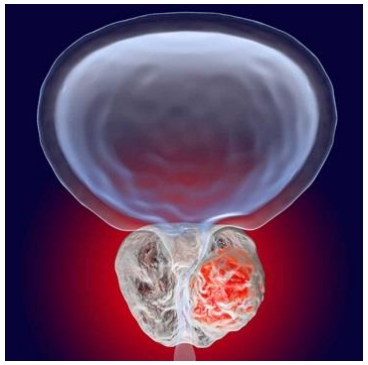
10/2024

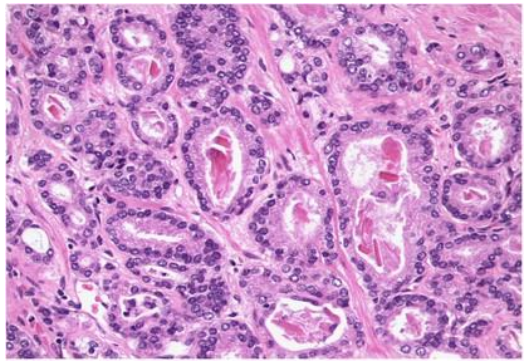
Medizinische Universität Graz

Die Ärztekammer Steiermark

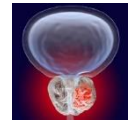
34. Grazer Fortbildungstage der Ärztekammer für Steiermark

Onkologie 2.0 in der Urologie





G.C. Hutterer
Universitätsklinik für Urologie
Medizinische Universität Graz



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➢ *Disclosures:*

Bayer HealthCare

Pierre Fabre

astellas

AMGEN

Eisai

Bristol Myers Squibb

Pfizer Oncology

Roche

IPSEN Innovation for patient care

EUSAPharma

janssen Oncology

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

MSD INVENTING FOR LIFE

SANOFI

AstraZeneca

➢ Prostatakarzinom - Epidemiologischer Abriß:

CA CANCER J CLIN 2021;0:1–41

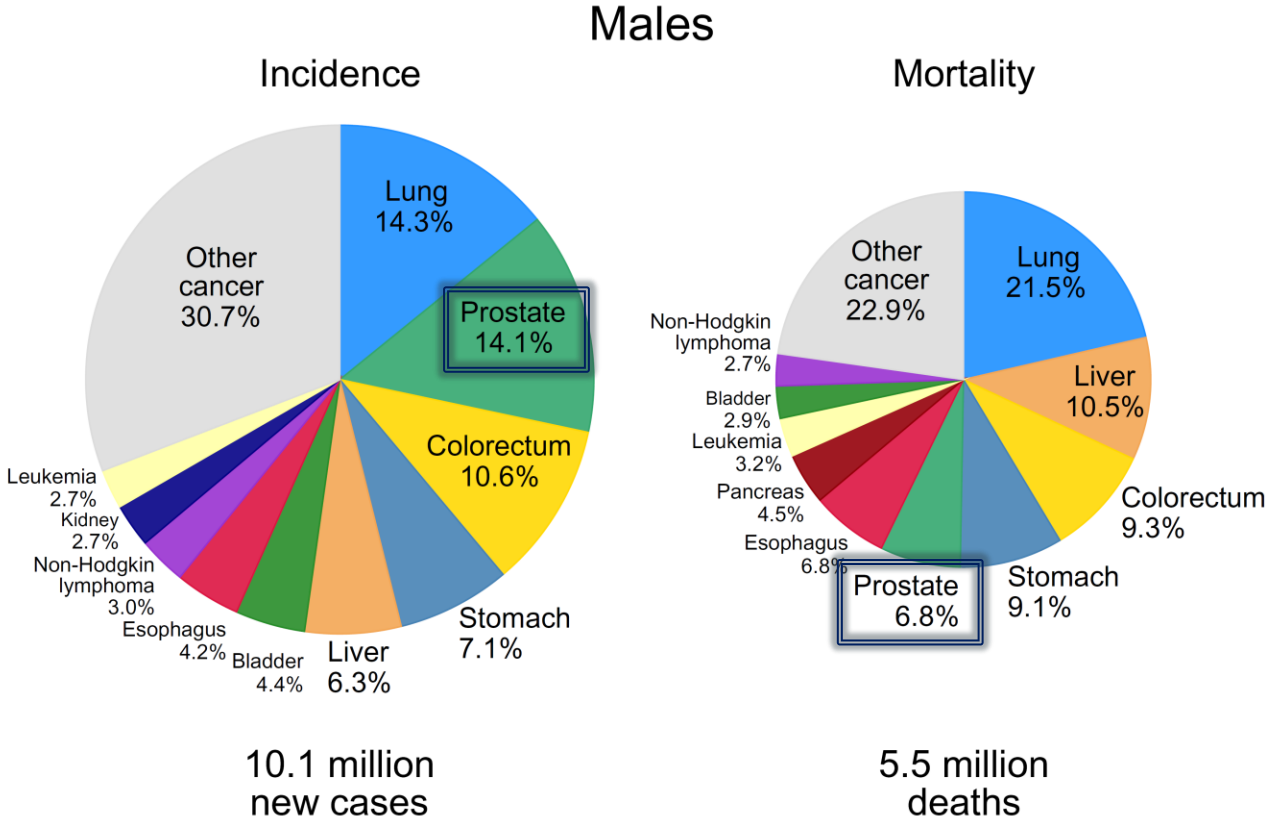
Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries

Hyuna Sung, PhD [1]; Jacques Ferlay, MSc, ME[2]; Rebecca L. Siegel, MPH [1]; Mathieu Laversanne, MSc[2]; Isabelle Soerjomataram, MD, MSc, PhD[2]; Ahmedin Jemal, DMV, PhD[1]; Freddie Bray, BSc, MSc, PhD[2]

TABLE 1. New Cases and Deaths for 36 Cancers and All Cancers Combined in 2020

CANCER SITE	NO. OF NEW CASES	(% OF ALL SITES)	NO. OF NEW DEATHS	(% OF ALL SITES)
Female breast	2,261,419	(11.7)	684,996	(6.9)
Lung	2,206,771	(11.4)	1,796,144	(18.0)
Prostate	1,414,259	(7.3)	375,304	(3.8)
Nonmelanoma of skin[a]	1,198,073	(6.2)	63,731	(0.6)
Colon	1,148,515	(6.0)	576,858	(5.8)
Stomach	1,089,103	(5.6)	768,793	(7.7)
Liver	905,677	(4.7)	830,180	(8.3)
Rectum	732,210	(3.8)	339,022	(3.4)
Cervix uteri	604,127	(3.1)	341,831	(3.4)
Esophagus	604,100	(3.1)	544,076	(5.5)
Thyroid	586,202	(3.0)	43,646	(0.4)
Bladder	573,278	(3.0)	212,536	(2.1)

B



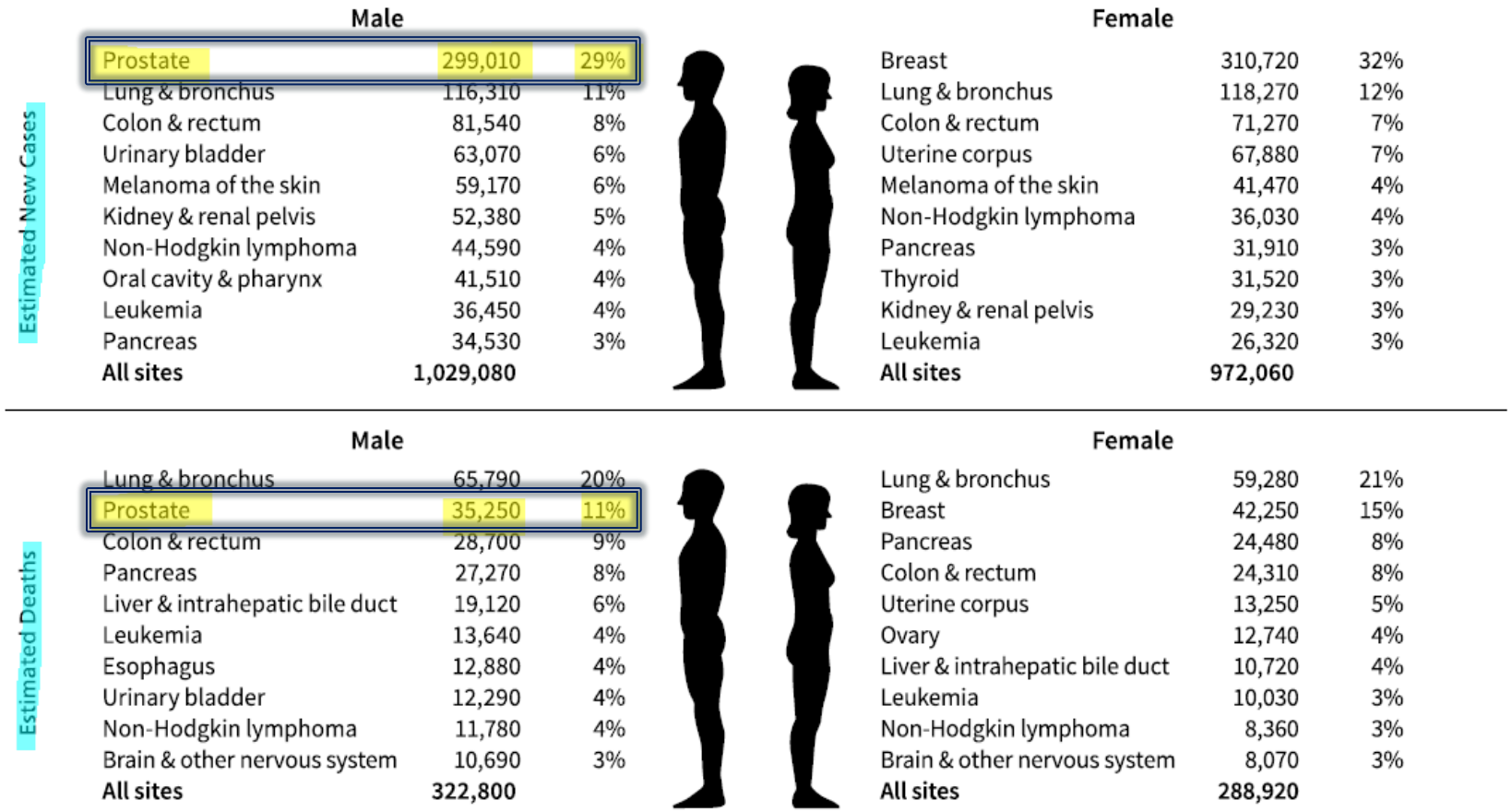
Sung H, *et al*. *CA CANCER J CLIN 2021*

Cancer statistics, 2024

Rebecca L. Siegel MPH[1] | Angela N. Giaquinto MSPH[1] | Ahmedin Jemal DVM, PhD[2]

➢ 1.

➢ 2.

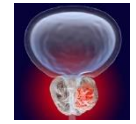


Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates do not include Puerto Rico or other US territories. Ranking is based on modeled projections and may differ from the most recent observed data.

FIGURE 1 Ten leading cancer types for the estimated new cancer cases and deaths by sex, United States, 2024. Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Ranking is based on modeled projections and may differ from the most recent observed data.

