Tallaght University Hospital
Ospidéal Ollscoile Thamhlachta
An Academic Partner of Trinity College Dublin

TUH Cancer Clinical Trials Newsletter

Issue 16, February 2026

Dear Investigator,

Welcome to the Q1 edition of the TUH Cancer Clinical Trials Newsletter. In this issue we will update you on the trials we have currently recruiting. Our mission is to keep you informed about the trials we have available in Tallaght University Hospital and offer these trials to patients not only in TUH, but throughout the country.

We welcome our newest team member Fiona Smith. Fiona, an experienced Oncology Nurse, has started with us as a CNM 2 in Cancer Clinical Trials.

We are delighted to have randomised the first patient in Ireland to the De-Escalate trial 'Intermittent Androgen deprivation Therapy in the era of AR pathway inhibitors; a phase 3 pragmatic randomized trial'

Prof Ray Mc Dermott

Dr Lynda Corrigan

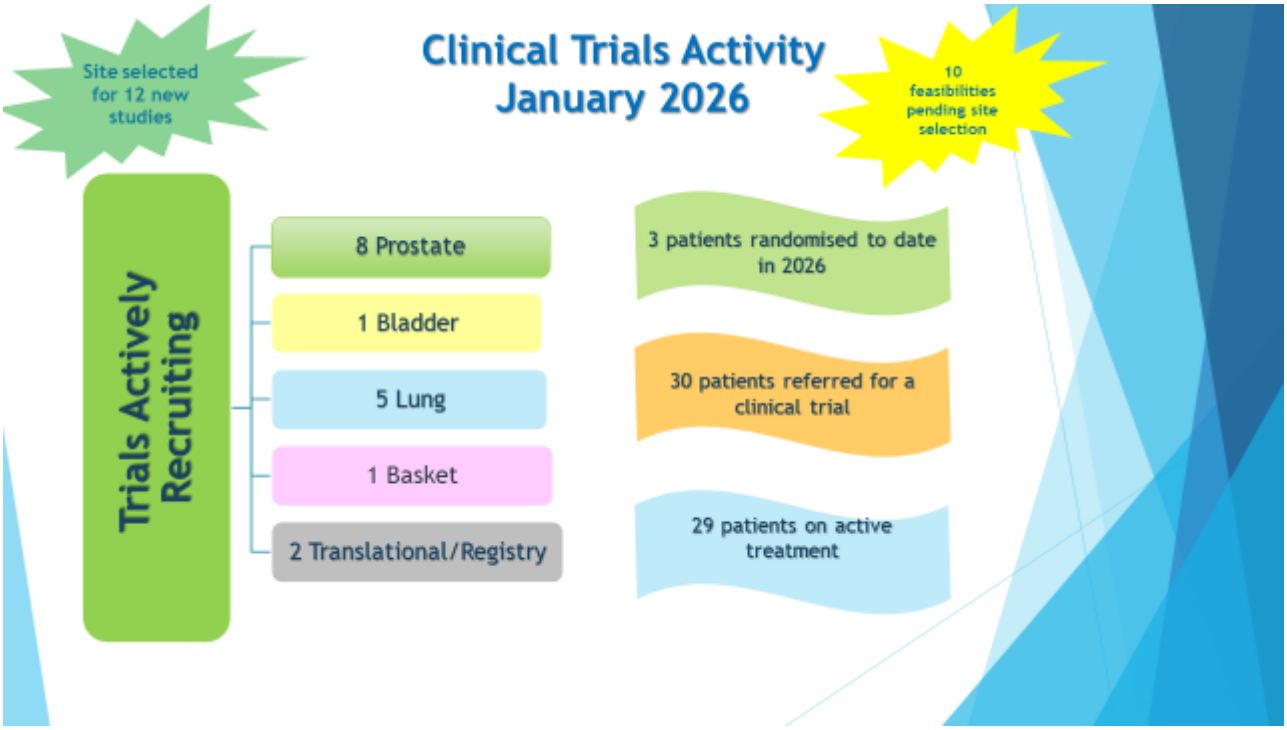
Dr Sebastian Trainor

Our Principal Investigators

Prof Fergal Kelleher

Dr John Greene

Prof Helen Enright



For patient referrals

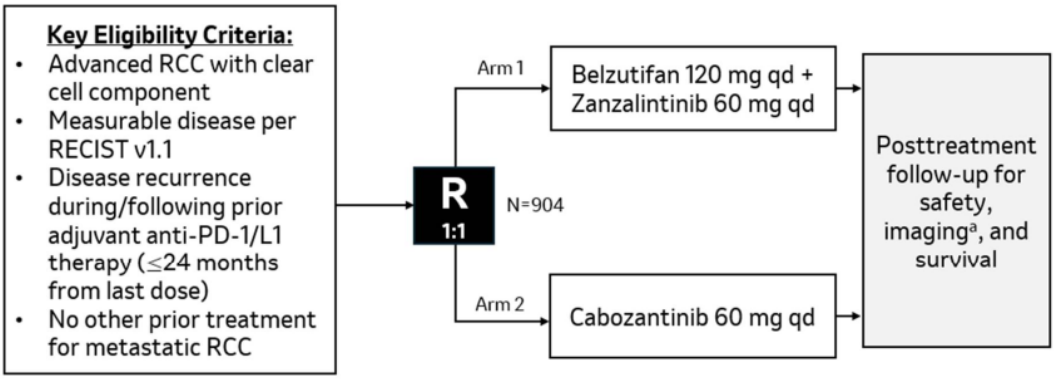
ashley.bazin@tuh.ie

christine.leonard@tuh.ie

