



Swansea  
University  
Prifysgol  
Abertawe

# Swansea Trials Unit Uned Dreialon Abertawe



Ymchwil Iechyd  
a Gofal Cymru  
Health and Care  
Research Wales



Ariennir gan  
Lywodraeth Cymru  
Funded by  
Welsh Government

## 2016-17 Annual Report





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# 2016-17 Annual Report of the Swansea Trials Unit

## Foreword

During the period 2016-17, the Swansea Trials Unit, or **STU** as we like to call it, has consolidated, and somewhat extended, our standing as a relatively new clinical trials unit (CTU). We have seen our staff numbers grow reflecting an increase in the projects we are undertaking and the new work bids under development. STU is one of three CTUs in Wales with there being a total of about 50 (some are provisional so number not exact) of these across the UK as a whole. STU has seen continued development in terms of its major ongoing studies, its more recently started work and proposals submitted to various funders both within Wales and at a UK-wide level. STU has continued its work with other Health and Care Research Wales Infrastructure groups including the Centre for Primary and Emergency Care Research (PRIME) and the Secure Anonymised Information Linkage (SAIL) group and has expanded the relationship with the Diabetes Research Unit, Cymru (DRUC) and looks to continue to do so more going forward. STU has extended its leadership base with Professor Hayley Hutchings now being named as Co-Director to work alongside Professor Greg Fegan, who retains the title Director. We believe this approach best reflects the balance of work with Hayley's leadership of the important Research Design and Conduct Service (RDCS) being a key conduit for future work being taken up by STU.

*STU is one of three CTUs based in Wales registered by UKCRC with there being over fifty such units throughout the UK*



## Introduction

### Mission and strategic aims

STU's overarching aim is improvement of the health of people in Wales and beyond through the use of data from trials in medicine, health and social care. We look forward to an exciting future, as STU continues its support of academics and professionals working in health and social care to undertake trials and other rigorous studies aimed at shaping future healthcare delivery.

Following our successful CTU registration in 2015, and infrastructure funding from Health and Care Research Wales, STU has taken a strategic approach to trial development, delivery and dissemination; focusing particularly on trials in secondary care, pre-hospital emergency care, and at the interface between primary and secondary care. STU will prioritise trials in chronic conditions, in particular those arising from diabetes, gastroenterology, respiratory medicine, cardiology and mental health.

Methodologically STU will continue our interest in patient reported outcome measurements (PROMs) and are extending this into new areas such as Diabetes. We look to maintain and extend our interest on the development of trials using innovative 'e-trials' approaches to efficient study design.

STU's strong commitment to involving patients and service users in trial development and delivery remains key.

We are also looking to become a centre with expertise and close linkages with investigators looking to do randomised controlled trials in surgical studies which have historically been little studied.

Our key strategic priorities are to:

1. Continue to attract large-scale, externally funded, high quality trials and other rigorous studies, supported by STU
2. Deliver high quality large scale trials and other rigorous studies on time
3. Disseminate findings and achieve high and demonstrable research impact
4. Build capacity for research
5. Extend the Swansea University Medical School (SUMS) portfolio of commercial and social care trials

## Team STU

STU has continued to grow and as a result of successful bid capture appointed 5 new members of staff in the past year.



**Greg Fegan**  
Professor of Clinical Trials  
and Director of STU

Greg holds a PhD in Epidemiology from Tulane University. Greg has continued to adapt to the

Welsh and UK trials and health research environment following his 25 year sojourn outside of the UK. He has published over 100 journal articles and has taken on scientific leadership roles within UK based institutions including being a sitting member of the Wellcome Trust's Population and Public Health Expert Review Group and as a reviewer and funding panel member of the Welsh Government funded Clinical Research Time Awards. Greg works very closely with Hayley Hutchings and asked that Hayley become Co-Director of STU in recognition of Hayley's key contributions to STU. Greg wishes to look for opportunities to develop Global Health links in the future and develop research support opportunities for low and middle income countries who are starting to experience some of the chronic health problems prevalent in the Global North.



**Hayley Hutchings**  
Professor of Health Services  
Research, Co-Director of STU  
and Director of Swansea  
RDCS

Hayley has been pioneering trials work at Swansea University for almost twenty years. She has a specific research interest in the methodological aspects of patient reported outcome measures. She has a major role in postgraduate research supervision within the medical school and has supervised 4 postgraduate students to successful completion and is currently supervising a further 10 students. Many of these aim to go on to become health researchers, with the ambition of becoming independent researchers and applying for funding in their own right. Hayley's key roles within STU and the wider Swansea University Medical School, including being the Director of the Swansea based RDCS, were key determinants of her role within STU being retitled as Co-Director instead of Deputy Director.



