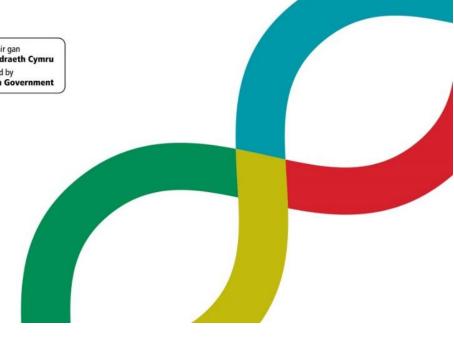


# **Swansea Trials Unit**





2020-21 Annual Report



# Acknowledgements: Funders and Collaborators







Bwrdd lechyd Prifysgol Bae Abertawe

















































Bwrdd lechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board

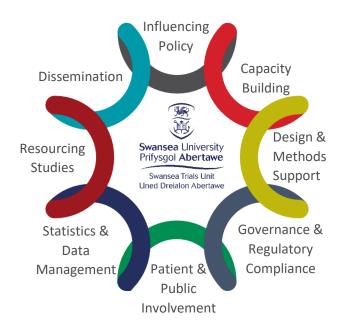
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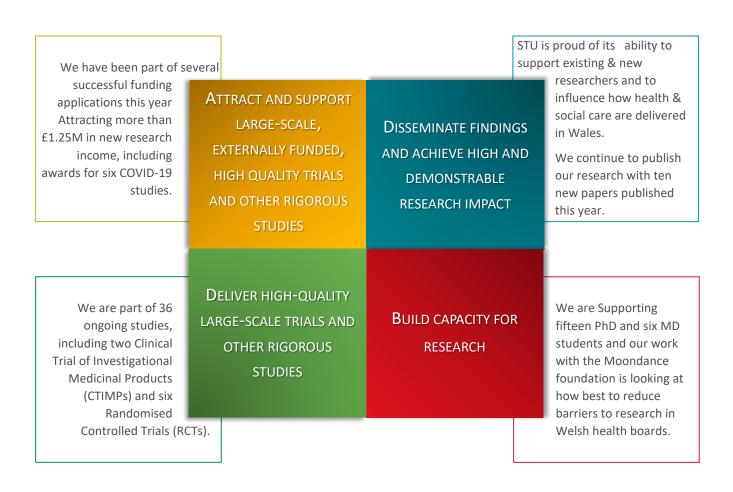
# Foreword

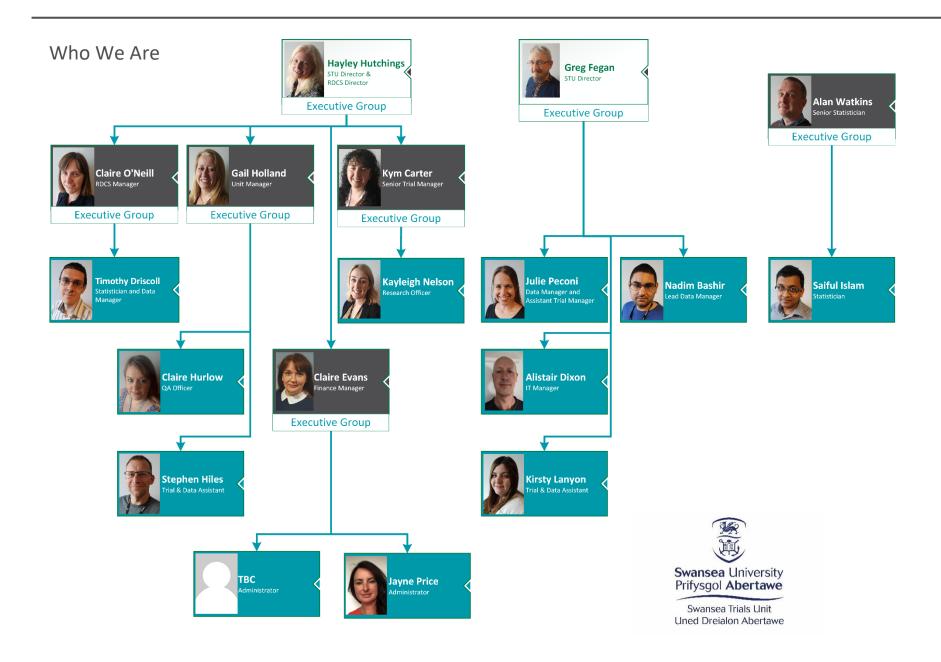
#### What we do

Swansea Trials Unit (STU) is funded by Welsh Government through Health and Care Research Wales. STU's overall aim is to drive improvements in the health of people in Wales, the other UK nations and worldwide. Our Research Design and Conduct Service (RDCS) is highly valued by our clients and continues to play an important role in supporting our partners in the NHS and social care.



