





## **HSE West and North West Cancer Clinical Trials Newsletter** for Clinicians, Patients and Members of the Public

## December 2025

Please find current cancer clinical trials open to participant enrolment in our HSE West and North West Health Region with contact details for clinician referral or self - referral.

Site Manager Contact Details	Email address
Irish Research Radiation Oncology Group	laura.nally@hse.ie / helen.mcloughlin6@hse.ie
Cancer Clinical Trials Sligo	margaret1.burke@hse.ie / moira.maxwell@hse.ie
Clinical Cancer Trials Galway	oleksii.noreiko@universityofgalway.ie
Cancer Clinical Trials Letterkenny	marygrace.kelly@hse.ie
Cancer Clinical Trial Set-up Officer	rinumary.thomas@universityofgalway.ie

If you are interested in running a clinical trial/clinical research project within the region and/or need support in developing your protocol, please contact:

## **HSE WNW Region Cancer Clinical Trials Programme Manager**

Dr Veronica McInerney: veronica.mcinerney@universityofgalway.ie

	Principal Investigators		
1	Dr Silvie Blazkova		
2	Dr David Breen		
3	Prof Peter Carr		
4	Dr Sonya Chew		
5	Ms Caitríona Duggan		
6	Dr Paul Donnellan		
7	Ms Breege Farrelly		
8	Prof Ananya Gupta		
9	Prof Amjad Hayat		
10	Dr Jacub Hlasny		
11	Prof Aoife Lowery		
12	Prof Maccon Keane		
13	Prof Michael Kerin		
14	Dr Lore Komanyane		
15	Prof Janusz Krawczyk		
16	Prof Joseph Martin		
17	Dr Michael Martin		
18	Dr Michael McCarthy		
19	Dr Ronan McDermott		
20	Dr Nicola Miller		













	BREAST CANCER TRIALS	
1.	Disease area	Breast Cancer
	Title	<b>Destiny 15:</b> A Phase 3b, Multicenter, Global, Interventional, Open-label, Study of Trastuzumab Deruxtecan (T-DXd), an Anti-HER2-Antibody Drug Conjugate (ADC), in Subjects who Have Unresectable and/or Metastatic HER2-low or HER2 Immunohistochemistry (IHC) 0 Breast Cancer (BC)
	Recruiting Sites	
	PI	
	Research	
	coordinator	Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	Coordinator	Trials Team: 087 2431601
	Key Inclusion	Must agree to provide a newly obtained or archival baseline biopsy from
	Criteria	primary and/or metastatic lesion.
	Criteria	Pathologically documented BC tumor that:
		a) Is unresectable and/or metastatic, b) Is hormone receptor-negative or hormone
		receptor-positive, c) Has confirmed HER2 IHC 1+ or IHC 2+/ISH- (HER2-low) status or HER2 IHC 0 status d) Was never previously HER2-positive (IHC 3+ or IHC 2+/ISH+) on prior pathology testing, e) Was never previously treated with anti-HER2 therapy in the metastatic setting.
		<ul> <li>Has had at least one and up to two prior lines of therapy in the metastatic setting</li> </ul>
		Presence of at least one measurable lesion based on CT or MRI, or at least 1 lesion, not previously irradiated, that can be measured accurately at baseline as
		≥10 mm in the longest diameter with CT or MRI, which is suitable for accurate repeated measurements, or non-measurable, bone-only disease that can be assessed by CT, MRI, or X-ray
		16 Subjects with brain metastases are allowed in the study. The brain lesion(s) should be small (<2 cm), untreated, asymptomatic, not requiring urgent medical intervention, and are asymptomatic and clinically stable
	Key Exclusion Criteria	<ul> <li>Atopoisomerase I inhibitor including prior participation in a study involving an ADC produced by DSI and/or AstraZeneca.</li> </ul>
		<ul> <li>Uncontrolled or significant cardiovascular disease</li> <li>Has a corrected QT interval (QTc) prolongation of &gt;470 ms (females) or &gt;450 ms (males) based on the average of the Screening triplicate 12-lead ECG.</li> <li>Has a history of (non-infectious) ILD/pneumonitis that required steroids, has current ILD/pneumonitis, or where suspected ILD/pneumonitis cannot be ruled</li> </ul>
		<ul> <li>out by imaging at Screening.</li> <li>Has spinal cord compression or clinically active central nervous system metastases or requiring therapy with corticosteroids or anticonvulsants to</li> </ul>
		control associated symptoms.
2.	Disease area	Breast Cancer
	Title	
		Safety Of Camizestrant (Azd9833, A Next Generation, Oral Selective Estrogen
		Receptor Degrader) Vs Standard Endocrine Therapy (Aromatase Inhibitor Or
		Tamoxifen) As Adjuvant Treatment. Patients with ER+/HER2- early breast cancer and
		an intermediate-high or high risk of recurrence who have completed definitive
		locoregional treatment and have no evidence of disease
	Recruiting Sites	
	PI	
	Research	Ms Olive Forde: Olive.Forde@hse.ie
	coordinator	Ms Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	Key Inclusion	Documented histologically confirmed ER+/HER2- early-stage resected invasive
	Criteria	breast cancer with absence of any evidence of metastatic disease