CA CANCER J CLIN 2024

➢ Die Zahl der Patienten, die an einem Prostatakarzinom versterben, wird sich in den nächsten 20 Jahren verdoppeln[1]



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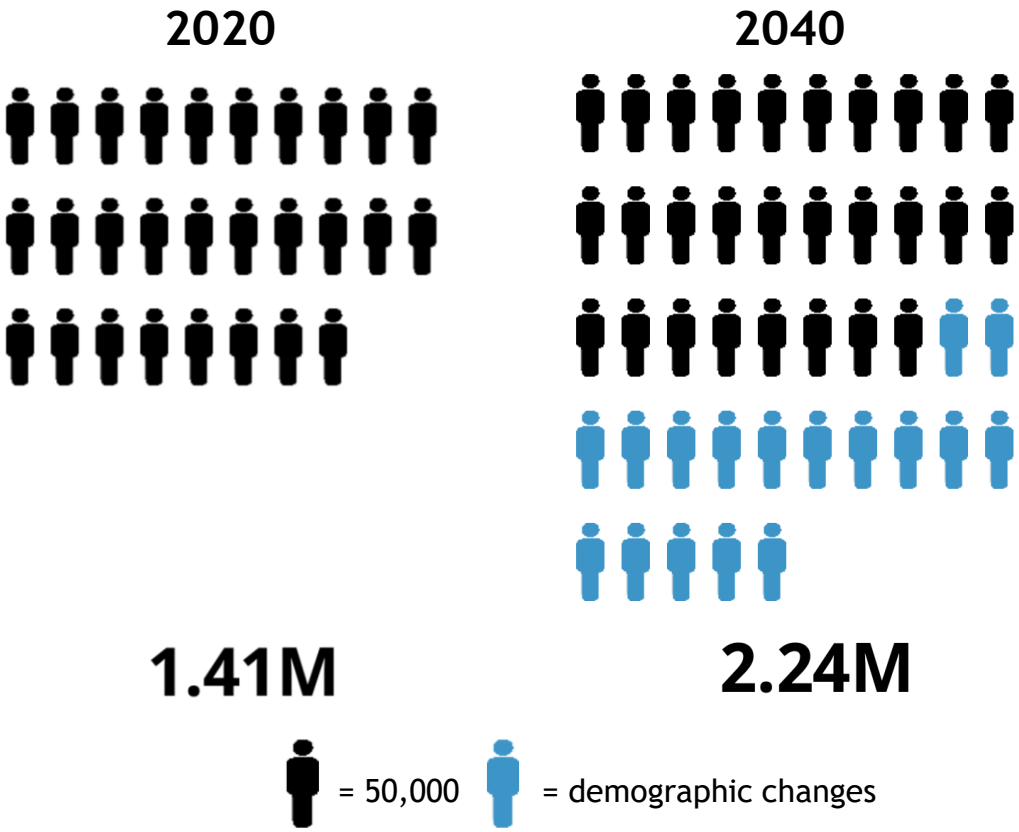
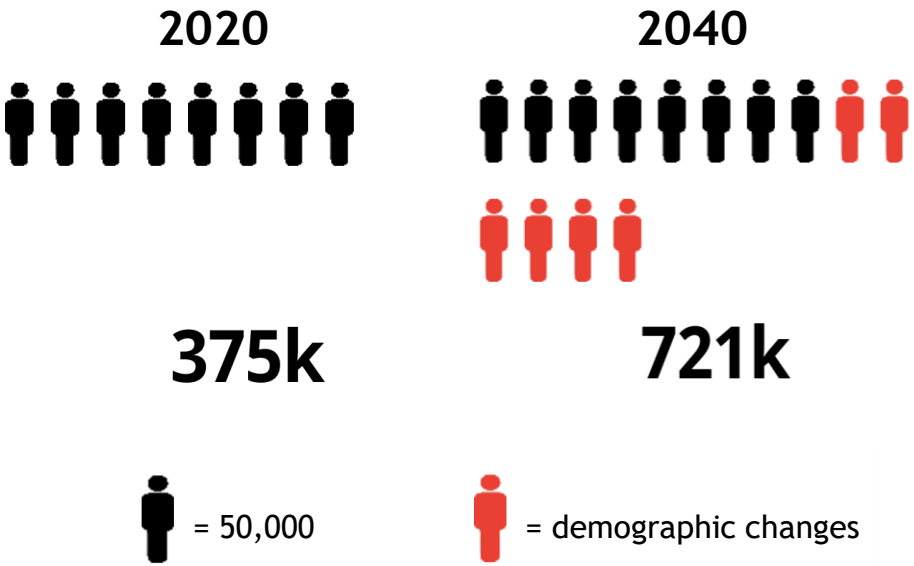
Estimated no. of new cases of prostate cancer
worldwide, from 2020 to 2040, males, all ages



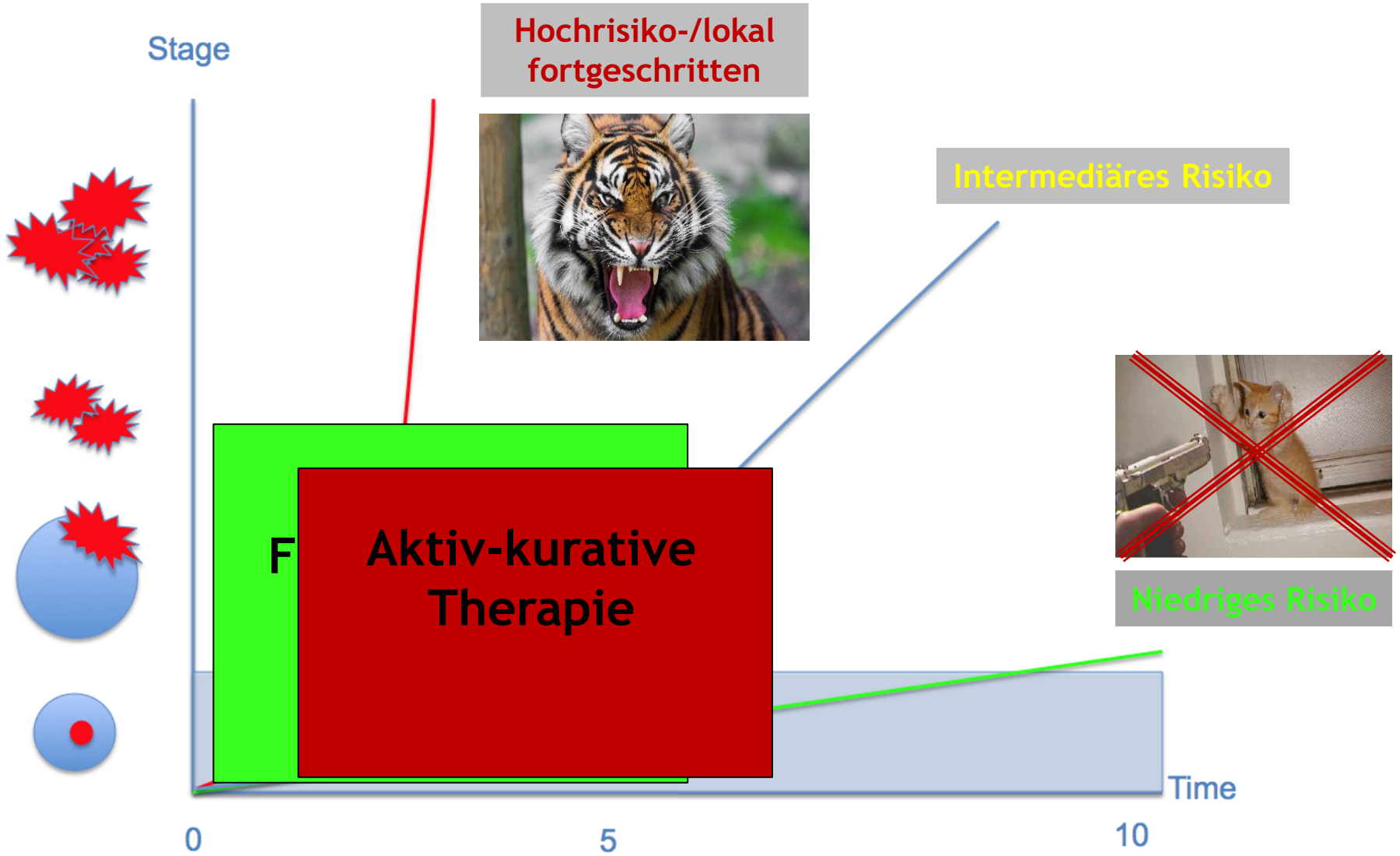
Estimated no. of deaths from prostate cancer
worldwide, from 2020 to 2040, males, all ages



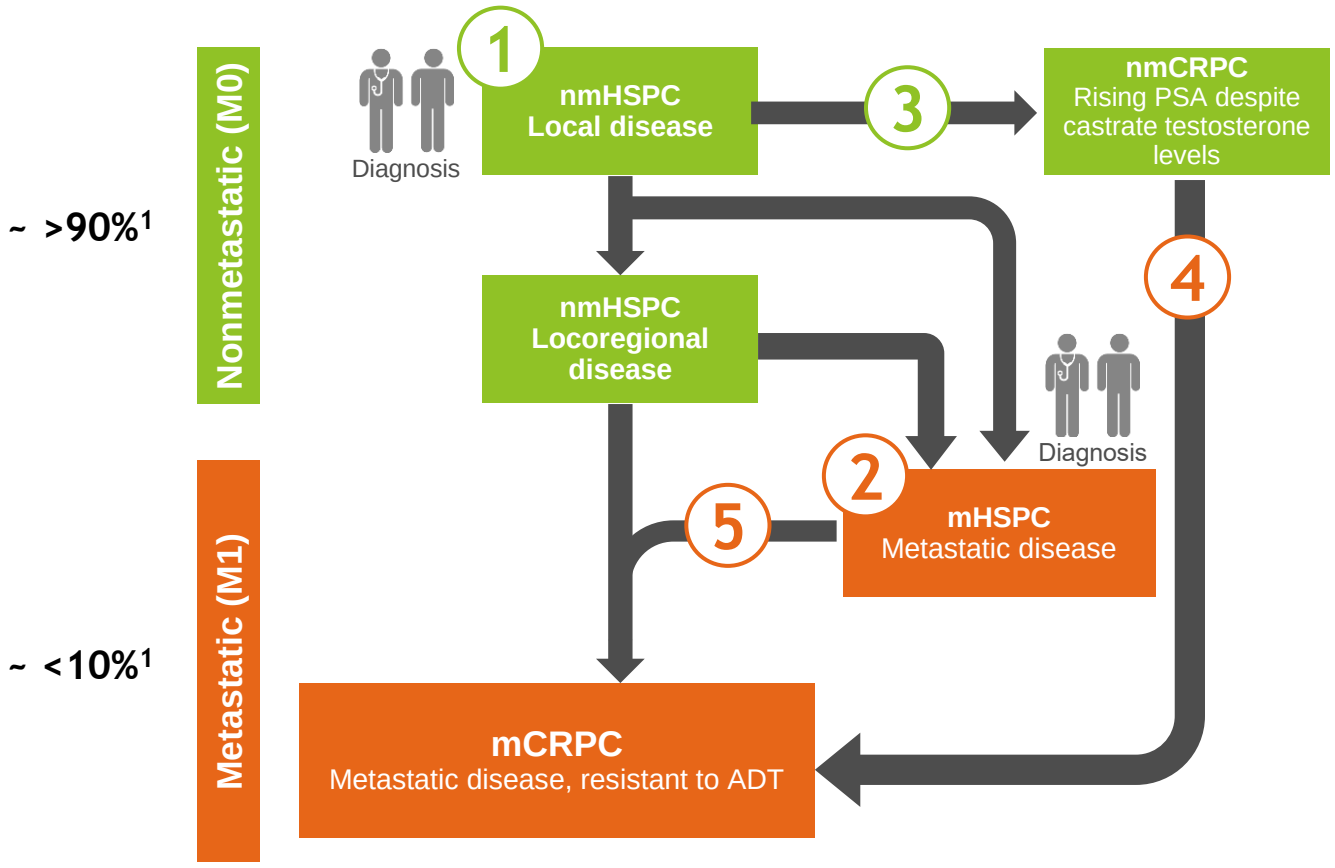
[1]GLOBOCAN 2020 Statistics. http://gco.iarc.fr