**Dr Alan Watkins**  
**Associate Professor of**  
**Statistics**

Alan has been working at Swansea University for almost thirty years and has played key roles supporting the analysis of clinical trials for the past fifteen plus years. He has more recently taken on looking at best utilising routinely collected data as a means of carrying out “eTrials” where studies can use data repositories such as the SAIL databank, also at Swansea University, as a means of collection of either exposure (think causes) or outcome measures (think consequences) at lower cost.



**Dr Kym Thorne**  
**Senior Trial & Data Manager**  
**for SAILOR, IRMINE, & RAMAN**

Kym has a background in biological sciences from her undergraduate studies which she subsequently supplemented with an MPhil degree in haematological aspects of iron and rounded out her formal training with a PhD in evaluating the modernisation of endoscopy services in the NHS. She has worked for the Medical School in Swansea since 2003 with a brief sojourn in the private sector of trials for a couple of years within this period before returning to the academic fold in 2013.



**Dr Anne Seagrove**  
**Trial Manager for**  
**TIER and RAPID**

Anne has worked at Swansea University for nearly 25 years, spending the last 14 years working on trials in the Medical School, initially focussing on gastroenterological studies whilst completing a PhD. The two feasibility trials that she is working on now form part of the work led by PRIME’s Helen Snooks in pre-hospital care trials with Welsh Ambulance Service paramedics.



**Dr Gail Holland**  
**STU Unit Manager**

Gail was formally trained in molecular biology, clinical pharmacology and has a PhD that looked at gastrointestinal bacteria within pigs. Apart from academic clinical trials regulatory related work, at the University of Aberdeen (2009-14) and with STU since 2014, she has worked in the pharmaceutical industry as a clinical research associate and project manager. She is an active member of the Research Quality Association and sits on their Global Engagement Team. At STU she is the “go to” person for advice on all matters regulatory and has the enjoyable task of enlightening investigators with this!



**Dr Claire O’Neill**  
**Manager of Swansea RDCS**

Claire has a background in health services research with a particular emphasis on qualitative research methods. She has been working in health related research since 2003 and she is usually the first person that new investigators meet when they come to STU in her role as the lead day to day researcher for the RDCS. Her main role is to help researchers to turn their “hunches” into competitive research funding applications.



**Dr Muhammad Saiful Islam**  
**Statistician**

Saiful joined STU shortly after completing his PhD in applied statistics in 2014. He also has BSc and MSc degrees in the same subject. Saiful has been the trial statistician for a number of recently completed pieces of work and retains a role within RDCS in helping investigators to develop competitive funding proposals. He is keen to assist investigators

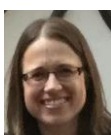


with the statistical aspects of a wide variety of trials and is rapidly gaining broad experience across a range of different studies.



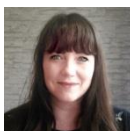
**Dr Buddug Rees**  
**Trial Manager for HART**

Buddug joined the Cardiff and Vale University Health Board (CVUHB) in 2014 to work on HART after working in the pharmaceutical industry working in various roles within clinical trials since 2000. Previous employers included pharma giants Eli Lilly and Astra Zeneca. Buddug obtained her PhD in Cancer Research at the Paterson Institute at the highly regarded Christie Hospital in Manchester. Although Buddug is formally employed by CVUHB we consider her a “STU-er” and value her input into our strategic planning and team building exercises.



**Dr Julie Peconi**  
**Data Manager and Assistant Trial Manager for DESCANT**

A Canadian native who has been in Swansea since 2003 Julie obtained her PhD in 2014 in Medical and Health Care studies at Swansea University whilst working on trials since 2005. She works part time for STU with the other half of her time devoted to being a project coordinator for a national charity, Skin Care Cymru, a charity giving a voice to those with skin conditions in Wales.



**Zoë Abbott**  
**Trial & Data Manager for STUMBL**

Zoë joined STU in January 2017 as the Trial and Data Manager for STUMBL, a feasibility study into the management of blunt chest trauma. Her background is in health research delivery. She is currently on secondment from the Health and Care Research Wales South West Wales Workforce where she has

worked for the past 6 years. Zoë is interested in ways of improving efficiency in health research, and increasing public awareness and access to research participation. Along these lines, Zoë also supports the work of the RDCS as a patient and public involvement expert one day a week. She is also studying for an MSc in Advancing Healthcare Practice which she aims to complete in the summer of 2017.



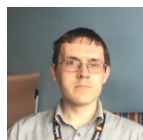
**Mihaela Barbu**  
**STU IT Manager**

Mihaela holds a Masters degree in Computer Science from Swansea University in addition to her BSc from the University of Timisoara in her native Romania. Mihaela has worked at SUMS since 2009. In addition to keeping a close eye on the systems and servers that STU relies on she has been developing her knowledge and skills in assisting people with the translation of their paper based data collection forms into a format suitable for electronic data capture.



