Prostate Adenocarcinoma (PRAD)

Instructions: The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial melanoma diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contact" on this form).

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS cannot answer the question because the answer is not known at the TSS. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained. If for example, a test was not performed the results of that test cannot be provided because it was "Not Evaluated."

| Γissue Source Site (TSS): | | TSS Identifier: | TSS Unique Patient Identifier: |
|---|---|--|---|
| Comp | oleted By (Interviewer Name | e on OpenClinica): | Completed Date: |
| Gene | eral Information | | |
| # | Data Element | Entry Alternatives | Working Instructions |
| 1 | Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form? | ☐ Yes ☐ No | Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection) Note 2: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 2 | Primary Site of Disease | Prostate | 2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. |
| 3 | Histological Subtype | Prostate Adenocarcinoma, Acinar Type Prostate Adenocarcinoma, Other Subtype (please specify) | 3081934 Using the patient's pathology/laboratory report, Indicate the histologic subtype for the prostate adenocarcinoma tumor sample being submitted to TCGA. Note: Adenocarcinoma, not otherwise specified; and Adenocarcinoma, Acinar Type, are synonymous |
| 4 | Other Histological Subtype | | 3124492 If the histological subtype is not included in the provided list, specify the histological subtype of the prostate adenocarcinoma tumor that is being submitted to TCGA. |
| 5 | Zone of Origin | Peripheral Zone Overlapping Transition Zone / Multiple Zones Central Zone Unknown Zone | 65104 Using the patient's pathology/laboratory report in conjunction with the patient's medical record, indicate the location or position by zone of the prostate tumor. |
| Gleason Score (For Entire Prostatectomy Specimen) | | | |
| 6 | Primary Gleason Pattern | □/5 | 2534617 Using the patient's pathology/laboratory report from the entire prostatectomy specimen, indicate the numeric value of the most frequent pattern or pathologic grade, using the Gleason Score, as interpreted by the pathologist. |
| 7 | Secondary Gleason Pattern | □/5 | 2534618 Using the patient's pathology/laboratory report from the entire prostatectomy specimen, indicate the numeric value of the second-most frequent pattern or pathologic grade, using the Gleason Score, as interpreted by the pathologist. |

Enrollment FormProstate Adenocarcinoma (PRAD)

| # | Data Element | Entry Alternatives | Working Instructions |
|---|---|---|--|
| 8 | Overall Gleason Score | □□ / 10 | 2534619 Using the patient's pathology/laboratory report from the entire prostatectomy specimen, indicate the numeric value of the Total Gleason Score by adding the primary and secondary patterns, as interpreted by the pathologist. |
| 9 | Tertiary Gleason Pattern | □/5 | 2783875 Using the patient's pathology/laboratory report from the entire prostatectomy specimen, indicate the numeric value for the third most prominent Gleason pattern or pathologic grade, as interpreted by the pathologist |
| 10 | Tumor Laterality | ☐ Left ☐ Right ☐ Bilateral | 827 Using the patient's pathology/laboratory report in conjunction with the medical record, designate the side (lobe) from which the prostate tumor originated. |
| 11 | Tumor Level (check all that apply) | ☐ Apex ☐ Middle ☐ Base | 3348845 Using patient's pathology/laboratory report in conjunction with medical record, designate level from which prostate tumor originated. |
| 12 | Gender | Female Male | 2200604 Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc. |
| 13 | Is This a Prospective Tissue Collection? | ☐ Yes ☐ No | 3088492 Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. |
| 14 | Is This a Retrospective Tissue Collection? | ☐ Yes ☐ No | 3088528 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. |
| Date | of Birth | | , |
| 15 | Date of Birth | | Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year) |
| 16 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth | | 3008233 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the patient's date of the birth. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 17 | Has the Patient Had Any Prior Cancer Diagnosed? | □ No □ History of Prior Malignancy □ History of Synchronous / Bilateral Malignancy | Indicate whether the patient has a history of prior malignancies. Note 1: If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. Note 2: If the patient has any history of prior malignancies, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. If the patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types. |
| 18 | History of Neo-Adjuvant Treatment to Tumor Specimen Submitted for TCGA | □ No □ Radiation Prior to Sample Procurement □ Pharmaceutical Treatment Prior to Sample Procurement □ Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement | Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions. Note: Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary. |
| Date of Initial Pathologic Diagnosis (of Tumor Associated with Tissue Procurement for TCGA) | | | |
| 19 | Date of Initial Pathologic Diagnosis | | Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year) |

