









2017-18 Annual Report











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Foreword



Director, Professor William Gray

There is as always, a fast pace of change in neuroscience research, yet the year 2017-18 has been the best so far for the BRAIN Unit.

We have achieved a lot over the past twelve months to cement ourselves as a leading centre of excellence for the delivery of novel therapeutics to the brain and for the treatment of neurological and neurodegenerative diseases.

It goes without saying that none of these achievements have been possible without the hard working and dedicated team at the BRAIN Unit, who I would like to thank for their continued support this year.

Some of last year's highlights have been our collaborative work with industry partners Renishaw, to further develop the delivery of cells to the brain; a successful phase 1 IONIS trial to test a new treatment for Huntington's disease; and reaching out to over four thousand people through a diverse range of public and patient involvement and engagement events.

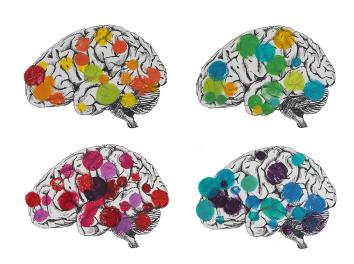
Going forward the BRAIN Unit has an exciting year to come, including work to expand and refresh our Public and Patient Involvement group BRAIN Involve, as well as developing our strategic direction for 2020 and beyond.

I hope you enjoy reading our annual report and will continue to follow us on our journey to become a centre of excellence in the development and delivery of complex therapies to the human brain.

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BRAIN Unit Director,
Professor William Gray

Executive Summary



The Brain Repair And Intracranial Neurotherapeutics (BRAIN) Unit is a research organisation working to develop new therapies for brain diseases. Our work focuses on neurological and neurodegenerative conditions such as Huntington's disease, epilepsy, Parkinson's disease and multiple sclerosis.

This annual report provides an overview of the BRAIN Unit's activities for 2017/18, and includes our key achievements, research highlights and a look to the year ahead for each of our 9 work packages.

This information has been collated by our 31 unit members, 11 of which are funded by Health and Care Research Wales.

Key highlights this year have been:

- 1. Securing funding to undertake 5 transplantations of cells in people with Huntington's disease.
- 2. Demonstrating that we are able to successfully deliver fetal cells for the treatment of neurological diseases and disorders using a CE marked device.
- 3. Expansion of our Neuroscience Research Unit, allowing us to increase our portfolio of both commercial and non-commercial studies.
- 4. Enrolling two participants with Huntingtons disease onto the IONIS clinical trial which received national and international acclaim.
- 5. Exceeding our targets for sample biobanking across both our biobanking sites.
- 6. International network developed through the inaugural meeting for the Stem Cells for Huntingtons Disease (SC4HD) in California, USA.
- 7. Expansion of BRAIN Involve and an increase in the number of public events held.

Overall, it has been a fantastic year for the BRAIN Unit, growing in research income and size, therefore cementing itself as a leading centre for neurological drug generation and delivery.

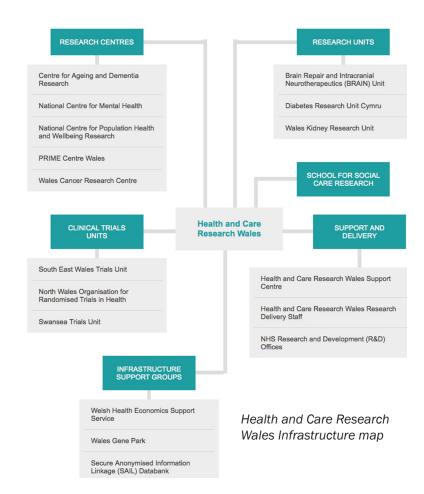
Going forward in 18-19, our main focus will be on the strategic planning of the BRAIN Unit's direction for the future and our focus for the 2020 bid.



Introduction

Funded by Welsh Government through Health and Care Research Wales, The Brain Repair and Intracranial Neurotherapeutics (BRAIN) is a Research Unit within the Infrastructure, developing novel therapeutics and treatment delivery systems for neurological conditions.

The Unit operates under the directorship of Professor Gray with 31 principle investigators (PIs) and collaborators, with a grant income of over £22million since the Unit's inception in 2015.



