



Swansea University  
Prifysgol Abertawe

Swansea Trials Unit  
Uned Dreialon Abertawe

# Swansea Trials Unit



Ymchwil Iechyd  
a Gofal Cymru  
Health and Care  
Research Wales



Ariennir gan  
Lywodraeth Cymru  
Funded by  
Welsh Government

2022 - 2023

Annual report



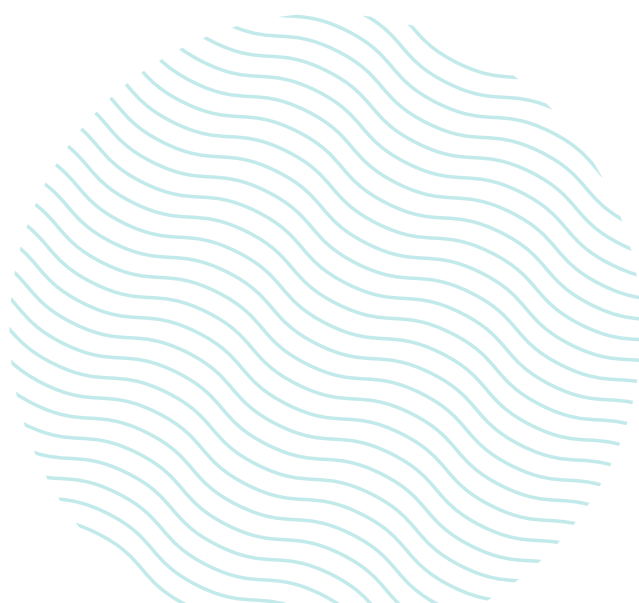
# Acknowledgements

Swansea Trials Unit would like to take this opportunity to thank Health and Care Research Wales and all our funders and collaborators for their help and support in the past years. We are also immensely grateful for the support of our NHS and social care collaborators who make our work possible. Finally, none of our studies could be undertaken without the enthusiasm and generosity of the many patients (and their families) who agree to participate in our studies.



# Table of Contents

Foreword.....	1
What We Do.....	1
Who We Are (March 2023).....	2
Governance & Key Partnerships .....	3
Key Achievements 2022/23 .....	4
Work Packages.....	6
WP1: Unit development and management.....	6
WP2: Development of new studies .....	7
WP3: Oversight of funded studies .....	8
WP4: Dissemination and engagement.....	10
WP5: Build capacity for research.....	11
WP6: Research Design and Conduct Service .....	12
RDCS supported researchers from across Wales.....	13
PPI, Engagement & Collaboration.....	14
Conclusions and Looking Forward .....	15





# Foreword

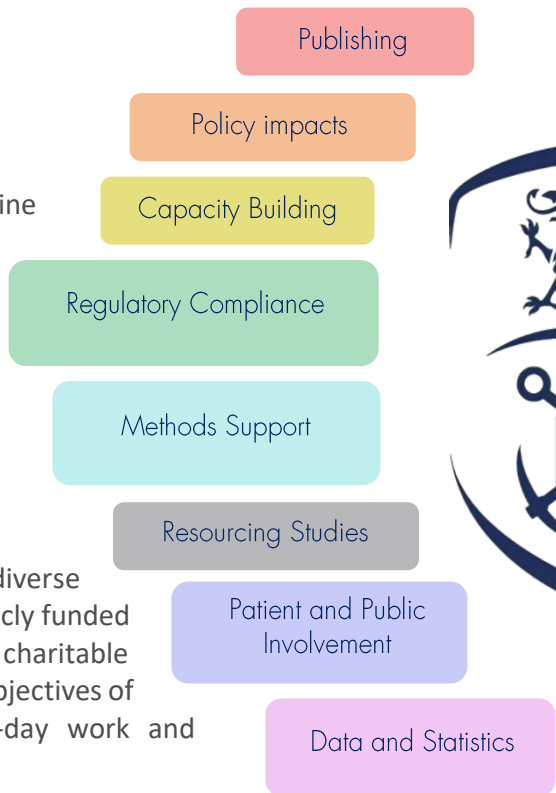
## What We Do

Swansea Trials Unit (STU) is based in the School of Medicine in Swansea University. Part of its funding comes from Welsh Government through Health and Care Research Wales and the rest of the funding comes from competitively awarded grant income as well as a contribution from the Faculty of Medicine, Health and Life Science at Swansea University. STU's research portfolio is diverse, and the team contribute to studies Wales, the UK and beyond.

The work done by the STU team is highly valued by a diverse range of clients. We receive excellent feedback from publicly funded health and social care, private companies and charitable organisations in Wales and further afield. Delivering the objectives of Welsh Government policies is central to our day-to-day work and underpins everything we do.

The STU team has incorporated the South-West Wales Research Design and Conduct Service (RDCS). With the creation of the new Faculty, Health and Care Research Wales are looking at other ways of supporting researcher development and will no longer be funding RDCS from April 2023.

Patient and Public Involvement (PPI) is central to STU's work and the patient (and public) voice plays a key role in influencing and enhancing researchers' study planning and delivery decisions.