Figs. adapted from GLOBOCAN[1]

➢ Prostatakarzinom = heterogener Tumor



Prostate Cancer Disease Progression:



1. The majority (90%) of patients with PCa have localized disease at initial diagnosis[2]
   - 5-25% of new PCa diagnoses will present as *de novo* mHSPC[3,4]
2. 10-20% of men diagnosed with PCa develop castration-resistant disease (CRPC) within ~5yrs. of follow-up[5]
3. The majority (86%) of patients with mCRPC progress from nmCRPC[6]
   - 1/3 of nmCRPC cases progress to mCRPC within 2yrs.[5]
4. Most men with metastases progress to CRPC within a median of ~1yr., although most patients have an initial response to androgen deprivation therapy (ADT)[7]

1. Liede A, *et al*. ESMO Open 2016 2. Sun F, *et al*. Agency for Healthcare Research and Quality 2014 3. Siegel RL, *et al*. CA Cancer J Clin 2018 4. NICE guidance https://www.nice.org.uk/advice/esuom50/chapter/Full-evidence-summary 03/2020 5. Kirby M, *et al*. Int J Clin Pract 2011 6. Scher HI, *et al*. PLoS NE 2015 7. Fizazi K, *et al*. N Engl J Med 2017

➢ Kastrationsresistenz (CRPC):

- ↑ intrazellulärer Androgenspiegel
+
- AR-Überexpression (adaptativer Mechanismus)[1]

→ AR-abhängig

→ AR-unabhängig

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European Association of Urology

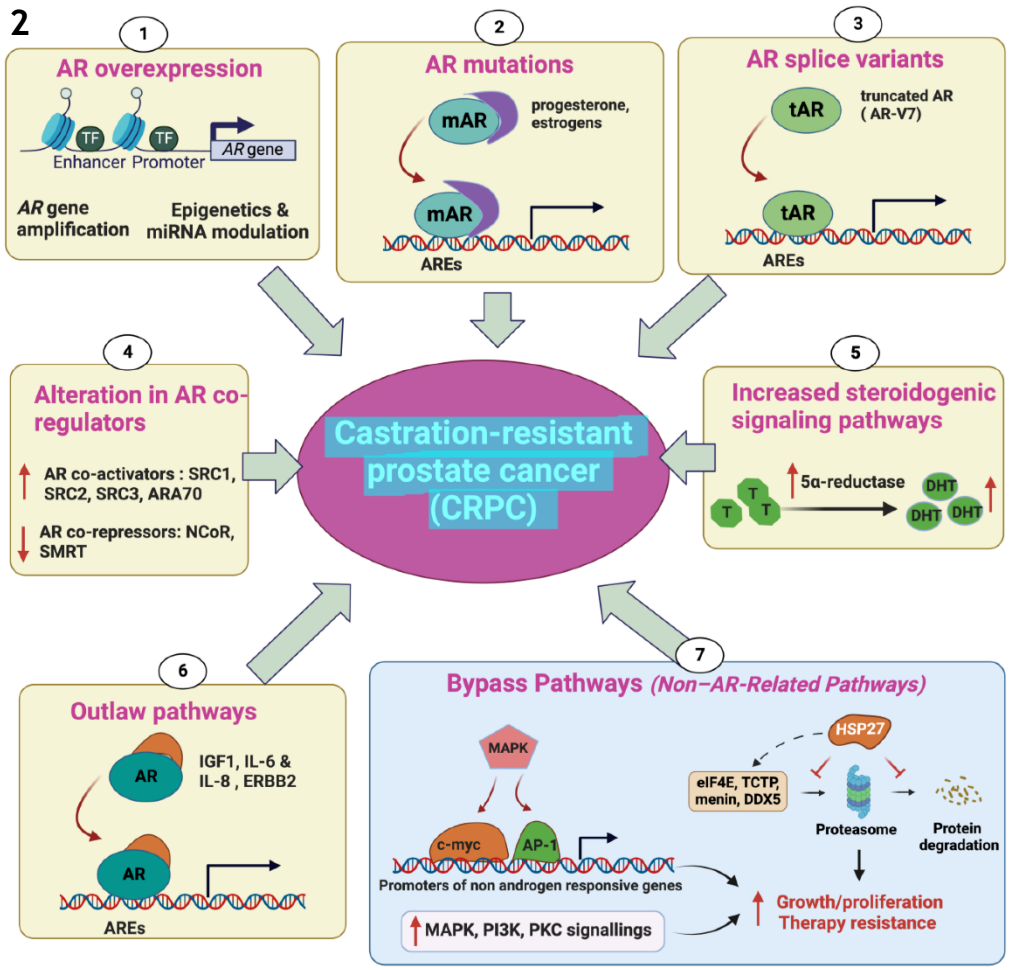
EANM

European Society of Urogenital Radiology

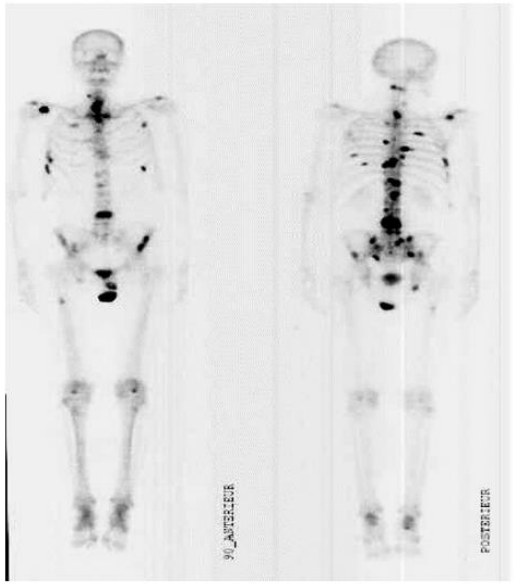
ESTRO European Society for RADIOTHERAPY & ONCOLOGY

SIOG INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY

2



PROSTATE CANCER IS HORMONE DEPENDENT



"Despite regressions of great magnitude, it is obvious that there are many failures of endocrine therapy to control the disease"

Charles B. Huggins
Nobel Lecture
December 13, 1966

[1]Montgomery RB, *et al*. Cancer Res 2008; [2]Le TK, *et al*. cancers 2023

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TREATMENT OPTIONS FOR mHSPC

2015	2017	2019	2021	2022
DOCETAXEL	ABIRATERONE	ENZALUTAMIDE	DOCETAXEL PLUS ABIRATERONE	DOCETAXEL PLUS DAROLUTAMIDE
CHAARTED STAMPEDE-C	LATITUDE STAMPEDE-G	ENZAMET ARCHES	PEACE-1	ARASENS
		APALUTAMIDE TITAN		

Kyriakopoulos CE et al. J Clin Oncol. 2018 Apr 10;36(11):1080-1087. Clarke NW et al. Annals of Oncology30:1992-2003, 2019. Fizazi K et al. Lancet Oncol 2019 May; 20(5):686-700. James N et al. 2020 ESMO. Davis IA et al. N Engl J Med 2019;381:121-131. Armstrong AJ et al. Annal Oncol 2021;32(5):S1283-S1346, LBA25. Chi KN et al. J Clin Oncol. 2021 39:2294-2303.

PRESENTED BY: Elisabeth I. Heath, MD, FACP

Leitlinienprogramm Onkologie

S3-Leitlinie Prostatakarzinom

Version 7.0 – Mai 2024
AWMF-Registernummer: 043-022OL

Tabelle 14: Schema der Empfehlungsgraduierung

Empfehlungsgrad	Beschreibung	Ausdrucksweise
A	Starke Empfehlung	soll
B	Empfehlung	sollte
0	Empfehlung offen	kann

mHSPC

a. Patienten in gutem Allgemeinzustand (ECOG 0-1) mit metastasiertem (M1) hormonsensitivem, Prostatakarzinom (mHSPC) soll zusätzlich zur Androgendeprivation eine Hormontherapie mit Apalutamid oder Enzalutamid angeboten werden.
(Empfehlungsgrad: A)

b. Patienten in gutem Allgemeinzustand (ECOG 0-1) mit neu-diagnostiziertem (de novo), metastasierten (M1), hormonsensitiven, high-risk Prostatakarzinom (mHSPC) soll zusätzlich zur Androgendeprivation eine Hormontherapie mit Abirateron (plus Prednison / Prednisolon) angeboten werden.
(Empfehlungsgrad: A)

c. Patienten in gutem Allgemeinzustand (ECOG 0-1) mit metastasiertem (M1) hormonsensitivem Prostatakarzinom, die für eine Docetaxel Chemotherapie geeignet sind, soll zusätzlich zur Androgendeprivation eine Hormontherapie mit Darolutamid in Kombination mit 6 Zyklen Docetaxel angeboten werden.
(Empfehlungsgrad: A)

d. Patienten in gutem Allgemeinzustand (ECOG 0-1) mit neu-diagnostiziertem (de novo), metastasiertem (M1) hormonsensitivem Prostatakarzinom und hohem Tumorvolumen („*high volume disease*“), die für eine Docetaxel Chemotherapie geeignet sind, kann zusätzlich zur Androgendeprivation eine Hormontherapie mit Abirateron (plus Prednison/Prednisolon) in Kombination mit 6 Zyklen Docetaxel angeboten werden.
(Empfehlungsgrad: 0)

