IRENE MORENO MD,**  
Department of Oncology/START MADRID, HM SANCHINARRO HOSPITAL  
MADRID (SPAIN)

Together with **BETH RUSSELL** and **GINCY GEORGE**  
Translational Oncology & Urology Research, School of Cancer &  
Pharmaceutical Sciences, King's College London, UK)

*On behalf of the Uro-oncology Team*



# Background



- Prostate cancer is the most common cancer (335000 cases/year) and the second most deadly cancer (69900 deaths/year) in men across Europe (Globocan 2020)
- Death by prostate cancer is mainly due to metastatic spread
- In metastatic Castration Sensitive Prostate Cancer (mCSPCa), Androgen Deprivation Therapy (ADT) through surgical or hormonal castration remains the backbone of systemic treatment
- Since 2015 several systemic agents in addition to ADT have shown efficacy in improving overall survival in mCSPC patients
- Docetaxel (DOC); Abiraterone Acetate (ABI); Apalutamide (APA) and Enzalutamide (ENZ) have been approved for mCSPC in Europe
- No comparative prospective evidence of these drugs' efficacy is available to the best of our knowledge
- Real World Evidence may help to define the best therapeutic strategy in mCSPC

# Study Design



## Treatment patterns and survival outcomes for metastatic castration sensitive prostate cancer: real world evidence from four different European countries

- Retrospective, observational study
- EMRs data of mCSPCa patients treated with either DOC, ABI ENZ or APA in four European countries, from 2016 to Jan 2022
- Eligible patients (men aged  $\geq 18$  years) had diagnosed, histologically or cytologically confirmed mCSPC, and were treated with ADT either plus DOC or one of ARATA (ABI, ENZ or ABA), as the first line treatment in mCSPC stage.
- **Data analysis :**
  - Site-specific data analyzed locally
  - Aggregated results pooled (I2 statistics)
- Narrative comparison for a subgroup analysis

# Study objectives



- **Primary Objectives**

- Overall survival for mCSPCa treated by either DOC, ABI, ENZ or APA in the real world setting in four cancer centers from four European countries

- **Secondary Objectives**

- Treatment pattern for mCSPCa patients including both DOC, ABI, ENZ and APA in four cancer centers from four European countries
- Overall survival for both DOC and ABI in subgroup of mCSPCa patients that match patient population in RCTs

# Study Centres



## The Netherlands ●

CAPRI foundation,  
nation-wide registry in  
Netherlands

## United Kingdom ●

King's College London  
Statistical and  
epidemiological support

## France ●

Pitié-Salpêtrière Hospital

## Spain ●

Start Madrid-HM  
Sanchinarro hospital




## Italy ●

Fondazione IRCCS  
Istituto Nazionale dei  
Tumori  
Azienda Ospedaliera SS  
Antonio e Biagio e  
Cesare Arrigo di  
Alessandria.