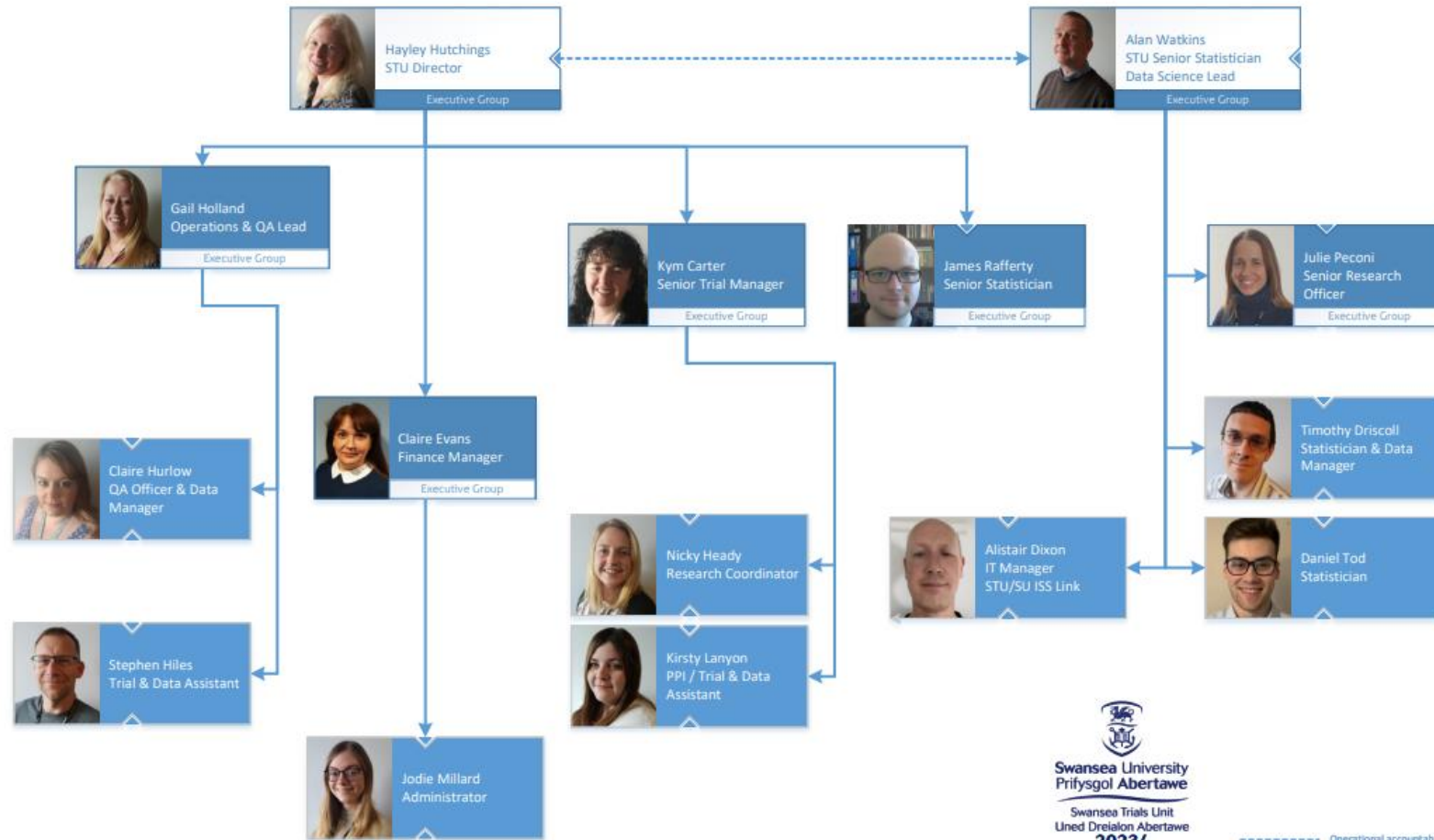
"I've been impressed with the many varied ways in which I've been able to contribute my perspective as a parent of primary school-aged children to the Sunproofed research project. From the feedback I've received I know that my contributions have been considered and where appropriate, acted upon. It feels good to know that - in my own little way - I will be helping school children of the future be able to enjoy the sun safely. "

