

Swansea Trials Unit





2019-20 Annual Report



Acknowledgements: Funders and Collaborators







Bwrdd lechyd Prifysgol Bae Abertawe Swansea Bay University Health Board

















































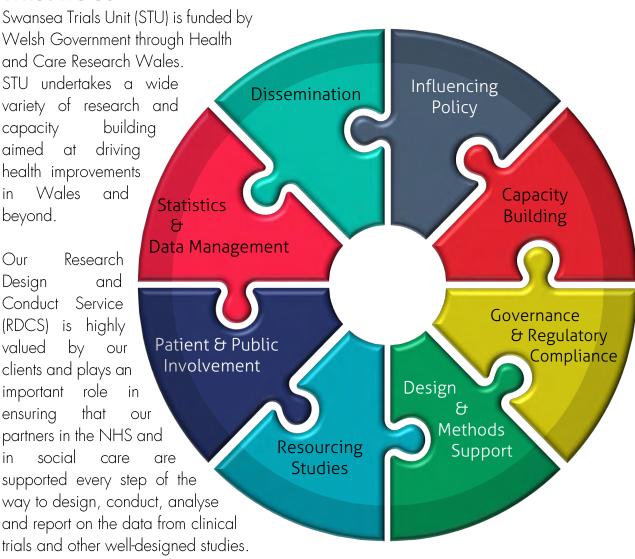


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Foreword

What we do



As the unit has grown so has our ability to support the next generation of researchers and to influence how health and social care are delivered in Wales.

We have been in touch with Hayley every day, often multiple times! Always I am incredibly impressed with her-her speed of reply, depth and quality of involvement and generally being a pleasure to work with.

- Iain Whitaker, Consultant Plastic and Reconstructive Surgeon, SB UHB Since our founding we have prioritised involving patients and service users in every aspect of its studies. We are very proud of the impact our Population Advice Research Committee (PARC) panel has had on speeding up researchers' access to high quality patient and public involvement.

STU's Strategic Priorities

The Swansea Trials Unit has been with us every step of the way from conception, funding application, data management and analysis - we could not have done the HART Trial without them.

Professor Jared Torkington, Consultant Colorectal Surgeon, Cardiff & Vale University Health Board

ATTRACT AND SUPPORT LARGE-SCALE, EXTERNALLY FUNDED, HIGH QUALITY TRIALS AND OTHER RIGOROUS STUDIES

DELIVER HIGH QUALITY

LARGE SCALE TRIALS

AND OTHER RIGOROUS

DISSEMINATE **FINDINGS AND ACHIEVE HIGH AND DEMONSTRABLE RESEARCH IMPACT**

Swansea Trials Unit provides an important platform for research being conducted here in Wales and beyond. The staff work with a wide range of clinicians and other health and social care providers through the NHS and third sector partners and is a source of high quality publications and reports. STU enables our academic colleagues to engage with the wider

community and it provides an excellent pathway for changes to healthcare policy and practice.

Dr Laura Healy, Research Excellence Framework Coordinator, Swansea University Medical School

- 21 new papers published
- 1122 people attended events

37 studies ongoing this year: 1 Clinical Trial of Investigational Medicinal Product (CTIMP), 8 Randomised Controlled Trials (RCTs)

6036 patients enrolled on studies

7 new studies started

From start to finish, the Swansea Trials Unit (STU) provided the type of friendly-independent oversight needed to successfully complete our large multi-site randomised controlled trial of a new treatment for refractory depression (project RefraMED).

STUDIES ON TIME team at STU ensured that our trial was of the highest

caliber and was actively involved in all phases of the study. Their advice was always helpful, practical, and scholarly; making the complex task of seeing a clinical trial through from start to finish a rewarding and successful experience.