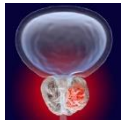

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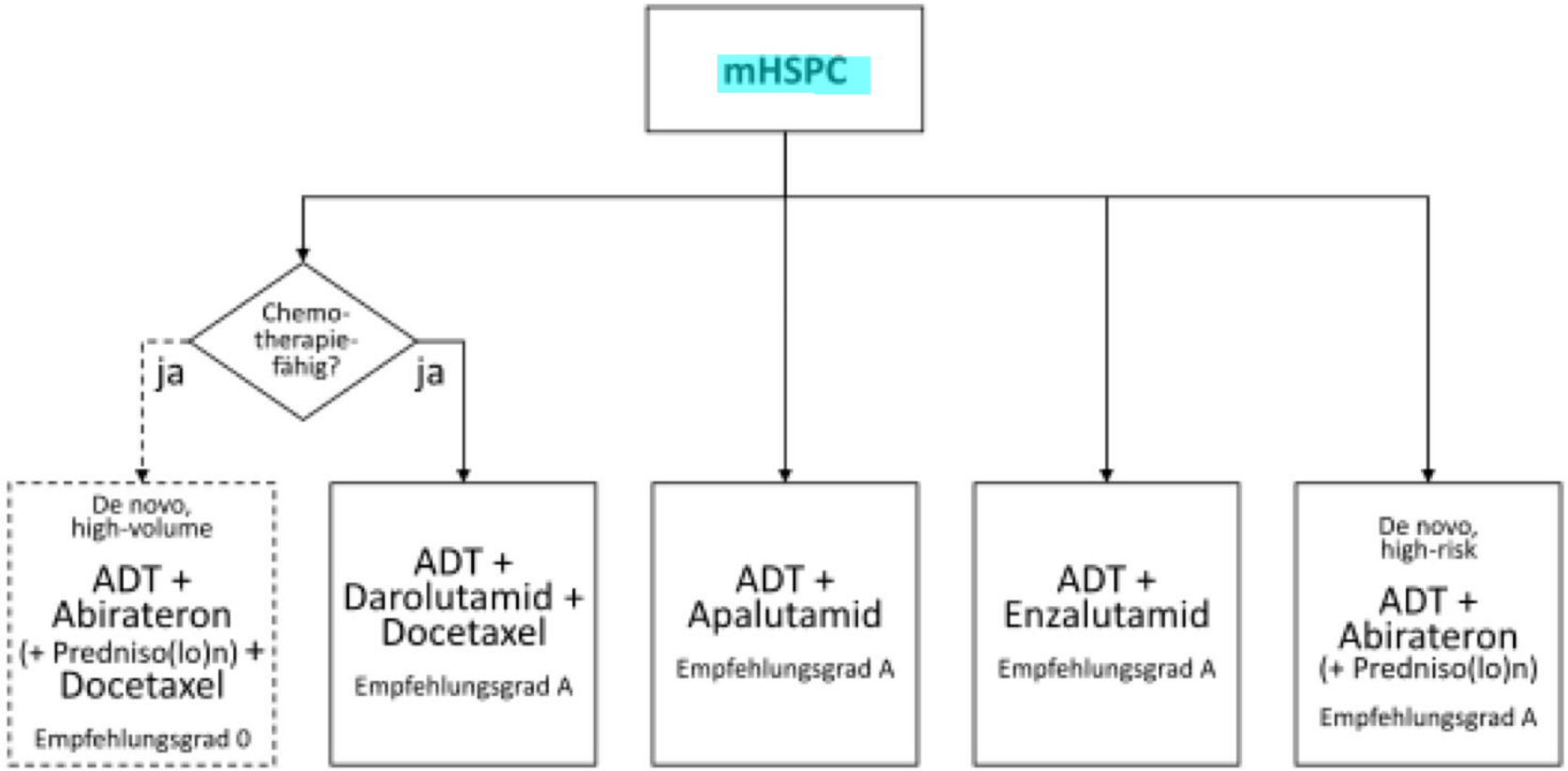
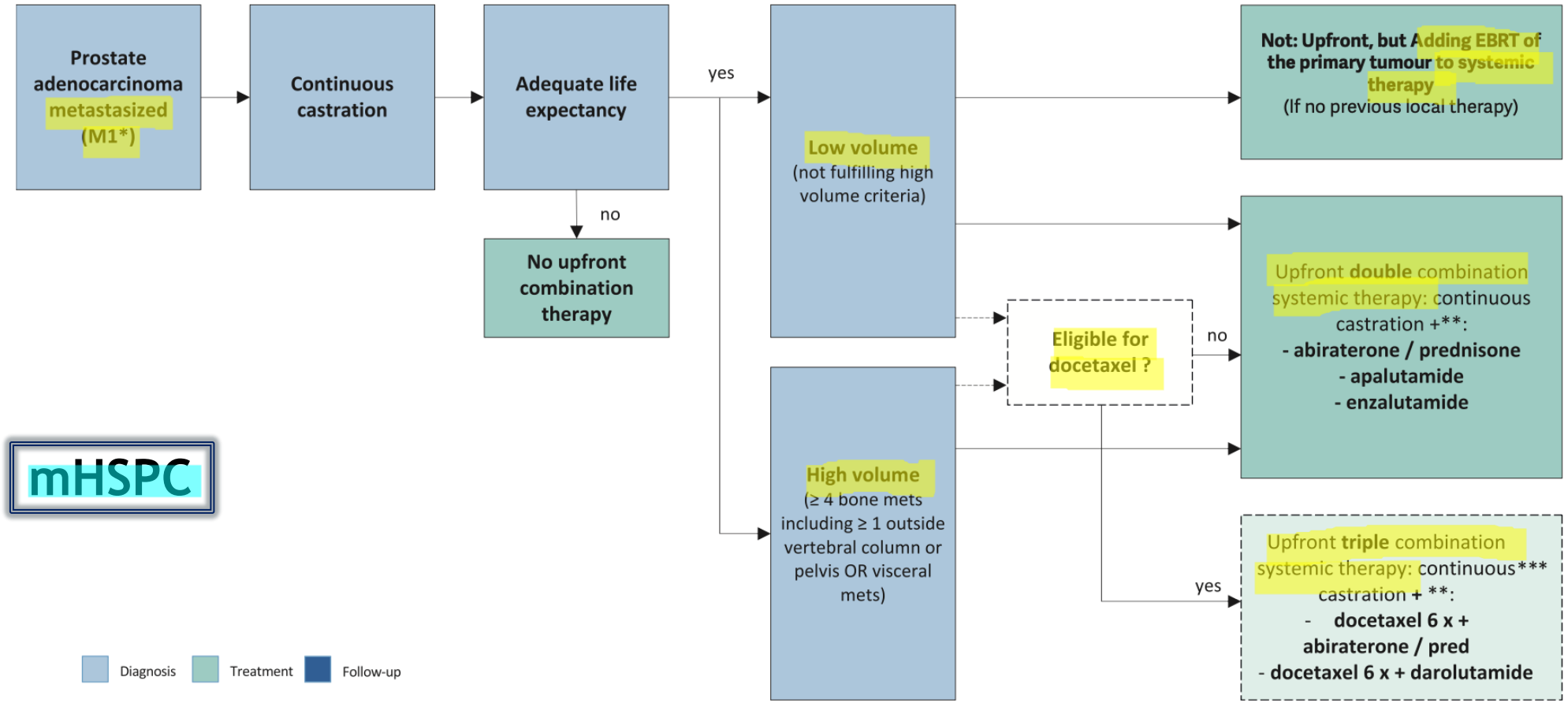
Table 6.6.2.1 Definition of high- and low-volume in CHAARTED [1088-1090] and high- and low-risk in LATITUDE [1070]

	High	Low
CHAARTED (volume)	≥ 4 Bone metastases including ≥ 1 outside vertebral column or pelvis **AND/OR** Visceral metastasis*	Not high
LATITUDE (risk)	≥ 2 high-risk features of: • ≥ 3 Bone metastasis • Visceral metastasis • ≥ ISUP grade 4	Not high

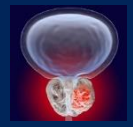
**Lymph nodes are not considered as visceral metastases.*

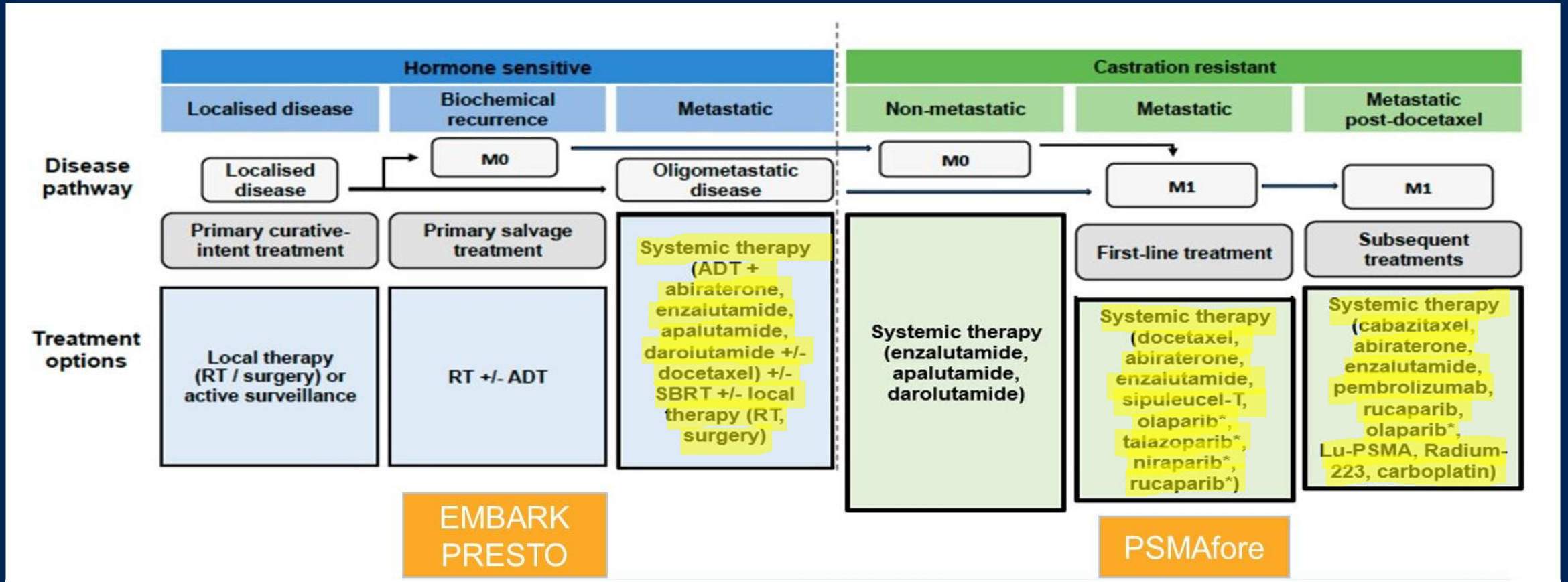




* Based on staging using combination of bone scan and CT.
** Alphabetical order.
***not for low volume, metachronous disease.
1EBRT: IMRT/VMAT + IGRT of the prostate (equivalent of up to 72 Gy in 2 Gy fractions).
= weak recommendation.
EBRT = external beam radiotherapy; IGRT = image-guided radiotherapy; IMRT = intensity-modulated radiotherapy.
#Note: Please be aware that the various options in the following flowcharts present a generalised approach only, and cannot take the management of individual patients into account, nor the availability of resources.

