

Supplemental Appendix for:  
 Comparative Effectiveness of Mitoxantrone plus Prednisone versus Prednisone Alone in Metastatic Castrate-Resistant Prostate Cancer after Docetaxel Failure  
 Angela Green et al.

Appendix S1. Inclusion and exclusion criteria for SUN 1120 and TROPIC trials.

SUN 1120	TROPIC
<b>Inclusion Criteria</b>	
<ul style="list-style-type: none"> <li>• Histologically or cytologically confirmed adenocarcinoma of the prostate.</li> <li>• Progressive, metastatic castration-resistant prostate cancer after failure of docetaxel chemotherapy (resistant or intolerant).</li> <li>• Progressive disease based on PSA progression, RECIST, or positive bone scan.</li> <li>• ECOG 0 or 1.</li> </ul>	<ul style="list-style-type: none"> <li>• Histologically or cytologically confirmed adenocarcinoma of the prostate that is refractory to hormone therapy and previously treated with a Taxotere®-containing regimen.</li> <li>• Documented progression of disease (demonstrating at least one visceral or soft tissue metastatic lesion, including a new lesion). Patients with non-measurable disease must have documented rising prostate-specific antigen (PSA) levels or appearance of new lesion.</li> <li>• Surgical or hormone-induced castration</li> <li>• Life expectancy &gt; 2 months</li> <li>• ECOG performance status 0 - 2</li> </ul>
<b>Exclusion Criteria</b>	
<ul style="list-style-type: none"> <li>• Prior treatment with sunitinib and/or more than 1 prior chemotherapy regimen in the metastatic disease setting.</li> <li>• Chemotherapy within 3 weeks.</li> <li>• Impending complications from bone metastases.</li> <li>• Ongoing urinary obstruction.</li> <li>• Cardiac dysfunction, QTc &gt;470 msec.</li> <li>• CNS involvement.</li> </ul>	<ul style="list-style-type: none"> <li>• Previous treatment with mitoxantrone</li> <li>• Previous treatment with &lt;225 mg/m<sup>2</sup> cumulative dose of Taxotere (or docetaxel)</li> <li>• Prior radiotherapy to ≥ 40% of bone marrow</li> <li>• Surgery, radiation, chemotherapy, or other anti-cancer therapy within 4 weeks prior to enrollment in the study</li> <li>• Other prior malignancy, except for adequately treated superficial basal cell skin cancer, or any other cancer from which the patient has been disease-free for less than 5 years</li> <li>• Known brain or leptomeningeal involvement</li> <li>• Other concurrent serious illness or medical conditions</li> <li>• Inadequate organ function evidenced by unacceptable laboratory results</li> </ul>