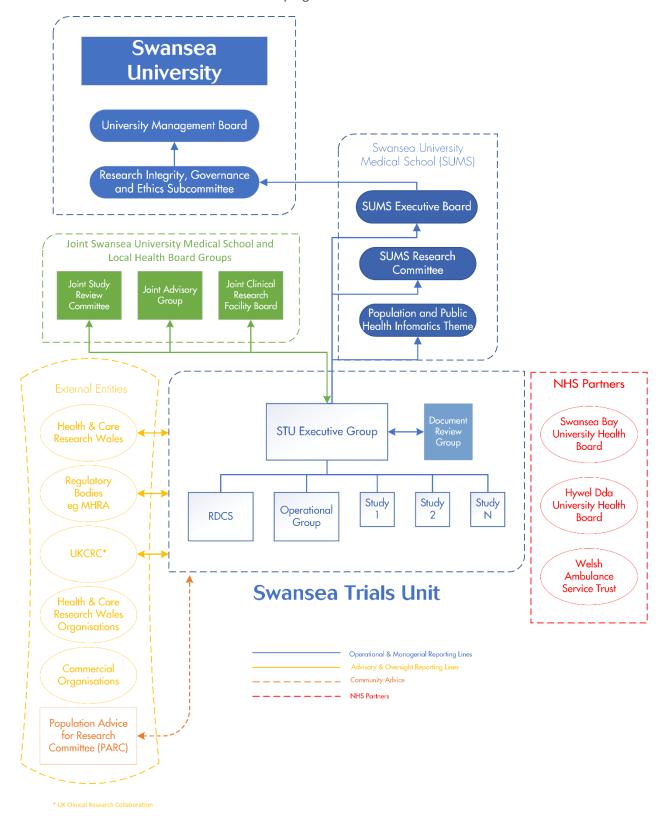
Although COVID-19 has necessitated some changes, our strategic goals remain the same:





### 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 each stakeholder has and in shaping STU.



# Year in Summary

### **Core Metrics**

Reporting period: 2020/2021



Health and Care Research Wales infrastructure award to the group



Jobs created through direct funding



### Grants won during reporting period

Grants won	Led by group	Group collaborating
Number	1	16
Value	£40000	£1.25M
Funding to Wales	£36000	£882000
Funding to group	£29000	£290000
Additional jobs created for Wales	1	14
Additional jobs created for group	1	8



