ICHOM

International Consortium for Health Outcomes Measurement

LOCALIZED PROSTATE CANCER **DATA COLLECTION REFERENCE GUIDE**

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LOCALIZED PROSTATE CANCER

We are thrilled that you are interested in measuring outcomes for your localized prostate cancer patients according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets, comprehensive yet parsimonious sets of outcomes and case-mix variables we recommend all providers track.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open up new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include initial conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary is included in the appendix.

Working Group Members for Localized Prostate Cancer

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Localized Prostate Cancer in partnership with ICHOM, under the leadership of Dr. Hartwig Huland, Founder and Chairman of the Martini Klinik in Hamburg, Germany.

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Supporting Organizations

The Localized Prostate Cancer Standard Set is made possible only through the support of the Movember Foundation, an organization changing the face of men's health.

Thank you.

Conditions and Treatment Approaches Covered for Localized Prostate Cancer

For Localized Prostate Cancer, the following conditions and treatment approaches (or interventions) are covered by our Standard Set.

Conditions	Localized prostate cancer
Treatment Approaches	Active Surveillance | Watchful Waiting | Radical Prostatectomy* | External Beam Radiation Therapy* | Androgen Deprivation Therapy (ADT)* | Focal Therapy* | Other* * These should also be collected as salvage treatments where necessary

ICHOM Standard Set for Localized Prostate Cancer

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
Patient Factors				
All patients	Age	Date of birth	Before treatment	Clinical or patient-reported
	Comorbidities	Modified Self-administered Comorbidity Questionnaire (SCQ)		
	Urinary incontinence	Tracked via EPIC-26	Before treatment; 6 months after treatment; Annually up to 10 years	Patient-reported
	Urinary frequency / urgency / irritation			
	Bowel irritation			
Patients who received ADT	Hormonal symptoms			
All patients	Sexual dysfunction	Tracked via EPIC-26 + additional questions from the Utilization of Sexual Medications/Devices questionnaire and the EORTC QLQ-PR25		
Baseline Tumor Factors				
All patients	Date of diagnosis	Date of initial diagnosis	Before treatment	Clinical or administrative data
	PSA level	Most recent PSA value before histologic diagnosis		Clinical
	AJCC 7th Clinical Stage	cT category, cN category, and cM category		
	Number of biopsy cores involved	Number of cores take; number of cores positive		
	Greatest percentage involvement	Greatest percentage involvement from biopsy results		
	Gleason score	The highest primary and secondary Gleason grade		
Pathological Information				
RP patients	AJCC 7th Pathologic Stage	pT category, pN category	After surgery	Clinical
	Margin status	Negative/Positive (if positive, focal/multifocal)		
	Gleason score	The highest primary and secondary Gleason grade		

Treatment Variables

Patient Population	Measure	Supporting Information	Timing	Data Source
All patients	Active surveillance	N/A	Within 6 months after treatment initiation	Clinical
	Watchful waiting	N/A		
	Radical prostatectomy	Nerve-sparing or non-nerve-sparing		
	External beam radiation therapy	Total dose and dose per fractions		
	Brachytherapy	High- or low-dose rate		
	Androgen deprivation therapy	Was ADT part of the primary treatment?		
	Focal therapy	Type		
	Other	N/A		

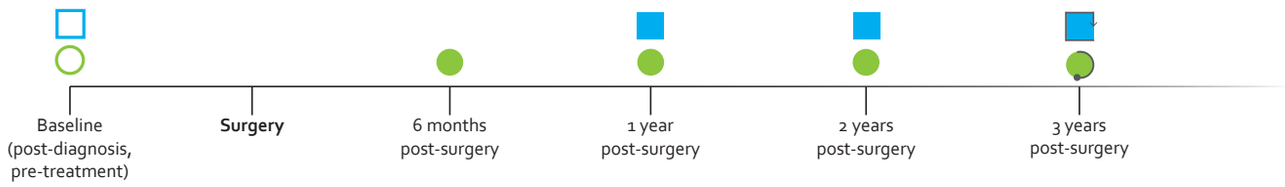
Outcomes

Patient Population	Measure	Supporting Information	Timing	Data Source
Acute Complications of Treatment				
Surgery patients	Major surgical complications	Presence or absence of Clavien Dindo grade 3, 4	Occurring within 6 months after treatment	Clinical
Radiation (or other) patients	Major radiation complications	Presence or absence of CTCAE grade 3, 4 including name of the adverse event		
Patient-Reported Health Status				
All patients	Urinary incontinence	Tracked via EPIC-26	Before treatment; 6 months after treatment; Annually up to 10 years	Patient-reported
	Urinary frequency / urgency / irritation			
	Bowel irritation			
Patients who received ADT	Hormonal symptoms			
All patients	Sexual dysfunction	Tracked via EPIC-26 + additional questions from the Utilization of Sexual Medications/Devices questionnaire and the EORTC QLQ-PR25		
Survival and Disease Control				
All patients	Overall survival	Date of death	For life	Administrative data (Death registry)
	Cause-specific survival	Was death attributed to prostate cancer on death certificate?		
	Development of metastasis	Including whether diagnosed clinically or radiographically		Clinical
	Biochemical recurrence	Indicate date of PSA recurrence if applicable All PSAs and dates following treatment should be collected		

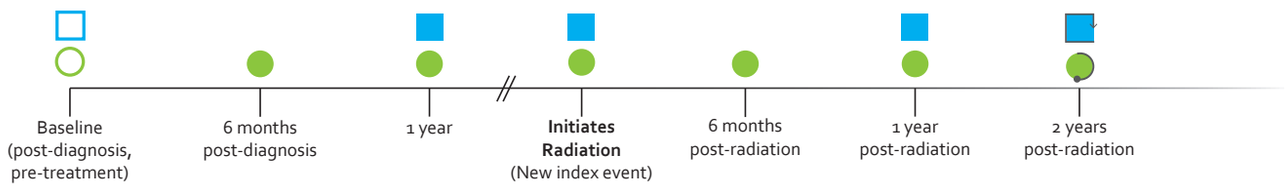
Follow-Up Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

