HENRY ROYCE INSTITUTE

ROYCE

MATERIALS FOR BIOELECTRONICS IN HEALTHCARE

STRATEGY AND ACTION PLAN

THIS REPORT

This document has been commissioned by the Henry Royce Institute and prepared by CPI, ScotChem and Urban Foresight in collaboration with a team of global expertise across industry, government and academia. It presents the findings from a strategy development process completed between February and July 2024.

All statements and recommendations in this document have been developed in a research setting and are not current policy of the UK Government, UKRI, Royce, or other named public bodies. Please contact Urban Foresight if you have any questions about this report.

ROYCE'S BIOELECTRONICS WORKING GROUP

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FOREWORD

I am delighted to introduce this important report. It sets out how novel advanced bioelectronic solutions, currently just beyond our current reach, could drastically improve the quality of life of a large population of patients.

However, the report also tells us that the main challenge to realising this opportunity is the large gap between existing materials and the next phase of advanced materials.

A general shortfall in capacity, protracted development timescales and a lack of sector integration across industry and academia, has impeded investment and prevented this global sector from leveraging its strengths.

This report calls for a much more integrated approach, one which combines world-leading research capabilities with those in translation such as clinical trials, R&D funding, regulations and standards.

If we can join forces around this, we can ensure a thriving global market in material systems for bioelectronic applications, and, most importantly realise its potential in transforming healthcare by offering more precise, efficient, and personalised solutions for a range of pressing medical challenges.

Bioelectronics is a hugely exciting area that interfaces biological systems with electronic materials.

The field of bioelectronics has captured the attention of the public with some exciting new devices reaching the clinic, for example as a treatment for motor dysfunction resulting from neurological conditions or disorders.

Bioelectronics to date has relied heavily on materials developed for other purposes. However, as this report shows, there is an urgent need for new, bespoke materials to be developed specifically for bioelectronic applications – not least due to the challenges of operating in complex biological environments, e.g. in human bodies, for long periods of time.

The report paints a promising picture – the UK has invested £33.5 million into bioelectronics research over the last two decades. However it also tells us that we need to do much more to capitalise on this investment, in particular by joining up all parts of the sector. Our universities, and businesses of every size, are already active in this area and if we get this right, the UK can position itself as a key player in an-ever growing global bioelectronics in healthcare market.

I look forward to being part of efforts for greater sector co-ordination and would like to thank everyone who contributed their views to this important report.

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- University of Utah
- University of York

EXECUTIVE SUMMARY

Bioelectronics is the electronic monitoring and control of biological systems for applications in medicine, agriculture, industry, and the environment.

In healthcare, these are electronic systems that directly interface with biological systems (in vivo or in vitro) for the purposes of prevention, diagnosis, monitoring, treatment and curing of disease, and for patient rehabilitation.

Pacemakers, blood glucose monitors and cochlear implants are examples of established bioelectronic healthcare solutions, as are a wide range of emerging solutions in neurotechnology and regenerative medicine.

The estimated global market size for bioelectronics was between £7.8 billion and £17.6 billion in 2024. This could reach between £16.2 billion and £27.9 billion by 2030.

The UK has an active research sector in bioelectronics, producing around 11% of scientific papers published globally in the sector and 2.64% of all bioelectronics patent applications – the highest of any European country.

Biolelectronics businesses

There are 56 businesses active in bioelectronics innovation in the UK, 55% of which are micro or small businesses headquartered here.

Academic research

There are 22 UK universities actively researching bioelectronics, a third of which have a dedicated group or institute.

Materials will play a key role in supplying safe and responsible – but disruptive – bioelectronic healthcare solutions. This strategy has been developed by the Henry Royce Institute, the UK's centre for advanced materials, to define the materials needs of the sector and the actions needed to deliver them.

Over 60 stakeholders active in materials for bioelectronics research, commercialisation and clinical use were consulted in the development of this strategy.

MATERIALS FOR BIOELECTRONICS IN HEALTHCARE

This strategy includes a roadmap for materials properties required by bioelectronics applications. It details the physical, electronic, and biological characteristics for materials needed by the sector up to 2040. Three Grand Challenges for materials for bioelectronics in healthcare have been distilled from the roadmap.

Materials for bioelectronics in healthcare Grand Challenges

1. Long-term (>10ys) implantable materials

Materials that can withstand implantation for very long periods of time (many years) but maintain all their required functions.

2. Materials with ideal electrical properties

Electrically conducting materials with good biocompatibility and mechanical properties similar to tissue, making them ideally suited to interfacing electronics with the body for long periods of time.

3. Materials which improve sensor performance in vivo

Materials that avoid biofouling or inflammatory responses around a sensor, which shorten its lifetime and cause unpredictable changes in its response characteristics.

BIOELECTRONICS MATERIALS INNOVATION IN THE UK

Materials innovation in the UK is shaped by a variety of scientific, commercial, regulatory and cultural forces. It takes many years and is expensive to certify a new material for bioelectronic applications.

The sector has strengths in the international reach of its research outputs, its well-networked community, and its competitive development environment.

However, the sector is being held back by its poor definition, access to funding, awareness of industry and clinical needs, availability of data about materials, appropriate supply of materials, capability to scale up, and accessibility of high-standard testing, fabrication and prototyping facilities.

ACTION PLANS

The highest priority actions for improving the translation environment for materials solutions for bioelectronics in healthcare are:

KEY AREA	REQUIREMENTS	>>> MUST DO ACTIONS
Facilities	Elevate the quality control standards and skills in existing facilities, and invest in new facilities for the standards required by this highly controlled sector.	• Ensure that the Current Good Manufacturing Practice (CGMP) standards are being met by material fabrication facilities • Upskill clean room testing, prototyping and fabrication facilities in the standards required in bioelectronics • Create a network of testing, prototyping and fabrication facilities available to those working in bioelectronics, identifying gaps in this network and establishing new facilities where needed • Direct funding at manufacturing research and innovation
Materials supply	Improve access to, and knowledge of, biocompatible materials through data standards, networking and advisory services.	• Fund research into material biocompatibility and behaviour in biological environments • Establish a standard for material biocompatibility data • Create a database or other data sharing service for material biocompatibility data • Collaborate on a catalogue of materials in use and in development for bioelectronics • Establish a UK-based biocompatible materials fabricator or supplier
Standards	Create new standards or refresh existing ones to make them suitable for bioelectronic materials, speeding up timescales and lowering development costs.	• Create digital and AI toolkits for materials computational modelling and predictive testing • Engage with Medicines and Healthcare products Regulatory Agency (MHRA) to ensure the refresh or innovations in standards meets the profiles of bioelectronic material development
Clinical focus	Promote the challenges and needs of clinicians and their industrial suppliers to those researching solutions.	• Create an industrial review process for researchers • Define unmet clinical needs that can be addressed by bioelectronic solutions and share these with innovators • Build connections between university medical school and engineering or biology researchers working in bioelectronics • Match industry challenges with relevant researchers • Attract and retain early career researchers to the UK by providing them with unique opportunities to innovate

NEXT STEPS

A new national hub for materials innovation in bioelectronics should lead the delivery of these high priority actions. It would champion the sector and ultimately create a unique and globally-significant innovation capacity in the UK.

A Materials for Bioelectronics Challenge Programme should be launched to coordinate the progression of the three Grand Challenges and other material properties from the roadmap.

WHAT IS BIOELECTRONICS?

Although the term "bioelectronics" was first proposed in 1968 to describe intermolecular electron transfer found in biological systems[1], its current meaning has evolved significantly. Over the following decades, it became generally accepted that the term broadly describes research, devices, and applications that establish and use synergies and the interface between electronics and biology[2,3].

However, as a highly multi-disciplinary and emerging field, it is still poorly defined and can be interpreted as a broad spectrum of any electronic device interfacing with humans, from consumer wearable technologies to long-term implantable prosthetics.

Under the guidance of the Royce Bioelectronics Working Group and with reference to existing definitions and research interests of academic and industry stakeholders, the scope of this study was refined to provide clear boundaries on the definition of bioelectronics materials in healthcare:

"Bioelectronics is the electronic monitoring and control of biological systems for applications in medicine, agriculture, industry, and the environment.

The focus of this project is on materials for bioelectronics in healthcare. These are defined as materials which are important to the function of electronic systems that directly interface with biological systems (in vivo or in vitro) for the purposes of prevention, diagnosis, monitoring, treatment and curing of disease, for patient rehabilitation, and for improving health in general."

This project scope includes materials with healthcare applications that involve making electrical connections at the tissue-material interface or electronic interfaces targeting sensing or modulation of biological processes.

Despite some of the following topics falling within the general definition of bioelectronics, they were deemed to be out of scope for this strategy:

- Applications which are not human healthcare (e.g. agriculture, animal health, etc.)
- In vitro diagnostic tests not using an electrical sensing modality (e.g. those using photonics)
- Devices that provide therapy without using an electrical interface to the biological system (e.g. ionising radiation)
- Neuromorphic computing
- Bio-inspired materials with no connection to bioelectronics

This scope has underpinned the landscape mapping, stakeholder engagement activities, observations and recommendations presented here.

[1] Szent-Györgyi, A., "Bioelectronics," Science, vol. 161, pp. 988–990, 1968.
[2] Turner, A. P. F., "Biosensors and bioelectronics 20 years on," Biosensors and Bioelectronics, vol. 20, p. 2387, 2005.
[3] Turner, A. P. F., "Biosensors and Bioelectronics journal: aims and scope" July 17 2013.

THE BIOELECTRONICS MARKET

Through a landscape mapping activity, the study has identified the current status of the UK market and potential areas of growth and interest in the sector to ensure that, in the immediate to mid-term, the UK's materials ecosystem effectively fosters the sector.

The mapping activities have included:

- Literature review
- Patent search
- Company search
- Funding search
- Investment system review

LITERATURE REVIEW

Databases of research papers were searched for relevant activity. The terms used in this search were "bioelectronic" and "bioelectronics".

Searches using relevant terms beyond these two specific words produced many more results. However, most of them were judged to be "false positives". For example, research papers in adjacent sectors, including agriculture and computer science, which deviated from the specific materials challenges and opportunities within the scope of this strategy.

This table summarises the search methods and sources used:

Search terms	• Bioelectronic • Bioelectronics
Search parameters	• Title • Abstract • Keyword • Topic
Search limits	• Articles • Journals
Databases	• Web of Science • Scopus • Scifinder

This search identified 2,531 publications globally and 261 from the UK between 2018 and January 2023. The highest affiliations for the UK papers were from the University of Cambridge, Imperial College London, University of Oxford, University of London, and University College London.

The publication rate steadily increases globally. There is also an overall upward publication trend in the UK.

Bioelectronic research publications by year

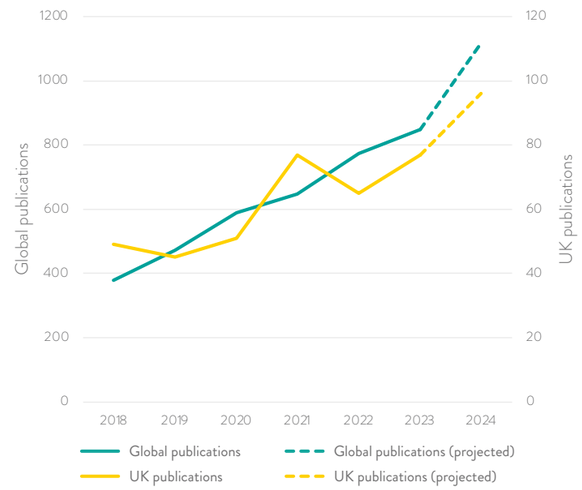


Figure 1: Bioelectronic research publications by year, globally and from the UK, correct as of 1st August 2024.

The UK reflects the distribution by subject area – shown in Figure 2 – with around one in four papers published on materials science, indicating the value of materials to innovation in this sector.

The journal with the most publications in bioelectronics is *Advanced Functional Materials*.

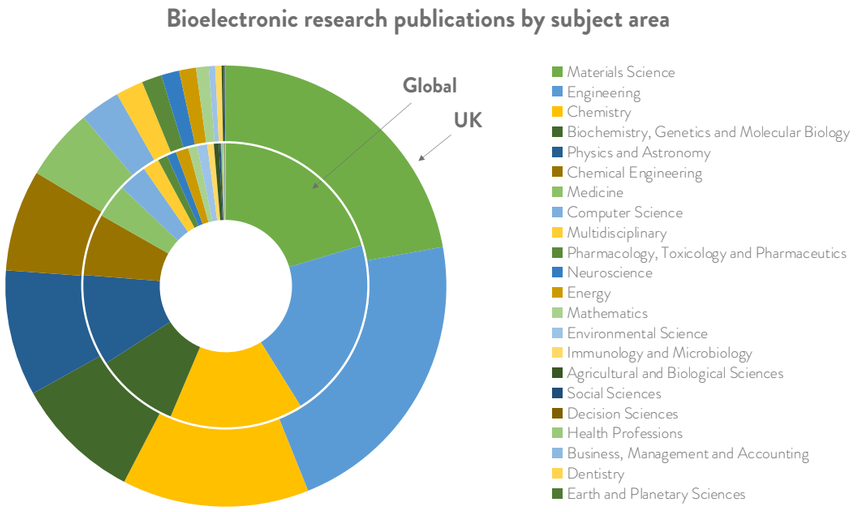


Figure 2: Bioelectronic research publication subject areas, globally and from the UK.

PATENT SEARCH

The patent search also used the terms "bioelectronic" and "bioelectronics". Again, when the search terms were broadened, a significant proportion of false positives was recorded.

Country names were matched according to the International Organization for Standardization (ISO) codes from the priority numbers to find the locations where the patents are likely being developed.

The search used the lens.org patent database and identified over 25,800 global patents. These are being generated at an increasing rate, reflecting the trend seen in the research publication rate. "Materials" is also the most frequently used word in these patent abstracts, further demonstrating the value of materials science to innovation in bioelectronics.

However, UK patents have a lower relative volume globally than papers published by UK-affiliated authors. Total UK papers represented around 11% of the global search, whereas patents filed in the UK account for only 0.03% of global activity and patents filed from the UK account for only 2.64% of global activity.

This indicates a trend of UK researchers not raising their patents in the UK, but elsewhere, and/or that UK researchers are not translating their research into IP.

Patent activity is concentrated in the USA – with 65% of patents raised from there – with activity rising in China, the origin of 11% of global patents.

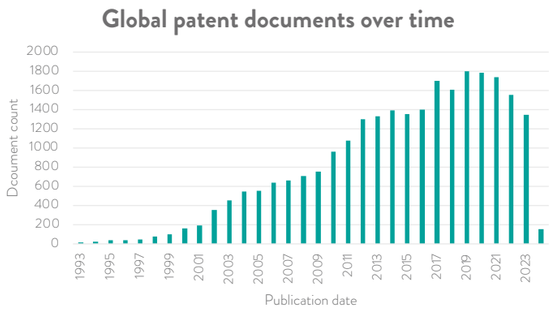


Figure 3: Global bioelectronic patent documents published per year.

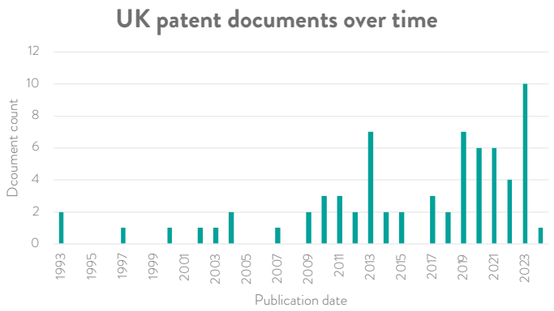


Figure 4: UK bioelectronic patent documents published per year.

The number of patents in the USA is significantly higher than in the rest of the world, which is thought to be due to the country's unique patenting system. US patents give more protection to intellectual property rights (IPR) than other patent offices, US courts are known as being patentee-friendly, and US patents are more likely to be granted than elsewhere. These advantages, therefore, encourage a greater number of applications to the US patent office.

In the USA, a higher proportion of patents also do not progress further or become inactive. Patents in the USA are specific, which means that many derivative patents are filed to protect IPR. In addition, the 1980 Bayh-Doles Act encouraged extensive patenting of academic inventions, even if, ultimately, they were not commercialised. This is because federally funded academic inventors could retain titles, and therefore, university spinouts could take these to market without competition. Patents are often necessary to apply for government support, and so the ease of application in the USA encourages further patenting, even if, ultimately, they become inactive.

China has embraced a similar approach in the last 15 years, which explains its relatively high volume of patents. This is further boosted by the fact that China only recognises Chinese patents. This means that companies often must duplicate their patents if they intend to commercialise their products in China to ensure adequate IPR protection.

UK business patent activity is dominated by QV Bioelectronics and Galvani Bioelectronics, two companies engaged in this strategy's development. QV Bioelectronics patents focus on cranial implants and electrode materials and Galvani Bioelectronics patents focus on neuromodulation and electrode devices. Both companies' patents relate to research on materials or combinations of materials (devices or components) and their functional properties, which correlates to materials being the most dominant subject area for bioelectronics publications.

