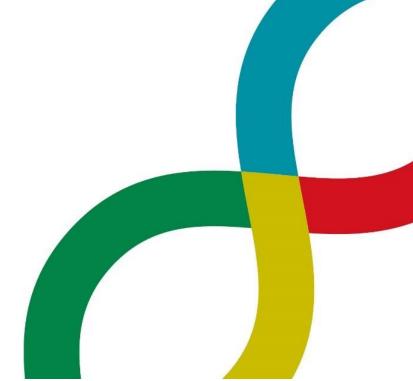


Swansea Trials Unit





2021 - 2022 Annual report



Acknowledgements: Funders and Collaborators



Table of Contents

Foreword	1
What We Do	1
Who We Are	2
Governance & Key Partnerships	3
Key Achievements 2021/22	4
Work Packages	6
WP1: Unit development and management	6
WP2: Development of new studies	8
WP3: Oversight of funded studies	9
WP4: Dissemination and engagement	11
WP5: Build capacity for research	13
WP6: Research Design and Conduct Service	15
PPI, Engagement & Collaboration	17
Conclusions and Looking Forward	19





Swansea University Prifysgol Abertawe

Swansea Trials Unit Uned Dreialon Abertawe

Foreword

Dissemination

What We Do

Swansea Trials Unit (STU) is hosted by Swansea University and is funded by Welsh Government through Health and Care Research Wales. In addition to its core funding STU works with a range of organisations and funders to undertake a wide variety of research and capacity building aimed at driving health improvements in Wales and beyond.

STU is committed to developing the next generation of researchers in Wales. Feedback from clients and demand for its services shows that STU is highly valued by our clients from across the commercial, health and social care sectors in Wales and plays an important role in delivering a healthier Wales.

Influencing Policy

Capacity Building

Governance and Regulatory Compliance

Design and Methods
Support

Resourcing Studies

Patient and Public Involvement

Statistics and Data Management

One key way STU can do this is via its in-house Research Design and Conduct Service (RDCS) for South-West Wales. RDCS's role is to ensure that researchers in the NHS and Social Care in Wales are supported every step of the way to plan, design, conduct, analyse and report on studies so that they can influence decision making in years to come.

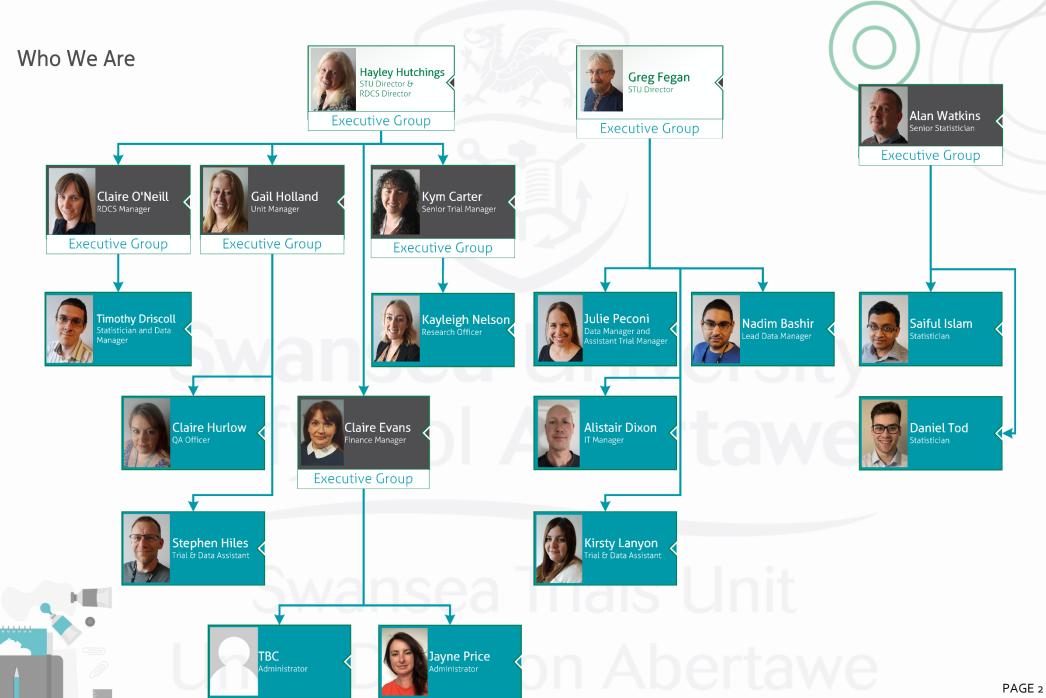
At the heart of STU's work is a commitment to patient and service user involvement in every aspect of our studies. STU's Population Advice Research Committee (PARC) panel enables researchers to gain timely access to high quality patient and public involvement support and advice. It plays a key role in influencing and enhancing researchers' study planning and delivery decisions.