	Key Exclusion Criteria	<ul> <li>Patients must have undergone adequate (definitive) locoregional therapy</li> <li>Patients may have received up to 12 weeks of ET either in the adjuvant or neoadjuvant setting prior to randomisation.</li> <li>Pre-, peri-, and post-menopausal women, and men are eligible if they meet at least 1 of the criteria below:</li> <li>T4 Tumours</li> <li>Tumour of any size with involvement in ≥2 ipsilateral lymph nodes</li> <li>T1c-T3 N0 or with involvement of 1 lymph node (pN1mi is allowed)</li> <li>Patients with inoperable locally advanced breast cancer, without known distant metastasis or distant metastatic (including contralateral axillary lymph nodes) disease.</li> <li>Patients with pathological complete response (pCR) or residual cancer burden (RCB)-0 following treatment with neoadjuvant chemotherapy.</li> <li>Patients with a history of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered a very low risk of recurrence per investigator's judgement</li> <li>Patients with a history of previous breast cancer are excluded with the exception of ipsilateral ductal carcinoma in situ (DCIS) treated by locoregional therapy alone ≥5 years ago or contralateral DCIS treated with locoregional therapy at any time.</li> </ul>
3.	Disease area	Breast Cancer
	Title	MK 2870: A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and
		Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus
		Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast
		Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a
		Pathological Complete Response (pCR) at Surger
	Recruiting Sites	Galway University Hospital
	PI	Professor Maccon Keane
	Research	Olive Forde: Olive.Forde@hse.ie
	coordinator	Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	Key Inclusion	Has centrally confirmed TNBC
	Criteria	No evidence of locoregional or distant relapse
		Had neoadjuvant treatment based on the KEYNOTE-522 regimen, followed by  TNDG G.
		surgery according to NCCN treatment guidelines for TNBC. Completed at least
		5 doses of neoadjuvant pembrolizumab and chemotherapy, including at least one dose of anthracycline
		Had adequate excision and surgical removal of all clinically evident disease in
		the breast and/or lymph nodes and have adequately recovered from surgery
		is a sum and the sum of the sum o
	<b>Key Exclusion</b>	Has a known germline BRCA mutation
	Criteria	Has Grade >2 peripheral neuropathy
		History of documented severe dry eye syndrome, severe Meibomian gland
		disease and/or blepharitis, or corneal disease that prevents/delays corneal
		healing
		Has active IBD requiring immunosuppressive medication or previous history of
		IBD
	7.1	
4.	Disease area	Breast Cancer
	Title	ATNEC is a phase III, open, randomised, multicentre trial comparing standard axillary
		treatment (either, axillary lymph node dissection [ALND] or axillary radiotherapy















ALWK		
		[ART]) with no axillary treatment post-surgery, in early stage (T1-3N1M0) breast
	Dagwyiting Cites	cancer patients
	Recruiting Sites PI	Galway University Hospital Professor Aoife Lowery
	Research	Olive Forde: Olive.Forde@hse.ie
	coordinator	Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	Key Inclusion	Female or male with cT1–3N1M0 breast cancer
	Criteria	Biopsy-proven axillary nodal metastases at presentation
		Radiological node-negative (ycN0) post NACT
		Radiological flode-flegative (yervo) post tvAC1
	Key Exclusion	Distant metastases (M1)
	Criteria	Incomplete or no neo-adjuvant chemotherapy
		Residual clinically or radiologically positive nodes (ycN+)
		generally process (jew )
5.	Disease area	
	Title	Incorporation of telemedicine monitoring in HR+/HER2- advanced breast cancer
		patients receiving Ribociclib
	D '4' G'4	
	Recruiting Sites	Galway University Hospital
	PI Research	Dr Sonya Chew Olive Forde: Olive.Forde@hse.ie
	coordinator	Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	Key Inclusion	Patients with advanced HR+/HER2- breast cancer starting Ribociclib
	Criteria	
	Criteria	<ul> <li>Able to provide written informed consent</li> <li>Age &gt; 18 years</li> </ul>
		<ul> <li>Age &gt; 16 years</li> <li>Able to speak and read English</li> </ul>
		Own a mobile telephone with capabilities to support a virtual
	Key Exclusion	Patients whose caregivers coordinate their health care
	Criteria	Patients unable to speak and read English
		<ul> <li>Patients who do not have access to a mobile telephone with capabilities to</li> </ul>
		support a virtual call
6.	Disease Area	Breast cancer
	Title	Relationship changes impacting Couples following breast cancer diagnosis – a cross-
	D a averitin a Citaa	Column Hairmaite Hamital
	Recruiting Sites PI	Galway University Hospital  Ma, Vimong Du/Prof Paul Garrett/Prof Acife Lowery /Dr. Sanya Chay
	Researcher	Ms, Yimeng Du/ Prof Paul Garrett/ Prof Aoife Lowery /Dr Sonya Chew.  Ms, Yimeng Du: y.du8@universityofgalway.ie
	Key Inclusion	Diagnosed with local or regional breast cancer (Stages 0-III);
	Criteria	<ul> <li>married or living with their partners</li> </ul>
		normal mental state
		fluent in English language
		Consent
	Key Exclusion	Patients under 18 years of age.
	Criteria	Previous participant in biobank program
7.	Disease area	Breast Cancer
	Title	<b>ECONSENT</b> : A Randomized Controlled Trial To Test Efficacy of Electronic Informed
		Consent Process Versus Paper Informed Consent Process, as a Methodological
	<b>7</b>	Approach for Biobank Research In Patients With Cancer
	Recruiting Sites	GUH