These businesses are relatively small. In general, the patent search has highlighted a lower-than-expected level of activity from large, multi-national organisations in this sector. This may be due to researchers working in bioelectronics using materials that have already been tested and approved for human health use, and applying their research to the functional outcomes of the device rather than exploring new materials. As such, innovation in bioelectronics may be constrained by the properties of existing materials and could be stimulated through the development of new materials designed for specific functions of a bioelectronic device.

From stakeholder engagement, it is understood that large businesses are cautious of the risks involved in R&D in healthcare bioelectronics. Instead of owning materials development activities themselves, they are opting to fund and invest in smaller businesses.

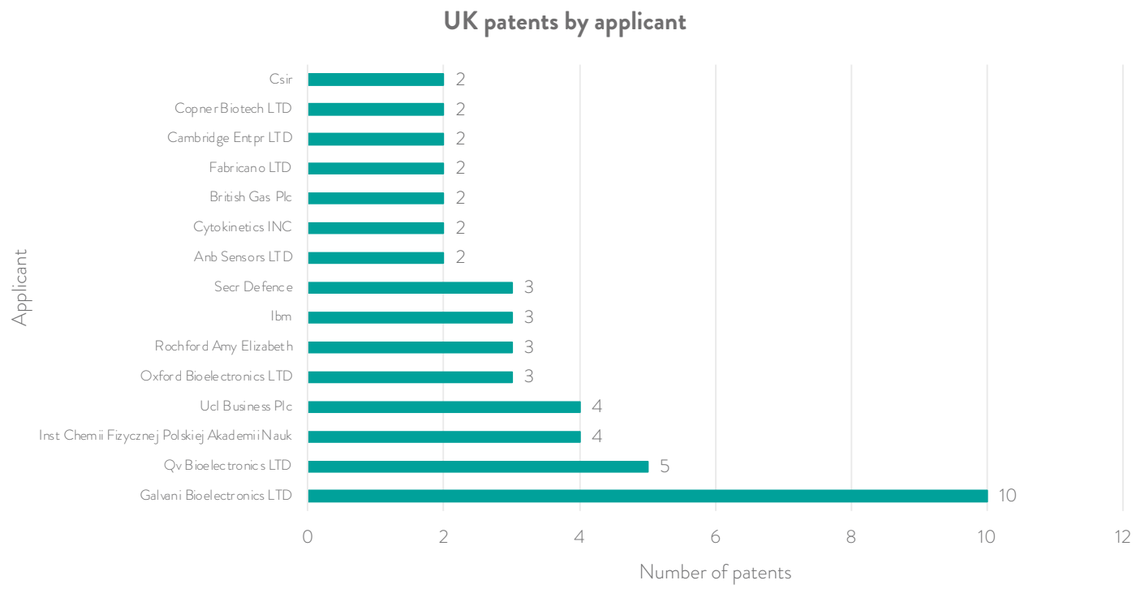


Figure 5: Top applications of UK patents relating to bioelectronics.

COMPANY SEARCH

The patent search also provided the Cooperative Patent Classification (CPC), International Patent Classification (IPCR), and Standard Industrial Classification (SIC) codes used by businesses active in the area, which were used in the company search.

CPC CLASSIFICATION CODES	IPCR CLASSIFICATION CODES	SIC CODES
A61B5/0536 Human necessities: Impedance imaging, e.g. by tomography	**A61B5/053 Human necessities:** Measuring electrical impedance or conductance of a portion of the body	**26400:** Manufacture of consumer electronics
A61B5/24 Human necessities: Detecting, measuring or recording bioelectric or biomagnetic signals of the body or parts thereof	**A61B5/145 Human necessities:** Measuring characteristics of blood in vivo, e.g. gas concentration, pH-value measuring of blood pressure or blood flow non-radiation detecting or locating of foreign bodies in blood	**26600:** Manufacture of irradiation, electromedical and electrotherapeutic equipment
A61B5/4893 Human necessities: Locating particular structures in the body, nerves	**A61N1/05 Human necessities:** Electrodes, for implantation or insertion into the body, e.g. heart electrode	**33190:** Repair of other equipment
A61B5/6877 Human necessities: Extracorporeal blood circuites to be attached or implanted, nerves	**A61N1/36 Human necessities:** Applying electric currents by contact electrodes, for stimulation, e.g. heart pacemakers	**62020:** Information technology consultancy activities
A61N1/0556 Human necessities: Spinal or peripheral nerve electrodes, cuff electrodes	**B33Y80/00 Performing operations; transporting:** Products made by additive manufacturing	**72110:** Research and experimental development on biotechnology
A61N1/36034 Human necessities: Control systems specified by the stimulation parameters	**B82Y30/00 Performing operations; transporting:** Nanotechnology for materials or surface science, e.g. nanocomposites	**72190:** Other research and experimental development on natural sciences and engineering
A61N1/3605 Human necessities: Implantable neurostimulators for stimulating central or peripheral nerve system	**C12Q1/00 Chemistry; metallurgy:** Measuring or testing processes involving enzymes, nucleic acids or microorganisms; Compositions therefore; processes for preparing such compositions	**74909:** Other professional, scientific and technical activities not elsewhere classified
A61N1/3606 Human necessities: Implantable neurostimulators, adapted for a particular treatment	**C12Q1/26 Chemistry; metallurgy:** Measuring or testing, involving oxidoreductase	**86900:** Other human health activities
A61N1/36135 Human necessities: Control systems, using physiological parameters	**C12Q1/68 Chemistry; metallurgy:** Measuring or testing, involving nucleic acids	
A61N1/36139 Human Necessities: Control systems, with automatic adjustment	**C12Q1/6825 Chemistry; metallurgy:** Nucleic acid detection involving sensors	
A61N1/36157 Human necessities: Intensity, current	**G01N27/30 Physics:** Electrodes, e.g. test electrodes; Half-cells	
A61N1/36171 Human necessities: Timing, e.g. stimulation onset, frequency	**G01N27/327 Physics:** Biochemical electrodes	
C12Q1/001 Chemistry; metallurgy: Enzyme electrodes	**G01N27/416 Physics:** Systems	
C12Q1/005 Chemistry; metallurgy: Enzyme electrodes, involving specific analytes or enzymes	**G01N33/50 Physics:** Chemical analysis of biological material, e.g. blood, urine; Testing involving biospecific ligand binding methods; Immunological testing	
G01N33/5438 Physics: Electrodes	**G01N33/543 Physics:** Double or second antibody, with an insoluble carrier for immobilising immunochemicals	

The company search found that industrial activity in the sector is relatively low compared to research activity. This is typical of such a nascent sector and indicates the scale of potential for industrial growth.

Number of bioelectronics companies identified

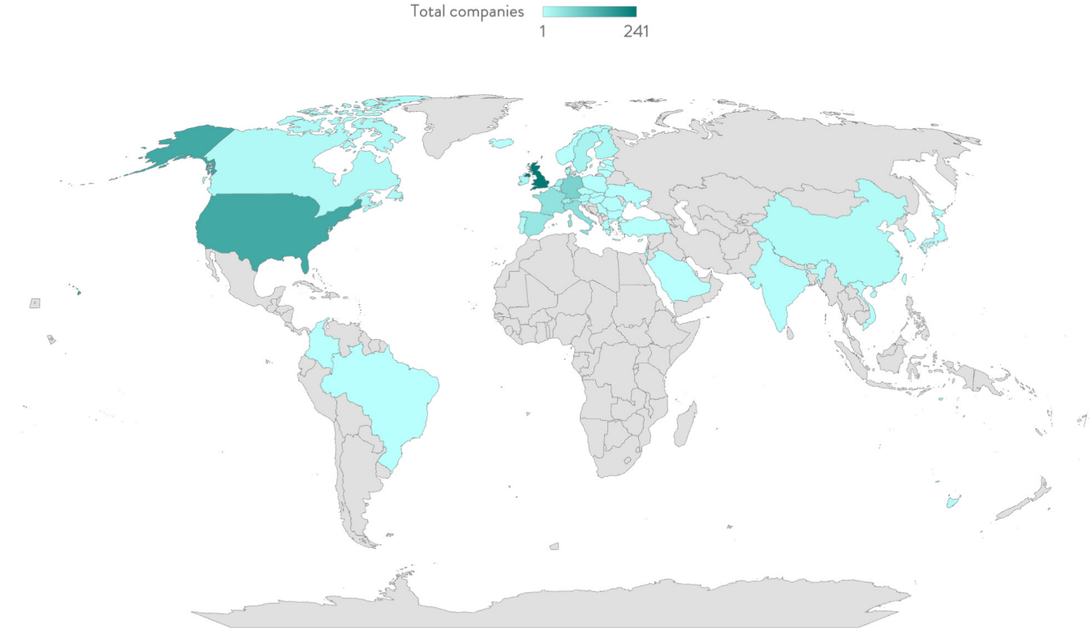


Figure 6: Location of bioelectronic companies identified in the initial company search.

Over 1,030 companies worldwide were identified in this initial search as having an interest in materials for the bioelectronics in healthcare sector. 241 of these companies are based in the UK, which is a significant proportion of companies worldwide.

FUNDING SEARCH

Research funding

A funding search was used to support the company and other organisation mapping. Sources used included:

- The Horizon database of EU research funding
- Research Gate and Gateway to Research for UK academic (research) funding
- National Science Foundation funding for US academic (research) funding

A search of UKRI (UK Research and Innovation) funding for any project that used "bioelectronic" or "bioelectronics" in its description found that the UK has invested £33.5 million into bioelectronics research between 2006 and 2023.

Cumulative UKRI funding into bioelectronics research

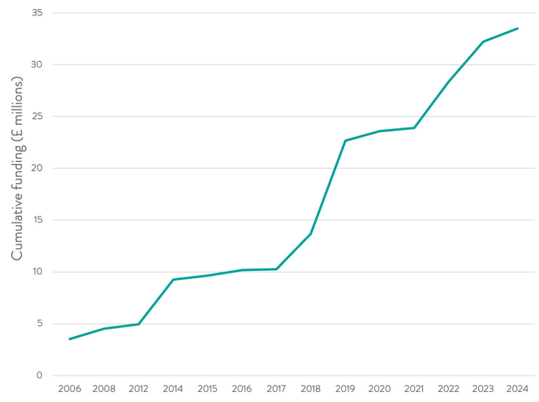


Figure 7: Cumulative total of UK Government funding into bioelectronics through UKRI.

Research funding has shown a steady increase over time with more significant increases from 2017 onwards. This reflects increased interest, research activity, and investment in bioelectronics. This also mirrors the UK research publication trend.

Translation and venture funding

No current sources of UK translational grant funding specific to bioelectronics were identified. Projects may qualify for Innovate UK programmes, but a challenge is the limited timeframe of most of these calls. Other short-term grant schemes (such as Knowledge Transfer Partnerships) can provide time-limited (12-36 months) funding for postgraduate placements.

Early-stage translational projects, particularly those supporting partnerships to spin out companies from universities, may be eligible for Horizon Europe funding. These projects require at least one collaboration partner from an EU member state.

Initial capital funding for micro and small companies remains a challenge because of the lag between spin-out and application. Much of the current investment funding depends on successful clinical trials of devices. However, this development stage is drawn out and expensive. The National Institute for Health Research (NIHR) can provide some financial and practical assistance for clinical trials, but its budget is limited.

Any development work in this area could be eligible for R&D tax relief, but this is paid back to companies retrospectively. Therefore, it does not provide working capital to undertake the work, although it will provide a source of cash for subsequent years if the company qualifies for R&D cash credits.

For patentable inventions emerging from development work, there is potential for Patent Box relief, but this is only relevant once the company is in revenue and paying corporation tax.

Although there may be opportunities for equity investment into early-stage businesses, particularly if they have the potential to generate intellectual property, the study was unable to identify any angel syndicates or investment funds that have a specific focus on biomedical enterprises. There may be individuals involved in some angel syndicates with a personal interest in the area, but this is difficult to ascertain.

However, the review of venture funding reflects the observation from the patent search of a pattern of larger businesses funding start-ups or small businesses to develop particular bioelectronics applications rather than investing internally in the materials solutions for bioelectronics. Stakeholders indicate that this may be a de-risking strategy for larger companies.

Whilst there is access to UKRI (and other) research grant funding for discovery and early development, and potential private investment post initial clinical trials, there is a gap in funding early-stage spinout to initial clinical trial stages.

ECONOMIC MODELLING

As an emerging technology sector, economic models of bioelectronics are mainly in their early stages of development. Further restricting the scope of this sector to materials for bioelectronic healthcare reduces the simplicity of economic modelling; nuances in the language used and sector definitions increases complexity.

The economic modelling that forms the basis for this strategy includes a global economic model and a high-level estimate for the size of the bioelectronics sector in the UK. Materials are the fabric of all products, and materials innovation is assumed to be fundamental to this economic growth.

To account for these complexities, reasonable assumptions have been made and are explained alongside the following economic analysis.

Global market size

The global market size for bioelectronics is estimated by plotting the projections from various market reports:

- Health Research International (2018) "Emerging Bioelectronic Medicine & Neurostimulation Technologies: Growing & Disrupting Global Medical Device Markets"
- Industry Research. (2023). "Bioelectronics Market: Analysis of Present and Future Growth | 2031"
- Global Information. (2023). "Bioelectronics Market Forecasts to 2030 – Global Analysis By Type, Product Type, Application, End User and By Geography"
- Grand Research Store. (2024). "Bioelectronics and Biosensors Market, Global Outlook and Forecast 2024-2030"

These reports have slight variations in their definitions of bioelectronics, so the reports that are included fit within the scope defined for this project. Figures have been converted from US Dollars to GB Pounds using the exchange rate of $1 = £0.79 (correct as of 4th April 2024).

Estimated global market sizes and growth 2018 – 2031 from different sources

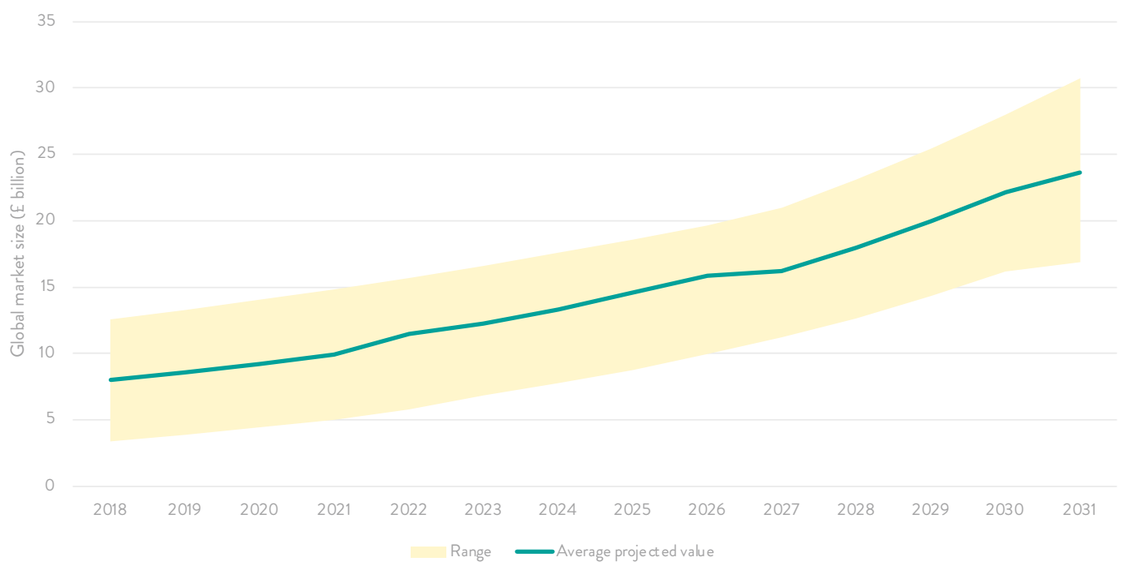


Figure 8: Estimated global market size of the bioelectronics for healthcare sector, showing projections from various market reports.

This model found that the estimated global market size for bioelectronics was between £7.8 billion and £17.6 billion in 2024 and could reach between £16.2 billion and £27.9 billion by 2030.

This growth range represents compound annual growth rates (CAGRs) of 6% to 14%, with an average projected growth rate of 10.5%.

UK market size

The estimated market size for the bioelectronics sector in the UK in 2024 is between £132 million and £163 million in turnover. The projected market size for the bioelectronics sector in the UK by 2030 could be between £240 million and £298 million.