Our Mission

It is our vision to make the BRAIN Unit top-5 worldwide as a pre-eminent centre for international leadership and a Wales and UK national centre for excellence in:

- 1. Delivering novel cell, drug, growth factor and other complex therapies to the human brain.
- 2. Supporting translational research underpinning disease modification and brain repair in people with neurological conditions.

Our Aims

Through innovation and collaboration, the BRAIN Unit aims to:

- Develop new and refine existing systems for delivery of therapeutics into the human brain.
- Develop the appropriate infrastructure for capturing relevant, high quality patient data to measure real clinical and social impact, as well as continuing to support ongoing mechanistic translational research.
- Build a clinical and health economic outcome, social care and service delivery research portfolio.





Who are we?

Newly Appointed

Dr Cassy Ashman- "I'm thrilled to have joined a neuroscience research unit working on world-leading research. The next few years look exciting for the Unit so I'm pleased to be able to play a part in it."



Dr Feras Sharouf- "Joining the BRAIN Unit as a Clinical Research Fellow has been an amazing and rewarding experience. It has allowed me to participate in cutting edge research and pursue a PhD in stem cell therapy."



The Team

Director

Professor William Gray - Professor of Functional Neurosurgery at the University Hospital of Wales (UHW), Cardiff

Deputy Director

Professor Anne Rosser - Professor of Clinical Neurosciences & Consultant Neurologist at UHW

Administration

Dr Cassy Ashman - Research Manager

Neuroscience Research Unit

Belinda Gunning - Research Nurse Manager Joanne Bagshawe, Andy Davison & Rebecca Cousins - Research Nurses

Research Associates & Fellows

Dr Erini Messaritaki - Imaging Research Associate

Dr Mark Postans - Computer Programmer/ Research Associate

Dr Feras Sharouf - Clinical Research Fellow

Research Technicians

Dr Samantha Loveless - Biobank Officer (Cardiff)

Beata Fonferko-Shadrach - Biobank Officer (Swansea)

Dr Chloe Ormonde - Stem Cell Technician Shirin Davies - MRI Physicist

Principle Collaborators & Partners

BRAIN is a multi-disciplinary research unit with strong academic and NHS clinical leadership. Based in Cardiff, the Unit's all-Wales brief involves key research excellent groups in Swansea and Bangor.

The Wales Neurological Alliance (WNA) is a forum of not-for-profit organisations representing people affected by neurological conditions in Wales. WNA sits on both the BRAIN and BRAIN Involve executive boards, and continues to support BRAIN Unit activities with its far-reaching membership and input.















Lay Summary

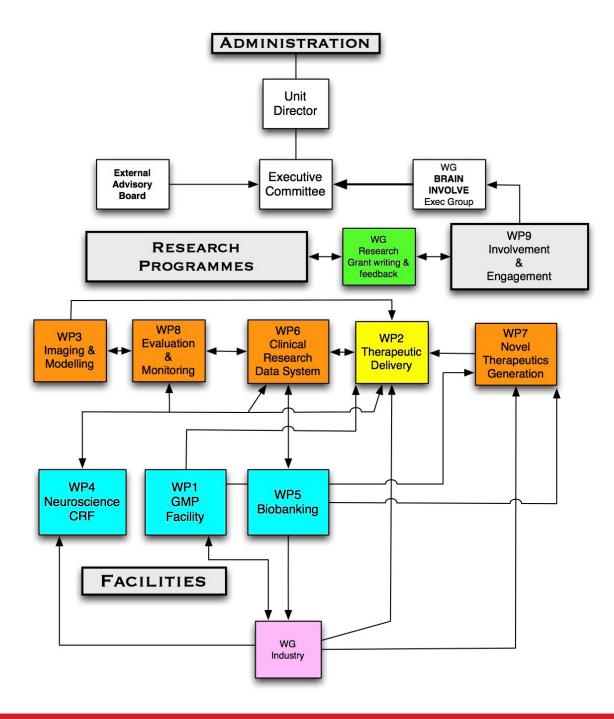
BRAIN Unit is working towards becoming a UK centre of excellence for delivering novel cell, drug and growth factor therapies to patients with currently untreatable neurological and neurodegenerative diseases.

This includes conditions such as:

- Huntington's disease
- Epilepsy

- Parkinson's disease
- Mutliple Sclerosis

BRAIN Unit Organogram







Lay Summary



Tom Phipps, Chair of Bristol and District Branch, Parkinson's UK

Public and Patient Involvement

If you are interested in playing a role in shaping our work, you can become a member of our BRAIN Involve community.