Prof. Thomas Lynch, Chief Investigator RefraMED trial, University of Southampton

BUILD CAPACITY FOR RESEARCH

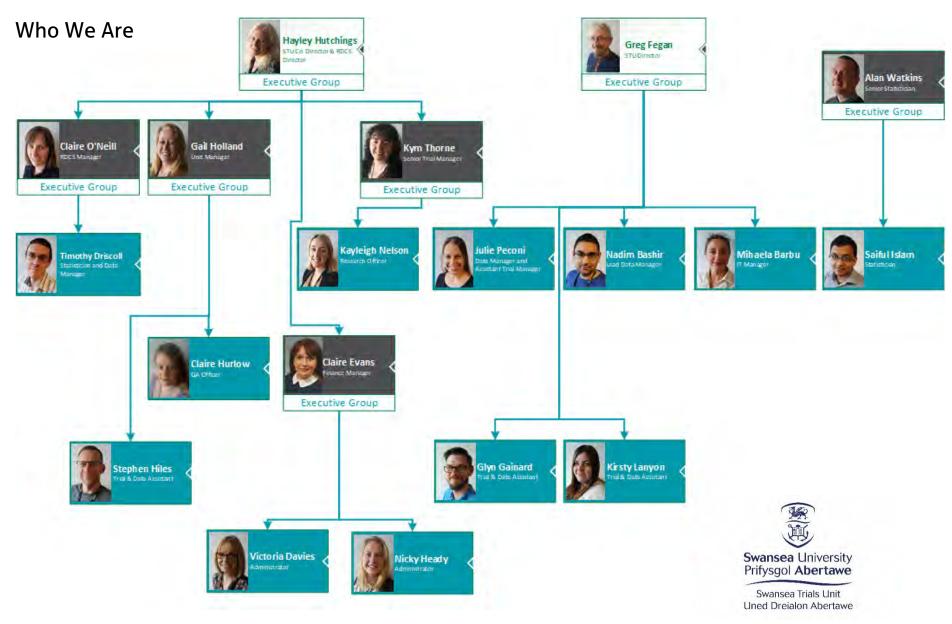
- Supporting 14 PhD and 5 MD students 10 Pathway to Portfolio studies supported, 5 awaiting funding decisions on follow on studies
- Moondance funded project changing the way nurse endoscopists are trained

Swansea Trials Unit have been amazing in supporting my academic career by assisting me to set up my study and supporting my

applications for grants in order that I can carry out my research. They have continued to support the development of my study by mentoring and supervising me academically. From a research naive background STU have developed my research skills with close mentoring.

- Dr Anwen Williams, Colorectal Surgeon, Swansea Bay UHB





Lay Summary





Swansea Trials Unit (STU) was set up in Swansea University in 2015. STU is funded in part by Health and Care Research Wales (a research arm of Welsh Government). This money enables STU to support researchers and develop their research ideas. STU brings people together to produce the best quality research.

STU is part of a group of registered trials units throughout the UK. This means STU has proven that it:

- is well set-up to do research;
- has the right staff who are trained to carry out its work;
- has processes and structures to ensure studies are safe;
- has systems to ensure that the data collected are reliable.

UKCRC Registered Clinical Trials Units



The term "research" covers everything from distributing questionnaires to testing new drugs. STU's research aims to improve treatments and care for the public. STU works with the public to plan its research and highlight the patient/public point of view. In this way, research is done "with the people" rather than "to the people".

Types of research include:

Clinical trials which are used in medicine to compare different types of treatments and diagnostic tests. They aim to find out if a new treatment or procedure:

- is safe;
- has side effects;
- works better than (or as well as) what is already available.



Health and social care research is carried out to understand how to help people to manage their long-term conditions e.g. carers might want to know how they can help people live independently for longer.





Our aim is to help researchers put their ideas into practice. STU works with them to understand how to provide evidence to answer their questions.

STU helps researchers develop the description of the problem and to explain their strategy to solve it. STU can then work out how to design a study so that it works in the real worlds of the NHS and social care.

STU also guides researchers through the process of making sure the study meets legal and safety requirements. This way of working, with STU providing advice and coordination, and researchers bringing their health/social care expertise helps to ensure successful projects.



All of our studies start in the same way. Someone working in the NHS or social

care has a question and wants to know the answer.

These questions takes lots of forms:

How can we give the best care?