Number of publications



Number of public engagement events



Number of public involvement opportunities

#### **Clinical Trials Unit metrics**



20

Number of studies awarded



19

Number of studies led by Welsh Chief Investigators



2050

Total number of participants recruited



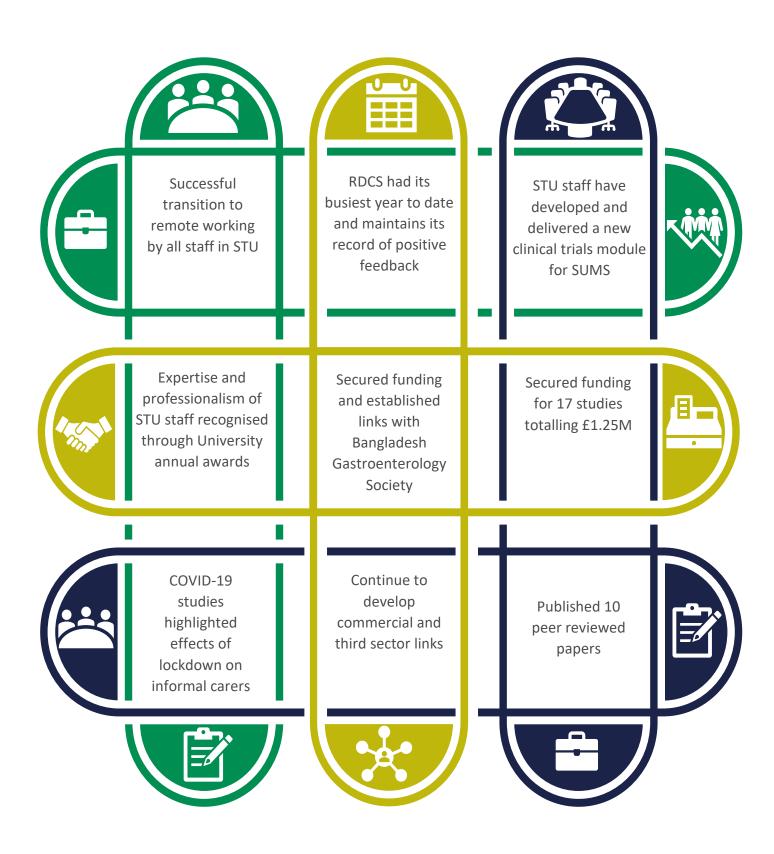
18

% of Welsh participants recruited





### Key Achievements & Impact



# 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:

We were joined by Alistair Dixon and Jayne Price, who have been great additions to the team. Their additional skills in the areas of IT, marketing and study administration are of real benefit to the group.

Our friend and colleague Vicky Davies retired after many years of service to the Trials Unit and the University and we said goodbye to Mihaela Barbu.

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

NIHR / National Institute For Health Research Kym Carter continues to work on the UKCRC PPI Task and Finish group work. Their work encountered delays due to COVID-19

preventing face to face meetings to discuss literature but their proposal for the contents of a central repository for Patient and Public Involvement and Engagement (PPI&E) is currently under review the public contributors of the group.

TRAINING

Between them Greg Fegan, Hayley Hutchings, Alan Watkins and Claire O'Neill support 22 post-graduate researchers.

Timothy Driscoll became an accredited ONS researcher



Claire O'Neill continues to be part of the Aurora



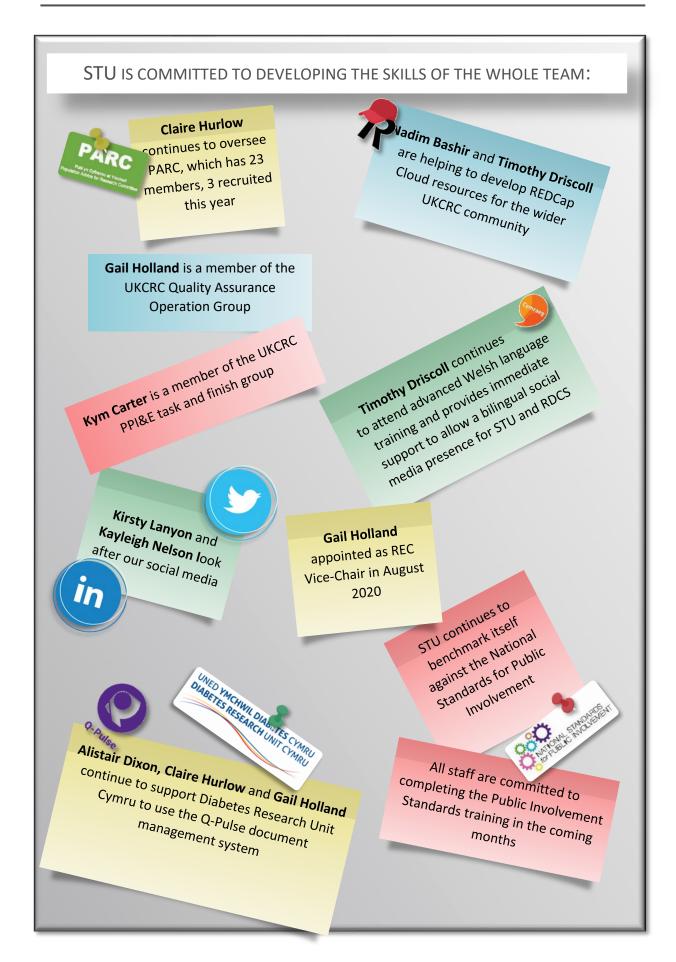
programme network and continues to study for her Open University BSc (Hons) Maths and Statistics

Saiful Islam completed Statistics with SAS® training a course for SAS software users who perform statistical analyses using SAS/STAT software



All STU Staff have continued to learn new skills and are all now working using cloud-based systems but looking forward to returning to the office soon





### 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.

The Extraperitoneal End Colostomy Trial (ExPECT) is a multi-centre Feasibility Trial which aims to understand whether the Extraperitoneal (EP) technique of colostomy formation will reduce the chances of parastomal hernias developing. Recruiting 60 patients from across three Welsh sites, ExPECT aims to test study processes and understand patient acceptability to inform the development of a future large-scale trial. The Team at STU have been instrumental in driving the project forward by providing trial and data management support, including protocol development and submission for ethical review.