Prostate Cancer Treatment Landscape





→ mCRPC = the most aggressive form of prostate cancer and is associated with poor prognosis[1]

[1]Scher HI, *et al*. PLoS One 2015

➢ Genetische Testungen bei PC:

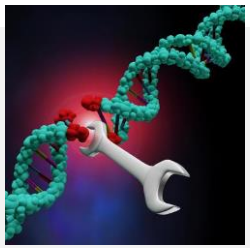
➢ DNA Damage Response and Homologous Recombination Repair:

DNA damage can occur in many ways

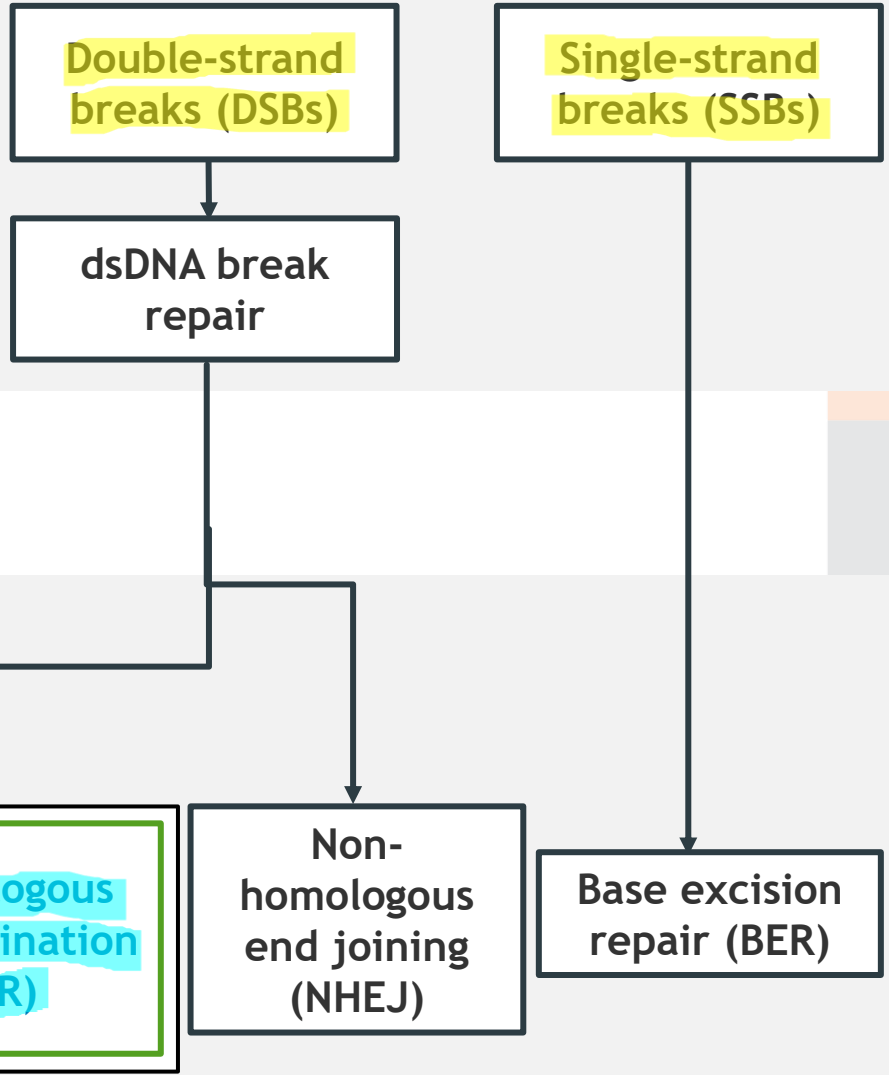
- SSBs represent the most common kind of DNA damage, occurring >10.000 times/cell/day due to oxidative stress and erroneous enzymatic activity[1,2]
- Unrepaired SSBs can be converted to more deleterious DSBs[1,2]
- DSBs can also arise as a result of DNA damage by ultraviolet light, ionizing radiation, cigarette smoke, industrial chemicals, and anti-cancer agents[3,4]

DNA damage response (DDR) is a repair mechanism

- DDR[4] is a term encompassing any mechanism of SSB or DSB repair


Homologous recombination repair (HRR)[4] is a specific DDR pathway for DSB repair



[1]Caldecott KW Nat Rev Genet 2008; [2]Hossain MA, *et al*. Int J Mol Sci 2018; [3]Cannan WJ, *et al*. J Cell Physiol 2016; [4]Lord CJ, *et al*. Nature 2012

➢ HRR Alterations in Prostate Cancer:

Based on a comprehensive review of multiple studies and/or pooled datasets reporting the prevalence of HRR alterations in mCRPC:

~25%

of men with mCRPC have an HRR alteration[1,2]

Note that HRR rates can vary depending on the study, as studies utilize patient populations with different characteristics, sequencing methods, and mutational definitions

HRR-mutated disease:

- ✓ is typically diagnosed with prostate cancer at an earlier age compared with non-mutated prostate cancer patients[3,4]
- ✓ represents a more aggressive tumor with worse prognosis[3-6]

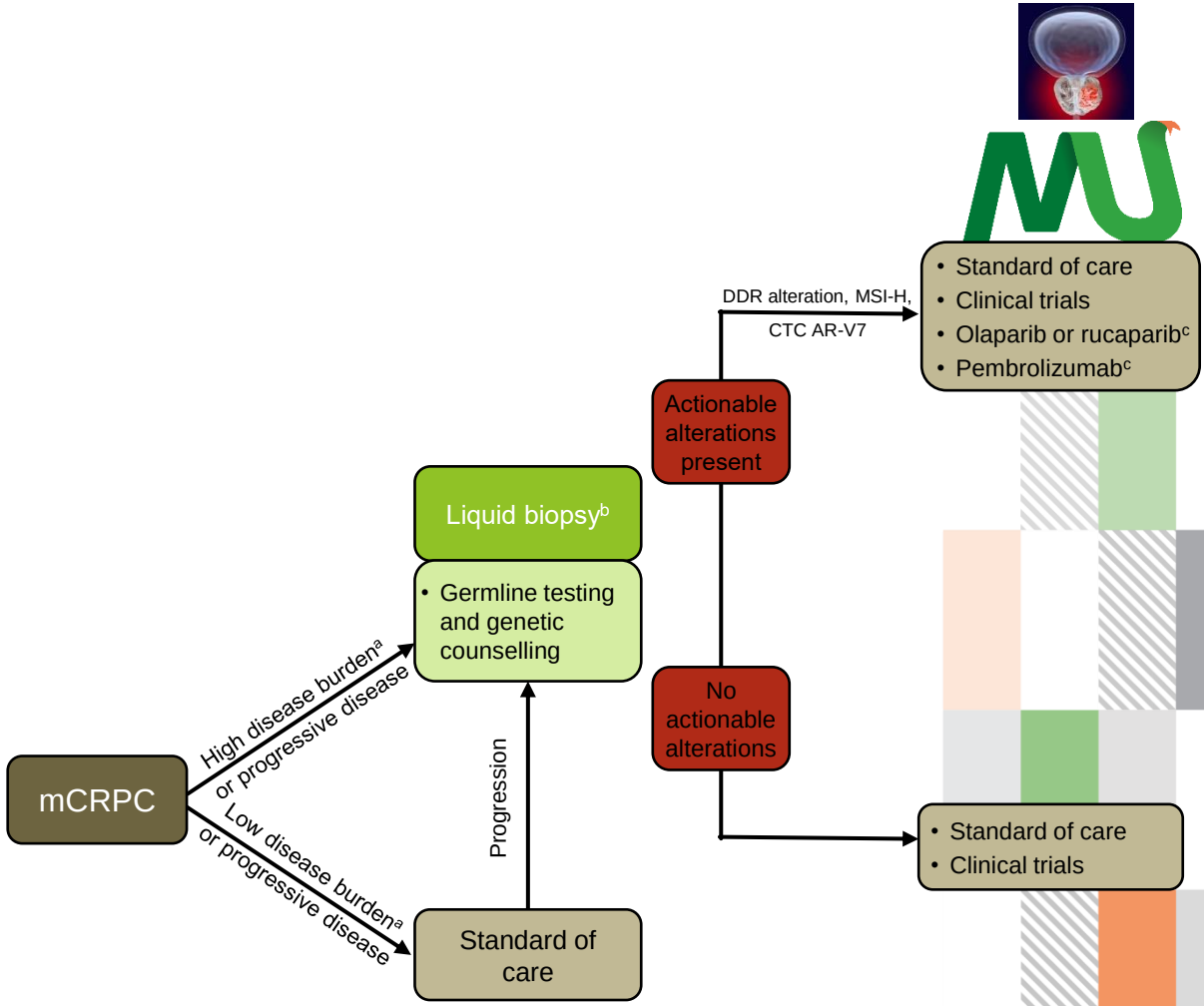
Some examples of HRR genes include *ATM*, *ATR*, *BRCA1*, *BRCA2*, *CDK12*, *CHEK2*, *FANCA*, *MLH1*, *MRE11A*, *NBN*, *PALB2*, and *RAD51C*[1,2]

HRR = homologous recombination repair; mCRPC = metastatic castration-resistant prostate cancer

[1]de Bono JS, *et al*. Lancet Oncol 2021; [2]Chung JH, *et al*. JCO Precis Oncol 2019; [3]Castro E, *et al*. J Clin Oncol 2019; [4]Annala M, *et al*. Eur Urol 2017; [5]Armenia J, *et al*. Nat Genet 2018; [6]Na R, *et al*. Eur Urol 2017

➢ Precision genetic testing: Why?

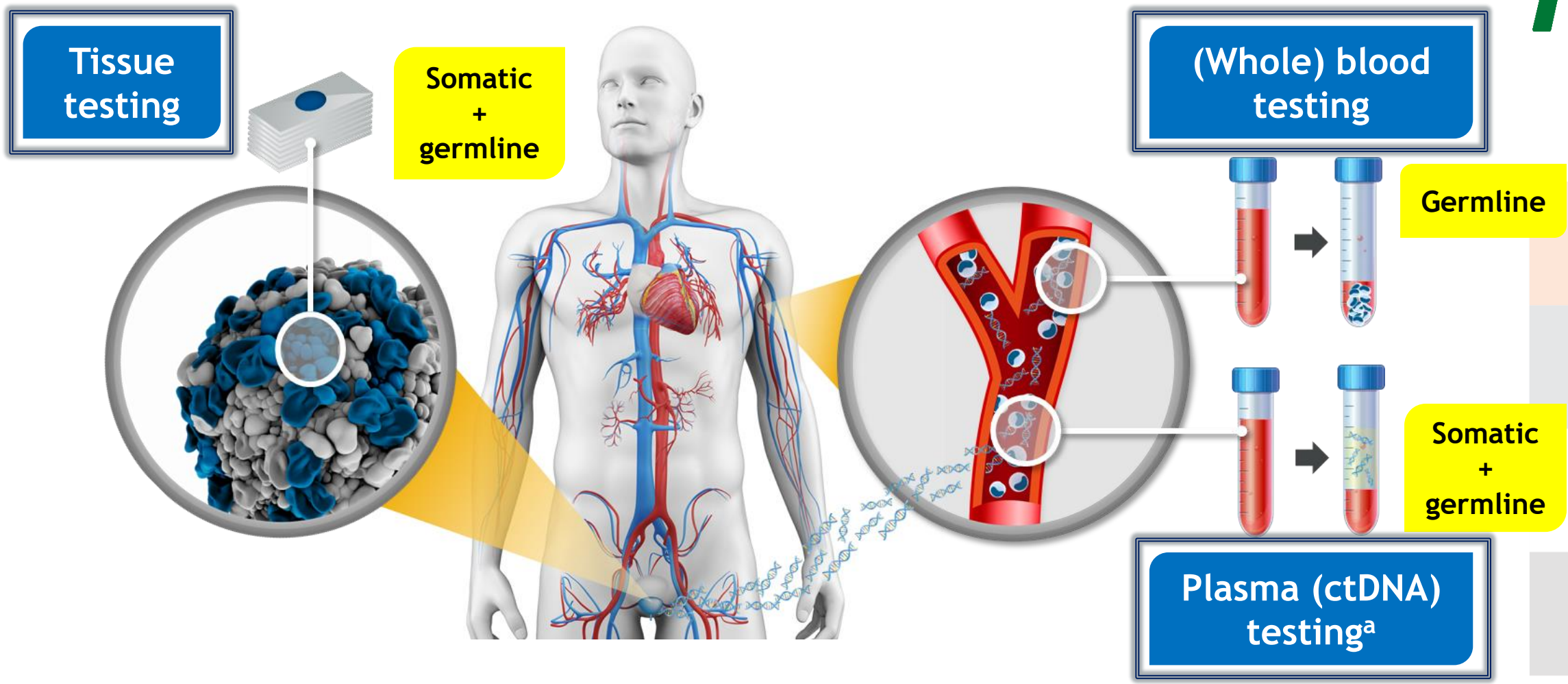
1. **Inform treatment decisions to improve survival, clinical benefit, and chance of remission**
   - DNA: HRR mutation → PARPi,
   - MSI-high mCRPC → pembrolizumab
   - RNA: AR-V7 and AR therapy resistance
   - Histology/Phenotype:
     - small cell transformation → platinums;
     - PSMA expression → Lu^{177}
2. **Inform hereditary cancer risk, family counselling and risk reduction**
   - DNA/RNA: *BRCA2*, *ATM*, Lynch Syndrome, HOXB13, other DNA repair enzymes
3. **Assess for clinical trial eligibility (research)**
   - PTEN loss, PI3K/Akt mutations, CDK12 mutation, PSMA expression, TP53/RB1 loss



