This is the final year of the current infrastructure grant. Whilst this report highlights the achievement during 2019-20, it is also an important time to reflect on our achievements over the last five years. Over this period, we have seen NWORTH’s portfolio strengthen considerably and so too have our performance metrics. Since 2015, we have worked hard to create a supportive team environment, where we actively support and work collaboratively with our Chief Investigators to design studies that answer important questions in healthcare.

We have developed a robust portfolio in a diverse range of clinical areas, including ageing and dementia, neurodegenerative diseases and oral health. Our currently active studies represent £19.1M in total grant value. During 2019-20, we have maintained our high success-rate, with over a third of our applications being funded, which is markedly higher than the national average. This highlights the quality and expertise of the team at NWORTH and ensures our Return on Investment for the Welsh Government remains high.

In terms of delivery, the different metrics that we use to measure the quality of our internal processes remain high and all our studies have been delivered within their agreed timeframe. A number of studies over the last five years have also made a significant impact. One of our largest trials has gone on to influence policy at a regional and national level (testing a new method for detecting bowel cancer). Equally, two of our dental studies form the basis of restructuring the dental workforce and NHS contracts.

Another satisfying aspect of reviewing our performance over the last five years is seeing members of staff develop over this timeframe. One example of this is seeing one of our talented junior members of staff being promoted to Senior Statistician in 2020.

Following the success of our bid for further infrastructure funding, we look forward to working as a cohesive team to promote a supportive service that delivers impactful research for Wales and beyond.
NWORTH’S MISSION

Our overarching mission is to conduct clinical trials and studies of complex interventions of the highest quality; delivering research with impact and advancing methodological developments in clinical trials research.

Our key objectives are to:

1. Support a research development infrastructure that promotes an active and accessible choice for researchers across Wales.

2. Provide specialist support for empirical designs that involve trials of complex interventions and pragmatic studies.

3. Continue the development of our expertise in trials of oral health, dementia and ageing for the Health and Care Research Wales infrastructure.

4. Deliver high quality collaborations on time and to budget.

5. Develop our public involvement and engagement in research.

6. Advance the theory and practice of randomised controlled trials and other rigorous methodologies.

7. Increase research opportunities through the medium of Welsh.
**Lay Summary / Overview**

**Who are we and what do we do?**

NWORTH is one of three Clinical Trials Units in Wales.

We are funded by Health and Care Research Wales, (part of Welsh Government).

Clinical Trials Units, (CTUs), are specialist research units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies.

A clinical trial is a type of study that is used to test whether an intervention works or not.

Interventions can be treatments, therapies, or medicines. Clinical trials help us to understand if these interventions improve people’s health. This can include research to understand how interventions or medicines work.

**NWORTH is fully accredited by the UK Clinical Research Collaboration (UKCRC).**

To have achieved this level of accreditation, a CTU must consistently demonstrate experience in the coordination of multi-centre trials. Its staff must possess the appropriate skills to design and develop studies, utilising robust quality assurance systems to continually produce on-going evidence of its long-term viability and capacity for trials coordination.

NWORTH can achieve these expectations by fully utilising its team of experts who work together to design, co-ordinate and deliver complex clinical trials. They include Statisticians, Researchers, Data Managers, IT Specialists, Trial Managers, Quality Assurance Officers, Methodologists and Administrators.

NWORTH achieves its coordination of multi-centre trials by working with research teams both in Wales and across the United Kingdom.

Because NWORTH has consistently demonstrated the required levels of expertise and experience needed to support clinical trials, we are able to provide support and mentorship for our research teams. The experience gained from the interactions between multi-centre trials from our base in North Wales has allowed us to provide a unique rural Welsh dimension to our mentor base.

The extensive knowledge, experience and co-production within our teams enables the solutions to ongoing problems to be found quickly and thereby enhances the team’s skill sets constantly.

This enables the studies to be designed and delivered to the highest quality, enabling the evidence produced at the end of the study to be more robust and thereby more likely to justify a change to practice.