STU and RDCS provides a vital service to aid the development of research questions and improve the quality of research studies in Wales and beyond. The staff work with our researchers to develop studies and get them to think about their study or idea in different ways. In addition, they focus on how to strengthen research teams where a study might be short of skills and how that can be strengthened either by adding stakeholders or collaborators from NHS, third sector organisations which also improves the impact of grants.

Dr Rebecca Thomas Chief Investigator DESW COVID, Diabetes Research Group

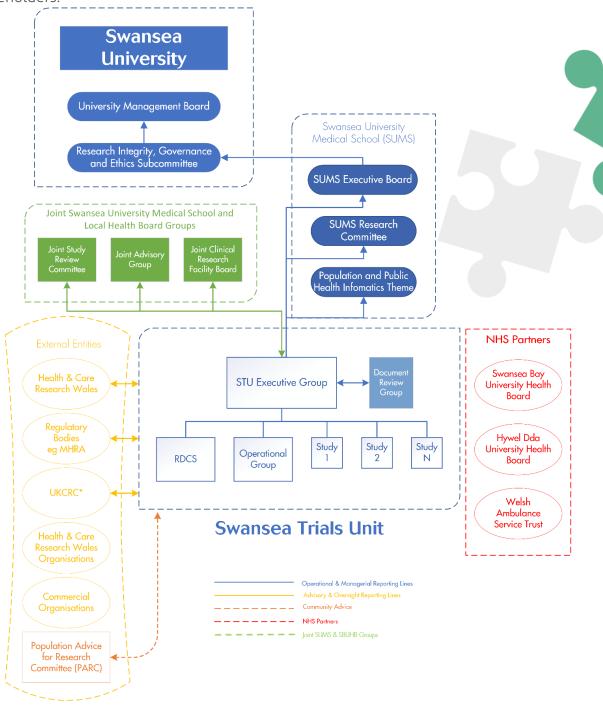






Governance & Key Partnerships

STU has robust governance processes involving relationships that are both internal and external to Swansea University. This structure ensures that STU operates in a sustainable and accountable manner to deliver its portfolio of research projects. STU remains committed to collaborating with our NHS partners and other Health and Care Research Wales funded organisations while continuing to build collaborations with other NHS organisations and the commercial sector. We value the advice and feedback of all of our stakeholders.



Key Achievements 2021/22

Core Metrics

Reporting period: 2021/2022



Jobs created through direct funding



Health and Care Research Wales infrastructure award to the group

Grants won during reporting period

Grants won	Led by group	Group collaborating
Number	1	6
Value	£250000	£1.76M
Funding to Wales	£250000	£1.75M
Funding to group	£230000	£275000
Additional jobs created for Wales	3	4
Additional jobs created for group	2	2