Greg Pyecroft  
PPI Representative Sunproofed

# Who We Are (March 2023)



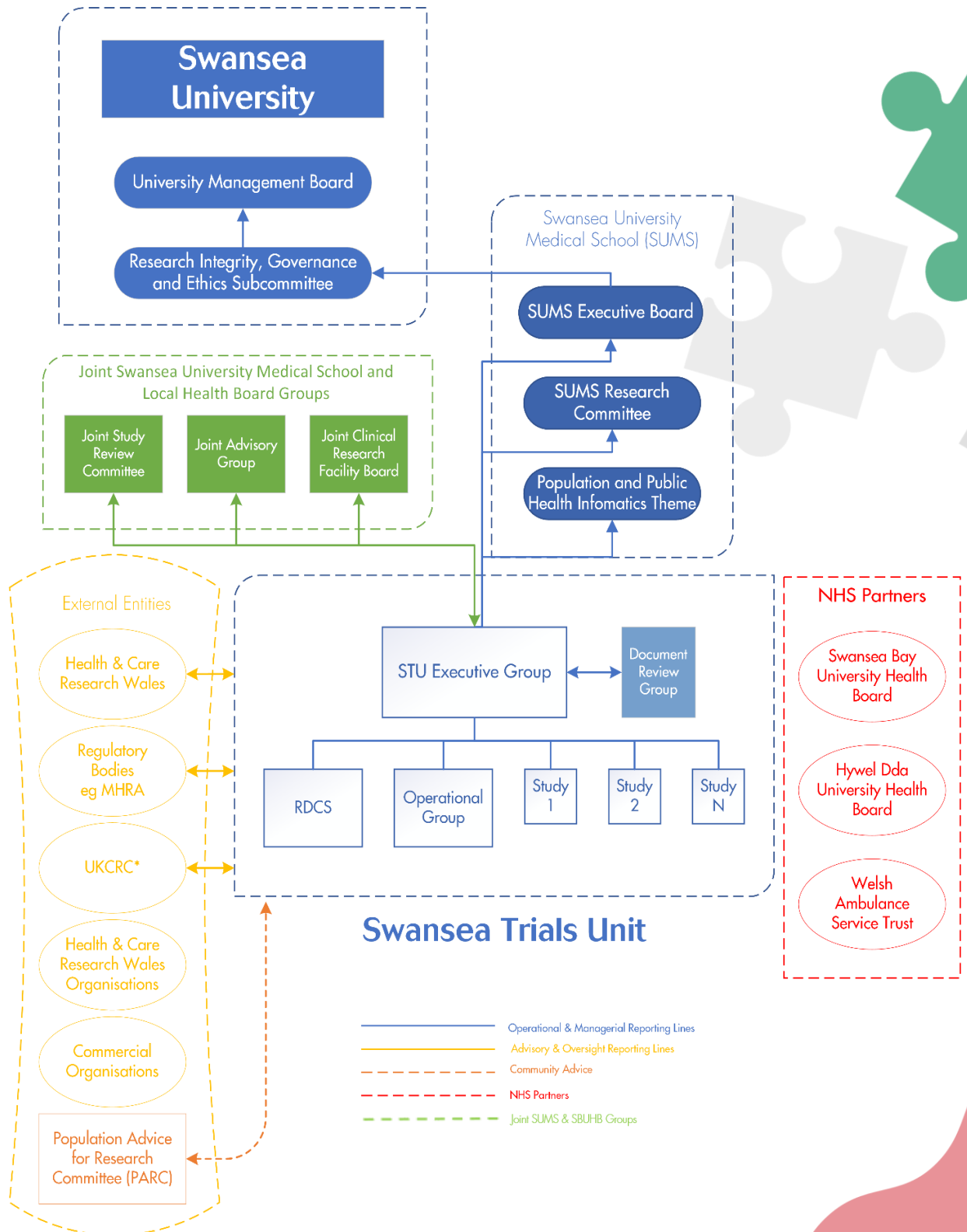
## STU Staff & Operational Management Structure



----- Operational accountability

# 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.



\* UK Clinical Research Collaboration

# Key Achievements 2022/23

## Core Metrics

Reporting period: **2022/2023**

**Health and Care  
Research Wales  
infrastructure award  
to the group**



Direct  
funding  
awarded

**£364k**

Jobs created  
through direct  
funding



### Grants won during reporting period

Grants won	Led by group	Group collaborating
Number	<b>1</b>	<b>7</b>
Value	<b>£9k</b>	<b>£6.6M</b>
Funding to Wales	<b>£9k</b>	<b>£4.3M</b>
Funding to group	<b>£9k</b>	<b>£1.8M</b>
Additional jobs created for Wales	<b>3</b>	<b>9</b>
Additional jobs created for group	<b>2</b>	<b>5</b>