This public and patient involvement group helps inform our research and forms a key part of the BRAIN Unit structure. It's members contribute to the design, development, implementation and dissemination of our research around brain repair and developing new therapies.

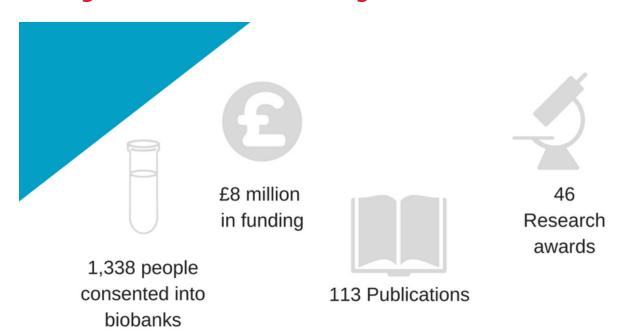
Being a member is not about taking part in research but about using your experiences to help inform and develop research ideas and projects relevant to you. This could be through attending or contributing to events, reviewing grants and study materials or writing research grants.

How to get involved

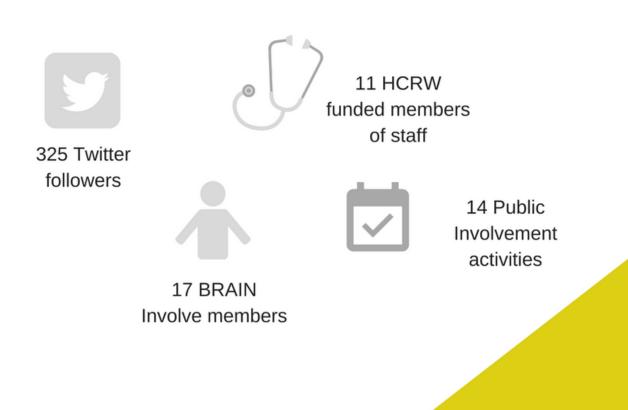
To become a member or for more information, please email:

brainunit@cardiff.ac.uk

Lay Summary



KEY ACHIEVEMENTS



Cardiff GMP facility

Work Package 1

Work package aim: Provide a Human Tissue Authority licensed facility to prepare and deliver cell therapies for human use in clinical trials for neurodegenerative diseases.

Research Highlights

Year 3

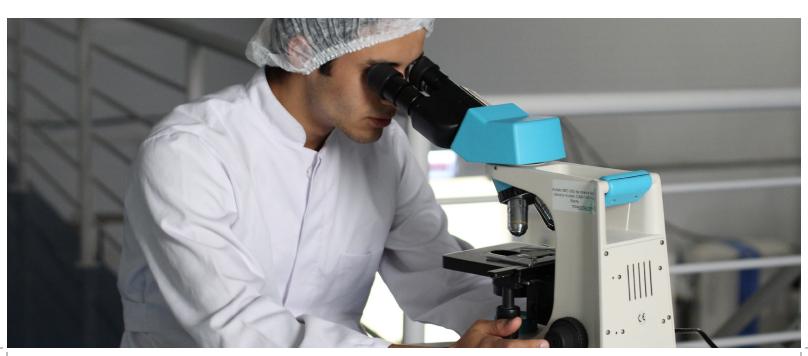
- The facility obtained funding to transplant
 5 Huntington's disease patients in Cardiff
 by 30 March 2018.
- These were the first human neural transplantations performed in Wales, using the Good Manufacturing Practice (GMP's) fetal tissue.
- Validation of tissue preparation for human use underway and on target to be ready for first surgery in the TRIal DEsigns for delivery of Novel Therapies for neurodegeneration (TRIDENT) trial.
- The Annual Governance committee for the GMP Facility was held on 17 May 2018 and the committee recorded its satisfaction with the management of the facility.

Key investigators: Professor Rosser, Professor Dunnett and Professor Li.



Going forward

Human fetal tissue transplantation in people with HD is a key element of our work plan, thus the human tissue collection and GMP facility are critical for this core element of our work and to the future of BRAIN. Moving forward the GMP facility will support transplantation up to March 2020 for grants including TRIDENT (see page 12).



Therapeutic Delivery

Work Package 2

Work package aim: Refine existing systems for effective delivery of cell therapy and other therapies into the human brain.

