SUMMARY REPORT	ABM University Health Board
	Date: 26th January 2017 **Agenda item: 3 (iii)**

Subject	**Research and Development (R & D) Report**
Prepared by	Jemma Hughes, R&D Manager
Approved & presented by	Hamish Laing, Executive Medical Director

Purpose

To provide the Board with the 6 month update R&D Report.	**Decision**	
	Approval	
	Information	X
	Other	

Corporate Objectives

Excellent Population Health	Excellent Population Outcomes	Sustainable & Accessible Service	Strong Partnerships	Excellent People	Effective Governance
x	x	x	x	x	

Executive Summary

The report provides the Board with the latest half-yearly update of R&D developments.

Key Recommendations

To note the content of the Report.

Assurance Framework

Assurance is provided through memoranda of understanding between the Board and University Partners and through joint meetings of key Board members with their University counterparts, providing a report back to Board members.

Next Steps

A further report is scheduled for six month's time

MAIN REPORT		ABM University Health Board
		26th January 2017 Agenda No: 3 (iii)
Subject	**Research and Development 6-month Update Report**	
Prepared by	Jemma Hughes, R&D Manager	
Approved & presented by	Hamish Laing, Executive Medical Director	

Situation
This report provides the Board with the latest half-yearly R&D update

Background
Welsh Government performance metrics for R&D in Wales includes regular reporting to Board. Here we present to the Board key updates on Research & Innovation (R&I) activity and report on patient stories, achievements and activity figures contained within the appendices.

Assessment
The Health Board through its commitment to strong collaboration with partners has seen the delivery of some key R&I achievements over the past 6 months including being partner, through ARCH, to the £13.3 million scheme '***AgorIP***' led by Swansea University. AgorIP has been funded by WG and EU monies to provide an effective platform to turn innovative research led by the NHS into new products & services through the effective management and exploitation of intellectual property. Working with Fujitsu, ABMU is the first Health Board to be accessing the service to further develop an interactive app for the management of pressure ulcers, led by Dr Lorna Tasker. The importance of this development cannot be underestimated for the potential impact it will have on unlocking innovation in the NHS and ensuring the benefits from such innovative activities are not lost to the Health Board.

Improvements to patient care and services arising from R&I activity is broad, ranging from the direct positive experiences of patients enrolled in clinical trials to the wider economic benefits to the region, in turn supporting healthier communities. Anticipated benefits from the potential City Deal investment and the realisation of key ARCH REI projects notably expansion of ILS/JCRF facilities, delivery of the Health and Well Being Academy in early 2017 and the Health Technology Centre building on the bio-technology capabilities of the region, will be reported on in future reports.

The Board's request to understand the tangible benefits to patients from R&I activity within ABMU has been escalated to Health and Care Research Wales communication team to support all HBs with a collective approach to the development of a system which will ensure experiences are routinely captured and reported back to the Health Boards. Within ABMU, we have started this process and are pleased to share with the Board some of our patients research stories (please see next section).

Building on the success of projects previous funded via the WG Efficiency through Technology Funds, we have submitted several proposals for the current round which, if successful, will support the HB in progressing with some key innovative projects to support service improvements. Alongside this, the HB is also working with Swansea Trials Unit (STU) to prepare to submit to the next call for Research for Patient and Public Benefit research scheme (RfPPB). Through the support of STU, the Health Board has recently launched two new major clinical studies. SAILOR is a multi- centre study led by Prof Dean Harris, funded by the Bowel Disease Research Fund evaluating early surgery alone in low rectal cancer. For some patients it is not always clear whether having radiotherapy before the operation will add any health benefit, particularly if the surgeon is able to fully remove the tumour. The question is whether radiotherapy before surgery can be considered overtreatment or if it is of benefit. This study will provide evidence for whether, in certain situations where the chances of the cancer returning are small and equal in both situations, it is better to avoid pre-operative radiotherapy and proceed directly to having the tumour surgically removed.

The HB has also launched a pilot study in trauma care led by Prof Ian Pallister, looking at inflammatory response in major injury and recombinant human erythropoietin (IRMINE). The primary objective of this pilot study is to test the trial design and logistics, in preparation for a full multi-centre randomised controlled trial (RCT). Secondary objectives will examine: a) whether the use of rhEPO reduces organ failure after severe trauma in adults b) the effect of rhEPO on the clinical, cellular, mitochondrial & bio molecular manifestations of the systemic inflammatory response to injury c) Whether human haemopoietic bone marrow responds to rhEPO after severe injury d) Whether rhEPO associated with an increase in thromboembolic vascular events (TVE) despite appropriate standard of care prophylaxis and e) whether the use of rhEPO reduces 30 day mortality after severe trauma in adults.

Dr Ceri Battle, Physiotherapist working within trauma has also been successful in securing funding from Health and Care Research Wales RfPPB scheme to undertake a multi-centre randomised feasibility study evaluating the impact of a prognostic model for management of blunt chest wall trauma patients. There is research that suggests that there are a number of risk factors for longer hospital stays and greater chance of chest infection in patients who have injured their chest wall. It is sometimes difficult for Emergency Dept. doctors to manage these patients because there are no visible symptoms. A patient may go on to develop pneumonia, but this may not happen until up to 72 hours after they have been injured. Doctors need to be able to decide which patients can be sent straight home from the Emergency Department, or which need to go to a ward or to the Intensive Care Unit (ICU). Over the last six years, Ceri and her team have designed a simple questionnaire that calculates a risk score that the doctors in the Emergency Department can use to decide which patients will develop pneumonia. The doctor scores the patient on five pieces of patient information which are normally collected as part of their care. In the long-term, the aim is to complete a large trial which will test whether the risk score works by helping doctors make the right decisions for patients and whether it saves the NHS resources and money.

Finally, many congratulations to Prof Dean Harris and the Lymphoedema Research Network who were announced as Winners of the ‘Research Excellence in the NHS award’ and ‘Efficiency Through Technology Award’ respectively at the recent Innovation Awards, supported by MediWales.

The following pages include further highlights of some key research activities, publications and patient stories. Research activity figures are saved in the resource centre.

Recommendations
The Board is asked to note the contents of this Report.

Appendices available via Resource Centre

"My husband and I had just been told at a scan that our unborn baby was not moving. I was already in hospital to have steroid injections incase I needed a c-section. My diabetes, previously very well controlled, was suddenly causing me to have low blood sugar all the time. We were beside ourselves with fear.

I had seen the Salvo signs around the ward and I had already read the leaflet. I believe wholeheartedly in assisting research if I can but in this instance I just wanted my baby out of me and safe. It was the research advisor's calm manner and friendly approach that convinced me to join the project.

Just before the c section I heard that I had been randomly selected to have my blood cleaned and given back to me. My usual distrustful self was thinking oh maybe I'm only being TOLD I'm being given my blood back and that it's not really happening. Either way, I felt more confident about my recovery with the knowledge I had my blood back in my body.

The operation was a success and our little boy Joseff was born. He was absolutely fine but he was taken to SCBU immediately where he remained for 3 weeks. My recovery from the operation was painful and the emotional pain of being parted from my baby did break my heart.However, I definitely felt more assured in my recovery because of the Salvo project." ***- SALVO Study Patient***

"My cancer journey began 18 years ago when I was just 42. I not only had breast cancer but I was stage 3+ and I quickly realised how advanced that was. Chemotherapy, mastectomy and radiation completed with few side effects thankfully but the shock factor was much harder to deal with and it took 3 months after diagnosis to adjust mentally to my new life situation. I had a second mastectomy 5 years later and then 12 blissful years before I was diagnosed as stage 4. Once again this was mentally challenging but nowhere near as bad as before as I had always suspected it would happen.

All the years I have lived with cancer I have been fit and well but now had debilitating physical conditions which made it difficult to leave the house. To be honest you start to think-" well I've done well surviving for these 18 years and if this is how it's going to end, well maybe the sooner the better". But then again your family and friends are so precious that you really want to hang in there too.

Seeing the Oncologist for the first time after diagnosis is rather nerve racking and I was dreading chemotherapy purely because I personally don't believe it to be very effective for the kind of cancer I've got. I was delighted though to be selected for a trial taking Palbociclib which I believe interferes with the way cells divide along with hormone therapy. Initial results indicated that this drug may help to delay disease progression so it was not a difficult choice to agree to participate. There are however some possible side effects of which I was made fully aware. Being on the trial as opposed to standard treatment does involve far more trips to the hospital for blood tests, oncology appointments and scans and I keep a daily diary, but to say it has been worth it is an understatement! My physical symptoms have cleared up and I have been able to return to life as normal.

This is not a disease you would wish for anyone else to suffer. My mother had a partial mastectomy at 37 and I have daughters and granddaughters. I have normal brac1 and brac2 genes but can't help thinking there are more yet to be discovered and my descendant are at risk of developing cancer at an early age. I feel if I can play a small part in any treatment advances that can be made, to help not only my family but everybody else's, then whilst I am able to do so I certainly will!!

Before closing this I would like to take the opportunity to thank all the staff both medical and otherwise that are involved in my care for their dedication and kindness for which I am extremely gratefully." ***- Kathryn Davies, Parsifal Trial***

Patient Stories

"I have been involved with Pioneer 3 diabetes trial. I will be having my eighth appointment in October since I started the trial my numbers have been tumbling down which I believe a combination of me losing 60lbs weight and the tablets I am taking on the trial.

The reason I went on the trial in the first place was 2 fold 1 was to hopefully help me control my diabetes to avoid complications and the other was maybe it would help other sufferers in the future.

Another benefit is every 6 to 7 weeks I have a physical including blood tests so if something was going wrong it would be picked up pretty quick while maybe still treatable which I find reassuring."

- Pioneer 3 Study Patient

Key research activities and publications

Two of Professor Steve Bain's diabetes studies have completed within the year. One is Sustain 1, a once weekly injection which shows the potential to help people achieve good glycaemic control together with demonstrable weight loss, and the other is the LEADER study showing benefits in respect of Cardiovascular outcomes for Liraglutide.