| # | Data Element | Entry Alternatives | Working Instructions |
|-----------------------------------|---|--|---|
| 20 | Method of Initial Diagnosis | Core Needle Transurethral Resection | 65096 Using the patient's prior pathology/laboratory reports in conjunction with the medical record, indicate the surgical method that was performed to initially diagnose the patient's prostate cancer. |
| Rese | ction of Prostate-TURP] Prior to Rad | (Information to be Obtained from Clinical Findings [Including Didical Prostatectomy) ad (cT1-cT4) questions should be answered. | gital Rectal Exam-DRE; Radiographic Studies and Transurethral |
| 21 | Clinical Spread Prostate (cT1): No Evidence of Induration or Nodularity on Digital Rectal Exam (DRE) | Primary Tumor Not Assessed / Unknown (cTx) Tumor Incidental Histologic Finding in ≤ 5% of Tissue Resected at TURP (cT1a) Tumor Incidental Histologic Finding in > 5% of Tissue Resected at TURP (cT1b) Tumor Identified by Needle Biopsy (cT1c) (e.g., because of elevated PSA) | 3351881 If there is no evidence of induration or nodularity on DRE, indicate the histologic findings of the prostate tumor at the time of resection or needle biopsy prior to radical prostatectomy. |
| 22 | Clinical Spread Prostate (cT2): Induration and/or Nodularity Present on Digital Rectal Exam (DRE) but No Evidence of Local Extension | Induration and/or Nodularity Involves ≤ ½ of one lobe (cT2a) Induration and/or Nodularity Involves > ½ of one lobe (cT2b) Bilateral Induration and/or Nodularity (cT2c) Abnormal DRE, Without Evidence of Extraprostatic Extension (cT2x) | 3351882 If there is evidence of induration and/or nodularity, but no evidence of local extension present on DRE, indicate the most extensive clinical involvement prior to radical prostatectomy. |
| 23 | Clinical Spread Prostate (cT3): Digital Rectal Exam (DRE) Suspicious for Local Extraprostatic Extension | Unilateral or Bilateral Local Extracapsular Extension Suspected (cT3a) Suspected Involvement of Seminal Vesicle (cT3b) | 3351883 If the DRE is suspicious for local extraprostatic extension, indicate the most extensive clinical involvement prior to radical prostatectomy. |
| 24 | Clinical Spread Prostate (cT4): Digital Rectal Exam (DRE) Suspicious for Invasion of, or Fixation to, Adjacent Organs | □ Yes □ No | 3351886 Indicate if the DRE was suspicious for invasion or fixation to adjacent organs prior to radical prostatectomy. |
| 25 | Date of Bone Scan (If performed) | | If a bone scan was performed during the initial workup, provide the date the bone scan was performed. 3351884 (month), 3351889 (day), 3351887 (year) |
| 26 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Bone Scan | | 3412936 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of bone scan. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 27 | Bone Scan Results | Normal (no evidence of prostate cancer) [cM0] Prostate Cancer Metastases Present [cM1b] Abnormal (not related to prostate cancer) Equivocal | 3351888 If bone scan was performed during initial workup, indicate the results of the bone scan. |
| 28 | Did Patient Have CT Scan ABD/Pelvis? | Yes No Unknown | 3194099 Indicate if the patient had a CT Scan of the Abdomen/Pelvis performed during the initial workup to evaluate the extent of the prostate cancer. |
| CT Scan Abd/Pelvis (If Performed) | | | |
| 29 | Date of CT Scan ABD/Pelvis | Month Day Year | If a CT Scan of the Abdomen/Pelvis was performed during the initial workup, provide the date the CT Scan was performed. 3151134 (month), 3151132 (day), 3151133 (year) |
| 30 | Number of Days from Date of Initial Pathologic Diagnosis to Date of CT Scan ABD/Pelvis | | 3414503 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of CT Scan Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |

| # | Data Element | Entry Alternatives | Working Instructions |
|-----|---|--|---|
| 31 | CT Scan ABD/Pelvis Results (Check all that apply) | □ No Evidence of Extraprostatic Extension □ Extraprostatic Extension Localized (e.g. seminal vesicles) □ Extraprostatic Extension (regional lymphadenopathy) [e.g. cN1] □ Distant Metastasis [e.g. cM1] □ Equivocal | 3351890 If CT Scan of Abdomen/Pelvis was performed during initial workup, indicate the results of the CT Scan. |
| MRI | (If Performed) | | |
| 32 | Did Patient Have an MRI? | Yes No Unknown | 2632191 Indicate if the patient had an MRI performed during the initial workup to evaluate the extent of the prostate cancer. |
| 33 | Date of MRI | Month Day Year | If an MRI was performed during the initial workup, provide the date the MRI was performed. 3151491 (month), 3151492 (day), 3151493 (year) |
| 34 | Number of Days from Date of Initial Pathologic Diagnosis to Date of MRI | | 3414554 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of MRI. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 35 | MRI Results (Check all that apply) | □ No Evidence of Extraprostatic Extension □ Extraprostatic Extension, Localized (e.g. seminal vesicles) □ Extraprostatic Extension (regional lymphadenopathy) [e.g. cN1] □ Distant Metastasis [e.g. cM1] □ Equivocal | 3351891 If an MRI was performed during initial workup, indicate the results of the MRI. |
| 36 | Clinical Spread Prostate (cM): Distant Metastases (Clinical or Pathological) | No Distant Metastasis (cM0) Distant Metastasis Not Otherwise Specified (cM1) Metastasis to Non-Regional Lymph Nodes (cM1a) Metastasis to Bone (cM1b) Metastasis to Other Sites with or without bone metastasis (cM1c) | 3351892 If evidence of distant metastasis is present, indicate the extent of known metastatic disease identified either prior to or immediately following radical prostatectomy. |
| | | (Information to be Obtained from Pathology Report of I | |
| | | " questions related to Pathological Spread (pT2-pT4) sho | |
| Whi | • | es" must then have the follow-up question answered to s | 3351893 |
| 37 | Pathologic Spread Prostate (pT2): Disease Confined to the Prostate | ☐ Yes ☐ No | Using the pathology report from the radical prostatectomy specimen, indicate if the prostate cancer is confined to the prostate. |
| 38 | Pathologic Spread Prostate (pT2): If Disease Confined to the Prostate, Specify Level of Involvement | Unilateral involvement ≤ ½ of one lobe (pT2a) Unilateral involvement > ½ of one lobe (pT2b) Bilateral involvement (T2c) | 3351894 Using the pathology report from the radical prostatectomy specimen, specify the level of involvement for the prostate cancer that is confined to the prostate. |
| 38 | Pathologic Spread Prostate (pT3): Extraprostatic Extension | ☐ Yes ☐ No | 3351895 Using the pathology report from the radical prostatectomy specimen, indicate if there is extraprostatic extension. |
| 39 | Pathologic Spread Prostate (pT3): If Extraprostatic Extension is Present, Specify Level of Extension | Extraprostataic Extension Only (pT3a) Seminal Vesicle Invasion (pT3b) | 3351897 Using the pathology report from the radical prostatectomy specimen, specify the level of extraprostatic extension. |
| 40 | Pathologic Spread Prostate (pT4): Invasion of Rectum, Levator Muscles, and/or Pelvic Wall | ☐ Yes ☐ No | 3351898 Using the pathology report from the radical prostatectomy specimen, indicate if there is invasion of the rectum levator muscles and/or pelvic wall. |
| 41 | Were Lymph Nodes Examined at the time of Primary Presentation? | Yes No Unknown | 2200396 Indicate whether any lymph nodes were examined at the time of the primary resection for the tumor submitted to TCGA. Note: If Lymph Nodes are staged on the pathology report as pNx, the selected value should equal "No" |

| # | Data Element | Entry Alternatives | Working Instructions |
|--|--|---|---|
| 42 | Pathologic Spread Prostate (pN):Regional Lymph Node Assessment | No Positive Regional Nodes (pN0) Metastases in Regional Nodes (pN1) | 3351899 Using the pathology report from the radical prostatectomy specimen, indicate the results of the regional lymph node assessment. |
| 43 | Number of Lymph Nodes Pathologically Examined | | 3 Provide the number of lymph nodes pathologically assessed if one or more lymph nodes were removed. |
| 44 | Number of Lymph Nodes Positive by H&E Light Microscopy | | 3086388 Provide the number of lymph nodes identified as positive through hematoxylin and eosin (H&E) staining and light microscopy. |
| 45 | Residual Tumor (Margin Status at Time of Radical Prostatectomy) | RX (Margins Undetermined) R0 (Margins Negative) R1 (Margins Microscopically Positive) R2 (Margins Macroscopically Positive) | 2608702 Indicate the status of a prostatectomy tissue margins following surgical resection as defined by the American Joint Committee on Cancer (AJCC). |
| 46 | Vital Status | ☐ Living ☐ Deceased | 5 Indicate whether the patient was living or deceased at the date of last contact. |
| 47 | Date of Last Contact | | If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year) |
| 48 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact | | 3008273 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Last Contact. Note 1: Do not answer this question if the patient is deceased. Note 2: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 49 | Date of Death | Month Day Year | If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year) |
| 50 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Death | | 3165475 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 51 | Cause of Death | Prostate Cancer Other Malignancy (not prostate cancer related) Other Non-Malignant Disease Unknown Cause of Death | 2554674 Indicate the patient's cause of death. |
| 52 | Source of Death Information | ☐ Death Certificate ☐ Autopsy Medical Record | 2390921 Indicate the source used to identify the patient's cause of death. |
| 53 | Tumor Status (at date of last contact) | Tumor Free Unknown Tumor Status | 2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death. |
| Prognostic / Predictive / Lifestyle Features Used for Tumor Prognosis or Responsiveness to Treatment | | | |
| Date of Most Recent PSA (at time of completion of Enrollment Form) | | | |
| 54 | Date of Most Recent PSA | | Provide the month of the most recent (postoperative) PSA, as reported by the patient's physician or medical record. Note: Do not answer this question if the patient has not had a postoperative PSA at the time of submission of the Enrollment Form. |
| | | Month Day Year | 3351900 (month), 3351901 (day), 3351902 (year) |