Key investigators: Professor Gray, Professor Rosser, Dr Feras Sharouf and Renishaw, a world leading engineering and scientific technology company.

Research Highlights

Year 3

- In August 2017, we appointed Dr Feras Sharouf who took over from Dr Joseph Merola's role as the BRAIN Unit's Clinical Research Fellow. Dr Sharouf is a Junior doctor and PhD researcher who was involved in setting up and delivering the cell transplantation trial in Huntington's disease (HD).
- We secured funding through 2 grants to undertake 5 transplantations in people with HD (Research for Public and Patient Benefit, RfPPB and Life Sciences Bridging Fund, LSBF).
- We prepared and completed the ethical applications required to support the clinical transplantation of fetal cells for Huntington's disease (TRIDENT).
- The LSBF project work has demonstrated that we are able to successfully deliver fetal cells for the treatment of neurological diseases and disorders using a CE marked device.

Going forward

- Dr Feras Sharouf has been awarded a PhD studentship to investigate the role of the inflammatory micro-environment on stem cell survival when used as a therapy for HD, continuing his work to ensure the successful delivery of cells in HD patients.
- Our study, TRIDENT, had ethics approved for the clinical transplantation of fetal cells for HD and will next identify and recruit potential HD participants for the study.
- After the completion of the LSBF project, we will now hold further discussions with Renishaw regarding a commercial development pathway for the device to deliver cells to the human brain.



MRI and Tissue Modelling of Cell and Drug Delivery

Work Package 3

Work Package aim: To utilize high resolution and microstructural MRI and PET scans to support accurate modelling of cell and drug delivery to the brain.

Key investigators: Professor Gray, Professor Jones, Shirin Davies, Research Associates Dr Messaritaki and Renishaw.

Research Highlights

Year 3

- Collaborations with UCL, Manchester University and Nottingham University instigated to test models.
- Carried out the first microstructural MR imaging in patients with HD and epilepsy.
- Pre-surgical functional imaging scans of epilepsy patients tested.
- Model for drug delivery further defined.
- Successful development of a CFD model that uses imaging to predict the drug spread in the brain at an individual patient level.
- Will begin validating models of drug and cell delivery to the brain by:
- Scanning patients with neurological conditions to test and adapt models in order to better predict the accuracy of drug and cell delivery in different disorders.
- Undertaking experimental validation using EMRIC scanners during convection enhanced delivery (CED) in animals (Life Sciences Bridging Fund, Professor Gray).



Dr Eirini Messaritaki

Going forward we plan to validate the computational fluid dynamics model by infusing gadolinium in animal brains or in phantoms that mimic the human brain microstructure. This is essential because it will give credibility to the model and its ability to produce reliable predictions for the drug concentration achieved through convection-enhanced delivery.

We also plan to run simulations to predict the drug distribution in brains affected by Huntington's and epilepsy. This is important because the microstructure of diseased brains is different to that of healthy ones, affecting the distribution of the drug in the brain extracellular space.

Neuroscience Research Unit

Work Package 4

Work Package aim: To establish a fully functional clinical research facility at the University Hospital Wales, Cardiff.

Research Highlights

Year 3

- The Neuroscience Research Unit (NRU) away day (12 October 2017) brought together staff (nurses, clinicians, finance and administration) to discuss the day to day running of the NRU and the development of a strategy for long term development.
- The BRAIN Connections meeting was an opportunity for staff from the Centre for Trials Research to outline support opportunities within the centre for neuroscience research.

IONIS

- IONIS launched in Wales in March 2017.
 We took part in the trial of an innovative drug, developed by Ionis Pharmaceuticals (based in the USA). The drug achieves this by a process called 'gene silencing' which works by stopping the generation of a toxic product called huntingtin, which causes the devastating disease.
- The drug is delivered through an injection into the spinal cord, so it can reach affected areas of the brain and therefore requires the expertise and resources that can be found in our 4 bed clinical research facility. This treatment is in hope of slowing down the progression of the symptoms of the disease, thus improving the lives of the people is affects.
- 2 participants with Huntington's disease were enrolled in the IONIS trial in 2017 and due to the success of this trial, these participants have now been recruited into an extension which will run for a further 18 months.

Key investigators: Dr Hamandi (NRU Director), Belinda Gunning (BRAIN Research Nurse Manager) and Research Nurses Joanne Bagshawe, Andy Davison and Rebecca Cousins.



Belinda Gunning

This has been an exciting year for the NRU.

