

EA8184 - A Phase II Randomized Double Blinded Study of Green Tea Catechins (GTC) vs. Placebo in Men on Active Surveillance for Prostate Cancer: Modulation of Biological and Clinical Intermediate Biomarkers

Pre-Screening / Screening Workflow

- Generate a list of potential study participants on active surveillance for prostate cancer (Gleason 3+3/GG1 or 3+4/GG2) at your site
- Track when the potential subject had the last biopsy (Note: baseline biopsy must have occurred 6-18 months prior to pre-registration to Step 0)
- Set up a call schedule in order to present EA8184 to the potential participant(s) based on the biopsy timing (Note: ideally, 7-8 months prior to their upcoming standard of care [SOC] biopsy)
- Tumor tissue (FFPE) can be submitted any time during screening
- The FFPE sample will be centrally reviewed for verification of Gleason Score and evaluation of % Ki-67 expression (must be 3% or more)
 - If the subject meets the criteria of % Ki-67 expression (3% or more) with confirmed Gleason of 3+3/GG1 or 3+4/GG2, continue screening for all other criteria
 - Serum PSA must be obtained within 30 days of pre-registration
- Eligible subjects will be registered and randomized
 - Note: there is no specific timeframe between registration and randomization, but intervention must start 6 months prior to the planned prostate biopsy