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LW		
	PI	Prof Michael Kerin
	Research	Olive Forde: Olive.Forde@hse.ie
	coordinator	Gráinne McDonnell: grainneb.mcdonnell@hse.ie
	<b>Key Inclusion</b>	
	Criteria	Diagnosis of Cancer/Consenting to participate in Biobank programme.
		Read and Understand English Language or Irish Language
		Who consent to partake in this study
		BASKET TRIALS
8.	Disease area	
	Title	<b>DPAC:</b> A Randomised Controlled Trial of Deprescribing versus Standard of Care in Patients with Advanced Cancer.
	Recruiting Sites	
	PI	
	11	Dr Lars
	Research	
	coordinator	Dorota Chambers dorota.chambers@hse.ie
		Katherine Cussen Katherine.cussen@hse.ie
	IZ I1	Margaret1.burke@hse.ie
	Key Inclusion	• Patients over aged >/= 18 years
	Criteria	Ability to read and understand English
		Diagnosis of advanced cancer
		Patients currently prescribed medications detailed in the OncPal deprescribing
		guidelines (appendix 1)
		Suitable for de-prescribing as determined by the physician
	<b>Key Exclusion</b>	Patients who do not consent to study participation
	Criteria	Patients who are not currently taking any medication that can be deprescribed as per
		Onc Pal International guidelines
9.	Disease area	
	Title	
		Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study.
	Recruiting Sites	Sligo University Hospital
	PI	
	Research	Margaret1.burke@hse.ie Moira.Maxwell@hse.ie
	coordinator	
[	<b>Key Inclusion</b>	Adult aged ≥ 18 years
	Criteria	Diagnosed with breast or prostate cancer
		Receiving endocrine therapy cancer treatment
		Experiencing vasomotor symptoms, such as hot flushes or night sweats
	Key Exclusion	Prior use of cooling mats for vasomotor symptoms
	Criteria	· Allergy to Polyvinyl chloride (PVC)
		Patients who are unable to co-operate with the study protocol
		Patients who are unable to give informed consent
10.	Disease area	Basket (All Cancer Types)
[	Title	Can-React: Cancer Rehabilitation Action- A Personalised Exercise programme for
		Rehabilitation and Recovery
[	Recruiting Sites	Galway University Hospital
	PI	Professor Ananya Gupta
	Research	Ms Marian Jennings marian.jennings@hse.ie
	coordinator	Ms Alyssa Paz alyssa.paz@hse.ie















T W		
	Key Inclusion	Cancer survivors who are currently on or have completed active treatment
	Criteria	Aged 18 years or older;
		• fluent in English;
		Completed PAR-Q questionnaire and ePARmedx if required
		Performance status ECOG 2 or less
		No communication deficit or moderate-to-severe cognitive deficit
	Key Exclusion	No Consent
	Criteria	<ul> <li>Performance status ECOG =/&gt; 3</li> </ul>
	Critcria	Ferformance status ECOG =/> 3
11.	Disease area	Basket (All Cancer Types)
	Title	
	11110	Stereotactic Ablative Radiotherapy for the Comprehensive treatment of Oligo-
		metastases/progression
	Recruiting Sites	
	PI	
	Research	
	coordinator	
	<b>Key Inclusion</b>	
	Criteria	Histologically confirmed malignancy with metastatic disease detected on
		imaging
		Controlled primary tumour defined as at least 3 months since original tumour treated
		definitively, with no progression at primary site
	<b>Key Exclusion</b>	Uncontrolled concurrent malignant cancer
	Criteria	Lesion in femoral bone requiring surgical fixation
		Substantial overlap with a previously treated radiation volume
		Current malignant pleural effusion
12.	Disease area	
	Title	
	Daamiiin a Citaa	irradiation
	Recruiting Sites	
	PI	I
		Laura Nally laura.nally@hse.ie
	coordinator	Helen McLoughlin helen.McLoughlin6@hse.ie
	<b>Key Inclusion</b>	Pathologically confirmed cancer, including local and locoregional recurrence,
	Criteria	metastases or new primary tumour from the following list of cancers: breast,
		non small cell lung cancer, small cell lung cancer, colorectal, prostate,
		endometrial, cervical, squamous H&N, glioma and meningioma
		High-dose re-irradiation planned or ongoing
		• Re-irradiation type 1 being a new course of radiotherapy that has geometrical
		overlap with the previously irradiated volume (irrespective of concerns for
		toxicity) and re-irradiation type 2 being a new course of radiotherapy without
		geometric overlap but with concerns of toxicity from the cumulative doses
	<b>Key Exclusion</b>	• Life expectancy as assessed by the treating physician is less than 3 months
	Criteria	Palliative non-therapeutic re-irradiation doses
		Missing information of previous radiotherapy
13.	Disease area	Basket (All Cancer Types)
	Title	
		(EUPIC) insertion by oncology nurses versus traditional (touch and feel)
1		(20110) institute of enteregi norses versus traditional (continuant total)
		approaches. A Randomized Controlled Trial (RCT).