Number of publications



16

Number of public engagement events



Number of public involvement opportunities

Clinical Trials Unit metrics



ımbe

Number of studies awarded



8

Number of studies led by Welsh Chief Investigators



728

Total number of participants recruited

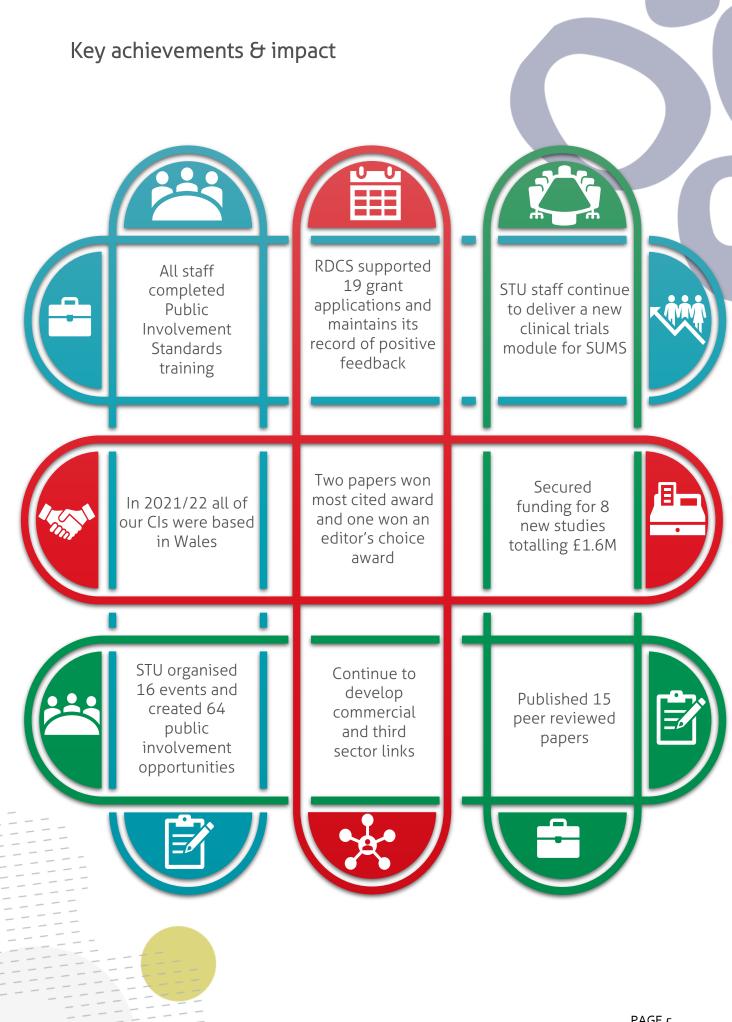


18

% participants from Wales







Work Packages

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:

Julie Peconi secured promotion as well as securing funding for her Sunproofed study.

Timothy Driscoll enrolled for a PhD supervised by Alan Watkins and Hayley Hutchings

Daniel Tod joined the team as a statistician

Saiful Islam and Nadim Bashir left the unit to pursue other opportunities and to undertake further study









Training

Between them Greg Fegan, Hayley Hutchings, Alan Watkins and Claire O'Neill supported 24 post-graduate This year 3 completed and were researchers. successfully examined

Daniel Tod completed eTables training delivered at the STATA Symposium

Claire O'Neill and Saiful Islam delivered research methods training to the physicians involved in the GANGES-B study

Everyone at **STU** competed the UK Standards for Public **Involvement Training**

Claire Hurlow became an accredited Microsoft Office Specialist

Awards

Two papers written by the Trauma Aid team won most cited papers

A paper written by Sarah Hughes, Alan Watkins and Hayley Hutchings was named Editor's Choice



Rasch Analysis of the Listening Effort Questionnaire—Cochlear Implant

Hughes, Sarah E.; Watkins, Alan; Rapport, Frances; More

Ear and Hearing. 42(6):1699-1711, November/December 2021.

⊕ Abstract ☆ Favorites 🕒 PDF © Get Content & Permissions









STU is committed to developing the skills of the whole team:

Claire Hurlow continued to oversee PARC, which has 23 members

Alistair Dixon and Timothy Driscoll completed the REDCap Validation

Kym Carter continued in her role on the UKCRC PPI&E task and

Gail Holland continued in her role as a member of the **UKCRC** Quality Assurance Operation Group

STU continues to benchmark itself against the National Standards for Public Involveme

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 2021-2022 we have successfully developed a wide range of studies and broken ground in new areas. And our partners are always pleased with the work the team do:

Swansea Trials Unit have worked closely with the Centre for Lactation, Infant Feeding and Translational Research and been involved in two applications for funding focused on intervention development to support mothers who wish to breastfeed to meet their breastfeeding goals. So far one of the studies has been funded, and the second, a fellowship application, has secured an interview.