rhonda.mooney@tuh.ie

RENAL

Protocol	**MK6482-033 LITESPARK-033**
	A Phase 3, Randomized, Open-label Study of **Belzutifan + Zanzalintinib** Versus **Cabozantinib** for the Treatment of Participants with Locally **Advanced** or **Metastatic RCC** who Experienced **Disease Recurrence** During **or After Prior Adjuvant Anti-PD-1/L1** Therapy
PI	Prof Ray Mc Dermott
Research Nurse	TBC email: christine.leonard@tuh.ie Phone: 01-414 4204
Key Inclusion/ Exclusion Criteria	• Advanced renal cell carcinoma with clear cell component • Disease recurrence during/following prior adjuvant anti-PD-1/L1 therapy ≤24 months from last dose. • No prior systemic treatment
Expected Closing	**Opening February 2026. Last patient in projected November 2027**

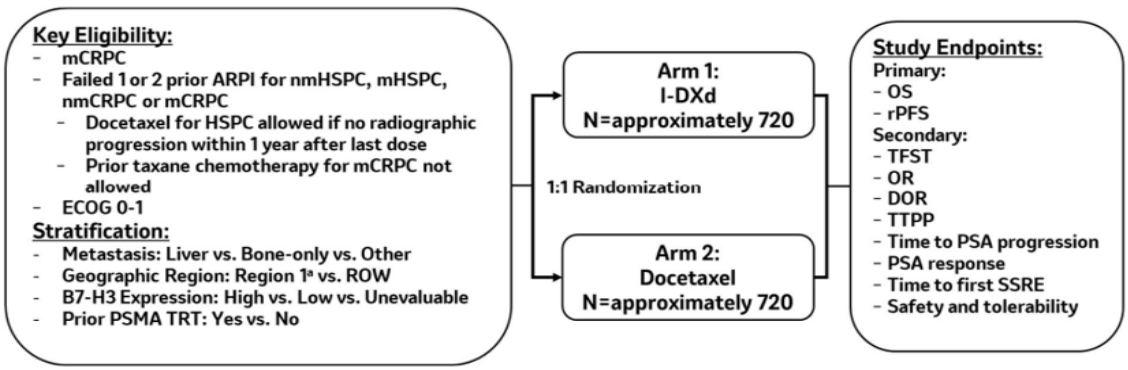


PROSTATE

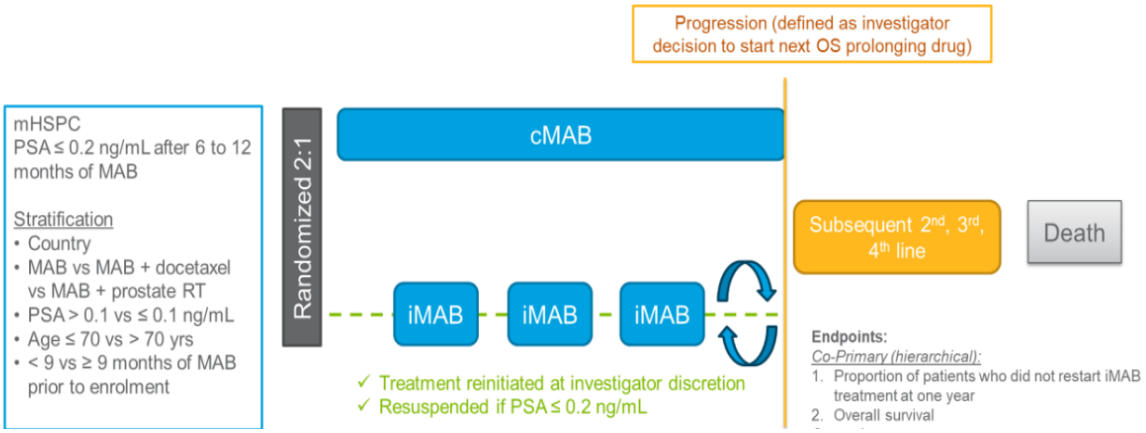
Protocol	**MK2400-001 (IDEATE-Prostate01)**
	A Phase 3, Open-label Study of **Ifinatamab Deruxtecan** Versus **Docetaxel** in Participants with Metastatic Castration-Resistant Prostate Cancer **(mCRPC)** (IDeate-Prostate01)
PI	Dr Lynda Corrigan
Research Nurse	Heather Sloane Email: heatherj.sloane@tuh.ie Phone: 01-414 4208