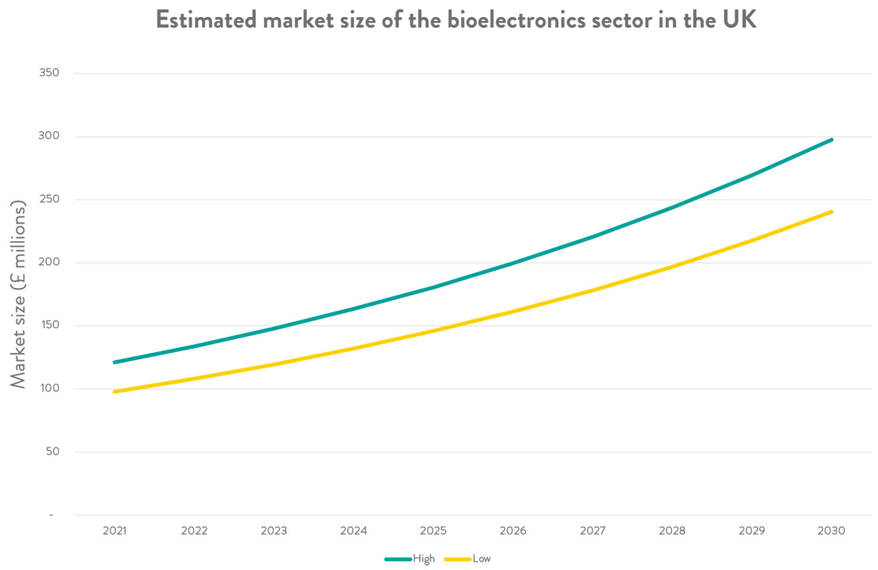


Figure 9: Estimated market size of the bioelectronics sector in the UK. Sources are listed above under "Global market size".

This model found the estimated UK bioelectronics market size using the total turnover of the 241 UK companies identified in our search.

It was assumed that large companies (those with over 250 employees) do not focus entirely on bioelectronics. Therefore, the percentage of turnover attributed to bioelectronics is limited to 10%, which is the average percentage of patent activity that large companies focus on bioelectronics out of their total patent activity.

This percentage was calculated by creating a patent dataset with a selection of large companies from Lens.org. The ratio of bioelectronics patents filed (using the search parameters mentioned previously) versus the total patents filed was calculated for each company. The average of these ratios was then taken to give a result of 10%.

To estimate future growth, the UK market is assumed to grow at the average CAGR estimated across the global market reports of 10.5%.

BIOELECTRONICS MARKET OPPORTUNITIES

Although the sector's emergent nature poses a challenge to effectively capturing all current activity and future potential, the data suggests that the emerging high-technology bioelectronics sector has significant potential to create research and industry activity in the UK.

In addition, combining notable capabilities in research with capabilities in translation (for example, clinical trials), regulations and standards, and IPR management places the UK in a good position to lead in developing materials for bioelectronics.

Our universities and businesses (large and small) are already active in this area and could capitalise on the growing global bioelectronics in healthcare market.

Four UK case studies are included to illustrate the full range of materials solutions for bioelectronics in healthcare – ranging from early-stage research to commercial deployment.

CASE STUDY 1: EARLY STAGE RESEARCH

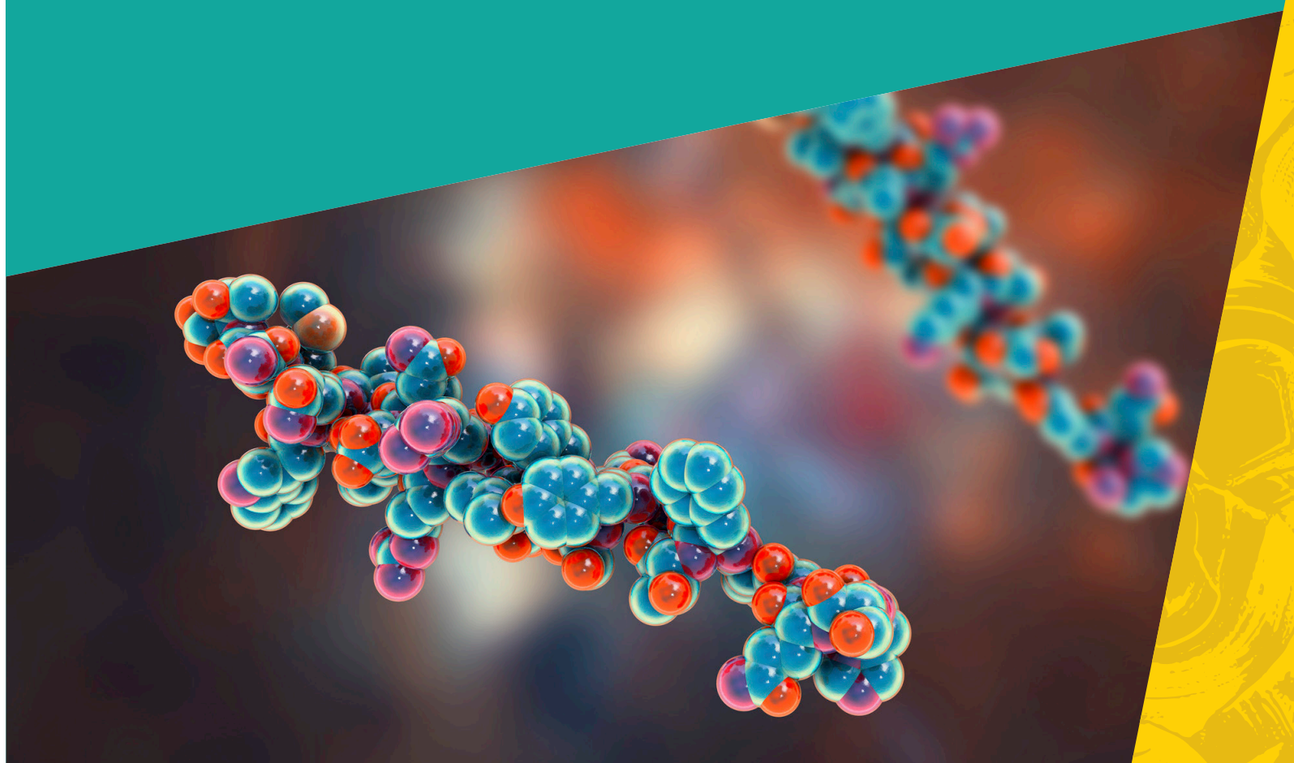
CONDUCTIVE HYDROGEL SCAFFOLDS FOR NEURAL TISSUE REPAIR
IMPERIAL COLLEGE LONDON

Imperial is home to one of the UK's leading Bioengineering departments, with 95% of its research judged either *world-leading* or *internationally excellent* in the Research Excellence Framework (REF). They have pioneered a range of bioelectronics-based treatments and spinouts from the department include medical device company EMcision, acquired by Boston Scientific in 2018.

Head of department, Professor Rylie Green, is leading on an exciting new area of bioelectronic materials research – the potential of self-assembling hydrogel structures to repair damage to brain tissue. Hydrogels are a class of biomaterial consisting of chains of polymers suspended in a fluid with the potential for a wide variety of biomedical uses.

Self-assembling peptides (SAPs) – a class of conducting hydrogels – are considered particularly promising for healthcare applications due to their favourable mechanical properties and ability to form ordered structures that mimic healthy biological tissue. For patients with traumatic brain injuries or neurodegenerative diseases, SAPs could act as a scaffold to promote cell growth in the affected area, and transmit therapeutic electrical stimulation.

For patients with traumatic brain injuries or neurodegenerative diseases, SAPs could act as a scaffold to promote cell growth in the affected area, and transmit therapeutic electrical stimulation.



STAKEHOLDER ENGAGEMENT IN THIS STUDY

First-hand stakeholder insight is essential to developing a strategy for an emerging sector that is specific to its needs.

This strategy's development saw over 60 researchers, innovators, funders, policy makers and clinicians share their experiences and views on materials innovation for bioelectronics in healthcare.

This engagement developed new data on the activity of bioelectronics for healthcare in the UK, resulting in a map of clusters for the developing sector.

VALUE CHAIN MAPPING

The pipeline for materials innovation for bioelectronics in healthcare was modelled as six sequential processes and two supporting infrastructural activities.

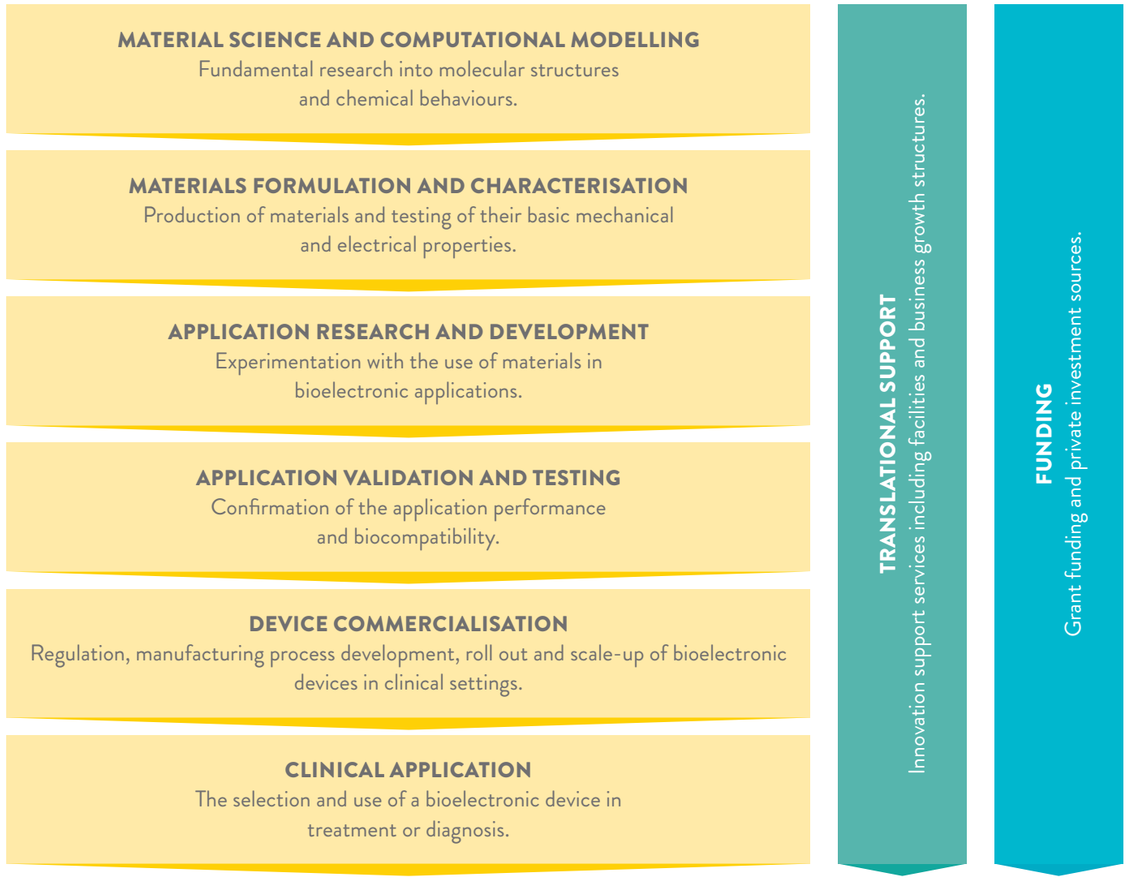


Figure 10: A value chain map for novel material development and translation for bioelectronics in healthcare.

This model was referenced to ensure that stakeholder engagement was representative of the full spectrum of pipeline activities and mitigate any bias towards a more active or vocal section of the ecosystem.

The eventual distribution was in keeping with the levels of activity observed in the literature review. That is, that more research and development is happening in the UK compared to commercialisation.

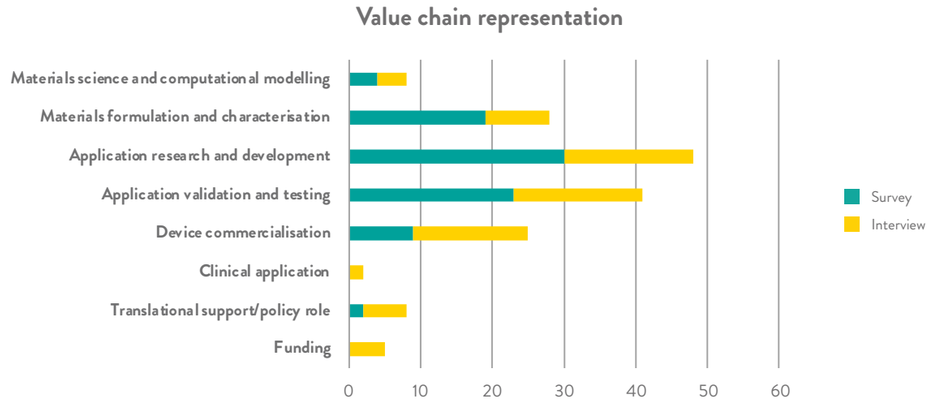


Figure 11: Engagement was spread across the value chain in a distribution that reflects the levels of activity observed in the paper and patent searches.

STAKEHOLDER IDENTIFICATION

Stakeholders were identified from various sources including:

- Bioelectronics actors already known to Royce and the strategy development team, including Royce's academic and industry working groups.
- Named contacts from the paper, patent and funding searches.
- Bioscience and health technology sector statistics.
- Online searches of key terms including: cardiology, electrostimulation, neuromodulation, cochlear implants, nerve stimulation, and conducting polymers.
- Attendee lists from relevant events including the Cambridge Bioelectronics Symposium and a neurotechnology supplier event.
- Innovate UK's KTN Neurotechnology map.

All sources were filtered against the proposed scope for bioelectronics, mapped against their area and categorised based on relevance, then approached either for an interview or a survey.

When interviewed, stakeholders were also asked to recommend other contacts to further identify active individuals and supplement the stakeholder map.

ENGAGEMENT

An online survey and one-to-one interviews were used to capture both a breadth of structured insights and a depth of understanding from personal accounts of undertaking materials innovation for bioelectronics in healthcare.

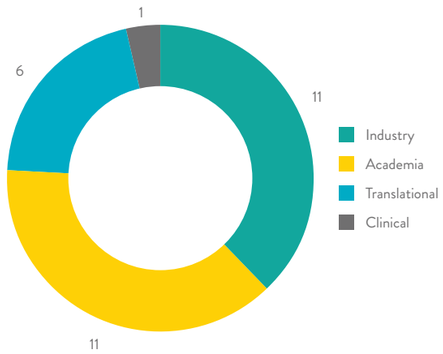
All stakeholders were asked questions on:

- the areas they work in, both in terms of the development pipeline and application area,
- their material innovation (development, translation, validation and commercialisation) capabilities,
- which materials they use, why, and where they source them,
- challenges faced when sourcing, developing or adopting materials for bioelectronics,
- desirable properties in bioelectronic materials,
- expectations on future emerging materials and applications,
- how they engage with others in the sector and at other points in the development pipeline,
- support that would help materials innovation,
- the UK's strengths and weaknesses in this sector.

The results of this engagement have informed the materials roadmap, profile of UK strengths and challenges, and the final recommended actions of this strategy.

Engagement has been key to creating sector-specific intelligence and recommendations. A list of contributing organisations is attached as an appendix.

Stakeholder interviews



Survey respondents

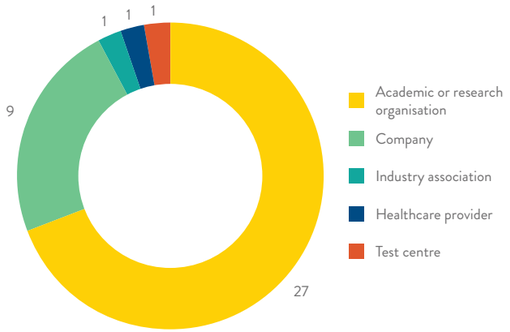


Figure 12: Contributing stakeholders represent different materials pipeline activities, with the over-representation of academic researchers in the survey responses reflecting the size and enthusiasm of the UK's impactful community, compared to a relatively small industrial community. This agrees with the observations of the bioelectronics market in the literature review.

A SNAPSHOT OF UK ACTIVITY

All UK-based industrial organisations and universities active in bioelectronics and identified in this research were mapped by location to illustrate an active and growing sector.

BIOELECTRONIC STAKEHOLDERS: BUSINESSES

There are 56 businesses active in bioelectronics innovation in the UK, 55% of which are micro or small businesses headquartered here.