ALWA		-3-2
	Recruiting Sites	Portiuncula, Galway and Letterkenny University Hospitals
	PI	Dr Peter Carr/ Ms Catriona Duggan
	Research	Caitríona Duggan c.duggan23@universityofgalway.ie
	coordinator	Mary Grace Kelly marygrace.kelly@hse.ie
		Marian Jennings: Marian.jennings@hse.ie
		Alyssa dela Paz: alyssa.Paz@hse.ie
	<b>Key Inclusion</b>	Patients with a diagnosis of cancer
	Criteria	Attending the Oncology/ Haematology Day ward
		• Age >18 years and above
		Scheduled to receive intravenous anti-cancer therapy.
		Require a peripheral intravenous catheter
		6 Provide written informed consent
	Key Exclusion	Patients under 18 years of age.
	Criteria	• (2) Persons who are unable to co-operate with the study protocol
	011001111	(2) Persons who are unable to give informed consent
		(3) Tersons who are unable to give informed consent
14.	Disease area	Basket (All Cancer Types)
	Title	Cares: A Phase 1/2 Trial of the Synthetic Cannabinoid ART27.13 in Patients with
		Cancer Anorexia and Weight Loss
	Recruiting Sites	Galway University Hospital and Sligo University Hospital
	PI	Prof Dympna Waldron
		Dr Michael Martin
	Research	Marian Jennings: Marian.jennings@hse.ie
	coordinator	Alyssa dela Paz: Alyssa.Paz@hse.ie
		Margaret1.burke@hse.ie Moira.Maxwell@hse.ie
	<b>Key Inclusion</b>	Have cancer documented by histopathology or cytology.
	Criteria	Have anorexia as determined by self-reported decrease or lack of appetite or aversion to food
		• Have documented, unintentional weight loss of >5% of body weight and a
		continuous downward trend in the past 6months (±2 weeks)
		• Patients on either: no anti-cancer therapy for the 2 weeks before enrolment and
		are not expected to have anti-cancer therapy/radiotherapy for the first
		• stable dosing from 2 weeks before enrolment and expected to be on such
		therapy for another 12 weeks of anti-cancer therapies
	Key Exclusion	Primary brain tumour or symptomatic brain metastasis
	Criteria	Oral mucositis or oral fungal infection causing anorexia or impairing taste
		Unable to swallow food + PO medications
		Be on, been on within 4 weeks prior to enrolment, or expected to be on
		medications that have the potential to affect anorexia or caloric intake. Be on
		strong CYP3 A4 inhibitors or inducers
		Hx of any illicit drug use, alcohol misuse, or other drug misuse within the last
		24 months. Current medicinal use of cannabinoids also excluded.
		Recent diagnosis of Clinical Depression starting on medication within 4 weeks
		prior to enrolment
		LUNG CANCER
15.	Disease area	Lung Cancer
10.	Title	Harmoni: A Randomized, Double-blind, Phase 3 Study of Ivonescimab +
	1100	Chemotherapy V Pembrolizumab + Chemotherapy for the First-line Treatment of
		Metastatic NSCLC(Squamous and Non Squamous
	Recruiting Sites	Galway University Hospital
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Research   Research   Marian Jennings: Marian, jennings@hse.ie
Coordinator   Alyssa dela Paz: alyssa.Paz@hse.ie
Coordinator   Alyssa dela Paz: alyssa.Paz@hse.ie
Criteria   ECOG 0-1     Measurable disease as per RECIST 1.1     Documented PD-L1 expression status
Criteria   ECOG 0-1     Measurable disease as per RECIST 1.1     Documented PD-L1 expression status
Measurable disease as per RECIST 1.1     Documented PD-L1 expression status      Radiologically documented evidence of major blood vessel invasion/ or tumor invading organs.     Known actionable genomic alterations for which first-line approved therapies are available.     Active or untreated CNS metastases     History of bleeding tendencies or coagulopathy and/or clinically significant bleeding symptoms or risk within 4 weeks prior to randomization     Active autoimmune disease  16. Disease area  Lung Cancer  Title Mirati Trial: 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 NSCLC with KRAS G12C Mutation  Recruiting Sites Galway University Hospital  PI Dr Silvie Blaskova  Marian Jennings: Marian.jennings@hse.ie  Coordinator  Key Inclusion Criteria Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  Measurable disease per RECIST 1.1  ECOG 0-1
Criteria   Radiologically documented evidence of major blood vessel invasion/ or tumor invading organs.   Known actionable genomic alterations for which first-line approved therapies are available.   Active or untreated CNS metastases   History of bleeding tendencies or coagulopathy and/or clinically significant bleeding symptoms or risk within 4 weeks prior to randomization   Active autoimmune disease
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Known actionable genomic alterations for which first-line approved therapies are available.     Active or untreated CNS metastases     History of bleeding tendencies or coagulopathy and/or clinically significant bleeding symptoms or risk within 4 weeks prior to randomization     Active autoimmune disease  16. Disease area Lung Cancer  Title Mirati Trial: 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 NSCLC with KRAS G12C Mutation  Recruiting Sites Galway University Hospital  PI Dr Silvie Blaskova  Research coordinator Alyssa de la Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  Marsurable disease per RECIST 1.1  ECOG 0-1
are available.  • Active or untreated CNS metastases  • History of bleeding tendencies or coagulopathy and/or clinically significant bleeding symptoms or risk within 4 weeks prior to randomization  • Active autoimmune disease  16. Disease area Lung Cancer  Title Mirati Trial: 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 NSCLC with KRAS G12C Mutation  Recruiting Sites Galway University Hospital  PI Dr Silvie Blaskova  Research coordinator  Key Inclusion Criteria  • Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  • Measurable disease per RECIST 1.1  • ECOG 0-1
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bleeding symptoms or risk within 4 weeks prior to randomization  • Active autoimmune disease  16. Disease area
• Active autoimmune disease  16. Disease area   Lung Cancer   Title   Mirati Trial: 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 NSCLC with KRAS G12C Mutation  Recruiting Sites   Galway University Hospital   PI   Dr Silvie Blaskova   Research   Marian Jennings: Marian.jennings@hse.ie   coordinator   Alyssa de la Paz: alyssa.Paz@hse.ie   Key Inclusion   Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)   • Measurable disease per RECIST 1.1   • ECOG 0-1
16. Disease area Lung Cancer  Title Mirati Trial: 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 NSCLC with KRAS G12C Mutation  Recruiting Sites Galway University Hospital  PI Dr Silvie Blaskova  Research Coordinator Alyssa de la Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  • Measurable disease per RECIST 1.1  • ECOG 0-1
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Pembrolizumab and a Phase 3 Trial of Adagrasib in Combination with Pembrolizumab versus Pembrolizumab in Patients with Advanced NSCLC with KRAS G12C Mutation  Recruiting Sites Galway University Hospital  PI Dr Silvie Blaskova  Research coordinator Alyssa de la Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  • Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  • Measurable disease per RECIST 1.1  • ECOG 0-1
versus Pembrolizumab in Patients with Advanced NSCLC with KRAS G12C Mutation         Recruiting Sites       Galway University Hospital         PI       Dr Silvie Blaskova         Research coordinator       Marian Jennings: Marian.jennings@hse.ie         Alyssa de la Paz: alyssa.Paz@hse.ie         Key Inclusion Criteria       Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)         Measurable disease per RECIST 1.1       ECOG 0-1
Recruiting Sites       Galway University Hospital         PI       Dr Silvie Blaskova         Research coordinator       Marian Jennings: Marian.jennings@hse.ie         Key Inclusion Criteria
PI Dr Silvie Blaskova  Research drian Jennings: Marian.jennings@hse.ie  coordinator Alyssa de la Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Criteria  Marian Jennings: Marian.jennings@hse.ie  Histologically confirmed diagnosis of NSCLC (squamous or non squamous)  with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)  Measurable disease per RECIST 1.1  ECOG 0-1
Research coordinator       Marian Jennings: Marian.jennings@hse.ie         Key Inclusion Criteria       Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)         Measurable disease per RECIST 1.1         ECOG 0-1
coordinator       Alyssa de la Paz: alyssa.Paz@hse.ie         Key Inclusion       • Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)         • Measurable disease per RECIST 1.1         • ECOG 0-1
<ul> <li>Key Inclusion         <ul> <li>Criteria</li> <li>Histologically confirmed diagnosis of NSCLC (squamous or non squamous) with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)</li> <li>Measurable disease per RECIST 1.1</li> <li>ECOG 0-1</li> </ul> </li> </ul>
<ul> <li>Criteria with KRAS G12C mutation and PD-L1 Tumor ≥ 50%. (both central testing)</li> <li>Measurable disease per RECIST 1.1</li> <li>ECOG 0-1</li> </ul>
<ul> <li>Measurable disease per RECIST 1.1</li> <li>ECOG 0-1</li> </ul>
• ECOG 0-1
No prior systemic therapy for advanced Disease
Key Exclusion • Prior KRAS G12C inhibitor treatment
Criteria • Untreated or Unstable CNS Metastases
Active autoimmune disease
Hx of CVA /TIA /MI within 6 months
17. Disease area   Lung Cancer
Title Neo-Coast 2: Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and
Adjuvant Treatment in Patients with Resectable, Early-stage (II to IIIB) NSCLC.
Recruiting Sites   Galway University Hospital
PI   Dr Silvie Blazkova
Research Marian Jennings: Marian.jennings@hse.ie
Research Marian Jennings: Marian.jennings@hse.ie coordinator Alyssa dela Paz: alyssa.Paz@hse.ie
Research coordinator       Marian Jennings: Marian.jennings@hse.ie         Key Inclusion       ◆ Newly diagnosed and previously untreated patients with histologically or
Research coordinator Alyssa dela Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Research Marian Jennings: Marian.jennings@hse.ie  Alyssa dela Paz: alyssa.Paz@hse.ie  • Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.
Research coordinator Alyssa dela Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be
Research coordinator  Key Inclusion Criteria  Criteria  Marian Jennings: Marian.jennings@hse.ie Alyssa dela Paz: alyssa.Paz@hse.ie  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be deemed achievable
Research coordinator Alyssa dela Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be deemed achievable  T4 tumours will only be eligible if they are defined as T4 based only on their
Research coordinator Alyssa dela Paz: alyssa.Paz@hse.ie  Key Inclusion Criteria  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be deemed achievable  T4 tumours will only be eligible if they are defined as T4 based only on their size (more than 7 cm)
Research coordinator  Key Inclusion Criteria  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be deemed achievable  T4 tumours will only be eligible if they are defined as T4 based only on their size (more than 7 cm)  Documented PD-L1 expression status
Research coordinator   Alyssa dela Paz: alyssa.Paz@hse.ie     Key Inclusion Criteria   Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.     At screening, complete surgical resection of the primary NSCLC must be deemed achievable     T4 tumours will only be eligible if they are defined as T4 based only on their size (more than 7 cm)     Documented PD-L1 expression status     Key Exclusion   Patients with sensitising EGFR mutations or ALK translocations.
Research coordinator  Key Inclusion Criteria  Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.  At screening, complete surgical resection of the primary NSCLC must be deemed achievable  T4 tumours will only be eligible if they are defined as T4 based only on their size (more than 7 cm)  Documented PD-L1 expression status
Research coordinator   Alyssa dela Paz: alyssa.Paz@hse.ie     Key Inclusion Criteria   Newly diagnosed and previously untreated patients with histologically or cytologically documented NSCLC.     At screening, complete surgical resection of the primary NSCLC must be deemed achievable     T4 tumours will only be eligible if they are defined as T4 based only on their size (more than 7 cm)     Documented PD-L1 expression status     Key Exclusion   Patients with sensitising EGFR mutations or ALK translocations.















