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	
Eisai 218 - Efficacy of Lenvatinib/Everolimus in Renal Cell Carcinoma	A Randomized, Double-blind, Phase 2 Trial to Assess Safety and Efficacy of Lenvatinib at Two Different Starting Doses (18 mg vs. 14 mg QD) in Combination with Everolimus (5 mg QD) in Renal Cell Carcinoma Following One Prior VEGF-Targeted Treatment
First in Human, Dose Escalating Study of HuMaX®-TF-ADC in solid Tumour	First in human, dose escalating safety study of tissue factor specific antibody drug conjugate (HuMax® TF ADC) in patients with locally advanced and/or metastatic solid tumors known to express tissue factor
DESCRIBEIII: Retrospective Chart Review for Patients in IPP	Describe III: Retrospective chart review of dabrafenib monotherapy and/or dabrafenib-trametinib combination therapy in patients with metastatic melanoma to characterize patients with long term benefit in the Individual Patient Program (IPP).
CANC - 3831 MBC - disease registry study	UK A disease registry study to prospectively observe treatment patterns and outcomes in patients with HER2-Positive unresectable locally advanced or metastatic breast cancer
NCRN443: PREAMBLE observational myeloma	PROSPECTIVE RESEARCH ASSESSMENT IN MULTIPLE MYELOMA: AN OBSERVATIONAL EVALUATION
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
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 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)
CANC - 4644	A Phase 1b Dose Escalation and Dose Expansion Study of ONO/GS-4059 Combined with Idelalisib in Subjects with B-cell Malignancies

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
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)
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
Long-term Extension for GEN701 and GEN702	"A MULTI-CENTER, OPEN-LABEL TRIAL INVESTIGATING THE EFFICACY AND SAFETY OF CONTINUED TREATMENT WITH TISOTUMAB VEDOTIN IN PATIENTS WITH SOLID TUMORS KNOWN TO EXPRESS TISSUE FACTOR"
Cardiovascular disease	
3708 CARD e-ULTIMASTER Registry	Prospective,single-arm, multi-centre, observational registry to further validate safety and efficacy of the ultimaster DES in real-world patients.
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
CCRN 2794 (Coronary artery stent)	MILES - UK: Post Marketing, Multicenter, Single Arm, Observational Clinical Registry to Evaluate Safety and Efficacy of BioMime Sirolimus Eluting Stent System In All Comers Real World Population With Coronary Artery Stenosis in United Kingdom.
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
CHIL 5253	A PHASE 1, OPEN-LABEL, SINGLE-DOSE, NON-RANDOMIZED STUDY TO EVALUATE PHARMACOKINETICS AND PHARMACODYNAMICS OF EDOXABAN IN PEDIATRIC PATIENTS
MCRN2303 (D3820C00016)	A Phase I, Open-Label, Multicentre Study to Assess the Pharmacokinetics and Safety of Naloxegol in Paediatric Patients Ages = 6 Months to < 18 Years Receiving Treatment with Opioids
Pfizer Pediatric VTE Treatment study	A RANDOMIZED, OPEN-LABEL, ACTIVE CONTROLLED, SAFETY AND EXTRAPOLATED EFFICACY STUDY IN PEDIATRIC SUBJECTS REQUIRING ANTICOAGULATION FOR THE TREATMENT OF A VENOUS THROMBOEMBOLIC EVENT
Post-Authorization Study of HyQvia in Pediatric PIDD subjects	Post-Authorization Safety, Tolerability and Immunogenicity Evaluation of HyQvia in Pediatric Subjects with Primary Immunodeficiency Diseases
Dementias and neurodegeneration	
Retrospective-prospective cohort study to observe Safinamide safety	European multicenter retrospective-prospective cohort study to observe Safinamide safety profile and pattern of use in clinical practice during the first post-commercialization phase– Study Z7219N02

Dermatology	
BASICHR0009	Longitudinal study of human skin wounds BASICHR0009
Collection of Chronic Wound Fluid	Collection of Chronic Wound Fluid A) to Develop a Point of Care Diagnostic Device to Detect Various Biomarkers in Wound Fluid and B) to Develop a Laboratory-Based System for Remote Testing of Chronic Wound Fluid
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
PluroGel and leg ulcers	A pilot randomised study to investigate the efficacy of PluroGel in healing venous and mixed aetiology leg ulcers
Prevalon boots or alternative heel protection	The incidence of heel pressure ulcers among orthopaedic patients who wear Prevalon boots or alternative heel protection: Exploratory study.
WWIC Speckle study	A single centre open label study measuring microcirculatory flux using Speckle imaging Device, in patients with Arterial, Mixed and Diabetic Foot Ulcers using geko™ neuromuscular electro stimulation device
Diabetes	
Evaluation of Blood Glucose Monitoring Systems	Evaluation of Blood Glucose Monitoring Systems
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.
PROMINENT	PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES
Study of the Accuracy of the SmartSensor telemed OGTT Device	Study of the Accuracy of the SmartSensor telemed (SSt) Oral Glucose Tolerance Test Device
Gastroenterology	
GAST 3847	Entyvio (vedolizumab) long-term safety study
High Energy High Protein Tube Feed Study	Evaluating the tolerance, compliance and acceptability of a nutritionally complete, high energy, high protein, enteral feed in adults – a pilot study
Haematology	
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