- **Amy Brown,** Professor of Public Health and Director of the Centre for Lactation, Infant Feeding and Translational Research

A dedicated, hard-working and highly professional team who were unrivalled in providing all of the necessary support and advice needed for a complex grant application. The CTU is a truly incredible resource. The team is professional, detail-oriented, incredibly hard working and extremely capable. I should never have doubted them. Additionally, the CTU team is friendly and personable and simply a joy to work alongside. I truly believe that the CTU team is an asset to the Wales clinical research community

- Dr Vasim Faroog, Consultant Cardiologist, Cardiff and Vale UHB



Professor Colin Dayan and Dr Lakdasa Premawardhana, LIONSS Study, Cardiff and Vale UHB

Kirsty made an invaluable contribution to data processes for the LungCAST research project. These included systematic assessments of data quality and processing of data items into analysable states. This work has maximised the utility of this project and it's data. The support provided has had a positive impact on our capacity to undertake research and have confidence in the quality of the study outcomes. In addition, Kirsty has committed support to various publications and steered the preparation, allowing us to grow outputs from our studies and building on collaborative opportunities.

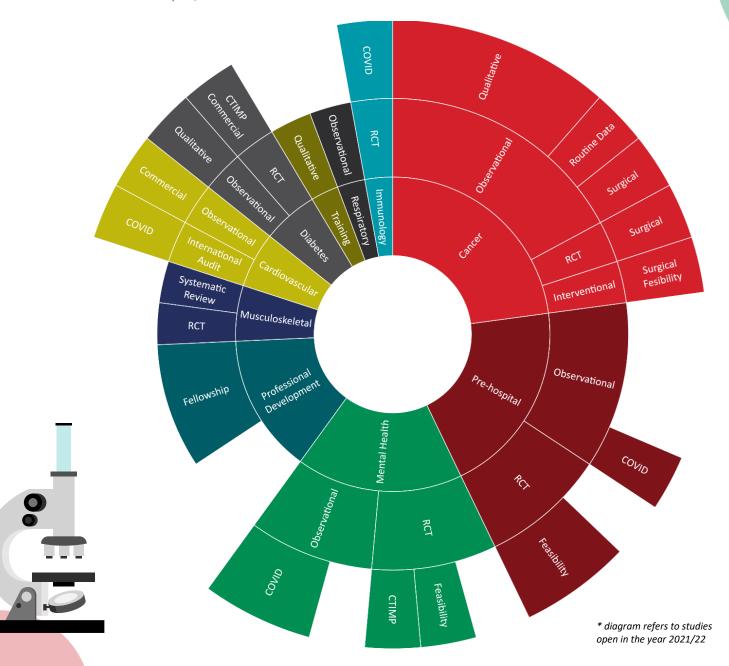
LungCAST Team, Hywel Dda University Health Board

WP3: Oversight of funded studies

In 2021/22 STU's portfolio grew to more than £12.7M 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:

- 2 CTIMPs
- •10 other RCTs
- •24 student projects



Important updates from our portfolio:

A 2-year, Health and Care Research Wales funded study that aims to understand how primary schools in Wales are responding to the growing problem of skin cancer and explore the effectiveness of sun safety policies in schools on knowledge and behaviour. A key output of the study will be co-producing evidenced-based guidance on best methods for implementation enabling Wales to move towards greater skin cancer prevention and keeping people healthier for longer.



A multi-centre trial looking at the impact of early exercise on reducing longer-term complications such as chronic pain and disability in patients with blunt chest wall trauma. Since funding was received in

October 2021 the ELECT2 Trial has opened all five sites and is ahead of recruitment targets with the first of the 3-month follow-up surveys already sent out to participants.

All survey follow-ups and qualitative interviews completed with a subset of survey respondents and is currently in analysis stage. The project team has also been working on various upcoming publications including the protocol paper, currently available in pre-print. A brief presentation will be given on the project at the South West Research Hub Conference

Moondance Foundation funding was secured by Dr Phedra Dodds (Powys THB) and Dr Neil Hawkes (Cwm Taf UHB) to deliver accelerated training for non-medical endoscopists. The STU team were co-applicants on the associated evaluation of the programme. Demand for endoscopy services is at an all-time high and fast track training of nurses to deliver endoscopy diagnoses and treatment has the potential to alleviate pressure on the service The training programme has so far seen two cohorts of trainees complete their accreditation and take up new posts across Wales. The results of the training will be presented at the British Society of Gastroenterology annual conference in Birmingham this summer.



