

2022-23 Annual report

Ymchwil lechyd a Gofal Cymru Health and Care Research Wales



Ariennir gan Lywodraeth Cymru Funded by Welsh Government



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Foreword

I am pleased to present our 2022-23 annual report reflecting on the achievements of the BRAIN Unit over the past year.

I am also delighted to welcome several new members to our team including:

- Senior technician, Thomas Brown
- Clinical Research Fellow, Susruta Manivannan who will support our ongoing collaborations in Advanced Therapeutics Medical Product delivery research
- Research associate, Francesco Bedogni who will support our living human brain tissue lab and research.

We bid a fond farewell to:

- Clare Anderson who was the BRAIN Unit's administrator for 4 years
- Benjamin Dummer who has taken up a post-doctoral research position at the University of Miami
- Neurosurgical trainee and Cardiff University clinical lecturer, Dr Malik Zaben, who has been appointed as Dean of Medicine at the Arab American University of Jenin
- Clinical Research Fellow, Dr Feras Sharouf will take up his national training post in neurosurgery at the Walton Neurosciences Centre in Liverpool
- Dr Rob Spencer, our Neuro-oncology Clinical Research Fellow was also successful at National Selection and started in Cardiff last autumn.

We continue to make progress with our Advanced Therapies work and were delighted to receive funding from Advanced Therapies Wales to support the development work behind our vision to create an internationally recognised Centre of Excellence for the delivery of advanced therapeutics to the brain. In addition to this we have successfully delivered the UniQure trial to the first cohort of patients in the UK and are about to start the second cohort in June (see page 9).

I would like to thank all of the BRAIN Unit members, staff and administrative team for their commitment to the work of the BRAIN Unit and hope that you enjoy reading this report.



Professor William Gray BRAIN Unit Director



The Team

Director Professor William Gray

Deputy Director

Professor Anne Rosser

Work Package Leads

Professor Neil Robertson Professor Owain Howell Professor Khalid Hamandi Dr Emma Lane Dr Cheney Drew Peter Roberts

Neuroscience Research Unit*

Belinda Gunning Dr Mohamed Mustafa Dr Zin Min Htet Dr Sai Ambati Dr Magdalene Randa Dr Karim Kreft Cynthia Butcher Alison Johnson Rajimol Sibichen Megan Voisey Dympna McAleer Elizabeth Perreira

Clinical Research Fellows

Dr Dmitri Sastin* Mr Susruta Manivannan* Dr Robert Spencer Mr Harsh Bhatt* Dr Ronak Ved*

Laboratory Team

Dr Samantha Loveless* Dr Anne-Marie McGorrian* Dr Ben Dummer Dr Francesco Bedogni Dr Chloe Ormonde Dr Valerie Anderson* Dr Lauren Griffiths Thomas Brown

Administration

Jo Baker Clare Anderson Victoria Saunders* Catrin Hopkins* Julia Pearce*

*These posts receive funding from other sources including MRC, Brain Research UK and Guarantors of Brain.

Introduction

Funded by Welsh Government via the Health and Care Research Wales infrastructure, the Brain Repair and Intracranial Neurotherapeutics (BRAIN) is a research unit developing novel therapeutics and treatment delivery systems for neurological conditions.

BRAIN is a multi-disciplinary research unit with strong academic and NHS clinical leadership, operating under the directorship of Professor William Gray along with 24 principal investigators and collaborators. Since 2015, the Unit has received a total grant income of over £50m.

The BRAIN Unit is primarily based in Cardiff but involves research groups from Swansea University and health boards across South Wales. Our work is informed by individuals who are affected by neurological conditions in Wales; The Wales Neurological Alliance (WNA) forum sit on both the BRAIN and BRAIN Involve executive boards and continue to support activities with farreaching membership and input.



Our mission

Our mission is to be a UK national centre of excellence, and on a path towards international leadership for:

- Delivering novel cell/gene/small molecules and other pioneering complex therapies to the human brain
- Supporting translational research, underpinning disease modification and brain repair in patients with neurological conditions.

