Title: Shaping the future of European epilepsy research: final meeting report from EPICLUSTER

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Abstract  Collaboration is essential to the conduct of basic, applied and clinical research and its translation into the technologies and treatments urgently needed to improve the lives of people living with brain diseases and the health professionals who care for them. EPICLUSTER was formed in 2019 by the European Brain Research Area (EBRA) to support the coordination of epilepsy research in Europe. A key objective was to provide a platform to discuss shared research priorities by bringing together scientists and clinicians with multiple stakeholders including patient organisations and industry and the networks and infrastructures that provide healthcare and support research. Additional objectives were to facilitate access and sharing of data and biosamples, working together to ensure epilepsy is a priority for research funding, and embedding a culture of public and patient involvement (PPI) among epilepsy researchers. In this meeting report, we summarise the shared research priorities discussed by the leadership of EPICLUSTER at the recent final meeting. We also briefly review the discussion on patient and industry priorities, guidance on starting PPI for epilepsy researchers, and the sustainability of funding and infrastructures needed to ensure a comprehensive stakeholder-embedded community for epilepsy research.

Keywords: Research agenda; Brain; Diagnosis; Epilepsy; Horizon Europe; Public Patient Involvement; Stakeholders; Therapeutics
1.1. Introduction

The European Brain Research Area (EBRA) was established by the Horizon 2020 programme as a Coordination and Support Action led by the European Brain Council (EBC). The objective was to bring together brain research communities in Europe to avoid fragmentation and duplication of efforts, create connections, improve coordination and ensure multi-stakeholder involvement in agreeing and setting research agendas. One of the mechanisms used was to establish “clusters” where shared disease or topic-specific research priorities could be developed through meetings, workshops and coordination activities. The first cluster to be funded was EPICLUSTER. This report provides an overview of the fourth and final EBRA-supported activity of EPICLUSTER.

EPICLUSTER was established in 2019 to enhance the coordination and avoid fragmentation and duplication of epilepsy research in Europe and to guide future research priorities. EPICLUSTER brought together various large-scale current and former epilepsy projects that first joined forces at the EpiXchange meeting in 2018 (Pitkanen et al., 2019). A follow-up event, EpiXchange II, was held in 2020 (Henshall et al., 2021). EPICLUSTER expanded the EpiXchange community to include representatives from the EpiCARE network and the International League Against Epilepsy (ILAE) and International Bureau for Epilepsy (IBE) as well as leading figures in industry and key opinion leaders in the field. The main objectives were to:

• Provide a platform to identify shared research priorities and accelerate translation.
• Facilitate access and sharing of research infrastructures including data and biosamples.
• Embed a culture of PPI among epilepsy researchers, particularly basic scientists.
• Work together to ensure epilepsy is a priority for research funding.

The focus of the final meeting of EPICLUSTER was to look to the future and ask what are our research priorities and how we can improve the way we do our research. This complements other initiatives from the European epilepsy community (Council, 2022; Pitkanen et al., 2019), and community priority-setting exercises such as the NINDS-led Epilepsy Benchmarks (Binder et al., 2020; Chang et al., 2020; Jones et al., 2020; Traynelis et al., 2020).

1.2. Background to the event – changing the landscape of European epilepsy research

The World Health Organisation (WHO) ranks epilepsy among the most burdensome neurologic disorders with an estimated 0.56% of the global burden of disability adjusted life years (DALYs)
globally (Collaborators, 2019a; Collaborators, 2019b). Seizures contribute to burden by harming health, through premature mortality and by causing disability. Epilepsy annually contributes to 13.5 million disability-adjusted life-years (DALYs), a rate similar to that for schizophrenia and several times the rate for Parkinson’s disease (Charlson et al., 2018; Collaborators, 2019b). Drug-resistant epilepsy is the major contributor to economic costs due to healthcare, outpatient and emergency department admissions, side effects of treatment, as well as indirect costs from loss of productivity.