KEY

- **Micro business** (<10 employees)
- **Small business** (<50 employees)
- **Medium business** (<250 employees)
- **Large business** (>250 employees)

UK-BASED

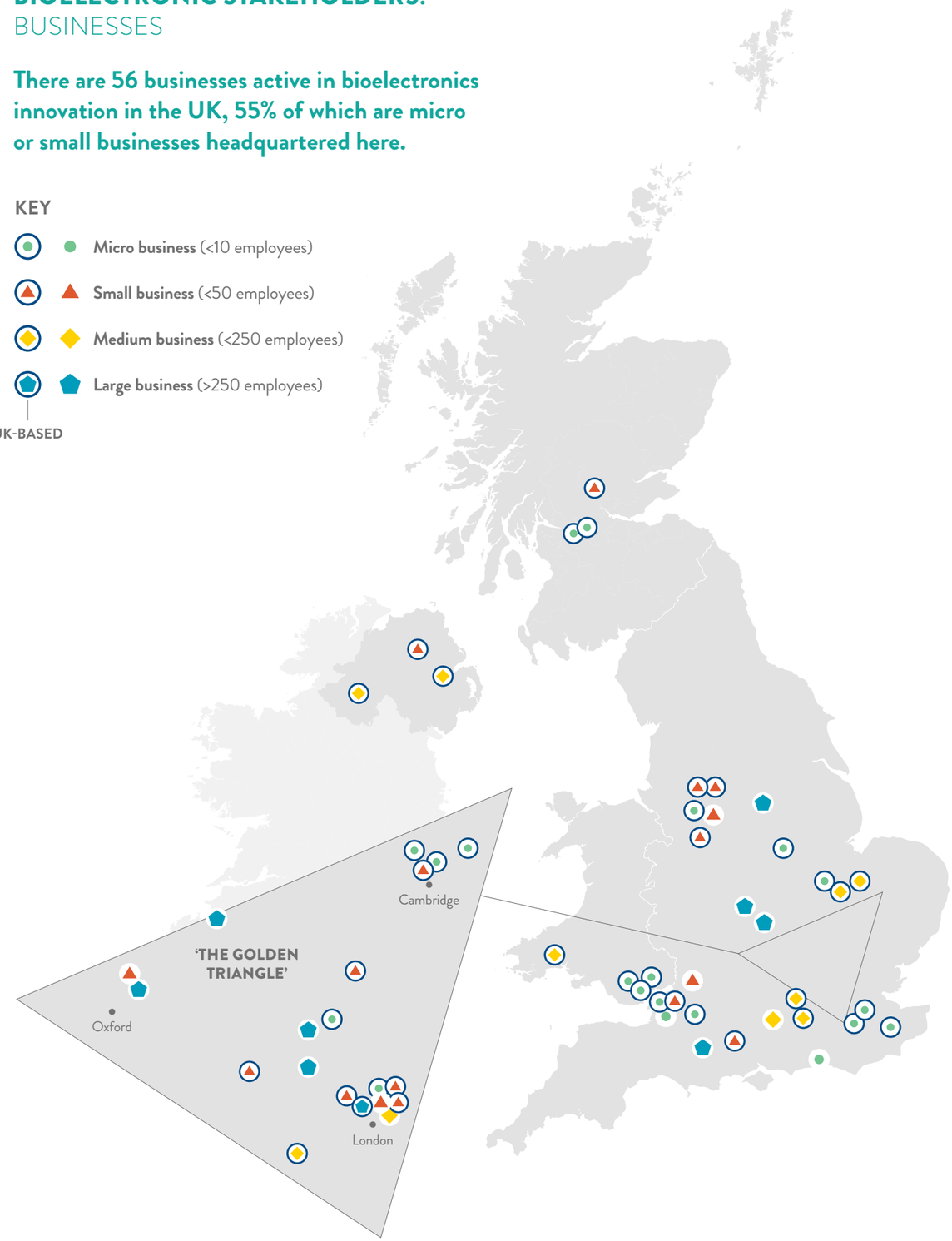


Figure 13: Key industrial organisations in the UK identified in this strategy's development

BIOELECTRONIC STAKEHOLDERS: ACADEMIC RESEARCH

There are 22 UK universities actively researching bioelectronics, a third of which have a dedicated group or institute.

Dedicated centres

1 **Bioelectronics Unit**
University of Glasgow

2 **Henry Royce Institute, Bioelectronics Network**
University of Manchester

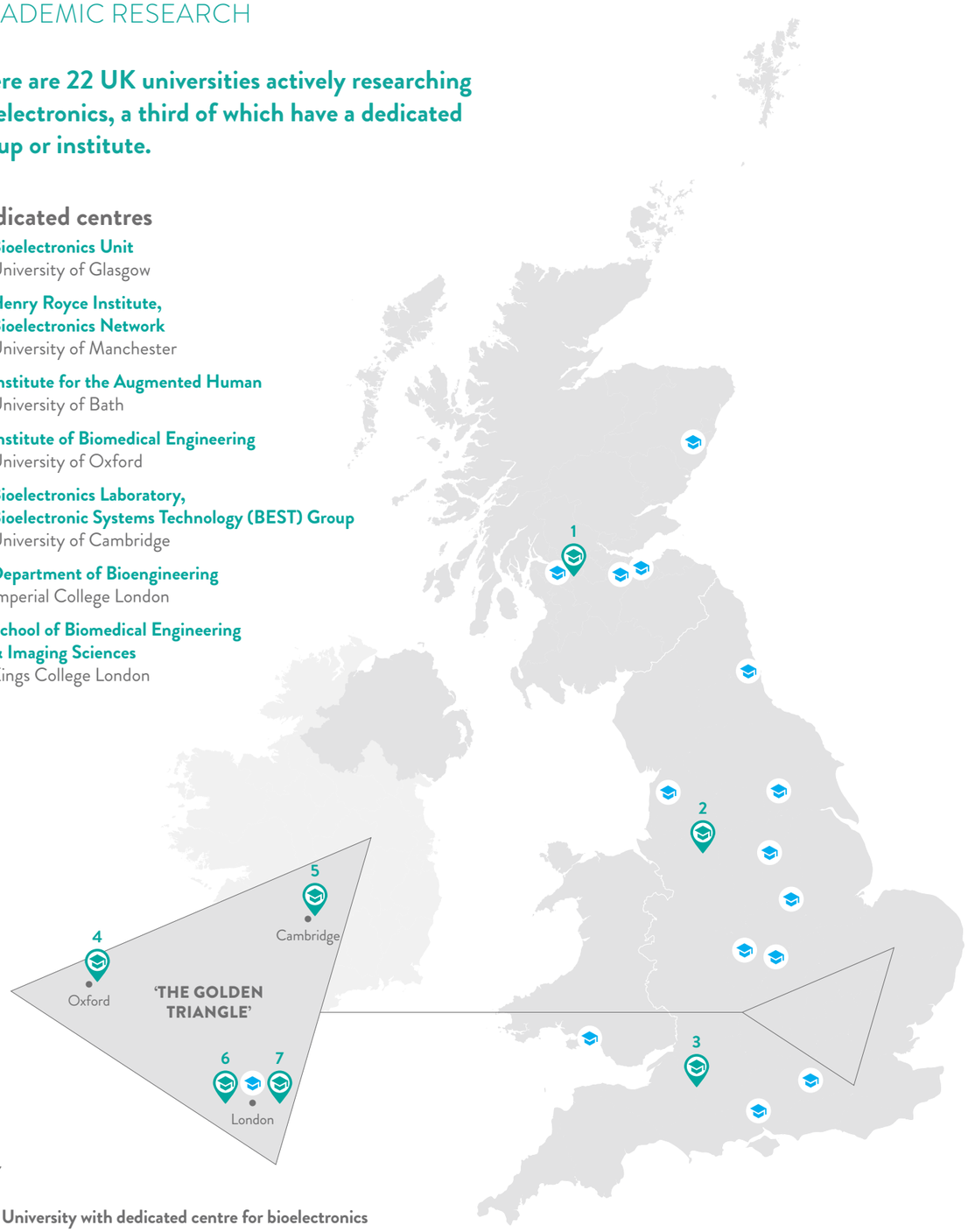
3 **Institute for the Augmented Human**
University of Bath

4 **Institute of Biomedical Engineering**
University of Oxford

5 **Bioelectronics Laboratory, Bioelectronic Systems Technology (BEST) Group**
University of Cambridge

6 **Department of Bioengineering**
Imperial College London

7 **School of Biomedical Engineering & Imaging Sciences**
Kings College London



KEY

University with dedicated centre for bioelectronics

University

Figure 14: Key academic organisations in the UK identified in this strategy's development

BIOELECTRONIC MATERIALS FOR HEALTHCARE ROADMAP

Conductive and long-life implantable materials are the most desirable for bioelectronic healthcare applications.

Information about which materials are currently being used for bioelectronics in healthcare, how they are being used, what are the most desirable properties of those materials and which materials will have the highest impact on bioelectronics in the future has been gathered through engagement.

This includes the online survey, one-to-one interviews and an interactive Q&A with a group of 70 researchers attending the Cambridge Bioelectronics Symposium held in July 2024.

From this, a roadmap of materials currently in use in the sector and the desired materials properties for future innovation has been created.

Properties that were referenced most frequently by consulted stakeholders have been identified as recommended focus areas – they represent key future opportunities for impactful innovation from the UK market.

The results were aligned against a timeline showing the readiness level for use in application development based on how the respondents reported using specific materials which had those properties, and whether those materials were being used by companies for their product development or they were being used in academic research.

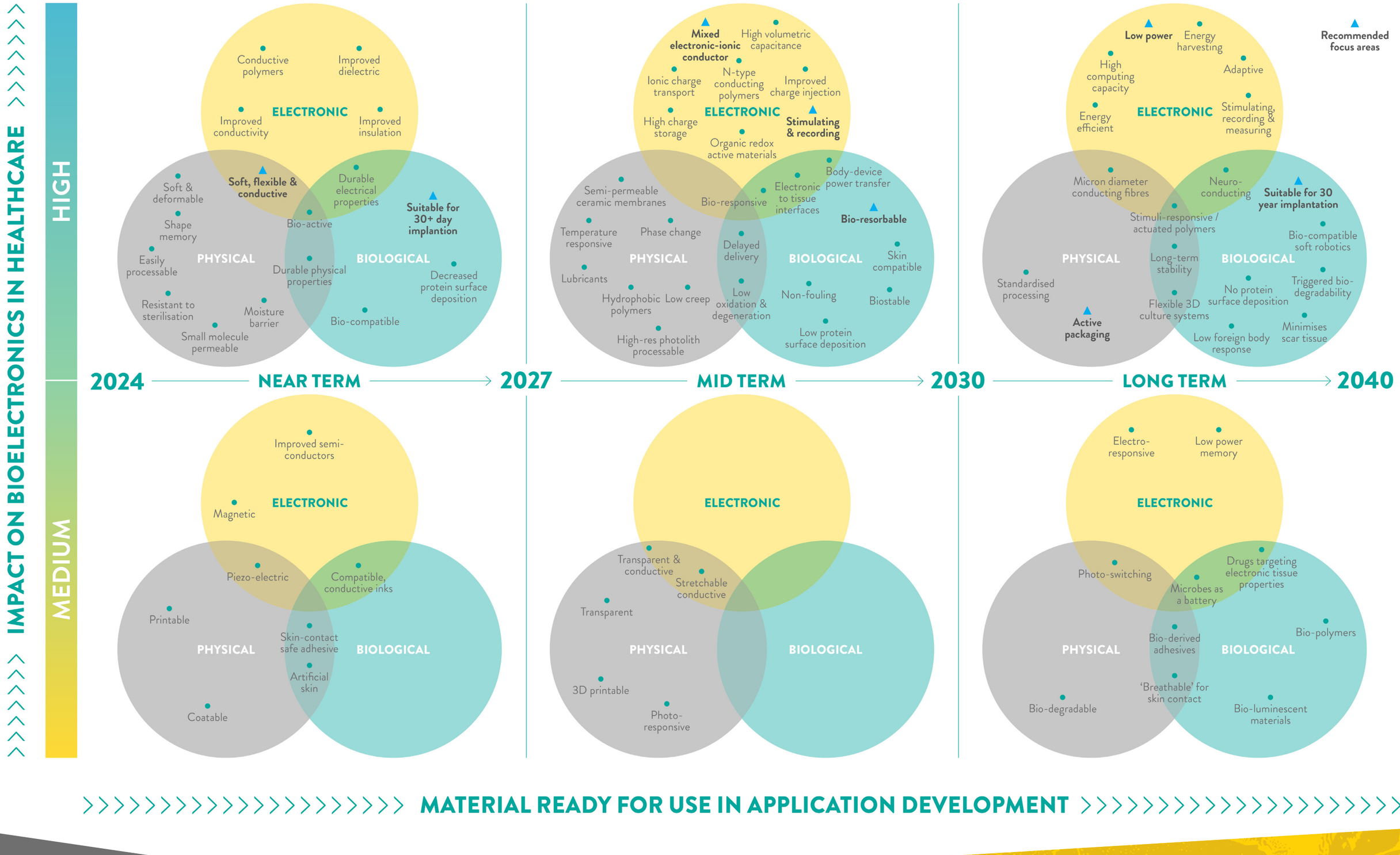
MATERIAL PROPERTIES

Responses were first grouped according to whether they related to the electronic (including magnetic), physical or biological properties of the material. They were then ranked according to their impact (high, medium, or low) on the sector.

In this context, impact was deemed higher if the material property was mentioned by multiple respondents or if the material property was cited in the context of product/ application development beyond the laboratory.

MATERIALS FOR BIOELECTRONICS ROADMAP

Figure 15: A roadmap of materials properties for the bioelectronics in healthcare sector.



MATERIAL READY FOR USE IN APPLICATION DEVELOPMENT

Companies stated that the materials innovations they would like to have available in the future would be:

- New metal alloys
- Soft and flexible materials
- Substrates with the mechanical properties of tissue
- Conducting materials using both electronic and ionic charge transport
- Thin film materials suitable for screen printing
- Wearable electrodes that were easy to apply
- Hydrophilic small molecule permeable polymers what were also non-fouling and biostable
- Semi-permeable membrane materials
- Polymers with low moisture absorption which are also very stable against biodegradation
- Triggered degradability
- Polymers with good fatigue resistance and biostability
- New charge injection materials that are approved by regulators
- Hydrophobic coatings, lubricants, and delayed delivery materials

The materials properties that companies saw as emerging included:

- materials that withstand implantation for very long periods of time (years),
- soft and flexible materials,
- transparent for non-liquid touching,
- low-power, energy-efficient quantum materials.

There was a concern expressed, however, that most new materials are used only in the laboratory and don't seem to reach the marketplace.

The academics surveyed during the symposium overwhelmingly cited stability in the body (Figure 16) as the most important material property lacking at present (79%).

The topics of stability and biocompatibility also came up repeatedly in the face-to-face interviews. It was pointed out that there are a ***"lot of nuances in the term 'biocompatibility' – the distinction between industrial and medical polymers is often not the material itself but the production process/ quality control of manufacturing that material".*** The diverse other materials properties cited by academic respondents are summarised in the roadmap graphic (Figure 15).

The most cited emerging material property from the online survey was "soft" (three citations). "Flexible" and "quantum" both got two citations, though the low frequency of citation is indicative of the diverse range of properties suggested.

Figure 16: Word cloud illustrating response frequency at the Cambridge Bioelectronics Symposium to the question "Which are the most important material properties lacking at present?"

SPECIFIC MATERIALS

Consulted stakeholders were asked which materials they are currently using and which materials they thought would be important for the future. The responses were grouped into four categories; metals and metal alloys, polymers, carbon and low-dimensional materials, and others.

Responses were then split according to whether the material was currently in use by companies for product/application development beyond the laboratory or whether the material was still being used in earlier stage research. This distinction can be useful to identify materials with high potential, but which currently lack evidence on biocompatibility and stability.

As one interviewee stated, ***"there is definitely a danger in assuming that every solution to a materials problem is a new polymer. Existing supply chains, raw material availability and regulatory approval often trumps a novel material".***

The symposium audience, with the majority being academics, were asked which material they think will be most impactful on the field of bioelectronics for healthcare, and the clear favourite, with 32% of the vote, was PEDOT:PSS (Figure 17).

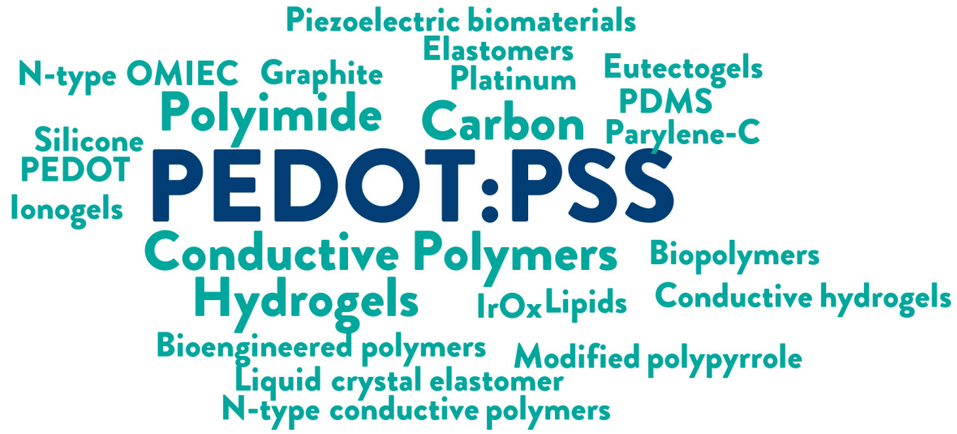


Figure 17: Word cloud illustrating response frequency at the Cambridge Bioelectronics Symposium to the question "Which material do you think will be most impactful on the field of bioelectronics for healthcare?"