(Chief Investigator: Mr Gregory Taylor)



**TRIM** is a study of triage systems used by East of England, East Midlands Ambulance Service; West Midlands Ambulance Service and Yorkshire Ambulance Service to manage 999 callers with suspected COVID-19. It includes a survey of UK ambulance services; interviews with patients, ED clinicians and ambulance service staff; and an investigation into the elements and outcomes of triage using routine linked data.

(Chief Investigator: Professor Alan Watkins)



**ICE-COVID** looks at the efficacy of iota-carrageenan in the form of an over-the-counter nasal spray as prophylaxis for COVID-19. It is a double-blind randomised placebo-controlled trial that was set up very rapidly within 10 weeks of securing funding. Initial plans were for the study to recruit frontline health professionals but the successful rollout of the vaccine programme in this group meant that recruitment is now focussing on the frontline workers and the public more generally. The team at STU were integral in supporting ethical and regulatory review, study management support, database design and delivery within 8 weeks of first meeting.

(Chief Investigators: Professor Iain Whitaker & Dr Zita Jessop)



### WP3: Oversight of funded studies

Unsurprisingly, studies were impacted by COVID-19 with most experiencing delays. The teams involved took advantage of the opportunity to revisit some design decisions and worked creatively with sites, funders and sponsors to ensure the time was used well.

The team quickly responded to the restrictions imposed due to the pandemic and submitted a "dose at home" amendment to allow existing

participants to continue with their treatment so the trial was kept on track and existing participants were not lost. They also adapted measurement of c-peptide to use dried blood spot cards if visits 5 and 8 were not permitted at the hospital to ensure that primary outcome data could still be collected.



The team moved over to using e-consent to support the study. The study now has 140+ participants from six Welsh primary care sites (spanning 3 Health Boards), two English primary care sites, and one secondary care

site. The team are now busy opening a further three Welsh primary care sites, one Welsh secondary care site, and three English primary care sites. GPs have been very positive about the use of e-consent to support the trial.

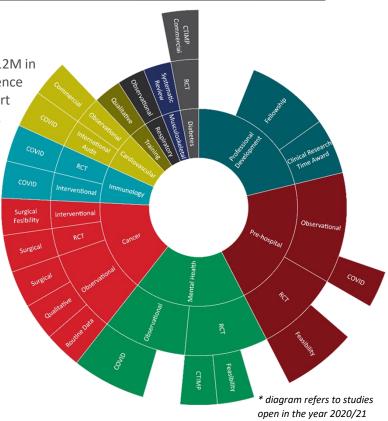


The role of informal carers came to attention during the pandemic. The Trauma-Aid team was quickly able to pivot their work to focus on the effects of lockdown on informal carers of adults /children with Learning disabilities in Wales and the wider UK. To date two papers on this topic have been published with another under review.

In 2020/21 STU maintained a portfolio of £12M 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
- 6 other RCTs
- 21 student projects
- 2 Clinical Research Time Awards (CRTA)
- 3 Fellowships



### 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 **STU team** participated in events marking International Clinical Trials Day 2020 on the theme of "Be Part of Research"



Kayleigh Nelson attended the Wales Cancer Partnership Allied Health Professionals and Nursing Research Network conference

The **Trauma AID** team published an article in Journal of Applied Research in Intellectual Disabilities



Claire Hurlow presented at the PRIME Annual Meeting 2020, representing the CRAFT study



PASTA project, with STU's **Saiful Islam**, published an article in JAMA Neurology



Timothy Driscoll represented the team at the annual HCRW conference. He gave a talk on the BHF funded PHECG2 study

Kayleigh Nelson attended the 3day Health Service Research UK Annual Conference

Kirsty Lanyon, and the team at Hywel Dda, presented an abstract at the 2020 ERS International Congress with the European Respiratory Journal



The **Trauma AID** team published an article in Journal of Applied Research in Intellectual Disabilities



STU staff contribute to the following research groups and networks:

Swansea University Prifysgol Abertawe Swansea Trials Unit Uned Dreialon Abertawe









### 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. This year we have picked out a few highlights from our 3 core areas: academic, commercial and third sector.