Having an additional two nurses allowed us to increase our portfolio of both commercial and non-commercial studies.

Successfully participating in our first Phase 1 study has exemplified that we have the right infrastructure and support in place to carry out future trials of this kind.

The collaborative working between Cardiff and the Vale UHB, Cardiff University and CUBRIC, was key to its success.

Moving forward, increasing the nursing and administrative staff, as well as the recently appointed NRU research fellow, will allow us to grow our portfolio further; all in the hope of making a difference to patients suffering with debilitating conditions.



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Biobanking

Work Package 5

Work Package aim: Expansion of sample collection across neurological and neurodegenerative conditions in the Welsh Neurosciences Research Tissue Bank (WNRTB) Cardiff and Swansea Neuroscience Bank (SNB)

Key investigators: Professor Robertson, Professor Rees, Dr Loveless (BRAIN Biobanking officer, Cardiff) and Ms Fonferko-Shadrach (BRAIN Biobank Officers, Swansea).

BIOBANKING IN FIGURES



1,678
TISSUE SAMPLES USED



10,873 NEW TISSUE SAMPLES COLLECTED



88,846 TISSUE SAMPLES HELD





51 NEW SAMPLE REQUESTS

Research Highlights

Year 3

- To date we have exceeded our key performance indicators for sample Biobanking across WNRTB and SNB.
- Have exceeded 300 participants per year.
- To date there are 88,000 sample aliquots left in the bank with sample types including serum, plasma, CSF, blood and DNA.
- For the year April 2017-March 2018 WNRTB recruited 199
 patients and a further 95 for the epidemiology project,
 bringing the number of recruited patients to 294.
- Successful award of £15,000 from SREF towards a new refrigerated centrifuge and Olympus microscope both purchased in January 2018.
- 14 grants submitted within the group.
- Successful regrading of Dr Loveless from senior technician to lab manager. She will continue to be Biobank coordinator as part of her role.

Going forward

- WNRTB will merge sample and clinical databases into single formation system with a new bar code based storage system to increase the speed and accuracy of sample retrieval.
- SNB will collect 200 samples annually in addition to the 300 in epilepsy and rare neurological phenotypes.
- A second recruitment nurse began in Swansea and a third one due to start in September, so a large increase is expected in ascertainment for Swansea.



Work Package 6

Work package aim: Develop and implement a clinical research database system that supports clinical care and is integrated within BRAIN Biobanks and the NRU. Providing real time data capture that will also benefit NHS service delivery.

Key investigators: Professor Gray, Professor Robertson, Dr Wardle, Dr Hamandi and Dr Postans (BRAIN Computer programmer Research Associate)

Research Highlights

Year 3

- We have now delivered a fully operational Clinical Research Systems Database in routine use by NHS staff across South Wales in Multiple Sclerosis, Epilepsy and Parkinson's disease.
- We have tested the hand held technology for providing clinical trial patient information forms and showcased our progress at our Advancing Technology Workshop in September 2017.
- Ongoing database development across epilepsy and Parkinson patient cohorts.
- Our Electronic Patient Record system (EPR) supports clinical care, patient phenotyping and allows researchers to securely collaborate.
- The EPR supports both patient held and clinic based mobile devices, with a specific focus on capturing patient related outcome measures and as a patient monitoring test in Parkinson's disease clinics.

Supporting clinical networks and individual patient care Supporting clini

Electronic Patient Record (EPR) system

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Going forward

The extension period will allow us to continue to increase patient accrual into our clinical research databases and embed its use in routine clinical care across MS, epilepsy, PD and possibly HD, providing an increasingly valuable resource over time.

This period will allow us to roll-out the electronic patient record and research system to other health boards in Wales. In addition, we would be able to trial our existing PD patient-reported outcome measures smart device work to cohorts of patients with epilepsy and MS.

We have demonstrated the effectiveness of the platform and wish to enable wider usage for both clinical and research use across Wales.



Apple Research Kit-based IPad application



Work Package 7

Work package aim: To support the generation of pre-clinical grade cell therapies, drug development and evaluation of biologically active molecules for potential therapeutic use.

Key investigators: Professor Gray, Professor Rosser, Professor Barde, Professor Li, Professor Rees, Professor J Morgan and Dr Chloe Ormonde (Stem Cell Technician).

