



E.J. Whitten Foundation Prostate Cancer
Research Centre at Epworth

Stage	Study short name	PI	Study title	Notes
M1a/b/c prostate cancer	SIMCAP	Nathan Lawrentschuk	Surgery in Metastatic Carcinoma of Prostate. Phase 2.5 multi-institution randomized prospective clinical trial evaluating the impact of cytoreductive radical prostatectomy combined with best systemic therapy on oncologic and quality of life outcomes in men with newly diagnosed metastatic prostate	<u>Exclusion:</u> -Life expectancy of <6 months -prior ADT for >6 months
Low grade prostate cancer	CONFIRM	Nathan Lawrentschuk	The Diagnostic Utility of PSMA PET/CT in Men with Newly Diagnosed Low-Grade Prostate Cancer with High-Risk Features, on Active Surveillance, Awaiting Confirmatory Biopsy	<u>Inclusion:</u> -GG2 Pca: amount of pattern 4 is $\leq 10\%$ -GG1 (high volume) -GG1 (low volume but high PSA) -GG1: PIRADS 4 or 5 lesion on the MRI
High-risk prostate cancer	PRIMORDIUM	Arun Azad	A Randomized, Controlled, Multicenter, Open-label Study to Investigate the Efficacy and Safety of Adding Apalutamide to Radiotherapy and LHRH Agonist in High-Risk Patients with PSMA-PET-Positive Hormone-Sensitive Prostate Cancer, with an Observational Follow-up of PSMA-PET-Negative Patients	-PSMA PET scan required at screening <u>-Inclusion:</u> mandatory prior treatments: RP, LND <u>-Exclusion</u> -Already received treatment for BCR -prior treatments: ADT, CYP17 inhibitors, AR antagonists.

For further details, please contact:

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DDR gene mutated Castration-sensitive prostate cancer	TALAPRO-3	Arun Azad	Phase 3, randomized double-blind study of talazoparib with enzalutamide versus placebo with enzalutamide in men with DDR gene mutated metastatic castration-sensitive prostate cancer	<u>Prior treatments (allowed, but not mandatory):</u> -docetaxel, 6 cycles -oestrogens -cyproterone acetate -1st gen anti-androgens -ADT \leq 6 months -Abiraterone + Prednisone, apalutamide, or enzalutamide \leq 3 months
mHSPCa or mCRPCa	IRONMAN	Ben Tran	International Registry for Men with Advanced Prostate Cancer	Observational
High risk non-muscle invasive bladder cancer	SunRISe-3	Ben Tran	A Phase 3, Open-Label, Multi-Center, Randomized Study Evaluating the Efficacy of TAR-200 in Combination with Cetrelimab Versus Intravesical Bacillus Calmette-Guérin (BCG) in Participants with BCG Naïve High-Risk Non-Muscle Invasive Bladder Cancer (HR-NMIBC)	<u>Inclusion:</u> -High grade papillary Ta or T1 or CIS -BCG naïve (or stopped BCG >3 years before enrolment) <u>Exclusion:</u> -muscle invasive, locally advanced, non-resectable or metastatic urothelial carcinoma -Concurrent extra-vesical non-muscle invasive transitional cell carcinoma of the urothelium

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