#### Dr Kayleigh Nelson

Kayleigh led the development of the Early Career Researcher (ECR) Development and Mentorship work package for Health Services Research UK, which led to matching 12 ECRs with academic mentors from across the UK and a range of

exciting engagement and networking events are planned. She has also been working with Swansea Bay & Hywel Dda UHBs to deliver a Nurse & Allied Health Professionals Research Conference, which aims to showcase individuals' research, promote networking and increase research skills. Kayleigh has also been teaching research methods to MSc Nursing (Adult) and MSc Nursing (Mental Health).





STU staff have developed and run a new "Introduction to Clinical Trials" module for Swansea University's Medical School students with 42 enrolled in the first term. The module was run remotely and covered all aspects of clinical trials from data management to governance and ethics with a focus on examples of Covid-19 trials and studies.



Can Sense CanSense Ltd are an early stage MedTech company developing a blood test for bowel cancer detection. The South West Wales RDCS were instrumental in

shaping a recent £1.5 million NIHR Artificial Intelligence Award commercial funding application. STU has supported them to make funding applications, giving advice on evaluation trial design.



Accelerate Wales was co-funded by the European Regional Development Fund, the Welsh European Funding Office, Welsh

Government's Health and Social Services group, universities, Life Sciences Hub Wales,

and the health boards, the ultimate aim of Accelerate is to create lasting economic value for Wales. Accelerate helps innovators in Wales to translate their ideas into solutions, enabling them to be adopted in health and care. Hayley Hutchings sits on the on the Accelerate UK panel. Hayley and Greg Fegan act as advisors to the team.



Through her work with Skin Care Cymru, raising the profile of skin health and dermatological provision in Wales, Julie Peconi led a qualitative research project funded by AbbVie Pharmaceuticals, exploring barriers to recruitment and



Cyflymu

**Accelerate** 

Skin Care



We are delighted to be working on another Moondance Foundation funded study. Following on our Research which will run in 4 Welsh health boards. It aims to support the development of research projects

#### STU receives excellent feedback:



Dr Mesbah Rahman, Consultant Gastroenterologist, Swansea Bay University Health Board

Swansea Trials Unit has been excellent in helping us in developing our international research project. The whole experience in the application process for GANGE S-B (Gauging the Impact of COVID-19 in Gastroenterology Services in Bangladesh) Project and the Health Partnership Project Application for THET (Tropical Health Education Trust) has been smooth. Our partners from four top Institutions in Bangladesh were very impressed and expressed their gratitude in this learning process. I am also very impressed with the commitment and enthusiasm of the staff in developing the research collaboration with international partners and their willingness to continue this in future.



Dr Zita Jessop, Senior Lecturer at Swansea University and Plastic Surgery Registrar at Swansea Bay University Health Board

The STU team has been instrumental in helping to design and implement a randomised, double-blinded, placebo-controlled phase III trial investigating if a nasal and throat spray can prevent or reduce the severity of COVID-19 infection. They provided invaluable expertise in protocol writing, statistics, database design & build and guided us through the ethical approval process. The commitment and input from the team was particularly impressive given the time pressures of getting a COVID-19 related clinical trial off the ground during a pandemic. The type of resources and support offered by STU are pivotal in allowing clinical academics to be able to answer key research questions with real-world impact.



Mr Quentin Nunes, Consultant & Clinical Lead, Hepatobiliary and Pancreatic Surgery, East Lancashire Hospitals NHS Trust (ELHT)

It has been a pleasure working with the Swansea Trials Unit on our heparinrelated projects in COVID-19. The team is very professional, accessible and merrly experienced. They are enthusiastic in supporting research proposals, where feasible, and provide honest feedback in a timely manner.



Professor L.D. Premawardhana, Hon. Consultant Physician, Cardiff and Vale University Health Board

STU have been an excellent partner in developing our RCT, investigating a novel long acting liothyronine (T3) preparation in hypothyroid patients. Their expertise in trial design, protocol development and patient public involvement have been a great asset to our team, and we value their help very much. Having guided many investigations through the funding application process before, we are confident that we will benefit from their experience with regard to our application.

### STU staff act as supervisors & mentors to PhD students & new researchers:

STU are actively involved in developing collaborations and identifying potential new projects and our students are busy developing new skills and informing the future of research in Wales. We are proud of how they have adapted their studies to the realities of working in a global pandemic. They have all used the time to gain new skills and new insights into their research areas and broadened their skillsets.