The epilepsy research community shares a commitment and responsibility to improve the lives of people with epilepsy, supporting their families and the health professionals who care for them. This spans a broad horizon, stretching from research to discover new genes and understand the biochemistry and physiology of brain cells, through to drug and biomarker development and clinical diagnosis, surgery and implementation of new practice, among others. Investment in epilepsy research has produced important advances. There has been an acceleration in our understanding of the mechanisms underlying the epilepsies, we have developed new treatments and interventions that reduce seizures, and we have improved our toolkit for diagnosis. Nonetheless, rates of drug-resistance have not improved for decades (Perucca et al., 2020). It is increasingly clear that uncontrolled seizures damage the brain (Lariviere et al., 2020). Treatment side effects are sometimes worse than the disease (Perucca et al., 2020). Diagnosis can be an odyssey of frustration for patient and clinician and we await validated and clinically-used biomarkers of epileptogenesis (Simonato et al., 2021). Seizures are not the only challenge with psychosocial aspects of epilepsy often as debilitating as the seizures (Mula et al., 2021). Sudden unexplained death in epilepsy (SUDEP) takes the lives of about 1 per 1000 person years (Devinsky, 2011; Harden et al., 2017). We must identify the gaps and focus and prioritise our research. Ongoing breakthroughs are transforming our ability to model the human brain (Andersson et al., 2016; Chiaradia and Lancaster, 2020); neuroscience tools enable us to record and manipulate neurons in brain structures (Driscoll et al., 2021); the molecular landscape of the epileptic brain can be defined at unprecedented resolution (Kumar et al., 2022); genes can be selectively activated or deactivated in vivo (Colasante et al., 2020). Collectively, these and other technologies are transforming what can be achieved in translational epilepsy research.
But other changes are needed too. Primarily, in how we work as a community. We have the best chance to make an impact on the challenges faced by people living with epilepsy and the people who care for them by working together, identifying the most important challenges we face and collectively bringing what we have to the table. Science has been a team sport for some time. Big ambitious projects (e.g. human genome project, human brain project) achieved what they did by bringing together many different disciplines; the sum becomes greater than the parts. Delivering patients and their healthcare providers with the technologies, treatments and connected health solutions that will produce meaningful change for the better requires not only scientists working with clinicians, or scientists in one discipline coming together with scientists in another: the community must comprise all stakeholders. That includes industry and the agencies and instruments that fund research and patients and those who advocate for them. Public Patient Involvement (PPI) transforms research by including patients at each step of the pathway, imparting their knowledge, that complements that of scientists and clinicians.

1.3. PPI in epilepsy research

PPI can cover the entire research spectrum, beginning with objective setting and onto experimental design, and the tracking and measurement of the outcomes of the research. The objective is to ensure that research delivers what is needed by patients and healthcare professionals. Evidence is accumulating supporting the impact of PPI, in clinical trials (Boivin et al., 2018) and preclinical research (Carroll et al., 2022), and tools are available for biomedical researchers to implement PPI (Maccarthy et al., 2019). The commitment to and uptake of PPI is, however, variable across diseases, geography and discipline. Digital and connected health research are among leading proponents of PPI. Learning from the mistakes of connected health solutions that no-one wanted, PPI input has produced interactive platforms co-developed with patients that are used in everyday lives and facilitate patient reported outcomes and consultation interactions (Fitzsimons et al., 2021). Such innovations in telemedicine had an impact on patient care during the COVID pandemic and is here to stay (Banks et al., 2021).

The uptake of PPI in basic and translational epilepsy research and its impact is not being formerly tracked but is likely to be limited. This must change. Taking new drug development as an example, laboratories are now working on precision and gene therapy approaches to deliver the next
generation of disease-modifying treatments (Mesraoua et al., 2019; Morris and Schorge, 2022). But without PPI, we risk developing treatments that will never be taken by patients. What is the acceptable risk for an individual? Is it just the seizures that matter and how will this treatment change other aspects of living with epilepsy? As basic and translational researchers, what we should ask is: Am I working on something that is going to be valued by patients? Will it be used? Embedding PPI in research programmes offers the ability to co-create the solutions that patients not only need but will embrace.