Research Highlights

Year 3

- The Neuroscience Research Unit (NRU) was used as a site for the first ever commercial trial using a 'gene silencing' drug in people with Huntington's disease in the Phase 1 IONIS trial.
- Collaboration with Zebra Biologicals testing against antibodies across a number of disease models.
- Discussions have began with Professors
 Attack and Ward in the new Drug Discovery
 Institute.
- Repair HD has generated a research grade cell line for future translational cell therapy in patients with Huntington's disease.
- BRAIN hosted a stand at the REPAIR HD public lecture held at the Pierhead, Cardiff Bay. This event was to showcase the work being undertaken by the FP7 EU consortium in developing stem cell therapies for Huntington's Disease.
- A successful first meeting took place in California at the stem cell therapies for HD conference. The aim was to establish an international network called Stem Cells for Huntington's disease (SC4HD).
- Our Fluoxetine, Learning and Memory in Epilepsy (FLAME) clinical trial has been testing the clinical effectiveness of a cheap and widely available drug to combat learning and memory problems in people living with temporal lobe epilepsy (TLE).



Neuroscience Research Unit



Going forward

- Ongoing work with Zebra Biologics including further meetings in 2018.
- We will be working collaboratively with the newly established Drug Discovery Institute on novel glutamateric agonists in brain plasticity and learning & memory.
- The FLAME study has been extended until Autumn 2018.

Trial Design, Evaluation & Patient

Monitoring

Work Package 8

Work package aim: To develop more accurate and reliable testing of mobility and cognitive dysfunction across trials, through developing novel clinic based and remote monitoring.

Key investigators: Professor Busse, Professor Rosser, Dr McLauchlin, Dr Eslambochilar, Dr Wardle, Dr Lane, Dr Hamandi, Dr Postans (BRAIN Computer programmer Research Associate) and **Professor Gray**



C3t demonstrations at the modernising assessments event

Research Highlights

Year 3

18

- Through REPAIR-HD, Professors Rosser and Busse developed a novel dual task functional assessment (Clinch Token Transfer Test: C3t).
- With MRC funding they are in the process of developing a C3t commercial prototype version.
- In September 2017 we hosted an open day to showcase the work within the BRAIN Unit developing novel ways of assessing conditions in clinical neuroscience. The event, 'Modernising assessments in clinical neurosciences was attended by 60 people.



Modernising assessments in clinical neuroscience event which consisted of a mixture of talks and interactive stands.

Professor Busse

We have progressed the C3t work and there are now license agreements in place with KU Leuven in Belgium and Columbia University NY for validation to be extended to Parkinson's disease.

A major focus of the last year has been the completion of recruitment to the CAPIT-HD2 study which was part of the EU funded REPAIR-HD programme.

We have also now completed the recruitment for the iWEAR study and data analyses is ongoing.

Going forward we will continue to develop and test our novel assessment tools, which will be critical for informing clinically relevant outcomes in intervention studies. However we will extend this program to include more work on trial design.

Through our increasing experience of funded clinical trials within BRAIN, we have come to realise that complex interventions have similar critical features in common that require a fresh approach to trial design. This will include all necessary activities related to development and evaluation of complex interventions to broaden our expertise and to expand our ability to translate novel interventions into clinical practise.

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Public Involvement

Work Package 9

Key investigators: Dr Emma Lane and Dr Cassy Ashman

We believe that active involvement from members of the public leads to research that is more relevant and more reliable.

To embed this core belief into the structure of the unit we have developed a patient and public involvement group called BRAIN Involve, comprised of people who are, or have been, affected by neurological diseases.

Through members bringing their personal experiences to the research table, they contribute enormously to BRAIN's wider work by helping to inform and develop research ideas.

Want to get involved?

Become a member or for more information, please email: brainunit@cardiff.ac.uk

BRAIN involve



15 PUBLIC INVOLVEMENT ACTIVITIES



2 MEMBERS GRANT CO-APPLICANTS

SUPPORTED 3
ADVISORY PANEL
REQUESTS TO
RECRUIT PI
MEMBERS

Meet Astrid

Astrid Burrell's husband had Huntington's Disease for over 30 years and she now finds it very fulfilling to have the opportunity to put her experience to good use as a member of BRAIN Involve.

After six and a half years of working with Cardiff HD researchers, I am currently the PPI member on the Trial Management Group for TRIDENT. I have learned so much at our monthly meetings, about the enormous complexity of setting up this trial. I've seen first hand, the dedication and thoroughness of the brilliant team. It is so exciting to have been involved from the very start and I feel privileged to be playing a small part in such an important trial. ??





