Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Research Directory

Commercial Research Register

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Ariennir gan Lywodraeth Cymru
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Commercial Research Register	
Study Name	
Cancer	
Cancer - Breast	
CANC - 3490 OLYMPIA	A randomised, double-blind, parallel group, placebo-controlled, multi-centre, Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy
Cancer - Gynaecological	
CANC 4403	An open label, single arm, multicenter study to assess the clinical effectiveness and safety of Lynparza (olaparib) capsules maintenance monotherapy in platinum sensitive relapsed BRCA mutated ovarian cancer patients who are in complete or partial response following platinum based chemotherapy (ORZORA)
Cancer - Haematological Oncology	
NCRN443: PREAMBLE observational myeloma	PROSPECTIVE RESEARCH ASSESSMENT IN MULTIPLE MYELOMA: AN OBSERVATIONAL EVALUATION
NCRN525 - AZACITIDINE + BSC v PLACEBO + BSC in MDS	A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLEBLIND STUDY TO COMPARE THE EFFICACY AND SAFETY OF ORAL AZACITIDINE PLUS BEST SUPPORTIVE CARE VERSUS PLACEBO PLUS BEST SUPPORTIVE CARE IN SUBJECTS WITH RED BLOOD CELL TRANSFUSION-DEPENDENT ANEMIA AND THROMBOCYTOPENIA DUE TO IPSS LOWER-RISK MYELODYSPLASTIC SYNDROMES
CANC - 3527 Ixazomib in Multiple Myeloma	A Phase 3, Randomized, Placebo Controlled, Double-Blind Study of Oral Ixazomib Maintenance Therapy After Initial Therapy in Patients With Newly Diagnosed Multiple Myeloma Not Treated With Stem Cell Transplantation
CANC - 3619	A non-interventional post authorisation registry of patients treated with pomalidomide for relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy
CANC - 4957	A MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PHASE III STUDY OF IDASANUTLIN, AN MDM2 ANTAGONIST, WITH CYTARABINE VERSUS CYTARABINE PLUS PLACEBO IN PATIENTS WITH RELAPSED OR REFRACTORY ACUTE MYELOID LEUKEMIA (AML)
Cancer - Lung	
A Phase I trial of oral CCT245737	A Phase I trial of oral CCT245737 (a CHK1 inhibitor) given in combination with gemcitabine plus cisplatin or gemcitabine alone in patients with advanced cancer
Cancer - Other	
CANC - 4997	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination With nab Paclitaxel Plus Gemcitabine Compared With Placebo Plus nab Paclitaxel and Gemcitabine in Subjects with Hyaluronan-High Stage IV Previously Untreated Pancreatic Cancer
A Phase I trial of CCT245737 in patients with advanced cancer	A Phase I trial of CCT245737 (a CHK1 inhibitor) administered orally inpatients with advanced cancer

Open Label Study of Relugolix in Men with Advanced Prostate Cancer	HERO: A Multinational Phase 3 Randomized, Open-label, Parallel Group Study to Evaluate the Safety and Efficacy of Relugolix in Men with Advanced Prostate Cancer
Study of AZD4573 in Relapsed or Refractory Haematological Malignancies	A Phase 1, Open-Label, Multicentre, Non-Randomized Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of AZD4573, a Potent and Selective CDK9 Inhibitor, in Subjects with Relapsed or Refractory Haematological Malignancies
IMmotion010	A PHASE III, MULTICENTER, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND STUDY OF ATEZOLIZUMAB (ANTI−PD-L1 ANTIBODY) AS ADJUVANT THERAPY IN PATIENTS WITH PD-L1−SELECTED RENAL CELL CARCINOMA AT INTERMEDIATE TO HIGH RISK OF DEVELOPING METASTASIS FOLLOWING NEPHRECTOMY
CHRONOS-4	A Phase III, randomized, double-blind, controlled, multicenter study of intravenous PI3K inhibitor copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma (iNHL) - CHRONOS-4
Phase 2 study of ACE-536 in MPN-associated myelofibrosis & anaemia	A PHASE 2, MULTICENTER, OPEN-LABEL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF LUSPATERCEPT (ACE-536) IN SUBJECTS WITH MYELOPROLIFERATIVE NEOPLASM-ASSOCIATED MYELOFIBROSIS AND ANEMIA WITH AND WITHOUT RED BLOOD CELL-TRANSFUSION DEPENDENCE
MEDI0680 with Durvalumab vs Nivolumab Alone	A Phase 1/2, Open-label Study to Evaluate the Safety and Antitumor Activity of MEDI0680 (AMP-514) in Combination with Durvalumab versus Nivolumab Monotherapy in Subjects with Select Advanced Malignancies
A phase 1/2 study with Acalabrutinib and AZD6738 in high risk CLL	A Phase 1/2 Proof-of-Concept Study Investigating AZD6738 monotherapy and Acalabrutinib in Combination with AZD6738 (ATR inhibitor) in Subjects with Relapsed or Refractory High-risk Chronic Lymphocytic Leukemia (CLL).
