Research and Development

Edition 21

Cardiff and Vale UHB January 2018 Newsletter

Research and Development Twitter Account

The Research and Development office Twitter account is now up to 459 followers.

Join in and follow us on Twitter www.twitter.com/@CAV_Research and get the latest R&D news and learn about new research opportunities that you can be a part of.

Health and Care Research Wales Support & Delivery annual event

15 March 2018 | 09:00 - 17:00 | Cardiff City Stadium | £0.00

Save the date

It is open to Health and Care Research Wales support & delivery staff.

Registration will open in January 2018.

If you would like to be notified when registration opens, please email: healthandcareresearch@wales.nhs.uk

Clinical Research Facility Study of the Month

For the first time, the Clinical Research Facility (CRF) at the University Hospital of Wales (UHW), Velindre Cancer Centre's Clinical Trials Unit (CTU) and TC BioPharm Ltd. have joined forces, to deliver a study looking into an immunotherapy treatment in patients with advanced cancers.

This Phase IIb clinical trial is looking into a new form of targeted, cell therapy treatment for patients with solid tumours, by using the body's own lymphocytes to try and boost the immune system into destroying the cancer cells. The study will look how safe the ImmuniCell® treatment is, whether it has anti-cancer activity, and also how a patient immune response changes following treatment. This study is being offered to patients with melanoma, renal cell cancer or non-small cell lung cancer, in the hope that boosting the body's natural immune system can fight cancer cells. If this early phase trial is successful then it is hoped that more patients can receive this type of treatment.

The first patient in Wales has been successfully enrolled into this study and it's hoped many more will follow. The leukapheresis team in the department of haematology at UHW successfully obtained cells of a high enough quality from the patient to enable the company – TC BioPharm - to manufacture ImmuniCell® for a full course of treatment. Due to the nature of early phase clinical trials we are not yet sure what impact this treatment will have on the patient's cancer, and only when a larger number of patients are treated will the trial be able to assess early signs of activity.

Dr Rob Jones, who leads Phase 1 Clinical Trials at Velindre, said, 'This is a very exciting time and will hopefully open doors for future successful collaborations enabling us to offer more complex studies to patients in Wales. A collaboration of this nature has been discussed for many years between both teams, and we are proud to have to come together to deliver this study together with TC BioPharm which will we hope will help improve future anti-cancer treatments.'
Dr Steve Knapper, who is investigating the trial at the Clinical Research Facility said, 'This case proves that by successful working together and collaborating within healthcare you can potentially have a positive impact into the health and wellbeing of patients in Wales. Both Research & Development departments at Velindre Cancer Centre and University Hospital of Wales were instrumental in making this collaboration possible. Many teams have pulled together to offer patients a new treatment that we hope will lead to improved patient treatments and outcomes.'

By working together the ambition is to increases the number of early phase studies open in Wales to give Welsh patients more treatment options closer to home.

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

First Nurse Led PI Trial Open

The team have opened their first nurse-led trial, with Emma Williams, our Research Nurse Manager, acting as Principal Investigator. We also have Katja Williams, Research Nurse, acting as Sub-Investigator. The trial is a cohort study exploring recovery of health and well-being in adults diagnosed with cancer. The CRG will recruit patients with Non-Hodgkin's Lymphoma but will also work closely with two other teams to recruit patients with varying cancer diagnoses. The two other teams will be led by:

- Sara Elias—Gynaecology (UHW)
- Zoe Davies—Breast (Llandough)

The CRG look forward to collaborating with both teams on this trial.

Alongside this, Emma has also started studying for her masters degree in Advanced Nursing Practice. We all wish her well for her studies!

RGG documents – October 17

ISR-RD-004 Research Funding Applications involving Cardiff and Vale UHB

SR-RD 002 Financial Procedure for Supporting Non-Commercial Income

SR-RG-012 Research Audit

SR-RG-013 Notification of Serious Breaches of the GCP Protocol

Clinical Board R&D Lead Job Description

Directorate R&D Lead Job Description

ToR-RG-001 Terms of Reference (ToR)

GR-RP-010 Guidance On Completing Data Protection Permissions Coordinating Process Governance Checks

Critical care consultant wins UK-wide award for contribution to research

A consultant in critical care at Cardiff and Vale University Health Board has won the Established Clinician award for his work over the last 5 years to increase participation in critical care research.