Key Inclusion/ Exclusion Criteria	• Metastatic Castration-resistant prostate cancer
	• Failed one or two prior ARPI for nmHSPC, mHSPC, nmCRPC, mCRPC
	  ○ Docetaxel for **HSPC allowed** if no radiographic progress within one year of last dose
	  ○ Prior **taxane** chemotherapy for **mCRPC not allowed**
	• ECOG 0-1

Expected Closing	**August 2027**

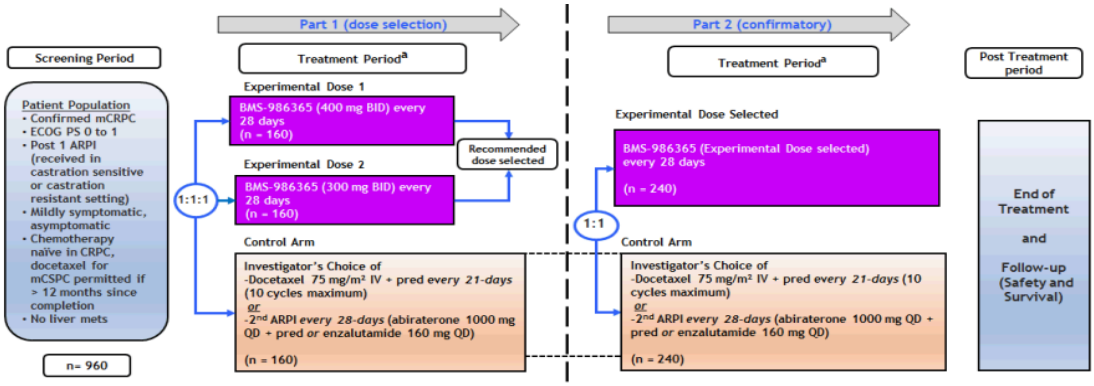


Protocol	**DE-ESCALATE** Intermittent Androgen deprivation Therapy in the era of ARpathway inhibitors; a phase 3 pragmatic randomized trial
PI	Dr Lynda Corrigan
Research Nurse	Fiona Smith Email: fiona.smith4@tuh.ie Phone: 01-414 4259
Key Inclusion/ Exclusion Criteria	• Treated with ADT and an ARpI for mHSPC for six-12 months • PSA ≤ 0.2 ng/mL • May have received docetaxel and radiotherapy **Excluded** • Patients with M1a on modern imaging technique • Underwent or will undergo a bilateral orchiectomy • Systemic anti-prostate cancer treatment not approved by EMA
Expected Closing	**April 2028**

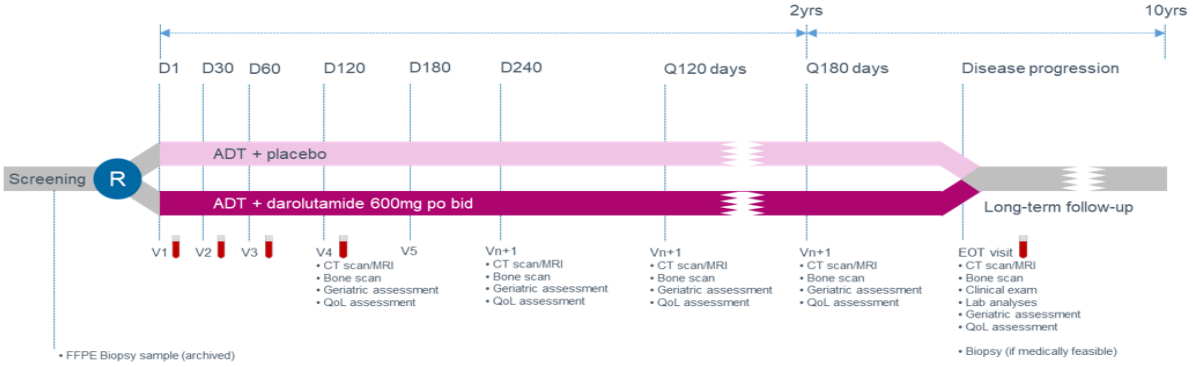


Protocol	**MK3475-365** Phase Ib/II Trial of **Pembrolizumab** (MK-3475) Combination Therapies in **Metastatic Castration-Resistant Prostate Cancer COHORT I Open to recruitment**
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: Heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	**I : t-NE mCRPC*** • Prior ADT for metastatic disease • < 2 chemo for mCRPC • < 2 second generation hormonal therapies for mCRPC • PD within six months before screening • ECOG PS 0-1
Expected Closing	12th June 2026