**Nadim Bashir**  
**Data Manager for HART and EE-ASI**

Nadim has a BSc in Pharmacology and has been working in clinical trials since 2009. Previous positions have been held at SEWTU and the Wales Cancer Trials Unit, both of which are in Cardiff. He also has had pharmaceutical industry experience with the company PRA Health Sciences based in Swansea prior to his coming on-board with STU in December 2014.



**Timothy Driscoll**  
**RDCS Statistician & Data Manager for PHRASE**

Timothy joined STU in February 2017 following four years working in social research as a data analyst, and holds an MPhys Physics degree from Oxford University. Timothy is



the designated statistician for the RDCS, and the data manager for the PHRASE trial. In his spare time, Timothy is a Scout Leader, and is in his fifth year of Welsh evening classes.



**Claire Hurlow**  
**Joint Quality Assurance & Governance Officer**

Claire has a BSc in Psychology and an MSc in Early Childhood Studies. Previously a Trial Manager at DECIPHER @Cardiff, Claire moved back to Swansea and took up a position with the Planning department at Swansea University, working in project management and business planning, including QA on a WEFO funded portfolio of projects. Claire joined STU in December 2016 and she is using her previous experience to support STU and Abertawe Bro Morgannwg University Health Board (ABM UHB) R&D with quality assurance and governance.



**Amy Clinch**  
**Quality Assurance Officer & Trial Manager**

Amy completed her undergraduate studies at Swansea in Geography, then returned to complete an MSc in Environmental Dynamics and Climate Change after taking a few years out to live and work abroad. Amy has been involved in clinical research since 2013, spending the last three and half years working in the commercial sector developing medical and cosmetic light-based therapeutic devices as a Clinical Trials Coordinator. Amy joined STU in 2017 and is supporting STU in a QA role as well as assisting with the ongoing trial management of some of our funded trials.



**Claire Evans**  
**Finance & Communications Manager for STU and Directors PA**

Claire is the institutional memory of STU. She came to SUMS in 2010 joining the clinical trials unit in 2012. Previous work experience in the private sector in the fields of banking and insurance for twenty years is well utilised by STU as Claire is the key person involved in keeping track of the financial aspects and progress reports concerning grants for all of STUs stakeholders. Her importance to STU was recognised within this past year with a well deserved promotion.



**Vicky Davies**  
**RDCS Administrator**

Vicky has a keen interest and skills in producing nice to look at reports, graphics and promotional material. Vicky works with Claire and Gail in making sure that the day to day logistics of STU are taken care of. She has been working with SUMS, and its predecessor the Swansea Clinical School since 1997.



**Neil Jenkinson**  
**STU Administrator**

Neil joined the STU team in 2017 and comes from a background in event and project management, working in the public sector including the Royal College of Surgeons and Royal College of Physicians, further education and charities. He brings his organisations skills and administrative experience, working with Claire and Vicky to support the STU team in its various projects and administration needs.

## Work Packages

The following work package areas were identified and agreed upon with Health and Care Research Wales to be covered over the three year funding cycle of 2015-18.

### WP1 Unit Development and Management

This work package concentrates on the staffing, structure, management, information and paper based systems and processes required to deliver high quality trials and studies. Some key elements are:

- Maintenance of registration with UKCRC
- To increase staff in the Unit by at least one FTE and develop staff capacities to better manage the processes required to achieve this growth
- All trial managers and data managers trained to use the MACRO4 Electronic Clinical Data Management System (CDMS) by end 2016
- All STU standard operating procedures (SOPs) and policies reviewed and revised to ensure compliance with the EU clinical trials directive and port these into the Q-Pulse Quality Management system by the end of 2016

#### *Progress to date for WP1*

To further our work alongside colleagues at DRUC we now host a statistician within STU who is funded by them but mentored and supported by senior colleagues within STU, including Greg Fegan who is an Accredited Statistician of the American Statistical Association. This statistician, Dr Wai-Yee (aka "Ivy") Cheung previously worked at Swansea University within a forerunning trials unit located at the University. All of our trial managers have now been trained and exposed to the use of the MACRO4 CDMS. We have purchased and deployed the Q-Pulse quality management system using servers provided by Swansea University's Information Services and Systems (ISS). Also using services provided by ISS, we have put into production another trials management system called REDCap that many CTUs across the UK are starting to use more often. We built the data capture and management system for the STUMBL trial using this technology.

### WP2 Development of new studies

This work package is focussed around generating new trials and studies from both on-going, well established and long standing collaborations as well as by finding new investigators and groups to collaborate with. Some key elements are:

- Liaise with and take up sign-posted leads from RDCS
- Assist with proposal development and submission to funding bodies
- Increase in the SUMS portfolio of commercial and social care trials
- Expect to win 1 or 2 bids per year such as the Welsh Government's Research for Public and Patient Benefit (RfPPB) awards
- Expect to win every year or two larger awards around the £1M mark funded through NIHR schemes

#### *Progress to date for WP2*

The strong collaboration with DRUC has resulted in the development of a bid proposal with Professor Colin Dayan of Cardiff University in response to a specific call by the National Institute of Health Research's (NIHR) Efficacy and Mechanism Evaluation (EME) programme for work in type 1 diabetes immunotherapy.