Dr Matt Wise has recently been appointed as a Specialty Lead in his field by Health and Care Research Wales to champion and support research development and delivery within critical care.

The National Institute for Health Research (NIHR) Clinical Research Network's award, in partnership with the Faculty of Intensive Care Medicine (FICM), recognises consultants and trainees who are making an outstanding contribution to research.

Recruiting participants for research into critical care is particularly challenging. Many studies require patients to be randomised within limited timeframes, and most emergency patients are treated outside normal working hours.

Researchers also face challenges regarding patient consent to participate, as patients often lack capacity.

Dr Wise, who joined the University Hospital of Wales in 2005 as Consultant in Critical Care, has established a unique research infrastructure within critical care, with a team of research nurses recruiting to studies 24/7.

As Critical Care Research and Development Lead for the Cardiff and Vale University Health Board from 2010-2015, Dr Wise has increased opportunities for patient participation in critical care research exponentially, optimizing consent and implementing 24/7 recruitment.

Now, Cardiff is consistently amongst top recruiting sites for many studies, with recruitment increasing from fewer than 45 patients per year in 2010 to a total in excess of 1,800 in the last five years. Moreover, it has been possible to attract a number of landmark trials including SPICE III, SUP-ICU, RGNOSIS and TTM. The Target Temperature Management (TTM) trial was published in the New England Journal of Medicine in 2013 and has >950 citations to date, with an Altmetric score of 785 it is in the 99th centile of medical articles and was a major contributor to national and international consensus guidelines on post-resuscitation care.

He said: "Effectively communicating the importance of research in emergency medicine, including areas such as critical care, is extremely important. It has been shown to optimise opportunities for patients, relatives and healthcare professionals to participate in portfolio research."

NIHR Clinical Research Network Specialty Cluster Lead, Professor Stephen Smye said:

"Critical Care is a challenging environment for clinical research but the applicants to the joint FICM/NIHR CRN Research Awards described numerous impressive examples of excellent clinical research leadership, with impact extending beyond critical care to the wider clinical research community and NHS.

"The winning applications confirmed that the critical care research community in the UK is vibrant, ambitious and led by outstanding clinical researchers who are determined to increase patient access to high quality research."

The awards were presented during the Intensive Care Society's State of the Art Meeting on 6 December 2017

Progression of the Joint Research Service Project with Cardiff and Vale UHB & Cardiff University

We are continuing to make progress, gathering momentum towards the presentation of an options appraisal which includes detailed models and recommendations. From an initial presentation to the UHB Executive team in September looking at 6 potential options, these were narrowed to 3 substantive options with some variance in the scale and scope of each. The models being developed focus on "clinical" and research include:

- Improved collaboration through existing structures
- Co-location of CVUHB and CU Research Services staff in to a shared space, joining up some processes and support services through existing structures
- Creation of a Joint Research Service with new structure

More than 20 Clinical Researchers joined in a workshop held at the start of January 18, to contribute their views on the research scope and scale of support services offered by a new Joint Research Service or co-located teams. The group were unified in their desires for:

- a pro-active, researcher focussed service,
- with seamless, shared and simplified processes,
- offering one "front door" entry point to the system,
- providing guidance for researchers and research teams from initiation to conclusion.

There was unanimous support for all aspects of Human research to be included so that there is a clear distinction between the support offered by a Joint Service and the existing Cardiff University Research and Innovation Services. The group were also committed to including primary care research activity as inclusion of this in Health Boards is a particular strength in Wales, providing additional research opportunities. Creating a structure that is future proof, allows for changes in the research environment and growth in multi-agency partnerships was also a priority for researchers.