Number of publications



Number of public  
engagement events



Number of public  
involvement opportunities

### Clinical Trials Unit metrics



**8**

Number of  
studies  
awarded



**8**

Number of studies  
led by Welsh Chief  
Investigators



**155**

Total number of  
participants  
recruited

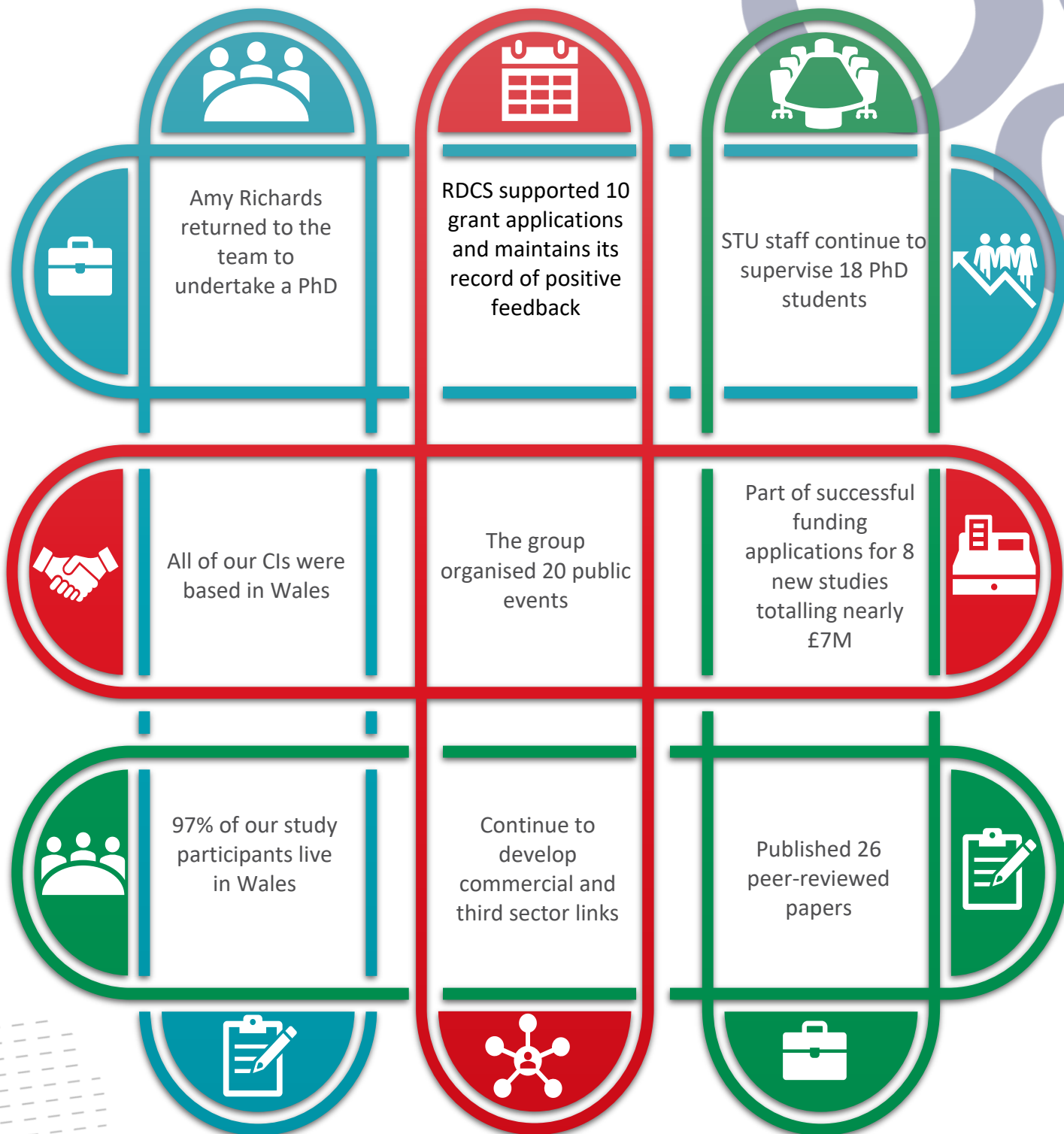


**97**

% participants  
from Wales



## Key achievements & impact



# 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 funding for further studies SunCHAT and SunView.

**Nicky Heady** completed her HCRW funded PhD supervised by **Alan Watkins** and **Hayley Hutchings** and joined the team as a study manager.

**James Rafferty** joined the team as a senior statistician.

**Kirsty Lanyon** joined Swansea University's public engagement forum.

**Greg Fegan** left the unit to take up a new position with Oxford University based in Bangkok.

### Training

Between them **the team** supported 18 PhD researchers. This year 3 were successfully examined and graduated.

**Jodie Millard** completed qualitative data analysis training.

**Kirsty Lanyon** did research interview training.

**Julie Peconi** completed Research impact training.

**Alan Watkins** and **Gail Holland** completed updated NHS REC training.

**Kym Carter** and **Gail Holland** attended A Systems Approach to Good Pharmacovigilance Practice at the Research Quality Association.

**The whole team** completed GDPR Refresher in Research Context as well as embedding the national standards for public and patient involvement in research.

## 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 2022-2023 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:

LIONNS-D2 (Liothyronine Sulphate (T3S) use in hypothyroid subjects on T4 homozygous for the Thr92Ala Deiodinase2 (D2) polymorphism)- This MRC-(Medical Research Council) funded trial officially opened in May 2023 and is busy organising the relevant contracts to procure the investigational medical product needed. The trial is a crossover trial aiming to recruit up to 76 patients who have hypothyroidism and have a genetic mutation that means they are not as responsive to traditional medication (thyroxine) as most patients. The trial will recruit eligible patients from the GenThyr cohort based in Cwm Taf Morgannwg University Health Board, Wales.

PEACE (Protecting Emergency Medical Services (EMS)) Staff from Aggression and Violence in Conflict Encounters – This study is being undertaken in collaboration with Wales Ambulance Services Trust. The study involves two work packages: PEACE 1 will involve a survey of the public and in PEACE 2 will involve interviewing EMS staff and construct a grounded theory exploring this issue from their perspective.