## Local centers study status

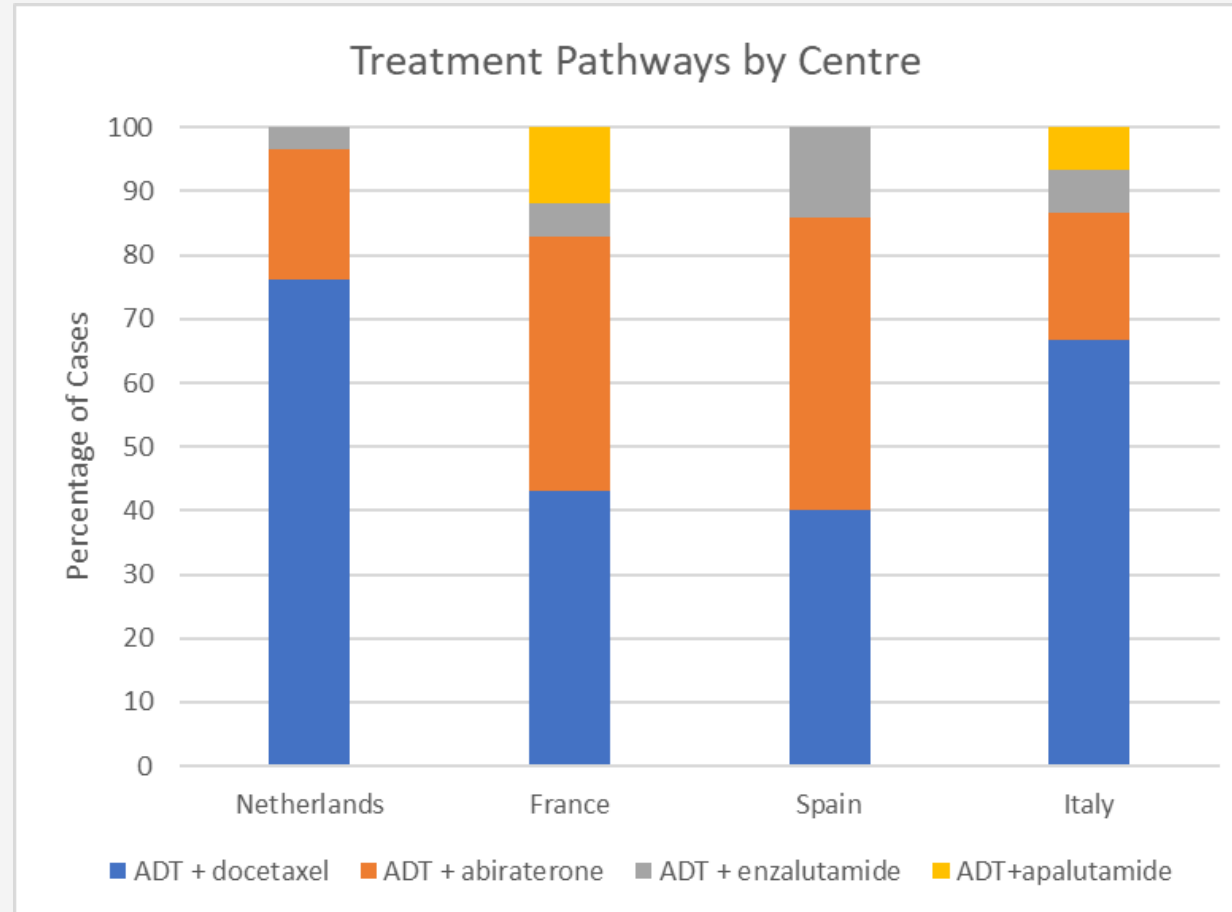


Country	Number of patients	Data Collection	Ethics Completed	Local Statistical Analysis
 NL	172	✓	✓	✓
 IT	15	✓	✓	✓
 FR	58	✓	✓	✓
 SP	50	✓	✓	✓
Overall	295	✓	✓	✓

## Preliminary results: Overall survival

	Netherlands			France			Spain			Italy		
	Months	Lower CI	Upper CI	Months	Lower CI	Upper CI	Months	Lower CI	Upper CI	Months	Lower CI	Upper CI
<b><u>OS by median time</u></b>	63.8	55.8	71.9	33.3	30.6	N/A	N/A	N/A	N/A	62	29	62
<b><u>OS by time at which 25% have died</u></b>	32.1	26.1	40.6	23.2	19.5	37.7	43	28.9	59.1	45.4	41.6	49.9

# Preliminary results: Treatment pathways by centre





# Preliminary results: Outcomes



	Netherlands		France		Spain		Italy		Total		
	N=172		N=58		N=50		N=15		N=295		
	N	%	N	%	N	%	N	%	n	%	
<b>Biochemical progression</b>											
Yes	0	0	46	79.3	12	24	7	46.7	65	22.0	
No	0	0	12	20.7	38	76	3	20	53	18.0	
Missing	172	100	0	0	0	0	5	33.3	177	60.0	
<b>Radiological progression</b>											
Yes	0	0	20	66.7	12	24	7	46.7	39	13.2	
No	0	0	10	33.3	38	76	3	20	51	17.3	
Missing	172	100	28	48.3	0	0	5	33.3	205	69.5	
<b>Death</b>											
Yes	58	33.7	29	50	13	26	2	13.3	102	34.6	
No	114	66.3	29	50	37	74	11	73.4	191	64.7	
Missing	0	0	0	0	0	0	0	0	0	0.0	
<b>Loss to follow-up</b>											
Yes	16	9.3	2	3.4	7	14	2	13.3	27	9.2	
No	156	90.7	56	96.6	43	86	0	0	255	86.4	
Missing	0	0	0	0	0	0	0	0	0	0.0	

# Challenges encountered



1. Timeline commitment
2. Effective communication between team members (especially during conflicts/setting goals)
3. Understanding individual circumstances/successful motivation in all team members
4. Poor engagement from one team member
5. Personality conflicts



Unfortunately, **Vejle Hospital (DK)** investigators decided to leave the project

# Lessons Learnt



## 1. Trust among team members

- Act with high integrity
- Anticipate and analyze early when expectations / comitment are not aligned
- Resolve Conflict- open discussion

## 2. Commitment (*-realistic-* deadlines)

## 3. Communicate as much as possible

## 4. Everyone's happiness/individual context are equally important

“The challenge is to make the team feel safe enough to state their feelings and opinions during meetings without feeling like it could backfire on them. The more this happens, the more trust gets built over time”.

# Next steps

1. Add more sites? (Jan/2024)
2. Running in parallel the analysis with current data available?
3. Article/abstract writing and submission

Team meeting on  
**21st November**

1. Short-term actions:
  - Review results on the 21/11/2023
  - Review demographics (total no, charlson index)
2. Mid-term actions:
  - Abstracts: Which congress?
  - Article(s):
    - Target journal
    - Authorship
    - 1 or 2 articles?



# Study Team



Paul  
Gougis



Irene  
Moreno



Malou  
Kuppen



Beth  
Russell



Luigi  
Cerbone



Patrizia  
Giannatempo



Gincy  
George



Aida  
Santaolalla



# Thank you