

## **Project Summary Report**

**YODA Project Protocol #: 2022-5058**

### **The impact of long-term proton pump inhibitors use on the prognosis of patients receiving Androgen-annihilation therapy**

#### **Objective**

Using individual patient data from ACIS which including patients treated with apalutamide + abiraterone or abiraterone to explore the impact of long-term PPI use on the prognosis.

#### **Methods**

Participants who received identical treatment will be stratified based on their use of proton pump inhibitors (PPIs) into two groups: long-term PPI users (those who used PPIs before randomization and continued during the treatment process) and other patients. Propensity score methods (PSM) will be employed to mitigate baseline differences among various racial groups. PSM will be implemented using the MatchIt package in RStudio. Subsequently, based on the data after PSM, the Mantel-Byar test and the Simon-Makuch survival plot will be conducted in R, considering the time-dependent nature of PPI usage as a covariate. Finally, a time-dependent Cox model will be established using the survival package. However, given the unavailability of specific time points and durations of PPI usage, the Mantel-Byar test and time-dependent Cox model cannot be performed in this analysis.

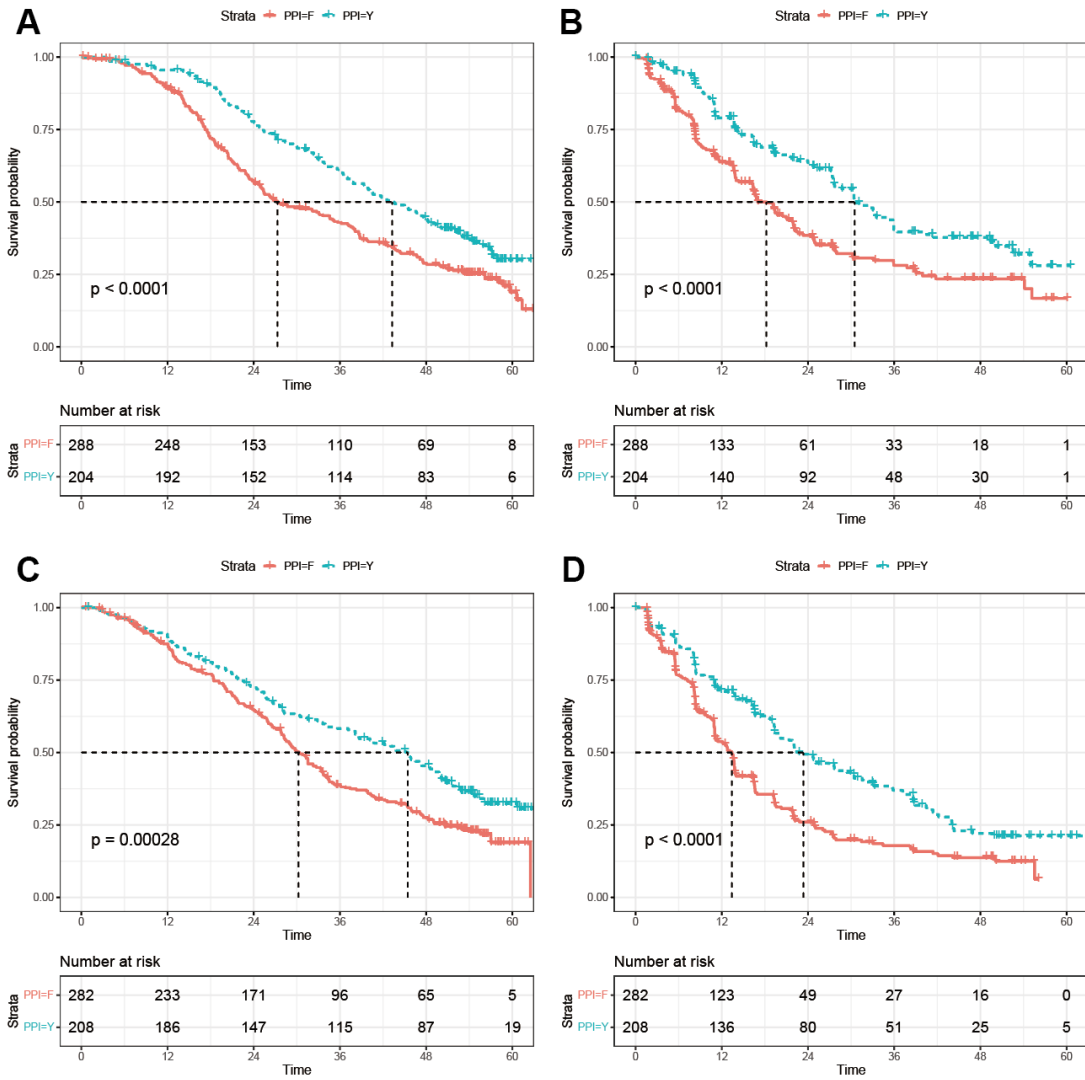
#### **Results**

Although lacking the necessary time parameters, we conducted preliminary exploratory analysis on the data. Patients were simply categorized into PPI users and non-users based on medication usage records. The results indicated better prognosis among PPI users (Figure 1). It is important to note that this result may be subject to immortal time bias as the timing and duration of PPI usage were not properly adjusted for in the analysis.

#### **Conclusions**

N/A

Figure 1



**Figure 1.** The Kaplan-Meier curve was generated by dividing the patients into two groups based on PPI usage (used PPI vs. never used PPI). (A) OS in apalutamide + abiraterone cohort; (B) rPFS in apalutamide + abiraterone cohort; (C) OS in abiraterone cohort; (D) rPFS in abiraterone cohort.