Having a Clinical Trials Unit available to support this complex process makes a real difference. It provides researchers with security and stability throughout their journey from trial design to trial delivery.

Karen Shepherd,
PARC-Bangor Public Involvement Member.

**ORGANISATION FOR 2019-20**

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THE TEAM

Our staff are our key resource and all NWORTH staff are supported to develop the skills, behaviour and knowledge they need to achieve the objectives of their role and those of the Unit. We encourage all staff to engage in continuous learning and support our staff to identify their development needs via our performance development review process.

This year we welcomed a new Trial Manager to the team, Dr Hana Pavlickova. We also appointed Dr Gabriella Rossetti as the Community of Scholars Facilitator.

We were sorry to say goodbye to Ian Woodrow, our Senior Software Engineer at the end of March 2020. Ian was instrumental in developing our IT systems and processes and will be missed. We wish him all the best in his new role.

We were delighted to appoint Rachel Evans as Senior Statistician this year. Rachel began her career at NWORTH doing some work experience after University and has never left!

HIGHLIGHTS:

2019 – 2020 has been another very busy year for NWORTH. Some of our highlights are summarised below...

Portfolio Development

Portfolio development is the backbone to everything we do at the Unit. This encompasses the triage process of all new proposals received at the Unit via our project screening process, through to applications development, costing, contracting and set-up of newly awarded studies. We constantly monitor our pipeline to maintain consistent turnover of applications and to ensure that quality collaborations are being developed proactively to secure ongoing business development.

During 2019-2020 we submitted 10 funding applications and added three large-scale studies to our portfolio – with a total grant value of £5.5M.

We currently have 13 active studies on our portfolio with a total grant value of £19M. We have an active pipeline of studies in development with another 6 studies currently in submission with a total grant value of £2.6M.

We are also actively working up a further 6 studies with three of these being in response to the COVID-19 pandemic.

This year has seen the end of three large studies, (further details on the H-T study and CARIAD below). RHINO also concluded after 5 years.

NWORTH has been instrumental in the delivery of this Clinical Trial of an Investigational Medicinal Product, (CTIMP) and has developed bespoke systems to handle randomisation (two linked randomisation systems), drug allocation and unblinding procedures. 768 children were recruited to the study and the final report and papers are now being drafted. The study addresses respiratory health in preterm neonatal outcomes and the results will inform our understanding of the underlying mechanisms of chronic airway obstruction observed in symptomatic children who are born preterm. Results will establish if there are different phenotypes of this condition that do or do not respond to standard inhaled therapy.
Research and Innovation for Global Health

NWORTH CTU is delighted to be collaborating with Professor Peter Fonagy and his team in University College London, along with Columbia University, who have been awarded £3.8 million from the National Institute for Health Research (NIHR) to fund a new study in Lebanon and Kenya looking at the treatment of post-natal depression, child development, and the mother-child relationship.

In the study, entitled Evaluating the Impact of Group Interpersonal Psychotherapy (IPT) in Lebanon and Kenya on Child Developmental Outcomes, Maternal Depression and the Mother-Child Relationship, we will work with researchers and policymakers in Kenya and Lebanon to adapt, deliver and evaluate group interpersonal psychotherapy for maternal depression. Local researchers in Kenya and Lebanon will work with the core team to investigate how maternal depression is thought about locally, adapt group IPT to the local culture and evaluate the effectiveness of the therapy.

To ensure group IPT can continue being delivered once the project ends, it will be designed for delivery in primary care or the community by non-specialists after brief training. During the project, local health services and local researchers will be trained to deliver and evaluate the therapy. Culturally tailored training and educational resources will also be developed to support sustainable development of maternal mental health services.

Dr Zoe Hoare, NWORTH co-applicant on this bid, is one of only three successful applicants/co-applicants to the Global Health Research funding stream from Wales.