An NIHR funded study into a paramedic-administered local anaesthetic injection for patients with hip fractures. It will recruit 1,400 patients across five sites (an ambulance service area and

receiving emergency department) in England and Wales. It is hoped that this will provide effective pain relief with less side effects than morphine. RAPID2 is in the final stages of set-up, with the first site due to open in June 2022. Research ethics approval was granted in August 2021, and Confidentiality Advisory Group approval in December 2021.

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.



The Trauma Aid team continued their very successful partnership with Wiley (medical journal publishers) recently, recognising the immediate impact of this important research within its field. Investigators from the Trauma-AID study hosted by Swansea Trials Unit, used the pandemic enforced

hiatus to design and distribute an online survey to assess the impact of lockdown on carers of adults and children with learning disabilities. The survey was disseminated via charities, parent groups and social media to parents and carers throughout the UK. The team based in England and Wales produced three papers from the survey responses received and follow-up qualitative interviews, two of which were awarded Top Cited Article 2020-21. One of these articles was cited over 71 times in the review period.





Nicola Heady (Welsh Government and ESRC funded PhD student) was successful in getting her systematic literature review protocol paper published in Systematic Reviews -

Prevalence of neurodevelopmental disorders and their impact on the health and social well-being among looked after children (LAC): a systematic review protocol.



DIABETES RESEARCH UNIT CYMRU

UNED YMCHWIL DIABETES CYMRU

Long-time collaborators in the Diabetes Research Group as well as Dr W.Y Cheung published their research into repeat non-attendance for Diabetes related retinopathy

screening in the journal Diabetic Medicine. The paper was based on a retrospective observational study using anonymised data from Diabetic Eye Screening Wales for people with a full history of screening invitations and attendances was linked with primary and secondary care records held in the Secure Anonymised Information Linkage Databank.





choice award for her research published in the Journal Ear & Hearing on developing a listening effort PROM among

patients who are candidates for cochlear implantation. The PROM assesses perceived listening effort in everyday life in adults with severeprofound hearing loss.

Rasch Analysis of the Listening Effort Questionnaire—Cochlear Implant

TRANSPORT TO THE PROPERTY OF T

STU staff contribute to the following research groups and networks:

Government & NHS



- Alan Watkins
- **Greg Fegan**
- Gail Holland
- **Nadim Bashir**
- Julie Hepburn (STU PPI)



- Alan Watkins Gail Holland
- (REC) Claire O'Neill
- R&D
 - Health Board R&D committees
 - **Gail Holland**

Greg Fegan

- **Kym Carter**
- Saiful Islam



- Alan Watkins
- **Hayley Hutchings**
- Saiful Islam
- Julie Hepburn

Academic



ROYAL STATISTICAL SOCIETY

ASA

Greg Fegan Greg Fegan

PLOS ONE

PRioRiTy

Hayley Hutchings

Julie Hepburn

EDCTP

Greg Fegan Hayley Hutchings

Third Sector & Other

wellcome trust **KEMRI**

Greg Fegan

British Society of Audiology

Hayley Hutchings

RQA Researe

Gail Holland



Hayley Hutchings

DIABETES UK .

Claire O'Neill

Arthritis Research UK

Alan Watkins

CROHN'S& COLITIS UK

Alan Watkins



Julie Peconi

Public Engagement



Kym Carter

STU Team



Day 2021

RDCS Team

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:

The GANGES-B project which has been exploring the impact of COVID-19 on gastroenterology services and staff in Bangladesh. By working together and supporting local training, the collaboration is helping to build and improve endoscopy services, and develop research expertise and capacity, with positive impacts on national policy for the development of the specialty.

- **Professor (Emeritus) John Williams,** Swansea University and Senior Research Leader, Health and Care Research Wales

Alistair (Dixon) is the best. It was refreshing to receive a reply which was timely, informative and concise. I am extremely grateful indeed. It is clear that you have a wealth of expertise.

.....

- Dr Zyllan Spilsbury, Anaesthetist, Swansea Bay UHB

Professor Hayley Hutchings is a master of keeping things on track and bringing imagination, leadership and a deep knowledge base to enable ideas to become projects, and projects to become publications. She is endlessly supportive, generous and energetic within the research team and communicates with us as needed. She makes research inclusive, accessible and exciting!