The LEADER study, for which Professor Bain is the Chief Investigator for within the UK was presented at the American Diabetes Association and simultaneously **published in the New England Journal of Medicine.**

Senseonics: Continuous Glucose Monitor (Eversense CGM)

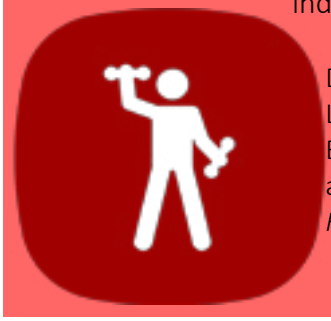
The Joint Clinical Research Facility (JCRF) were one of the 3 UK sites who took part in the PRECISE study which was providing data for the devices' CE mark application.

JCRF was the first UK site to enter a patient. This implantable device lasts throughout a 90 day period unlike current CGM systems that require weekly insertion. Its wearable and removable transmitter calculates glucose levels, with a mobile app for real time display of glucose readings. CE mark was achieved in May 2016.

Working with Consultant Urologist Mr Andrew Thomas, the JCRF team undertook a study in the development of the Green Light Laser for Benign Prostatic Hyperplasia (BPH). A **minimally invasive device** which has now been adopted by NICE.

"Using the Greenlight XPS is more convenient for patients than other surgical procedures as they don't need to stay in hospital overnight and they can return to normal activity faster" statement by Professor Carole Longson MBE, Director of the NICE Centre for Health Technology Evaluation June 2016.

Success for the Emergency Medicine team, with Dr Gareth Davies' research paper 'Effects of exercise intensity on clot microstructure and mechanical properties in healthy individuals' has been ***published in 'Thrombosis Research'.***



Davies,N.,Llwyd,O.,Brugniaux,J.,Davies,G.,Marley,C.,Hodson,D., Lawrence,M.,D'Silva, L.,Morris,R.,Hawkins,K.,Williams,P.,Bailey,D. & Evans,P. (2016).Effects of exercise intensity on clot microstructure and mechanical properties in healthy individuals. *Thrombosis Research* 143, 130-136.doi:10.1016/j.thromres.2016.05.018

Pharmacy Research Wales launches a new strategy for research in Wales

The Pharmacy Research Wales collaboration has formally launched 'Pharmacy Research for Wales: a 5 year strategic action plan for research in Pharmacy'. This will enable ABMU to build on current Pharmacy research. Details of the strategy and the groups work are available at: *www.pharmacyresearch.wales*

A current example of Pharmacy research is that led by Dan Harris. There are two parts to the research:

1) Data linkage of patients who have had an MI across Wales, detailing patient outcomes, post MI management (including prescribing, management of hypertension, dyslipidaemia and other risk factors) and identification of discriminating factors that lead to poor outcomes with a particular focus on those patients that have CAD complicated by the presence of AF.

2) A focused study using data from patients that have undergone Percutaneous Coronary Intervention (PCI) at the Morriston regional cardiac unit. This study links data from the PCI with co-morbidities, presence of AF and prescribing practices titled: Antithrombotic Selection in Percutaneous Coronary Intervention Evaluation of Outcomes (A-SPiCE)

For the latter Dan and the team now have detailed data from over 4000 patients undergoing PCI that will be uploaded to SAIL for data linkage to post discharge prescribing, management of risk factors and patient outcomes.

As an aside to this research and through working closely with our IT department the team have been able to automate a download of all discharge prescriptions as patients are discharged from secondary care across ABM. The data has been arranged to identify the drugs that patients were admitted on that are to continue post discharge, those that have been stopped and those that are newly started in hospital to be continued post discharge. The data has been run for patients discharge over the last two years and currently have over 500,000 prescription records.

The team aim to upload this data to SAIL, test the 'data linkage' and develop the protocols around its use. The ambition is to test the use of this data with the ABM cohort and eventually repeat this process across Wales. Hopefully this will lead to the complete mapping of prescribing across all health care setting within Wales that can be linked to patient diagnoses, admissions, pathology data and patient outcomes. This will give an unique research opportunities to examine the gaps in patient care, perform pharmacovigilence, support the prudent agenda and aid the development of precision medicine **in Wales and a Pharmacy Research Laboratory centred** at Swansea University.

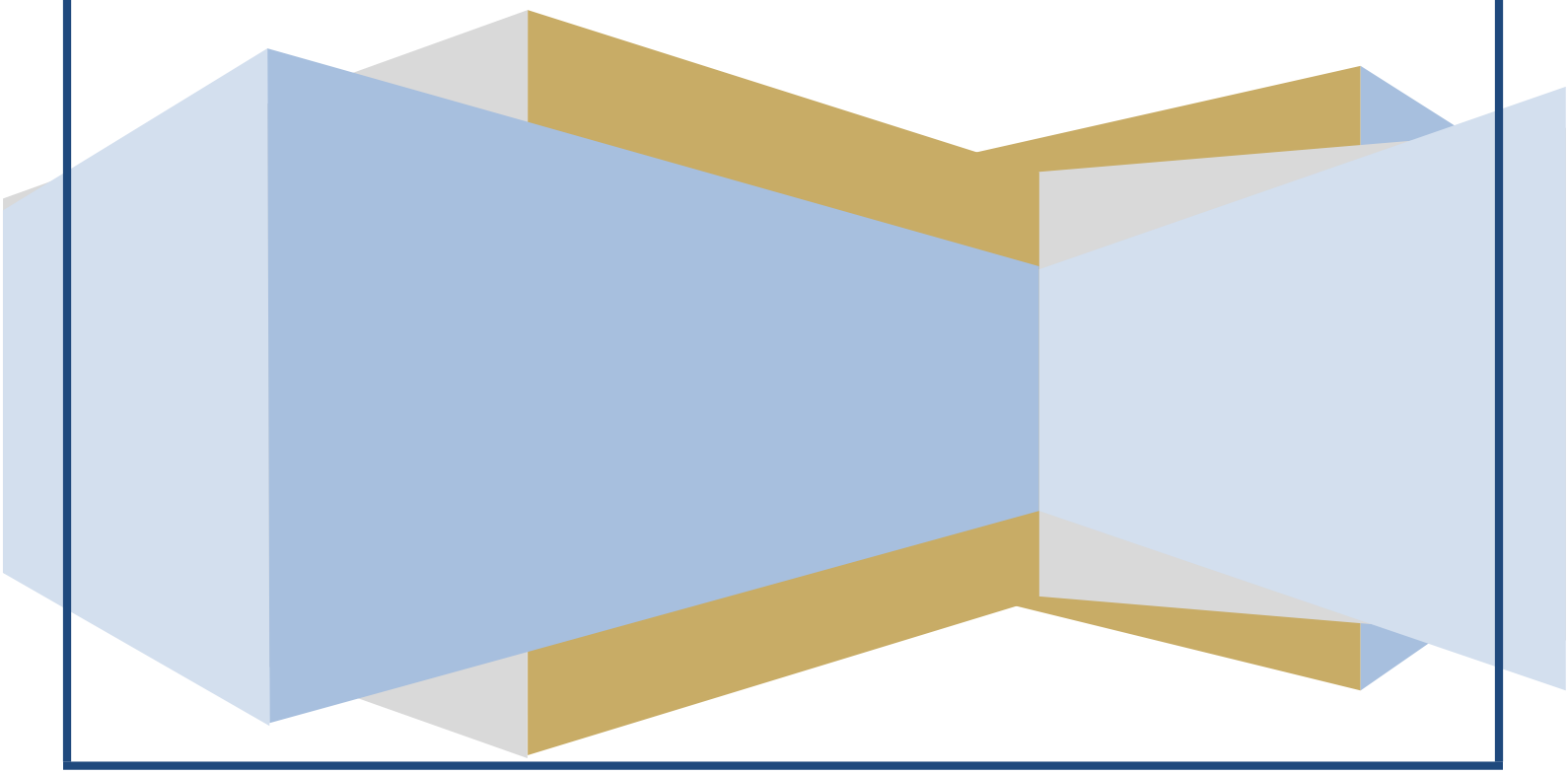
R&D

RESEARCH & DEVELOPMENT

Abertawe Bro Morgannwg University Health Board

ABMU Health Board Research & Development Activity

December 2016



Closed - In follow up/ Closed to recruitment	
Commercial Status	**Study Title**
Commercial	GLORIA-AF: Global Registry on Long-Term Oral Anti-thrombotic TReatment In PAtients with Atrial Fibrillation (Phase II/III – EU/EEA Member States)
Commercial	The effects of storage on human blood and investigation of ways of reversing the changes that occur

Open	
Commercial Status	**Study Title**
Commercial	The effects of storage on human blood and investigation of ways of reversing the changes that occur
Non-Commercial	Two linked cluster randomised trials to evaluate feedback interventions embedded within a national audit of blood transfusion practice
Non-Commercial - PhD	V1: Development of a PRO Measure in Haematological Practice

Open	
Commercial Status	**Study Title**
Commercial	SESAME: Observational Study with Metvix daylight in AK
Non-Commercial	Impact and Evaluation of a Burns Risk Assessment of Neglect and Maltreatment in Children Tool. BuRN-Tool A multi centre study
Non-Commercial	Surgical Biopsies for Regenerative Medicine - Collection of Surgical Biopsies for Regenerative Medicine and Related Research