In addition, following the expected completion of the IRMINE pilot with Prof Ian Pallister we plan to submit an outline bid to the EME late 2017 following a request to resubmit.

Working with PRIME, STU has been successful in gaining funding from the NIHR HS&DR programme for the 'GPs in EDs' study with a value of approximately £900,000.

## WP3 Oversight of Funded Studies

Deliver high quality large scale trials and other rigorous studies on time. Some key elements are:

- Expect to finish 10 funded studies within the specified funding period
- Finish all studies within budget whilst being mindful of the time taken
- Where delays occur we will report causes and lessons learned

### *Progress to date for WP3*

STU working with the HART study team has expanded the number of sites opened for this important and large surgical trial (Please see below for more details) and saw a major increase in the rate of study participants enrolled within the period covered in this report. The total number of participants enrolled by March 2017 was 561 compared with the 157 recruited by the end of the same month in the previous year. Similarly the REFRAMED trial was completed in this period and the report submitted to the funders. We are currently awaiting their feedback.

Details of other studies that have completed and recently reported to their funders in this past year are found below.

## WP4 Dissemination and Engagement

Dissemination of findings and achievement of high and demonstrable research impact. Some key elements are:

- A number of papers published in high quality journals with an average of approximately five per year expected
- Links to all published studies to be on the STU website
- A number of public engagement and science events held
- Raise the profile of STU within the University

### *Progress to date for WP4*

Aligned to the REF publication policy STU's journal articles have been made "open access" either through depositing them in the University Cronfa repository or by paying for gold open access. We have also provided links to these publications via our regularly updated and maintained STU website ([STU.swansea.ac.uk](http://STU.swansea.ac.uk)).

STU have now decided to enter the social media environment and we plan to have scheduled tweets three times a week to disseminate news, publications, events and general items of interest.

## WP5 Build capacity for research

The focus of this work package is the continued emphasis on recruiting, supporting and developing the careers of postgraduate research students and early years researchers. Some key elements are:

- Identify possible research projects within trials and studies carried out within STU and associated groups e.g. PRIME Centre Wales
- Assist with proposal development and submission to funding bodies
- Mentor trial staff doing theses related work, usually methodological work, as it fits within funded studies

### *Progress to date for WP5*

STU continues to build on its excellent track record working with postgraduate students within the area of health services research. Professor Fegan currently supervises 1 student whilst Professor Hutchings supervises 10 students. Many of these are undertaking innovative research that has the potential for future development into large scale funding bids.

We also plan to submit applications to the Health and Care Research Wales Social Care studentship and the Diabetes UK studentship call in line with our strategy for increasing links with other NHS infrastructure

## WP6 Research Design and Conduct Service

Delivering a high quality and responsive research advisory service to the NHS and Wales School for Social Care Research in ABM UHB and Hywel Dda Health Boards and the Welsh Ambulance Services NHS Trust (WAST). Some key elements are:

- Funding applications submitted/grants won having benefited from support given by STU's RDCS
- Provide advice and input to research ideas in the NHS or social care
- Contribute to the development of a single identity for the RDCS
- Host all-Wales RDCS meetings and contribute to others

### *Progress to date for WP6*

The success of the RDCS is measured in a number of ways.

63 researchers (individuals and teams from ABM UHB, Hywel Dda, WAST, Betsi Cadwaladr and C&V UHB) approached the RDCS in 2016/17 for support (of which 4 were later deemed ineligible). Of the 59 who were seeking support for a grant application 20 have already been submitted to grant funders within this period:

- 4 have received funding
- 5 were shortlisted for RfPPB review process and are awaiting decisions
- 1 is awaiting NIHR HTA review at the second stage
- 1 has been provisionally funded by NIHR EME
- 1 is awaiting a decision by the Health Foundation
- 8 were unsuccessful

Grants applications take a great deal of time, often spanning more than one financial year and those which are unsuccessful are routinely reviewed and possibly revised for subsequent applications. There can also be significant time lag between making an application and hearing about funding decisions means that the team are currently working with a number of researchers on further applications the outcome of which will not be known until next year at the earliest.

Feedback to the RDCS from researchers is consistently very high with over 95% of researchers rating the service as very good and again over 95% saying they would definitely use the service again.