Building on existing and evolving activity through the Centre for Trials Research, Clinical Research Facilities, Cardiff University Biobank and the Clinical Innovation Partnership there will be a chance to increase understanding and to remove some of the barriers currently preventing some research. Recommendations for improvement of contractual collaborations and communications have already been agreed by the project board, discussions are in progress to identify some improvement opportunities for workforce development and financial interactions. Re-affirming the value of the partnership through the CU and CVUHB partnership steering group that is led jointly by Len Richards, CEO CVUHB and Colin Riorden, Vice Chancellor CU is one of the next steps.

It is recognised by researchers and management that the success of this project will require commitment at all levels of both organisations. We are learning from other Joint Research Offices across the UK and will use the information to design a service that best suits our local infrastructure. Key decisions taking us to the final phase of the project are due to be made late spring. If you would like any further information or would like to contribute your views please contact me, Allison Hanbury, Senior Project Manager, hanburya2@cardiff.ac.uk

The Children and Young Adults Research Unit Open Day

The Children and Young Adults Research Unit (CYARU), which is the first of its kind in Wales, was officially opened on 11th October 2017 the Cabinet Secretary for Health, Wellbeing and Sport, Vaughan Gething.

The CYARU offers the first protected research space for under 18s in Wales and offers significant potential to expand and enhance the current levels of research and development within paediatric services across Wales.

If you have a study that would benefit from the support of the CYARU please contact Rhian Thomas-Turner – rhian.thomas-turner@wales.nhs.uk - ext 47816

Role of the Non-Commercial Contracts Managers

Within the CVUHB R&D Dept, separate teams manage commercial and non-commercial studies. The Non-Commercial Contracts Managers work with study teams, the wider R&D Dept and colleagues across the UHB and beyond (e.g. universities) in negotiating, reviewing, agreeing and implementing contractual arrangements for all non-commercial studies.

The main purpose of a contract or agreement for a research study is to document clearly:

- what activities and responsibilities are expected of each contracting party or organisation;
- details of any goods, services, payments or materials being provided;
- the standards and timeframes that are to be met;
- arrangements for performance monitoring, identification of any issues and how these will be addressed;
- liability and indemnity – the extent to which each party will accept responsibility (and thus potentially bear costs) for acts, omissions and negligence in the course of the study.

A non-commercial study may require one or more contracts for a range of reasons:

- grant awards;
- funding arrangements;
- supplies of devices, IMP, equipment or consumables;
- use of lab, pharmacy or other support services within the UHB or from an outside third party;
- data transfer or transfer of clinical samples;
- intellectual property rights;
- assurance of confidentiality for commercially sensitive information (non-disclosure agreement)
- to provide clarity on sponsorship arrangements, delegated responsibilities, etc.
- to document changes arising from a study amendment.

The Contracts Managers review each non-commercial study to evaluate the risks to CVUHB and to identify whether contracts are required. Some studies may not require a contract, depending on their complexity and the arrangements required to support them: others may require multiple contracts. For those studies requiring contracts, a suite of standardised, model contract templates is available: these have been agreed nationally between government, the NHS and key stakeholders. At present, many sponsors seek to use their own adapted versions of these model documents. The CVUHB Contracts Managers have built relationships with many of the key Higher Educational Institutions to ensure that negotiation of any adaptations to the models is completed as quickly and easily as possible. The model contracts are currently under review by a UK stakeholder working group, with revised versions expected to be published for use soon.

To support the contracts process, the Contracts Managers need access to detailed information on the study, most of which is submitted routinely as part of the application package via IRAS. Contracts form just one part of the wider local governance process through which studies must pass before being approved within CVUHB. Key personnel within the R&D Team work on separate parts of the process, aspects of which overlap. The whole R&D Team aims to work together to avoid duplication of effort and to minimise demands on study teams to supply additional information.

It's essential that the Contracts Managers receive full details of the study activities, including costs, funding and any support service involvement (e.g. radiology, pharmacy, laboratories, CRF, Research Delivery staff). Contracts cannot be signed until support departments have confirmed capacity and capability to participate and the Directorate within which the study will sit has confirmed acceptance of any financial arrangements. A study cannot be approved to open in CVUHB until contracts have been fully signed, but the issue of the formal approval letter – not the signing of the contract – is the point at which recruitment of participants may begin.