Which treatment is best?

Where is the best place to deliver care?

Can we improve how we currently train our staff?

Our role is to work out how to answer these questions and how to test possible solutions. This will take many forms from undertaking surveys to drug trials.



STU staff work closely with our Patient and Public Involvement representatives as well as our Joint Advisory Group (JAG) to ensure that the research we undertake meets the needs of the public.

As a trials unit STU can help researchers at all stages of their research journey.



STU works with the health and social care sectors to influence the delivery of these services in Wales. One way to do this effectively is via research to ensure that only proven treatments and services are being offered to the public. In order to prove that a treatment works better than (or as well as) an existing one, researchers must first secure funding to undertake a new study. STU has an

in-house Research Design and Conduct Service (RDCS) whose primary focus is to make funding applications which will be successful in gaining funding.

STU achieves this by:

- Involving members of the public in the planning and evaluating research at every stage
- Working with a range of partners on the JAG to ensure that research is carried out in the best interests of the public and gives value for money.
- Working with researchers to make sure that the results of studies are made widely known.



STU staff attend conferences and meetings talking to decision-makers about research findings. STU reports are published in journals and highlighted via Twitter @STU_Swan and @RDCS_SWW as a way of talking to other researchers and the public.

Executive Summary

Throughout the year the team have continued to work with researchers, funders, policy makers, charities and academics across Wales and the UK to provide a responsive service. We do this in a number of ways, including via our Research Design and Conduct Service (RDCS) and our in-house Population Advice for Research Committee (PARC). Our @STU_Swan and @RDCS_SWW Twitter accounts are followed by 750+ individuals and organisations interested in health services research and the work we do.

Our RDCS continues to grow and this year we met with 58 researchers and were part of 25 funding applications. Our engagement with social care colleagues is growing and we are delighted that Ms Nicky Heady and Dr Julie Peconi will be working to raise the profile of social care research in STU.

Our foresight in developing our in-house public involvement panel PARC has been rewarded in quicker turnaround times for patient involvement in funding applications. It has also been recognised by researchers across Wales who are now creating their own panels based on the PARC model.

We continue to prioritise staff training to further embed a culture of quality and innovation. Our RDCS team devised and conducted two research sandpit events with Welsh Ambulance NHS Services Trust (WAST); contributed to a research workshop for occupational therapists in Swansea Bay University Health Board (SBUHB); and delivered researcher training for midwives in Hywel Dda University Health Board (HDUHB). We were delighted to be part of the Science Festival held in Swansea University in October.

We are pleased with our growth and progress this year and look forward to increasing our portfolio and continuing to drive health improvements in Wales and beyond over the coming year. We were supported in this by our new recruits - Glyn Gainard, Steve Hiles and Kirsty Lanyon who have quickly settled in, supporting the delivery of several studies and helping us to implement our new REDCAP Cloud data management platform.

2019-20 was a year for embedding our recent successes, sharing our expertise and planning for the future of Swansea Trials Unit. In December we were joined by Jane Luo from Shanghai Center for Drug Evaluation and Inspection on placement with us to share experiences about trial management and governance. We submitted our extension funding application to Health and Care Research Wales in May 2019, and we were delighted to be informed of our success in September. We are due to shortly apply for re-registration with UKCRC.

Of course, COVID-19 has necessitated some changes and we are proud of the positive way in which the staff have adapted. From day one of lockdown we have had constant requests for STU and RDCS support and we are working with our collaborators to support the NHS and social care and to build the future of health and social care research in Wales. Greg has also accepted an invitation to join the Data Sharing Working Group of the COVID-19 Clinical Research Coalition, which was formed in early April to accelerate COVID-19 clinical research in resource-limited settings. We look forward to reporting on this and all of our COVID-19 work next year.



Greg Fegan
Professor of Clinical Trials



Hayley Hutchings Professor of Health Services Research

Swansea Trials Unit Director and Co-Director June 2020

Work Packages (WP)

WP1: Unit development and management

The focus of this work package is twofold: the development and maintenance of systems that underpin the research undertaken by the Unit and the staffing structures and management processes in place to ensure these are of the highest quality.