# Key Achievements and Performance Management Information

## Delivering high quality large scale trials

We currently have 18 studies on our portfolio:

Title	Status	
	2015-16	2016-17
DESCANT trial	In set-up	Recruiting
DESCANT Observational Study	In set-up	Recruiting
DISSECT	In analysis	Reporting
EE-ASI	Recruiting	Recruiting
ERA	In set-up	Recruiting
HART	Recruiting	Recruiting
IRMINE pilot	In set-up	Recruiting
PASTA	In set-up	Recruiting
PHRASE	-	In set-up
PRISMATIC	In analysis	Reporting
RAMAN – CRC	-	In set-up
RAPID	In set-up	Recruiting
ReFRAMED	In analysis	Reporting
SAILOR	In set-up	Recruiting
SAFER-2	In analysis	Reporting
STUMBL	-	Recruiting
SWISH	In analysis	Reporting
TIER	In set-up	Recruiting

We have submitted final reports to funders for five of our trials within the past year:

- DISSECT funded by National Institute for Social Care and Health Research
- PRISMATIC funded by NIHR HS&DR programme
- ReFRAMED funded by an NIHR EME grant led by Southampton University
- SWISH funded by National Institute for Social Care and Health Research

- SAFER2 funded by NIHR HTA programme

Two of the larger studies, done in conjunction with PRIME investigators, had major papers submitted and either accepted or under final review.

Support and assessment for fall emergency referrals (**SAFER 2**). The final report was published in *Health Technology Assessment* (<http://dx.doi.org/10.3310/hta21130>) with the paper published in *Annals of Emergency Medicine* (<https://doi.org/10.1016/j.annemergmed.2017.01.006>).

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GERIATRICS/ORIGINAL RESEARCH

Paramedic Assessment of Older Adults After Falls, Including Community Care Referral Pathway: Cluster Randomized Trial

Helen A. Snooks, PhD<sup>1</sup>; Rebecca Anthony; Robin Chatters; Jeremy Dale, PhD; Rachael T. Fothergill, Dr (Clinical); Sarah Gaze; Mary Haller, PhD; Ioan Humphreys; Marina Koniotou; Phillipa Logan, PhD; Ronan A. Lyons, PhD; Suzanne Mason, PhD; Jon Nichol, PhD; Julie Peconi, PhD; Carl Phillips, PhD; Alison Porter, PhD; Aloysius Niroshan Sivarajana, PhD; Mushtaq Wani; Alan Watkins, PhD; Lynsey Wilson; Ian T. Russell, PhD

<sup>1</sup>Corresponding Author. E-mail: [h.a.snooks@swansea.ac.uk](mailto:h.a.snooks@swansea.ac.uk); Twitter: @HRSnooks.

**Study objective:** We aim to determine clinical and cost-effectiveness of a paramedic protocol for the care of older people who fall.

**Methods:** We undertook a cluster randomized trial in 3 UK ambulance services between March 2011 and June 2012. We included patients aged 65 years or older after an emergency call for a fall, attended by paramedics based at trial stations. Intervention paramedics could refer the patient to a community-based falls service instead of transporting the patient to the emergency department. Control paramedics provided care as usual. The primary outcome was subsequent emergency contacts or death.

**Results:** One hundred five paramedics based at 14 intervention stations attended 3,073 eligible patients; 110 paramedics based at 11 control stations attended 2,841 eligible patients. We analyzed primary outcomes for 2,391 intervention and 2,264 control patients. One third of patients made further emergency contacts or died within 1 month, and two thirds within 6 months, with no difference between groups. Subsequent 999 call rates within 6 months were lower in the intervention arm (0.0125 versus 0.0172; adjusted difference -0.0045; 95% confidence interval -0.0073 to -0.0017). Intervention paramedics referred 8% of patients (204/2,420) to falls services and left fewer patients at the scene without any ongoing care. Intervention patients reported higher satisfaction with interpersonal aspects of care. There were no other differences between groups. Mean intervention cost was \$23 per patient, with no difference in overall resource use between groups at 1 or 6 months.

**Conclusion:** A clinical protocol for paramedics reduced emergency ambulance calls for patients attended for a fall safely and at modest cost. [Ann Emerg Med. 2017;■:1-11.]

Please see page XX for the Editor's Capsule Summary of this article.

0196-0644/\$-see front matter  
Copyright © 2017 American College of Emergency Physicians. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).  
<http://dx.doi.org/10.1016/j.annemergmed.2017.01.006>

INTRODUCTION

Background

Falls in older people are an important issue internationally,<sup>1-3</sup> with high human and organizational costs. It is estimated that approximately 30% of home-dwelling people aged 65 years or older fall every year.<sup>3-5</sup> Falls are associated with high mortality, morbidity, and immobility.<sup>3</sup> Recovery from fall injury is often delayed in older people, which increases the risk of subsequent falls.<sup>3</sup> In the United Kingdom, falls account for 3% (approximately \$1,312 [£980] million) of total National Health Service (NHS) expenditure,<sup>6</sup> and the prevention of falls in older people has been highlighted as a priority.<sup>7</sup>