Contracts arrangements can be quite complex, particularly when grants are involved, so study teams are strongly encouraged to involve the Contracts Managers as early as possible. Within CVUHB, only the R&D Director is authorised to sign contracts for any aspects of research studies: early liaison with the Contracts Managers helps to ensure that all assurances and process requirements are met and that sign-off can be arranged as quickly as possible.

Please contact the Non-Commercial Contracts Managers if you have any queries: Arwen Hutchings (arwen.hutchings@wales.nhs.uk) and Philippa Farmer (philippa.farmer@wales.nhs.uk)

The UK Policy Framework for Health and Social Care Research

The UK policy framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research in the UK. It replaces the separate Research Governance Frameworks in each UK country with a single, modern set of principles for the whole of the UK.

It is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers.

Colleagues across the R&D community should familiarise themselves with the new framework in its entirety. There are three key changes to be aware of:

1. Change to sponsor's legal representative requirements for non-CTIMPs

The previous Research Governance Framework stipulated that if the sponsor was outside of the UK, the study must have a legal representative in the UK. This requirement is currently included in RES SOPs, IRAS and in the validation checklist in HARP.

The new UK Policy Framework for Health and Social Care Research removes the requirement for non-CTIMPs to have a legal representative of the sponsor in the UK and it is no longer necessary for REC staff to check this as part of the validation process. IRAS, HARP and RES SOPs will be updated as soon as possible.

For CTIMPs, it is still necessary to ensure that details of a legal representative based in the European Economic Area (EEA) have been provided if the sponsor is based outside of the EEA.

2. Student Research

The current validation checklist in HARP states that for doctoral-level studies, the student will usually be named as the chief investigator.

In contrast, the new UK Policy Framework for Health and Social Care research states that students should not normally take the role of chief investigator **at any level of study**, as this function should be undertaken by academic supervisors or course leaders *(An exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship).*

The validation checklist will be revised in HARP as soon as possible.

3. Definition of Research

The 'Is it research?' decision tool available via the HRA website has been updated to reflect the revised definition of research as set out in the UK Policy Framework for Health and Social Care Research.
Please refer to paragraph 3.1 of the framework to read the revised definition of research. The Research Ethics Service 'Defining Research' leaflet has now been withdrawn, however the table from within this leaflet, which sets out differences between research, audit and service evaluation, has been updated in line with the UK Policy Framework and is available via the tool.

Research and Development

Cardiff & Vale Research Forum

The Cardiff & Vale Research Forums are to be held on a quarterly basis. This will be an opportunity to:

- hear from Research Staff about the exciting work they are doing and the challenges they have faced
- keep up to date with important information
- be involved in forming a collaborative Research Community in Cardiff and Vale contributing towards raising awareness of the importance of research and the impact it has on our patients and services.

The next four research forum dates will be confirmed shortly and we are always looking for speakers and volunteers to get involved with the forum. For further information please contact Zoe Boult, Senior Nurse, R&D: Zoe.Boult@wales.nhs.uk

Good Research Practices Seminars – February 2018 – April 2018

Specific Training	Presenter	Date and time	Venue
Human Tissue Act and Research	Carina Hibbs (CU HTA Coordinator)	Thursday 15th February – 12.30-13.30pm	CRF (Clinical Research Facility, UHW)
Safety Reporting and Adverse Events	Kelly Gee (Specialist in Pharmacovigilance and Safety Assistant, Cardiff University)	Tuesday 27th March – 12.30-13.30pm	CRF (Clinical Research Facility, UHW)
Research Contracts: what you need to know	Philippa Farmer (Contracts Manager, R&D, CVUHB)	Tuesday 24th April 2018 - 12.30-13.30pm	CRF (Clinical Research Facility, UHW)

For further information and how to book please contact Jemma.cross@wales.nhs.uk