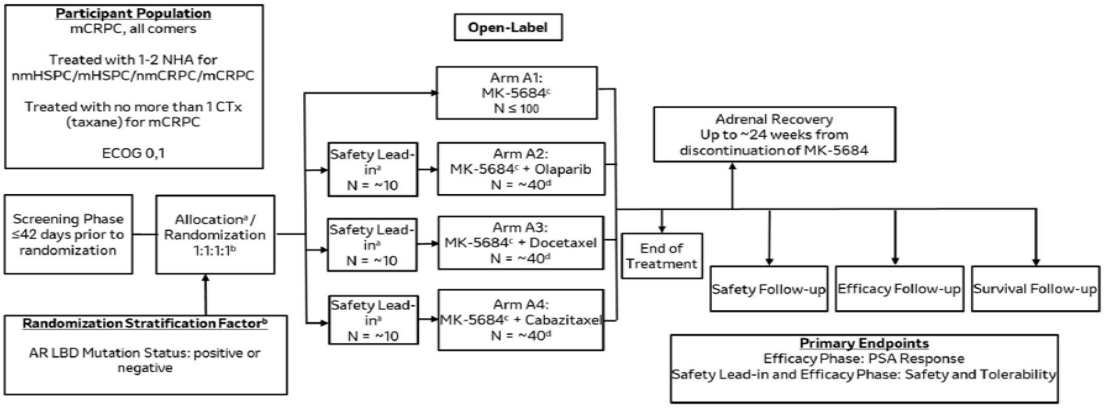
Protocol	**BMS 071-1000 -RechARge** A Phase 3, Two-part, Randomized, Open-label, Adaptive Study Comparing **BMS-986365** versus **Investigator's Choice** of Therapy Comprising Either Docetaxel or Second Androgen Receptor Pathway Inhibitor (ARPI), in Participants with Metastatic Castration-resistant Prostate Cancer **(mCRPC)** – RechARge
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• Confirmed mCRPC • ECOG PS 0 to 1 • Post ARPI (received in castration sensitive or resistant setting • Mildly symptomatic, asymptomatic **(score of <4 as logged on BPI-SF.** *A score of 2-3 will be considered mildly symptomatic)* • Chemotherapy naïve in CRPC (docetaxel for mCRPC allowed if >12 months since completion) • No liver metastases. • No use of opioid analgesics for cancer-related pain currently or any time within 4 weeks. • No impaired cardiac function or clinically significant cardiac disease
Recruitment Period	Part One complete (dose finding) ***Currently paused*** Part Two will open following two month pause for analysis (likely March)



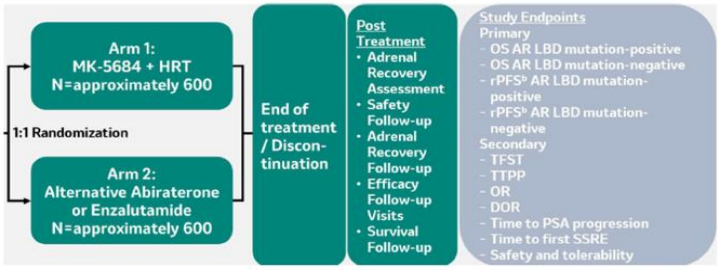
Protocol	**PEACE-6 Vulnerable** A Double-Blind Randomised Phase III Trial Evaluating the Efficacy of ADT +/- Darolutamide in de novo Metastatic Prostate Cancer Patients with Vulnerable Functional Ability and not Elected for Docetaxel or Androgen Receptor Targeted Agents**.**
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• Men with histologically or cytologically confirmed adenocarcinoma of the prostate • De novo metastatic disease defined by clinical or radiographic evidence of metastases. • Ineligible for treatment with all of the following drugs: docetaxel, abiraterone, enzalutamide, apalutamide
Expected Closing	TBC 2026



