

## **CCTSI – Element E, April, 2024 update**

### *A Randomized, Pragmatic, Adaptive trial of Metformin for Glucose Intolerance or Increased Body Mass Index in Prostate Cancer Patients*

This protocol has been developed in collaboration with UHealth Information technology, in close coordination with the regulatory compliance and with investigators across the UHealth system.

- This protocol is open to accrual.
  - Includes over 20 trained Co-Investigators (Co-I's) in all three geographic regions of UHealth (Northern Colorado, Metro Denver and Southern Colorado).
  - Urology, Medical Oncology and Radiation Oncology Co-Investigators involved.
    - EMR study interruptions/pop ups are limited to these trained investigators.
- It utilizes a 2-step consent process.
  - Step 1: Enter a prostate cancer consortium to see additional research opportunities.
  - Step 2: Consent for the specific Pragmatic Metformin/Lifestyle.

Patients with a prostate cancer diagnosis (based on ICD codes) and My Health Connection account (patient portal) are electronically presented a consent to join the prostate cancer consortium (Step 1). As of March of 2024, 1,111 patients have consented to join the consortium. This number exceeds the preliminary expectations of engagement with the consortium.

Patients in the consortium are screened for eligibility for the specific Pragmatic Metformin/Lifestyle protocol. This screening occurs within the electronic medical record (EMR) and includes assessment of BMI, creatinine, existing diagnosis of diabetes, contraindicated medications, and other eligibility factors. Patients are randomized between the metformin and the lifestyle modification arms and presented a second consent if electronically screened as eligible. The patients are officially enrolled on the trial after signing the second consent in the EMR and then seeing one of the study investigators, who confirms their eligibility/understanding, prior to enrolling.

As of March 2024, 23 patients been enrolled in the Pragmatic Metformin/Lifestyle, confirmed by one of the study Co-I in a routine clinic visit. This conversion proportion from the consortium to full enrollment is below our initial estimates. We are taking several actions to address:

- We have worked with the UHealth IT team to develop a dashboard to track patients in the process. We used this information to help identify potential gaps and obstacles.
- We are working with the PEET team and plan for additional engagement in using their expertise in dissemination and implementation to address this.
- One area identified in the initial assessment of the study dashboard data is that a substantial number of patients are entering the consortium, but not regularly coming in for routine prostate cancer follow up or not seeing one of the trained study Co-I's.
  - We have worked with the IRB and UHealth to obtain approvals for study recruitment posters. These will be placed in the clinics of the study Co-Is in the Anschutz Medical Campus. This is not able to be pursued in other regions, which will facilitate a pilot of this approach at this one site.
  - It is envisioned that patients already being seen at the clinics with this poster will enrich the number of actively engaged patients in the consortium.