# Nicky Heady, PhD Candidate funded by Health and Care Research Wales and ESRC funding

Nicky has been very busy progressing her PhD "Estimating the social care needs of looked after children (LAC) and those at risk of being in care: Utilising anonymised linked data". During the last year she has submitted 2 papers for publication and her research has been featured in the ESRC Wales DTP newsletter and on their website. She is also part of the COVID-19 Outbreak Expert Database on mental health and Neurodevelopmental disorders, which is made of up over 4100 experts who can support Parliament in addressing the COVID-19 outbreak and its impacts.



#### Miss Anwen Williams, PhD Candidate and Registrar in General Surgery

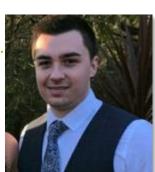
Swansea Trials Unit have been fundamental in setting up my research project. As a trainee with no previous research experience, they have helped me develop a study design and protocol and continued to support me through every phase. Their knowledge and support have been invaluable. I have been very impressed with both the academic support but also the holistic support. STU have been key in achieving grants to support the study. The commitment from the staff at STU is incredible which has allowed me to convert the research from M.D. to a PhD.



### Mr Oliver Richards, PhD Candidate funded by Diabetes UK

COVID-19 has meant patient recruitment for Oliver's PhD entitled "Disrupting the diagnostic paradigm of gestational diabetes mellitus using blood-based vibrational spectroscopy" has been suspended. However, during the pandemic, Oliver focussed on the qualitative aspect of his PhD. This involved exploring the opinions of NHS staff on the current diagnostic paradigm versus the proposed test in which Oliver is trying to develop. A questionnaire was formulated and sent to NHS staff in Swansea Bay University Health Board and later extended to

to NHS staff in Swansea Bay University Health Board and later extended to Aneurin Bevan University Health Board. Additionally, preparation for patient interviews is underway, and when easing of restrictions permits, patient interviews will take place to gauge how welcome the new proposed test will be. Oliver has also recently published a review article on the potential use of vibrational spectroscopy in obstetric care.



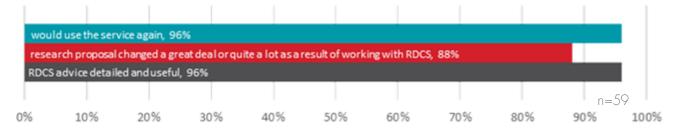
### WP6: Research Design and Conduct Service



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. 2020/21 was our busiest year to date. The number of clients is higher than the last year (91 compared with 58 in 2019/20). Researchers and funders have been working to tighter deadlines than ever before and RDCS adapted quickly to changes - some studies were developed, funded and started in weeks rather than months.

Feedback about the service is very positive:





RDCS based in STU were simply superb! A dedicated, hard-working and highly professional team who were unrivalled in providing all the necessary support and advice needed for a complex grant application. Investigator initiated multicentre clinical trials are complex to initiate and execute effectively and efficiently. Having expertise provided by RDCS based at STU on your team can be the ace in your back pocket.

- Dr Vasim Farooq, Consultant Cardiologist, Cardiff and Vale University Health Board

As soon as we started looking at our research proposal and application, we knew exactly who to contact for help and assistance. Claire and Tim are extremely professional and their

patience throughout was commendable. The links with their team here at Swansea Bay UHB are a credit to the service and everyone should be extremely proud to have them as a resource to call upon. They really got us thinking in ways that we had not considered and without this guidance, we would have been lost. A short paragraph cannot covey how valuable the RDCS team are, and we look forward to their ongoing help and support.

- Paul T. Lee, Medical Devices Training Manager, Swansea Bay University Health Board



The RDCS has provided us with invaluable support in developing and submitting research proposals. They not only helped with development of the initial research idea but supported us in producing a competitive proposal.

- Dr Charity Knight, Consultant in Obstetrics and Gynaecology, Swansea Bay University Health Board

### **RDCS Highlights**

RDCS in 2020/21:

Studies awaiting decision, 22

£3,443,206

Researchers supported, 91

Bid Submissions, 47

Studies funded, 14

#### **RDCS Calendar**

The pandemic meant the usual way of working had to change. We opted for an approach based on the Sandpit model. Whereby, we quickly agreed the scope of studies, identified the participants' expertise, plugged any gaps and used online collaboration tools to concurrently write funding applications leading to outputs in the form of funding applications. This way of working was made possible because of the flexibility shown by our staff, our public and patient representatives and our NHS and Social Care clients. In fact the "live" working style was stimulated creativity and we foresee continuing to work this way in future.