STUMBL 2 (STUdy evaluating the impact of a prognostic model for Management of BLunt chest wall trauma patients) is a follow up study being prepared for an NIHR HS&DR application. The study will involve 20 sites (and over 1000 patients) across the UK and with the aim of updating how EDs

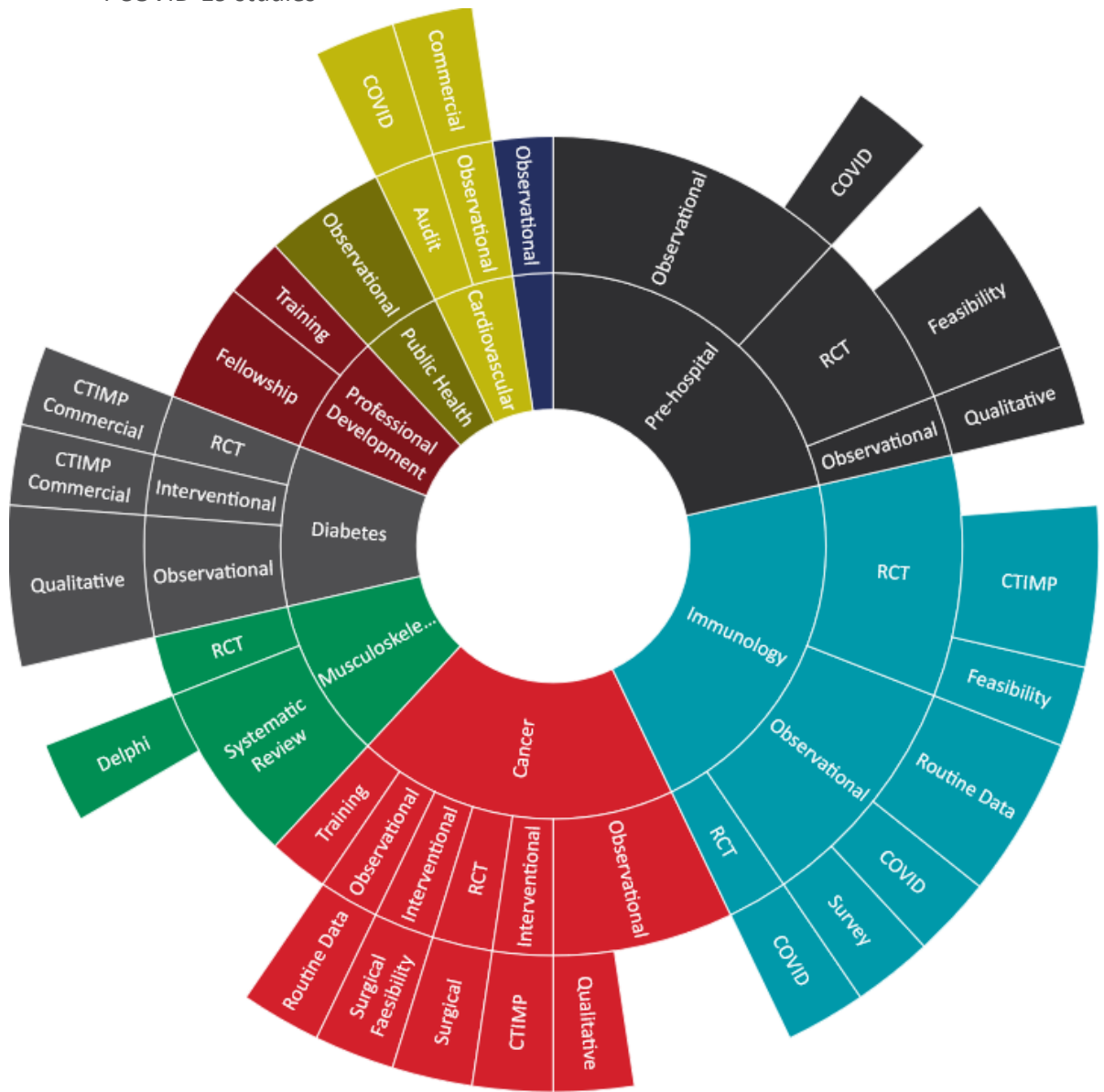
SunView: How the Sun Sees You – this study is funded by an RWIF (Research Wales Innovation Fund) Collaboration Booster External Engagement grant is a yearlong collaboration with Oriol Science Swansea, an organisation which brings science to the community through exhibits, workshops and talks. SunView consists of a permanent exhibit showcasing key findings from Sunproofed as well as 6-8 workshops with schoolchildren.

## WP3: Oversight of funded studies

In 2022/23 STU's portfolio continued to grow with the team adding more studies in situations as diverse as hospitals, community care, prisons and primary schools. The variety of studies showcases the experience and expertise of the team and their ambitions to support and deliver high quality research projects. We are proud to produce research that has an impact on the health and wellbeing of all people who need care and support.