C16029: Phase 2/3 Randomized, Open-Label Study in Multiple Myeloma	A Phase 2/3, Randomized, Open-Label Study Comparing Oral Ixazomib/Dexamethasone and Oral Pomalidomide/Dexamethasone in Relapsed and/or Refractory Multiple Myeloma
ABL001 versus Bositunib in Chronic Myeloid Leukaemai	A phase 3, multi-center, open-label, randomized study of oral ABL001 versus bosutinib in patients with Chronic Myelogenous Leukemia in chronic phase (CML-CP), previously treated with 2 or more tyrosine kinase inhibitors
NCRN - 3131: EPOCH TheraSphere in Metastatic Colorectal Carcinoma of the Liver (TS102)	EPOCH: A Phase III Clinical Trial Evaluating TheraSphere® in Patients with Metastatic Colorectal Carcinoma of the Liver who have Failed First Line Chemotherapy
ARTIST 1	A Randomized Phase 3 Study of AM0010 in Combination with FOLFOX Compared with FOLFOX Alone as Second-line Therapy in Patients with Metastatic Pancreatic Cancer that has Progressed During or Following a First-Line Gemcitabine Containing Regimen
INCYTE, Efficacy and Safety of INCB054828 in Cholangiocarcinoma	Study Title: A Phase 2, Open-Label, Single-Arm, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma Including FGFR2 Translocations Who Failed Previous Therapy
Gilteritinib as Maintenance After Induction/Consolidation in CR1 AML (Astellas AML Maintenance Study	A Phase 3 Multi-Center, Randomized, Double-Blind, Placebo-Controlled Trial of the FLT3 Inhibitor Gilteritinab (ASP2215) Administered as Maintenance Therapy Following Induction/Consolidation Therapy for Subjects with FLT3/ITD AML in First Complete Remission
NCRN - 3032 - Ibrutinib + Lenalidomide, +/- Rituximab in DLBCL	A Multicenter Open-Label, Randomized Phase 1b/2, Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Lenalidomide, with and without Rituximab in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Cardiovascular Disease	
CARD 4843	A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The Dal-GenE trial
PERSPECTIVE	A multicenter, randomized, double-blind, active-controlled study to evaluate the effects of LCZ696 compared to valsartan on cognitive function in patients with chronic heart failure and preserved ejection fraction
1245.110 EMPEROR-Preserved Study	A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF).
1245.121 EMPEROR-Reduced Study	A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with reduced Ejection Fraction(HFrEF).