### Apr

Online bid development group to develop a study looking at the use of carrageenan in the prevention of Covid-19 infection

### Jul

Online bid development group to develop a study looking at supporting gastroenterology services in Bangladesh during COVID-19

## Aug

Online bid development group to develop a study looking at the use of virtual wards in Hywel Dda University health board

## Oct

Development group with SBUHB looking at the use of ultrasound by community nurses

### Dec

Online bid development group to develop a bid for the NIHR Artificial Intelligence call.

### Jan

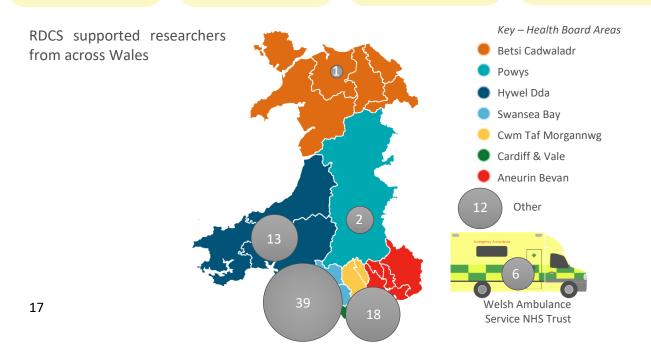
Online bid development group with endocrinologists from C&VUHB and Cwm Taf UHB - NIHR EME Researcher Led Call

### Feb

Online bid development group with representatives from obstetrics and gynaecology from Swansea Bay

## Mar

Welsh Ambulance Service Trust Point of Care Testing online study development group with clinicians and patient representatives.



# PPI, Engagement & Collaboration

Case 1: Hypothyroidism A novel treatment for hypothyroidism that requires rigorous evidence of efficacy and safety before being recommended for use. The treatment is costly, so the team need strong patient backing to strengthen its application for funding.

Case 2: Atrial Fibrillation study **EQUAL-AF** is an observational feasibility study investigating the effect of bleeds on patients diagnosed with atrial fibrillation and who are also taking oral anticoagulant medication.

Two patient focus groups & one group consisting of key thyroid charities. Asked to discuss the proposed study design, to identify any issues with participation and any ideas on how to improve the proposal need strong patient backing to strengthen its application for

Project team includes one patient and one public representative - one is CEO of Arrythmia Alliance, one is a patient with a diagnosis of atrial fibrillation, providing a real-life perspective of potential complications and decline in quality of life due to atrial fibrillation.

The patient groups provide extremely useful advice on how the study design would impact them if they were to consent. They discussed how best to arrange the HOW dig Steering Committee along with multidisciplinary hospital appointments for those who worked, how to incentivise participants to ensure visits were completed and had useful dialogue about the data being collected. They challenged the scientific justifications for the study design and brought useful ideas to the forum which were accepted and integrated into the proposal. As a result, there is a far stronger proposal to submit.

it help

Two public and patient representatives joined the Trial members of the EQUAL-AF project. Both representatives provided key input to trial design and helped to draft patient-facing documents to cater appropriately for what could potentially be a sensitive subject. The representative for the study who works as the CEO for Arrythmia Alliance also permitted researchers to post the study survey on the online forum for the public to complete. This offer resulted in improved recruitment.

We were delighted to be included in the focus group. Members' opinions led to changes to the design. Gathering feedback from patients at such an early stage in the design of research projects is welcome and should be an essential part of the research process. We hope that other research groups will follow the example of STU.

- Julia Priestley, CEO, British Thyroid Foundation

We are delighted to have been able to use our insights to have a positive influence on a study.

- Lorraine Williams, Director, The Thyroid Trust

I enjoyed being part of the team looking at How bleeds affect the quality of life for those on anticoagulant medication. The team took on board many of the observations I made, such as useability of the questionnaire and the effect that anti-coagulation has on perceptions of risk.

-Arfon Hughes, PPI representative - Equal-AF trial

I have felt included and my opinions and contribution valued. The group is inclusive, and collaboration has been superb. I enjoy meetings knowing that it is not just a tick-box exercise.