Our aims

We have the following aims:

- Develop new and refine existing systems for therapeutics delivery into the human brain
- Develop appropriate infrastructure for:
 - Advance adult and fetal brain tissue resources, supporting translational research and therapy validation across neurological diseases
 - Bio-banking and bio-resource management using linked and deeply phenotyped clinical data
- Consolidate and extend appropriate clinical trials and expertise, including refinement of appropriate methodologies for evaluating novel complex interventions
- Embed cross-cutting excellence in the relation to:
 - Public and Patient Involvement and Engagement
 - Industry and NHS Engagement and Collaboration.

Work Packages and Cross Cutting Themes

Cross Cutting Theme: NHS, Commercial and Industry Engagement

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Research Programmes

WP4

WP5

WP1 Intracranial Delivery

Providing human adult neural tissue to model disease + validate novel therapies

WP2

Welsh Neuroscience **Research Tissue Bank** (WNRTB) + Swansea **Neurology Biobank** (SNB)

WP3

Neurosciences **Research Unit** (NRU)

Patient and Public Involvement + Engagement

Cross Cutting Theme: WP5 PPI and Engagement

Glossary

- In vitro- (Latin for "in the glass") studies performed with microorganisms, cells, or biological molecules outside their normal biological context.
- Stem Cell- Cells of the body (somatic cells) that can divide and become differentiated. When an organism grows, stem cells specialize, and take specific functions. For instance, mature tissues like skin, muscle, blood, bone, liver, nerves, all have different types of cells.
- Advanced therapy medicinal products (ATMPs)- are medicines for human use that are based on genes, tissues, or cells. They offer ground-breaking new opportunities for the treatment of disease and injury.

- Neurotherapeutics- The treatment of disorders that affect the nervous system.
- Striatum- The striatum or corpus striatum (also called the neostriatum (a cluster of neurons) in the subcortical basal ganglia of the forebrain. The striatum is a critical component of the motor (movement) and reward (pleasure) systems.
- **Hippocampus** The hippocampus (Greek for "seahorse") is a major component of the brain of humans and other vertebrates. Humans and other mammals have two hippocampi, one on each side of the brain. The hippocampus is part of the limbic system and plays important roles in the consolidation of information from short-term memory to long-term memory, and in spatial memory that enables navigation.

- Intracranial- Within the skull.
- Cerebrospinal fluid (CSF)- is a clear, colourless body fluid found in the brain and spinal cord.
- and the striate nucleus) is a nucleus Peripheral blood mononuclear cell (PBMC)- is any peripheral blood cell having a round nucleus. These cells consist of lymphocytes (T cells, B cells, NK cells) and monocytes.
 - Neurogenesis- is the process by which nervous system cells, the neurons, are produced by neural stem cells (NSC).
 - AMPAKine molecules- A subgroup of AMPA receptor modulators currently being investigated as potential treatments for a range of conditions involving neurological and psychiatric disorders.

Core Metrics Reporting period: 2022/2023

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	11	6
Value	£1.8m	£2.2m
Funding to Wales	£1.8m	£2m
Funding to group	£1.4 m	£0
Additional jobs created for Wales	5.7	9.9
Additional jobs created for group	5	0





Ymchwil Iechyd a Gofal Cymru Health and Care Research Wales



Intracranial Delivery

Work package aim: We are on the cusp of a new era of potential disease-modifying therapies for neurodegeneration, with many of the most promising requiring direct delivery into the central nervous system. Despite this, there are no optimised devices or protocols for delivering therapies directly to the human brain.

Our objectives are to:

- 1. Address this unmet need relating to delivery devices and expertise.
- 2. Establish Cardiff as a major international centre for delivering advanced therapies to the human brain.

Work package leads: Professor William Gray and Professor Anne Rosser

We are delighted to have successfully delivered the UniQure Phase I/II gene therapy trial focussing on knocking down Huntington protein production within neurons in Huntington's Disease, to three patients in Cardiff. This gene therapy is potentially curative or significantly slowing disease progression in this fatal neurodegenerative disease.

Early results are encouraging and if replicated in the ongoing study will represent a major advance in the treatment of this devastating neurological disease **bit.ly/uniQure**.

As well as being a cutting-edge Gene Therapy, its delivery is minimally invasive, with the complete operative procedure taking place within an MRI scanner so that the delivery targeting can be monitored and performed safely in real-time.