Materials in use by companies

METALS AND METAL ALLOYS	POLYMERS	CARBON AND LOW DIMENSIONAL MATERIALS	OTHER MATERIALS
Metals – titanium, platinum, gold, silver, iridium, niobium, lanthanides, lithium (for batteries) **Metal oxides** – iridium oxide, metal oxide foams, magnetite **Alloys** – containing titanium, nickel, cobalt, chromium and iron, stainless steel, platinum-iridium	**Synthetic** – polyurethanes, polyether urethane, polycarbonate polyurethane (PCU), polyurethane isobutylene co-polymer, co-polymers of silicone and polyurethane, epoxy-urethane-acrylic-silicone-acrylate adhesives, polyimides, polyethylene terephthalate, polydioxanone, polycarbonate poly(styrene-block-isobutylene-block-styrene) ("SIBS"), polyisobutylene, PEEK Parylene-C, hydrogels, silicones, polydimethylsiloxane **Conductive** – PEDOT:PSS, PEDOT:PSS composites, conducting silicones **Naturally occurring/biopolymers** – natural rubber, hydrogels	Graphene Carbon fibres Conductive hydrogels with carbon Nanotubes Nanorods Nanoparticles	**Biological** – DNA/RNA, proteins, enzymes, antibodies, cells, tissues **Ceramics** – glasses, aluminium oxide, sapphire, zirconia, titanium nitride **Inorganic hydrogels**

Materials used in research

	METALS AND METAL ALLOYS	POLYMERS	CARBON AND LOW DIMENSIONAL MATERIALS	OTHER MATERIALS
CURRENT	Silver nanoparticles Gallium-based liquid metals	**Synthetic** – polycaprolactone (PCL), poly(lactic-co-glycolic acid) (PLGA), polyvinylidene fluoride (PVDF), polylactic acid (PLA) **Conductive** – polypyrrole, polyleucine hydrogels **Naturally occurring/ biopolymers** – proteins, carbohydrates, glycoproteins, mucopolysaccharides, silk, fibronectin, collagen, Matrigel™	**MXenes** – inorganic compounds composed of atomically thin layers of transition metal carbides, nitrides, or carbonitrides **MBenes** – 2D transition metal borides Gallium nitride and zinc oxide nanodiamonds Activated carbon	**Ceramics** – zinc oxide, barium titanate, silicon nitride, iron(II, III) oxide **Biological** – conjugated oligo-electrolytes **Natural organic pigments** – melanin (squid ink), bilirubin
FUTURE	New alloys	**Synthetic** – medical grade polyimide, PFAS replacements	Polycrystalline diamond	**Biological** – bacteria, electroactive micro-organisms

APPLICATIONS

Respondents were asked about what they are using their materials for, and these responses were complemented by information gathered on uses cases from both the stakeholder lists and from looking at the topics of conferences in bioelectronics.

The list below gives some of the therapeutic areas which bioelectronic materials are currently being used to address.

THERAPEUTIC AREA	CONDITIONS
Brain and neurological	Brain cancers (e.g. glioblastoma), multiple sclerosis, Parkinson's disease, seizures/epilepsy, neuropathy, paralysis, spinal cord injuries, motor neurone disease, brain aneurysms, central neuropathic pain, neurodevelopmental conditions (e.g. ADHD, dyslexia, Tourette's syndrome), Alzheimer's disease, vascular dementia
Psychiatric and mental health	Schizophrenia, depression, stress, post-traumatic stress disorder (PTSD), addiction (e.g. tobacco)
Cardiovascular and vascular	Resistant hypertension, hypertension, other cardiovascular diseases, bleeding, circulatory disorders
Respiratory	Chronic obstructive pulmonary disease (COPD), sleep apnoea, other respiratory diseases
Gastrointestinal and metabolic	Crohn's disease, ulcerative colitis, obesity, diabetes mellitus (type 1 and 2)
Musculoskeletal	Chronic pain, musculoskeletal disorders, ankylosing spondylitis
Autoimmune and inflammatory	Rheumatoid arthritis, psoriatic arthritis, systemic lupus erythematosus (SLE)
Sensory and organ impairment	Hearing loss, sight loss, bladder dysfunction, bladder disease

The different application areas in which materials for bioelectronics are being used has also been identified in this research.

TREATING AND DIAGNOSING	IMPROVING FUNCTION AND WELLBEING
• Recording muscle activities • Control of gene expression • Brain-computer interface • Rehabilitation • Diagnosis of disease • Spinal cord "bypass" • Nerve graft surgeries • Stroke rehabilitation • Neuro prosthetic systems • Deep brain stimulation • Vagus nerve stimulation • Functional neuroimaging • Adhesive bonding (to the body and of materials making up devices) • Blood pumps • Organ transplants • Drug delivery • Measuring pressure • Heart valve replacement • Continuous Glucose Monitoring • Stents • Brain frontal lobe electrostimulation • Neuromodulation • Monitoring brain activity	• Metabolic control • Improving physical wellbeing • Improving memory • Improving organ activity • Relaxation • Post surgical complications • Assistive communication devices • Reducing scarring around implanted devices • Retinal prosthesis • Monitoring of spinal implants • Cochlear implants • Control of prosthetic limbs • Meditation • Learning • Performance enhancement • Batteries to power implanted medical devices • Cardiovascular stimulation • Tissue repair • Interfacing with cells • Wireless power • Wearable ECG measurement • Animats (robots controlled by neural cultures) • Biomarker testing, e.g. lactate, cortisol

An observation from this research is that as the risk of patient harm of a use case increases, the number of materials with a demonstrated history of use goes down and the time and expense to certify a material goes up.

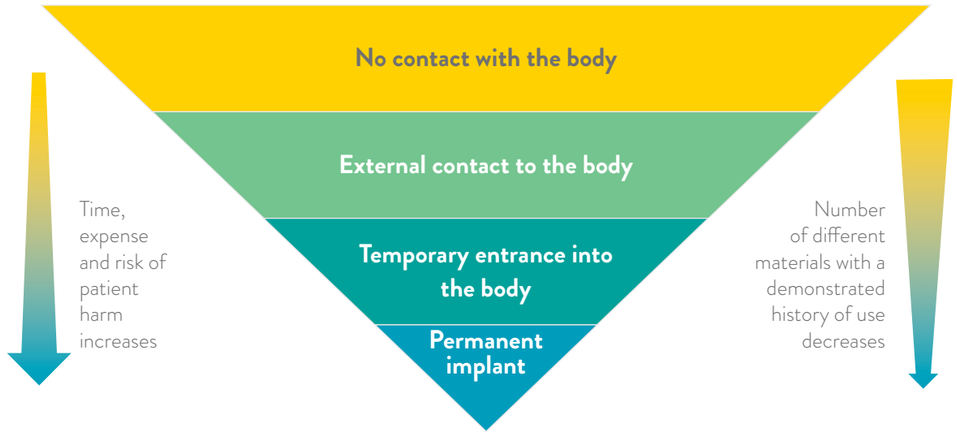


Figure 18: Summary graphic of a key observation of correlation between the number of materials with a demonstrated history of use and the implantation period.

MATERIALS ROADMAP CONCLUSION

There are a diverse range of applications for which bioelectronic materials are being used in healthcare and there are a wide range of different materials either in use or in development. However, not all of the currently available materials with desirable properties can be incorporated into healthcare devices because of the significant challenges in achieving regulatory approval.

Approval to place a new medical device on the market is given at the product level and and, therefore, any change in material would require device reapproval. Ideally, any new material would already have a demonstrated history of safe medical use for the intended contact type and device lifetime. As this is unlikely to be available for many materials, and certainly all novel materials, the required time and effort to collect a sufficient body of evidence, particularly for high risk or long duration devices, presents a challenging barrier to successful utilisation.

While new materials may be interesting to the sector as potential solutions to performance challenges, there was a strong preference within industry and device researchers to utilise proven material sets because they have 'good enough' performance, are well understood and are have proven biocompatibility.

Only materials that offer a significant step change in performance are likely to be progressed into longer term studies with the material implanted into the body, due to the high cost and significant time required to demonstrate that the material's performance endures without causing harm to the patient.

Rather than referring to, or prescribing, specific materials, material properties have instead been captured in this roadmap to identify those which are likely to have the highest future impact.

In the near-term, materials with desirable electrical properties as well as good biocompatibility are likely to have the highest impact – which is why metals such as titanium, platinum and iridium and existing metal alloys are commonly chosen for electrically interfacing with the body. Where new conductors are introduced, a corresponding insulating material with the same physical and biocompatibility properties may also be required.

Polymers provide softness and flexibility, which, when combined with good biocompatibility, makes them a desirable choice for packaging and insulation applications. If the polymer materials are also conducting (like PEDOT:PSS) then they are very useful for connecting electronics to the body.

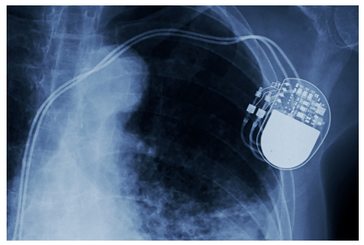
In the future, this research suggests that higher impacts will come from materials which have combinations of desirable electronic, physical and biological properties. Examples of this are stretchable, flexible and conductive biocompatible materials, or bioresponsive materials which change their properties according to their environment in the body. Some combinations would be unique to the specific application, such as conductive materials which are bioresorbable.

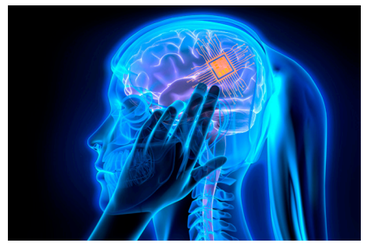
The ease of processing of a material is also important, as it must be incorporated into a device to reach the market. Materials which can be processed from solution or coated at low temperature are preferred, as well as materials for which a standard process of patterning or forming exists, such as printing or photolithographic patterning.

Looking out further into the future, materials which are active or "smart" in their response to stimuli will be important, along with materials which can withstand degradation in the body for extended periods of time (years). Materials which may not contact the body directly, but which contribute to improvements to the performance of the electronics or to improvements in the system engineering, will also be important.

It is likely that combinations of materials will be needed to solve certain challenges where opposing properties are required. For example, where a material needs to be non-adherent to prevent protein deposition and biofouling within the body but yet make good electrical contact to tissues and the rest of the device.

In order to provide some focal points for future materials development activities in line with the roadmap, three key Grand Challenges around materials for bioelectronics in healthcare are proposed.





1. Long-term (>10ys) implantable materials

Materials that can withstand implantation for very long periods of time (many years) but maintain all their required functions (i.e. mechanical strength, permeability). Decreasing or moderating the foreign body response (through drug release, morphology and material properties) and decreasing protein deposition onto the surface are potential solutions.

2. Materials with ideal electrical properties

Electrically conducting materials with good biocompatibility and mechanical properties similar to tissue, making them ideally suited to interfacing electronics with the body for long periods of time. These materials should allow good charge injection across a wide range of frequencies. Materials with mixed electronic and ionic conduction, for example, have improved biocompatibility compared to metals and can perform better when interacting with ion channels and signalling pathways.

3. Materials which improve sensor performance in vivo

In vivo sensors suffer from biofouling, caused by the accumulation of proteins or cells on the sensing surface or inflammatory response of the body to the sensor. Biodegradation causes unpredictable changes in the sensor's response characteristics (e.g. sensitivity, baseline, selectivity, etc.) and may lead to a rapid device failure. New materials would enable sensors to be deployed in the body for extended periods of time without loss of performance.

Four UK case studies are included to illustrate the full range of materials solutions for bioelectronics in healthcare – ranging from early-stage research to commercial deployment.

CASE STUDY 2: MATERIALS VALIDATION

PEDOT:PSS SENSING OF INFLAMMATION IN GASTRIC TISSUE
UNIVERSITY OF CAMBRIDGE

Led by Professor Róisín Owens, the Bioelectronic System Technology (BEST) Group is a key part of the University of Cambridge's Bioelectronics Laboratory. The group is researching the potential of bioelectronic materials for healthcare, including electroactive conducting polymers and organic electrochemical transistors.

Unlike much of the existing research in the field of bioelectronics, which focuses on materials interfacing with cardiac or brain tissues, this group is exploring electrical activity in the gut-brain axis. There is a growing recognition within the sector of the potential of utilising the electrical properties of many different types of cells.

A recent study involved connecting thin-film electrodes, made from the conducting polymer PEDOT:PSS, with barrier tissue in the gastrointestinal tract or airway epithelium. By measuring the cells' electrical impedance, the group can identify signals which are consistent with inflammation. This technology could be used to understand and treat inflammatory bowel disorders such as ulcerative colitis or Crohn's disease.

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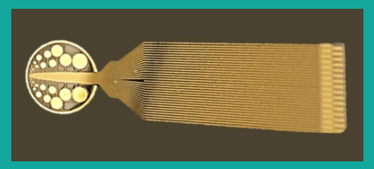


Microfabricated flexible conformal device placed on intestinal tissues. S. L. Barron, et al. 'A Conformable Organic Electronic Device for Monitoring Epithelial Integrity at the Air Liquid Interface' Advanced Materials (2024) https://doi.org/10.1002/adma.202306679

THE STRENGTHS AND CHALLENGES TO BIOELECTRONIC MATERIAL INNOVATION FOR HEALTHCARE IN THE UK

Materials innovation in the UK is shaped by a variety of scientific, commercial, regulatory and cultural forces.

A profile of the sector has been created, where observations made by stakeholders on the innovation environment have been categorised either as strengths to the UK sector or as challenges faced by it.

These statements provide an illustration of the experiences researchers, innovators, entrepreneurs and clinicians face in developing and applying a novel material to a bioelectronic solution in healthcare.

They must be addressed to achieve the material performance requirements of the roadmap and Grand Challenges, and so they have directly informed the recommendations for actions to take to develop an impactful UK sector.

THE UK'S STRENGTHS

Materials science and computational modelling

- A cluster is growing with researchers in the "golden triangle" of London, Cambridge and Oxford.
- The UK research sector is viewed internationally as being an open, exciting environment in which to start your career, so it is attracting early-career researchers.
- Historically, the UK has strengths in fundamental materials research and a respected reputation for it.
- The primary focus for researchers in this area is developing a material that works, and this is where the sector is most likely to see a transformative breakthrough.
- There are also possibilities for transformative innovation in the processing of the large quantity of data that bioelectronic devices and their sensors will produce. The UK has an established research function in computing – including quantum computing and AI – that could contribute to a breakthrough.

Materials formulation and characterisation

- Currently, the bioelectronics materials market is dominated by a few global companies that supply well-researched materials including PEDOT:PSS and iridium. However, there is a wider range of materials that are biocompatible and conducting which, if supplied for the medical rather than the industrial market, would unlock new possible applications.
- Even where materials are found to be unsuitable for interaction with the body, there are other applications that may make use of them, such as circuitry, neural networks and hybrid applications. The UK has research strengths in these areas, which are networked with bioelectronics research.

Application research and development

- This phase of material translation is very different depending on the intended length of contact of the material with the body and the level of invasiveness. UK researchers have experience across this range.
- The are lots of recognised UK strengths in advanced materials for two key areas: interfacing electronic materials, and computing materials and microelectronics.
- The UK academic system is very open, and it is much easier for researchers to arrive at a university and establish a research area than in other European countries.
- There is a need to be open and flexible at this stage to the eventual utilisation of an application. The UK has an advantage due to the NHS and its clinical networks providing insight into all clinical needs across specialities in one organisation.
- There is scope to take inspiration from previous medical innovations where the UK has led – such as drug discovery.

Application validation and testing

- A couple of UK universities have clinical engineering departments and can conduct their own in-human testing for non-commercial research.
- In-silico toxicity screening is already available in the UK.
- New legislation has been developed around implantable medical devices over the last 5 years. Now, researchers need to prove the efficacy and utility of devices in addition to safety. Implants and their components will also be centrally tracked. These changes will feed de-risked solutions to investors, who know that the efficacy has been proven and that any failing units can be quickly and easily recalled.
- The Medicines and Healthcare products Regulatory Agency (MHRA) regulatory processes have been undergoing improvements in recent years.
- There is an opportunity post-Brexit for the UK to define its own regulations.
- Experience is growing in using "device exemptions" to fast-track the United States Food and Drug Administration (FDA) approval of devices that use materials already proved in one in-human environment to a different application. Businesses can collaborate with regulators on using this pathway.

Device commercialisation

- There is good availability and affordability of clinical data in the UK compared to overseas. Industry needs to be laser-focussed on evidencing the clinical need that the solution addresses, and data enables this.
- The UK has a cheaper operating environment, at around a third or less of the cost of commercialisation in the US, and is viewed as being a more altruistic environment for healthcare research and testing than the US.
- The NHS is a significant asset to commercialisation in the UK, representing a single, easy to navigate framework for scaling across the whole country. As a national health care system, it also allows for patients to be tracked more easily and the long-term impact of therapies to be monitored better than (for example) in the US.
- There is a growing community of spin-outs and start-ups in the UK.
- Large medical technology companies are identifying start ups with experience and partner with them, integrate them, or fund them to conduct innovation commercialisation and derisk solutions, rather than doing it on their own.
- Although it is common for UK businesses to be acquired overseas, people who exit these companies are still active in the sector and have lots of experience in commercialisation.
- UK IP protection is strong, but isn't necessarily considered as a significant barrier to innovation in this sector where a strong product or novel material is clearly owned by an individual innovator or team.
- The University Spin-out Investment Term Guide (the USIT Guide) is an agreed set of recommendations for university spin-outs. Although it is a relatively new resource, it provides researchers with a pathway for fast tracking IP from university research and has been adopted by all the "golden triangle" universities.