2. EPICLUSTER meeting
The final EPICLUSTER meeting was entitled “Shaping the Future of Epilepsy Research in Europe”, and was held in Brussels as well as online on September 29th 2022.

2.1. Structure of the meeting
The meeting was organised into five sessions. The day opened with a welcome address by Paul Boon, the current President of the European Academy of Neurology, followed by an overview by Tarun Dua of the World Health Organisation (WHO)’s intersectorial global action plan (IGAP) on epilepsy and other neurological disorders. Together, these talks reinforced the scale of the burden and urgency of the unmet needs. Neurological diseases affect one in three people and are the largest contributor to disability adjusted life years (DALYs) globally (276 million DALYs) (Collaborators, 2019b). The socioeconomic costs put neurological disorders above cancer, cardiovascular diseases and diabetes. Epilepsy is the fourth most common neurological disorder. Epilepsy interrupts and shortens lives, contributes to un- and under-employment and comes with a host of disabling co-morbidities.

2.2. Scientific priorities – perspectives from the leadership of EPICLUSTER
The main session focused on research priorities from the perspective of basic, translational and clinical science by the coordinators of the research projects that formed EPICLUSTER (DESIRE, EpimiRNA, EpiPGX EPISTOP, EPITARGET and EPIXCHANGE), EpiCARE and key opinion leaders involved in other major epilepsy research initiatives. The collective scientific outputs from these projects have been reported previously (Pitkanen et al., 2019). Each presenter gave their
expert opinions, both personal and on behalf of the project’s they represented, on directions in the field and the priorities for research, the objective being to identify shared research priorities.

2.2.1. EpiCARE  Alexis Arzimanoglou provided the view from the EpiCARE European Reference Network (ERN) on rare and complex epilepsies (https://epi-care.eu). While not research projects, the 24 ERNs represent 2000 medical teams from 500 healthcare providers in the EU. The ERN EpiCARE is a network of 50 medical teams, spread across 26 EU countries. It involves more than 500 neurologists and child neurologists with expertise in epilepsy care and clinical research, working in close collaboration with many other centres of expertise in Europe and internationally. The network can facilitate research in important ways including by helping develop long-term research strategies and priorities, connecting and liaising between members, tracking projects, liaising with the patient groups and associations to identify areas of patients’ need. The EpiCARE Research Council offers advice and support for Horizon Grant requests, dissemination of funding opportunities and the outcomes of call submissions. EpiCARE also supported the creation, within the non-profit organization Epilepsy Alliance Europe, of a European Collaboration for Epilepsy Trials (ECET) consortium, providing expertise for the design and feasibility of drug trials. Discovery and implementation of genetics, surgery and trials are all supported by EpiCARE. An in-development central registry is planned that will be a powerful enabler of research and trial recruitment. A dedicated genetic platform (https://epi-care.eu/collaborative-genetic-research/) facilitates recruitment for cohorts of patients carrying rare variants in genes.

2.2.2. EPITARGET  Coordinated by Merab Kokaia, the EPITARGET project focused on targets and biomarkers of epileptogenesis. This included assessing combinatorial drug approaches and circulating molecular, EEG and imaging biomarkers. Among project highlights were the more than 160 publications emanating for the project’s research. Among the research priorities highlighted were gene and cell therapy and new directions that may improve safety and efficacy. This included prospects for on-demand gene therapy and innovations that would couple gene delivery to network hyperactivity. For example, through use of light-activated (opto) receptors and channels delivered via a suitable vector enabling specific cells to be activated or inactivated. Cell therapy offers an alternative strategy via delivery of exogenous inhibitory cells, reprogramming or conversion of existing excitatory or glial cells into inhibitory neurons or stimulating neurogenesis and directing
endogenously produced cells toward an inhibitory phenotype. Additional recommendations were for continued development of better translational infrastructures including models and preclinical trial networks.