Cancer

Closed - In follow up	
Commercial Status	**Study Title**
Commercial	A Single-Arm, Open-Label, Multicentre Clinical Trial with Nivolumab (BMS-936558) for Subjects with Histologically Confirmed Stage III (unresectable) or Stage IV Melanoma Progressing Post Prior Treatment Containing an Anti-CTLA-4 Monoclonal Antibody. CheckMate 172: Checkpoint pathway and nivolumab clinical trial evaluation 172 - BMS CA209-172 (BMS172)
Commercial	ALTTO - Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation A randomised, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer
Commercial	Anti-PD-1 - A Randomized, Open-Label, Phase 3 Study of BMS-936558 vs. Everolimus in Subjects with Advanced or Metastatic Clear-Cell Renal Cell Carcinoma Who Have Received Prior Anti-Angiogenic Therapy - BMS Ref: CA209025 (or CA209-025)
Commercial	CA209-067 - Nivolumab or Nivolumab + Ipilimumab vs. Ipilimumab in Advanced Melanoma - Phase 3, Randomized, Double-Blind Study Comparing BMS-936558 monotherapy, BMS-936558 combined with Ipilimumab, and Ipilimumab monotherapy in Subjects with Previously Untreated Unresectable or Metastatic Melanoma
Commercial	CA209-214 Nivolumab combined with Ipilimumab versus Sunitinib in RCC - A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma
Commercial	CheckMate 238: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 238 - CA209-238
Commercial	GO28667 - PH III, OPEN-LABEL, IN RELAPSED/REFRACTORY PATIENTS WITH CLL
Commercial	Millennium 2 (MLN9708) C16019 - - A Phase 3, Randomized, Placebo-Controlled, Double-Blind Study of Oral Ixazomib Citrate (MLN9708) Maintenance Therapy in Patients With Multiple Myeloma Following Autologous Stem Cell Transplant
Commercial	MILLENNIUM: C16010: Phase 3 study of MLN9708 in Multiple Myeloma
Commercial	OSCAR1 - AN OBSERVATIONAL STUDY OF AVASTIN® (BEVACIZUMAB) AS FIRST LINE THERAPY IN PATIENTS WITH ADVANCED OVARIAN CANCER
Commercial	PRESIDE (9785MA1001)
Commercial	PUMA: NCRN081 - A Randomized Double-blind Placebo-Controlled Trial of Neratinib (HKI-272) After Trastuzumab in Women With Early-Stage HER-2/neu overexpressed/Amplified Breast Cancer

Commercial	SafeHer - Safety study with subcutaneous trastuzumab in breast cancer
Commercial	Selene - Luster - A Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, PCI-32765 (Ibrutinib), in Combination with Either Bendamustine and Rituximab (BR) or Rituximab, Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (RCHOP) in Subjects with Previously Treated Indolent Non-Hodgkin Lymphoma (iNHL)
Commercial	SPARTAN - Study of ARN509 in Prostate Cancer
Commercial	The NEMO trial (NRAS melanoma and MEK inhibitor): A randomized Phase III, open label, multicenter, two-arm study comparing the efficacy of MEK162 versus
Non-Commercial	Axi-STS - A clinicopathological phase II study of axitinib in patients with advanced angiosarcoma and other soft tissue sarcomas
Non-Commercial	CHIPS-Child
Non-Commercial	IPAC: Inflammatory biomarkers in Prognosis in Advanced Cancer a multicentre prospective observational study.
Non-Commercial	MANTA - A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer
Non-Commercial	PERSEPHONE: Duration of Trastuzumab with Chemotherapy in women with early breast cancer: 6 months vs. 12.
Non-Commercial	PLACE - Prevention of Lymphoedema after Clearance by External Compression
Non-Commercial	SURTIME: Randomized Phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma.

Open	
Commercial Status	**Study Title**
Commercial	*HRA C31005 MLN0128 and MLN0128+MLN1117 Compared With Everolimus in mccRCC
Commercial	A PHASE 3, MULTICENTER, RANDOMIZED, OPEN LABEL STUDY TO COMPARE THE EFFICACY AND SAFETY OF POMALIDOMIDE, BORTEZOMIB AND LOW-DOSE DEXAMETHASONE VERSUS BORTEZOMIB AND LOW-DOSE DEXAMETHASONE IN SUBJECTS WITH RELAPSED OR REFRACTORY MULTIPLE MYELOMA
Commercial	A Phase 3, Randomised, Controlled, Multi-Centre, Open-Label Study to Compare Tivozanib Hydrochloride to Sorafenib in Subjects With Refractory Advanced Renal Cell Carcinoma
Commercial	CheckMate401: Clinical Trial of Nivolumab (BMS-936558) Combined with Ipilimumab Followed by Nivolumab Monotherapy as First-Line Therapy of Subjects with Histologically Confirmed Stage III (Unresectable) or Stage IV Melanoma
Commercial	GALLIUM: A multicentre, Phase III, open label, randomised study - GA101 or rituximab plus chemo in 1st line indolent NHL
Commercial	IMMotion 151 - WO29637. A Study of anti PDL1 Antibody in Renal Cell Carcinoma (RCC)
Commercial	Ipilimumab dose comparison study in Metastatic Melanoma

Commercial	ML29659 - ESTHER Disease Registry Study
Commercial	MLN9708 in Multiple Myeloma Not Treated with Stem Cell transplantation
Commercial	ORZORA An Open Label, Single Arm, Multicentre 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
Commercial	POMPASS - CC-4047-MM-015-Pomalidomide for relapsed and refractory MM patients_Ob
Commercial	PREAMBLE Study: Observational Study in Multiple Myeloma
Commercial	YONDELIS (or ORCCYD) - A YONDELIS® (trabectedin) Study in Advanced Relapsed Ovarian Cancer
Commercial - PIC	A single-arm, multicenter, nilotinib treatment-free remission study in patients with BCR-ABL1 positive Chronic Myelogenous Leukaemia in chronic phase who have achieved durable minimal residual disease (MRD)status on first line nilotinib treatment
Non-Commercial	POSNOC - POsitive Sentinel NOde: adjuvant therapy alone versus adjuvant therapy plus Clearance or axillary radiotherapy. A randomised controlled trial of axillary treatment in women with early stage breast cancer who have metastases in one or two sentinel nodes.
Non-Commercial	A Trial for Older Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome
Non-Commercial	AddAspirin - A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours. - MORRISTON
Non-Commercial	AddAspirin - A phase III double-blind placebo-controlled randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.POW Additional Site
Non-Commercial	ARISTOTLE - A phase III trial comparing standard versus novel CRT as pre-operative treatment for MRI defined locally advanced rectal cancer.
Non-Commercial	ASPIRE - Does aspirin increase the clinical response to chemo-radiotherapy?
Non-Commercial	AURORA: Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer
Non-Commercial	Biomarkers for Ovarian Pathology
Non-Commercial	BOCS - Identification and molecular analyses of families with susceptibility to breast and/or ovarian cancer (formerly 'Identification and molecular analyses of families with susceptibility to breast cancer')
Non-Commercial	CANDID - CANcer DIagnosis Decision rules
Non-Commercial	CaPP3 -A randomised double blind dose non-inferiority trial of a daily dose of 600mg versus 300mg versus 100mg of enteric coated aspirin as a cancer preventive in carriers of a germline pathological mismatch repair gene defect, Lynch Syndrome. Project 3 in the Cancer Prevention Programme

Non-Commercial	CEDAR - A Phase II, randomised, open-label study of Gemcitabine/Carboplatin first-line chemotherapy in combination with or without the antisense oligonucleotide Apatorsen (OGX-427) in advanced squamous cell lung cancers
Non-Commercial	CONSCOP - A feasibility randomised controlled trial (RCT) of contrast enhanced vs. no enhanced colonoscopy in index bowel cancer screening to reduce bowel cancer mortality
Non-Commercial	De-ESCALaTE HPV_Version 2.0_08 Feb 2012
Non-Commercial	early Surgery Alone In LOw Rectal cancer (SAILOR)
Non-Commercial	ESPAC 4: EUROPEAN STUDY GROUP FOR PANCREATIC CANCER - TRIAL 4. Combination versus single agent chemotherapy in resectable pancreatic ductal and peri-ampullary cancers.
Non-Commercial	ESPAC5F: European Study Group for Pancreatic Cancer Trial 5F Am 01
Non-Commercial	Exploiting 3D scanning technology in Lymphoedema for accurate and fast measurements of volume and shape
Non-Commercial	Familial Gastric Cancer Study
Non-Commercial	FASTForward: a randomised clinical trial testing a 1week course of curative whole breast radiotherapy against a standard 3week schedule in terms of local cancer control and late adverse effects in women with early breast cancer.
Non-Commercial	FineSA MRI-calculation of metastatic spinal bone structure
Non-Commercial	FLAIR version 1.0
Non-Commercial	FOCUS4 – Molecular selection of therapy in colorectal cancer: a molecularly stratified randomised controlled trials programme
Non-Commercial	GO2 - GO2: Alternative chemotherapy for frail or elderly patients with advanced gastric or oesophageal cancer.
Non-Commercial	Health care professionals' and patients' communication via telehealth Negotiating conversation and interaction through videoconferencing in speech language therapy
Non-Commercial	How important are therapeutic relationships in cancer rehabilitation?
Non-Commercial	ICON8: An international phase III randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer
Non-Commercial	InterAACT A Multicentre Randomised Phase II Advanced Anal Cancer Trial
Non-Commercial	LaCeS Feasibility: Laparoscopic versus Open Colorectal Surgery in the Acute setting
Non-Commercial	Ll-1 Trial: Leukaemia Lymphoma Research and NCRI Working Group Pick a Winner Programme
Non-Commercial	LUNGCast - Smoking status and lung cancer
Non-Commercial	NIMRAD :-A randomised placebo-controlled trial of synchronous NIMorazole versus RADiotherapy alone in patients with locally advanced head and neck squamous cell carcinoma not suitable for synchronous chemotherapy or cetuximab.
Non-Commercial	PAKT - A Phase II, randomised, placebo-controlled study of paclitaxel in combination with the AKT inhibitor AZD5363 in triple-negative advanced or metastatic breast cancer
Non-Commercial	PALLET