H-T Study results Inform dental policy:

Across the United Kingdom (UK), many dental ‘check-ups’ undertaken in the National Health Service (NHS) result in no further treatment. As the oral health of regular dental attenders in the NHS continues to improve, it is likely that an increasing number of these patients will be judged as being at low risk. The delivery of health promotion and simple treatments could be provided by different members of the dental team. This raises the question as to whether dental therapists could provide the ‘check-up’ in the future in the NHS or perform reviews between ‘check-ups’ by dentists, when patients have been judged to be low risk.

Using dental therapists to undertake ‘check-ups’ on low risk patients could improve the efficiency of dental provision in the NHS and release time for the dentist to focus on more complex cases. It could also be a way of freeing up resources in dental practices to treat patients who currently do not or cannot access NHS care.

NWORTH was funded by the National Institute of Health Research (HS&DR 16/01/79) to deliver the H-T Study, (Can Hygiene Therapists maintain the oral health of routine low-risk dental recall patients in “high street” dental practices: a pilot study), which was led by Professor Paul Brocklehurst.
The reason why this is important is the latter would require far fewer participants in the final trial. We also wanted to understand what dentists and dental therapists thought about the idea and canvas the views of patients who might receive this type of care in the future.

The pilot study was randomised, which meant that participants either saw the dental therapist for their treatment or their normal dentist. 217 low-risk patients were recruited into the study, which was undertaken in NHS dental practices in the North-West of England. The current practice of using dentists to provide NHS dental ‘check-ups’ formed the control arm (treatment-as-usual) and was compared to the intervention arm, where this care was provided by dental therapists.

Each patient received a detailed dental examination by blinded independent examiners, before the dental examination by blinded independent examiners. The patient ‘cross-overs’ were found. This would suggest that the question for the definitive randomised controlled trial should be “are dental therapists as good as dentists at providing dental ‘check-ups’”. This does pose some challenges for the future trial, as it means that we will have to recruit a lot of patients to test this from a statistical perspective. We also found ‘floor-effects’ in the data, meaning that the level of disease across the two groups was so low, that detecting changes in a future trial might prove problematic.

However, despite this, no difference was found in any of the measures when NHS patients are cared for by a dental therapist, except for the fact that dental therapists provided more health promotion, when compared to dentists. These findings have subsequently helped to inform policy-makers on how to design NHS services in the future in Wales and beyond.

The results from the extensive interviews found that policy-makers and commissioners of services saw real benefits in using dental therapists in the NHS ‘check-up’ and recall process. The use of dental therapists was also preferred by owners and partners of NHS dental practices, rather than other dentists working in the same dental team (given concerns over dental therapists competing for the same business and leading to less income for these types of dentists).

The study aimed to determine whether carer-administration of as-needed subcutaneous medication for four frequent breakthrough symptoms (pain, nausea, restlessness and noisy breathing) in home-based dying patients is feasible and acceptable in the UK.

Adult patients anticipated to be in the last weeks of life who were likely to lose the oral route and expressed a preference to die at home were recruited with their carers to an external randomised pilot trial across three UK sites (North Wales, South Wales and Gloucestershire).

Patient/Carer dyads randomised to the intervention arm received a manualised training package delivered by their community nursing teams. Dyads in the control arm received usual care. Carers in both arms completed carer diaries and outcome measures.
Methodological developments

We were delighted to have a strong methodological presence at the International Clinical Trials Methodology Conference held in Brighton in October 2019. Two NWORTH staff members, (Dr Karolina Rusiak and Rachel Evans), presented their work and we had four posters on display.

Professor Paul Brocklehurst has been contributing to the PROMETHEUS project (www.york.ac.uk/healthsciences/research/trials/research/swats/prometheus) and will include a study within a trial, (SWAT), on care-home recruitment as part of his upcoming SENIOR Trial. This will be novel, as we will be testing the impact of an animation (containing information about the study) and financial incentives in a factorial design. This hasn’t been undertaken before and will provide valuable information about the types of activity that promote care-home engagement in trials.

The DECADE study (Development of a Core outcome set for oral health services research involving Dependent older adults) is active and ongoing and will also inform SENIOR in terms of core outcomes.