ALWK		
		Uncontrolled central nervous system ( CNS) metastases
18.	Disease area	Lung Cancer
	Title	LCO: A feasibility assessment of Lung Cancer Orchestrator and surveillance
		pathway as an intervention for early detection of lung cancer in patients with
-	Recruiting Sites	incidental radiological pulmonary nodule findings Galway University Hospital
-	PI	Dr David Breen
-	Research	Ms Imelda Fleming Advanced Nurse Practitioner imelda.fleming@hse.ie
	coordinator	Ms Nansi Corcoran Rapid Access Lung Cancer Coordinator nansi.corcoran@hse.ie
	<b>Key Inclusion</b>	• Patients aged >/= 18 years
	Criteria	Ability to read and understand English
		Recent chest radiology within 28 days
		Documented pulmonary nodules on report triggered by lung cancer orchestrator
		system
		Clinical and/ or Radiological assessment required.
		Patients who provide written informed consent
	Key Exclusion	Patients currently the care of a pulmonologist
	Criteria	Patients already with a current diagnosis of cancer
		Patients currently being worked up / screened for cancer.
		Patients who are unable to co-operate with the study protocol
		Patients who are unable to give informed consent
19.	Disease area	Lung Cancer
	Title	Radiomics: A Retrospective Multi-Centre Study to Explore the value of Diagnostic
-	D:4: C:4	Imaging and Radiomics in Characterising and Predicting ILD/Pneumonitis
-	Recruiting Sites PI	Galway University Hospital Dr Paul Donnellan
-	Research	Sunaina Ashok Kodalkar: sunaina.kodalkar@hse.ie
	coordinator	Trials Team: 087 2431601
-	Key Inclusion	INCLUSION
	Criteria	• Patients ≥18 years
		Pathologically verified NSCLC diagnosis acquired through tumor cytology or
		biopsy.
		Documented diagnosis of TNM
		Stage III unresectable NSCLC (7th/8th TNM International Association for the
		Study of Lung Cancer [IASLC] edition)
		Patients treated with radiotherapy.
		Patients may also have been treated with immunotherapy and/or chemotherapy
-	<b>Key Exclusion</b>	Patients with inadequate follow- up scans.
	Criteria	Patients who were not treated with radiotherapy
		Patients treated with less than 40 Gy or patient treated with palliative intent
		Patients showing ILD/pneumonitis findings not associated with cancer therapy
		in the initial imaging.
		Gynaecology
	Disease area	Gynaecology