Portfolio highlights include:

- 5 CTIMPs (Clinical Trial of an Investigational Medicinal Product)
- 7 other RCTs (Randomised Controlled Trial)
- 3 projects principally using routine data
- 3 projects with commercial support
- 4 COVID-19 studies



n=42 studies

## Important updates from our portfolio



Trauma-AID has secured a two year funded extension with NIHR HTA, now due to end April 2025. After the pandemic caused a substantial impact to learning disability (LD) services and a two-year delay in the trial, 9 sites have opened for recruitment to the main trial throughout 2022 and 2023. This led to a significant increase in service user

participant and carer recruitment throughout the same period. Trauma-AID is now back on track with revised milestones to meet original trial objectives. The investigators published the validation of an LD adapted questionnaire for diagnosis of PTSD (Post-traumatic stress disorder) to ICD-11 (International Statistical Classification of Diseases and Related Health Problems) in British Journal of Clinical Psychology.



BICCC (Brief Intervention Cyclophosphamide in Colorectal Cancer) - This CRW (Cancer Research Wales) funded open label trial investigating giving a low dose of cyclophosphamide for 4 weeks spread over a 9 week period to patients who have completed treatment for colorectal cancer to assess if it this will improve disease free survival. The trial will recruit 500 patients over 10 UK sites and is in the process of gaining all of the approvals required for this.



FASAR (Randomised Control Trial of fluoxetine for the treatment of problematic sexual arousal in adult males serving a custodial sentence for a sexual offence) - This NIHR HTA-funded trial is investigating the effect of fluoxetine on patients serving a custodial sentence for a sexual offence. This RCT is led by Nottingham Trent University and STU are providing trial and data management support as well as statistics. The trial is being rolled out in 8 prisons in the UK.



RAPID2 (Randomised trial of clinical and cost effectiveness of Administration of Prehospital fascia Iliaca compartment block for emergency hip fracture care Delivery) follows up on a Health and Care Research Wales funded feasibility trial. This randomised trial is funded by NIHR HTA and compares prehospital fascia iliaca compartment block (a local anaesthetic injection) with morphine in patients with hip fractures. It will recruit 1,404 patients across five linked hospital + ambulance service sites in England and Wales. Site initiation meetings are underway, and we expect patient recruitment to start early this summer.

## WP4: Dissemination and engagement

The STU team are actively involved in publishing and disseminating the research undertaken in the Unit. They regularly present at national conferences via poster and oral presentations. The purpose of this work is to gain recognition for the contribution the studies make to current thinking and practice in health and care in Wales and beyond. These activities enable the team to showcase the quality research and methodology practice being undertaken in STU. Dissemination and engagement activities like these offers an opportunity to reflect on outcomes and impacts as well as on the professionalism and hard work of the team.



**ICTMC**  
**2022**

STU staff presented five posters from three projects to the 6th International Clinical Trials Methodology Conference (ICTMC) being held in Harrogate during October 2022. Feedback on the event was very positive and we look forward to the next event in 2024.



UKCRC  
Registered  
Clinical  
Trials Units

Staff from 5 UKCRC registered trials units (Swansea, Cardiff, Bristol, Exeter and Plymouth) have formed a virtual Southwest Research Collaboration. Three STU led projects were presented under the methodology theme at the meeting in June.



**MOONDANCE**  
CANCER INITIATIVE

The Moondance Cancer Initiative funded project “Enabling research activity across Wales” which aims to make it easier for thousands of patients in Wales with gastrointestinal cancers to access clinical trials held a conference in Llandrindod Wells in February 2023.



**BRITISH SOCIETY OF  
GASTROENTEROLOGY**

Dr Phedra Dodds and the Moondance funded Non-medical Endoscopy Training team won best education and training poster at the British Society of Gastroenterology Annual Conference.

**NIHR**

**National Institute  
for Health Research**

The HART team completed the final report for NIHR HTA and the main results paper was published in the British Journal of Surgery. A Health and Care Research Wales funded follow up study using routine data is underway.



## 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 and NHS.

STU staff act as trainers, supervisors and mentors to PhD students. The team regularly recruits new researchers who are trained and mentored by the team and are actively encouraged to develop new projects.

Support for future researchers has always been central to the work of the unit. Over the last 3 years we have been delighted to see a number of our PhD students graduate. The team also deliver teaching and supervision at undergraduate and postgraduate levels. We are delighted that the undergraduate module “Introduction to Clinical Trials Research” will be taken forward by Dr James Rafferty our new senior statistician.

### STU receives excellent feedback:

Gail was a wonderful speaker - clear, structured, engaging, with helpful slides. Did her best to answer all questions comprehensively even when they were repetitive.

Training Delegate, Research Quality Association

Swansea Trials Unit were friendly and interested in the research right from the first meeting. We opted to choose Swansea over other trials units in our NIHR bid because they were friendly, helpful and were interested in the research right from the beginning. Gail and Hayley were extremely helpful and responsive all through the application stage, but I only fully realised what strengths STU brought to this complex clinical trial when the project started. The Senior Trials Manager at STU is a veritable force of nature (in a good way!), and I feel extremely grateful that we have such expertise and experience from Kym, Gail, Hayley and colleagues to guide us as we navigate the UK's first clinical drugs trial in UK prisons.