IN THE LAST YEAR:

STU has supported 3 successful applications to the Health and Care Research Wales Infrastructure call

Julie Peconi & Kayleigh Nelson both submitted research fellowship applications

STU, as one member of a consortium of five UKCRC trials units, secured funding from NIHR to develop information for electronic data management practices

Hayley Hutchings was invited to write a review article for Patient Reported Outcome Measures
Journal

Alan Watkins was appointed as Professor of e-Trials Research



ealth and Care

AWARDS

Two of our PhD students, Nicky Heady & Oliver Richards, won best poster awards at the Swansea University Medical School

Post Graduate Research Conference

CRaFT won Outstanding Research & Innovation Collaboration at Swansea University's Research & Innovation Awards 2020 for its collaboration with Biospectroscopy in the early diagnosis of bowel cancer

Hayley Hutchings was shortlisted for Outstanding Research Supervision at Swansea University's Research & Innovation Awards

Training

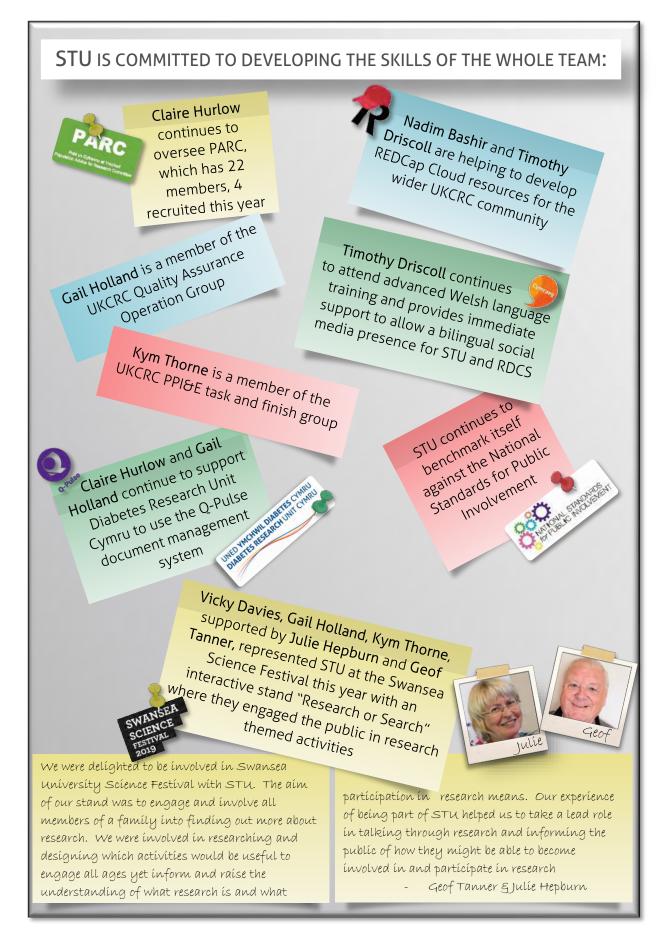
Between them **Greg Fegan**, **Hayley Hutchings**, **Alan Watkins** and **Claire O'Neill** support 19 post-graduate researchers. This year 2 completed and both were successfully examined

Julie Peconi attended Introduction to Analysis Qualitative Interviews training delivered at Oxford University

Claire O'Neill has attended training through the 2020 Leadership Foundation Aurora programme

Steven Hiles, Kirsty Lanyon and Glyn Gainard, as new employees, attended GCP and core University training.

All **STU Staff** have learned new skills and undertaken fast track training to achieve a rapid transition to home-based working



WP2: Development of new studies

STU is committed to working with existing research teams and to seek opportunities to actively link with new investigators with the aim of identifying potential collaborators and leading to successful funding applications.