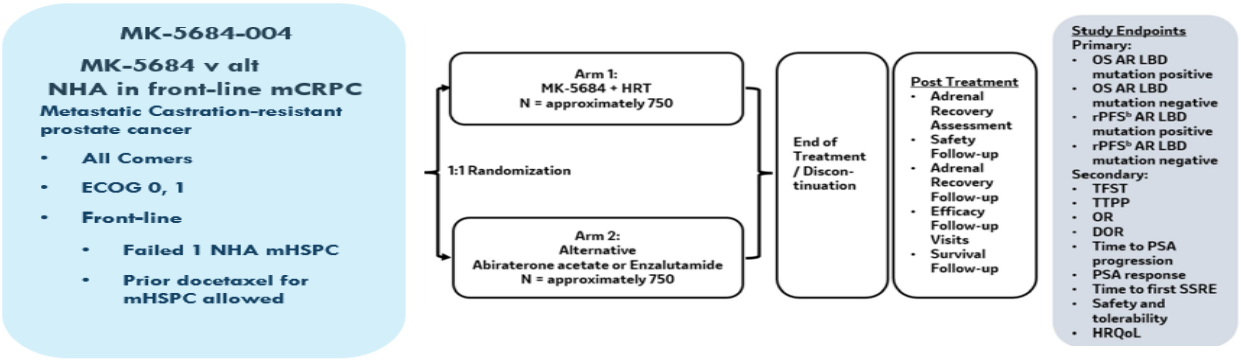
Protocol	**MK5684-01A (OMAHA)** A Phase 3 Randomized, Open-label Study of **MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide** in Participants With Metastatic Castration-resistant Prostate Cancer **(mCRPC) Previously Treated** With Next-generation Hormonal Agent **(NHA) and Taxane-based Chemotherapy**
PI	Prof Ray Mc Dermott
Research Nurse	Una Murtagh Email: una.murtagh@tuh.ie Phone: 01-414 2328
Key Inclusion/ Exclusion Criteria	• Metastatic Castration-resistant prostate cancer • **AR-LBD status confirmed by central lab** • ECOG 0, 1 • Late-line • Failed 1 NHA mHSPC, nmCRPC, or mCRPC • Failed docetaxel
Expected Closing	**November 2026** **Two part screening for AR-LBD status.**



Protocol	**MK5684-003 (OMAHA)** A Phase 3 Randomized, Open-label Study of **MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide** in Participants With Metastatic Castration-resistant Prostate Cancer **(mCRPC) Previously Treated** With Next-generation Hormonal Agent **(NHA) and Taxane-based Chemotherapy**
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• Metastatic Castration-resistant prostate cancer • **AR-LBD status confirmed by central lab** • ECOG 0, 1 • Late-line • Failed 1 NHA mHSPC, nmCRPC, or mCRPC • Failed docetaxel
Expected Closing	**July 2026** **Two part screening for ARLBD status.**

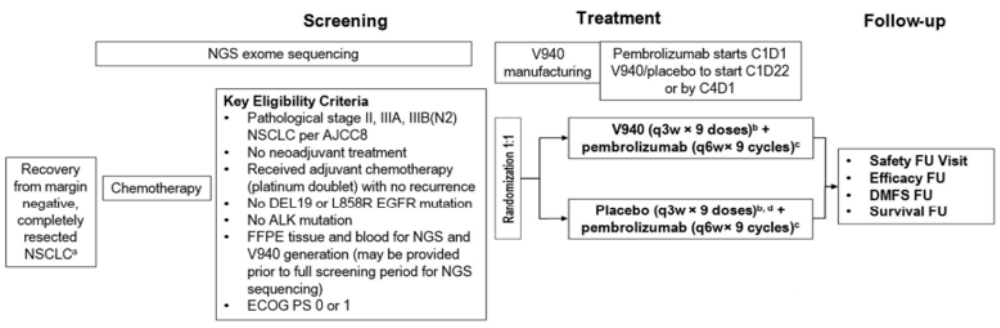


Protocol	**MK5684-004 (OMAHA)** A Phase 3, Randomized, Open-label Study of **MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide** in Participants with Metastatic Castration-resistant Prostate Cancer **(mCRPC)** That **Progressed** On or After Prior Treatment with One Next-generation Hormonal Agent **(NHA)**
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: Heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• Metastatic Castration-resistant prostate cancer • Front-line • **AR-LBD status confirmed by central lab** • ECOG 0, 1 • Failed 1 NHA mHSPC • Prior docetaxel for mHSPC allowed
Expected Closing	**Currently paused. Will open with two part screening (for AR-LBD) in Feb/Mar-26**