[a] High disease burden based on the presence of known adverse prognostic factors in men with mCRPC, such as visceral metastases, high volume of bone metastases, anaemia, rapid PSA kinetics, high circulating tumour cell count, high LDH or alkaline phosphatase, pain, and progression despite multiple prior therapies. [b] If tumour biopsy is not available/inadequate or remote. Liquid biopsy can include ctDNA and/or CTC biomarkers such as AR-V7 testing. [C]Timing of these treatments dependent on product labels

Adapted from: Hawkey N, *et al*. Clin Cancer Res 2021

➢ → several ways to identify *BRCA*/HRR mutations in prostate cancer



[a]Tumour cells shed DNA into the circulation through necrosis or apoptosis. ctDNA can be isolated from a plasma sample; BRCA, breast cancer gene; ctDNA, circulating tumor DNA; HRR, homologous recombination repair

[1]Cheng HH, *et al*. J Natl Compr Canc Netw 2019; [2]Haber DA, *et al*. Cancer Discov 2014

➢ Sample Collection Process for HRR Alteration Assessment:

Solid Tumor Biopsy[1]

- historically → considered the gold standard sample type for biomarker testing

Test Requirement: tissue from the tumor (preferably recently acquired)

Types of Mutations Detected: somatic and germline alterations

Time Frame for Results: up to 4 weeks[3]

Liquid Biopsy

- various cancer biomarkers can be assessed with liquid biopsies, of which ctDNA is the most prominent which assesses both germline and somatic alterations[2]
- A growing number of clinical trials over the past 15 years have been utilizing ctDNA liquid biopsies; this may be due to improvements in technology and high concordance rates with tissue tests[1,2]
- At present, assay sensitivity is the main concern with ctDNA liquid biopsy, but this sensitivity will improve as technologies mature[2]

Plasma ctDNA[1]

Test Requirement: blood sample

Types of Mutations Detected: somatic and germline alterations

Time Frame for Results: 10-11 days[3]

Whole Blood[1]

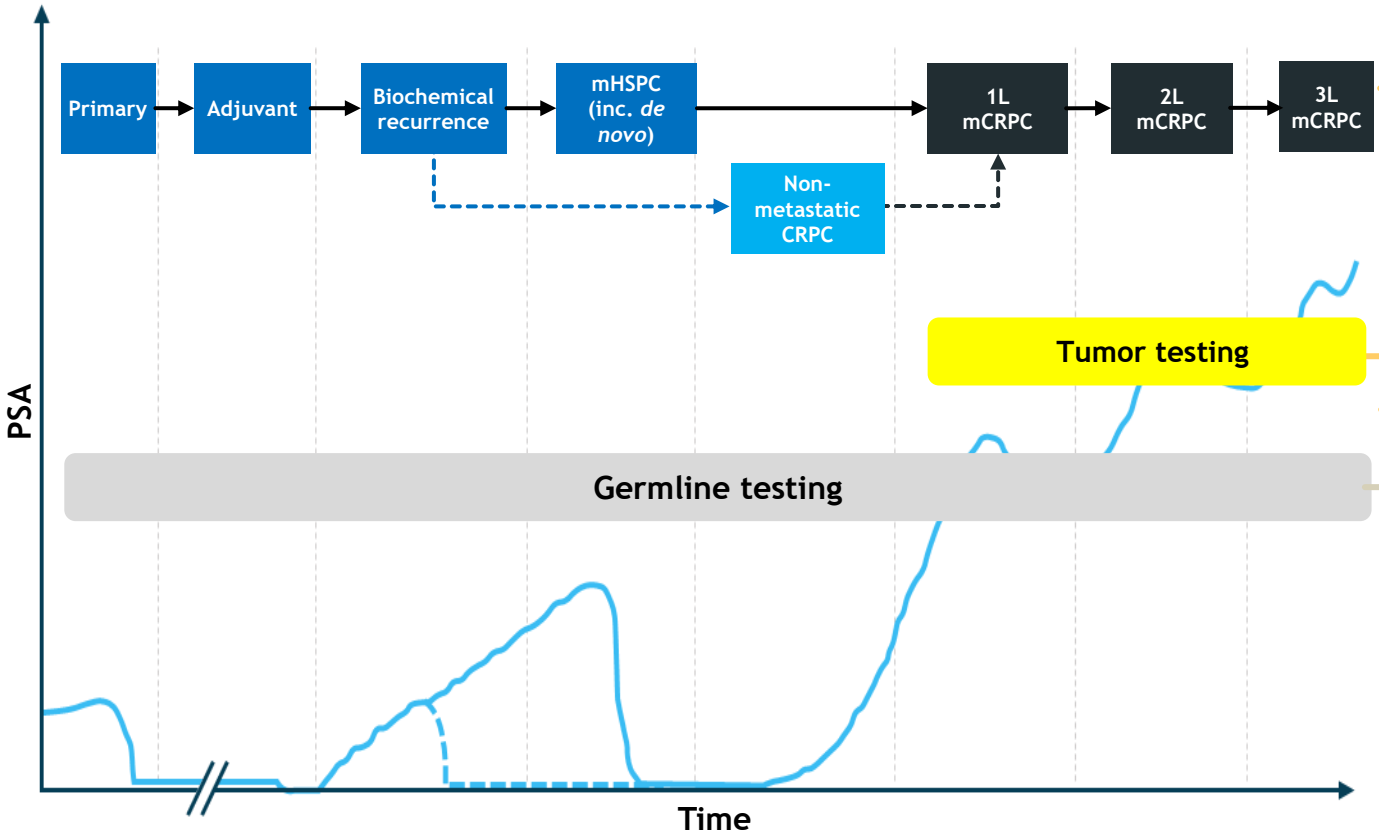
Test Requirement: blood sample

Types of Mutations Detected: germline alterations only

Time Frame for Results: within 2 weeks[4]

[1]Scott RJ, *et al*. Oncotarget 2021; [2]Xie W, *et al*. Nat Rev Drug Discov 2023; [3]ASCO Daily News 2024; [4]Myriad Genetics. https://myriad.com/genetic-tests/bracanalysiscdx-germline-test/

➢ Considerations for when to test for *HRR*m (internat. Guidelines)



Based on Scher HI, *et al*. 2016

ESMO[1,2]

- Recommended for ***BRCA2*** and other **DDR genes** associated with cancer predisposition in patients with family history of cancer
- Should be considered in all patients with metastatic prostate cancer

- **Consider HRRm** and **MSI dMRR** testing in patients with **mCRPC**

EAU/EANM/ESTRO/ESUR/ISUP/SIOG[3]

- Men with metastatic PCa;
- Men with high-risk PCa and a family member diagnosed with PCa at age <60 years;
- Men with multiple family members diagnosed with csPCa at age <60 years or a family member who died from PCa cancer;
- Men with a family history of high-risk germline mutations or a family history of multiple cancers on the same side of the family.

- **Consider HRRm** and **dMRR** testing in all patients with **mPC**

NCCN[4]

- Metastatic, regional (node positive), very-high-risk localised, or high-risk localised PCa
- Family history of certain cancers
- Known family history of familial cancer risk mutation
- Personal history of breast cancer

- Recommend **HRRm** testing in patients with **mPC.** Consider for regional PC
- Recommend testing for **MSI-H, dMMR for mCRPC.** Consider for regional or CSPC
- Consider **TMB** testing for **mCRPC**

AUA/SUO[5]

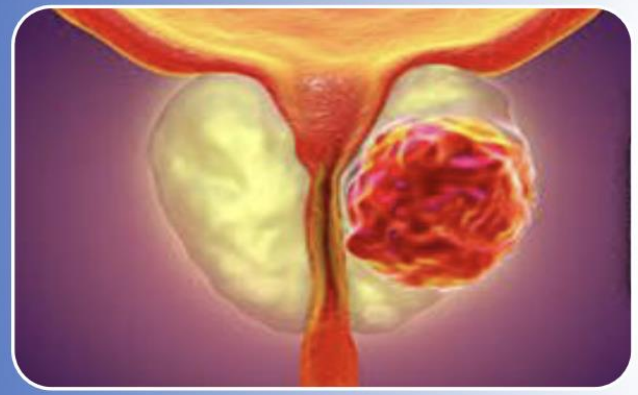
- Testing for **DDR, MSI dMMR, TMB** and other potential mutations **in mCRPC** patients
- Consider for **mHSPC patients**

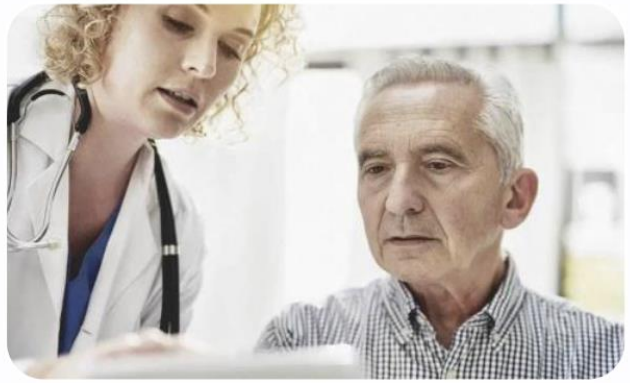
- Testing for **DDR, MSI dMMR, TMB and other potential mutations in mCRPC** patients
- Consider for **mHSPC patients**

1L/2L/3L, first/second/third line; BRCA2, breast cancer gene 2; CRPC, castration-resistant prostate cancer; csPCa, clinically significant PCa; DDR, DNA damage repair; dMMR, mismatch repair damage; HRRm, homologous recombination repair mutation; mCRPC, metastatic CRPC; mHSPC, metastatic hormone-sensitive prostate cancer; mPC, metastatic prostate cancer; MSI, microsatellite; PCa, prostate cancer; PSA, prostate-specific antigen; TMB, tumor mutational burden

[1]Parker C, *et al*. Annals of Oncology 2020; [2]Fizazi K, *et al*. Annals of Oncology 2023; [3]Mottet N, *et al*. EAU - EANM - ESTRO - ESUR - ISUP - SIOG Guidelines on Prostate Cancer 2023; [4]National Comprehensive Cancer Network, Prostate Cancer (Version 4.2023); [5]Lowrance W, *et al*. J Urol 2023; [6]Scher HI, *et al*. J Clin Oncol 2016

Faktoren bzgl. der Therapieauswahl:





Tumour Factors

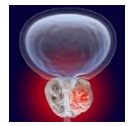
- Disease volume / risk
  - High vs low
- Metastasis timing
  - Synch vs metachronous
- Sites of mets
- Gleason score
- Sensitivity to treatment
- Biomarkers

Patient Factors

- Age
- Performance status
- Co-morbidities
- Symptoms
- Concurrent meds
- Logistics & support
- Preference

Treatment Factors

- Mode of action
- Efficacy
- Side effects
- Administration
- Availability
- Expertise
- Access & cost



Faktoren bzgl. der Therapieauswahl:

Drug-drug interaction potential of ARPIs

Drug	Substrate	Effector of:		Recommendations (including FDA drug label)
		Inhibitor	Inducer	
Abiraterone	CYP3A4	CYP2D6 *(moderate)*, CYP2C8 *(weak)*	None	Avoid strong CYP3A4 inducers Avoid the use of CYP2D6 substrates with a narrow therapeutic window
Apalutamide	CYP2C8 (major) CYP3A4 (minor)	CYP2B6	CYP3A4 *(strong)*, CYP2C19 *(strong)*, CYP2C9 *(weak)*, UGT (?), BCRP *(weak)* , P-gp *(weak)* and OATP1B1/1B3 *(weak)*	Be aware of tolerability issues when combined with strong CYP3A4 and CYP2C8 inhibitors Concomitant use of medication that are substrates of CYP3A4, 2C19, 2C9 UGT, P-gp, BCRP or OATP1B1 may lead to loss of activity of these drugs.
Enzalutamide	CYP2C8, CYP3A4	MRP2, P-gp	CYP3A4 *(strong)*, CYP2C9 *(moderate)*, CYP2C19 *(moderate)*	Avoid strong CYP2C8 inhibitors. Avoid strong CYP3A4 and CYP2C8 inducers Avoid CYP3A4, 2C9 and 2C19 substrates with a narrow therapeutic window.
Darolutamide	CYP3A4 *(minor)*, P-gp *(minor)*, UGT1A9, UGT1A1	ABCG2, OATP1B1/1B3	CYP3A4 *(weak)*	Avoid strong CYP3A4, P-gp inducers; Extra monitoring when combined with CYP3A4, P-gp inhibitors; Avoid combination with BCRP substrates with a narrow therapeutic window

Bernard A et al., Clin Pharmacol Drug Dev. 2015; Benoist GE et all., Clin Pharmacokinet. 2016; Podgoršek E., *et al. Clinical Pharmacokinetics* 2023;

BARCELONA 2024 ESMO congress

➢ Nebenwirkungsspektrum (‚NHT') [New hormonal therapies]:

Medikament	Interaktionen	Nebenwirkungen
Abirateron	CYP3A4-Hemmer/-Induktoren, Kortikosteroide, Antihypertonika	Hypertonie, Hypokaliämie, Flüssigkeitsretention, Lebertoxizität
Enzalutamid	CYP3A4-Hemmer/-Induktoren, CYP2C8-Hemmer, Antiepileptika, Warfarin	Müdigkeit, Hypertonie, Kopfschmerzen, Schwindel, Krampfanfälle (selten)
Apalutamid	CYP3A4-Hemmer/-Induktoren, CYP2C8-Hemmer, Antiepileptika	Müdigkeit, Hautausschlag, Hypertonie, Frakturen, Hypothyreose
Darolutamid	CYP3A4-Hemmer/-Induktoren, P-gp-Substrate	Müdigkeit, Stürze, Frakturen, Hautausschlag

Faktoren bzgl. der Therapieauswahl:

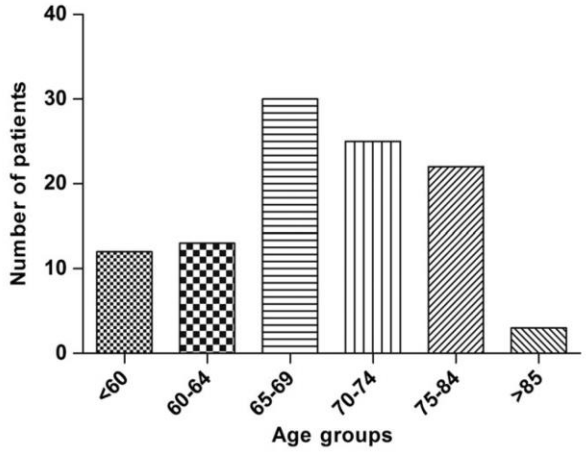


Figure 1
Age groups: the distribution of patients in the cohort in six age groups. Median age was 69 years (range 48–91 years)

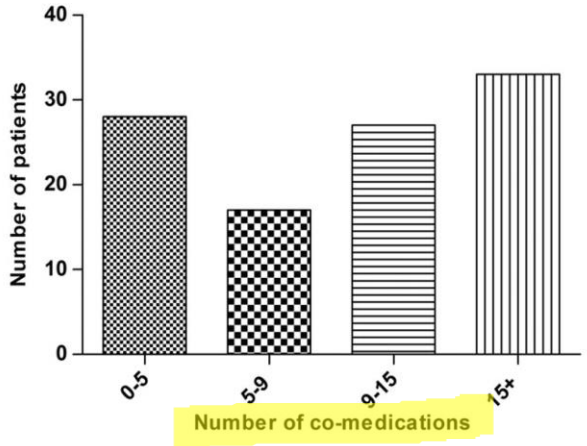


Figure 2
Number of co-medications per patient. The median number of co-medications per patients was 10 (range 1–26)

British Journal of Clinical Pharmacology
Br J Clin Pharmacol (2018) **84** 122–129 122

DRUG INTERACTIONS

Drug–drug interaction potential in men treated with enzalutamide: Mind the gap

G. E. Benoist et al.

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mCRPC

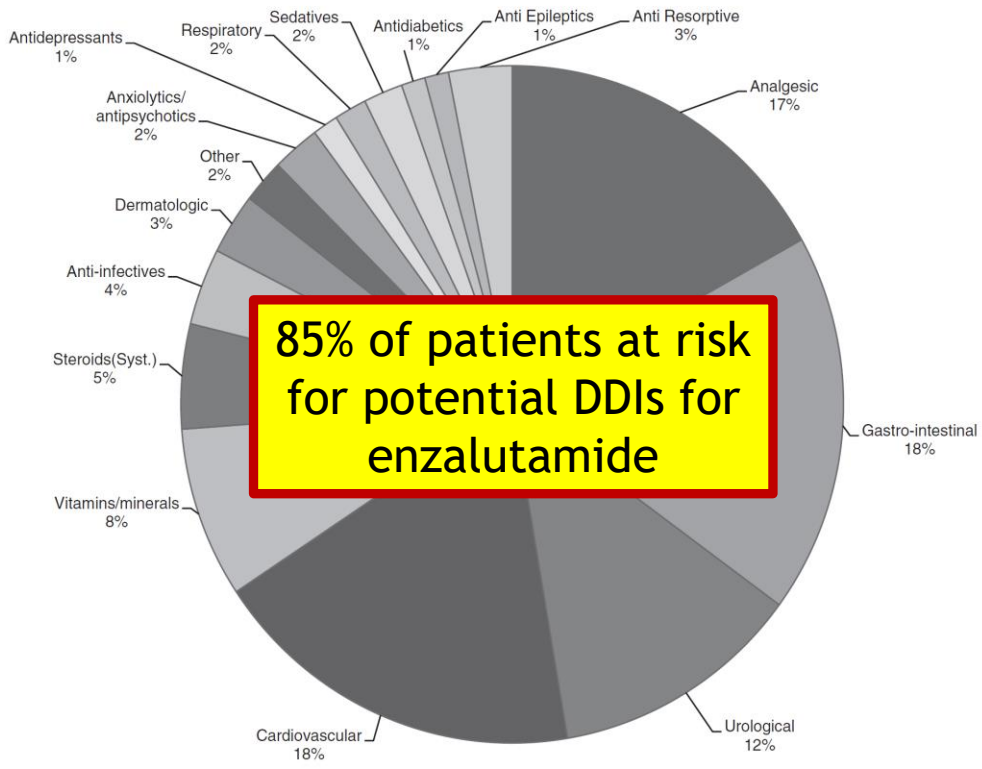
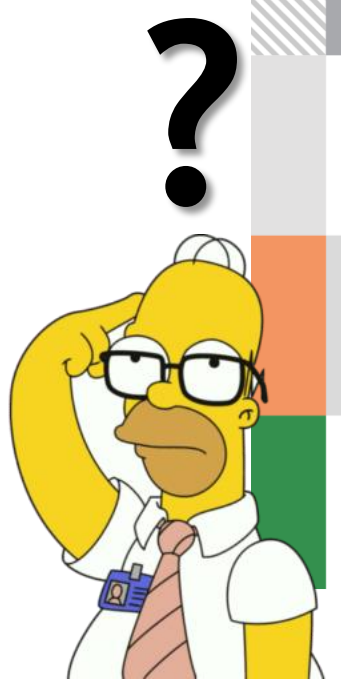


Figure 3
Classes of co-medications during enzalutamide therapy represented as percentages of the total number of co-medications (n = 1200) administrated to all patients included in the study (n = 105)



Applications of Artificial Intelligence in Prostate Cancer Care: A Path to Enhanced Efficiency and Outcomes

06/2024

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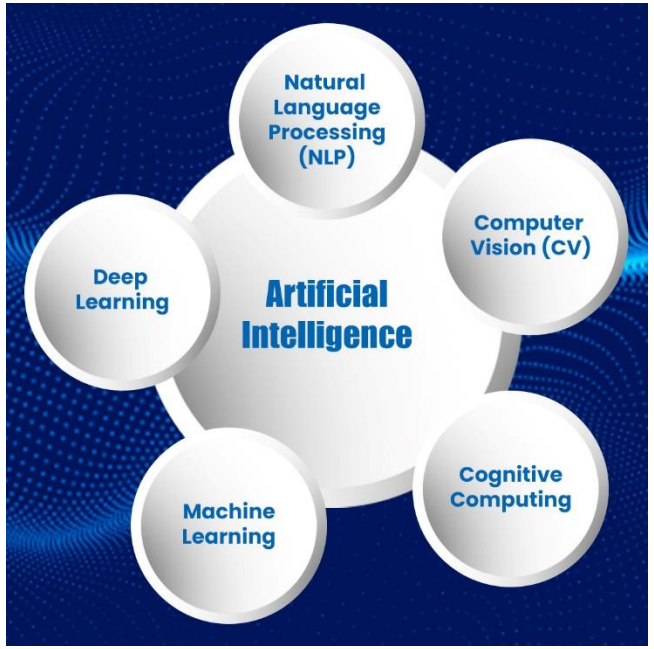
DOI https://doi.org/10.1200/EDBK_438516