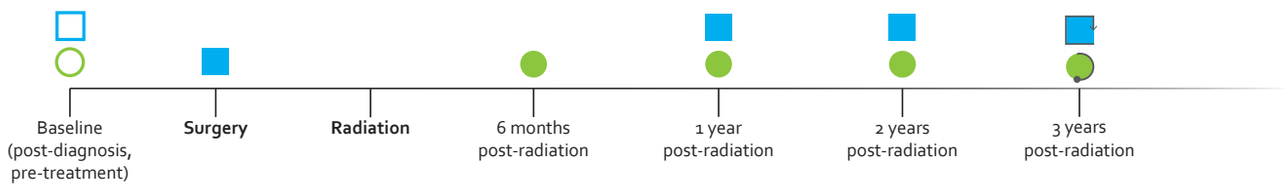
Example 1:



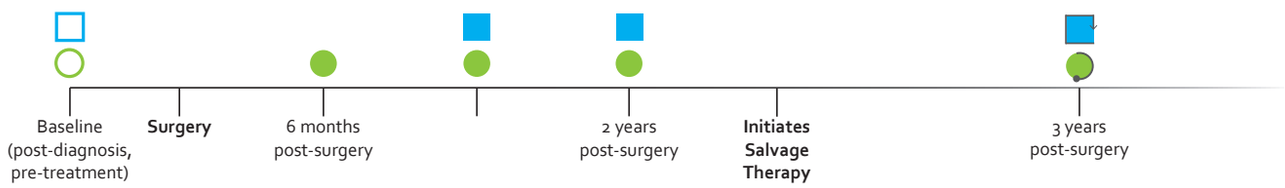
Example 2:



Example 3:



Example 4:



The following questionnaires should be administered at the indicated time points

- Baseline Patient-Reported Form (link)
- Baseline and Post-Procedure Clinical Form (link)
- Follow-Up Patient-Reported Form (link)
- Follow-Up Clinical Form (link)
- Tracked Ongoing Annually for Life
- Tracked annually for 10 years

Index Events

The entry point for measurement of the Localized Prostate Cancer Standard Set is the diagnosis of localized prostate cancer, regardless of treatment choice. We recognize some institutions may not have access to diagnosed patients who are currently under active surveillance or watchful waiting, and we recommend them to start by focusing on those patients they treat directly.

When men currently on active surveillance or watchful waiting progress to curative treatment, such as surgery or radiation therapy, we recommend a reset of the measurement scheme and timeline, including the reassessment of case-mix factors. Likewise, when patients are diagnosed with advanced prostate cancer, not treated by salvage therapy, we recommend the transition of measurement to the ICHOM Advanced Prostate Cancer Standard Set. We do not recommend restarting the measurement timeline when a man goes on to need salvage therapy.

Collecting Patient-Reported Outcome Measures

Survey(s) Used	Licensing Information	Scoring Guide
Expanded Prostate Cancer Index Composite (EPIC-26)	The EPIC-26 is free for all health care organizations, and a license is not needed.	The scoring guide may be found at **http://www.med.umich.edu/urology/research/EPIC/EPIC-26-Scoring-1.2007.pdf**
Utilization of Sexual Medications/ Devices	The Utilization of Sexual Medications/Devices is free for all health care organizations, and a license is not needed.	N/A; Refer to **http://dx.doi.org/10.1016/j.urology.2006.01.077** for more information
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-PR25)	The EORTC QLQ-PR25 is free for all health care organizations, but a license is needed for use. For more information, please visit **http://groups.eortc.be/qol/eortc-qlq-c30**	See link at left

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at **implement@ichom.org**, or visit **http://www.ichom.org/measure**.

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Localized Prostate Cancer Standard Set as consistently as possible to the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Data Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Patient Factors

Variable ID:	AGE
Variable:	Age
Definition:	What is your date of birth?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical or patient-reported
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	COMORB
Variable:	Comorbidities
Definition:	Have you been told by a doctor that you have any of the following?
Supporting Definition:	Based upon the Self-administered Comorbidity Questionnaire (Sangha et al, 2003)
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Patient-reported
Type:	Multiple answer Separate multiple entries with ";"
Response Options:	0 = I have no other diseases 1 = Heart disease (for example angina, heart attack, or heart failure) 2 = High blood pressure 3 = Leg pain when walking due to poor circulation 4 = Lung disease (for example asthma, chronic bronchitis, or emphysema) 5 = Diabetes 6 = Kidney disease

7 = Liver disease
8 = Problems caused by stroke
9 = Disease of the nervous system (for example Parkinson's disease or multiple sclerosis)
10 = Other cancer (within the last 5 years)
11 = Depression
12 = Arthritis

