EE507

# Preprogression Health State Utility Values From the TALAPRO-2 Clinical Trial in Patients With Metastatic Castration-Resistant Prostate Cancer Unselected for DDR Mutations

Alexander Niyazov,[1] Evangelia Simou,[2] Melissa Kirker,[1] Katie Houghton,[2] Jean-Gabriel Le Moine,[2] Jane Chang,[1] Stuart Yarr,[2] Christine Barnett,[3] Deirdre Mladsi[3]

[1]Pfizer Inc., New York, NY, United States; [2]RTI Health Solutions, Manchester, United Kingdom; [3]RTI Health Solutions, Research Triangle Park, NC, United States

## Objective

The aim of this research was to estimate preprogression health state utility values (HSUVs) in patients with first-line metastatic castration-resistant prostate cancer (mCRPC) to inform economic evaluations of cancer treatment.

## Conclusions

Health economic researchers and health technology assessment authorities need the most up-to-date information to determine treatment cost-effectiveness. This analysis generated preprogression HSUVs suitable for use in cost-effectiveness analyses in first-line mCRPC. Overall, results were consistent using UK, Canada, and US value sets.

PRESENTING AUTHOR:

**Evangelia Simou, PhD**
**Senior Research Statistician**

RTI Health Solutions
2nd Floor, The Pavillion
Towers Business Park
Wilmslow Road
Didsbury, United Kingdom

Phone: +0161 447 6022
Email: esimou@rti.org

## BACKGROUND

- Worldwide, prostate cancer is the second most frequently diagnosed cancer in men and was the fifth leading cause of cancer death among men in 2020.[1] 10% to 50% of prostate cancer cases progress into mCRPC within 3 years of diagnosis.[2]
- TALAPRO-2—an international phase 3 randomized controlled trial (NCT03395197) comparing first-line treatment of adult patients with mCRPC unselected for DNA damage repair mutations (all comers) with talazoparib (TALA) + enzalutamide (ENZA) vs. placebo (PBO) + enzalutamide (ENZA)—showed statistically significant improvement in the primary endpoint of radiographic progression-free survival (hazard ratio [HR] = 0.627; 95% confidence interval [CI], 0.506-0.777; $P < 0.0001$).[3]
- There is evidence that mCRPC has a negative impact on patients' health-related quality of life.[4] To our knowledge, limited information has been published assessing the relationship between health states and utility values in patients with mCRPC.

## METHODS

### DATA

- Patient-level data from TALAPRO-2 were analyzed for TALA + ENZA (n = 402) or PBO + ENZA (n = 403) in all patients with mCRPC.
- EQ-5D-5L[5] data were collected at baseline, every 4 weeks until week 53 or radiographic progression or death, every 8 weeks after week 53 until radiographic progression or death, or every 12 weeks after progression until the end of the study.