- Dr Phedra L Dodds, Jets Workforce Lead, JAG and Health Education England South West Endoscopy Program Lead Nurse and Lead Nurse, Endoscopy Training Management Group, HEIW

It has been such an uncertain time for all of us working in clinical research through a pandemic, but STU's support and guidance have been invaluable again. They are like a lighthouse guiding us through stormy waters in the dark nights!

- **Dr Ceri Battle,** Consultant Respiratory Physiotherapist in Trauma and Emergency Care, SBUHB and Health and Care Research Wales Specialty Lead in Trauma and Emergency Care Research

STU engages with innovative companies, organisations and other key stakeholders:



peptido

Swansea Trials Unit have always been very well-informed and accessible in all our interactions with them to date.

Dr. Uwe Wahren, CEO, Peptido GmbH



EQUAL-AF

I have very much enjoyed being part of the team in looking at the important issue of how bleeds can affect the quality of life for those on anti-coagulant medication. The professional team was very inclusive and took on board many of the observations I was able to add on matters such as useability of the questionnaire and the effect that anti-coagulation has on perceptions of risk. I think that this initial investigation will open up an area of research that will greatly assist those with AF and other coagulation issues

.....

Arfon Hughes, Patient Representative EQUAL AF study

Tenovus Cancer Care are pleased to see that Swansea Trials Unit are gofal canser focussing on this important issue and are grateful to Health and Care Research Wales for reflecting this in funding the project. Sun safety is vital in the fight against preventable cancers, and early years education can and should be a central element of this. The knowledge this study will provide around the range of policies and understanding about sun safety in primary schools across Wales, and the guidance this project will ultimately provide, is hugely valuable

- Hannah O'Mahoney, Insight and Engagement Lead, Tenovus Cancer Care

RECONREGEN s

As part of our ongoing work to transform surgical service delivery across several domains (skin cancer treatment and surgical reconstruction), we have collaborated with Hayley for several years. Doctoral students in The Reconstructive Surgery & Regenerative Medicine Research Centre benefit from Hayley's co-supervision, particularly in the fields of patient reported outcome measures and advanced qualitative research methods. Hayley's availability, support and commitment to our students foster an environment of sustained excellence. She is a pleasure to work with and I feel fortunate to have her as a collaborator.

.....

-Professor lain Whitaker, Reconstructive Surgery & Regenerative Medicine Research Centre

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.



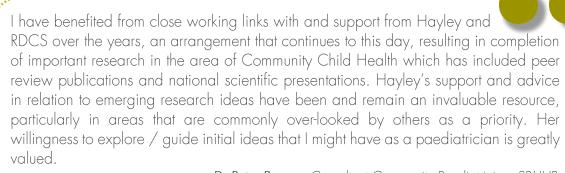
Research Design & Conduct Service South West Wales

Gwasanaeth Cynllunio a Chynnal Ymchwil De Orllewin Cymru



WAST has a longstanding relationship with Swansea Trials Unit who support many trials in Ambulance services. We value the continued access and support our people receive from RDCS. They are always enthusiastic and helpful. They engage on a one-to-one basis and their advice is invaluable.

Dr Nigel Rees, Head of Research and Innovation, WAST

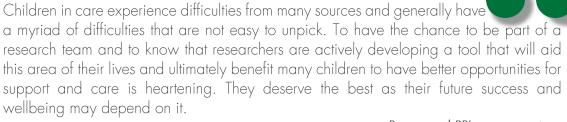


- Dr Peter Barnes. Consultant Community Paediatrician. SBUHB

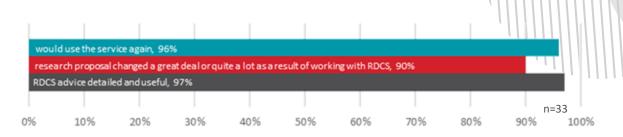


The RDCS has provided excellent support and understanding in the formation and delivery of interdisciplinary projects; working effectively with our NHS partners and funders to support the production and successful capture of research bids

- Professor Peter Dunstan, on behalf of the RAMAN team



Parent and PPI representative



We have close links with the other Welsh RDCS units as well as the Health and Care Economics Cymru 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 given the limitations imposed on us by COVID-19 we continued to utilise the Research Development Group and Sandpit models to ensure ongoing and innovative engagement events in partnership with HDUHB, SBUHB and WAST.