Baseline Tumor Factors

Variable ID:	DIAGDATE
Variable:	Date of histological diagnosis
Definition:	Indicate the initial date of histological diagnosis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical or administrative data
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PSA
Variable:	Most recent PSA value before histological diagnosis
Definition:	Indicate most recent PSA value before histological diagnosis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of PSA level in ng/mL
Variable ID:	TNMCT
Variable:	Clinical tumor stage
Definition:	Indicate the clinical tumor stage (per AJCC 7th)
Supporting Definition:	Pathologic staging preferred, if available cT0: No evidence of primary tumor cT1: if not able to select cT1a, cT1b or cT1c: Clinically inapparent tumor neither palpable nor visible by imaging cT1a: Tumor incidental histologic finding in 5 percent or less of tissue resected cT1b: Tumor incidental histologic finding in more than 5 percent of tissue resected cT1c: Tumor identified by needle biopsy (eg, because of elevated PSA) cT2: if not able to select cT2a, cT2b or cT2c: Tumor confined within prostate* cT2a: Tumor involves one-half of one lobe or less cT2b: Tumor involves more than one-half of one lobe but not both lobes cT2c: Tumor involves both lobes cT3: if not able to select cT3a, cT3b or cT3c: Tumor extends through the prostate capsule cT3a: Extracapsular extension (unilateral or bilateral) cT3b: Tumor invades seminal vesicle(s) cT4: Tumor is fixed or invades adjacent structures other than seminal vesicles such as external sphincter, rectum, bladder, levator muscles, and/or pelvic wall cTX: Primary tumor cannot be assessed
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = cT0 1 = cT1 2 = cT1a 3 = cT1b

	4 = cT1c 5 = cT2 6 = cT2a 7 = cT2b 8 = cT2c 9 = cT3 10 = cT3a 11 = cT3b 12 = cT4 13 = cTX 999 = Unknown
Variable ID:	TNMCN
Variable:	Clinical nodal stage
Definition:	Indicate the clinical nodal stage (per AJCC 7th)
Supporting Definition:	Pathologic staging preferred, if available cN0: regional lymph node metastasis cN1: Metastasis in regional lymph node(s) cNX: Regional lymph nodes were not assessed
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = cN0 1 = cN1 2 = cNX 999 = Unknown
Variable ID:	BIOPCORE
Variable:	Number of biopsy cores taken
Definition:	Indicate the number of cores taken during the patient's biopsy
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of number of biopsy cores
Variable ID:	BIOPPOS
Variable:	Number of biopsy cores positive
Definition:	Indicate the number of cores that are positive
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of number of biopsy cores
Variable ID:	BIOPINVOL
Variable:	Greatest percentage involvement
Definition:	Indicate the greatest percentage cancer involvement in any one biopsy core
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of greatest percentage involvement of any one biopsy core
Variable ID:	GLEASONBIOP1
Variable:	Gleason score: Primary
Definition:	If yes, indicate the primary Gleason score at time of initial diagnosis
Supporting Definition:	N/A

Inclusion Criteria: All patients
Timing: Before treatment
Data Source: Clinical
Type: Numerical value
Response Options: 1-5

Variable ID: GLEASONBIOP2
Variable: Gleason score: Secondary
Definition: If yes, indicate the secondary Gleason score at time of initial diagnosis
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
Data Source: Clinical
Type: Numerical value
Response Options: 1-5

Pathological Information

Variable ID: TNMPT
Variable: Pathological tumor stage
Definition: Indicate the pathological tumor stage (per AJCC 7th)
Supporting Definition: Pathologic staging preferred, if available
pT2: if not able to select T2a, T2b or T2c: Organ confined
pT2a: Unilateral, one-half of one side or less
pT2b: Unilateral, involving more than one-half of side but not both sides
pT2c: Bilateral disease
pT3: if not able to select T3a, T3b: Extraprostatic extension
pT3a: Extraprostatic extension or microscopic invasion of bladder neck
pT3b: Seminal vesicle invasion
pT4: Invasion of rectum, levator muscles, and/or pelvic wall
pTX: Primary tumor cannot be assessed
Inclusion Criteria: Patients who undergo surgical interventions
Timing: After primary or salvage surgery
Data Source: Clinical
Type: Single answer
Response Options: 1 = pT2
2 = pT2a
3 = pT2b
4 = pT2c
5 = pT3
6 = pT3a
7 = pT3b
8 = pT4
9 = pTX
999 = Unknown

Variable ID: TNMPN
Variable: Pathological nodal stage
Definition: Indicate the pathological nodal stage (per AJCC 7th)
Supporting Definition: Pathologic staging preferred, if available
pN0: No positive regional nodes
pN1: Metastases in regional node(s)
pNX: Regional nodes not sampled
Inclusion Criteria: Patients who undergo surgical interventions
Timing: After primary or salvage surgery
Data Source: Clinical
Type: Single answer
Response Options: 0 = pN0
1 = pN1
2 = pNX

	999 = Unknown
Variable ID:	MARGIN
Variable:	Margin status
Definition:	Indicate margin status
Supporting Definition:	N/A
Inclusion Criteria:	Patients who undergo surgical interventions
Timing:	After primary or salvage surgery
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = Negative 1 = Positive 999 = Unknown
Variable ID:	MARGINFOC
Variable:	Margin status focality
Definition:	Indicate if margin status is focal or multi-focal
Supporting Definition:	N/A
Inclusion Criteria:	Patients who undergo surgical interventions If answered 'positive' to margin status (MARGIN)
Timing:	After primary or salvage surgery
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Focal 2 = Multi-focal 999 = Unknown
Variable ID:	GLEASONPATH1
Variable:	Pathological Gleason grade: Primary
Definition:	If yes, indicate the primary Gleason score based upon surgical pathology
Supporting Definition:	N/A
Inclusion Criteria:	Patients who undergo surgical interventions
Timing:	After primary or salvage surgery
Data Source:	Clinical
Type:	Numerical value
Response Options:	1-5
Variable ID:	GLEASONPATH2
Variable:	Pathological Gleason grade: Secondary
Definition:	If yes, indicate the secondary Gleason score based upon surgical pathology
Supporting Definition:	N/A
Inclusion Criteria:	Patients who undergo surgical interventions
Timing:	After primary or salvage surgery
Data Source:	Clinical
Type:	Numerical value
Response Options:	1-5

*** For registries choosing to implement the EPIC-CP rather than the EPIC-26, we recommend using the same variable IDs as the corresponding EPIC-26 questions. This means that only questions 2, 3, 4a, 4b, 4d, 4e, 5, 6e, 6b, 7, 8b, 9, 12, 13a, 13c, and 13d of the EPIC-26 are administered.**