This trial will allow people in Wales access to access innovative Advanced Medicinal Therapeutic Medicinal Products (ATMPs), a core objective of Health & Care Research Wales and of our BRAIN Unit. Given the advanced nature of the neurosurgical techniques involved, this trial will be delivered via our Neurosciences Research Unit (NRU) at University Hospital Wales but

will be open to participants across Wales and the UK.

We are currently screening an additional three people to continue the trial. Participants in the UK cohort are also referred from University College London (UCL) as we are the only surgical site in the UK with the MRI stereotaxis delivery system.

The images taken during the UniQure trial have allowed us to 3D model the infusion delivery, to investigate how the gene therapy is distributed to further improve therapy delivery and device design in future trials.



This image shows the distribution of gene therapy (yellow) during delivery into the Anterior Putamen (purple) and Caudate nuclei (blue) on the right and left sides of the brain during surgery.

Providing human adult neural tissue to model disease and validate novel therapies

Work package aim: To support and expand a previously funded unique human adult (hA) tissue facility to perform 2D & 3D culturing of primary brain tissue (Gray, Zaben), for disease modelling and extend this to developing 3D cultures to support brain tumour research.

Work package lead: Professor William Gray

We have been pleased to see the outcomes of our collaborative work within the human tissue research lab resulting in grant income for our collaborators. It has been really encouraging to see tissue harvested from patients undergoing neurosurgery being used in a multitude of ways, supporting patients with different diseases, such as cancer, brain tumours and dementia.

This past year has been successful for collaborative grants using human and adult neural tissue including:

- Dr. F Siebzehnrubl was awarded a £1.6M grant from the Medical Research Council for the proteostatic regulation of glioblastoma stemness
- Professor Alan Parker was awarded a £149, 835 grant from Cancer Research Wales for the development of a precision virotherapy for glioblastoma multiforme (GBM)
- Professor Derek Jones and co-applicants Professors Gray and Hamandi were awarded £1.2M from the Medical Research Council (MRC) to examine the microstructure of human brain in epilepsy using both advanced MRI and histology on human brain tissue.

Dr F Siebzehnrubl

Our project investigates differences in proteins between more aggressive and less aggressive glioblastoma cells to find new ways for treating glioblastoma by stopping more aggressive cells from growing.

We want to understand how protein production is conducted in each glioblastoma cell type, and we will combine different ways of investigating proteins inside glioblastoma cells.

As part of this study, we are using a new type of microscope for measuring protein amounts inside glioblastoma cell types and this is exciting because this technology has the potential to readily identify more aggressive glioblastoma cells, with increased sensitivity and quicker than ever before.

We will test this in living human patient material, provided by the BRAIN Unit to evaluate its diagnostic/prognostic value. This new technology could help other scientists and clinicians in the future by making it easier to identify and study more aggressive cancer cells.

Dr Alan Parker

Our funding from Cancer Research Wales focusses on the development and assessment of "smart viruses" engineered to only recognise and infect glioma (brain cancer) cells.

Once inside glioma cells, these viruses replicate and eventually burst the glioma cell, spreading daughter virions to surrounding cells to repeat the process. To make them even more effective, we alter the viral DNA further so that they additionally force the infected cells to produce anti-cancer immunotherapies. These medicines, produced by infected glioma cells, signal to immune cells to recognise and kill the tumour cells.

So far, we have only been able to test these "smart viruses" in commercially available cell lines, which – whilst useful – fail to recreate the complexity of primary patient tumours. Our new funding will allow us to test how well these agents work in material immediately derived from patients undergoing glioma resection, which is surgically removed and processed by the human tissue team at the BRAIN Unit. This represents the most relevant pre-clinical model we can use before progressing towards clinical trials in patients.



The figure shows cells infected with either unmodified virus or a glioma selective "smart virus" infecting cells either from conventional cell lines (top), or more complex, patient derived samples, directly isolated from patients undergoing resection of their brain cancer. When cells are infected, they produce a green protein called GFP, which we can observe under fluorescence light.