2.2.3. EPIXCHANGE Coordinated by Michele Simonato, EPIXCHANGE was an industry-academia partnership project that combined gene and cell therapy approaches and tested the effects of sustained delivery of therapeutic proteins into epileptogenic sites in preclinical models. Results included evidence for sustained disease-modifying effects of the neuropeptide glial-derived neurotrophic factor. Research priorities included technologies and innovations to improve encapsulation of cells and provide on-demand and individualised release of neuroactive molecules. Additional recommendations included the value of EU-wide preclinical trial networks, strengthening basic-translational-clinical cooperation and access to enabling funding mechanisms.

2.2.4. EpimiRNA Coordinated by David Henshall, the EpimiRNA project focused on the influence of microRNAs on brain excitability and gene expression in temporal lobe epilepsy and the potential applications as circulating biomarkers and therapeutic targets. Outcomes that were highlighted included how the project fed into the establishment of several additional brain research centres in Europe (FutureNeuro, CePTER and Brainscapes) and a spin-out company (Omiics). Research priorities included leveraging technologies such as single cell analyses to resolve the mechanisms influencing miRNA control of gene expression in epilepsy, broadening the focus to genetic epilepsies, integrating microRNAs with other molecular biomarkers into multi-modal panels, and exploiting and distributing more human-based models of the epilepsies. Enabling mechanisms include multi-stakeholder funding initiatives and the need for revision of legislation that creates excessive barriers to access clinical data and animal use which threaten research progress and are particularly challenging for early-career researchers.

2.2.5. DESIRE Coordinated by Renzo Guerrini, the DESIRE project focused on strategies for innovation in the diagnosis and treatment of children with difficult to treat epilepsy. The project established important multi-disciplinary research networks that have accelerated new gene discovery, particularly in the developmental and epileptic encephalopathies (DEEs) and established infrastructures such as DNA and tissue biobanks, human cell models and clinical trial
networks for precision and gene therapies. Several key genes identified by the project have driven research in other fields of medicine, demonstrating the ability of epilepsy research to support the wider brain research community. Priorities included support for genomic collaborations that would increase the number of recognised rare disorders that compose the DEE spectrum, improve the connections between clinical/genetic discovery and functional expertise, long-term support and mechanisms that facilitate access to the project’s registries and biobanking at the EU level and promoting a regulatory ecosystem that is simple, supported, and rewards collaboration with industry partners for developing precision medicines for DEEs.

2.2.6. **EPISTOP** Coordinated by Sergiusz Jozwiak, the EPISTOP project centred on an innovative preventative clinical trial which reported disease-modifying effects of early anti-seizure pharmacological treatment in infants with tuberous sclerosis complex (TSC). The project also identified EEG predictors, neuroimaging and circulating biomarkers of epilepsy development and neurodevelopmental outcomes in TSC. This included integration of multi-modal molecular biomarkers to increase predictive value for outcomes such as seizure-freedom and intellectual disability. The project has also shaped the development of follow-on projects including clinical trials and development of new drug-screening models.

2.2.7. **EpiPGX** Coordinated by Sanjay Sisodiya, the EpiPGX project principally explored how genetic variation influences responses to anti-seizure medicines. This included a comprehensive analysis of the pharmacogenomics of the epilepsies, identification of risk variants for serious adverse reactions to anti-seizure medicines and contributions to new gene discoveries through collaboration in major genomics consortia. Future research priorities included applying the learnings on pharmacogenomics across the epilepsies and to drive new drug and gene therapy development. Also highlighted were the need to initiate further EU-wide longitudinal cohorts for discovery of predictors for drug-resistance and bring in more data science and explore multi-modal biomarker approaches that integrate genomic with other (e.g. MRI, EEG, circulating molecular) data. Finally, focusing on next-generation deep phenotyping technologies and the standardisation and distribution of human models for the epilepsies, including at individualised level. To achieve these goals will require further scaling of trans-project, international and cross-
disciplinary cooperation and expansion of stakeholder involvement including healthcare systems and new projects.

