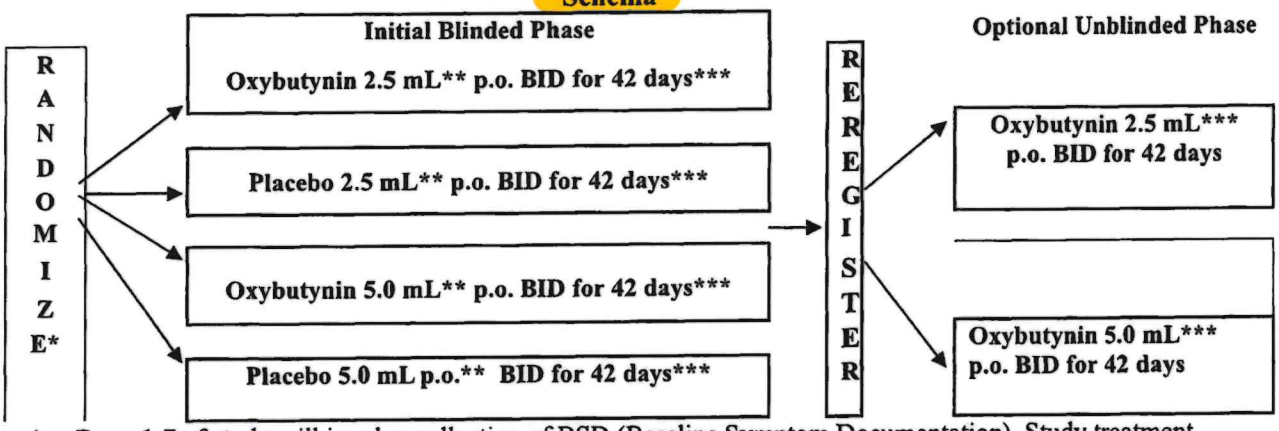
A Randomized, Double-Blind, Placebo-Controlled Phase II Study of Oxybutynin versus Placebo for the Treatment of Hot Flashes in Men Receiving Androgen Deprivation Therapy

Eligibility Criteria (see Section 3.0)

Required Initial Laboratory Values
None

- Men who are currently receiving androgen deprivation therapy (ADT) for the treatment of prostate cancer. (See §3.2.1)
- Patients must be on a stable dose of all hormone-directed therapies for at least 28 days prior to registration. Patients receiving radiation therapy are eligible. (See §3.2.2)
- Eligible patient must have bothersome hot flashes for ≥ 14 days prior to registration. (See §3.2.3)
- No current or future planned use of any of the agents listed in Section 3.2.4 during the study period. (See §3.2.4)
- No current or prior use of oxybutynin as a treatment for hot flashes. (See §3.2.5)
- Patients with a history of any of the contraindications to oxybutynin listed in Section 3.2.6 are not eligible. (See §3.2.6)
- IPSS score < 20 (See §3.2.8)
- Life expectancy of greater than 6 months. (See §3.2.9)
- Age ≥ 18 years. (See §3.2.10)
- ECOG Performance Status 0, 1 or 2. (See §3.2.11)
- Participants must be able to speak and read English. (See §3.2.12)

Schema



* **Days 1-7** of study will involve collection of BSD (Baseline Symptom Documentation). Study treatment is to be administered from Days **8-49**.

** The concentration of oxybutynin is 1 mg per 1 mL, so that placebos and active treatments will maintain blinding.

*** Following 6 weeks of study treatment, the patient will be given the option of being unblinded (Section 8.3.2), and if he was on placebo, will be allowed to cross-over, be re-registered (See Section 4.7), receive either 2.5 or 5.0 mL of oxybutynin, equivalent to the amount of the placebo the patient had received prior to unblinding, for 6 weeks..

Please refer to the full protocol text for a complete description of the eligibility criteria and treatment plan.

If the Group credited for enrollment is a non-Alliance Group, then other requirements from the credited Group may apply.