Professor Derek Jones

With our MRC funded collaboration with Professors Gray & Hamandi, Dr Marco Palombo and investigators at UCL and in the USA, we are examining the microstructure of human brain in patients with focal cortical dysplasias using both advanced MRI and histology on human brain tissue. This will help us to develop new MRC scanning sequences to reveal lesions currently invisible to clinical MRI for patients being worked up for epilepsy surgery. We look forward to updating you in the next report with progress on this exciting collaboration.

Biobanking

Work package aim:	To develop and expand our comprehensive bio-resources of clinical and biological data to facilitate translational, and clinical research across a wide range of neurological diseases, allowing efficient participant engagement and recruitment to study-ready cohorts.
Work package lead:	Professor Neil Robertson (Welsh Neuroscience Research Tissue Bank - WNRTB) & Professor Owain Howell (Swansea Neurology Biobank - SNB)

Cardiff

Overall, recruitment for 2022-2023 has been very successful, and we are now back to prepandemic levels.

Over the last year, we have consented 57 individuals to the WNRTB and 191 to SNOWDONIA^{*}, totalling 248. There have been 13 tissue applications, of which 12 have been approved to date. We have supplied 13 projects with samples (896 aliquots) for their research, some are on-going fresh sample collections, approved in previous reporting periods.

We are pleased that we have several papers referencing biobank samples in the pipeline. Other external sample cohorts are in the process of being imported to the biobank for future studies (DREAMs, DELIVER, DECISIVE).

In total since the WNRTB began (in 2014), we have had 82 applications for biological samples, from 48 collaborations and 80 of these have been approved. In total, 13087 sample aliquots have been requested, of which 7122 had been supplied by the end of March 2023.

*SNOWDONIA is an epidemiology for Multiple Sclerosis study and participants are consented to this with the option of depositing half of their samples to the WNRTB.



Swansea

We were pleased that the biobank ethical approval was successful and the new REC approval extends until 2027. Samples from the Swansea Neurology Bank (SNB) have contributed to international studies and supported 3 new studies this year through the provision of 200 individual patient samples.

The BRAIN co-funded laboratory scientist, Dr Lauren Griffiths has contributed key data to a number of grant funding applications and is enabling a number of new and important collaborative projects with other UK and international partners. The BRAIN sponsored post has supported the continued growth of neuroscience research capacity and capability in the region.

For example, Swansea researchers supported by BRAIN, have been successful in capturing £2.49 million in grant income this year. This represents an excellent return on the BRAIN investment in Swansea neurosciences. Grants awarded include significant funds from the MRC to support lipidomics and a new pan-UK collaboration (led by Swansea and involving University College London, Manchester and Cardiff) under the UK Rare Diseases platform. Specifically, the project, led by Professor William Griffiths at Swansea University Medical School, will bring expertise from the UK lipidomic/metabolomic community into the domain of rare disease diagnosis to translate the latest knowledge and methods from research settings to the clinical laboratory to accelerate and improve patient care and monitoring.

Other studies supported by the laboratory scientist include the first nation-wide quantitative neuropathology and linked genetic analysis of multiple sclerosis and two new projects with European partners, investigating the nature of the immune response that is locked in the multiple sclerosis brain and which is not affected by current treatments.

Other studies include ongoing collaborations with Sorbonne University and a biomarker study in collaboration with the Cardiff Biobank. The BRAIN laboratory scientist has also supported the initiation of a new Academy of Medical Sciences/ MRC Springboard Fellowship project (the first such lab-based project awarded to a Swansea Investigator) in the department and is currently working with collaborators at the Dementia Research Institute at Cardiff to transfer cutting edge techniques in human cell cultures to Swansea University.



Neurosciences Research Unit (NRU)

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The Neurosciences Research Unit (NRU), based in Cardiff and Vale UHB, is led by Professor Khalid Hamandi (consultant neurologist) and Belinda Gunning (Nurse manager). Three additional studies to those listed below are due to open imminently with another four currently in the set-up process.

Motor Neurone Disease studies



Principal Investigator: Dr Ken Dawson **Sponsors**: University of Edinburgh

Motor Neurone Disease Smart: Motor Neurone Disease Systematic Multi-arm adaptive randomised trial

- Opened in January 2022
- The first MND multi-arm adaptative randomised study in Wales, in a disease area with great clinical need and expanding therapeutic trials.