Treatment Variables

Variable ID:	PRIMARYTX
Variable:	Treatment modalities used
Definition:	Indicate the primary treatment modalities used for this patient
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Multiple answer
Response Options:	1 = Watchful waiting 2 = Active surveillance 3 = Radical prostatectomy 4 = External beam radiation therapy (primary treatment or adjuvant following surgery) 5 = Brachytherapy 6 = Androgen deprivation therapy 7 = Focal therapy 888 = Other
Variable ID:	PRWATCHDATE
Variable:	Date watchful waiting initiated
Definition:	Indicate date watchful waiting initiated
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Watchful waiting' (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PRACTIVEDATE
Variable:	Date active surveillance initiated
Definition:	Inidicate date active surveillance initiated
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Active surveillance' (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PRRADPROTXDATE
Variable:	Date of primary radical prostatectomy
Definition:	Indicate date of primary radical prostatectomy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Radical prostatectomy' (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PRNERVESPARE
Variable:	Primary nerve sparing status
Definition:	Indicate if the primary surgical approach was nerve-sparing or non-nerve-sparing
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Radical prostatectomy' on primary treatment modalities

	(PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Non-nerve-sparing 2 = Nerve-sparing
Variable ID:	PREBRTTOTDOSE
Variable:	Primary external Beam Radiation Therapy: Dose (Gray)
Definition:	Indicate the total dose of primary External Beam Radiation Therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'External beam radiation therapy (primary treatment or adjuvant following surgery)' on primary treatment modalities (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of dose in Gray (###)
Variable ID:	PREBRTDOSEPERFRACT
Variable:	Primary external Beam Radiation Therapy: Average dose per fraction (Gray)
Definition:	Indicate the average dose per fraction of primary External Beam Radiation Therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'External beam radiation therapy (primary treatment or adjuvant following surgery)' on primary treatment modalities (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Numerical value
Response Options:	Numerical value of average dose per fraction in Gray (##.#)
Variable ID:	PREBRTTXSTARTDATE
Variable:	Start date of primary external beam radiation therapy
Definition:	Indicate start date of primary external beam radiation therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'External beam radiation therapy' (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PREBRTTXSTOPDATE
Variable:	Stop date of primary external beam radiation therapy
Definition:	Indicate stop date of primary external radiation therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'External beam radiation therapy' (PRIMARYTX)
Timing:	Within 6 months after primary treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	PREBRTTXONGOING
Variable:	Ongoing primary external beam radiation therapy
Definition:	Indicate if primary external beam radiation therapy is ongoing
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'External beam radiation therapy' (PRIMARYTX), and no end date is entered (PREBRTTXSTOPDATE)
Timing:	Within 6 months after primary treatment initiation

Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: PRBRACHYTXSTARTDATE
Variable: Start date of primary brachytherapy
Definition: Indicate start date of primary brachytherapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRBRACHYTXSTOPDATE
Variable: Stop date of primary brachytherapy
Definition: Indicate stop date of primary brachytherapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRBRACHYTXONGOING
Variable: Ongoing primary brachytherapy
Definition: Indicate if primary brachytherapy is ongoing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' (PRIMARYTX), and no end date is entered (PRBRACHYTXSTOPDATE)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: PRBRACHYDOSERATE
Variable: Primary brachytherapy dose
Definition: Indicate whether high-dose or low-dose brachytherapy was given
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' on primary treatment modalities (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Low dose
2 = High dose
999 = Unknown

Variable ID: PRADTTXSTARTDATE
Variable: Start date of primary androgen deprivation therapy
Definition: Indicate start date of primary androgen deprivation therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Androgen deprivation therapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRADTTXSTOPDATE

Variable: Stop date of primary androgen deprivation therapy
Definition: Indicate stop date of primary androgen deprivation therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Androgen deprivation therapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRADTTXONGOING
Variable: Ongoing primary androgen deprivation therapy
Definition: Indicate if primary androgen deprivation therapy is ongoing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Androgen deprivation therapy' (PRIMARYTX), and no end date is entered (PRADTTXSTOPDATE)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: PRIMARYTXFT
Variable: Type of focal therapy
Definition: Indicate the type of focal therapy used for this patient
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' on primary treatment modalities used (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Free text
Response Options: Primary treatment modality

Variable ID: PRFOCTXSTARTDATE
Variable: Start date of primary focal therapy
Definition: Indicate start date of primary focal therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRFOCTXSTOPDATE
Variable: Stop date of primary focal therapy
Definition: Indicate stop date of primary focal therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PRFOCTXONGOING
Variable: Ongoing primary focal therapy
Definition: Indicate if primary focal therapy is ongoing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (PRIMARYTX), and no end date is entered (PRFOCTXSTOPDATE)

Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: PRIMARYTXOTHER
Variable: Primary treatment modality other than those explicitly listed
Definition: Indicate the other primary treatment modality used
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Other' on primary treatment modalities used (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Free text
Response Options: Primary treatment modality

Variable ID: PROTHERTXSTARTDATE
Variable: Start date of other primary therapy
Definition: Indicate start date of other primary therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Other' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PROTHERTXSTOPDATE
Variable: Stop date of other primary therapy
Definition: Indicate stop date of other primary therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Other' (PRIMARYTX)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: PROTHERTXONGOING
Variable: Ongoing other therapy
Definition: Indicate if other primary therapy is ongoing
Supporting Definition: NA
Inclusion Criteria: All patients
If answered 'Other' (PRIMARYTX), and no end date is entered (PROTHERTXONGOING)
Timing: Within 6 months after primary treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: SALVAGETXINI
Variable: Salvage treatment initiated (within last year?)
Definition: Indicate whether the patient has undergone salvage therapy in the last year
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 0 = No
1 = Yes