During the year 2019-2020 we have successfully developed studies including:

- Group based positive psychology for people living with Acquired Brain Injury (known as Positive Psychology)
- Assessment of a structured, accelerated colonoscopy training programme for Clinical Endoscopists (known as The Moondance Study)

Positive Psychology is a feasibility study exploring if 60 people with Acquired Brain Injury can be identified, recruited and complete a positive psychology intervention. This study will verify if a full scale randomised controlled trial is required to determine the clinical and cost effectiveness of positive psychotherapy in people with Acquired Brain Injury

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[Chief Charactica Controlled Prifysgol Base Abertawe]

(Chief Investigator: Dr Andrew Kemp)

Moondance funded Assessment of a structured, accelerated colonoscopy training programme for Clinical Endoscopists is a multicentre assessment of trainee clinical endoscopist and their trainers' perceptions of the current integrated colonoscopy training programme aiming to provide a basis for future training courses.

(Chief Investigator: Professor Hayley Hutchings)

And we responded to researchers' urgent needs during COVID-19

As we publish 2 studies are active:





Swansea Bay University Health Board

And we have been providing guidance and advice on:

EPoC

Effect of the COVID-19 pandemic and associated control measures on the mental health of carers of people with intellectual disabilities

Chief Investigator: Professor Paul Willner, Swansea University

HIP-CoV

An International audit of Heparins in Practice – COVID-19 infection

Chief Investigators:
Professor Hayley Hutchings
& Dr Quentin Nunes, Liverpool
University

ICE-COVID

Efficacy of iota-carrageenan nasal spray prophylaxis for healthcare professionals treating patients during the COVID-19 pandemic – A double blind randomised placebocontrolled trial

Chief Investigator: Professor lain Whitaker, Swansea University

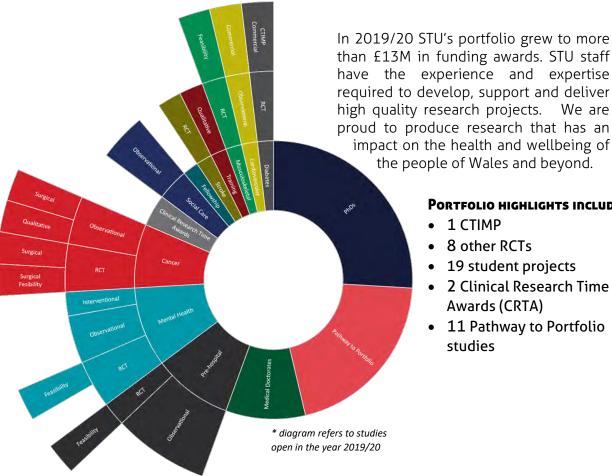
Feasibility
Match Controlled
Trial of complement activation
directed therapy using the c5
inhibitor LFG316 for the
treatment of severe sars-CoV2
(COVID-19 Infection)

Chief Investigator: Dr Matthew Wise, Cardiff & Vale University Health Board

Sequelae COVID-19 Observational

Chief Investigator: Dr Matthew Morgan, Cardiff & Vale University Health Board

WP3: Oversight of funded studies



than £13M in funding awards. STU staff have the experience and expertise required to develop, support and deliver high quality research projects. We are proud to produce research that has an impact on the health and wellbeing of the people of Wales and beyond.

Portfolio Highlights include:

- 1 CTIMP
- 8 other RCTs
- 19 student projects
- 2 Clinical Research Time Awards (CRTA)
- 11 Pathway to Portfolio studies

Important updates from our portfolio:

LungCAST



- Co-located staff member
- Recruited 4239 patients to date
- Database developed which has allowed seamless data entry and live tracking of 43 sites in the Hywel Dda UHB area



- Looking at the health and welfare of people with atrial fibrillation (AF) taking blood thinning medicines
- Study will assess if bleeding events have an impact on quality of life of AF patients.
- Recruitment over Wales, England and Scotland

DESCANT

- 10 NHS Trusts across Wales and England involved
- 468 early-stage dementia patients and carers
- Final stages of analysis and write up





Staff at sites recruited and completed training with the

intervention

- First site open
- Developed a COVID-19 study to raise awareness of carer mental health



- Assessing two closure receiving surgery for colorectal cancer
- Recruited 802 participants from 27 sites in Wales and England
- Analysis complete, reporting in June 2020

WP4: Dissemination and engagement

The STU team are recognised for their contributions to high quality research and methodology practice, with staff representatives on numerous and wide-reaching groups and networks. This is a great achievement and a reflection of the professionalism and hard work of the team.