Non-Commercial	PARSIFAL I - A randomized, multicenter, open-label, phase II trial to evaluate the efficacy and safety of palbociclib in combination with fulvestrant or letrozole in patients with HER2 negative, ER+ metastatic breast cancer.
Non-Commercial	PIANO: A Phase II Trial of PLX3397 in the Treatment of KIT Mutated Advanced Acral and Mucosal Melanoma
Non-Commercial	POSSUM: A tool to predict morbidity & mortality in HNFFS
Non-Commercial	Post-operative adjuvant treatment for HPV-positive tumours (PATHOS)
Non-Commercial	POUT: A Phase III randomised trial of PeriOperative chemotherapy versus sUrveillance in upper Tract urothelial cancer
Non-Commercial	Raman spectroscopy and colorectal cancer
Non-Commercial	RIAltO version 2 - A Randomised Investigation of Alternative Ofatumumabcontaining regimens in less fit patients with CLL
Non-Commercial	SCOPE 2 A randomised Phase II/III trial to study radiotherapy dose escalation in patients with oesophageal cancer treated with definitive chemo-radiation with an embedded Phase II trial for patients with a poor early response using positron emission tomography (PET)
Non-Commercial	Treatments for urogynaecological problems and patient selfreports v1
Non-Commercial	UK GPCS - UK Genetic Prostate Cancer Study - UKGPCS
Non-Commercial	UK Multicentre Study of Children with Opsoclonus Myoclonus Syndrome (UMSCOM) This is the UK arm of EU study "Multinational Européan Trial for Children with the Opsoclonus Myoclonus Syndrome/Dancing Eye Syndrome".
Non-Commercial	UKALL14 - A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia
Non-Commercial - PIC	Hybrid - A multicentre randomised phase II study of HYpofractionated Bladder Radiotherapy with or without Image guided aDaptive planning
Non-Commercial - PIC	PIN - A randomised phase II trial of Olaparib maintenance versus placebo monotherapy in patients with non-small cell lung cancer

Closed - In follow up/ Closed to recruitment	
Commercial Status	**Study Title**
Commercial	SPIRE 2 - Pfizer B1481038 Phase 3 PF04950615 in Reducing Major CV Events
Non-Commercial	AliveCor: Assessment of remote heart rhythm sampling to screen an at risk population of Atrial Fibrillation.

Open	
Commercial Status	**Study Title**
Commercial	CELTIC Bifurcation Study
Commercial	CONSISTENT CTO CONventional antegrade vs. SubIntimal Synergy sTENTing in Chronic Total Occlusions
Commercial	PORTICO I STUDY - International longterm followup study of patients implanted with a PORTICO valve
Commercial	SPIRE 1 - Pfizer B1481022 - Phase 3 PF-04950615 in Reducing Major CV Events
Commercial	STRENGTH -A Long-Term Outcomes Study to Assess STatin Residual Risk Reduction with EpaNova in HiGh Cardiovascular Risk PatienTs with Hypertriglyceridemia (STRENGTH)
Commercial	TRANSITION _LCZ696 pre/ post discharge in acute heart failure
Non-Commercial	IDEAL LM: Improved drug eluting stent for percutaneous coronary intervention of the left main artery in a real world allcomers population
Non-Commercial	The UK TAVI Trial (version 1.0) - The United Kingdom Transcatheter Aortic Valve Implantation (UK TAVI) Trial. A multi-centre randomised controlled trial to assess the clinical effectiveness and cost-utility of TAVI, compared with conventional surgical aortic valve replacement, in patients with severe symptomatic aortic stenosis at intermediate or high operative risk.
Non-Commercial - PIC	TIME V2.0

Closed - In follow up/ Closed to recruitment	
Commercial Status	**Study Title**
Commercial	DRN 559: CAROLINA Trial: A multicentre, International, randomised, parallel group, double blind study to evaluate Cardiovascular safety of Linagliptin vs Glimepiride in patients with type 2 diabetes mellitus at High Cardiovascular risk.
Commercial	DRN525 - BEACON- Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease and Type 2 Diabetes: the Occurrence of Renal Events
Commercial	Fourier - AMG 145 - A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination With Statin Therapy In Patients with Clinically Evident Cardiovascular Disease
Commercial	Impact of hypoglycaemic events in diabetic patients
Commercial	REWIND: The Effect of LY2189265 on Major Cardiovascular Events in Patients with Type 2 Diabetes: Reducing Cardiovascular Events with a Weekly Incretin in Diabetes
Commercial	SENIOR
Commercial	THEMIS - A Multinational, Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus
Commercial	Long-Acting Insulin Glargine Titration Meter
Non-Commercial	ROSE - An Observational Postauthorization Safety Specialist Cohort Event Monitoring Study (SCEM) to Monitor the Safety and Utilization of Rivaroxaban (Xarelto®) for the Prevention of Stroke in Patients with AF, Treatment of DVT and PE, and the Prevention of Recurrent DVT and PE in the Secondary Care Hospital Setting in England

Open	
Commercial Status	**Study Title**
Commercial	A 24-Week, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of Toujeo® and Tresiba® in Insulin-Naive Patients with Type 2 Diabetes Mellitus Not Adequately Controlled with Oral Antihyperglycemic Drug(s) ± GLP-1 Receptor Agonist
Commercial	CARMELINA DM CV Outcome Study 1218-22 - A multicenter, international, randomized, parallel group, double blind, placebo-controlled CArdiovascular Safety & Renal Microvascular outcomE with LINAgliptin, 5 mg once daily in patients with type 2 diabetes mellitus at high vascular risk. CARMELINA
Commercial	CREDENCE - A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy

Commercial	D1690R00009: The DECIDE Study
Commercial	DRN 362: CAROLINA Trial: Evaluation of a DPP-4 inhibitor vs a sulphonylurea on cardiovascular (CV) death and CV events in type 2 diabetes patients at high CV risk
Commercial	DRN 564: EXSCEL- A randomised placebo controlled clinical trial to evaluate Cardiovascular outcomes after treatment with Exenatide once weekly in patients with Type 2 Diabetes Mellitus
Commercial	EXPLORER Study: Assessment of the efficacy and safety of a new wound dressing in the local treatment of diametib foot ulcers. A Prospective, randomised, controlled, doubleblind, European multicentre clinical trial
Commercial	Investigation of GMC-252 in Healthy Volunteers and Type 2 Diabetics
Commercial	PIONEER 3 - 4222: Efficacy and long-term safety of oral semaglutide versus sitagliptin in subjects with type 2 diabetes mellitus. A 78-week, randomised, double-blind, double-dummy, active-controlled, parallel-group, multi-centre, multi-national, four-armed trial
Commercial	PIONEER 6 – Cardiovascular outcomes
Commercial	Sustain 4 - 3625 SUSTAIN™4 Semaglutide vs. Basal Insulin in Type 2 Diabetes
Commercial	4150: NNC0114-0006 and liraglutide in newly diagnosed type 1 diabetes
Commercial	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus - Study Two
Non-Commercial	Adipose tissue and Ghrelin Version 1
Non-Commercial	Bariatric surgery and diabetes mellitus; effects on insulin resistance, incretin hormones and inflammation
Non-Commercial	Dapagliflozin and endothelial function in type 2 diabetes
Non-Commercial	ISTID WALES - Immune Cell Studies in Type 1 Diabetes
Non-Commercial	Relationship between PA and metabolic control in children with T1DM.
Non-Commercial	SWENDIC-2: South West Newly Diagnosed Type 1 Diabetes Collection -2
Non-Commercial	The anti-inflammatory effects of dairy colostrum Neovite™ as a dietary supplement for humans
Non-Commercial - PhD & Masters	PREVIEW - Prevention of diabetes through a lifestyle intervention in children V1

Open	
Commercial Status	**Study Title**
Commercial	Non-interventional study of time to relapse of iron deficiency anaemia
Non-Commercial	BOSS (Barrett's Oesophagus Surveillance Study);Randomised controlled trial of surveillance and no surveillance for patients with Barrett's oesophagus:
Non-Commercial	Faecal Microbiota Transplantation in patients with newly diagnosed recto-sigmoid Ulcerative Colitis
Non-Commercial	HCV Research UK V1 - Host and viral factors associated with outcomes of infection with hepatitis C virus
Non-Commercial	Investigations into the Sex Differences of Barrett's Oesophagus
Non-Commercial	The UK-PBC Genetics Study (was "PBC Genetics Study - Investigation of the Genetic and Molecular Pathogenesis of Primary Biliary Cirrhosis (PBC)")
Non-Commercial - Post Doc	Genomic analysis of Helicobacter pylori strains

Closed - In follow up	
Commercial Status	**Study Title**
Non-Commercial	Electronically delivered, multi-component intervention to reduce unnecessary antibiotic prescribing in primary care. Cluster randomised trial using electronic health records (eCRT2 Study)

Open	
Commercial Status	**Study Title**
Commercial	EARP QUAL - The Use of Emergency Admissions and Frailty Risk Prediction Tools in UK Primary Care: A Qualitative Study.
Commercial - PIC	ZOOM :Determinants of Zoster Vaccination Acceptance
Non-Commercial	An exploratory study to investigate how community learning disability nurses (CNLD's) support adults with learning disabilities in Wales to access secondary healthcare
Non-Commercial	Assessment of a newly developed observational tool to assess care interactions in inpatient mental health settings.
Non-Commercial	Current Beliefs and Clinical Practice of Physiotherapists in the United Kingdom towards Sacroiliac Joint Dysfunction
Non-Commercial	Decision-making for intensive care unit admissions
Non-Commercial	EARS UK Survey
Non-Commercial	EDARA - An Evaluation of Alcohol Intoxication Management Services (AIMS): Implications for Service Delivery, Patient Benefit and Harm Reduction
Non-Commercial	Intraoperative Hypotension in Elder Patients (IHypE)
Non-Commercial	Mainstreaming Genomics: Re-contacting patients in a dynamic healthcare environment (ESRC)
Non-Commercial	Public and clinicians' views of Prudent Healthcare
Non-Commercial	WEB-RADR - Recognising Adverse Drug Reactions. WP4 Study - Comparison of Adverse Drug Reaction (ADR) reports received via Yellow Card mobile app with case notes
Non-Commercial	Fifty Shades of Grey - Assessing for association of grey hair and medical specialty
Non-Commercial - PhD	(EQUITY) An investigation into how qualitative methods interact with, influence and impact on clinical trials and the roles of research personnel and organisations using Narrative Synthesis and Case Study Methodology
Non-Commercial - PhD	Aseptic Technique (AT): What are undergraduate nursing students learning?- Phase 2 (Qualitative) of a mixed methods study.
Non-Commercial - PIC	Narratives of health and illness for www.healthtalkonline.org (formerly DIPEx) and www.youthhealthtalk.org V1