T W		
20.	Title	<b>XPORT 42:</b> A Phase 3, Randomized, Placebo-Controlled, Double-Blind, Multicenter
		Trial Of Selinexor In Maintenance Therapy After Systemic Therapy For Patients With
		P53 Wild-Type, Advanced Or Recurrent Endometrial Carcinoma
	Recruiting Sites	Galway University Hopsital and Sligo University Hospital
	PI	Dr Michael McCarthy
	11	Dr Lors
l	D	
	Research	Alyssa Dela Paz: alyssa.Paz@hse.ie /Marian Jennings: Marian.jennings@hse.ie
	coordinator	Margaret. Burke1@hse.ie / Moira.maxwell@hse.ie
	<b>Key Inclusion</b>	Centrally positive TP53 wild type
	Criteria	• ECOG 0-1
		<ul> <li>Completed a single line, at least 12 weeks of platinum-based therapy (not including adjuvant or neoadjuvant therapy for Stage I-III disease) and achieved confirmed partial or complete response (PR or CR) by imaging, according to RECIST version 1.1</li> </ul>
Ī	Key Exclusion	Uterine sarcomas (carcinosarcomas – not excluded), clear cell or small cell
	Criteria	carcinoma with neuroendocrine differentiation
	Criteria	Active Brain Metastases
		Haematology
21.	Disease area	Multiple Myeloma
	Title	Majestec -4
		Phase 3 Study of Teclistamab in Combination With Lenalidomide and Teclistamab
		Alone versus Lenalidomide Alone in Participants With Newly Diagnosed Multiple
		Myeloma as Maintenance Therapy following Autologous Stem Cell Transplantation.
	Recruiting Sites	GUH
	PI	
	Sub I	Dr. Muhammad Fawad Khan: MuhammadFawad.Khan@hse.ie
	Research	Dorota Matczuk: Dorota.Matczuk@hse.ie
		Katherine Cussen: Katherine.Cussen@hse.ie
	coordinator	Ŭ .
	Key Inclusion	18 years of age with New diagnosis of symptomatic multiple myeloma
	Criteria	according to IMWG criteria and have received 4 to 6 cycles of 3- or 4-drug
		induction therapy that includes a proteasome inhibitor and/or an IMiD with or
		without anti-CD38 monoclonal antibody and a single or tandem ASCT.
		• Received only one line of therapy and achieved at least a partial response (≥PR)
		as per IMWG 2016 response criteria.
		<ul> <li>Received high-dose chemotherapy and ASCT within 12 months of the start of</li> </ul>
		induction therapy and be within 6 months of the last ASCT at the time of
		randomization/Sponsor approval.
		Must not have received any maintenance therapy.
		• Have an ECOG performance status score of 0-2 at screening and immediately
		prior to the start of administration of study treatment.
	<b>Key Exclusion</b>	Previous therapy with a gene modified adoptive cell therapy (e.g., chimeric
	Criteria	antigen receptor modified T cells, NK cells).
	2	History of allogeneic SCT or prior organ transplant.
		D THE COLL
		Progressive disease as per IMWG 2016 criteria at any time prior to randomization.
		• Radiotherapy within 14 days or focal radiation within 7 days of C1D1.
		• Excluded for any of the following:
		a) Ongoing MDS or B cell malignancy (other than MM).
		b) History of malignancy, other than MM, which is considered at high risk of recurrence
		requiring systemic therapy.