We have also taken the lead for the Federation Dentair Internationale (www.fdiworlddental.org) in the development of an international co-design project. This has implications for how service users are incorporated into the design of future trials, ensuring their involvement is active, democratic and ongoing.

Managing the Paper Mountain: Systems and Processes for Tracing, Managing and Transforming High Volume Trial Data from Paper Sources

**BACKGROUND**

**IDEAL study:**
- **Objectives:** Improving the experience of people with dementia and their carers.
- **The IDEAL study** was running since 2016 and will finish at the end of 2018.
- A total of 29 study sites have been involved in participant recruitment over three time points (Time 1 – Baseline, Time 2 – one year follow-up and Time 3 – two year follow-up).
- A baseline 1547 participants with dementia, at associated conditions and 998 family members and carers were recruited.
- The aim of the IDEAL study was to explore long-term experiences of living with dementia and how their lives with dementia change over time by comparing interviews made up of multiple questionnaires with people along with dementia and their family carers across Greater Manchester.
- In total, IDEAL paper case report forms (CRFs) were received at the trials unit.

**OBJECTIVES**

To identify systems and processes:
- To reduce large volume of CRFs and data from these forms.
- To capture large volume of data from paper based CRFs and transfer to digital DMS data set.
- To test standardised design case report forms that can be captured by short form data entry staff.

**CONCLUSION**

The large volume of paper source data generated by IDEAL required closely managed digital systems. Established electronic trial management systems (MACRO and TrialCore) were used along with bespoke calculation and tracking tools to allow the trials unit to efficiently collect and manage the large volume of data without the cost and risk of developing or processing new combined system.

In terms of staff resources, data has taken a mammoth effort – chiefly from IT teams, Data team and QA teams. The knowledge developed and the sheer volume of string and validation scenarios to ensure all systems function appropriately and resulted in a massive data entry and data management system for almost 16,000 CRFs which has been a cornerstone to NWORTH’s success.

**RECOMMENDATIONS**

- Data entry to be implemented rather than CTU, to easily address any issues with collected data.
- Management of large volumes of paper data is expensive, consider approaches for direct data entry into a digital system such as the use of tables.
- A combined system may avoid integration issues that would be more expensive to develop than the adopted process that supports existing systems.
Research Design & Conduct Service

NWORTH hosts the Research Design and Conduct Service (RDCS) for Betsi Cadwaladr University Health Board and Powys Teaching Health Board. We offer support and advice to their staff to help develop high-quality research proposals which can be submitted for funding.

The RDCS provides advice and guidance in accordance with the RDCS Charter to enable potential researchers to identify appropriate sources of funding and to develop their research idea to a high standard.

This year we arranged two grantsmanship training sessions for those wishing to submit to RfPPB. Outreach sessions continued to be offered regularly across BCUBH and Powys, although often uptake has been poor.

Two research proposals were developed into RfPPB applications and both have proceeded to stage 2 of the scheme.

NWORTH contributed to the all-Wales RDCS stand for the Health and Care Research Wales conference held at Sophia Gardens in Cardiff in October. NWORTH also hosted the all-Wales RDCS face-to-face meeting in Bangor on 15th October. Members of the RDCS attended BCUBH’s Research and Innovation meeting on 12th December at Ysbyty Gwynedd.

An RDCS podcast has been recorded as part of the Community of Scholars project with input from RDCS members and clinicians.

Dr Gill Toms, our Social Care Lead provided input and support via the RDCS on potential RfPPB applications from Powys Teaching Health Board.

LLAIS

NWORTH is committed to language and cultural sensitivity, and via our Language Awareness Infrastructure Support (LLAIS), we translate and linguistically validate at least one health measure per year for the research infrastructure across Wales. We ensure that research being carried out by NWORTH in Wales meets the linguistic needs of the people of Wales and complies with the requisite statutory obligations.

LLAIS representatives attended a number of events this year to promote their work including the Clinical Trials Day event at Ysbyty Gwynedd, (May 2019), the Young Carers Conference at Bangor University, (June 2019), and provided a language awareness session at Bangor University’s summer school, (July 2019).