Variable ID: SALVAGETX
Variable: Salvage treatment modalities used

Definition: Indicate which treatment modalities were used for salvage therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered '1 = Yes' on salvage treatment initiated (SALVAGETXINI)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Multiple answer
Response Options: 1 = Radical prostatectomy
2 = External beam radiation therapy
3 = Brachytherapy
4 = Androgen deprivation therapy
5 = Focal therapy
888 = Other (free text)

Variable ID: SALVAGETXOTHER
Variable: Salvage treatment modality other than those explicitly listed
Definition: Indicate the other salvage treatment modality used
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered '888 = Other' on salvage treatment modalities used (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Free text
Response Options: Salvage treatment modality

Variable ID: SVRADPROTXDATE
Variable: Date of radical prostatectomy
Definition: Indicate date of radical prostatectomy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Radical prostatectomy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVNERVESPARE
Variable: Nerve sparing status
Definition: Indicate if the surgical approach was nerve-sparing or non-nerve-sparing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered '1 = Radical prostatectomy' on primary treatment modalities (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Non-nerve-sparing
2 = Nerve-sparing

Variable ID: SVEBRTTOTDOSE
Variable: External Beam Radiation Therapy: Dose (Gray)
Definition: Indicate the total dose of External Beam Radiation Therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered '2 = External beam radiation therapy (primary treatment or adjuvant following surgery)' on primary treatment modalities (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Numerical value
Response Options: Numerical value of dose in Gray (###)

Variable ID: SVEBRTDOSEPERFRACT

Variable: External Beam Radiation Therapy: Average dose per fraction (Gray)
Definition: Indicate the average dose per fraction of External Beam Radiation Therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered '2 = External beam radiation therapy (primary treatment or adjuvant following surgery)' on primary treatment modalities (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Numerical value
Response Options: Numerical value of average dose per fraction in Gray (##.#)

Variable ID: SVEBRTTXSTARTDATE
Variable: Start date of external beam radiation therapy
Definition: Indicate start date of external beam radiation therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'External beam radiation therapy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVEBRTTXSTOPDATE
Variable: Stop date of external beam radiation therapy
Definition: Indicate stop date of external radiation therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'External beam radiation therapy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVEBRTTXONGOING
Variable: Ongoing external beam radiation therapy
Definition: Indicate if external beam radiation therapy is ongoing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'External beam radiation therapy' (SALVAGETX), and no end date is entered (SVEBRTTXSTOPDATE)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: SVBRACHYTXSTARTDATE
Variable: Start date of brachytherapy
Definition: Indicate start date of brachytherapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVBRACHYTXSTOPDATE
Variable: Stop date of brachytherapy
Definition: Indicate stop date of brachytherapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Brachytherapy' (SALVAGETX)

Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	SVBRACHYTXONGOING
Variable:	Ongoing brachytherapy
Definition:	Indicate if brachytherapy is ongoing
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Brachytherapy' (SALVAGETX), and no end date is entered (SVBRACHYTXSTOPDATE)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Treatment ongoing
Variable ID:	SVBRACHYDOSERATE
Variable:	Brachytherapy dose
Definition:	Indicate whether high-dose or low-dose brachytherapy was given
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered '3 = Brachytherapy' on primary treatment modalities (SALVAGETX)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Low dose 2 = High dose 999 = Unknown
Variable ID:	SVADTTXSTARTDATE
Variable:	Start date of androgen deprivation therapy
Definition:	Indicate start date of androgen deprivation therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Androgen deprivation therapy' (SALVAGETX)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	SVADTTXSTOPDATE
Variable:	Stop date of androgen deprivation therapy
Definition:	Indicate stop date of androgen deprivation therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Androgen deprivation therapy' (SALVAGETX)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	SVADTTXONGOING
Variable:	Ongoing androgen deprivation therapy
Definition:	Indicate if androgen deprivation therapy is ongoing
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'Androgen deprivation therapy' (SALVAGETX), and no end date is entered (SVADTTXSTOPDATE)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Single answer

Response Options: 1 = Treatment ongoing

Variable ID: SVFOCTXSTARTDATE
Variable: Start date of focal therapy
Definition: Indicate start date of focal therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVFOCTXSTOPDATE
Variable: Stop date of focal therapy
Definition: Indicate stop date of focal therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVFOCTXONGOING
Variable: Ongoing focal therapy
Definition: Indicate if focal therapy is ongoing
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Focal therapy' (SALVAGETX), and no end date is entered (SVFOCTXSTOPDATE)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Single answer
Response Options: 1 = Treatment ongoing

Variable ID: SVOTHERTXSTARTDATE
Variable: Start date of other therapy
Definition: Indicate start date of other therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Other' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVOTHERTXSTOPDATE
Variable: Stop date of other therapy
Definition: Indicate stop date of other therapy
Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'Other' (SALVAGETX)
Timing: Annually after salvage treatment initiation
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: SVOTHERTXONGOING
Variable: Ongoing other therapy
Definition: Indicate if other therapy is ongoing
Supporting Definition: NA
Inclusion Criteria: All patients

	If answered 'Other' (SALVAGETX), and no end date is entered (SVOTHERTXONGOING)
Timing:	Annually after salvage treatment initiation
Data Source:	Clinical
Type:	Single answer
Response Options:	1 = Treatment ongoing