Huntington's Disease studies



Principal Investigator: Professor Liam Gray **Sponsors:** uniQure biopharma B.V

HD GeneTRX2: A Phase Ib/II study to explore safety, tolerability, and efficacy signals of multiple ascending doses of striatally-administered rAAV5-miHTT total Huntingtin gene (HTT) lowering therapy (AMT-130) in Early Manifest Huntington Disease. participants randomised so far and further three booked in for screening

further patients in screening and **third and fourth surgeries** planned for June 2022

Multiple Sclerosis studies



Principal Investigator: Dr Emma Tallantyre **Sponsors**: Queen Mary University of London

ChariotMS – A national, multi-centre, randomised, double-blind, placebo-controlled phase IIb efficacy trial with cost-utility analysis of cladribine tablets in people with advanced multiple sclerosis. Is cladribine superior to placebo in protecting upper limb function? patients screened since screening began in March 2022

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Patient and Public Involvement and Engagement (PPI)

Work package aim: To continue our work on PPI and engagement with patients, the public, the third sector, NHS and Industry.

Work package lead: Dr Emma Lane, Dr Chenev Drew and Mr Peter Roberts

As we move away from the challenges of COVID we have been able to harness the benefits of online tools and reimagine our involvement and engagement delivery.

Our Brain Involve group continues to meet online and this has enabled geographical spread across Wales and plans are ongoing for face-to-face activities in the coming year. Our Brain Involve team have informed and supported grant and fellowship applications for senior scientists and early career researchers.

From Brownies and Cubs, to people living with neurodegenerative diseases in the UK and abroad, our face-to-face engagement programme has made a welcome return. One of our biggest events was a full day of activities delivered to over 300 pupils at two local primary schools.

This formed part of the Radyr and Morganstown Festival and had huge support from Headway Cardiff, a brain injury charity. Everyone got involved in learning about the brain, testing their own brains, brain surgery assemblies and having a bounce on the inflatable brain! Year 6 pupils also produced some beautifully creative pictures and poems inspired by our day and the resources created have now been used in other primary schools.

We have also engaged heavily with the patient community. We have become a

driving force, ensuring that patient voices are regularly heard at the Network for European CNS Transplantation and Restoration (NECTAR) conference held this year in Athens in 2022, organising sessions that allow patients to share their voice directly with scientists.

In November, we held a Huntington's disease patient and family day, bringing the patient, clinical and scientific communities together to share the research that is going on. Our engagement enables us to build trust with our local communities to then create positive involvement, working with people living with neurodegenerative diseases to shape and inform our science.

One example of our involvement activities this year has been focus groups conducted with people living with multiple sclerosis, discussing their thoughts on genetic testing and their prognosis. We have also worked closely with people with Parkinson's to create resources to support their participation in clinical trials.



Meet the Researcher

Susruta Manivannan

Clinical Research Fellow at Cardiff University

As a Clinical Research Fellow in Neurosurgery, Susruta is working on identifying strategies for optimising the effective delivery of cell and gene-therapies to the brain, under the supervision of Professor Liam Gray.

About me

I am a neurosurgical trainee currently taking time out of my programme to develop my academic training with the BRAIN Unit.

I was keen to return to BRAIN's excellent environment for translational neurosurgical research, having completed my undergraduate and early-postgraduate medical training at Cardiff University.

The research

Cell and gene-based therapies, collectively known as advanced therapy medicinal products (ATMPs), are expected to revolutionise the treatment of neurological disorders in the upcoming future.

Following decades of pre-clinical investigation, we are at an exciting transition towards ATMPs entering clinical transplantation trials for debilitating neurological disorders such as Huntington's Disease (HD), Parkinson's Disease (PD) and temporal lobe epilepsy (TLE). In such diseases, ATMPs must be delivered surgically to specific targets within the brain.

Initially considered to be a trivial problem, achieving effective direct delivery is now recognised as a significant obstacle to treatment success. This is due to the hostile micro-environment arising from a complex combination of surgical delivery, the preexisting disease, and the patient's immune response to ATMPs.

Our research^{*} is focused on understanding how these inter-related factors can be modified to ensure that ATMP efficacy is maximised. This will require investigation using a series of different models.