We supported:

Apr

Research Development workshops with representatives from several Thyroid disease support groups as part of a major research bid to the MRC

Way

All staff were focussed on responding to feedback from the Health and Care Research Wales funding panels

Sep

Half-day RfPPB application workshop for Hywel Dda UHB staff on planning and preparing for research studies

Oct

Research Development Group on peri-natal mental health with staff from HDUHB

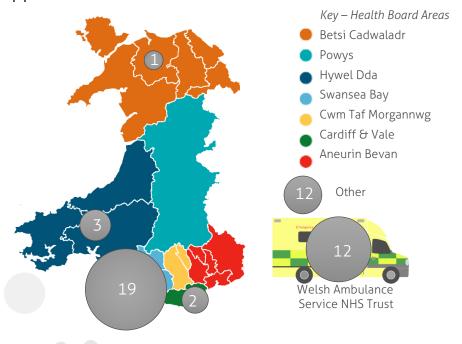
Dec

Midwives' half-day workshop on "Choosing the Right Research Design" for midwives in Hywel Dda UHB

Feb

Supported applicants to SBUHB's Pathway to Portfolio Scheme and we look forward to seeing the results of the funded studies in due course

RDCS supported researchers from across Wales



PPI, Engagement & Collaboration

The Sunproofed project aims to understand how primary schools in Wales are responding to the growing problem of skin cancer and explore the effectiveness of sun safety policies in schools

Wнат

The CRaFT project aims to explore patient and health professional attitudes to a combined Raman-FIT test as an alternative to colonoscopy for cancer diagnosis

Case 2:

Researchers from the Sunproofed project recruited a Welsh Primary School teacher and a Welsh language lecturer for teachers, who have collaborated with the project regularly since joining.

Who

Two patients with an experience diagnosis of colorectal cancer were recruited by the CRaFT study team.

PPI members reviewed drafts of a school survey and provided invaluable feedback from a school perspective. The feedback allowed research staff to improve questions to ensure maximum relevance, while helping to shorten the survey to potentially increase response rates.

HOW PID IT

PPI representatives reviewed all documentation that patients were given as part of the study to ensure that the content was understandable and acceptable for a patient perspective. In addition, the PPI representatives reviewed interview schedules for clarity and acceptability prior to interviews commencing and then reviewed the transcripts of the interviews as they were completed to help shape the ongoing process.

I enjoy being part of the team looking at how schools regard and deal with sun safety. The team take on board many of the observations I make, such as useability of the questionnaire and the ability of the target audience to answer certain questions. I very much enjoy the insight I gain from being part of this project and am reassured to know that every measure is being taken to ensure the validity and authenticity of this research.

Kara Lewis, Sunproofed PPI Representative

It's an honour being involved in Sunproofed, education on sun safety should be high priority across all schools. Being involved in the questionnaire process allows me to give my thoughts as a teacher so that other practitioners will be able to access the questionnaire with ease, enabling the roll out of the Sunproofed survey in schools to be effective.

Claire Evans, Sunproofed PPI Representative

I have been a member of the CRaFT and Raman Trial Management Groups for 6 years now and have seen the research coming to fruition with some very exciting results. As someone who has experienced bowel cancer in three generations of my family, with only one being diagnosed at an early stage, I fully appreciate the importance of a reliable, easy, acceptable early test for bowel cancer. The meetings have all been virtual since the start of the pandemic, but this has not been difficult and has saved me a long round trip from Newport! I am looking forward to the time when this test will become standard for GPs with the result of reducing the numbers of advanced stage diagnoses of

bowel cancer in the future.