Closed - In follow up/ Closed to recruitment	
Commercial Status	**Study Title**
Non-Commercial	Genetic Testing for SADS and the British Coronial System

Open	
Commercial Status	**Study Title**
Non-Commercial	Family studies of patients with Familial Hypercholesterolaemia (FH)
Non-Commercial	Genetics of Learning Disability, Epilepsy and Cortical Malformations Syndromic epilepsy and learning disability: characterisation of phenotype and detection of pathogenic genomic copy number variations.
Non-Commercial	Molecular Genetics of Adverse Drug Reactions
Non-Commercial	Studying the Implemention of GeNomics in wALes (SIGNAL): Evaluating exome sequencing as a diagnostic service for NHS patients
Non-Commercial	The Genetic Basis of Familial Epilepsy in Wales (West)
Non-Commercial - PIC	Experiences of People with Copy Number Variants

Open	
Commercial Status	**Study Title**
Non-Commercial	Albumin To prevenT Infection in chronic liveR failurE (ATTIRE)
Non-Commercial	DESEPTiW - Defining Sepsis on the Wards: point of prevalence study

Open	
Commercial Status	**Study Title**
Non-Commercial	(RAPID) Rapid Analgesia for Prehospital Hip Disruption
Non-Commercial	PATH-2: Platelet Rich Plasma in Achilles Tendon Healing
Non-Commercial	CARD1 - Fractal dimension (Df) of the incipient blood clot: A novel biomarker in Coronary Heart Disease (CAD)
Non-Commercial	DVT - An Investigation into whether the fibrin clot micro-structure formed in patients diagnosed with deep vein thrombosis (DVT) is abnormal using Gel Point and fractal analysis
Non-Commercial	PARAMEDIC 2: The Adrenaline Trial
Non-Commercial	The United Kingdom Aneurysm Growth Study

Open	
Commercial Status	**Study Title**
Non-Commercial	Identification of factors associated with speech disorder-cleft palate
Non-Commercial	The Cleft Collective Cohort Study
Non-Commercial	TOPS: Timing of Primary Surgery for Cleft Palate v1.1

Closed - In follow up/ Closed to recruitment	
Commercial Status	**Study Title**
Non-Commercial	SPRING Study: The Study of psychosis and the Role of Inflammation and GABA/Glutamate.

Open	
Commercial Status	**Study Title**
Non-Commercial	*HRA Dementia and Cognitive Impairment in Prison
Non-Commercial	AD Genetics - Detecting Susceptibility Genes for late-Onset Alzheimer's disease - Both Sites
Non-Commercial	Care coordination in a forensic mental health setting. - An ethnographic study of care co-ordination in a forensic mental health setting.
Non-Commercial	Dementia and Spirituality: A Pilot Study to explore how the spiritual needs of dementia patients are addressed within Care and Treatment Plans in three Health Boards in Wales.
Non-Commercial	Developing a patient-centred outcome measure for the identification and management of health related quality of life in patients suffering with Pernicious Anaemia
Non-Commercial	Gender in an acute mental health setting (Version 5).
Non-Commercial	Homicide by patients with schizophrenia: a case control study
Non-Commercial	Identifying treatment Side effects in adults with an Intellectual Disability and Epilepsy: Development of a Patient-Reported Outcome Measure (PROM) for identification of Anti-Epileptic Drug (AED) side effects (SIDE-PRO
Non-Commercial	Is helping helpful? What impact does working with traumatised individuals have on psychological therapists and what are the contributing factors?
Non-Commercial	Linking Cognition and Genetics in Schizophrenia and Bipolar Disorder.
Non-Commercial	Molecular Genetic Investigation (East) - Molecular Genetic Investigation of Bipolar Disorder and Related Mood Disorders - East
Non-Commercial	Molecular Genetic Investigation (West) - Molecular Genetic Investigation of Bipolar Disorder and Related Mood Disorders - West
Non-Commercial	Project Teulu - Evaluation of the introduction of the pilot Family Liaison Meetings (FLM) to two inpatient Rehabilitation and Recovery units within Abertawe Bro Morgannwg University Health Board.
Non-Commercial	PTSD Registry Version 1 - Establishment of an allWales cohort of patients with Posttraumatic stress disorder (PTSD) for future mental health research
Non-Commercial	RCT of Groups for Alcohol-misusing Short-term Prisoners (GASP) - A randomised controlled trial of an early group intervention to engage alcohol and other substance misusing short-term prisoners in appropriate health service use

Non-Commercial	SAIL - Exploratory Pilot Study of patients with Eating Disorders using the Secure Anonymised Information Linkage (SAIL)
Non-Commercial	Service users' perspective on the effectiveness of a self-management group within a forensic mental health setting: Promoting service user involvement in writing their own Care & Treatment Plans.
Non-Commercial	STRATA Version 1.0
Non-Commercial	The impact of masculinity upon males with psychosis
Non-Commercial - PhD	Implementation of evidence based practices in mental health teams.
Non-Commercial - PhD	The emotional impact of sudden death: Version 1
Non-Commercial - PIC	Online pcyhoeducation (PIC)
Research Tissue Bank	NCMH - National Centre for Mental Health - Wales Mental Health Network
Non-Commercial - Masters	Attribution, Coping and Adjustment in Coronary Patients
Non-Commercial - Masters	The impact of occupational therapy interventions which use the Cognitive Disabilities Model on the experience of caring for a relative with dementia.

Closed - In follow up	
Commercial Status	**Study Title**
Commercial	Auxillium - Outcome of treatment options for Dupuytren's Contracture

Open	
Commercial Status	**Study Title**
Commercial	Latella2 Evaluation of the LatellaTM Knee Implant System for Medial Osteoarthritis Pain Reduction (Latella-2 Study)
Non-Commercial	HRA The BOSS Study - The British Orthopaedic Surgery Surveillance Study: A nationwide service evaluation, and nested-cohort study.
Non-Commercial	PROM-COM - A randomised crossover trial to assess the acceptability and feasibility of electronic and paper based data collection of a patient reported outcome measure questionnaire for use in a clinical trial.

Closed - In follow up	
Commercial Status	**Study Title**
Commercial	ESTEEM Study to collect information on DMF utilization and safety

Open	
Commercial Status	**Study Title**
Commercial	A 12-month open-label study to evaluate the safety and tolerability of pregabalin as adjunctive therapy in pediatric subjects 1 month to 16 years of age with partial onset seizures and pediatric and adult subjects 5 to 65 years of age with primary generalized tonic-clonic seizures
Commercial	A0081105 - Lilac Research study - A randomized, double-blind, placebo-controlled, parallel group, multi-center trial of pregabalin as adjunctive therapy in pediatric and adult subjects with primary generalized tonic-clonic seizures - protocol A0081105
Commercial	An observational, Quality of Life study in Lemtrada MS patients
Commercial	ARPEGGIO: Laquinimod for Primary Progressive Multiple Sclerosis (PPMS)
Commercial	BASE: Brivaracetam And Seizure reduction in Epilepsy
Commercial	Multiple Sclerosis Study Using Ocrelizumab
Commercial	Plegridy Real World Observational Program (POP)
Commercial	Post authorisation observational study of Lemtrada in MS patients
Non-Commercial	A prospective study of clinical outcome in patients with anti-HU paraneoplastic antibodies
Non-Commercial	Investigation into the efficacy and application of non-invasive sensor technology to produce a community-based seizure alarm/monitor for epilepsy and apisodic hyperexcitability disorders
Non-Commercial	Prescribing DMTs for MS in the UK: A qualitative interview study (v1)
Non-Commercial	SANAD-II - A study of Standard and New Antiepileptic Drugs

Closed - In follow up	
Commercial Status	**Study Title**
Non-Commercial	FEMME Study:A Randomised trial of treating Fibroids with either Embolisation or Myomectomy to Measure the Effect on quality of life, among women wishing to avoid hysterectomy

Open	
Commercial Status	**Study Title**
Non-Commercial	Blood biomarkers in women with infertility and gynaecological cancer
Non-Commercial	Establishment of primary cell cultures using biopsy samples of human endometrium as a model to investigate differentiation and preparation for implantation
Non-Commercial	Immune Response and Pathogen-Fertility Interface (pilot study)
Non-Commercial	Signalling networks associated with endometrial pathology (Identifying determinants in the development of endometrial pathology)
Non-Commercial	The Prevalence of Coeliac's disease in a Cohort of Male Patients with Abnormal Sperm Count

Closed - In follow up	
Commercial Status	**Study Title**
Non-Commercial	PREDNOS - PREDnisolone in NephrOtic Syndrome: The PREDNOS study

Open	
Commercial Status	**Study Title**
Non-Commercial	An Ethnographic Study of Staff using Aseptic Non Touch Technique
Non-Commercial	ICISS: The International Collaborative Infantile Spasms Study: A randomised trial in the medicinal treatment of infantile spasms
Non-Commercial	National Registry of Babies, Infants and Children under 5 treated for Congenital Cytomegalovirus (CMV) Infection
Non-Commercial	Preterm Birth v1-The role of infection, nutrition and inflammation in preterm labour and birth Study REC also covers study: Chloride channels in pre-eclamptic pregnancies (CICEAP)
Non-Commercial	PUMA Paediatric early warning systems: Utility and Mortality Avoidance
Non-Commercial	The Genetics Basis of Severe Childhood Obesity (GOOS)
Non-Commercial	UK Cystic Fibrosis Registry
Non-Commercial - PIC	ECHO - Experiences of CHildren with VelO-Cardio-Facial Syndrome (ECHO) - V1
Non-Commercial - PIC	RANOPs -Respiratory and neurological outcomes in children born preterm study.