		<ul> <li>c) Active malignancy other than MM. (For exceptions please refer to protocol).</li> <li>PCL, sm.MM, WM, POEMS syndrome or light chain amyloidosis in the absence of underlying symptomatic myeloma as defined per IMWG criteria with the presence of CRAB and/or SLiM symptoms.</li> <li>CNS involvement or presence of cardiac conditions (see details).</li> <li>Have received an investigational drug (including investigational vaccines) or used an invasive investigational medical device within 4 weeks or 5 PK half-lives, before C1D1.</li> </ul>
22.	Disease area	Multiple Myeloma
	Title	<b>Successor:</b> Two-stage, randomized, multicenter, open-label, Phase 3 study, comparing the efficacy and safety of Mezigdomide, Bortezomib and Dexamethasone (MeziVd) versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in subjects with relapsed or refractory multiple myeloma (RRMM) who received between 1 to 3 prior lines of therapy and who have had prior Lenalidomide exposure.
-	<b>Recruiting Sites</b>	Galway University Hospital
	PI	Prof. Janusz Krawczyk:
-	Sub I	Dr. Muhammad Fawad Khan: MuhammadFawad.Khan@hse.ie
	Research	Dorota Matczuk: Dorota.Matczuk@hse.ie
	coordinator	Katherine Cussen: Katherine.Cussen@hse.ie
-	Key Inclusion	• ≥ 18 years having diagnosis of MM and measurable disease.
	Criteria	Received 1 to 3 prior lines of anti-MM therapy including lenalidomide-containing
		regimen and achieved MR or better to at least 1 prior anti-MM therapy.
		Documented disease progression during or after their last anti-myeloma regimen.
-		• ECOG performance status score of 0, 1 or 2.
	Key Exclusion	EXCLUSION
	Criteria	Progression during treatment or within 60 days of the last dose of a proteasome  inhibitor with few executions (see material)
		<ul> <li>inhibitor with few exceptions (see protocol for details).</li> <li>For subjects with prior treatment of a Bortezomib containing regimen, the best</li> </ul>
		response achieved was not a minimal response or better, or subject discontinued
		Bortezomib due to toxicity.
		Prior treatment with Mezigdomide or Pomalidomide.
		<ul> <li>History of any investigational agents within 28 days or 5 half-lives (whichever is shorter) of initiating study treatment.</li> </ul>
		• Received any of the following:
		<ul><li>a) Plasmapheresis within the last 28 days of initiating study treatment.</li><li>b) Major surgery within 28 days of initiating study treatment.</li></ul>
		c) Radiation therapy, other than local palliative therapy, for myeloma associated bone
		lesions within 14 days of initiating study treatment.
		d) Use of any systemic anti-myeloma drug therapy within 14 days of initiating study
		treatment.
		Previously received allogeneic SCT at any time during prior therapy or received
		autologous SCT within 12 weeks of initiating study treatment.
		Current or past history of PCL, WM, POEMS syndrome, or light-chain  amyloidesis.
		<ul><li>amyloidosis.</li><li>Known CNS involvement with myeloma.</li></ul>
		GI disease or surgery that may significantly alter the absorption of
		Mezigdomide and/or other oral study treatment.
		Prior history of malignancies, other than MM, unless the subject has been free
		of the disease for $\geq 3$ years (for exceptions please refer to protocol).
		Received immunosuppressive medication within the last 14 days of initiating
		study treatment (for exceptions please refer to protocol).
		Clinically significant cardiac disease