#DontBeALobster Campaign by Skin Care Cymru, in collaboration with STU. The message to the public was "be safe: protect yourself from the sun - even on Welsh beaches, wear sunblock, big hats, put on a t-shirt, don't burn". We

replaced the red dragon on the Welsh flag with a cartoon lobster and flew the new flags in many well-known Welsh locations including beaches, castles, the Severn Bridge and the Millennium Centre. We promoted the campaign bilingually on Twitter and in the media.



Reframed

RefraMED - This trial involved people diagnosed with depression who have not responded to medication or standard psychological therapies. We studied how they

responded to a new type of treatment aimed at changing everyday behaviour, and showed that people initially felt much better. Although that improvement reduced 18 months after treatment, participants still continued to feel better able to recognise and cope with their symptoms of depression.



STUMBL
STUMBL
STUMBL
STUMBL
OF BLunt chest wall trauma

STUMBL - A study which determined the feasibility of using a prognostic tool in

emergency departments to help assess and manage patients who had received a blunt chest trauma. Findings indicated that we could recruit sites and patients, that the tool was usable and was liked by clinicians and that it was possible to collect questionnaire information from patients and data from clinical systems on patient outcomes. We will now design and seek funding for a large trial to determine if patient outcomes improve using this prognostic tool when compared to usual treatment.

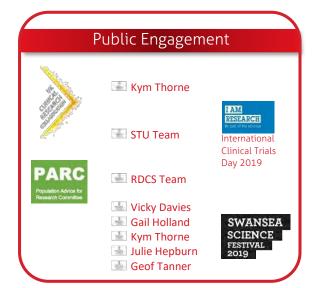


STU staff contribute to the following research groups and networks:











WP5: Build capacity for research

STU is extremely proud of its success in helping to develop new investigators by supporting staff in the social care sectors and NHS.



STU staff act as both supervisors and mentors to PhD students and new researchers, are actively involved in developing collaborations and identifying potential new projects.

STU receives excellent feedback:



Professor Andrew Godkin, Consultant Gastroenterologist and Hepatologist, Cardiff & Vale University Health Board

Swansea Trials Unit have been excellent in working with us to try and set up a large phase II trial in colorectal cancer. They have helped, in an extremely timely fashion, in developing a trial design and protocol, and importantly, we have been able to propose a trial which is as economical as possible.



Dr Matthew Morgan, Consultant in Intensive Care Medicine, Cardiff & Vale University Health Board

We have been impressed by the support, guidance and knowledge offered to us at every contact we have had with the STU team. They excel at finding ways to help us achieve solutions to potential stumbling blocks with our research.



Professor Susan J Moug, Colorectal Subspecialty Lead for The Royal College of Surgeons of England

I'm very happy with STU. They have been super helpful and supportive of the surgical trainees/Welsh Barbers. We are keen to work with STU on more European studies and to develop clinical trials with them. Following the success of the HART study STU has recognised expertise in surgical trials and ambitions to be recognised by RCSEng.



Tom Dobbs, Plastic Surgery Registrar, Swansea Bay University Health Board

STU have provided me with exceptional support through my academic career. The mentoring and experience afforded to me by my interactions with STU have assisted me immensely with my study.

STU engages with innovative companies and organisations:

Rutherford

Innovations

with Swansea Trials Unit as they have always been very approachable and knowledgeable in responding to our enquiries and hope to collaborate with them in the near future.

.....

- Dr lan Barwick, Chief Scientific Officer, Rutherford Innovations Ltd

Bristol Myers Squibb"

The EQUAL-AF quality of life study aims to bring the patient voice to the centre of decisions on effective anticoagulation in AF. STU has been collaborating closely with the BMS/Pfizer Alliance since January 2020 to design and execute this important research study. The study Steering Committee has involved the right clinical, methodological and patient experts and we expect study results, once published, to make a tangible difference to patients and the NHS.