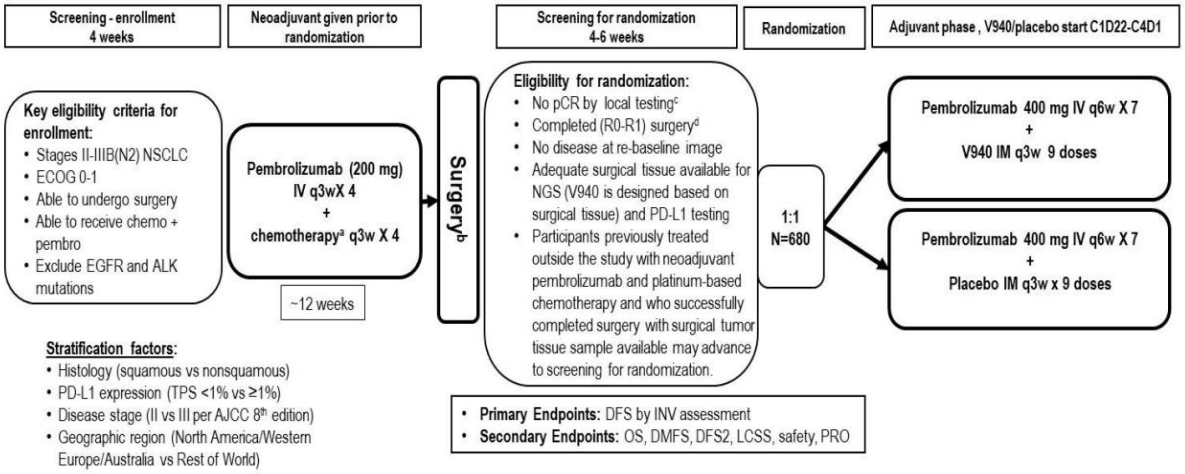


LUNG

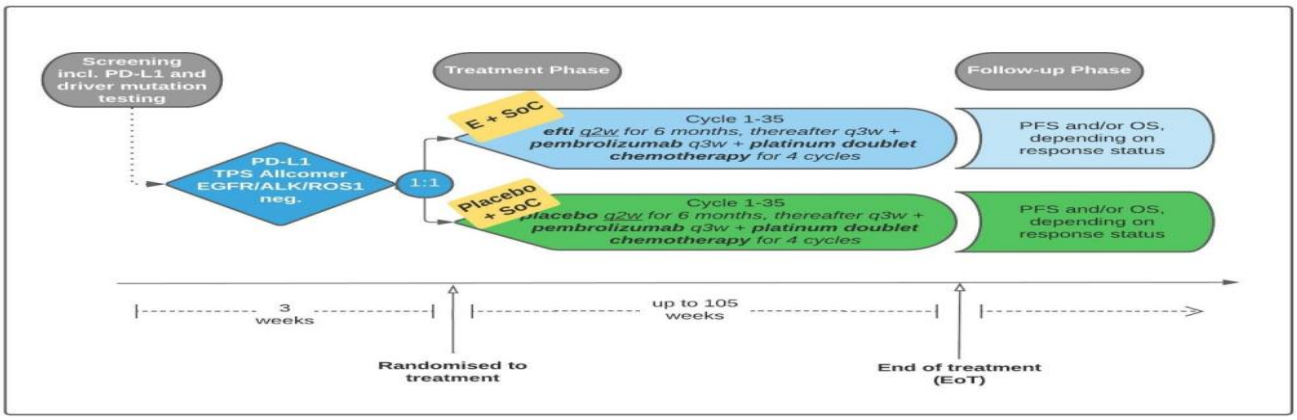
Protocol	**V940-002** A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator-Controlled Clinical Study of **Adjuvant V940 (mRNA-4157) Plus Pembrolizumab** Versus **Adjuvant Placebo Plus Pembrolizumab** in Participants With **Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer**
PI	Dr Sebastian Trainor
Research Nurse	Una Murtagh, Email: una.murtagh@tuh.ie Phone: 01-414 2328
Key Inclusion/ Exclusion Criteria	• Resected (R0) stage II, IIIA, IIIB(N2) NSCLC **(AJCC8)** • No neoadjuvant treatment • Received adjuvant chemotherapy (platinum doublet) with no recurrence • Confirmation that either EGFR-directed or ALK-directed therapy is not indicated as primary therapy. Absence of tumor-activating EGFR mutations [ie, DEL19 or L858R] or ALK mutations
Expected Closing	November 2026