Clinical application

- Once approved for use, it is relatively inexpensive to get a device used in a clinic.
- The NHS and Health Innovation Networks provide a single pathway to national procurement once a new device has demonstrated net gain.
- Word of mouth is very powerful in the UK, and accelerates the uptake of new solutions.

Translational support

- There is lots of support available in the UK from government bodies, including Innovate UK programmes from MedTech development (such as the KTN neurotechnology roadmap) and Department for Business and Trade advisory support on exploring new markets and capitalising export opportunities.
- The Medical Research Council (MRC) has a regulatory support centre that is available to help device regulation.
- The challenges faced by innovators and companies across the sector are rarely unique; there is a significant opportunity for knowledge sharing.

Funding

- Research into materials for bioelectronics can be supported by three UK Government funding councils (EPSRC, MRC, and BBSRC). They collaborate together, and have specific programme officers who are in constant communication to reduce the risks of innovation falling through any scope gaps between them.
- Each funding council runs three calls a year, so there is generally always a call open to respond to demand.
- These funding councils dedicate specific funds to networks and market gaps (such as creating pilot data) in high-priority areas, including aspects of bioelectronics. These stimulate research and networking.
- The UK has a vibrant charity sector that funds research and has access to lots of data. Charities know the MedTech sector, so understand and expect the long commercialisation timescales.
- There is a good level of philanthropic funding in the UK, although this tends to be a more cautious source of funding.
- The business funding community in the UK is strong, as it is generally assumed that raising a few million pounds is not too significant a challenge. There are angel investors who will contribute thousands, and Innovate UK grant funding for larger investments.
- Grants and investments tend to be driven by market needs and – where researchers identify a clear clinical need, patient group and business model – they are highly likely to win funding.

THE UK'S CHALLENGES

Materials science and computational modelling

- It is difficult to attract funding to exploratory fundamental science research that is not directly impact- or market-driven. But, fundamental research is not a linear process that can be directly commercially- or challenge-driven.
- This research works to a longer timescale than translational research, which is off-putting to investors.
- Start-ups can't compete in this sector in the UK due to a poor availability of computational power.

Materials formulation and characterisation

- Royalties for MedTech materials tend to be low. There are hundreds of component materials in a device, and so the royalties distributed are tiny fractions of the device's cost.
- The quantities of materials needed for bioelectronic devices are tiny, often at the milligram scale, making it even less commercially interesting to materials innovators.
- The detail of material characterisation data and development activities innovators require before considering it for applications is high – innovators are only interested in transformational new materials that are proven to be biocompatible, have desirable mechanical properties, and a manufacturing pathway.
- There are a huge number of biological environments that a material could be characterised in, from vascular and gastric to on-skin. Innovators need to invest in the environment that they anticipate the material performing best in.
- Characterisation data is not openly available from suppliers – often they will only provide it to regulators – and this stifles potential material translations.
- There is a lot of nuance in the term 'biocompatibility'. The distinction between industrial and medical polymers is often not based on the material itself – which can be biocompatible in principle – but the production processes and quality control of manufacturing it.
- The full formulation and manufacturing process needs to be considered when developing a new material that is intended to be biocompatible. For example, polymer formulation uses coupling reactions catalysed by metals, a lot of which ends up in the device and charging and discharging leads to poor long-term stability and degradation of the material. Further, the effect of in-use treatment of the materials, like cleaning processes, need to be considered.

- Many researchers fabricate their own materials, but struggle to access the clean and controlled environments needed to fabricate them to the high purity and quality standards required in medical technologies.
- Many application researchers purchase materials from companies and rely on off-the-shelf components. They don't consider the role of materials fabrication, characterisation and innovation in bioelectronics.

Application research and development

- The bioelectronics material supply chain is dominated by a few, global companies. This causes various problems for novel material adopters including:
  - **Purity:** the repeatability of each batch is not guaranteed and each new batch needs to be re-tested.
  - **Batch size:** these large suppliers want to supply large batches of material only (kilograms or above), whereas the quantities needed for bioelectronics applications may be very small (in the region of a few milligrams). Consequently, they can charge high prices for small quantities of materials typically used at the research stage and in this sector.
  - **Lead times:** the sales and production arms of these suppliers are not flexible and responsive to individual research requirements.
  - **Liabilities:** the materials suppliers do not want to be responsible for any liabilities due their material being used in clinical research, and will block sales to researchers who they believe will use them for bioelectronics applications.
- Large medical device companies often synthesise their own materials, meaning that these novel materials are not available on the market for other innovators.
- The FDA does not approve a material, it approves devices and their use cases. This does not encourage confidence in the translation of a material into a new application.
- A shortage of silicon hit electronic chip development in recent years.
- Commercial awareness at this stage is needed, but can be poor. Academics can be siloed from industry and drawn into focussing on technologies that use overly complicated functional materials that don't scale.
- Bioelectronic devices need accompanying circuitry and software, which is not currently a research strength in the UK.
- A degree of secrecy surrounds early-stage startups, as they are cautious about disclosing their new application or material to larger competitors.
- Researchers favour overseas and US research partnerships for accessing specific capabilities or commercial potential.
- Bioelectronics is interdisciplinary, and researchers can find it hard to interact with those from other disciplines.

Application validation and testing

- There are huge financial disincentives to researching new materials, including the recalibration of machinery and investments in validation and testing capabilities, and it can take up to two years to establish lab capabilities, so researchers default to the materials that they are already using (e.g. platinum and iridium).
- Each use case and environment of a material application requires regulatory approval – materials can't be approved in one device and used in another. Use in one device can establish a precedence for subsequent devices however. ISO 10993 asks applicants to collate evidence relating to safe use in other products.
- Testing facilities and clinical trials are costly (although they are cheaper in the UK than in the US) and can be difficult to access, for example, licences for animal testing are heavily restricted.
- UK regulatory processes for clinical trials and in vivo testing are very strict. This includes the pre-clinical trials required by MHRA that need time and investment.
- Innovators often balance FDA and EU approval at the same time at MHRA, but the FDA will not accept testing if it only takes place in the UK.
- As with fabrication, it can be difficult to access controlled testing environments that meet MedTech standards. Further, it is hard to convince funders of the need for specific, controlled, single-user fabrication and testing environments for these applications.
- The use of a novel material significantly increases the regulatory burden, timescale and cost of a new device.
- Innovators are not necessarily aware of existing standards for testing medical devices (e.g. IEC 60601) as they believe that they are exploring a whole new technology application.
- Innovators experience batch variations in material supply and rely on contract research organisations to conduct biocompatibility testing on a sample from each batch, costing around £20,000 – 30,000.
- Standards have not been refreshed for some time and would benefit from modernisation, which will reduce testing costs. A review is underway for ISO 10993, but it's not expected to be in force for another couple of years.

Device commercialisation

- Commercialisation is slow, with end-to-end development taking 6 to 8 years, or longer for complex devices.
- The emerging nature of the sector's definition means that not all areas are offered the same commercialisation opportunities. Neurostimulation and consumer wearables capture imaginations, whilst established applications like pacemakers, glucose monitors and cochlear implants dominate the market pull.
- The US has a strong, large medical technology market and young UK businesses are pulled there.
- The US also has more capital investment available, attracting UK businesses there after their first round of funding.
- The UK market appears smaller and more complex post-Brexit. Internationally, it is not a target market for device developers.
- Accessing clinical-grade, high replicability raw materials is a challenge for commercialisation and supply chain scaling. This is compounded by the fact that there is currently no large UK material supplier.
- Manufacturing capabilities are limiting commercialisation: it is difficult to access clinical-grade translational research and manufacturing facilities (especially for Grade III medical devices), consistency and quality control are hard to achieve, and medical device manufacturing methods have not progressed beyond hand assembly (although some research in photolithography and additive manufacturing methods has the potential to disrupt this).
- University spinouts are key players in this market. Compared to other European and US universities, the UK has fewer mechanisms and less experience in successfully creating spinouts.
- This is generally a conservative industry, that interfaces with social, ethical and political trends and drivers. A culture of caution and sensitivity dampens commercialisation.

Clinical application

- Clinicians need to see devices developed based on clinical needs, not as a response to grant funding. The clinician-engineer partnership must also be encouraged wherever possible.
- The UK healthcare system is under enormous financial pressure. New devices must be cost effective and comparable to existing solutions, making the UK market less attractive than other international markets with less financial pressure.
- NHS procurement is considered to be complex, too focussed on price, and adverse to creating a leading life sciences sector in the UK.
- There are big discrepancies in the working practices and device use between hospitals and even within them, with poor communication between wards and departments.
- Surgeons need devices to be designed with real-world tolerance levels. If a device is to be implanted, then a wide range of surgeons need to be able to implant them effectively, and for wearables, a wide range of individuals need to be able to apply them.
- If a new device increases surgery time, this impacts its cost-benefit analysis.
- The long-term stability of implantable devices and battery lifetimes limit potential medical applications.

Translational support

- The vague definition of the emerging sector means that there is a lack of awareness of it in government and public bodies, including funding councils, and a lack of confidence in industry that any body is taking ownership of bioelectronics.
- There is a very limited large business presence in the UK to lobby on behalf of the sector.
- Startups and small businesses outside of university research groups need a lot of support to purchase or access the specific equipment and facilities needed for this sector. Where affordable facilities do exist, skills to operate them are often lacking.
- The Catapults and other translation support organisations in the UK are often more comfortable with and experienced in dealing with larger businesses and projects, but need to work on a smaller scale in this sector.

- There is a policy precedent to balance a good spread of innovation across the country, but this needs to be done whilst protecting the benefits of growing a critical mass in one area (such as the "golden triangle" or the North West).
- Innovation in this sector is driven by micro- to small-businesses – larger businesses wait for them to de-risk the opportunity before they commercialise it, often by acquiring them – so the focus needs to be on growing an environment that supports them.
- Materials restrictions are developing internationally, for example the EU REACH regulations on PFAS chemicals, and the UK needs to be active in defining and reacting to restrictions.
- Critical minerals are needed for bioelectronic devices, and the UK Government needs to continue to secure the supply of them to the UK market.
- The translational divide between university and industry is stark in this sector, where technology-driven innovations are not attractive to risk-averse large businesses. UK innovation support is yet to address this.
- Regulation changes after Brexit and standards that lag behind the rate of innovation are both risking small business growth potential.
- There is not yet a single, proven pathway for UK innovations in bioelectronics.

Funding

- There is a big step up in funding needed for each technology readiness level (TRL) in this sector due to regulations and testing requirements. This is in the region of ten times more funding at each stage, and there are various "Valleys of Death" along the pipeline because of this.
- There are a limited number of grants that support international research collaboration.
- The grant schedule is inconsistent, and the bioelectronics sector does not sit under one research council, so can be inadvertently left without funding if schedules do not align.
- Funding applications can be lengthy and complicated, with grant application feedback taking months to be returned. This favours companies with professional application drafting experience, which damages the chances of this start up-dominated sector winning funding.
- Profit margins are much smaller for devices than pharmaceuticals, at around 30% as opposed to around 90% or more.
- Investors are discouraged by the high investments and long development lead times of this sector.
- Government funding cycles are often too short to provide support through the entire commercialisation process.
- There is very little start up investment funding outside of London.
- Building up enough data to attract investment can be difficult, especially prior to clinical trials.

SUMMARY

Innovating in materials for bioelectronics involves balancing the UK's unique strengths against the sector's challenges.

STRENGTHS

NETWORK

A collaborative and willing UK network, including regulators, the NHS, research councils, and charities.

"We've got a really good hospital network, close collaboration between academics and the NHS. There's a framework to deliver clinical studies at a very reasonable cost"

NHS CONSULTANT NEUROSURGEON

REACH

A core group of bioelectronics and materials science research teams, with an impactful and respected research output.

"There is a large group of research teams working in the bioelectricity space, probably more than anywhere else in the world."

BIOMEDICAL SCIENCES RESEARCHER

COMPETITIVE

A more affordable research environment for materials innovation than other international clusters, with structures that favour innovators.

"You have advantages in the UK: salaries are a bit lower, so it's easier to afford people compared to the US, and clinical trials are significantly less expensive here."

BIOELECTRONICS RESEARCHER

UK MATERIALS FOR BIOELECTRONICS IN HEALTHCARE SECTOR

CHALLENGES

FUNDING

High development costs and long timescales for technology translation make accessing grants and investment difficult.

"It's a very difficult market … early investors are typically looking at 7 years to develop an implantable device and the cost is £100 million."

BIOELECTRONICS RESEARCHER

FACILITIES

The cost and availability of facilities needed for formulation and testing of novel materials is a barrier to innovation.

"At the moment we don't have access to any facilities where we could manufacture a device under the right quality controls to conduct a clinical trial."

BIOELECTRONICS RESEARCHER

SCALING

Scale up funding is a barrier, and pathways are complex, including navigating manufacturing and regulation challenges.

"We're trying to access really small sums of money to run our business, but the grant funders need us to write War and Peace to get it."

CEO & CO-FOUNDER, BIOSENSING START UP

DATA

Data about novel materials and their interactions with biological systems is not openly available.

"I would like to use this novel material, but I don't have the data available to make the leap to adopt it."

BIOMEDICAL ENGINEERING RESEARCHER

SUPPLY

It is a challenge to access reliable novel materials in appropriate purities and quantities.

"Our material requirements are very small, only a few kilos per year. Most suppliers are used to selling in tons, so that is definitely a challenge."

TECHNICAL DIRECTOR, BIOWEARABLES COMPANY

AWARENESS

Researchers and developers aren't identifying, understanding and meeting the needs of industry and clinicians.

"There's often a discrepancy between people doing science and those using their solutions. As a result, you get problems to meet the solution rather than vice versa."

NHS CONSULTANT NEUROSURGEON

DEFINITION

Bioelectronics is an emerging sector that is incredibly multidisciplinary. Its poor definition is limiting its access to funding and skills.

"One of the key challenges in this area is that there's a lack of clear terminology."

PORTFOLIO MANAGER, UKRI RESEARCH COUNCIL

INTERNATIONAL INNOVATION ENVIRONMENTS

Bioelectronics in healthcare is a truly international sector. This engagement included contributions from scientists and innovators from outside of the UK, and UK innovators with experience of international markets. Insight into the operating environments of these markets is summarised here.

USA

STRENGTHS	CHALLENGES
• Big tech giants like Meta and Amazon are investing in bioelectronics companies, meaning that many are co-locating with these investors in Silicon Valley and other tech clusters in the US. • The US health care market is large and wealthy. It is considered the primary market for introducing a new medical technology. • The US regulatory market has greater clarity and a collaborative approach, not just in relation to materials but also their accompanying software solutions. • Once materials are approved for use in a device in the US, they are more likely to be considered for other applications. • The US FDA approval for in-human testing restricts testing only on the basis of safety, not efficacy. • Seed and Series A to C funding processes are much easier and clearer in US markets, where there is a larger population of investors and specific pools of biotechnology investors. • Existing big MedTech companies are mainly based in the US and are focussed on the solutions they know they need, providing valuable insight to researchers. • The investment landscape in the US is good for medical devices right now, as bubbles in pharmaceuticals and digital solutions are tapering off and MedTech is no longer competing with them.	• The US's security landscape is increasingly aware of bioelectronics research, and they have recently had a senate debate on adding export controls to brain-computer interface solutions. • Several researchers and businesses in the US report being aware of the UK's academic strengths, but have not collaborated with UK researchers – perhaps because of poor self-promotion or collaborative structures. • Large US material manufacturers are risk-averse due to historic cases of large liabilities being claimed against implantable polymers. Consequently, there is little interest in manufacturing and scaling novel materials. • It is considered essential to hire regulatory consultants including statisticians to navigate the FDA process, and this can drive up costs and timescales. • Bringing a new product to market reportedly cost one consultee around $50 million.

Europe

STRENGTHS	CHALLENGES
• Clusters in Germany, the Netherlands and Spain were observed. Large consortia already exist in Europe, and the UK should collaborate with these. • In Sweden, there is a model where academics are able to join start ups with a grace period to return to their old position if it isn't successful. • In the Netherlands, IMEC has grown a local ecosystem by supporting start ups to use its facilities. • European companies and researchers do not see specific barriers to collaborating with UK organisations, particularly now the UK is back in the Horizon programme. • Whereas the UK has limited electronics manufacturing, Germany and other European countries have electronic manufacturing capabilities that can be used by UK companies.	• Restrictions on the use of BPAs and PFASs within Europe are currently under development (EU REACH Regulations). This is likely to become an issue across other international markets as well. • In Germany, many of the standards for bioelectronics do not yet exist. Data on material performance needs to be generated to create these standards. • The EU regulatory scheme is stringent and viewed as holding the market back in comparison to the US approach. • There is new legislation in the EU, with the Active Implantable Medical Devices Directive (AIMDD) becoming part of the Medical Device Regulation (MDR). Broadly, MDR has not been viewed as a positive due to the complexity, costs of compliance and approval timelines.