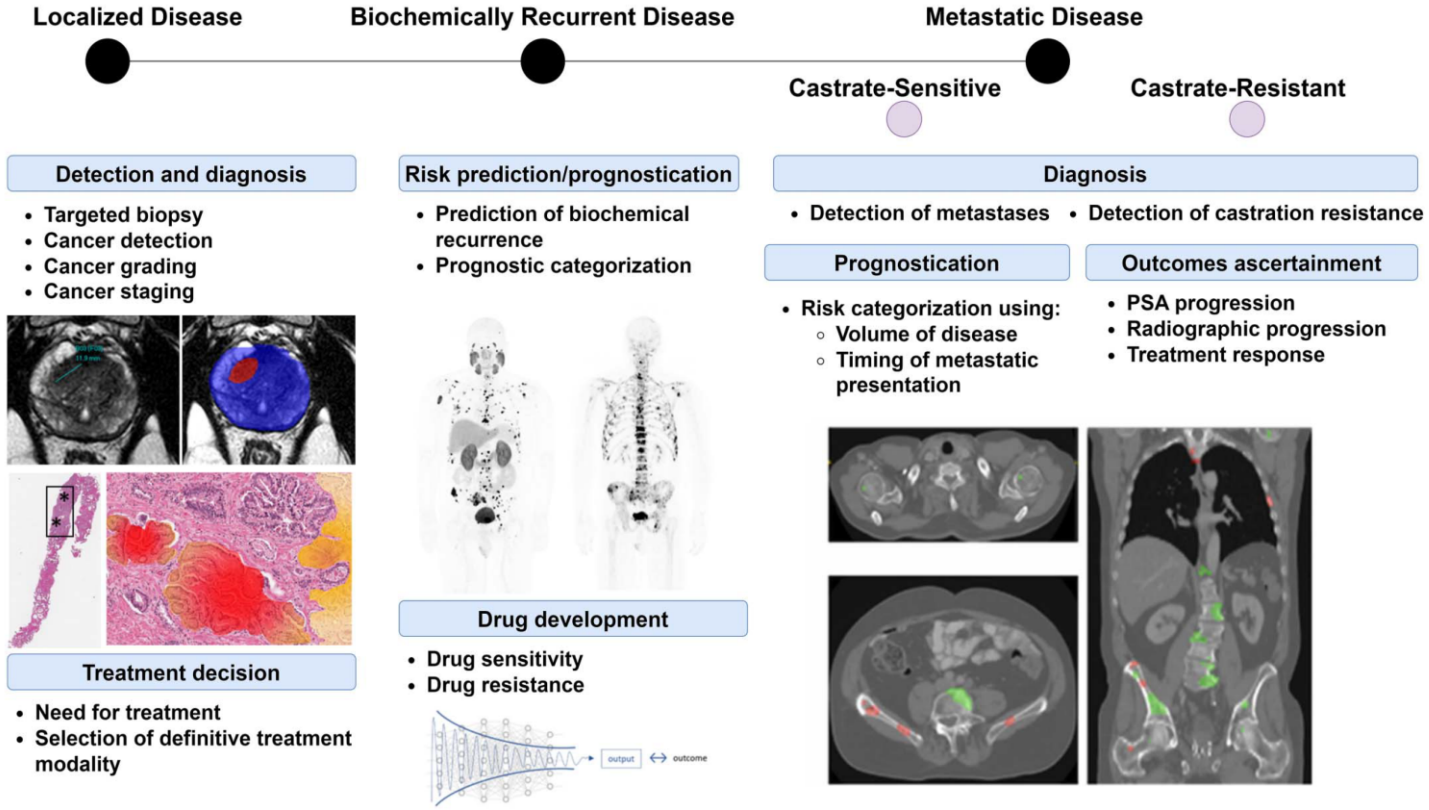


FIG 1. Major themes for translational artificial intelligence algorithms across the course of prostate cancer care. In the localized disease setting, majority of algorithm development has focused on improving diagnostics such as detection of suspicious areas on prostate MRI and detection/grading of cancerous regions on diagnostic biopsies. Further areas of interest include optimization of treatment selection and decision making. In recurrent disease, recent work has turned a focus to multimodal based models for prognostication and enhancing diagnostics. In both recurrent and late-stage disease, there exists a need for development of algorithms for disease monitoring, progression evaluation, and overall prediction of patient-centric outcomes. MRI, magnetic resonance imaging; PSA, prostate-specific antigen.

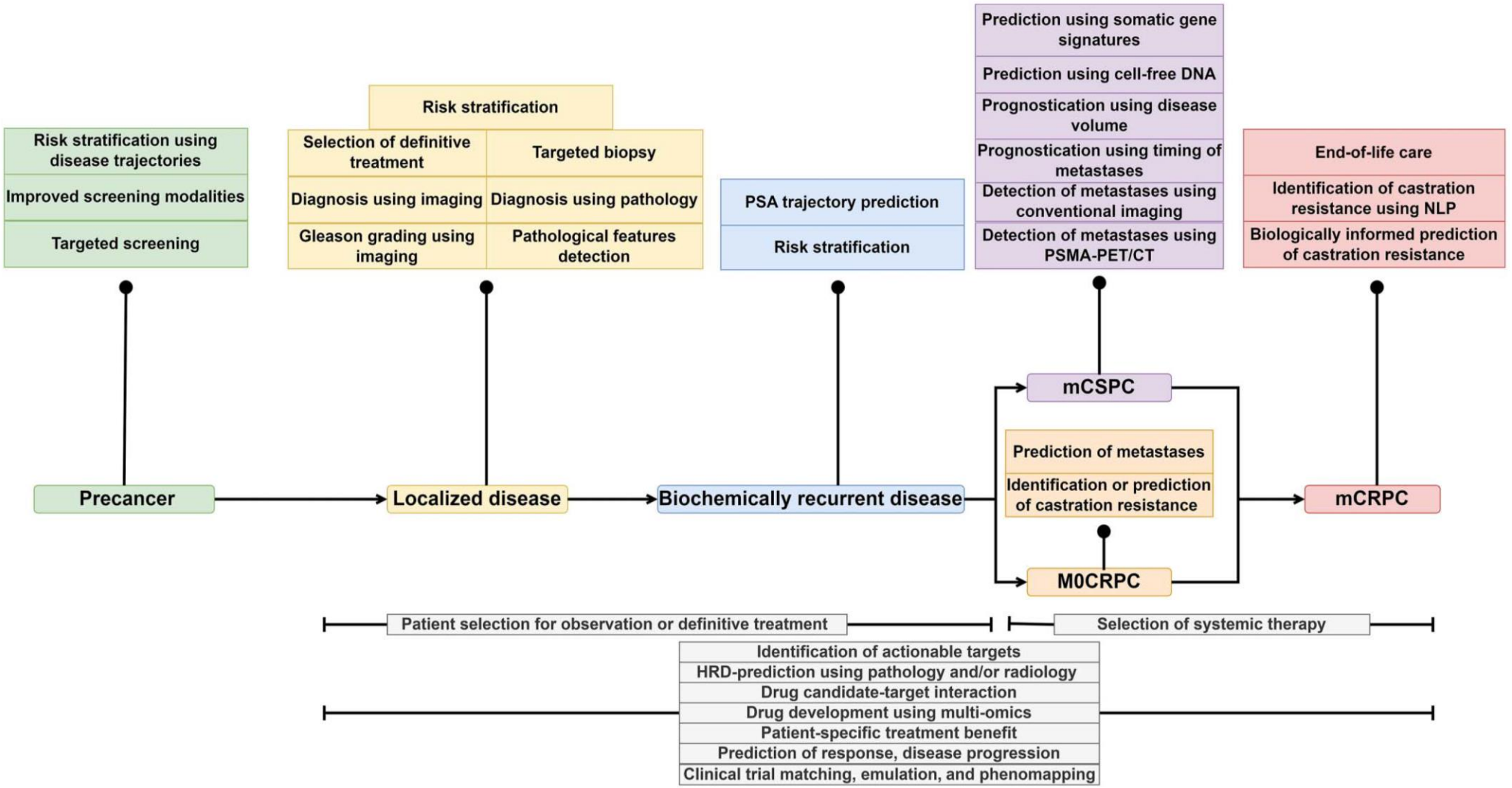


FIG 2. Framework for artificial intelligence applications across prostate cancer clinical settings. CT, computed tomography; HRD, homologous recombination deficiency; mCRPC, metastatic castration-resistant prostate cancer; mCSPC, metastatic castration-sensitive prostate cancer; NLP, natural language processing; PET, positron emission tomography; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen.

Riaz IB, *et al*. Am Soc Clin Oncol Educ Book 2024

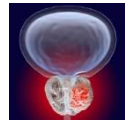


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TABLE 1. On-Going Studies for the Utility of Artificial Intelligence in Prostate Cancer Care

NCT | Study	Inclusion Criteria	Exclusion Criteria	Design	Primary Outcome Measures
NCT05355727 PROSAIC-DS Study	All patients referred to prostate MDT meetings with sufficient information for treatment decisions	Patients with inadequate data for treatment decisions, nonconsenting	Randomized parallel assignment double blind trial	Evaluation of PROSAIC-DS as a triage tool and its influence on MDTM concordance with guidelines over 6-9 months
NCT05384002 AI Platform Integrating Imaging Data	Histologically confirmed PCa or suspicion of PCa; MRI examination; age ≥18 years; signed informed consent	None specified	Nonrandomized cohort	Development of AI models for prostate cancer diagnosis and management
NCT05443412 AI-Assisted Risk-based Prostate Cancer Detection	Men ≥18 years; clinical suspicion of prostate cancer; PSA 4-20 ng/mL; digital rectal examination ≤cT2; able to provide consent	Prior prostate biopsy; past/current history of prostate cancer; contraindications to MRI or biopsy	Nonrandomized cohort	Diagnosis of csPCa; assessed by machine learning algorithms over an average of 1 year
NCT06363435 AI-based Measurements of Tumor Burden in PSMA PET-CT	Patients referred for clinically indicated 18F-PSMA-1007 PET-CT scan at Skåne University Hospital	Patients younger than 20 years	Nonrandomized cohort	Evaluation of tumor burden in relation to overall survival over a 5-year follow-up
NCT04605276 3DmpUS for Pca	Men ≥18 years with clinical suspicion or confirmed prostate cancer; scheduled for biopsy or prostatectomy; signed consent	No mpMRI performed prior; history of chemotherapy for PCa; recent prostate biopsy; hormonal therapy for prostate cancer within the past 6 months; severe pulmonary hypertension or other specified conditions	Nonrandomized cohort	Collection and analysis of 3D multiparametric ultrasound and histology data to train and improve the classifier algorithm
NCT06362291 MRI AI-cTB *v* Routine cTB	Age 45-85 years; complete mpMRI data; suspicious prostate lesions or indications of prostate biopsy; qualifying PSA levels or ratios	Received prior radiotherapy, chemotherapy, or surgery; unqualified or incomplete mpMRI data; patients not fitting the biopsy indication criteria; incomplete clinical information	Randomized parallel assignment single-blind trial	Comparison of the clinically significant prostate cancer (csPCa) detection rate between targeted biopsy and systematic biopsy combined approaches, evaluated 1 month after the biopsy procedure
NCT03452774 SYNERGY-AI	Patients with solid and hematological malignancies; cancer-related biomarkers detected; decision for clinical trial prescreening enrollment by provider and/or patient	ECOG PS >2; abnormal organ function; hospice enrollment	Nonrandomized cohort	Proportion of patients eligible for clinical trial prescreening enrollment versus actual enrollment, assessed through study completion, an average of 1 year

Abbreviations: 3D, three-dimensional; AI, artificial intelligence; csPCa, clinically significant prostate cancer; cT2, clinical T2 (stage of tumor); CTB, cognitive targeted biopsy; ECOG PS, Eastern Cooperative Oncology Group Performance Status; MDT, multidisciplinary team; MDTM, multidisciplinary team meeting; mpMRI, multiparametric magnetic resonance imaging; MRI, magnetic resonance imaging; NCT, National Clinical Trial; PCa, prostate cancer; PET-CT, positron emission tomography-computed tomography; PROSAIC-DS, Prostate Cancer Structured Assessment of Information and Decision Support; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen; PSMA-1007, a specific ligand used in PSMA-PET imaging; Skåne University Hospital, A hospital located in Skåne County, Sweden.

TABLE 2. Studies

Study	Results
Prostate cancer de	
Takeuchi et al[13] 2018	76
Ishioka et al[14] 2018	636-0.645
Mehralivand et a 2022	itivity: 0.728 itivity: 0.630
Mehralivand et a 2022	ity: 0.561 627 373
Seetharaman et 2021	t cancer 0.64-0.75 sive cancer 0.86-0.89

Prediction of clinically significant prostate cancer or PI-RADS

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