Steven Lister, Senior Health Economist, Bristol Myers-Squibb



Julie is an absolute joy to work with. She is always extremely professional and competent, while at the same time bringing cheerfulness and enthusiasm to everything she does.

Paul Thomas, Chair of Skin Care Cymru

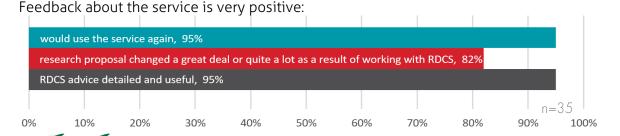
During my 6 month secondment with STU I have been left with a very positive impression of the team, their professionalism and thoughtfulness. I am very grateful to them for openly sharing practices and experiences with me. This depth of communication and the generosity of all at STU and their suggestions will greatly help me with building a long term management system for trials in Shanghai. I would like to give my sincere gratitude to all my colleagues at STU.

- Jane Luo, Inspector, GCP/GLP Department, Shanghai Center for Drug Evaluation and Inspection

WP6: Research Design and Conduct Service



The Research Design and Conduct Service (RDCS) South West Wales is a responsive advisory service accessible by researchers working in the NHS and social care who wish to apply for research funding. The service supports researchers to develop high quality funding applications.



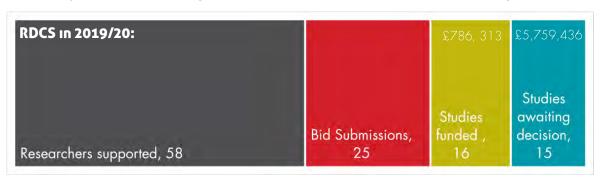
The help I received was absolutely brilliant. The strong links between Claire's team and the R&D team in Hywel Dda made the process so much easier. Seeing a small, non-experimental study evolve and shape into something bigger and better was challenging, but with their expertise and support, they helped bridge the gap between clinical practice and research, which is difficult. Their open-door policy and supportive, friendly attitude meant that I felt supported throughout. Their involvement and support has been invaluable. Thank you so much.

- Dr Meryl James, Principal Clinical Psychologist, Hywel Dda UHB

We have been very fortunate in creating links with the trial team at Swansea in the last year. Claire and her team have been very accessible and provided invaluable advice and support to a number of occupational therapists within our service. This has enabled those who are novice within the research arena to think more ambitiously about how we could develop research ideas and contribute to research in our field. They have also encouraged us to think seriously about further academic qualifications to achieve these ambitions and I am hopeful that occupational therapy will have more opportunities to work with the team in the future.

- Laura Ingham, Swansea Bay UHB, R&D lead Occupational Therapy

We have close links with the other Welsh RDCS units, the Wales School for Social Care Research, the Welsh Health Economics Support Service, and the Language Awareness and Infrastructure Support group. Through the All-Wales RDCS group, we have had the opportunity to observe funding panel discussions to help improve our funding applications.



RDCS Highlights

This year we tried some new and innovative engagement events in

partnership with HDUHB, SBUHB and WAST.

We supported:

Jun

Research sandpit for Occupational Therapists in Swansea Bay UHB. 24 OTs attended and led to a first research application for one

Contributed to Hywel Dda UHB research study day

Jul

First Welsh Ambulance Service sandpit looking at the use of point-of-care testing. Paramedics & unscheduled care managers came from across Wales and England. Event supported by commercial point of care testing (POCT) manufacturers

Half-day RfPPB application workshop for Hywel Dda UHB staff

Oct

Represented RDCS SWW on a joint stall in the Health and Care Research Wales Annual Conference

Represented RDCS SWW at Swansea Science Festival (held at the Swansea Waterfront Museum)

Dec

Midwives half-day workshop on "Choosing the Right Research Design" for midwives in Hywel Dda UHB, resulting in 2 requests for further support