Work Package 9



Dr Emma Lane delivering a talk at the Parkinson's UK Research Roadshow event.

Events & Collaborations

Over the past year we have been involved in hosting many events, collaborating with other related organisations and have developed a wide variety of engagement activities. Sunday 18 March saw one of our most successful engagement activities, the annual Brain Games, taking over the National Museum Cardiff. Organised by neuroscience researchers across the university, it consisted of a day of interactive games aimed to increase public awareness of brain research, from sensory illusions and inflatable brain domes to giant genes and DIY Brain Surgery.

Another huge success was our collaboration with the Parkinson's UK, Cardiff Research Roadshow. A UK wide event, inviting patients and family members to hear about exciting research taking place and providing information on how involvement in research could help move towards better treatments. The day consisted of a mixture of talks and more intimate table discussions which allowed patients to ask questions; combining public engagement activities with patient involvement proved a huge success.



Work Package 9

'Bri the Brain' is one of our most popular public engagement props. Often seen at conferences, public lectures, and the annual Brain Games at the National Museum Cardiff. Here, Richard Rogers from the School of Engineering at Cardiff University, talks through the process of making one of the Unit's most engaging games.

Meet Richard Rogers and 'Bri the Brain'

I was asked if I would be willing to help produce an 'Operation' style game to help with engagement activities.

The original design brief was for a 3D printed tray that held the game. After a bit of research it was clear that 3D printing was not the best way forward with this project. I came up with the idea of laser cutting layers of acrylic that when laid on top of each other would create a 3D representation of a life sized head and the game could sit inside it.

The buzzer was replaced with a speech module, amplifier and speaker system so that Bri the brain could actually speak.

It was a lot of hard work using manufacture techniques that I had never used before and finding new solutions, but it was also great fun. Since Bri the brain, I have used the same methods to make a mouse model, Dr. Stu Little for the Infection and Immunity team.



Richard Rogers



Bri the Brain at this year's annual Brain Games.

Outcomes & Impact

KEY ACHIEVEMENTS

113 Peer reviewed papers including Nature Biotechnology impact factor (IF)- 41.7, Nature Reviews Neuroscience IF- 29 and Science IF- 37.2

More than £3 million total grant income to Wales

Approximately
4,254 public
members attended
our events

Funding secured to undertake 5 cell transplantations in patients with HD

Received 46
Research Awards

2 patients with HD enrolled onto international IONIS trial Established an international network- Stem Cells for HD (SC4HD)



Conclusion

The third year of the BRAIN Unit has been a particular rewarding one; seeing lots of major achievements not only in the progression of our work packages, but also in solidifying ourselves in the scientific, NHS and public communities; locally, nationally and internationally.

Examples of this can been seen in our ever successful Brain Games event, welcoming over 3000 members of the public, returning year after year, to learn more about neuroscience and more specifically the neuroscience we do in Cardiff to help find cures for neurodegenerative and neurological disorders. A particular highlight this year saw our directors and members of the BRAIN Unit travel to California for the first meeting to establish an international network called Stem Cells for Huntington's disease (SC4HD). The outcomes of this meeting will feed into our forward planning for the BRAIN Unit.

We have seen fantastic, promising results in our collaborative project with Renishaw, demonstrating our ability deliver fetal cells into the brain of rat and pig models, using a CE marked device. Commercially, this work highlights the importance of continued active engagement with industry partners.

Our Neuroscience Research Unit has grown from strength to strength successfully enrolling 2 participants onto the multi-site world-wide IONIS clinical trial to treat Huntington's diseases with a new 'gene silencing' drug. This trial was so successful it received national and international acclaim, (www.bbc.co.uk/news/health-42308341), and has now been extended, requiring the use of our facility for a further 18 months.

Year 3 has also seen several changes, with our new Research Manager, Dr Cassy Ashman and new Clinical Research Fellow, Dr Feras Sharouf joining us, bringing fresh ideas and expertise to the Unit.

Looking to the year ahead, our main focus will be on the strategic planning of the BRAIN Unit's direction for the future. Our BRAIN Connections meeting is to be held in September 2018 working with our diverse membership to co-produce and develop the BRAIN Unit, in preparation for the 2020 bid and beyond.







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