CARD 4983 GALACTIC-HF	A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv mecarbil on Mortality and Morbidity in Subjects with Heart Failure with Reduced Ejection Fraction (HFrEF)
ENVISAGE	EDOXABAN VERSUS STANDARD OF CARE AND THEIR EFFECTS ON CLINICAL OUTCOMES IN PATIENTS HAVING UNDERGONE TRANSCATHETER AORTIC VALVE IMPLANTATION – IN ATRIAL FIBRILLATION
ONYX-one study	A Randomized Controlled Trial with Resolute Onyx in One Month Dual Anti Platelet Therapy for High-Bleeding Risk Patients
Children	
CHIL 4871 (VX14-661-110)	A Phase 3, Open-Label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation
Dermatology	
DERM 5560	One-year prospective, observational study of the journey of patients with plaque psoriasis prescribed calcipotriol/betamethasone aerosol foam or other standard care topical therapy
Diabetes	
Phase 1 study of IMCY-0098 in Recent Onset Type 1 Diabetes	A PHASE I, PLACEBO CONTROLLED, DOUBLE-BLIND, DOSE ESCALATION CLINICAL TRIAL TO EVALUATE THE SAFETY AND IMMUNE RESPONSES OF IMCYSE's IMCY-0098 IN PATIENTS WITH RECENT ONSET TYPE 1 DIABETES.
The SCORED Trial	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function
PROMINENT	PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES
Gastroenterology	
GAST 3847	Entyvio (vedolizumab) long-term safety study

Haematology	
MCRN2759 (BAY59-7939_14372)	Multicentre, open-label, active-controlled, randomized study to evaluate the efficacy and safety of an age and body weight-adjusted rivaroxaban regimen in children with acute venous thromboembolism
MCRN3225 (998HB303)	An Open-Label, Multicenter Evaluation of the Safety and Efficacy of Recombinant Coagulation Factor IX Fc Fusion Protein (rFIXFc; BIIB029) in the Prevention and Treatment of Bleeding in Previously Untreated Patients With Severe Hemophilia B
CCRN 757 (Haemophilia A)	EFFICACY AND SAFETY OF N8-GP DURING SURGICAL PROCEDURES IN PATIENTS WITH HAEMOPHILIA A
HAEM3406 (997HA306)	An Open-Label, Multicenter Evaluation of the Safety and Efficacy of Recombinant Coagulation Factor VIII Fc Fusion Protein (rFVIIIFc; BIIB031) in the Prevention and Treatment of Bleeding in Previously Untreated Patients With Severe Hemophilia A
Hepatology	
Efficacy and safety of oral GKT137831	A Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Assess the Efficacy and Safety of Oral GKT137831 in Patients with Primary Biliary Cholangitis Receiving Ursodeoxycholic Acid and with Persistently Elevated Alkaline Phosphatase
Infectious diseases and microbiology	
POSY-TEICO	Prospective, observational cohort, evaluating the incidence of nephrotoxicity, and other adverse events of interest, in patients treated with the higher recommended teicoplanin loading dose (12mg/kg twice a day), and comparison with external historical comparator data
Immunogenicity and Safety of TDV Co-administered with an Hepatitis A V	A Randomized, Observer Blind, Phase 3 Trial to Investigate the Immunogenicity and Safety of the Co-administration of a Subcutaneous Tetravalent Dengue Vaccine Candidate (TDV) and an Intramuscular Hepatitis A Virus (Inactivated) Vaccine in Healthy Subjects Aged 18 to 60 Years in a Non-endemic Country(ies) for Dengue
Musculoskeletal disorders	
MUSC 4535 (Degenerative Disease of the Hip)	A prospective, observational, multi-centre, cohort study of the G7™ acetabular system used with compatible femoral stems in patients with degenerative disease of the hip
MUSC 5224	Icatibant Outcome Survey (IOS) Registry Protocol
Neurological disorders	
CCRN 2944 (MS)	A Multicenter, Global, Observational Study to Collect Information on Safety and to Document the Drug Utilization of Tecfidera™ (Dimethyl Fumarate) When Used in Routine Medical Practice in the Treatment of Multiple Sclerosis (ESTEEM)