Outcomes

Acute Complications of Treatment

Variable ID:	COMPLSURG
Variable:	Clavien complication (maximum grade)
Definition:	Indicate whether patient experienced a Clavien grade III-V complication
Supporting Definition:	N/A
Inclusion Criteria:	Patients who undergo surgical interventions
Timing:	Occurring within 6 months after primary or salvage radical prostatectomy
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes, grade 3 2 = Yes, grade 4
Variable ID:	COMPLRAD
Variable:	CTCAE grade 3 or 4 complication during treatment or within 6 months after completing treatment
Definition:	Indicate whether the patient experienced a CTCAE grade 3 or 4 complication during treatment with radiation therapy or within the first 6 months following the completion of radiation therapy
Supporting Definition:	N/A
Inclusion Criteria:	All patients undergoing primary or salvage radiation therapy
Timing:	During primary or salvage radiation therapy treatment and the 6 months following completion of therapy
Data Source:	Clinical
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	COMPLRADDOMGRA
Variable:	CTCAE domain and grade
Definition:	If yes, note domain and grade
Supporting Definition:	The CTCAE defines Grade 3 and 4 complications for the following categories as follows: Fatigue - Grade 1: Fatigue relieved by rest - Grade 2: Fatigue not relieved by rest; limiting instrumental ADL - Grade 3: Fatigue not relieved by rest, limiting self care ADL - Grade 4: N/A Dermatitis radiation - Grade 1: Faint erythema or dry desquamation - Grade 2: Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema - Grade 3: Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion - Grade 4: Life-threatening consequences; skin necrosis or ulceration of full

thickness dermis; spontaneous bleeding from involved site; skin graft indicated
Diarrhea

- Grade 1: Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline
- Grade 2: Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline
- Grade 3: Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL
- Grade 4: Life-threatening consequences; urgent intervention indicated

Abdominal pain
- Grade 1: Mild pain
- Grade 2: Moderate pain; limiting instrumental ADL
- Grade 3: Severe pain; limiting self care ADL
- Grade 4: N/A

Rectal mucositis
- Grade 1: Asymptomatic or mild symptoms; intervention not indicated
- Grade 2: Symptomatic; medical intervention indicated; limiting instrumental ADL
- Grade 3: Severe symptoms; limiting self care ADL
- Grade 4: Life-threatening consequences; urgent operative intervention indicated

Proctitis
- Grade 1: Rectal discomfort, intervention not indicated
- Grade 2: Symptoms (e.g., rectal discomfort, passing blood or mucus); medical intervention indicated; limiting instrumental ADL
- Grade 3: Severe symptoms; fecal urgency or stool incontinence; limiting self care ADL
- Grade 4: Life-threatening consequences; urgent intervention indicated

Hot flashes
- Grade 1: Mild symptoms; intervention not indicated
- Grade 2: Moderate symptoms; limiting instrumental ADL
- Grade 3: Severe symptoms; limiting self care ADL
- Grade 4: N/A

Cystitis non-infective
- Grade 1: Microscopic hematuria; minimal increase in frequency, urgency, dysuria, or nocturia; new onset of incontinence
- Grade 2: Moderate hematuria; moderate increase in frequency, urgency, dysuria, nocturia or incontinence; urinary catheter placement or bladder irrigation indicated; limiting instrumental ADL
- Grade 3: Gross hematuria; transfusion, IV medications or hospitalization indicated; elective endoscopic, radiologic or operative intervention indicated
- Grade 4: Life-threatening consequences; urgent radiologic or operative intervention indicated

Urinary retention
- Grade 1: Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
- Grade 2: Placement of urinary, suprapubic or intermittent catheter placement indicated; medication indicated
- Grade 3: Elective operative or radiologic intervention indicated; substantial loss of affected kidney function or mass
- Grade 4: Life-threatening consequences; organ failure; urgent operative intervention indicated

Inclusion Criteria: All patients undergoing primary or salvage radiation therapy

Timing: During primary or salvage radiation therapy treatment and the 6 months following completion of therapy

Data Source: Clinical

Type: Multiple answer

	Arrange as array (see sample questionnaire)
Response Options:	0 = No grade 3 or 4 toxicity 1 = Fatigue grade 3 2 = Fatigue grade 4 3 = Dermatitis grade 3 4 = Dermatitis grade 4 5 = Diarrhea grade 3 6 = Diarrhea grade 4 7 = Abdominal pain grade 3 8 = Abdominal pain grade 4 9 = Rectal mucositis grade 3 10 = Rectal mucositis grade 4 11 = Proctitis grade 3 12 = Proctitis grade 4 13 = Hot flashes grade 3 14 = Hot flashes grade 4 15 = Cystitis non-infective grade 3 16 = Cystitis non-infective grade 4 17 = Urinary retention grade 3 18 = Urinary retention grade 4 19 = Other grade 3 (free text) 20 = Other grade 4 (free text)
Variable ID:	COMPLRADDOMOTHER
Variable:	CTCAE domain other than those explicitly listed
Definition:	Indicate the CTCAE domain of the grade 3 or 4 complication
Supporting Definition:	N/A
Inclusion Criteria:	All patients undergoing primary or salvage radiation therapy If answered '19 = Other grade 3' or '20 = Other grade 4' on CTCAE domain and grade (COMPLRADDOMGRA)
Timing:	During primary or salvage radiation therapy treatment and the 6 months following completion of therapy
Data Source:	Clinical
Type:	Free text
Response Options:	CTCAE domain

Patient-Reported Health Status

Variable ID:	EPIC26_Q01
Variable:	Question 1 of EPIC-26*
Definition:	This questionnaire is designed to measure Quality of Life issues in patients with Prostate cancer. To help us get the most accurate measurement, it is important that you answer all questions honestly and completely. Remember, as with all medical records, information contained within this survey will remain strictly confidential. 1: Over the past 4 weeks, how often have you leaked urine?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = More than once a day 2 = About once a day 3 = More than once a week 4 = About once a week 5 =Rarely or never
Variable ID:	EPIC26_Q02