Population growth and ageing, the increasing burden of chronic disease, and shortage of health care workers are affecting health care systems in many countries.<sup>8</sup> NHS emergency departments (EDs) are under considerable pressure, and crowding is a major international problem with negative consequences for both patients and providers.<sup>9</sup>

Emergency ambulances (999) are frequently called for older people who have fallen, composing 8% of emergency ambulance attendances in London, UK,<sup>10</sup> with a similar proportion reported in urban emergency medical services in the United States.<sup>10</sup> In the United Kingdom, United States, and Australia,<sup>11</sup> nonconveyance rates are high for this group;

Predictive risk stratification model: a progressive cluster-randomised trial in chronic conditions management (**PRISMATIC**). This trial was funded by the National Institute for Health Research (NIHR) Health Service and Delivery Research (HS&DR) programme. The final report is in the final editorial review

process and will be published in *Health Services and Delivery Research*. The main publication has been drafted and submitted to a major journal to coincide with the publication of the main report.

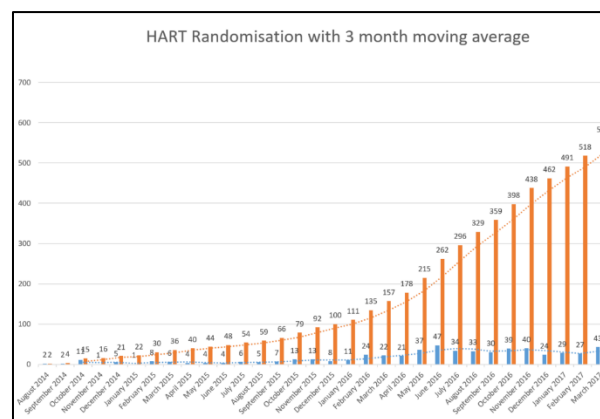
## Selected ongoing studies



Hughes Abdominal Repair Trial (**HART**). Chief Investigator: Mr Jared Torkington, Cardiff and Vale University Health Board. Funded by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) Programme.

HART is exploring a new surgical technique for abdominal closure and involves comparing clinical, quality of life and health economics outcomes across the intervention and control groups.

Following the consolidating 2015-16 period, where HART had managed to recruit 157 patients by the end of March 2016 across 19 UK sites, the trial has gone on to have a total of 561 participants recruited by the end of March 2017 across 27 sites. The research team is led by the Chief Investigator Mr Jared Torkington with support provided by Trial Manager Dr Buddug Rees. HART held a successful investigators meeting in September 2016 which brought together many site investigators along with the Chief Investigator and Trial Manager with STU being represented by Greg Fegan and Alan Watkins.



In December 2016 the HTA informed the HART CI that they would consider a contract variation to extend the recruiting period and funding.



"A multi-centre randomised feasibility study evaluating the impact of a prognostic model for management of blunt chest wall trauma patients. **STUMBL** Trial". Chief Investigator: Dr Ceri Battle, ABM UHB. Funded by the Health and Care Research Wales Research for Public and Patient Benefit (RfPPB) programme.

The STUMBL feasibility trial was successfully funded in the 2016 RfPPB round at a value of approximately £220,000 for two years. The study has made excellent progress to date achieving the following milestones:

- Recruitment of the Trial Manager
- Set-up and initiation of 4 sites at Newport, Taunton, Salford and Manchester
- Start of patient recruitment
- Submission of the STUMBL protocol paper to BMJ Open





## Attracting large-scale, externally funded, high quality trials and other rigorous studies

### Submitted Large Scale Proposals

In this period we currently have a number submitted proposals which are under review or have been shortlisted and we highlight a couple of these below:

*National Institute for Health Research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme:*



Ustekinumab in adolescents with recent-onset type 1 diabetes (USTEKID). Chief

Investigator: Professor Colin Dayan. £1,769,327.

The aim of the USTEKID trial is to see whether a monoclonal antibody currently licensed to be used in the treatment of psoriasis has benefit in maintaining the insulin secretory function in early onset type 1 diabetes patients.

Following an outline application submitted in October of 2016 EME requested a full submission which we provided in January 2017 and are now awaiting the outcome of this application.

*National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) Programme:*



A project we know as "GPs in ED" but formally called "A realist evaluation of effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments" with Chief Investigator Professor Adrian Edwards of Cardiff University was awarded £954,266 by HS&DR. STU's involvement is to provide statistical support to this study.

The aim of this study is to evaluate different models of how GPs work in or alongside emergency departments within hospitals.



## Submitted Pilot and Small Scale Projects

*Health and Care Research Wales Research for Public and Patient Benefit and Health Research Awards 2016:*



Support provided through our RDCS led to 9 submissions to the RfPPB and HRA schemes. One was advised not to submit and was subsequently not sent to the prioritisation panel but all remaining 8 were approved and submitted to the review panel.