NEUR 4539 Lemtrada PASS	A prospective, multicenter, observational post-authorization safety study to evaluate the long term safety profile of Lemtrada® (alemtuzumab) treatment in patients with relapsing forms of multiple sclerosis
NEUR 5478	A 12-MONTH NONINTERVENTIONAL, POSTMARKETING, MULTICENTER STUDY TO EVALUATE THE EFFECTIVENESS OF BRIVIACT® (BRIVARACETAM) AS ADJUNCTIVE THERAPY IN PATIENTS WITH EPILEPSY WITH PARTIAL-ONSET SEIZURES IN DAILY CLINICAL PRACTICE
215MS202 Efficacy & Safety of BIIB033 as an Add-on Therapy in RMS	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study in Subjects With Relapsing Multiple Sclerosis to Evaluate the Efficacy and Safety of BIIB033 as an Add-On Therapy to Anti-Inflammatory Disease-Modifying Therapies (AFFINITY)

UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE II)	Phase III: UbLiTuximab In Multiple Sclerosis Treatment Effects (ULTIMATE II STUDY)
Study of GWP42003-P in Tuberous Sclerosis Complex	A double-blind, randomized, placebo-controlled study to investigate the efficacy and safety of cannabidiol (GWP42003-P,CBD) as add-on therapy in patients with tuberous sclerosis complex who experience inadequately-controlled focal seizures
Ophthalmology	
OPHT 4776	An open-label, randomized, active-controlled, parallel-group, Phase-3b study of the efficacy, safety, and tolerability of 2 mg aflibercept administered by intravitreal injections using two different treatment regimens to subjects with neovascular age-related macular degeneration (nAMD)
Primary Care	
PRIM 5039	Pragmatic Randomised 104 Week Multicentre Trial to Evaluate theComparative Effectiveness of dapagliflozin and Standard of Care in Type 2 Diabetes. The DECIDE Study
PRIM 4852	Post-authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038).
Renal Disorders	
RENA 3971	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven phase 3 study to investigate the efficacy of finerenone on the reduction of cardiovascular morbidity and mortality in patients with type 2 diabetes mellitus and the clinical diagnosis of early diabetic kidney disease in addition to standard of care
Pro2tect-Conversion	Phase 3, randomized, open-label, active-controlled study evaluating the efficacy and safety of oral vadadustat for the maintenance treatment of anemia in subjects with non-dialysis-dependent chronic kidney disease (NDD-CKD) (PRO2TECT-CONVERSION)
RENA 5480	A double-blind, randomised, placebo-controlled study to assess the effect of SNF472 on progression of CAC score on top of standard of care in ESRD patients on haemodialysis
Pro2tect-Correction	Phase 3, randomized, open-label, active-controlled study evaluating the efficacy and safety of oral vadadustat for the correction of anemia in subjects with non-dialysis-dependent chronic kidney disease (NDD-CKD) (PRO2TECTCORRECTION)
CL010_168	A Randomized, double-blind, placebo-controlled, phase 3 study to evaluate the safety and efficacy of CCX168 in patients with anti-neutrophil cytoplasmic antibody (ANCA)-Associated Vasculitis Treated Concomitantly with Rituximab or Cyclophosphamise/ Azathioprine
RENA 4590 (ASCEND-ND)	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa
Respiratory disorders	
A study to observe the normal use and effectiveness of Nucala®.	A Multinational, Single Arm, Observational Study to Evaluate the Real-world Effectiveness and Pattern of Use of mepolizumab in Patients with Severe Eosinophilic Asthma (204710).

Investigating inhaled Promixin in the treatment of non-cystic fibrosis bronchiectasis	A double-blind, placebo controlled, multicentre, clinical trial to investigate the efficacy and safety of 12 months of therapy with inhaled Promixin (colistimethate sodium) in the treatment of subjects with non-cystic fibrosis bronchiectasis chronically infected with Pseudomonas aeruginosa (P.aeruginosa)