Variable:	Question 2 of EPIC-26*
Definition:	2: Which of the following best describes your urinary control during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = No urinary control whatsoever 2 = Frequent dribbling 3 = Occasional dribbling 4 = Total control
Variable ID:	EPIC26_Q03
Variable:	Question 3 of EPIC-26*
Definition:	3: How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = None 1 = 1 pad per day 2 = 2 pads per day 3 = 3 or more pads per day
Variable ID:	EPIC26_Q04a
Variable:	Question 4a of EPIC-26*
Definition:	4a: How big a problem, if any, has the following been for you during the last 4 weeks? Dripping or leaking urine
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q04b
Variable:	Question 4b of EPIC-26*
Definition:	4b: Pain or burning on urination
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem

	1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q04c
Variable:	Question 4c of EPIC-26*
Definition:	4c: Bleeding with urination
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q04d
Variable:	Question 4d of EPIC-26*
Definition:	4d: Weak urine stream or incomplete emptying
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q04e
Variable:	Question 4e of EPIC-26*
Definition:	4e: Need to urinate frequently during the day
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q05
Variable:	Question 5 of EPIC-26*
Definition:	5: Overall, how big a problem has your urinary function been for you during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment

	Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = No problem 2 = Very small problem 3 = Small problem 4 = Moderate problem 5 = Big problem
Variable ID:	EPIC26_Q06a
Variable:	Question 6a of EPIC-26*
Definition:	6a: How big a problem, if any, has the following been for you? Urgency to have a bowel movement
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q06b
Variable:	Question 6b of EPIC-26*
Definition:	6b: Increased frequency of bowel movements
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q06c
Variable:	Question 6c of EPIC-26*
Definition:	6c: Losing control of your stools
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No problem 1 = Very small problem 2 = Small problem 3 = Moderate problem 4 = Big problem
Variable ID:	EPIC26_Q06d
Variable:	Question 6d of EPIC-26*
Definition:	6d: Bloody stools

Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 0 = No problem
1 = Very small problem
2 = Small problem
3 = Moderate problem
4 = Big problem
Variable ID: EPIC26_Q06e
Variable: Question 6e of EPIC-26*
Definition: 6e: Abdominal/Pelvic/Rectal pain
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 0 = No problem
1 = Very small problem
2 = Small problem
3 = Moderate problem
4 = Big problem

Variable ID: EPIC26_Q07
Variable: Question 7 of EPIC-26*
Definition: 7: Overall, how big a problem have your bowel habits been for you during the last 4 weeks?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q08a
Variable: Question 8a of EPIC-26*
Definition: 8a: How would you rate the following during the last 4 weeks?
Your ability to have an erection?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = Very poor to none
2 = Poor
3 = Fair

	4 = Good 5 = Very good
Variable ID:	EPIC26_Q08b
Variable:	Question 8b of EPIC-26*
Definition:	8b: Your ability to reach orgasm (climax)?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Very poor to none 2 = Poor 3 = Fair 4 = Good 5 = Very good
Variable ID:	EPIC26_Q09
Variable:	Question 9 of EPIC-26*
Definition:	9: How would you describe the usual QUALITY of your erections during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = None at all 2 = Not firm enough for any sexual activity 3 = Firm enough for masturbation and foreplay only 4 = Firm enough for intercourse
Variable ID:	EPIC26_Q10
Variable:	Question 10 of EPIC-26*
Definition:	10: How would you describe the FREQUENCY of your erections during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	1 = I NEVER had an erection when I wanted one 2 = I had an erection LESS THAN HALF the time I wanted one 3 = I had an erection ABOUT HALF the time I wanted one 4 = I had an erection MORE THAN HALF the time I wanted one 5 = I had an erection WHENEVER I wanted one
Variable ID:	EPIC26_Q11
Variable:	Question 11 of EPIC-26*
Definition:	11: Overall, how would you rate your ability to function sexually during the last 4 weeks?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years

Data Source: Patient-reported
Type: Single answer
Response Options: 1 = Very poor
2 = Poor
3 = Fair
4 = Good
5 = Very good

Variable ID: EPIC26_Q12
Variable: Question 12 of EPIC-26*
Definition: 12: Overall, how big a problem has your sexual function or lack of sexual function been for you during the last 4 weeks?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q13a
Variable: Question 13a of EPIC-26*
Definition: 13a: How big a problem during the last 4 weeks, if any, has the following been for you?
Hot flashes
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q13b
Variable: Question 13b of EPIC-26*
Definition: 13b: Breast tenderness/enlargement
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q13c
Variable: Question 13c of EPIC-26*

Definition: 13c: Feeling depressed
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q13d
Variable: Question 13d of EPIC-26*
Definition: 13d: Lack of energy
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: EPIC26_Q13e
Variable: Question 13e of EPIC-26*
Definition: 13e: Change in body weight
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 1 = No problem
2 = Very small problem
3 = Small problem
4 = Moderate problem
5 = Big problem

Variable ID: LIBID_Q01
Variable: Question 50 of EORTC-PR25
Definition: During the last 4 weeks, to what extent were you interested in sex?
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Before treatment
6 months after treatment
Annually up to 10 years
Data Source: Patient-reported
Type: Single answer
Response Options: 0 = Not at all
1 = A little
2 = Quite a bit
3 = Very much

Variable ID:	LIBID_Q02
Variable:	Question 2 of Utilization of Sexual Medications/Devices
Definition:	Have you used any medications or devices to aid or improve erections?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No 1 = Yes

Variable ID:	LIBID_Q03a
Variable:	Question 3a of Utilization of Sexual Medications/Devices
Definition:	For each of the following medicines or devices, please indicate whether or not you have tried or currently use it to improve your erections: Viagra or another pill
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' to using medications or devices to aid or improve erections (LIBID_Q02)
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Have not tried it 1 = Tried it but was not helpful 2 = It helped but I am not using it now 3 = It helped and I use it sometimes 4 = It helped and I use it always