LLAIS’ poster on the Linguistic Validation of the Welsh language version of the PROMIS-10 global health measure was presented at the Health Measures User Conference in Chicago in June 2019. This poster was also presented at the Health and Care Research Wales Conference in Cardiff in October 2019.

Work has been completed now on the linguistic validation of stroke measures and the following measures have been added to the micym.org website:

- The Stroke Impact Scale (Graddfa Effaith Strôc)
- Arm A (Gweithgaredd Braich – Braich G)
- Leg A (Gweithgaredd Coes – Coes G)

An abstract outlining the process of linguistically validating Arm A has been submitted to the Health and Care Research Wales conference for 2020.

There are now 45 Welsh language measures listed on Mesurau Iechyd Cymraeg interactive web-site www.micym.org/llais/static/index.html. There are currently 506 followers on Twitter for @micymraeg.
KEY ACHIEVEMENTS
Key metrics of our cumulative performance for 2015-2020 are summarised below:

- **85 grants applications submitted**, (52 to NIHR NETSCC schemes)
- **31 grants awarded** (35% success rate)
- **£27.8M of grants being funded between 2015-2020**
- **£5.8M accruing to Wales**
- **£21.8M NETSCC income awarded**
- **101 articles published in peer-reviewed journals, (average impact factor = 3.25)**
- **£2.7M currently in submission**
- **£250k commercial income generated**

Key Performance Metrics developed inductively within the Unit are **all green**

PARC-BANGOR

On 11th July 2019, NWORTH hosted its second “Have Your Say” public involvement event.

With 35 attendees and a range of presentations from the University, Health Board, Health and Care Research Wales, Commercial Research Partners, and Public Involvement representatives, it was a varied programme which reflected the breadth and depth of the NWORTH portfolio as well as highlighting the progress that has been made with PARC-Bangor and our public involvement work.

By the end of the event, we had recruited more members to PARC-Bangor, (total membership now 19). We had also collated a range of public involvement input for a piece of research on Parkinson’s Disease which was in the early stages of development and subsequently went on to be submitted via Health and Care Research Wales’ Research for Patient and Public Benefit, (RfPPB) scheme.

Barbara Moore, (Health and Care Research Wales), attended our PARC-Bangor meeting in October and spoke about the “Discover your role” events being held in Cardiff throughout the autumn.

NWORTH produced new guidelines for payment for public involvement this year; we are grateful for the input from both Barbara Moore and Rebecca Burns on this.

ON 12th February, 2020, Dr Llinos Spencer, on behalf of NWORTH, facilitated the organisation of a public involvement and engagement event with the HCrW Public Involvement team. Attendees included a number of members of PARC-Bangor as well as colleagues from across the College of Human Sciences and beyond. Discussions were very wide-reaching and included consultation on a proposed plan for HCrW in order to take Public Engagement and Public Involvement forwards.

As part of the Community of Scholars pilot, members of PARC-Bangor contributed to a podcast on public involvement and engagement. Two members of PARC-Bangor have now been trained in qualitative interviewing techniques and have contributed to the qualitative interviews as part of the Hygiene Therapists study.

Having PPI embedded and active in the H-T Trial adds real credibility to this high-profile and policy-relevant study, which challenges traditional role boundaries.
Our Community of Scholars pilot, in collaboration with Betsi Cadwaladr University Health Board, has gone from strength to strength this year. With the appointment of Dr Gabriella Rossetti as the Facilitator for the pilot, progress continued at pace and levels of engagement from both health care professionals and researchers/academics has been excellent.

The main focus of the work has been on designing the website platform which will be a "one-stop" hub for clinicians who are looking to start their journey in research. Branding and design for the project and accompanying marketing and promotion materials was completed. A core advisory group of North Wales-based clinicians was set up to advise and provide feedback on proposed content. 13 podcasts with 30 panel guests have been recorded covering key aspects of research conduct. Each podcast is an open and accessible discussion on specific research topics with a range of guests from the Health Board, University and members of the public who either have expertise in a field or recent experience carrying out clinical research.