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
PNH Patient Registry	Paroxysmal Nocturnal Haemoglobinuria Patient Registry
Hepatology	
1943: Safety & Efficacy of SEL in Patients w/ NASH & Bridging Fibrosis	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis
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
Steatohepatitis-0238/0327-Shire	A Phase 2 Double-Blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of Volixibat Potassium, an Apical Sodium-Dependent Bile Acid Transporter Inhibitor (ASBTi) in Adults with Nonalcoholic Steatohepatitis (NASH)
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
Injuries and emergencies	
INJU 4681	ROSPECTIVE, OPEN-LABEL STUDY OF ANDEXANET ALFA IN PATIENTS RECEIVING A FACTOR XA INHIBITOR WHO HAVE ACUTE MAJOR BLEEDING (ANNEXA-4)
Metabolic and endocrine disorders	
Long-term safety of Omnitrope in adults.	Post-Marketing Surveillance to monitor the long-term safety and efficacy of Omnitrope® in the treatment of adults
Musculoskeletal disorders	
CCRN 2465 (MASTER SL femoral stem)	A prospective, observational, multi-centre, cohort study of the MASTERSL femoral stem in patients with degenerative disease of the hip
Corin MiniHip and Trinity Cup Clinical Surveillance Study	Corin MiniHip and Trinity Advanced Bearing Acetabular Cup System UK Clinical Surveillance Study
MUSC 3998	Efficacy and safety of BI 655064 in patients with active lupus nephritis

MUSC 4272	Assessment of Stelara® (ustekinumab) and other biologic therapies in patients with psoriatic arthritis in the normal health-care practice. A prospective, observational cohort PsA Bio Study
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 5107	A 52 week, double blind, randomized, placebo-controlled trial evaluating the effect of Nintedanib, 150 mg twice daily, on annual rate of decline in Forced Vital Capacity and safety in patients with RA associated ILD with UIP pattern.
MUSC 5224	Icatibant Outcome Survey (IOS) Registry Protocol
SERENA	Long-term observational, prospective study to collect in a real life setting data on the retention, effectiveness, safety, treatment pattern, quality of life, and efficiency of secukinumab in adult patients with moderate to severe plaque psoriasis, psoriatic arthritis and ankylosing spondylitis
Neurological disorders	
CCRN 2915 NMOSD	A MULTICENTER, RANDOMIZED, ADDITION TO BASELINE TREATMENT, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF SA237 IN PATIENTS WITH NEUROMYELITIS OPTICA (NMO) AND NMO SPECTRUM DISORDER (NMOSD)
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)
LemQoL	A prospective, observational study to evaluate quality of life, patient-reported outcomes, and safety in patients with relapsing - remitting multiple sclerosis who are being treated with alemtuzumab (LEMTRADA) in routine clinical practice
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
Vimpat	A NONINTERVENTIONAL STUDY OF VIMPAT® (LACOSAMIDE) ADDED TO ONE BASELINE ANTIEPILEPTIC DRUG THERAPY IN PATIENTS WITH BRAIN TUMOR-RELATED EPILEPSY (VIBES)
Ophthalmology	
SNT-IV-005 LEROS study	External natural history controlled, open-label intervention study to assess the efficacy and safety of long-term treatment with Raxone® in Leber's hereditary optic neuropathy (LHON)
Glaucoma-0240/0024-Santen	Preservative-free fixed-dose combination of tafluprost 0.0015% / timolol 0.5% in patients with open-angle glaucoma or ocular hypertension: Clinical effectiveness, tolerability and safety in a real world setting.
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)
OPHT 4824	DRAKO-A non-interventional study to assess the effectiveness of aflibercept in routine clinical practice in patients with visual impairment due to diabetic macular oedema (DMO)
Primary Care	
PRIM 4495	A multi-center, randomized, 52 week treatment, double-blind, triple-dummy, parallel-group study to assess the efficacy and safety of QMF149 compared with mometasone furoate in patients with asthma
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).
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
Renal disorders	
205270 (ASCEND-NHQ)	A 28-week, randomised, double-blind, placebo-controlled, parallel-group, multi-center, study in recombinant human erythropoietin (rhEPO) naïve non-dialysis participants with anaemia associated with chronic kidney disease to evaluate the efficacy, safety and effects on quality of life of daprodustat compared to placebo.
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
DIAB 3953	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven phase 3 study to investigate the efficacy of finerenone on the progression of deterioration of kidney function in patients with type 2 diabetes mellitus and the clinical diagnosis of advanced diabetic kidney disease in addition to standard of care.
Effect of Dapagliflozin in patients with Albuminuria and Renal Impairment (CKD 3-4)	An International, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of Dapagliflozin on the Incidence of the composite of ≥40% sustained reduction in eGFR, entering ESRD, CV or Renal Death in patients with Albuminuria and Moderate to Severe Renal Impairment (CKD 3-4)
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)
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)
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

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
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
Reproductive health and childbirth	
ASTEROID 5 (version 1.0)	A randomised, parallel-group, double-blind, double-dummy, active-controlled, multicentre study to assess the efficacy and safety of vilaprisan in subjects with uterine fibroids.
Lay User Performance Evaluation of myLotus®	Lay User Performance Evaluation of the myLotus® Ovulation (LH) and Pregnancy (hCG) tests
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)
Non CF Bronchiastasis-3636/0001 Queen's University Belfast	A randomized, blinded, parallel group, multi-center dose-finding study, to assess the efficacy, safety and tolerability of different doses of tobramycin inhalation powder in patients with Non-Cystic Fibrosis Bronchiectasis and pulmonary P. aeruginosa infection
RESP 4446	A 52-week, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe eosinophilic asthma
Study of Serlopitant for the Treatment of Refractory Chronic Cough	A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy, Safety, and Tolerability of Serlopitant for the Treatment of Refractory Chronic Cough