| # | Data Element | Entry Alternatives | Working Instructions |
|----|--|---|--|
| 55 | Number of Days from Date of Initial Pathologic Diagnosis to Date of Most Recent PSA | | 3414608 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of most recent PSA. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 56 | Results of Most Recent PSA (on Date Referenced in above question) | | 3351903 If recent prostate specific antigen was performed, indicate the value of this most recent postoperative PSA test. |
| 57 | Biochemical Recurrence | ☐ Yes ☐ No | 3351904 Indicate if the most recent PSA was positive for biochemical recurrence Note: Defined as two or more consecutively elevated PSA results greater than 0.2ng/ml. |
| 58 | Adjuvant Post-Operative Radiation Therapy | Yes No Unknown | 2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed. |
| 59 | Adjuvant Post-Operative Pharmaceutical Therapy | Yes No Unknown | 2785850 Indicate whether the patient had adjuvant / post-operative pharmaceutical therapy. Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed. |
| 60 | Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies) | Progressive Disease Stable Disease Partial Response Complete Response Not Applicable Unknown | 2786727 Provide the patient's response to their initial first course treatment. |
| 61 | New Tumor Event After Initial Treatment | Yes No Unknown | 3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event. |
| 62 | Type of New Tumor Event After Initial Treatment | □ Biochemical Evidence of Disease (Defined as two or more consecutively elevated PSA results greater than 0.2ng/ml.) □ Locoregional Recurrence □ Distant Metastasis □ New Primary Tumor (Non-Prostatic) | Indicate whether the patient's new tumor event was a biochemical recurrence, a loco-regional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor. Note: If this is the first biochemical recurrence, complete the date of first biochemical recurrence. If this is a subsequent biochemical recurrence complete the date of second or third biochemical recurrence whichever is applicable. |
| 63 | Date of New Tumor Event | Month Day Year | If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year) |
| 64 | Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment | | 3392464 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. |
| 65 | Site of New Tumor Event (Metastasis) | Bone Liver Peritoneal Surfaces Lung Non-Regional / Distant Lymph Nodes Other (please specify) | 3108271 Indicate the site of this new metastatic tumor event, as it relates to the tissue submitted for TCGA. |

Page 7 Enrollment Form

Enrollment FormProstate Adenocarcinoma (PRAD)

V4.7 102414

| # | Data Element | Entry Alternatives | Working Instructions | |
|-----------|---|---|--|--|
| 66 | Other site of New Tumor Event (Metastasis) (please specify) | | 3128033 If the metastatic site is not included in the list for the question above, designate the site of this new metastatic tumor event. | |
| 67 | Progression of Disease After Hormone Therapy | Yes Unknown | 3354944 Indicate whether the patient has had a progression or relapse of his prostate cancer following administration of a planned course of hormonal therapy. | |
| 68 | Type of Progression After Hormonal Therapy | Biochemical Recurrence (Defined as two or more consecutively elevated PSA results greater than 0.2ng/ml.) Distant Metastasis Not Evaluated Unknown | 3241479 If the patient had progression or relapse of his prostate cancer after hormonal treatment, indicate the type of progression. | |
| Date | e of First Biochemical Recurren | ce Not Applicable (Patient did not have Biochemica | al Recurrence) | |
| 69 | Date of First Biochemical Recurrence | Month Day Year | Provide the month of the first biochemical recurrence, as reported by the patient's physician or medical record. Note: Do not answer this question if the patient has not had a biochemical recurrence. 3351905 (month), 3351906 (day), 3351907 (year) | |
| 70 | Number of Days from Date of Initial Pathologic Diagnosis to Date of First Biochemical Recurrence | | 3414609 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of first biochemical recurrence. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. | |
| 71 | Additional treatment of New Tumor Event Radiation Therapy | Yes No Dunknown | 3008761 Indicate whether the patient received radiation treatment for this new tumor event. | |
| 72 | Additional Treatment of New Tumor Event Pharmaceutical Therapy | Yes No Dunknown | 2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event. | |
| Comments: | | | | |
| | | | | |
| Prin | Principal Investigator or Designee Signature Print Name Month/Day/Year | | | |