Julie Hepburn, CRaFT PPI

Representative



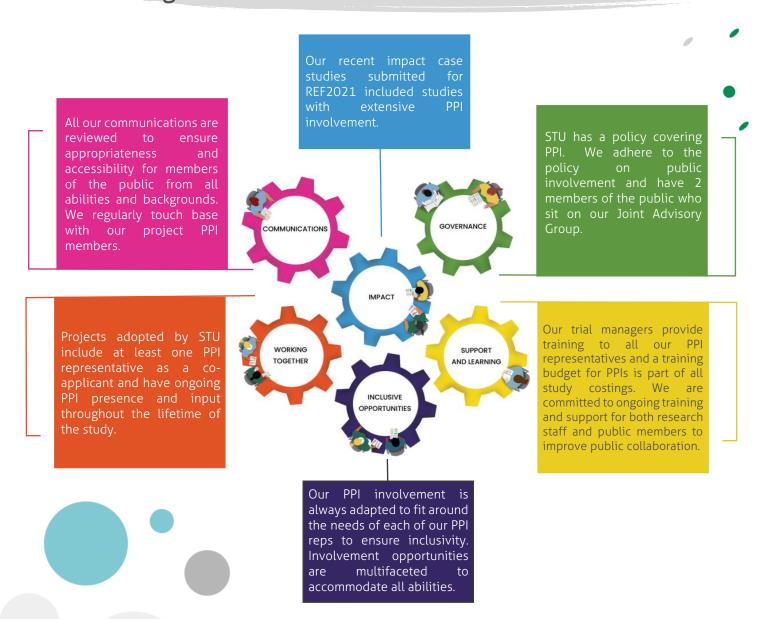


Our Population Advice for Research Committee (PARC) supports researchers who are being advised by the RDCS team. PARC helps to ensure all RDCS research ideas have PPI support and input to ensure the best possible submitted funding application and that proposed research questions outcomes are pertinent and

appropriate to members of the public.

Membership of PARC is open to members of the public who are also registered with the Health and Care Research Wales Public Involvement Community. Having PARC in place means that RDCS can help researchers access PPI support more quickly than advertising to the full Public Involvement Community. Our NHS colleagues are reassured that they can call on the panel for effective and reliable public involvement, particularly when working to short deadlines.

Embedding the UK National Standards for Public Involvement



Conclusions and Looking Forward

Conclusions

In the 5 years since STU gained full registered clinical trials unit status we have been busy building the team and spreading the word about the unit to researchers in Wales and beyond. STU has built its reputation and had success across a wide range of specialties and this year has created some space for reflection on the role of trials units in Wales. This year we spent a great deal of time working with Health and Care Research Wales, Swansea University and the other Welsh CTUs to consider the options and merits of a single merged trials unit for Wales. We are instead pursuing other options for ongoing core funding and we will shortly apply for re-registration with UKCRC.

As the team has grown so too has our reach and our outputs. 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 their work in these areas. Our IT team and data managers have worked with colleagues from our sister organisation the Centre for Trials Research in Cardiff University as they adopt the REDCap data management system. STU staff have unparalleled REDCap experience among Welsh researchers, are invited members of the UKCRC ISOG REDCap user group, and are working with the group to create a toolkit for its adoption and implementation. Kym Carter's work with the UKCRC public and patient involvement and engagement task and finish group, which is developing a central repository for PPI resources, is currently on hold and awaiting some completed elements from UKCRC. However, when this work does come to a close, its influence will be felt for years to come.

Looking Forward

Professor Hayley Hutchings will be taking over as sole director of STU, following the departure of her co-director, Professor Greg Fegan, who leaves us shortly to take up a post with Oxford University, which will see him based in Thailand.

We look forward to a time when an end of year round-up will not need to involve reflecting on the impact of COVID-19 on operations but the pandemic has brought about wide-ranging changes to the ways we work. However, the pandemic has delivered many benefits and positive changes to the conduct of research in Wales and beyond.

We are very proud of our increasing success in turning research ideas into funded studies is encouraging and we are currently look forward to hearing about several funding applications.

We are looking forward to completing the first Welsh led NIHR-EME funded project. The USTEKID trial managed to continue running throughout the COVID-19 pandemic speaking, volumes of the dedication and commitment of the trials' adolescent participants, their parents and the clinical care teams supporting them in this UK wide trial. In the autumn of 2022, we will know if Ustekinumab can help maintain beta cell function in these young people's lifelong challenge posed by type 1 diabetes.

Professor Hayley Hutchings, STU Director



Swansea University Prifysgol Abertawe

Swansea Trials Unit Uned Dreialon Abertawe



Swansea University Prifysgol Abertawe

Swansea Trials Unit Uned Dreialon Abertawe



STU Team 2021-22



Swansea Trials Unit Uned Dreialon Abertawe

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