2.2.8. European contribution to epilepsy genetics Representing projects including Euroepinomics, EpiCure, EpiPGX, SolveRD and EpiCare, Holger Lerche emphasised how past and current EU funding of these projects has been a major driver of genetic testing becoming integrated into routine clinical care. This has transformed diagnostic pathways and resulted in changes to treatment through precision and personalised medicine. The projects are also pivotal to biobanking in Europe and, if curated and when maintained long-term, enable re-analysis of genomes that can provide gene discovery and diagnostics into the future. Among key priorities were the need to support deep phenotyping, create frameworks for high-throughput and mechanistic insights into the function of genomic variants across model organisms and use human models to identify pathways of convergence for the epilepsies and development of new drug and gene therapies.

2.2.9. Towards pre-clinical multi-centre trials Successful translation of new target discoveries into approved medicines continues to have high attrition rates which discourage industry investment in epilepsy as well as other brain diseases. Asla Pitkanen highlighted how re-thinking and innovative preclinical research methods can help to overcome the low success rate in translational research. The necessary statistical power can be achieved by establishing networks of preclinical laboratories and implementation of clinical trial-inspired preclinical common data elements. These result in standardisation and increased reproducibility through harmonisation of preclinical studies. These frameworks will also accelerate biomarker discovery and validation. Implementation of this new approach will require, however, funding instruments that support and reward the necessary engagement of EU-wide preclinical teams.

3. Shared research agendas and priorities
There were a number of recurring themes among the identified research priorities. This suggests there is common, shared ground where focus should be greatest. These included:
Further scaling (and avoidance of fragmentation) of existing projects and their associated operational and research facilitating (e.g. biobank, registers) infrastructures

Cooperation across projects and approaches to develop multi-modal biomarker panels for epilepsy risk, recent seizure and drug-resistance in the epilepsies

Focus on the shared and separate mechanisms underlying epilepsy and leading to seizures and/or their co-morbidities

Creation of preclinical model drug and gene therapy trial networks that can enable testing of innovative treatments across labs, improving and accelerating translation

Sharing of expertise, standardisation and dissemination of human models of the epilepsies

Prioritise development of disease-modifying and precision-therapy treatments

Control of gene therapy, including designing ways to control delivery of the payload

Financing that is sustainable to support current and future initiatives

Importantly, many of the priorities overlap with those identified recently by patient groups, people affected by epilepsy and healthcare professionals in the UK (Partnership, 2022). This included better understanding of the mechanisms underlying the different epilepsies, the potential of gene therapy, the mechanisms of drug-resistance, biomarkers and other technologies to predict seizure risks, effects of treatment on brain function and application of big data and AI to the field. Other priorities included understanding the causes and risk for SUDEP and sex-specific aspects of epilepsy, particularly in women across the life-span. These recommendations, along with ongoing work by other organisations, aim to shape and influence the future of European epilepsy research in the years to come.