Three outreach events have been attended to promote the Community of Scholars across BCUHB and it has been very warmly received. Unfortunately, the launch of the new website along with planned outreach events and promotions have had to be paused due to COVID-19. However, due to the hard work of all involved, we are ready to launch as soon as circumstances allow.

A key aim of the pilot is to link academics and healthcare professionals who share common interests and research ideas so that these can be pursued in partnership. To aid this, the website will feature a sign-up facility so that those who do sign up will have access to a network map showing other members, which can be filtered by their clinical interests, skills, and current workplace. Registered members will be able to fill out a questionnaire to generate a tailored plan for expanding their skillsets.

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DISSEMINATION AND ENGAGEMENT

It has been another year full of promotional activity and engagement. Events attended and promotions undertaken have included:

- BCUQI Conference (Betsi Cadwaladr University Quality Improvement Hub)
  29th and 30th April 2019, Llandudno
- International Clinical Trials Day
  20th May 2019, Glan Clwyd Hospital
- H&CRW – Let’s talk research event
  6th July 2019, Bangor
- Have your say event!
  11th July 2019, Bangor
- H&CRW Conference – Partnership & Collaboration
  3rd October 2019, Cardiff
- ICTMC 2019 Conference
  7th – 9th October 2019, Brighton
- H&CRW X-mas campaign
  December 2019, Bangor/Online

In 2019-20, we had 173,691 impressions on Twitter. We tweeted 310 times and gained 70 followers. Unfortunately, due to the COVID-19 pandemic, many further dissemination activities have been paused or cancelled for the time being. We are looking to use social media and multimedia platforms going forwards as a more practical means of dissemination and engagement in the current context.
LOOKING AHEAD

As we embark upon a new funding period, NWORTH wishes to build on its consistently strong performance and unique position in North Wales to further expand our performance targets. Our key objectives for the upcoming funding period are:

1. Expand our project pipeline
   whilst maintaining our productivity and success rate in order to increase our return on investment for Welsh Government.

2. Increase the number of collaborations
   with researchers across Wales and rebalancing our portfolio

3. Further our links with Welsh research centres
   (as part of the H5CRW infrastructure) and policy-critical areas to address key recommendations in ‘A Healthier Wales’

4. Continue our growth
   by targeting UK-wide collaborators with an active plan of business development in key strategic areas of strength

5. Re-energize and expand our local research development infrastructure
   (see Community of Scholars above), further developing our support of applicants for the Clinical Research Time Award and Welsh project grant opportunities

6. Link our RDCS to the Community of Scholars
   to create a clearer pathway for aspiring researchers

7. Maintain the quality
   of our internal processes so that studies continue to run to time and target

8. Continue our patient and public involvement programme
   (PARC-Bangor) enabling members of the public to make a meaningful contribution to our research portfolio and the running of the unit

CONCLUSIONS

This report has demonstrated that there has been much to celebrate for NWORTH in 2019-20.

We have enjoyed another year of growth and have been delighted with the level of repeat-business the Unit receives as well as our consistent success rate with key funders.

We are currently living through an unprecedented time as the world grapples with the COVID-19 pandemic. Clinical Trials Units can play an instrumental role in designing and delivering vital research to inform policy and clinical practice.

I would like to congratulate and thank all the NWORTH staff for their hard work and achievements this year, but especially during the last few months when staff have demonstrated flexibility, resilience and creativity when faced with a myriad of changes and challenges to their usual working conditions and practices.

Thanks are also due to our colleagues in the College of Human Sciences, and School of Health Sciences at Bangor University and also our funders, Health and Care Research Wales.

Special thanks are due to all members of PARC-Bangor who contribute such a vast and varied amount of expertise to the Unit. All those who have given their time to help develop the Community of Scholars podcasts and resources are deserving of particular thanks this year and we look forward to being able to launch these valuable resources in the not-too-distant future.

NWORTH looks forward to the year ahead, when we will build upon our work to date and continue to provide outstanding input to quality research studies which will have positive impacts for the people of Wales and beyond.

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