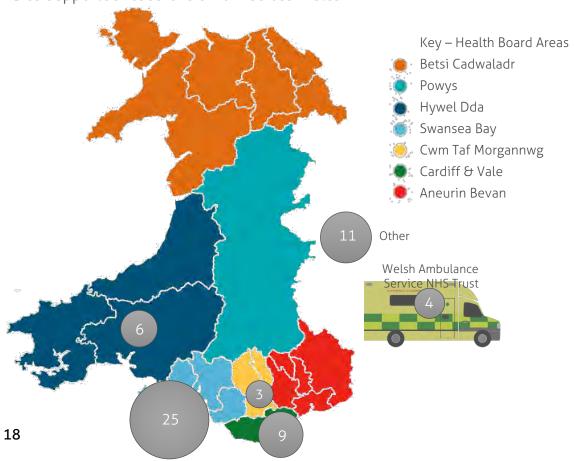
Feb

Second Welsh Ambulance Service sandpit looking at the use of point-of-care testing in the ambulance service. Paramedics and unscheduled care managers came from across Wales and England. This event was supported by commercial POCT

manufacturers

We continued to support last year's successful Pathway to Portfolio applications, resulting in 3 applications to this year's Research for Public and Patient Benefit funding scheme, 1 application in the 2nd round of Wellcome Trust and 1 application in the 2nd round for a Chartered Society of Physiotherapy award.

RDCS supported researchers from across Wales



Key Achievements

21 Publications

7 New Studies

7 Capacity Building Activities

37 Ongoing Studies

30 Funding Applications Made

In Response to COVID-19







Total value of the STU portfolio now exceeds £13M (65% staying in Wales 8 new public involvement opportunities



14 PhD students

5 Medical doctorate students

2 National priority setting groups



6036 patients enrolled

28 Cls supported

30 public involvement opportunities



4 NHS organisations

44% success rate (of outcome known)



2 studies initiated

5 studies in development



Conclusions and Looking Forward

Conclusions

It has been nearly 5 years since STU gained full registered clinical trials unit status and it has been a very busy time. STU has built its reputation and had success across a wide range of specialties.

But as regards trial-specific expertise, you cannot do better than the STU team as they know everything there is to know about conducting trials(!) and it's important to get it right otherwise no matter how good the idea, it will get thrown out because someone picks up some trial-specific point that's not right and say that the trial won't be effective in addressing the key questions around the safety and efficacy etc. of the intervention. I have always been super-impressed with them [Hayley and Claire and their colleagues], their advice in this respect will be invaluable.

- Dom Parkes, Swansea University

Our team is growing and with it our reach and our outputs. Everything we do is about maximising benefit to the health and wellbeing of the Welsh population and wider community.



Figures cumulative over 5 years

We are keen that the growth in our portfolio is carefully managed and matched to our strengths in study design, data management and patient involvement. We are delighted that our colleagues are recognised across the UK for this work. Nadim Bashir and Timothy Driscoll are invited members of the REDCap Cloud UK user group and are working with the group to create a toolkit for its adoption and implementation. Kym Thorne leads UKCRC public and patient involvement and engagement task and finish group, which is developing a central repository for PPI resources.

Looking forward

Our success in turning pathway to portfolio awards into funding applications is encouraging and we are currently look forward to hearing about several funding applications. 5 of our successful Health and Care Research Wales Pathway to Portfolio studies are awaiting funding decisions, 2 potential Health and Care Research Wales Fellows, and 1 potential Wellcome Trust Senior Investigator Fellowship have been invited to interviews. An earlier RfPPB study has been recommended for follow on funding by NIHR, with many more studies in the pipeline.

No end of year round-up would be complete without acknowledging the impact of COVID-19 on our operations. The very first days of lockdown led to several requests for STU and RDCS support and we are working with our collaborators to support the NHS and social care and to develop research in this area in Wales. RDCS activity is still vital to making links with new researchers Θ ensuring the future pipeline of funding into Wales.







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Thanks to all STU and NHS colleagues who contributed to this report. Special thanks go to Gail Holland, Claire Hurlow and Claire O'Neill who produced the report.