Variable ID:	LIBID_Q03b
Variable:	Question 3b of Utilization of Sexual Medications/Devices
Definition:	Muse (intra-urethral alprostadil suppository)
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' to using medications or devices to aid or improve erections (LIBID_Q02)
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Have not tried it 1 = Tried it but was not helpful 2 = It helped but I am not using it now 3 = It helped and I use it sometimes 4 = It helped and I use it always

Variable ID:	LIBID_Q03c
Variable:	Question 3c of Utilization of Sexual Medications/Devices
Definition:	Penile injection therapy (such as caverject)
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' to using medications or devices to aid or improve erections (LIBID_Q02)
Timing:	Before treatment 6 months after treatment

	Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Have not tried it 1 = Tried it but was not helpful 2 = It helped but I am not using it now 3 = It helped and I use it sometimes 4 = It helped and I use it always
Variable ID:	LIBID_Q03d
Variable:	Question 3d of Utilization of Sexual Medications/Devices
Definition:	Vacuum erection device (such as erect-aid)
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' to using medications or devices to aid or improve erections (LIBID_Q02)
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Have not tried it 1 = Tried it but was not helpful 2 = It helped but I am not using it now 3 = It helped and I use it sometimes 4 = It helped and I use it always
Variable ID:	LIBID_Q03e
Variable:	Question 3e of Utilization of Sexual Medications/Devices
Definition:	Other medication/device
Supporting Definition:	N/A
Inclusion Criteria:	All patients If answered 'yes' to using medications or devices to aid or improve erections (LIBID_Q02)
Timing:	Before treatment 6 months after treatment Annually up to 10 years
Data Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Have not tried it 1 = Tried it but was not helpful 2 = It helped but I am not using it now 3 = It helped and I use it sometimes 4 = It helped and I use it always

Survival and Disease Control

Variable ID:	DEATH
Variable:	Death: Patient died
Definition:	Indicate if the patient has died
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Collected for life, reported annually
Data Source:	Administrative data (Death registry)
Type:	Single answer
Response Options:	0 = No 1 = Yes
Variable ID:	DEATHDATE
Variable:	Death: Date of death
Definition:	Indicate date of death

Supporting Definition: N/A
Inclusion Criteria: All patients
If answered 'yes' on overall survival (OVERALLSURV)
Timing: Collected for life, reported annually
Data Source: Administrative data (Death registry)
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: DEATHLPC
Variable: Cause of death: Death attributable to localized prostate cancer
Definition: Indicate if death is noted to be directly attributable to prostate cancer
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Collected for life, reported annually
Data Source: Administrative data (Death registry)
Type: Single answer
Response Options: 0 = No
1 = Yes
999 = Unknown

Variable ID: METADEV
Variable: Disease control: Metastasis
Definition: Indicate if patient was diagnosed with metastatic disease
Supporting Definition: N/A
Inclusion Criteria: All patients
Timing: Collected for life, reported annually
Data Source: Clinical
Type: Single answer
Response Options: 0 = No
1 = Yes

Variable ID: METADATE
Variable: Disease control: Date metastasis identified
Definition: Indicate date of metastasis
Supporting Definition: N/A
Inclusion Criteria: Patients without known metastasis
If answered 'yes' on development of metastasis (METADEV)
Timing: Collected for life, reported annually
Data Source: Clinical
Type: Date by DD/MM/YYYY
Response Options: DD/MM/YYYY

Variable ID: BIOCHEM
Variable: Disease control: Biochemical recurrence
Definition: Indicate whether patient has biochemical recurrence
Supporting Definition: Biochemical recurrence is defined as:
- Per AUA definition, PSA>0.2 ng/mL after surgery, with a second confirmatory level of >0.2 ng/ml
- Phoenix criteria (nadir + 2 ng/mL) after radiation
Recommended that PSA is measured at least annually and providers record all PSA values and dates to accommodate future changes to definitions
Inclusion Criteria: All patients
Timing: Collected for life, reported annually
Data Source: Clinical
Type: Single answer
Response Options: 0 = No
1 = Yes

Variable ID: BIOCHEMDATE
Variable: Disease control: Date biochemical recurrence identified
Definition: Indicate date of recurrence
Supporting Definition: N/A

Inclusion Criteria:	All patients If answered 'yes' on biochemical recurrence (BIOCHEM)
Timing:	Collected for life, reported annually
Data Source:	Clinical
Type:	Date by DD/MM/YYYY
Response Options:	DD/MM/YYYY
Variable ID:	BIOCHEMPSA

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
2.0.1	Introduction to the Data Dictionary	Modifications to introductory paragraph
2.0.1	Follow-Up Timeline and Sample Questionnaires	Removed 6 month clinical follow-up timepoint from timeline
2.0.1	Data Dictionary; Treatment Variables Table	Added 'Type of focal therapy' [PRIMARYTXFT] to Treatment Variables
2.0.1	Collecting Patient Reported Outcome Measures; Outcomes Table	Added source of Libido questions (Utilization of Sexual Medications/ Devices questionnaire)
2.0.2	The Growing ICHOM Community	Removed map and updated information
2.0.3	Collecting Patient Reported Outcome Measures	Added additional source of Libido questions (EORTC QLQ-PR25)
2.0.4	Data Dictionary	Gleason score for primary and secondary response options are now listed as 1-5
2.0.4	Data Dictionary	Defitnition for BIOPINVOL variable modified.
2.0.4	Data Dictionary	Response option of 'Unknown' included in DEATHLPC variable.
2.0.4	Data Dictionary	Primary treatment modalities expanded
2.0.5	Contact Information	Removed inactive email address: ichomteam@ichom.org

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