-Trudie Lobban, CEO, Arrythmia Alliance

PARC

Pobl yn Cyfrannu at Ymchwil
Population Advice for Research

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 knowledge and support to ensure the best possible submitted funding application

Membership of PARC is open to members of the public who also registered with the Health and Care Research Wales Public Involvement Community. PARC means RDCS can help researchers to access PPI support more quickly than advertising to the full Public Involvement Community. Our NHS colleagues know that they can call on the panel for effective, reliable engagement prior to building PPI into their bids.

I have found my involvement with the health research projects rewarding, and interesting. The acknowledgement that public and patients can add value to the research from real life experience is welcomed and I feel that this work will help to shape and inform how services are developed and delivered in the future. PARC has played a key role in facilitating and making this involvement meaningful. I look forward to working with you in the future.

- Wendy Thomas, PARC Panel Member 🕽



COVID restrictions meant that the way we engaged with the

public changed but we still take pride in our commitment to Public and Patient Involvement in studies. We may not have been out and out meeting face to face in the last year, but we have developed a strong online presence using a variety of platforms. We also keep in touch with our collaborators via Twitter and study newsletters. These new ways of working have given us more flexibility and it has been easier to get people together. We've been delighted to see that online working has made it easier for working people and those with caring responsibilities to get involved.

Our work in this area is recognised by our partners - Dr Kym Carter still leads the Central Repository group for the UK CRC PPI&E Task and Finish Group

which is compiling a library of documents and forms based best practice in CTUs UK CRC will host the approved documentation in an online repository. Everyone at STU is committed to ensuring the best for patients and the public in Wales and we can only do that with the help of our excellent public and patient partners. We continue to benchmark our work against the national public involvement standards and everyone in the unit is working on completing the new training for Wales.

What do our PPI representatives say about us?

I have been involved with several research initiatives connected with the Swansea Trials Unit ranging from Consumer Groups such as SAIL and SUPER through to actual trials run by STU such as CRaFT and HART. All these experiences have been interesting and rewarding and have given me a good background knowledge which help me to make useful contributions to the Joint Advisory Group Meetings. I look forward to continuing membership of this group in the years to come

- Julie Hepburn, STU PPI representative

Being a PPI participant for several years in STU meetings has greatly enhanced my knowledge of the input required by researchers before they can move on. This can be important in displaying to the public how important research is and the detail required before proceeding. People should be aware that if a research project is successful, it could influence and enhance the health of the nation in the future. I think PPI involvement is important for translating research wording down to public level.

- Geof Tanner, STU PPI representative

# Conclusions and Looking Forward

#### Conclusions

In the 6 years since STU achieved full UKCRC registration as a clinical trials unit we have directed our priorities to develop and deliver excellent research that can improve the health of people in Wales, the other UK nations and beyond. We continue to expand our horizons and have succeeded in adding two international trials to our portfolio: GANGES-B is an observational study in Bangladesh and AID-ICU is a drug trial being undertaken in Denmark.

During this time we have continued to receive positive feedback from both researchers and our public and patient involvement collaborators as well as for our RDCS. This is a testament to the high calibre staff that we continue to attract and nurture. This was recognised in the invitation to develop and deliver a new clinical trials module for Swansea University Medical School thus enabling us to help support and train the next generation of researchers.



Figures cumulative over 6 years



### Looking forward

2020 has been another successful year for STU. As always, our work represents a huge collaborative effort. This has been tested by the ongoing pandemic but we have continued to work with our collaborators to reach project milestones and develop new research, with 17 bids won, worth

£1.25m. As always, we are hopeful that we will add to this with successful outcomes to our submissions to Health and Care Research Wales' funding calls - we are part of 6 projects shortlisted for RfPPB and 3 for the Health Research Grant funding scheme.

We watch excitedly as USTEKID, a drug trial involving patients newly diagnosed with Type I diabetes, is close to completing recruitment. Keeping the study going during the pandemic is a real testimony to innovation, determination and the commitment of everyone involved.

RDCS has had it busiest year to date. We met with many new investigators whilst being encouraged by the return of many familiar faces. We look forward to the prospect of embarking on new studies based on these submissions.

We will shortly begin the process of renewing our registration with UKCRC and we look forward to the opportunity it gives us to demonstrate our track record of delivering research which has an impact and to the new opportunities that 2022 will bring for STU and its collaborators.



# Swansea University Prifysgol Abertawe

Swansea Trials Unit Uned Dreialon Abertawe



Swansea Trials Unit Uned Dreialon Abertawe

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Special thanks go to Kym Carter, Gail Holland, Claire Hurlow and Claire O'Neill who produced the report.