Open	
Commercial Status	**Study Title**
Commercial	Affirm - Study to determine the safety and effectiveness of flutiform®(Affirm)
Non-Commercial	BATHE - Bath Additives for the Treatment of cHildhood Eczema
Non-Commercial	DeCoDeR - Debt Counselling For Depression in Primary Care: An Adaptive Randomised Controlled Trial
Non-Commercial	HEAT - Helicobacter Eradication Aspirin Trial
Non-Commercial	PACE - Primary care use of a C-Reactive Protein (CRP) Point of Care Test (POCT) to help target antibiotic prescribing to patients with Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) who are most likely to benefit
Non-Commercial	STAGE - SPARC: Pharmacogenetics of Statin-Induced Muscle Toxicity: Exploration Using the UK General Practice Research Database (RMG20100304/001)
Non- Commercial - Phd PIC	WellGP: A survey of wellbeing, burnout and error experience in GPs (PIC)

Closed - In follow up	
Commercial Status	**Study Title**
Commercial	Pyrenees - A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in End Stage Renal Disease Subjects on Stable Dialysis
Commercial	Trial to Compare the Efficacy and Safety of Tolvaptan A Phase 3b, Multicenter,Randomizedwithdrawal,Placebocontrolled,Doubleblind,Parallelgroup (45 to 120 mg/day, Splitdose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease
Non-Commercial	PIVOTAL: UK Multicentre open-label randomised controlled trial of IV iron therapy in incident haemodialysis patients

Open	
Commercial Status	**Study Title**
Commercial	15613211: Open Label Trial to Evaluate Long Term Safety of Tolvaptan
Commercial	The WATER Study: Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue
Non-Commercial	BARACK-D Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease
Non-Commercial	PERIT PD (Patient immune responses to infection in Peritoneal Dialysis)
Non-Commercial	Risk prediction for acute kidney Injury in acute medical admissionS in the uK : The RISK study. A prospective national, multi-centre study to collate data on all acute medical admissions in participating centres in order to develop a national risk assessment for AKI in secondary care.
Non-Commercial	STOP ACEi - Multi-centre Randomised Controlled Trial of Angiotensin Converting Enzyme inhibitor (ACEi) / Angiotensin Receptor Blocker (ARB) withdrawal in advanced renal disease; The STOP-ACEi Trial
Non-Commercial - PhD	SPEAK: Surveying People Experiencing young Adult Kidney failure

Open	
Commercial Status	**Study Title**
Non-Commercial	Attitudes of Midwives to Expanded Newborn Screening in Wales
Non-Commercial	PHOENIX Study Version 1
Non-Commercial	PITCHES: Phase III trial of UDCA in ICP: V1
Non-Commercial	PRE-EMPT: Preventing Recurrence of Endometriosis by Means of long acting Protestogen Therapy
Non-Commercial	QUIDS - Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour

Open	
Commercial Status	**Study Title**
Commercial	A Long-term Access Programme (LAP) for Subjects with Severe Asthma
Commercial	Genetics Of Atopy / Asthma
Commercial	GSK COPD - 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).
Non-Commercial	At-Risk Registers Integrated into primary care to Stop Asthma crises
Non-Commercial	Heterogeneity of Asthma: a pilot study to investigate its microbiome and how it relates to asthma severity
Non-Commercial - PhD	Estimating the social costs of asthma

Open	
Commercial Status	**Study Title**
Non-Commercial	A longer-term care strategy to support stroke survivors and their carers (LoTS2Care) – A feasibility study
Non-Commercial	Fluoxetine Or Control Under Supervision (FOCUS)
Non-Commercial	Rapid Intervention with GTN in Hypertensive Stroke Trial - RIGHT-2
Non-Commercial	RESTART - REstart or STop Antithrombotics Randomised Trial
Non-Commercial	RIVER Registry – RIVaroxaban Evaluation in Real life setting Prospective, multicentre, international Registry of male and female patients newly diagnosed with Atrial Fibrillation and treated with Rivaroxaban
Non-Commercial	Tranexamic acid for IntraCerebral Haemorrhage TICH-2

Closed - In follow up	
Commercial Status	**Study Title**
Non-Commercial	WOLLF - Wound Management of Open Lower Limb Fractures

Open	
Commercial Status	**Study Title**
Non-Commercial	Inflammatory Response In Major Injury & Recombinant Human Erythropoietin (IRMINE) - A Pilot Study

Closed - In follow up	
Commercial Status	**Study Title**
Non-Commercial	The OPEN Trial: Open urethroplasty versus endoscopic urethrotomy

Open	
Commercial Status	**Study Title**
Non-Commercial	Evaluation of biomarkers for the risk stratification of patients with urological malignancies
Non-Commercial	OAB and infection - Role of chronic urinary infection in the pathophysiology of overactive bladder syndrome
Non-Commercial	The PHOTO trial - PHOTOdynamic versus white light-guided treatment of non-muscle invasive bladder cancer: randomised trial of clinical and cost-effectiveness

Other

Closed - In follow up	
Commercial Status	**Study Title**
Commercial	PATRO Study: Post-marketing surveillance to monitor the long-term safety and efficacy of Omnitrope in the treatment of adults
Commercial	A Phase 2 Multicentre,rand,dbl-bnd,placebo cntrld study of the safety, clinical activity and pharmacokinetics of Bosutinib vs placeblo in subjects with ADPKD
Non-Commercial	OSTRICH: Oral steroids for otitis media with effusion in children study
Non-Commercial	SIFT: Speed of Increasing milk Feeds Trial

Open	
Commercial Status	**Study Title**
Non-Commercial	PREVENTT - A randomised doubleblind controlled phase III study to compare the efficacy and safety of intravenous ferric carboxymaltose with placebo in patients with anaemia undergoing major open abdominal surgery
Non-Commercial	HART - Hughes Abdominal Repair Trial abdominal wall closure techniques to reduce incidence of incisional hernias: multicentre pragmatic randomised trial
Non-Commercial	FiCTION - Filling Children's Teeth: Indicated or Not?
Commercial	BADBIR - British Association of Dermatologists Biological Intervention Register
Non-Commercial	Children’s drops for ear pain in acute otitis media
Non-Commercial - PhD	What impact has a specilaist care of the elderly Advanced Nurse Practitioner led secondary care early assessment service had on frail older patients' outcomes in comparison to a traditional acute mecical doctor led service?
Non-Commercial	The role of sperm PLC zeta in human oocyte activation
Non-Commercial	STOP-HCV Cirrhosis - Prognostic biomarkers in HCV cirrhosis.
Non-Commercial	Investigation of Immune function at birth and the consequences of meternal health parameters on functional responses of gestation-associated tissues and blood Study REC also covers study: The impact of Maternal Obesity on Endothelial Dysfunction Of the Newborn: implications for cardiovascular disease
Non-Commercial	C-STICH
Non-Commercial	UPATCH - The Role of Glasses Wearing in Amblyopia Treatment
Non-Commercial	Impact of Modern Oral Health Education on Oral Microbiota
Commercial	MiniHip - Corin MiniHip and Trinity Advanced Bearing Acetabular Cup System UK Clinical Surveillance Study
Non-Commercial	Pharmacy graduate preparedness for pre-registration training v1.0
Non-Commercial	Big CACTUS - Cost effectiveness of aphasia computer treatment versus usual stimulation or attention control long term post stroke

R&D Studies signed off between 19th December 2015 to 9th December 2016

Study Type	Number of studies
Commercial	29
Non-Commercial	49
Grand Total	**78**

Participant Information Centre Studies active as at 9th December 2016

Study Title	Study Type
ECHO - Experiences of CHildren with VelO-Cardio-Facial Syndrome (ECHO) - V1	Non-Commercial - PIC
A single-arm, multicenter, nilotinib treatment-free remission study in patients with BCR-ABL1 positive Chronic Myelogenous Leukemia in chronic phase who have achieved durable minimal residual disease (MRD)status on first line nilotinib treatment	Commercial - PIC
RANOPs -Respiratory and neurological outcomes in children born preterm study.	Non-Commercial - PIC
Online pcyhoeducation (PIC)	Non-Commercial - PIC
Narratives of health and illness for www.healthtalkonline.org (formerly DIPEx) and www.youthhealthtalk.org V1	Non-Commercial - PIC
Experiences of People with Copy Number Variants	Non-Commercial - PIC
PIN - A randomised phase II trial of Olaparib maintenance versus placebo monotherapy in patients with non-small cell lung cancer	Non-Commercial - PIC
Hybrid - A multicentre randomised phase II study of HYpofractionated Bladder Radiotherapy with or without Image guided aDaptive planning	Non-Commercial - PIC
TIME V2.0	Non-Commercial - PIC
ZOOM :Determinants of Zoster Vaccination Acceptance	Commercial - PIC
WellGP: A survey of wellbeing, burnout and error experience in GPs **(PIC)**	Non- Commercial - Phd PIC

Staff projects reviewed as Service Evaluations at Joint Study Review Committee (JSRC)

Date to JSRC	Project Title	Contact name	Department	JSRC decision	Action if applicable
Jan-16	A non-interventional study of the incidence and risk factors for alopecia in survivors on critical illness	Ceri Battle	Physiotherapy		
	Use of fibrin glue in the closure of ascitic drain sites in Chronic Liver Disease patients	Chin Lye Ch'ng	Consultant Gastroenterology and Hepatology		
	SenseIV Questionnaire and Observation Protocol	Paul Lee	Medical Devices		
	'iNICQ 2016: Choosing antibiotics wisely' with the Vermont Oxford Network. Vermont Oxford Network (VON)	Dr. Sujoy Banerjee	Neonatal Unit		Non research agreed via Chairman's action 28.01.2016
Feb-16	Workshops for medical trainees designed to explore mental wellbeing, resilience and reflective experiences	Naomi Marfell	Occupational and Physician Health	Non research agreed via outside of the JSRC with the Directors and JSRC Chairman - and R&D Manager	
	A Service Evaluation – gaining service user (parent) feedback regarding nursing and psychology support offered around their child's Alveolar Bone Graft (ABG) operation, to inform service improvement	Vanessa Hammond	Psychology, Cleft and Palate	Agreed as non-research - see comments in action	It might be helpful to indicate the risks of bias inherent when practitioners seek views of their own services. For example, there are risks of social desirability response biases on the part of respondents and of entrapment by expectation on the part of interviewers. After a year some respondents may have forgotten some of their experiences, but there is no certainty
	The RESCUER (Regional Examination of Standard Care During Evacuation Resuscitation) Study	Dr David Rawlinson	Emergency Medical Retrieval and Transfer Service (EMRTS) Cymru	Non- research	