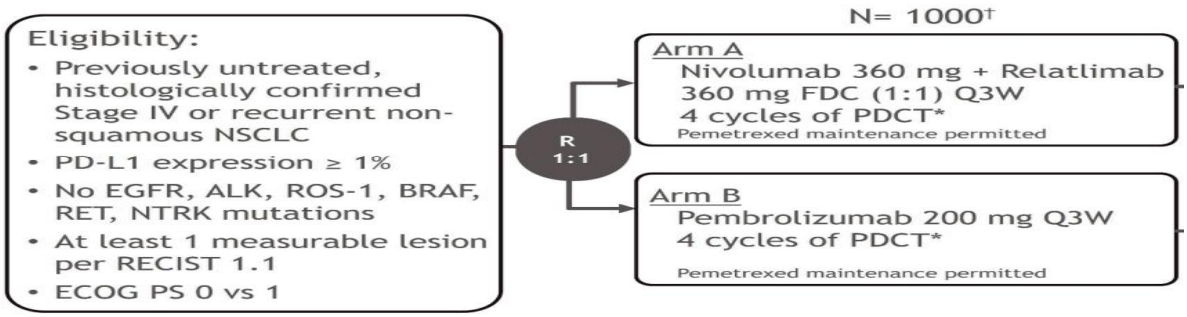
Protocol	**V940-009**
	A Phase 3 Randomized Double-blind Study of Adjuvant **Pembrolizumab With or Without V940** in Participants With **Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR** After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy (INTerpath-009)
PI	Dr Sebastian Trainor
Research Nurse	Una Murtagh, Email: una.murtagh@tuh.ie Phone: 01-414 2328
Key Inclusion/ Exclusion Criteria	• Resectable Stage II, IIIA, or IIIB (N2) NSCLC **(AJCC 8th Edition)** • ECOG 0-1 • Able to undergo surgery and receive chemo + Pembro • No EGFR /ALK mutations
Expected Closing	November 2028



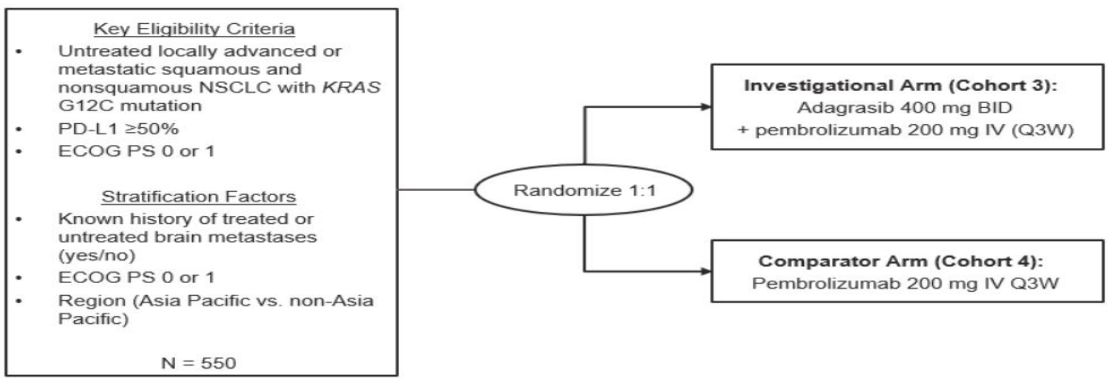
Protocol	**TACTI-004**
	TACTI-004, a double-blinded, randomized phase 3 trial in patients with advanced/metastatic non-small cell lung cancer (NSCLC) receiving Eftilagimod alfa (MHC class II agonist) in combination with pembrolizumab (PD-1 antagonist) and chemotherapy.
PI	Dr Sebastian Trainor
Research Nurse	Heather Sloane, Email: heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• Histologically- or cytologically-confirmed diagnosis of advanced or metastatic (stage IIIB/C or stage IV) NSCLC • Not amenable to curative treatment or locally available oncogenic driver mutation-based first-line therapy • Treatment naïve for systemic therapy given for advanced/metastatic disease (previous palliative radiotherapy for advanced/metastatic disease acceptable). • ECOG 0-1 • Measurable disease as defined by RECIST 1.1
Expected Closing	August 2026



Protocol	**CA224-1093**
	A Phase 3, Randomized, Open-label Study of Nivolumab + Relatlimab Fixed-dose Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy as First-line Treatment for Participants with Non-squamous (NSQ), Stage IV or Recurrent Non-small Cell Lung Cancer and with Tumor Cell PD-L1 Expression ≥ 1%
PI	Dr Sebastian Trainor
Research Nurse	TBC email chistine.leonard@tuh.ie Phone: 01-414 4204
Key Inclusion/ Exclusion Criteria	• Stage IV or recurrent NSCLC • No prior systemic anti-cancer therapy for advanced/metastatic disease • PD-L1 expression ≥ 1% as determined by a central laboratory • No EGFR mutations, ALK translocations, ROS-1, BRAF, RET, NTRK mutations • ECOG 0 - 1
Expected Closing	June 2027