### STATISTICAL ANALYSES

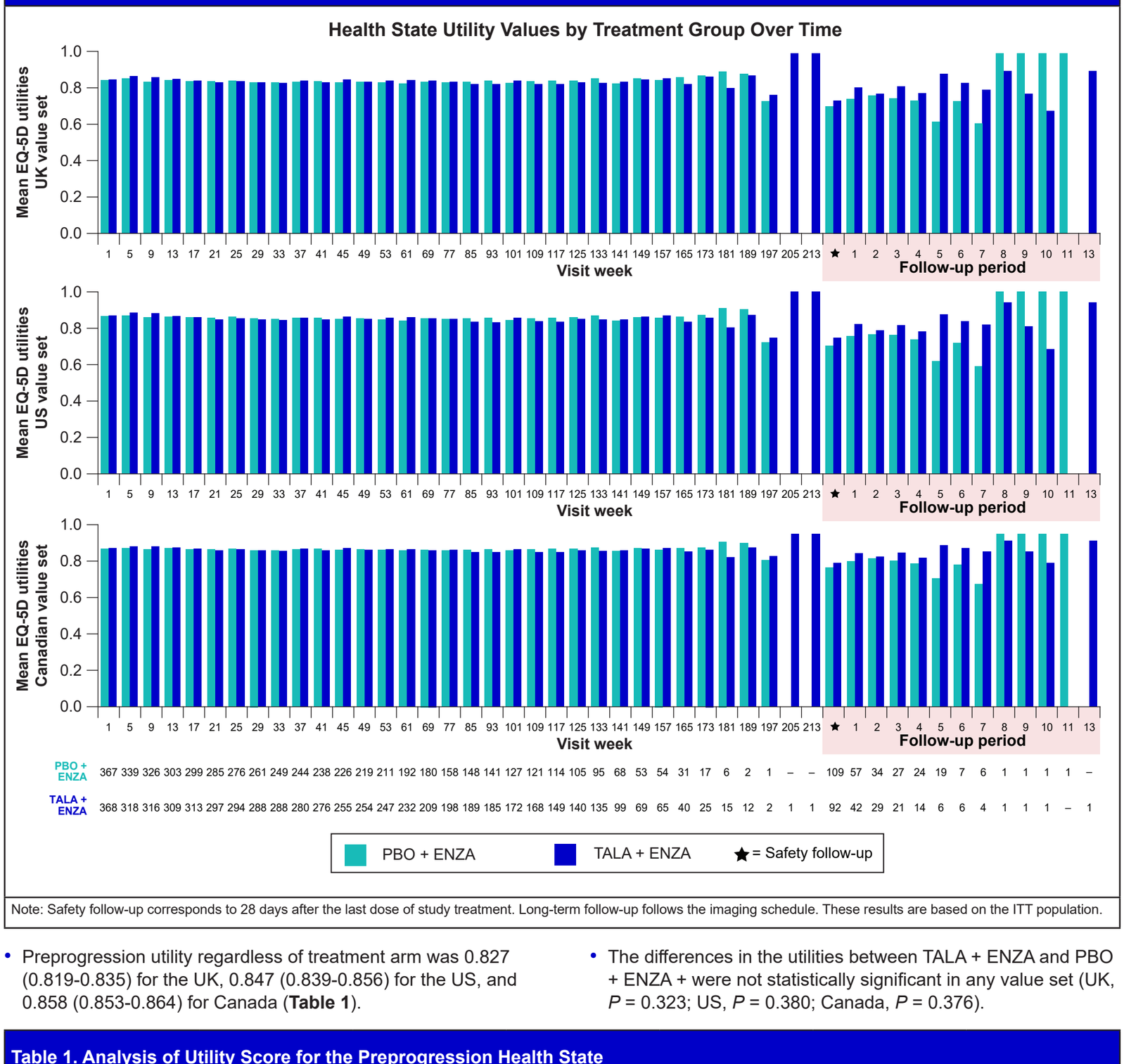
- Health state utilities were estimated, based on the time before and after radiographic progression (before and after progression).
- Utility was estimated regardless of and by treatment arm by independently applying the value sets for the United Kingdom (UK),[6] Canada,[7] and the United States (US)[8] to the TALAPRO-2 trial data.
- For each country, EQ-5D-5L analyses consisted of descriptive statistics on HSUV means and results from mixed-effects models.
- The analysis was conducted using linear mixed-effects models for repeated measures. Individual patients were modeled as random effects and the following covariates as fixed effects: health state, planned treatment, time of visit (since randomization), baseline age, baseline EQ-5D-5L utility, baseline Eastern Cooperative Oncology Group (ECOG) status, planned treatment, and an interaction term between planned treatment and health state (i.e., before and after progression).
- The linear mixed-effect model assumed the missing data mechanism to be missing at random
- A parsimonious model was selected using backward elimination, where covariates that were not significant were sequentially removed from the model according to their $P$ value ($P < 0.05$). Health state was forced into the model to ensure it was always a predictor.
- The descriptive statistics were based on the intention-to-treat population. The statistical models were fitted only to the patient-reported outcome (PRO) analysis population (patients with baseline and ≥ 1 follow-up value for EQ-5D-5L), and the present results correspond to the preprogression health state.



## RESULTS

- No differences in the treatment arms were identified in patient demographics (e.g., age, ECOG score, baseline pain score, baseline serum prostate-specific antigen, renal impairment, Gleason score, metastatic site, previous treatment with any neoadjuvant hormonal therapy or taxane-based chemotherapy, homologous recombination repair mutational status).
- Descriptive statistics showed that, while the sample was sufficiently large, mean utilities remained stable through the course of the trial in both treatment arms (**Figure 1**).

**Figure 1. Mean EQ-5D-5L Utility Values Over Time**




Note: Safety follow-up corresponds to 28 days after the last dose of study treatment. Long-term follow-up follows the imaging schedule. These results are based on the ITT population.

- Preprogression utility regardless of treatment arm was 0.827 (0.819-0.835) for the UK, 0.847 (0.839-0.856) for the US, and 0.858 (0.853-0.864) for Canada (**Table 1**).
- The differences in the utilities between TALA + ENZA and PBO + ENZA + were not statistically significant in any value set (UK, $P = 0.323$; US, $P = 0.380$; Canada, $P = 0.376$).

**Table 1. Analysis of Utility Score for the Preprogression Health State**

| | UK value set | | US value set | | Canadian value set | |
|---|---|---|---|---|---|---|
| **Treatment** | **Mean EQ-5D score (SE)** | **95% CI** | **Mean EQ-5D score (SE)** | **95% CI** | **Mean EQ-5D score (SE)** | **95% CI** |
| Overall | 0.827 (0.004) | (0.819-0.835) | 0.847 (0.004) | (0.839-0.856) | 0.858 (0.003) | (0.853-0.864) |
| TALA + ENZA | 0.831 (0.006) | (0.820-0.842) | 0.851 (0.006) | (0.839-0.863) | 0.861 (0.004) | (0.853-0.869) |
| PBO + ENZA | 0.823 (0.006) | (0.812-0.834) | 0.844 (0.006) | (0.831-0.856) | 0.856 (0.004) | (0.847-0.864) |

CI = confidence interval; SE = standard error.

Note: The results presented in this poster are from a model that includes data for both pre- and post-progression health states; only results for the preprogression health state are shown. Following backward elimination, the covariates that remained significant in the model were time of visit (since randomization), baseline age, baseline EQ-5D-5L utility, baseline ECOG status, planned treatment, and health state. These results are based on the PRO analysis population.

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