## Extending the portfolio of commercial and social care trials

### Social Care

We have made new connections with social care in this period notably through the new Director of the School for Social Care Research, Professor Fiona Verity, and Professor Vanessa Burholt and Dr Sarah Hillcoat-Nalletamby from the Centre for Ageing and Dementia Research (CADR). We are currently exploring ideas for social care proposals including links with third sector organisations and social enterprise schemes such as Solva Care. We are also in the process of developing proposals for the next Health and Care Research Wales Social Care studentship award with colleagues from ABM UHB and Hywel Dda.

We collaborated with Dr Christine Baker to complete the NISCHR Fellowship funded DISSECT study (ISRCTN80487202) which was a social care study of a Mindfulness based stress reduction intervention aimed at improving staff stress levels, job satisfaction and staff turnover rates in care homes for people living with dementia. The trial is now

complete, and we are in the process of writing up and publishing research papers describing the study and results.

### Commercial

Given the essential service function that STU has in relation with scientific Chief Investigators (CIs), most commercial collaborations come via such CIs. Specific current work includes collaborations with drug and delivery system manufacturers for the European Union FP7 funded EE-ASI study led by Professor Colin Dayan of Cardiff University. Furthermore, if the submitted NIHR-EME USTEKID proposal is funded it will have a substantial investment from the producers of the drug looking to be repurposed for the condition under investigation, early onset type 1 diabetes, in that the drug will be provided free of charge. In addition, the makers of the continual glucose monitors will provide this equipment for study participants also at no cost.

We are currently discussing the potential for commercial collaborations with Professor Marc Clement of the School of Management at SU and his long-term collaborators within SUMS, Kevin Fernquest and Gareth Davies.

We have recently started to explore a possible commercial research collaboration in conjunction with staff from Hywel Dda around the management of respiratory conditions based on a device for monitoring coughs.

### Third sector

We are keen to further develop our links with third sector organisations. We have already undertaken some work with such organisations in the current period.

Hayley Hutchings supported the charity Skin Care Cymru to undertake a scoping exercise to examine the landscape of skin care services in Wales. This resulted in a report that was presented at the Welsh Assembly and

subsequently the development of cross-party discussion groups. Jule Peconi continues to support Skin Care Cymru to develop research ideas for future funding.



A pilot evaluation of the Solva Care initiative involved collaborating with the volunteer group who developed and manage the service. Our relationship with the group has been mutually beneficial, and has provided the group with an independent evaluation of their service to use as evidence for further funding from charity groups. There are plans to move the evaluation to a second stage and Kym Thorne has been asked to be involved in future development work.



With the recent move of part of the British Heart Foundation to Swansea we are keen to develop deeper links with this charity. We have been approached to undertake an evaluation of part of their All-Wales Community Cardiology Service and we hope that we will be involved in this evaluation. We are optimistic that this will lead to further collaboration in the future.

## Public Engagement Activities

There are two types of public engagement that STU staff regularly works on. The first is aimed at the general public and usually takes place in publically accessible areas such as hospitals, sports facilities, leisure centres etc.

The aim is to increase the public's knowledge and awareness of clinical research and trials in general and to introduce STU in particular. STU typically gets involved in activities such as the International Clinical Trials Day (held on May 25<sup>th</sup> each year). In May 2016 STU staff attended four events around the Swansea and Bridgend area and interacted with over two hundred members of the public.

The second type of engagement, which we typically call "Patient and Public Involvement (PPI)" aims to bring on board suitably experienced individuals, often patients or carers of patients, to help studies and programmes get a lay persons perspective on how to set-up, manage and disseminate the results of studies.

In January 2017 STU's Claire O'Neill and Kym Thorne identified challenges regarding PPI input that was potentially holding back some research funding proposals. They recognised the importance of the Involving People Network (IPN) and the need to provide enough time for network members to respond and arrange the required paperwork. They worked to find an alternative process for the occasions where applicants need a quicker response. Following discussions with the IPN on their needs, the team submitted a proposal in February 2017. The proposal asked for support to give the same expenses to a smaller team of PPI who will be on hand to respond to requests with a quicker turn around. The work would be done mainly via email, reducing travel costs, and supported by a central member of staff within STU to reduce the burden on IPN. All members of this smaller team would be IPN members allowing them the same access to central training. A lead coordinator for the team was brought on board (Zoë Abbott), the name and branding finalised (Population Advice for Research Committee – or PARC) and the first information meeting arranged.

## Engagement with other Health and Care Research Wales Infrastructure

We have continued to build on our existing established partnerships within this period as well as developing new links to widen our reach and develop our core activities.

### Health Boards



We strengthened our working relationship with Abertawe Bro Morgannwg University Health Board (ABM UHB) by developing a co-sponsorship model for CTIMPs (Clinical Trials of Investigational Medicinal Products) and other interventional trials. We are represented on the ABM UHB R&D committee and the Swansea University and ABM UHB Joint Study Review Committee. We have continued to work with clinicians to develop research ideas for local portfolio funding.

