

FAST FACTS

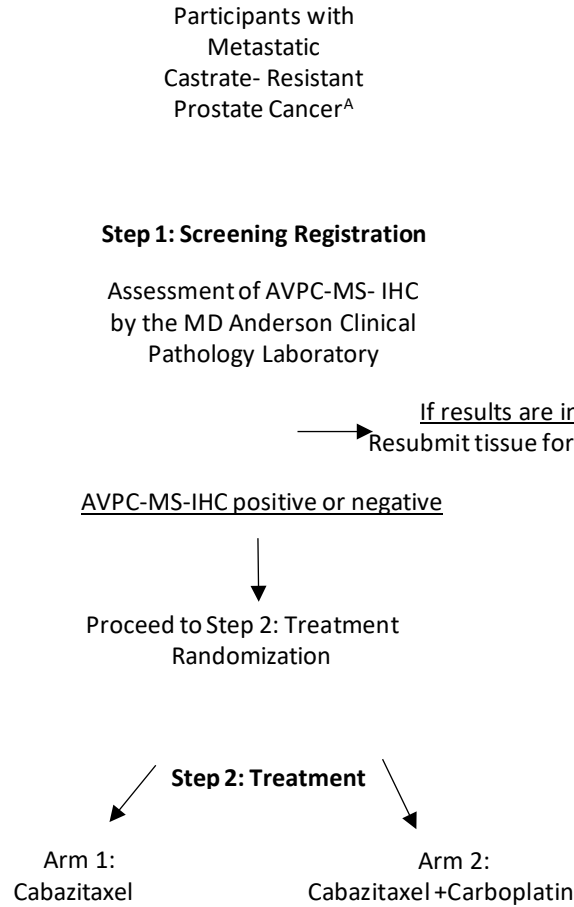
S2312: A PHASE III STUDY OF CABAZITAXEL WITH OR WITHOUT CARBOPLATIN IN PATIENTS WITH METASTATIC CASTRATE-RESISTANT PROSTATE CANCER (MCRPC), STRATIFIED BY AGGRESSIVE VARIANT SIGNATURE

Eligibility Criteria

1. Disease Related Criteria
 - a. Participants must have a histologically confirmed diagnosis of prostate adenocarcinoma cancer at the time of Step 1 Registration. Participants with treatment-related neuroendocrine carcinoma are eligible but participants with de novo treatment naive small cell prostate cancer are ineligible. Please contact the Study PI (Dr. Paul Corn) for any clarifications of this criteria.
 - b. Participants must have metastatic castrate-resistant prostate cancer to bone and/or RECIST measurable disease (i.e., soft tissue, visceral, lymph node) by bone scan and/or full-body imaging of the chest, abdomen, pelvis. Full-body imaging of the chest, abdomen and pelvis can be accomplished by CT, PET-CT and/or MRI.
2. Prior/Concurrent Therapy Criteria
 - a. Participants may have received any prior therapy, but one must be docetaxel or contain docetaxel in either the castrate-sensitive and/or castrate resistant disease state.
3. Clinical/Laboratory Criteria
 - a. Participants must be ≥ 18 years of age at the time of Step 1 Screening Registration.
4. Specimen Submission Criteria
 - a. Participants must have solid tumor (bone or soft tissue) biopsy material (formalin-fixed paraffin-embedded (FFPE) tissue blocks and/or 10 cut slides on four-micron thick unstained positive charged slides of FFPE tissue) available for submission for alterations in TP53, RB1 and PTEN by IHC using CLIA certified assays in the MD Anderson Clinical Pathology Laboratory. This specimen is required for central assessment of the AVPC-MSIHC regardless of whether the site has already locally evaluated the AVPC-MS status.
 - b. Participants must agree to have any leftover tissue (tissue that remains after central assessment of AVPC-MS status) retained for the use of future correlative studies.
 - c. Tumor samples submitted for analysis must have been collected within 36 months prior to Step 1 Screening Registration. Samples from metastatic lesions collected in the castrate-resistant disease state are preferable but not mandatory. Samples obtained during the hormone-naïve disease state are acceptable if collected within 36 months of Step 1 Screening Registration. If more than one tumor sample exists, the sample obtained closest to the date of registration should be submitted to MDACC for analysis.

NOTE: Sites will receive an email from SWOG Statistics and Data Management Center containing participant results of Aggressive Variant Prostate Cancer Molecular Signature (AVPC-MS) assessment within 5-12 business days after tissue submission to MD Anderson Clinical Pathology Laboratory. The participant's AVPC-MS signature result (Positive or Negative) is required BEFORE randomization on to Step 2. If sites receive a non-evaluable AVPC-MS signature result, SWOG Statistics and Data Management Center will provide instructions for resubmission.

SCHEMA



- ^A Participants may have received any prior therapy, but one must be docetaxel or contain docetaxel in either the castrate-sensitive and/or castrate resistant disease state. See [Section 5.0](#) for further eligibility requirements.
- ^B See [Section 15.1b](#) for additional information.
- ^C All participants must have biopsy tissue submitted to MD Anderson Clinical Pathology Laboratory prior to randomization for alteration assessment. See [Section 5.1](#).