4. Patient priorities and shaping the research agenda

After presentations on the scientific priorities, the EPICLUSTER meeting focused on PPI in epilepsy research. This built on the third activity of EPICLUSTER which was a workshop held in 2021 designed to introduce the epilepsy research community, particularly basic researchers, to the concept of PPI, examples of best practice from other brain diseases, and provide a roadmap for how to integrate this into laboratory and research centre activities. The final EPICLUSTER event featured two PPI activities, with the initial session focusing on examples of PPI underway in the epilepsy field and followed by a training-the-researcher style practical workshop. This part of the
programme was introduced by Joke Jaarsma, President of the European Federation of Neurological Associations, and advocate for PPI in brain research. This was followed by an overview of the Shape network initiative by Caoimhe Bennett on behalf of Epilepsy Research UK. This also included an introduction to their own research-setting agenda, co-developed with patients and researchers. This session was completed by a case study by Lorna Kerin on setting up PPI in a research setting, using the example of the PPI panel established at the FutureNeuro SFI Research Centre in Ireland. The second half of the session saw a participatory workshop led jointly by the PPI experts and with the involvement of Claire Nolan from the IBE. This focused on researchers discussing their views on what is needed to establish PPI in their own groups, what aspects of their programmes this might apply to and, at a practical level, how and who to identify to work with, as well as some resourcing considerations such as how to hold meetings and support the activities. This was complemented by an overview of IBE’s new strategy which will include a focus on increased engagement of members in research globally.

5. Industry trends, working with academia and priorities

As a key stakeholder in the discovery and development of new treatments for the epilepsies, the industry voice was included in a dedicated session. Stefanie Dedeurwaerdere, head of Epilepsy Discovery Research at UCB Pharma presented the past, present and future strategy. There is a shift from blockbuster to smaller patient segments dominated by (optimized) anti-seizure treatment and the emergence of new developments targeting genetic conditions at their root cause. Future research efforts will be directed to disease-modifying treatments, use of systems biology approaches to identify new targets, attention to personalised treatments and patients with the greatest unmet needs, including epilepsies of different aetiologies such as genetic, structural or emerging fields like autoimmune epilepsies.

The second presentation in this session was from Merab Kokaia, who has worked with a biotechnology start-up (Combigene) to develop a new gene therapy. This covered the entire journey from target discovery, through protection of IP and initiation of investor engagement. The relative advantages of starting a small company versus engaging with large partners (e.g. pharma) were discussed as were whether and when to disengage as an academic.
6. Final discussions of EPICLUSTER

The final session was moderated by Frédéric Destrebecq (executive director at the European Brain Council). Philippe Ryvlin presented an overview of the EBRAINS infrastructure that developed from the Human Brain Project (HBP). This focuses on digital neurosciences with multiscale models, simulations and atlases of neural networks, as well as advanced medical analytics. EBRAINS provides multiple resources for epilepsy and broader brain research including brain imaging, EEG and modeling capabilities. Key innovations are the medical informatic platform (MIP), which enables GDPR-compliant privacy-preserving federated analyses of clinical databases across hospitals and registries without moving the data outside their site of original storage. The human intra-cerebral EEG platform (HIP) aims at leveraging collaborative research based on intracerebral EEG recordings from persons with drug-resistant epilepsy undergoing presurgical evaluation. Last, the Virtual Brain model, which is currently being tested in a large epilepsy surgery randomized clinical trial. EBRAINS harnesses European-based supercomputing to support the system. With funding for HBP ending, EBRAINS is now transitioning to becoming a non-profit legal entity with a primary mission to operate and further develop the research infrastructures established by HBP.

The final session was a roundtable discussion by the leadership of EPICLUSTER. This focused on sustainability. The various FP7 and Horizon epilepsy projects that EPICLUSTER brought together have gone on to establish a number of major internationally-leading research centres, leveraged multi-million euro investments from industry in collaborative research, leading to remarkable technology development, commercialisation and spin-outs. But this innovation requires sustained investment. Members of the EPICLUSTER leadership and audience joined the discussion. This included reviewing calls in the Health programme relevant to epilepsy and bottom-up funding instruments. There was a recognised need for major investment in brain research. Funding was not the only threat to epilepsy research that was discussed, and comments also included the legislation in Europe on data and use of animals in research that create barriers to research. The view from the EBC and broader EU funding landscape was reviewed and discussion focused on what mechanisms might emerge in the future that will support the needs and
ambitions of the European epilepsy research community. This included the possibility for new joint-stakeholder research funding.

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Disclosures

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8. References