We also have representation on both the Hywel Dda and WAST R&D committees and have supported researchers from both these trusts in their grant submissions.

We are currently supporting an on-going trial, HART, sponsored by CVUHB and are developing joint working practices to support some diabetes trials which are currently sponsored by Cardiff University.

### Other Health and Care Research Wales Infrastructure Centres, Units and Groups

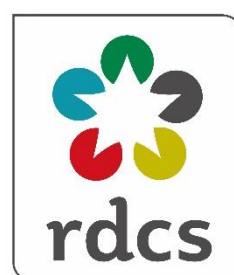
We have continued to work closely with partners in DRUC, SAIL and PRIME in developing research ideas for



portfolio funding and delivering on projects that have been funded.



### RDCS



Research Design  
& Conduct Service  
South West Wales

Gwasanaeth Cynllunio  
a Chynnal Ymchwil  
De Orllewin Cymru

We have actively engaged with the other Welsh RDCS units through the All-Wales RDCS group and have met twice this year, with the meetings held in Bangor and Cardiff. We were involved in organising a joint residential in Llandrindod Wells for writing research bids. Swansea will organise the next residential which we are planning to hold in November 2017 to coincide with people planning to submit following the announcement of the Health and Care Research Wales RfPPB and Health Research Award calls.

We operate our RDCS primarily by meeting individuals working in health and social care on a one-to-one basis, and then where appropriate setting up research development groups to further develop the proposed ideas up to bid submission. We have also been running bi-monthly research surgeries at Morriston Hospital through ABM UHB. Most of the initial contacts are managed by Claire O'Neill and our new statistician/data manager Timothy Driscoll, with Hayley Hutchings overseeing to ensure there is a strong research plan and a clear trajectory for the project. We engage with other specialists at

the research development group stage to ensure we cover all appropriate methodologies. These can include, amongst others, health economics, PROMs, statistics, qualitative analysis, data management, SAIL, and PPI.

We have developed dedicated web-pages for the RDCS component of STU, an audit system to monitor and collect information and outcomes relating to RDCS contacts (specifically in relation to the RDCS Key Performance Indicators), development of a RDCS consultation form and an online satisfaction questionnaire. These forms and key web pages are available in both Welsh and English. We follow up all RDCS contacts and encourage them to complete the satisfaction questionnaires. We engage with contacts at 1, 3 and 12 months to follow up the status of the project ideas.

Overall, the RDCS has had success in securing funding for projects that we have worked on in the current period and are optimistic that this will be maintained moving forward.

## Disseminating findings

We published 21 articles within the last year. These are listed on our web site (<https://stu.swan.ac.uk/Publications>) with links to the full text where these are readily available. Some of these have been provisionally rated by the Swansea University Medical School as being suitable for REF2021 and have been assigned provisional 3\* or 4\* ratings based on being returned to the UoA3A assessment panel.

## Strategic approach to achieving impact

In line with the strategic approach outlined in the previous report we have undertaken numerous activities to maximise the impact of our work. These included:

- Disseminating study findings through high impact journal publications and academic and health service conferences
- Maintaining an up to date, accessible web site and dissemination of information through public facing media, such as Twitter
- Engaging with key stakeholders (policy makers, NHS and social care staff, academics, patients and public)
- Improving our partnerships beyond health by engaging with commercial, social and other non-commercial or voluntary organisations
- Engaging with Welsh Government at senior committee and infrastructure level to help inform policy
- Strengthening and developing links with other research infrastructure groups
- Encouraging staff training and shared learning to enhance skills by conference and course attendance and secondments

## Anticipated types of impact

We anticipate that our work can have broad reach both nationally and internationally and has the potential to:

- Inform national policy, service delivery and patient care
- Be used as the basis for development of national standards
- Result in cost efficiencies to health and social care
- Inform regulatory guidelines
- Be beneficial to patient health and quality of life

## Conclusion

Over the past year we have undergone a period of relative transformation at STU with increasing our staff and total number of ongoing projects. We believe we have laid strong foundations on which to develop and further build upon in the coming years. We have also strengthened a number of our information systems which should improve our working practices going forward.

We are confident that we are competitive as a CTU that can help win funding within our key areas of expertise: pre-hospital and emergency care, e-trials and chronic conditions. We are developing and exploring new areas of activity such as in surgical trials and enhancing our expertise in data management.

We have strengthened our excellent team of staff who work hard to support each other and the work of the unit and we plan to invest further in them in order to build our capacity to support future research. Such development of our human resources will be the key to our continued success in the delivery and support of on-going trials, development of new studies and further expansion of the trials unit. We have also strengthened our sense of being a team through a number of team building exercises and aim to do more of this going forward.

We are hopeful that some of the projects we are developing for the coming year will enable us to further strengthen our unit.