Other international markets

STRENGTHS	CHALLENGES
• Australia has a strong presence in the new materials development landscape, with the development of Elast-Eon biocompatible polyurethane by CSIRO.	• Markets in Asia including China and South Korea are growing and attractive to innovators, however, the language barrier is significant in complex regulatory processes and innovators are less likely to attempt to launch in these markets first.

Four UK case studies are included to illustrate the full range of materials solutions for bioelectronics in healthcare – ranging from early-stage research to commercial deployment.

CASE STUDY 3: TECHNOLOGY DEMONSTRATION

TITANIUM-ENCASED NEUROSTIMULATION DEVICES TO TREAT EPILEPSY
AMBER THERAPEUTICS

Picostim is the world's first miniaturised deep brain stimulation (DBS) system for treating epilepsy. Originally developed by Bioinduction Ltd, the technology has recently been acquired by another UK MedTech company – Amber Therapeutics. Epileptic seizures are triggered by abnormal bursts of electrical activity in the brain, which the Picostim aims to block or disrupt by emitting a constant pulse of current.

The device is contained within a biocompatible titanium shell, directly attached to the skull. This eliminates the need for additional surgeries to run extension leads through the neck and implant the device in the patient's chest. Additionally, the Picostim is cosmetically invisible and around a third of the size of conventional DBS devices.

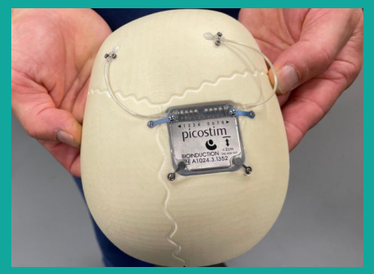
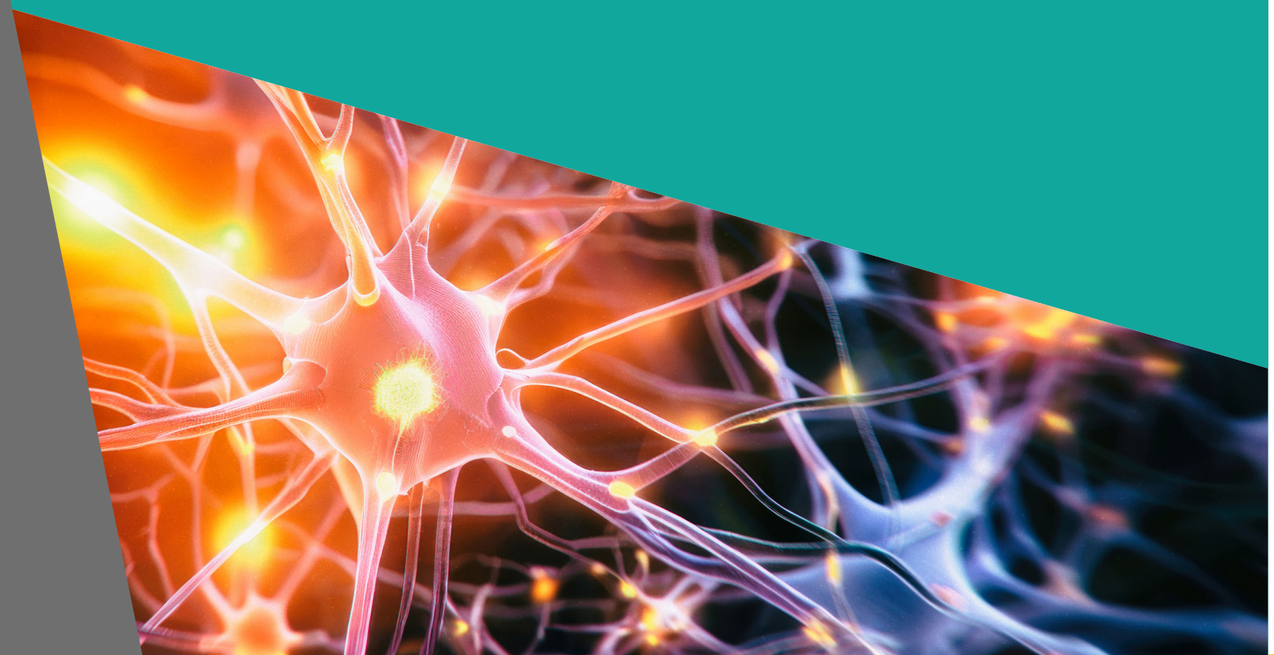


Image credit: https://www.bbc.co.uk/news/articles/cg33kgd81mvo

Initial results from a series of ongoing clinical trials have demonstrated an 80% reduction in daytime seizures for a young patient with severe epilepsy. Treatment of other neurological conditions (such as Parkinson's disease) is also being explored with the device, which can be configured to respond to tremors and other physiological signals to optimise the therapy.

Initial results from a series of ongoing clinical trials have demonstrated an 80% reduction in daytime seizures for a young patient with severe epilepsy.



ACTION PLANS

These suggested actions set out how to improve the translation environment for materials solutions.

The action plans provide prioritised recommendations for those with influence over innovation in materials for the bioelectronics in healthcare. They are stand-alone activities that can be combined or staged to be adopted at a time that suits the operations of supporting organisations and innovators themselves.

ACTION PLAN DEVELOPMENT PROCESS

Any actions identified in the course of stakeholder engagement were longlisted and processed through a sequence of categorisation activities. These ensured that each action was prioritised based on its direct impact on addressing the challenges to material innovation and harnessing the strengths of the UK's sector.

1
LONGLIST RECOMMENDATIONS
Actions identified from stakeholder engagement

2
ASSIGN TO STAKEHOLDER GROUPS
Who can take forward these actions and effect change

3
CATEGORISE THE TIMESCALE AND COMPLEXITY OF EACH ACTION
To illustrate the range of investments needed in delivering these actions

4
RATE EACH ACTION'S IMPACT ON STRENGTHS AND CHALLENGES
Score out of three the action's alignment with harnessing strengths and overcoming challenges

5
MOSCO RATING
Based on its overall impact rating and ease of delivery, each action is given a "must do, should do, could do" categorisation

6
IDENTIFY "MUST DO" THEMES
To summarise the recommended actions, key themes of the "must do" recommendations are identified

Figure 19: The stages of the action plan prioritisation and categorisation process.

The actions are assigned to stakeholder groups, identified as impactful clusters in the innovation ecosystem in the UK. These are:

1. **Royce:** the institute has a significant role to play in championing and supporting materials innovation for bioelectronics in healthcare, and specific actions can be taken on by its specialists.
2. **Universities and researchers:** those active in research materials and applying them to novel applications are key to creating new bioelectronics healthcare solutions, as are those who manage the university legal and funding structures that they operate in.
3. **Industry:** where solutions are progressed by private companies or services are provided by, for example, contract testers or manufacturers, their involvement in the sector is significant and specifically translates to economic growth.
4. **Investment community:** the private investors including angel investors, venture capitalists (VCs) and wealth funds that provide capital to businesses in the sector, mainly in exchange for equity stakes.
5. **Clinicians and healthcare bodies:** those active in the healthcare system and involved in the identification of clinical needs and introduction of new healthcare technologies.
6. **UK Government policy and regulation bodies:** the authorities and civil service departments that create policy and regulations for the bioelectronics in healthcare sector, including the Medicines and Healthcare products Regulatory Agency (MHRA), Department for Business and Trade (DBT) and Department for Science, Innovation and Technology (DSIT).
7. **UK Government funding bodies:** research and business funding, mainly through grants administered by UKRI's research councils (BBSRC, MRC and EPSRC) and Innovate UK.
8. **RTOs including Catapults:** UK-based non-profit research bodies that promote science and technology translation. Research and Technology Organisations (RTOs) include MAISI and Catapults including CPI and the Cell and Gene Therapy Catapult.

MUST DO RECOMMENDATIONS

The "must do" recommendations address the specific challenges faced by the materials for bioelectronics sector. The specificity of these actions mean that they have mainly been assigned to those stakeholder groups that are already actively developing the sector and supporting its growth, including Royce.

They have been grouped under four key themes that summarise the challenges faced by those developing materials for bioelectronics. These actions should be progressed as soon as possible to create an environment that encourages innovation.

Facilities

Elevate the quality control standards and skills in existing facilities, and invest in new facilities for the standards required by this highly controlled sector.

Ensure that the Current Good Manufacturing Practice (CGMP) standards are being met by material fabrication facilities

Facilities should be capable of meeting CGMP standards to manufacture materials to the quality assurance necessary for medical use. Current facilities should be encouraged to implement these standards and new facilities should be specified to meet them.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups: 1 6 8**

Upskill clean room testing, prototyping and fabrication facilities in the standards required in bioelectronics

Testing, prototyping and fabrication facilities may be missing out on bioelectronic commissions due to a misrepresentation of their capabilities. Build awareness of the requirements and skills needed by this sector and how to promote them.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups: 1 6 8**

Create a network of testing, prototyping and fabrication facilities available to those working in bioelectronics, identifying gaps in this network and establishing new facilities where needed

This network would be a one-stop-shop for capabilities for creating prototypes, so a level below the Catapult facilities for scaling up solutions – similar to MAISI. The demand in bioelectronics research is for: single- or restricted-user labs, animal testing, in vivo modelling or organ on chip capabilities, printing and fabrication of stretchable and flexible electronics, and clean room facilities for microsystems.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups: 1 2 8**

Direct funding at manufacturing research and innovation

Much medical device manufacturing is still completed by hand in small batches. Fund research and innovation into photolithography and other innovative manufacturing, high throughput screening, in-line testing, or processing methods that would reduce bioelectronic device costs and disrupt the market.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 1 4 7**

STAKEHOLDER GROUPS:

1. Royce
2. Universities and researchers
3. Industry
4. Investment community
5. Clinicians and healthcare bodies
6. UK Government policy and regulation bodies
7. UK Government funding bodies
8. UK RTOs including Catapults

Materials supply

Improve access to, and knowledge of, biocompatible materials through data standards, networking and advisory services.

Fund research into material biocompatibility and behaviour in biological environments

Create a wealth of research data on long term material behaviour. Begin with materials approved for use in certain scenarios (e.g. gastrointestinal) and test them in other environments (e.g. vascular).

Timescale: 3 years plus **Effort/complexity: Medium** **Stakeholder groups:** 1 7

Establish a standard for material biocompatibility data

Work with contractor research organisations on the design of a data standard on materials characterisation for bioelectronics, including functional performance (electrical and mechanical), modelling of in vivo stability and degradation, and biocompatibility/toxicity. Seek recognition and approval from regulators on this data standard.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 1 3 6 8

Create a database or other data sharing service for material biocompatibility data

Make it easier for researchers and innovators to compare different materials without investing in their own "trial and error" experiments. Share standardised data on material performance in biological environments with researchers to speed up the identification and translation of materials into bioelectronics.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 3 8

Collaborate on a catalogue of materials in use and in development for bioelectronics

Create a reference resource on the materials already available on the market, with documented properties and a reliable level of repeatability to the standard required by bioelectronic applications, and those in development with commercial potential.

Timescale: Less than 1 year **Effort/complexity: Medium** **Stakeholder groups:** 1 3 8

Establish a UK-based biocompatible materials fabricator or supplier

Create a fundamental sovereign capability in fabricating the biocompatible materials – mainly polymers but some metals – that are in used by innovators.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7

Standards

Create new standards or refresh existing ones to make them suitable for bioelectronic materials, speeding up timescales and lowering development costs.

Create digital and AI toolkits for materials computational modelling and predictive testing

Kick-start the use of AI tools in the discovery of new bioelectronic materials by supplying the tools and frameworks for their use. Utilise retrospective stability data and AI to develop these predictive materials testing and standardisation tools.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 1 6 8

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Engage with MHRA to ensure the refresh or innovation in standards meets the profiles of bioelectronic material development

Standards have not been refreshed for some time and would benefit from modernisation, including in their suitability for longevity in implantation for 50+ years, and more transparency on their anticipated refresh rates. Coordinate with DSIT, who have taken on responsibility for coordinating the Government's response to the Regulatory Horizons Council report on the regulation of neurotechnology.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 6

Clinical focus

Promote the challenges and needs of clinicians and their industrial suppliers to those researching solutions.

Create an industrial review process for researchers

Introduce an opportunity for academics to pitch their research to an experienced review body in a confidential and robust interview format. Academics will receive a strong steer on the experiments they need to pursue, and industry will have the opportunity to share their challenges with researchers and provide early feedback on manufacturing volumes and other in-use considerations of material choices. Ensure that any research shared is protected.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 3 6

Define unmet clinical needs that can be addressed by bioelectronic solutions and share these with innovators

Use data from MHRA, NIHR, the NHS and NICE to define and create the strategic cases for investment that are focussed on unmet clinical needs, not market potential.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 5 6

Build connections between university medical school and engineering or biology researchers working in bioelectronics

Clinical connections and advice can be invaluable for the commercial viability of a bioelectronics solution. Universities should proactively nominate touchpoints or research champions within their medical schools to build interdisciplinarity and maximise research impact.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 2 5

Match industry challenges with relevant researchers

Leverage new networks and connections in bioelectronics to the benefit of industry. Device manufacturers will have defined their specific needs, create a mechanism for matching those needs with research capabilities.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 3

Attract and retain early career researchers to the UK by providing them with unique opportunities to innovate

To truly maintain an internationally-recognised research and science capability, the UK needs to be attracting and retaining early career scientists and researchers (ECRs). Ensure that universities are competing international on employment practices. Empower them to innovate by sharing new material developments and foster clinical-research connections – cementing the UK as a destination for bioelectronics ECRs.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 6

STAKEHOLDER GROUPS:

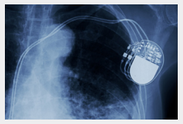
1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

SHOULD DO RECOMMENDATIONS

The "should do" recommendations offer more suggestions for promoting the sector that may be more complex and require further exploration or definition. It is highly recommended that these are taken on board by the responsible organisations, but a high degree of administration or funding may be required to implement them.

Often, some groundwork on the definition of the sector and more mature activity will be needed before these recommendations can be implemented.

Pursue the three Grand Challenges



Launch a challenge on long term implantable material interfaces

This is an area with significant potential for an impactful breakthrough. A coordinated national effort should be used to pool all data and align research, in order to capture the value of a potential breakthrough in the UK.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7 8

Launch a challenge on discovering an ideal bioelectronic conducting material

There is significant demand for a biocompatible mixed conductor with the mechanical and electrical properties of biological tissue. A coordinated challenge and fund to discover this would capture value and boost the profile of UK science.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7 8

Launch a challenge on increasing the lifetimes on in vivo biosensors

Biosensors are an important component of bioelectronic solutions and their commercial viability can be transformed with longer lifetimes. A coordinated challenge to improve biofouling and biodegradation, as well as manufacturing and unit costs, is needed.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7 8

Focus on support for start ups

Large businesses aren't investing directly in materials innovations. Rather, they are relying on start ups to progress technologies then acquiring them. Focus efforts to grow the sector on start ups to maximise impact.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 6 7 8

Create an aggregator fund for smaller scale and philanthropic investments

There is an appetite to make smaller scale and philanthropic investments in bioelectronics, but businesses usually need larger sums of money. Create an investment fund that directs undiluted, deep reserves of private capital funding towards bioelectronics innovation.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 1 4

Create step-up funds to overcome the valleys of death

Bioelectronic spin outs and start ups have some significant funding leaps during their growth – such as their first in vivo tests, first clinical tests, regulatory approval, and investments in manufacturing scalability – and research funding can be patchy. Private investment tailored towards these stages would have an impact on technology throughput. The UKRI-BioCatalyst can ring-fence funding and support for clinical trials in this area (using their current model for supporting pharma development).

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 4 7

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Form a specific fund for this interdisciplinary area

At the intersection of chemistry, biology, engineering, computer science and medicine, materials for bioelectronics can be discounted by research councils as being out of scope. Create a new fund that mixes funding from existing research councils for this area.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 7

Provide a consistent timeline of funding

The long timescales of bioelectronic material development means that a consistent and reliable source of funding is needed. Research council funding for this area is not consistent. Produce a timeline of funding opportunities that innovators can prepare for.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 7

Continue to fund fundamental science and research

Although the Research Excellence Framework rewards challenge-led research, the potential for a transformational breakthrough in materials lies in blue-skies and exploratory research. It is considered a UK strength, and should continue to be invested in.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 7

Subsidise access to testing, prototyping and fabrication facilities, particularly for early-career researchers and new research groups

Instead of diluting clusters, leverage the concentration of capabilities in the "golden triangle" to the advantage of the whole UK by subsidising access to facilities for those outside these universities or at an earlier stage in their research career.