Professor Belinda Winder  
CI, FASAR Study

Kym's talk on “What can a clinical trials unit offer” was really interesting and informative and highlighted the services available via CTUs. It was very useful to hear about how CTUs work. These have been a bit of a mystery to me before now but this talk was very clear and helpful

Trainee Delegate,  
Research Post Fellowship  
Study Day Programme for  
NHS Anaesthetists.

## 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  
& Chynnal Ymchwil  
De Orllewin Cymru

The RDCS team works alongside their sister organisations in Cardiff and Bangor to ensure a fair and equitable service is available to all eligible health and care researchers in Wales. They also draw upon the services of other partners including the Health and Care Economics Cymru Service, and the Language Awareness and Infrastructure Support group to ensure the advice they give is based on best practice in all spheres and is up-to-date. RDCS staff regularly observe funding panel discussions to help improve the advice given about funders and funding applications.



I just wanted to reach out and touch base following the brilliant study day with RDCS in Swansea. It was invaluable to have some time out in that environment, and with such a great diversity of clinical academics. It's really given me so much to think about.

Dr Rachel Hunter,  
Swansea University



The team at Swansea Trials Unit were very helpful when developing an MRC grant application, which I'm delighted to say was funded!

Dr Aimee Grant, Wellcome  
Trust Career Development  
Fellow

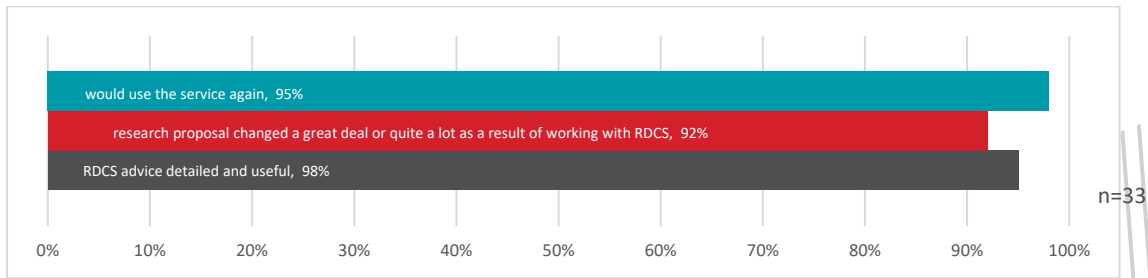
The RDCS team made me very welcome and made sure my perspective was listened to. I felt at ease and really valued. The study ideas were great...I really hope they get funded so that we can get started on doing all the work we discussed together at those meetings.

PPI representative



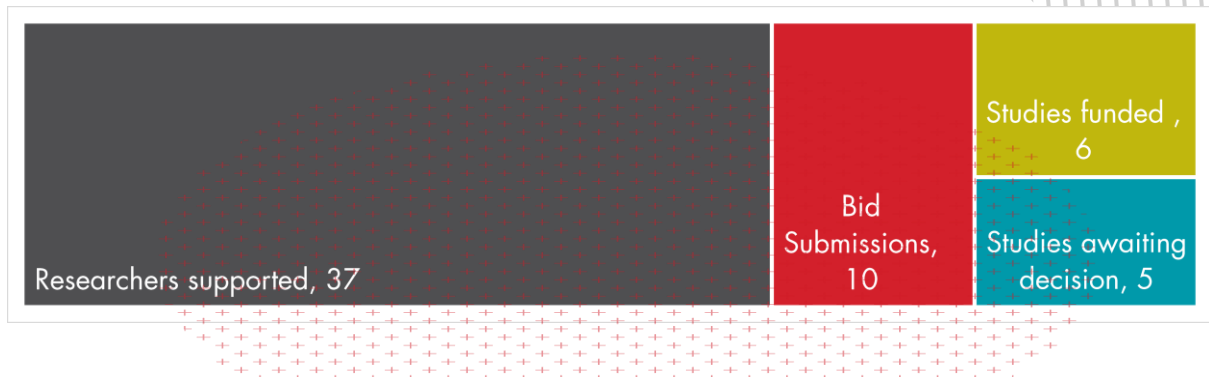
## Feedback about the Service

Each year the team collects feedback from clients to ensure the service is meeting their requirements and is delivering what they need. Feedback on the service is always excellent.