Staff projects reviewed as Service Evaluations at Joint Study Review Committee (JSRC)

	Perception of central sensitisation among the clinicians	Dr Monika Vijk	Obs & Gynae	Non- research	
	Data collecting - Our priority is to get data in the renal profiles of patients on boosted PIs			Non- research	Advice given by Anne-Claire Owen & Jemma Hughes - I think the Clinical Audit department should be contacted as I note the attached details on the British HIV Association National Audit 2015. Sharon Ragbetli is the Clinical Audit and Effectiveness Manager Sharon.E.Ragbetli@wales.nhs.uk. I also think that Dorian Edwards, Information Governance Manager should be contacted Dorian.Edwards2@wales.nhs.uk. Please let me know the outcome and let me know if there's anything further I can help with. However, I'm not clear on why the data is being collected and what will happen once it is collected? Response received from Jonathan Roberts Thanks for looking at this , I will contact the audit department and info governance dept to seek their advice. Terry from Gilead is collecting this data nationally to create a profile of HIV positive individuals renal function and CHD risk etc... on and off treatment . Im sure Terry can explain this in a more eloquent way !
Mar-16	Validation of the NOVA statSensor Creatinine analyser for Point of Care Testing in Radiotherapy at Singleton Hospital	Lee Peters	Laboratory Medicine	Agreed as non-research but to emphasise to the team that consent is needed for the extra blood sample	
	MRI Scanning	Professor Roger Taylor	Clinical Oncology	Non- research	
	Making Every Contact Count: a Pilot Project with Allied	Caryl Jones-Pugh	Orthoptics	Non-research	The Chairman has considered that you have made the case conclusively and will re-classify

Staff projects reviewed as Service Evaluations at Joint Study Review Committee (JSRC)

	Health Professionals				the project as non-research.
	Consent PLUS - Improvement the Consent Process in Elective Lower Limb Arthroplasty	Dr Paul Lee	T&O Registrar in ABM UHB until August 2015	Agreed as non-research but clarity needed on the 'small scale trial' to be performed (details on page 10 of the document reviewed).	
	Effect of a new ear mould tubing system on self management	Rhys Meredith	Audiology	Agreed as research, however, clarity needed on the current use of the device	
	An audit of Lymphoedema shoe production methods	Melanie Thomas	Lymphoedema	Agreed as research	
	Re-Registration Pharmacist Recruitment Evaluation	Joanne Kember		non-research/service evaluation	Confirm that we are content to agree with the other Health Boards' classification of your project that the project may be considered a 'non-research'/service evaluation. However, please could you keep us updated on phase 4 and whether or not you decide to end that phase.
Apr-16	Does Heart Rate Characteristics (HRC) index predict extubation failure in ventilated newborn infants in intensive care	Sujoy Banerjee	Neonatal	The study was reviewed by our Committee, they were happy to categorise the study as non-research, you're therefore ok to proceed without submission to Ethics/R&D. Jemma Hughes	Chairman's action was taken
	The role of professional identity in integrated teams	Stephanie Best	College of Human and Health Science	Agreed as research	
	C All Wales Study of Non-restorative Surgery for Rectal Cancer	Ffion Dewi	Plastic surgery	Agreed as non-research	
	Evaluation of how useful patients found a patient information film	Clare Ford	Physiotherapy	Agreed as non-research but the Committee raised the following points for consideration/clarity: Tenses vary throughout the document; therefore, it was unclear if the project had already	

Staff projects reviewed as Service Evaluations at Joint Study Review Committee (JSRC)

				been carried out. Second page of the document “Patients will be rung...” – you may wish to consider changing this to “... will be telephoned”?	
	A Proposal to Evaluate the Abertawe Bro Morgannwg University Health Board Dementia Training Programme	Ruth Gates	Learning and Organisational Development	Agreed as non-research but the Committee raised the following points for consideration/clarity: Page two of the document refers to patient/carer perspective.	
	The SAD Survey (Sub-Arachnoid Diamorphine Survey)	Laura Jackson	Theatre/Recovery	Agreed as non-research. The Chairman is satisfied with your response. Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was ratified as 'non-research'	
	UK and Irish Hospice and Specialist Palliative Care Unit Experience of Assisted Ventilation in Motor Neurone Disease	Faye Johnson	Palliative Medicine	Agreed as non-research	
	Major Trauma PROMs	Sue Evans		Agreed as non-research but the Committee raised the following points for consideration/clarity: Where was the validated children’s quality of life tool reviewed/validation Is this to be to be completed by the parents also?	
	Setting research priorities for Tissue Engineering in Reconstructive Surgery	Tom Dobbs		Agreed as non-research	

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May-16	All Wales Evaluation of Paediatric Lymphoedema Service	Dr Ruth Davies	College of Human and Health Science, Swansea University	Agreed as research	
	Evaluating health professionals' perceptions of aseptic non-touch technique and training for aseptic non-touch technique: an All-Wales approach	Clare Hawker		Agreed as a service evaluation	
	Pilot Scheme to Evaluate Provision of Spiritual Care for Older People Living in Care Homes	Rev Hilary Jardine	Chaplain's Office at POWH	Agreed as non-research but the Committee raised the following points: 1. The need for a control group 2. Subsequent assessment – in the summary information provided, page 2 states "... yet to be provided".	
	Patient outcomes after glosso-laryngectomy	Dr Yasmine Kamhieh		It's not classed as a SE in line with the decision of other HBs	
	Sexual Offending and Behaviours that Challenge Survey Report Caswell Clinic	Dr Sara Morgan	Forensic Mental Health	Agreed as non-research, however, the Committee agreed that the project should have been received at JSRC before and that the team are made aware that in future the R&D Department is contacted at the start.	
Jun-16	The role of professional identity in integrated teams	Stephanie Best	SU	Agreed as non-research	Chairman agreed in line with other Health Boards' decisions that this project is a SE/non-research project, the Chairman is content to re-classify the decision as SE/non-research. Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was ratified as SE/'non-research'.

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	Revision of Patellofemoral Unicompartmental Knee Replacement to Total Knee Replacement Does Not Have Poorer Outcomes Than Primary TKR	Andrew Davies	T&O	Agreed as non-research	1. Data is secure, but we presume is anonymised , and confirmation required that it meets with Caldicot approval. 2. Last paragraph discusses Ethical Objections, but this is not part of the remit of the JSRC. 3. As this is Service Evaluation, ethical approval is not required
	The readability of online patient resources for skin cancer treatment	Tom Dobbs	Burns & Plastics	Agreed as non-research	
Jul-16	An evaluation of a Transition Intervention in a medium secure environment	Kim Liddiard	Psychology, Caswell	Agreed as non-research	
	Exercise and Lifestyle Programme (ELP) Pilot Study Pathway	Chris Lamberts	Physiotherapy	Agreed as non-research	
	Impact of aortic valve disease, heart failure and their therapies on peripheral pulse wave velocity and flow-mediated changes in distensibility	Mark Ramsey	Cardiology	Agreed as non-research	
	Health Psychology Service Review Stakeholder Interviews	Vanessa Hammond	Psychology, Cleft team	Agreed as non-research	Decision within R&D, ratified by Chairman
	Nursing staff questionnaire on ICU delirium	Gabby Rowley-Conwy	Cardiac and burns ITU	Agreed as research	This is research – it wouldn't need ethics as staff only but will need R&D for nurse involvement, its more than a survey
Aug-16	PATIENT/REFERRER EXPERIENCE SURVEY FOR THE ACUTE CLINICAL RESPONSE SERVICE	Sarah Davies	Acute Clinical Response Service	Agreed as non-research	The committee suggested that the team may wish to consider revising the survey questions and that an option style may generate better responses.
	A Service Evaluation – gaining service user (parent) feedback regarding their and their child's experience of attending a speech group, to inform service improvement and to	Vanessa Hammond	Consultant Clinical Psychologist	Agreed as non-research	The committee requested clarification on whether the telephone interviews will be recorded? And if so, are participants informed of this? How will the data be stored and when will it be destroyed? The committee also suggested re-wording the second question of

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	evaluate the effectiveness of the group as an intervention				the Satisfaction with Speech section.
	Wound Management Product evaluation	Julie Evans	Rehabilitation Engineering	Agreed as non-research	
	Psychodermatology project	Dr. A. A. Mughal	Dermatology	Agreed as non-research	
Sep-16	An audit of thoracic surgical practice – outcomes and quality of life	Ira Goldsmith	Consultant Thoracic Surgeon	Agreed as non-research	Agreed as non-research/audit, however, members asked for confirmation that video-assisted thoracoscopy (VATs) assisted muscle sparing thoracotomy surgery is part of standard practice at ABM UHB.
Oct-16	Additional PBS projects, Caswell Clinic	Dr Bronwen Davies	Learning Disabilities, Caswell Clinic	More detailed requested	
	Computer-aided design for efficient patient specific device production	Dominic Eggbeer	Cardiff University	Agreed as non-research	
	The place of pharmacovigilance in the new cluster pharmacist role	Dr Louise Hughes	Cardiff University	Confirmed requested on how 'disclosures' will be address as undergrad students are carrying out the data collection.	
	Service Evaluation of Community Dermatology Practice in Swansea	Dr Avad Mughal	Consultant Dermatologist	Agreed as non-research with some suggestions to improve.	
	Should we offer patients a chaperone when performing fascia iliaca block?	Dr Sureh Pillai	Morriston ED Consultant	Agreed as non-research	
	Wales Air Ambulance/ EMRTS Wales fourth aircraft feasibility evaluation	Dr David Rawlinson	WAST	More information requested.	
	Project 1 Title: Evaluation of the client assessment Project 2 Title: Evaluation of an	Dr Bronwen Davies	Caswell Clinic	Agreed as non research with advice that to review retrospectively is the expection.	By Chairman's action following review at the meeting.