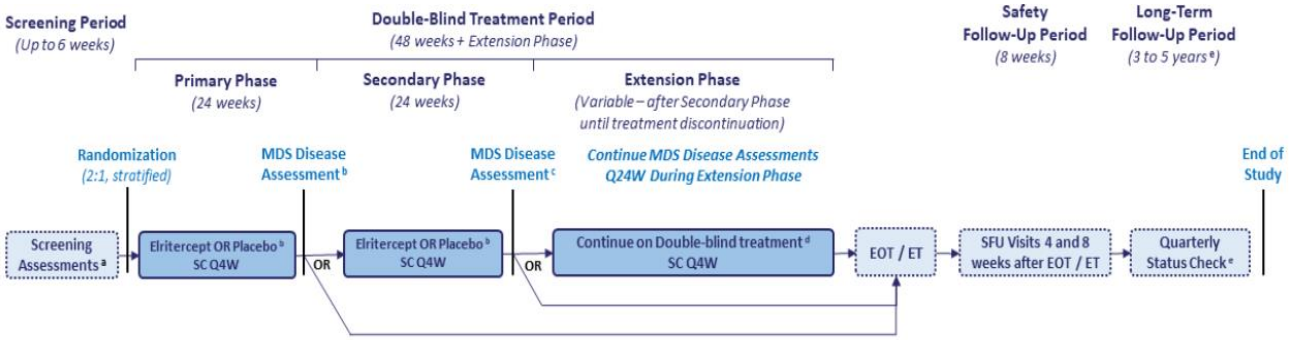


Protocol	**KRYSTAL-7 849-007**
	A Phase 2 Trial of Adagrasib Monotherapy and in Combination with Pembrolizumab and a Phase 3 Trial of **Adagrasib in Combination with Pembrolizumab** versus **Pembrolizumab** in Patients with **Advanced Non-Small Cell Lung Cancer with KRAS G12C Mutation – Phase 3 open TUH**
PI	Dr Sebastian Trainor
Research Nurse	Una Murtagh, Email: una.murtagh@tuh.ie Phone: 01-414 2328
Key Inclusion/ Exclusion Criteria	• Untreated locally advanced or metastatic squamous and nonsquamous NSCLC with KRASG12C mutations • PD-L1 TPS ≥50% • ECOG PS 0 or 1
Expected Closing	November 2026



HAEMATOLOGY

Protocol	**KER-050-D301 (RENEW)**
	A Phase 3, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Elritercept (KER-050) for the Treatment of Transfusion Dependent Anemia in Adult Participants with Very Low-,Low-, or Intermediate-Risk Myelodysplastic Syndromes
PI	Prof Helen Enright
Research Nurse	Una Murtagh, Email: una.murtagh@tuh.ie Phone: 01-414 2328
Key Inclusion/ Exclusion Criteria	• Diagnosis of MDS with or without RS that meets the IPSS-R classification of very low-, low-, or intermediate-risk MDS with transfusion dependence Refractory or intolerant to prior ESA treatment • Less than 5% blasts on bone marrow (centrally assessed) • ECOG 0-2
Expected Closing	January 2027



TRANSLATIONAL/REGISTRY

Protocol	**IRONMAN**
	International Registry for Men with Advanced Prostate Cancer
PI	Prof Ray Mc Dermott
Research Nurse	Heather Sloane Email: heatherj.sloane@tuh.ie Phone: 01-414 4208
Key Inclusion/ Exclusion Criteria	• **Metastatic hormone sensitive prostate cancer (mHSPC):** a) No more than 1 year of continuous ADT b) No more than 90 days of active systemic therapy c) Metastatic disease M1a, b, or c stage or • **Castration resistant prostate cancer (CRPC):** a) A rising PSA indicating progressing disease or new metastatic disease b) No more than 6 weeks of continuous systemic therapy for CRPC at the time of consent c) No active systemic treatment for a diagnosis of a second, non-prostate malignancy
Expected Closing	TBC
Protocol	**WAYFIND-R**
	A Registry to Collect the Natural History of Solid Tumour Cancers in Patients Profiled with a Next Generation Sequencing Test (WAYFIND-R)
PI	Prof Ray Mc Dermott
Research Nurse	Una Murtagh Email: una.murtagh@tuh.ie Phone: 01-4142328
Key Inclusion/ Exclusion Criteria	• Any type of solid tumour cancer, at any stage of the disease, at the enrolment date • Patient has undergone NGS testing, no longer than 3 months prior to the enrolment date, irrespective of the availability of test results
Expected Closing	TBC