Firstly, we will use a transgenic HD model to identify pro-inflammatory cell signalling pathways that are activated after surgical delivery procedures. We can then study the effects of modifying signalling pathways anticipated to have negative effects on ATMP success.

Secondly, we will use an established threedimensional cell culture model ('Hi Spot® model'), generated from human brain tissue collected from patients undergoing specific neurosurgical procedures. Comparing ATMP delivery in 'control' cortical Hi Spots with sclerotic hippocampal Hi Spots can provide valuable insight into the innate immune response to ATMPs in the inflamed microenvironment.

Research implications

We anticipate that this work will answer crucial questions regarding the 'science of ATMP delivery' and pave the way towards more successful treatment of currently incurable neurological disorders in the upcoming era of regenerative neuroscience.

*Funded by Guarantors of Brain



Spotlight on Patient voice in advanced therapies

Underpinning science is, of course, key to developing new therapies but a critical voice that plays as much of a part, is that of the patients themselves. Public and Patient Involvement and Engagement (PPIE) is a very broad phrase that covers a range of activities.

Participation in research is the act of being a trial subject, giving your information to the trial team, whilst engagement can be seen as the reversal of that, as researchers share their findings with patients or the public.

Involvement, however, is a more bidirectional exchange of information, as people living with disease work alongside researchers to guide the research or clinical trial, bringing their unique understandings together to provide a more effective pathway to delivering successful research.

Public patient involvement of those with lived experiences can, and indeed should, be part of the whole pipeline of advanced therapy development.

Cardiff has been leading the way on the patient voice in cell and gene therapy. This starting with extensive patient involvement in the design of the TRIDENT cell transplantation trial in Huntington's disease and the embedding of a process evaluation within the trial design, interviewing trial participants and staff about their experiences through the trial.

We have successfully obtained funding to interview people with Parkinson's who participated in neurosurgical trials in Parkinson's disease. This knowledge is then used to create resources that will support future trial participants as they consider trial participation in advanced therapies. This is also being used to determine how best to support trial participants as they go through the rigours of a challenging trial.

As part of our work to support widening knowledge of cell and gene therapies, Cardiff University and the BRAIN Unit are partners in the EuroGCT project, providing reliable and accessible information on the use of cell and gene therapies for the public, patients and researchers. www.eurogct.org

Both engagement and involvement are essential ingredients to effectively support informed participation in trials and at the BRAIN Unit, we are committed to listening to the patient voice at all levels of research.



Conclusion

As I reflect on another busy year for the BRAIN Unit and its collaborators, I am proud of what we continue to achieve together. The patient experience will always be at the heart of what we do and while the team are ensuring it is directly impactful for the advanced therapies work, it is also opening a new research area to be explored in and of itself.

Over the next year, we will continue talks with sponsors of groundbreaking Advanced Therapies trials and push forward with our plans for the dedicated facility to run these trials at maximum capacity and be a leading centre for research and innovation in delivery science. This will also allow us to expand our research across a range of neurological disorders, identifying the key factors which are fundamental to the success or failure of a novel advanced therapy.

We are currently in discussion with the sponsors of a significant trial to access the images taken during the global trial and analyse them to better quantify and model therapy delivery. With funding from the European Huntington's Disease Network, we are also working with neurosurgeons across Europe and the USA, and public and patient involvement and engagement groups, to share surgeon and patient experiences of gene and cell therapy delivery to identify key challenges and foster collaborative research.

We look forward to continuing our collaborative research, some of which is detailed on pages 10 and 11, and in collaboration with other UK and EU neurosurgical centres, are planning a major grant application to MRC to more fully utilise living human brain tissue, necessarily removed during neurosurgery, for wider neuroscience research. We continue to nurture the future generation of research active clinicians in neurosciences, with fellowships being secured and more in the pipeline.

A large focus of the upcoming year will be targeted funding calls, building on work that has been progressed over the past few years. Importantly, we will be applying for further funding of the BRAIN Unit to take us beyond 2025. Funding from Health and Care Research Wales is uniquely important for allowing us to bring together parts of the neurological and neurosciences communities under one umbrella, supported by a team of core staff, to progress research into neurological diseases that currently have little or no treatments and very poor outcomes.

Professor William Gray

BRAIN Unit Director



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