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	adapted functional assessment for forensic population Project 3 Title: PBS Ethos in psychiatric intensive Care Units, Caswell Clinic - Dr Bronwen Davies				
	The place of pharmacovigilance in the new cluster pharmacist role	Louise Hughes	School of Pharmacy and Pharmaceutical Sciences, Cardiff University	Agreed as non-reserach following confirmation that the students will be advised on how to deal with 'disclosures' as part of their training prior to data collection.	By Chairman's action following review at the meeting.
	Survey of pregnant women views regarding pain relief in labour	Dr Susan Williams	Consultant Anaesthetist	Agreed as non-research, hower, committee requested clarity on how the survey will be described to patients, including its purpose. The committee also suggested that the wording is revised to be in lay terms – such as analgesia and lscs.	By Chairman's action following review at the meeting.
Nov-16	Managing Fatigue in Clinical Practice: Telephone consultation with specialist rheumatology nurses	Dr Emma Dures	University of the West of England, Bristol	Agreed as non-research/service development	
	Training Needs Analysis of care staff in relation to attitudes, beliefs and knowledge relating to gender when providing care to patients in a medium secure forensic environment	John Griffiths	Caswell Clinic	Agreed as non-research/service development. The committee suggested that the team also contact a NHS Ethics Committee for their views.	
Dec-16	All Wales Survey of Doctors' use of Prescribing Advice Sources	Dr James Coulson	Cardiff University	Agreed as non-research/service evaluation	
	Joint working project between ABM UHB and AbbVie Ltd looking at the BBV Service	Dr Jagadish Nagaraj	Consultant Gastroenterologist, ABM UHB	No decision made - more information requested.	

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	delivered by ABM UHB				
	GATEKEEPING AND CLINICAL CASE MONITORING OF PATIENTS IN HIGH AND MEDIUM SECURE CARE	Andrew Simmonds	Caswell	Retrospective review - agreed as service evaluation however the committee suggested that some of the outcome measures are worked up to a new evaluation.	

Student projects reviewed as Service Evaluations by R&D

Date reviewed in R&D	Project Title	Contact name	Department	Action if applicable
Jan-16	Access to mental health services: In pursuit of shared values	Ian Stevenson	Mental Health, Tonna Hospital	Professional Doctorate - discussions with REC and Supervisor re this one. But both satisfed that the methods meet the requirement for (a) non research (b) prof doctorate - aco
Feb-16	Small Scale Review Project (SSRP) Proposal, Service Evaluation for Gwelfor	Jen Daffin currently on placement in Gwelfor with Richard Lingard and Judith Store	Cardiff University DClinPsy Programme	non-research/service evaluation project
	Exploring Lymphoedema Health Care Professionals Views and Actions on Lymphoedema Risk Reduction Recommendations Relating to Breast Cancer Utilising Questionnaires	Mel Thomas	Lymphoedema	non-research/service evaluation project
	Assessment of the Stability of Clinical Chemistry Serum Samples held in an Automated Add on Buffer MSc project	Lowri Rooke	Laboratory	non-research/service evaluation project
Apr-16	Screening of serum samples for the presence of macro thyroid-stimulating hormone	Lauren Ware-Andrews	Laboratory	non-research/service evaluation project
	The SAD Survey (Sub-Arachnoid Diamorphine Survey)	Laura Jackson	Anaesthetics	non-research/service evaluation project
May-16	Questionnaire about procedural skills training and outpatient clinics experience within core medical training (CMT) programmes in Abertawe Bro Morgannwg University Health Board.	Dr Iason Thomas	Postgraduate	Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was considered to be a service evaluation.

Student projects reviewed as Service Evaluations by R&D

	Essentially the student will be doing some testing on a commercial piece of software to see if its fit for purpose. The software is basically being used to match images taken with different equipment on the same patient such as with a CT scanner etc. We will be very closely directing and supervising the student so that we take full responsibility for everything that she does. We hope this work will help us to make sure we can use the commercial software on our patient images.	Dr Ruth Harding	Medical Physics and Clinical Engineering	
Jun-16	Evaluating the Implicit and Explicit Effects of Attachment Theory Training for Healthcare Support Workers within a Medium Secure Hospital	Christopher Stamatakis	Psychology	Following discussions with Chairman and the Committee Member who reviewed the project at the meeting last month, the main concern is that if these are the questionnaires that are being applied to the staff following the training, how will these address evaluating the training itself – they seem much broader than a simple assessment of the impact of the training on staff practice. I can advise that we think this is a non-research/ survey/service evaluation project. However, as this is a student project it should be confirmed with your supervisor and other student structures established in the College taking on board our comments. Please ensure you obtain appropriate ABM UHB Directorate permissions before commencing.
	Project involving helping to commission clinical software would be counted as research for purposes of Uni student work experience	Ruth Harding	Medical Physics and Clinical Engineering	Apologies for the delay in getting back to you. As this is a student undergrad, it wouldn't be reviewed at our JSRC. HR should be covered as it's a student placement, but the University College should agree that the proposed project constitutes enough for their studies

Student projects reviewed as Service Evaluations by R&D

	A study into ABMU user readiness in preparation of the Welsh Emergency Department System	Jodie Croxall's		We've discussed your project within the Department and also escalated to the R&D Deputy Director. I can now advise that we think this is a non-research/ survey/service evaluation project. However, as this is a student project it should be confirmed with your supervisor and other student structures established in the College, taking on board our comments. Please ensure you obtain appropriate ABM UHB Directorate permissions before commencing and in publishing your results, please confirm that the project was considered to be a service evaluation
Jul-16	Previously piloted a dermatology screening clinic and at the clinic we used anonymised patient satisfaction questionnaires	Kim Beddow	Dermatology	Following discussions with colleagues, as the data is anonymised we think it's fine that the results are used in your dissertation. However, as this is a student project, please ensure that it is confirmed with your Supervisor and other student structures established within the College, taking on board our comments. Before starting your project, please ensure you obtain appropriate directorate permissions and in publishing your results, please confirm that the project was discussed with R&D and our views are as above.
	Emotional Versus Physical Outcomes of Lymphovenous Anastomosis (LVA) Surgery	Cheryl Pike	Lymphoedema	Following discussions with the Deputy R&D Director, I can confirm that we consider this project to be a Service Evaluation. As this is a student project, this should also be confirmed with your supervisor and other student structures established in the College, taking on board our comments. Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was considered to be a service evaluation.

Student projects reviewed as Service Evaluations by R&D

	Exploring the utility of a proposed clinical prediction tool to estimate the probability of abusive head trauma in children less than two years of age	Laura Cowley	Paediatric Directorate	Following discussions with the Deputy R&D Director, I can confirm that we consider this project to be a service evaluation, which is also in line with Cardiff and Vale UHB's decision. As this is a student project, this should also be confirmed with your supervisor and other student structures established in the College, taking on board our comments. Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was considered to be a service evaluation
	Health economics of EUS staging of gastro-oesophageal cancer (GOC) and the current clinical practice and use of EUS staging of GOC	Seow Tien Yeo	Gastroenterology & Endoscopy	SE
Aug-16	Alcohol-Related Brain Damage (ARBD) prevalence in South Wales	Rob Heirene	University of South Wales, School of Psychology	Based on the information provided, and that other Health Boards consider this project a service evaluation, I can advise that we'll take the same view and consider this project a service evaluation. However, as this is a student project, we ask that you ensure this is confirmed with your supervisor and other student structures established in the College taking on board our comments. Please ensure you obtain appropriate ABM UHB directorate permissions before commencing and in publishing your results, please confirm that it was considered to be a service evaluation.

Student projects reviewed as Service Evaluations by R&D

	A Comparison of arthroscopic hip debridement versus repair for traumatic and atraumatic hip labral tears in active adult population using the I-HOT 12	Christina Morgan	Physiotherapy	Reply for Sharon Ragbetli: Yes as suspected this does not fit in with Clinical Audit. My only concern here is from a governance point of view – new techniques and procedures to be started up in ABMU should be OK'd by the Effective Practice Approval Committee (EPAC). Do you know if this happened Christine? How long have the two approaches been in use? It is not clear from the registration form if you require any support Christine. As it is not Clinical Audit we cannot prioritise it for support as our resources are limited I'm afraid and currently further reduced by long term absence of one of our team members. Should you require case-notes I would be happy to confirm with Health Records that the project is not a Clinical Audit (if it's CA it is our responsibility to pull the notes) and perhaps you can request notes via that route? Please let me know – Agreed as Non-Research
Sep-16	National Exercise on Referral for Obese Pregnant Women; does it help tackle health inequalities?	Frances Samuel	Public Health, ABM UHB	R&D Director and Assistant are happy to accept this is SE
	Is the current guidance on preoperative fasting time adhered to within the perioperative environment?	Laura Stephens	Cardiff Uni	As this is a student project, it should be confirmed with your supervisor and other student structures established in the College, taking on board our comments. Please ensure you obtain appropriate directorate permissions before commencing and in publishing your results, please confirm that the project was considered to be a non-research project at ABM UHB
Oct-16	The Psychological Impaction Patients of Using Radiological Terminology to Describe the Causes of Non-Specific Low Back Pain	Matt Webb	Physiotherapy	Research
	Verification of haemolysis indices on the automated Cobas 8000 system	Liz Palmer	Laboratory	We have reviewed within the Department and consider this project to be a service evaluation

Student projects reviewed as Service Evaluations by R&D

	Setting up an alert system for clinical trial patients who get admitted into ABMU so we get notifications sent directly to us which is linked to the data we input into Myrddin	Jenna Edwards	Cancer Institute	Agreed as Non-Research