23.	Disease area	Lymphoma
	Title	EBMT-02 Use of Brentuximab Vedotin and/or Checkpoint Inhibitors as a Bridge to
		Autologous Transplantation in Hodgkin's Lymphoma
	Recruiting Sites	Galway University Hospital
	PI	Prof. Amjad Hayat
		Dr. Muhammad Fawad Khan: MuhammadFawad.Khan@hse.ie
	Research	Dorota Matczuk: Dorota.Matczuk@hse.ie
	coordinator	Katherine Cussen: Katherine.Cussen@hse.ie
	<b>Key Inclusion</b>	• Age ≥ 18 years of age
	Criteria	Diagnosis: classical HL
		Decision to use BV and/or CPI-based salvage therapy as bridge to autologous
		SCT for HL
	Key Exclusion	Na
	Criteria	
24.	Disease area	Biobank
	Title	Blood Cancer Biobank Ireland (BCBI) sample collection and management
	<b>Recruiting Sites</b>	Galway University Hospital
	PI	Prof. Janusz Krawczyk:
	Sub I	Dr. Muhammad Fawad Khan: Muhammad Fawad. Khan@hse.ie
	Researchcoordin	Dorota Matczuk: Dorota.Matczuk@hse.ie
	ator	Katherine Cussen: Katherine.Cussen@hse.ie
	<b>Key Inclusion</b>	All newly diagnosed CLL (Chronic lymphocytic leukaemia), AML (Acute myeloid
	Criteria	leukaemia) and MM (Multiple myeloma) participants who have not yet received any
		treatment.
	Key Exclusion	Na
	Criteria	
25	D,	D: 1 1 II 4 1
25.	Disease area	Biobank Haematology
	Title	GEMS: The Impact of Genetic Expression Profile on Depth of Response and Survival
	D	In Multiple Myeloma
	Recruiting Sites	Galway University Hospital
	PI Sub I	Prof. Janusz Krawczyk: Dr. Muhammad Fawad Khan: MuhammadFawad.Khan@hse.ie
	Sub I Research	Dorota Matczuk: Dorota.Matczuk@hse.ie
	coordinator	Katherine Cussen: Katherine.Cussen@hse.ie
	Key Inclusion	All newly diagnosed Multiple Myeloma participants who are eligible for autologous
	Criteria	stem cell transplant.
	Criteria	siem een nanspiam.