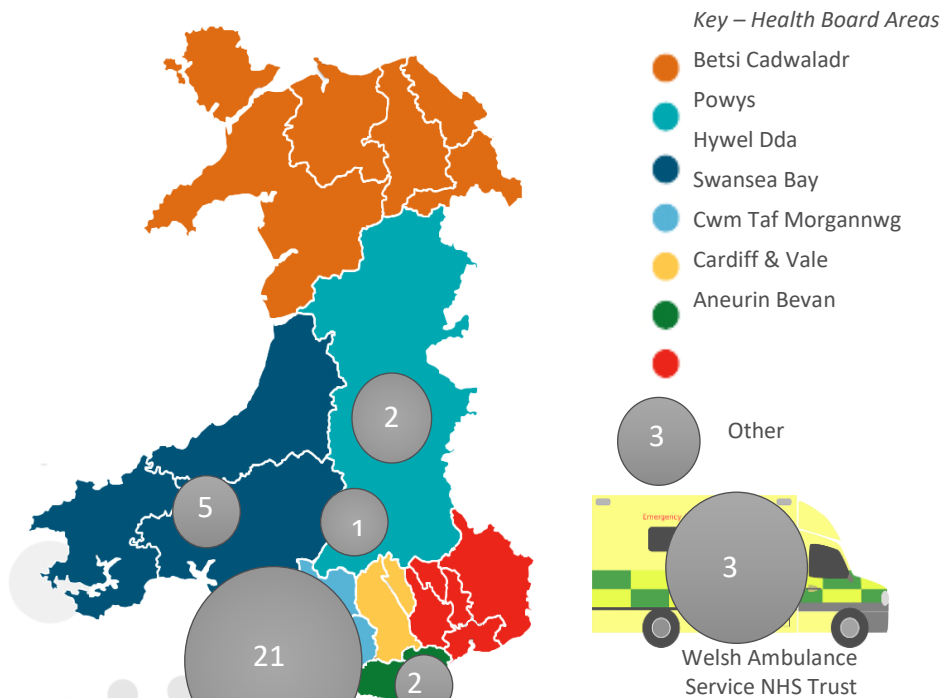


## RDCS Activity

This year things were largely back to normal with COVID-19 no longer impacting how advice was given and the location in which the team were able to work.



## RDCS supported researchers from across Wales



# PPI, Engagement & Collaboration

The national public engagement standards underpin everything we do. Our staff are committed to fully embedding high quality PPI&E at every stage of our work.



We know that good PPI enables us to:

- ✓ Improve our communications with patients and public
- ✓ Measure the impact of our work
- ✓ Support the learning of colleagues and collaborators
- ✓ Improve the oversight and governance of our studies
- ✓ Work with all stakeholders in a transparent way
- ✓ Encourage inclusivity and representation in everything we do

## Case 1: TRAUMA-AID

The Trauma-AID trial aims to explore a new therapy that may improve the quality of life of people with intellectual disabilities (PwID) who live with post-traumatic stress disorder (PTSD).

The researchers collaborated with the Research Advisory Group at the Tizard Centre comprised of PwID who have experience of grant proposals. Service user groups, of Men and Women with Learning Disability from Shropshire, the majority of whom have experienced, and been treated for, trauma.

PPI representatives contributed to the study design and discussed the acceptability of the proposed intervention to the patient population. They also provided feedback that helped shape how PwID were approached, reimbursed, and received information acceptable from their perspective. All documentation that patients would receive was reviewed and they are supporting the development of a website and recruitment video.

## What

The LIONNS-D2 study investigates the use of T3 sulphate to alleviate symptoms and improves quality of life in a group of hypothyroid subjects with a specific mutation.

## Case 2: LIONNS-D2

## Who

Staff and volunteers from patient support and lobby groups from across the UK (for the most part patients themselves) took part in focus groups with the team to ensure the “lived experience” of patients was understood. The groups were arranged to ensure a comprehensive understanding of the issues.

## How did it help

The LIONNS-D2 trial design benefitted significantly from the input of both patients with hypothyroidism and from representatives of key charities. Their advice and support to date has been invaluable in making sure that the trial will be done with the patient’s benefit in mind. We intend to invite all parties to join our committees and support the trial which has now received MRC (Medical Research Council) funding to support their regular participation.

# Conclusions and Looking Forward

## Conclusions

In spite of the upheaval of Covid-19 and recent changes in personnel and funding the STU have once again gained full registered clinical trials unit status with UKCRC. We are committed to continuing to build the team and the STU brand to ensure ongoing success. STU's reputation for high quality and efficient study delivery continues and we have had success across a wide range of specialties continues to attract new collaborators and partners.

Our portfolio is carefully managed, and our outputs show that we have key strengths in areas like study design, data management and patient involvement. We are delighted that our colleagues are recognised across the UK for their work in these areas.

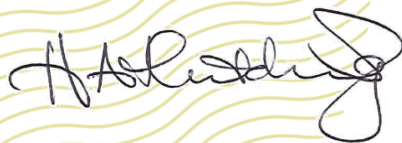
## Looking Forward

This year Professor Hayley Hutchings took over as sole director of STU as we move to a new phase without reliance on funding from Health and Care Research Wales. The team are well-placed to face the challenges and opportunities ahead.

We are very proud of our ongoing success in areas like diabetes, PROMS, mental health and surgery.

Our diverse portfolio and grant success is testament to the hard work and dedication of the team.

We are also immensely proud of the work done by our RDCS team and we look forward to STU staff continuing the excellent work to support new researchers to develop their ideas so that we can continue to deliver our ambition for a healthier Wales.



Professor Hayley Hutchings  
Director, Swansea Trials Unit



Swansea University  
Prifysgol Abertawe

Swansea Trials Unit  
Uned Dreialon Abertawe

Swansea University Medical School  
Singleton Park, Swansea, SA2 8PP  
Swansea University is a registered charity No. 1138342  
T: 01792 606545  
e: STU@swansea.ac.uk  
<https://swanseatrialsunit.org/>

Thanks to all STU and NHS colleagues who contributed to this report.