Timescale: 3 years plus **Effort/complexity: Medium** **Stakeholder groups:** 1 2 6 7 8

Provide access to small batch sizes of materials

Large material suppliers have minimum batch sizes and relatively slow purchasing procedures. Bioelectronic applications require materials on milligram scales, and are often forced to purchase by the kilogram. Collaborate with industry to improve access to smaller batches for research purposes.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 1 3

Attract a large materials supplier or fabricator into the sector

The bioelectronics materials sector is currently not represented by a large business in the UK. This would significantly boost investment and attract talent, as well as providing a voice for the sector. Aim to create the environment for this investment.

Timescale: 3 years plus **Effort/complexity: Medium** **Stakeholder groups:** 6

Monitor the speed of regulatory processes

The lead times in regulating bioelectronic devices deter investment. Define target processing times and monitor the progress of cases through them.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 6

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Create a "network of networks" for materials in bioelectronics

To avoid pulling focus too far towards a particular application, material group, value chain activity, or geographical cluster, create a network body that represents all activities in all areas of the UK in this sector. Enable the cross-fertilisation of ideas between biology, chemistry, materials science, engineering, computer science, and medicine, and connections across the value chain. Work with others (e.g. the University of Cambridge, the University of York, EPSRC and the Knowledge Transfer Network) who are already attempting this, to counter consultation fatigue. Build a "critical mass" that tips the sector into significant growth and a recognised economic impact.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 1 2 3 8

Create a lobbying function

Create an organisation or body that represents the needs of the sector in policy making. As the sector grows in recognition and matures along the Gartner hype cycle, it will hit a "trough of disillusionment", and proactivity is needed to navigate this. Wider representation and lobbying is also needed to raise awareness of bioelectronics in adjacent sectors.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 1 2 3 8

Prepare regulators to approve new materials for chronic, long-term implantation

Regulators will need to prepare for the approval of materials for ever increasing lengths of use in implantables with the growth of bioelectronics and the ageing population. Coordinate an effort in the UK to define the approvals process and clinical trials for this new challenge, and create the capabilities to lead the global market.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7

Create a mini-network of bioelectronic material supply companies

Engage with material suppliers to understand their barriers to supplying smaller batches of materials and not blocking their use in-human. Network with them to build their understanding of bioelectronics, the potential scale of the sector, and the needs of researchers and innovators. In particular, offer consultation for this network to better understand the structure of liabilities for their materials being used in implantables.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 1 3

Create a consultation service for accessing materials

Provide direct support for researchers and innovators who are experiencing barriers to accessing the materials they need, including liability agreements or supply chain problems.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 8

Use the Innovative Devices Access Pathway (IDAP) programme to build capacity and awareness

The IDAP is currently in its pilot phase. Use learnings from this programme to build capacity in deploying later-TRL devices in clinical settings.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 5 6

Identify surgeons to engage in bioelectronic research

Surgeons are a key end user of implantable bioelectronic solutions. Identify potential research advisors and create opportunities for advice and research engagement.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 2 5

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Capitalise on the Health Innovation Network to roll out devices

The health innovation networks are available to support the consistent uptake of innovative solutions across the NHS. Use their support services for innovators to build a business case and roll out solutions.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 3 5

Prepare the NHS AI Lab for data from bioelectronics

Bioelectronics will produce a significant quantity of diagnostic and monitoring data. AI and data processing is a potentially lucrative component of the bioelectronics market. The NHS is ideally placed to benefit from this, and has already established the NHS AI Lab. Explore programmes that create an environment for capitalising on this data.

Timescale: Less than 1 year **Effort/complexity: Medium** **Stakeholder groups:** 5

Create innovation centres for spin-outs or start ups to access university facilities, in exchange for equity

This model is used in Germany by IMEC and Merck, and sees start ups accessing facilities for fabrication and testing their early stage innovation at a centre in exchange for an equity stake. This will create a co-located cluster of expertise and de-risk investments.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 2

Support the creation of a sandbox for testing new devices in a controlled environment

The University of Cambridge are exploring the creation of a sandbox model for testing bioelectronic devices in a controlled group of patients outside of the standard clinical trial pathway. This will accelerate innovations, and should be supported by the regulation and funding ecosystem.

Timescale: Less than 1 year **Effort/complexity: High** **Stakeholder groups:** 1 6 7

Scout research that is of interest to industry and showcase it

Build awareness of the UK's research capabilities in industry by organising a method for showcasing research to industry outside of traditional academic peer reviewed conferences.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 1 2

Create a commercialisation "how to" guide for materials in medical devices for researchers

A brief, informative resource on the considerations and evidence needed to successfully commercialise a materials innovation in the medical device sector – including bioelectronics – will encourage enterprise skills in researchers.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 1 5 6

Collate existing relevant funds from different sectors

Engage across research councils, business funders and investors to identify potentially relevant funding aimed at adjacent sectors, such as Innovate UK's Biomedical Catalyst fund, and present them to the bioelectronics community.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 1 4 7

Identify and launch new Innovate UK Business Connect Innovation Networks that focus on key bioelectronic challenges

Five neurotechnology networks were funded in 2021/22 jointly by EPSRC and MRC. They act like mini-research councils: organising networks and distributing funding. Other bioelectronic materials challenges would be well suited to this model.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 7

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Write a how-to roadmap and myth busting guide on grant funding and regulation

Collaborate on a resource or website that tackles common misconceptions on the alignment of funding bodies and regulators. Include details of the end-to-end support available and who to contact at each body if innovators need advice.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 6 7**

Undertake PPI (Patient and Public Involvement) as soon as possible in application development

Resources from NIHR are available to guide PPI. Explore factors linked with use and acceptability (not just efficacy) as early as possible in the development process.

Timescale: Less than 1 year **Effort/complexity: Medium** **Stakeholder groups: 2 3**

Deploy and scale a new material in a less invasive or wearable application before translating it into an implantable device

Learn how to manufacture, regulate and scale a new material in a less invasive or consumer technology application – de-risking it before exploring its introduction in more invasive implants.

Timescale: Less than 1 year **Effort/complexity: High** **Stakeholder groups: 2 3**

Deploy a new application in the use case where the biggest improvement in short term quality of life can be demonstrated

For example, terminal patients can experience significant improvements in quality of life and outcomes, without having to demonstrate long term biocompatibility.

Timescale: Less than 1 year **Effort/complexity: Medium** **Stakeholder groups: 2 3**

Use device exemptions to accelerate new device development

Materials that are already used and approved in one device and biological environment can be accelerated through regulation using device exemptions. Engage with regulators on this pathway and shortcut approval processes.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups: 2 3**

Prioritise finding a clear clinical need, patient group and business case early in development

Establishing this strategic case for the solution will make it easier to attract investors.

Timescale: Less than 1 year **Effort/complexity: Medium** **Stakeholder groups: 2 3**

Address barriers to accessing ethical approvals for animal testing

The time and resources required for accessing ethical approval for animal testing studies (on top of personal and facility licences for testing) is prohibitive, and reported to be becoming increasingly difficult. Highlight this with responsible stakeholders in the Home Office and promote their collaboration with the sector.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 1 2 3 6 8**

Create a wish list of clinical solutions and share with researchers in all domains

Create a forum for industry and clinicians to share their specific technology needs and promote this with researchers and innovators. Specifically aim at researchers who may not be aware of the potential impact of bioelectronics, including biologists and chemists.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups: 1 3**

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Fund QMS overheads for fabrication and testing facilities

The management of facility, line and product quality management systems (QMS) is a large overhead for facilities, including designing, training and auditing these systems at all levels. It can mean that facilities let accreditations lapse or pursue other markets.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups: 7**

Introduce a programme for UK-US collaboration

UK research strengths are recognised in the US, but collaboration between the countries is low. Introduce a programme for research collaborations that bring US MedTech industrial knowledge and UK research capabilities together.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 2 6 7**

Develop alternative pathways to animal testing

In vitro models for testing biostability and cytotoxicity of implanted materials are in development in industry. Within the bioelectronics network, build awareness of the potential use and benefits of these tools as an alternative to animal testing default pathways.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups: 1 2 3 8**

COULD DO RECOMMENDATIONS

The “could do” recommendations typically relate to either generic challenges experienced across advanced materials and health technology – that is, those that are not the sole responsibility of a materials for bioelectronics initiative to address – or to challenges in the accessibility or dissemination of existing support structures and processes.

Ensure that research grant assessors represent a mix of disciplines

Grant assessors may be swayed by their pre-conceived expectations of a biology or engineering research proposal. Counter this potential bias in the interdisciplinary area of bioelectronics by creating mixed panels.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 7**

Convert medicines funders into bioelectronic device funders

The lead times and returns on medical devices are less appealing to investors than pharmaceuticals, but the two markets are merging as device technology matures. Identify where these investors can see commonalities and promote opportunities to them.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups: 4 6**

Use the material data hub as a research resource for materials discovery and research

The new data hub can act as a source of data for Materials 4.0 research and identification of gaps in materials data to be pursued.

Timescale: 3 years plus **Effort/complexity: Low** **Stakeholder groups: 1 2 8**

Market UK clinical trial capabilities to international researchers and innovators

The UK’s clinical trial capabilities are an asset. DBT and the FCDO needs to actively market this internationally.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups: 5 6**

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Create a purchasing consortium or body that procures polymers and purifies them

Access to standardised, purified feedstocks of polymers, including conjugated polymers and PEDOT:PSS, is a barrier to efficient research. There is currently no UK supplier for these materials. Creating a body to procure, purify and supply these materials will improve research productivity and build supply chain resilience.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 1 3

Introduce a standard, verified commercial agreement for SME use of university research services

Boilerplate agreements like the Lambert agreements are familiar tools for frictionless engagement between small businesses and universities. Create a similar agreement that is mutually acceptable in terms of the ownership of arising IP and data, and avoid university legal overheads.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 2

Create an encouraging, collaborative regulatory environment

The FDA approach of proactive collaboration with innovators is admired and should be a model for UK regulators. Introducing account managers or single-points of contact to maintain a dialogue with innovators could, for example, encourage progress.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 6

Introduce an award for early-career researchers to raise awareness of materials in bioelectronics

This award will help to identify active early-career researchers, promote the role and image of materials science in bioelectronics among all relevant disciplines, and raise the profile of UK research work internationally. The award can be interfaced with a training, fellowship, or sponsorship opportunity.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 1 2 3

Offer inter-disciplinary training opportunities for skills stacking

Create an upskilling opportunity for researchers and innovators in one discipline to learn about the practices of others.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 2 3 8

Coordinate actions on PFAS management or replacement for bioelectronics applications

As PFAS restrictions are introduced globally, supply chain challenges and in-use restrictions will tamper the bioelectronics market. Coordinate research into alternatives and engage with regulators to manage restrictions or exemptions in healthcare applications.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 1 6 7 8

Undertake social research and cultural engagement on bioelectronics

Bioelectronics potentially poses a specific ethical or cultural barrier that will impact on overall uptake and market growth. Social research and community engagement should be used to explore the nature of these barriers, and how best to engage with community groups on them.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 2 6

Align UK legislation with EU medical device regulations

UK regulations should be aligned with EU regulations (2016/745/EU) where possible, to aid the market potential of UK innovations.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 6

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Establish materials development consultants that champion innovations through the regulatory process

Create a role with specific expertise in material innovation in bioelectronic health technology, that provides consultancy and guidance to innovators on their regulatory journey.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 1 6

Promote the Health Innovation Network and NHS Innovation Service internationally

International bioelectronics innovators should be attracted to the UK as a large healthtech market with one procurement entity. Promote the Health Innovation Network and NHS Innovation Service as routes to market and build case studies in bioelectronics.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 5 6

Promote new UK regulations on implantables traceability

New device regulations in the UK are introducing unique identifiers for devices that are retained in clinical records. This enables the tracking of devices and the capability to identify and react to material safety concerns quicker. This is a regulatory environment that will encourage new implanted devices thanks to increased confidence in reaction to safety concerns. Once introduced, promote this internationally.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 6

Replicate incentive models for universities and researchers to invest in spin-outs

Explore international models for encouraging spin-out creation, such as funded sabbaticals and ownership models that generate revenue for universities. Introduce models from this evidence base.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 2 6

Promote the support available to first-time grant applicants

Grant applications can be a complex process, and various bodies offer support to first-time applications. Raise awareness of this within the bioelectronics materials network – particularly in early-stage researchers.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 7

Simplify grant application processes, learning from successful models overseas

Enable more efficient access to grants and ease international collaboration issues by modelling grant applications off successful processes from countries with healthy materials in bioelectronics sectors, like Germany and the US.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 7

Align grant funding requirements with international partner bodies

Facilitate international collaboration – necessary in this nascent sector – by lining grant application process and timescale up with theirs. Prioritise other international bioelectronic clusters first, including Germany, Italy and the US.

Timescale: 1–3 years **Effort/complexity: Medium** **Stakeholder groups:** 7

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Launch a study into IP off-shoring

It is a common observation that businesses develop and launch in the UK, but move to larger, more lucrative markets – particularly the US – to scale and commercialise. The value of IP generated in the UK does not get captured here and returns on public investments are lost. There are a number of factors encouraging this and it is a pattern observed in other markets. Explore this challenge in a concerted effort and introduce actions to encourage on-shore scaling and IP protection in the UK.

Timescale: 1–3 years **Effort/complexity: High** **Stakeholder groups:** 6

Contact research councils for guidance on meeting grant application requirements

The UKRI research councils have appointed programme managers who are available to support potential applications. Their contact details are available online and innovators should be in touch with them.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 2 3

Promote case studies and success stories

Demonstrate that the UK has a well-trodden path of materials innovation in this sector by identifying and promoting any success stories, focussing on their funding and regulation pathway.

Timescale: 1–3 years **Effort/complexity: Low** **Stakeholder groups:** 1 6 7

Develop a "reference human" data model

Use UK modelling and healthcare research strengths to develop a data model for researching the human body and its reactions.

Timescale: 3 years plus **Effort/complexity: High** **Stakeholder groups:** 2 6 8

Ring-fence funding for clinical trials

Clinical trial success can be a pre-requisite for VC and other private funders. UKRI and other public funders can de-risk investments by specifically targeting this stage in development.

Timescale: Less than 1 year **Effort/complexity: Low** **Stakeholder groups:** 7

STAKEHOLDER GROUPS:

1 Royce
2 Universities and researchers
3 Industry
4 Investment community
5 Clinicians and healthcare bodies
6 UK Government policy and regulation bodies
7 UK Government funding bodies
8 UK RTOs including Catapults

Four UK case studies are included to illustrate the full range of materials solutions for bioelectronics in healthcare – ranging from early-stage research to commercial deployment.

CASE STUDY 4: COMMERCIALLY PROVEN MATERIAL

STAINLESS-STEEL ELECTRODE PHARYNGEAL STIMULATION TO TREAT DYSPHAGIA

PHAGENESIS

Phagenesis is a small, Manchester-based bioelectronics company which uses direct electrical stimulation to treat dysphagia. Dysphagia causes difficulty with swallowing, often occurring as a result of a health condition such as a stroke, cancer, or learning disability. It can significantly impact quality of life and existing treatments can be very invasive – including feeding through a tube or surgical intervention to widen the throat.

The Phagenyx device consists of two biocompatible stainless-steel stimulation electrodes, a feeding tube, and a smart chip that measures and retains all patient treatment information. Direct electrical stimulation of the pharynx in the throat using this method has been shown to restore the patient's swallowing control.

The company was founded by an NHS neuro-gastroenterologist, and has accumulated over 10 years of clinical use of its non-surgical therapeutic devices in the UK. During this time they have conducted 7 randomised control trials to demonstrate the safety and efficacy of the technology.

Direct electrical stimulation of the pharynx in the throat using this method has been shown to restore the patient's swallowing control.

Image source: Phagenesis

NEXT STEPS

This roadmap and action plan lays the foundations for direct action to grow the UK's materials capabilities for bioelectronics in healthcare.

The notion of achieving a "critical mass" was referenced regularly during the development of this strategy by both internal and external stakeholders. Individuals from all perspectives believe that the UK could reach a tipping point in activity that would see commercialised solutions self-perpetuate.

Once achieved, the UK's research and translation actions would generate material and device solutions for the global market. Capturing this value in the UK and retaining talent here will be vital to translating this success into economic prosperity.

All the recommendations made in this report should be heeded to inform actions from the identified stakeholder groups. However, four key areas stood out as requiring immediate action and focus: facilities, materials supply, standards, and clinical focus.

These "must do" actions should be delivered by a virtual centre for materials innovation in bioelectronics.

This centre would network and connect the full value chain of UK materials characterisation, fabrication and testing capabilities for bioelectronics. It would champion the sector, representing its interests to government and regulators, and fostering clinical and research connections.

As a national hub for innovation, it would work closely to improve standards, attract investors, and tackle the root causes of materials supply issues. The must do actions from this strategy will directly inform its operations.

The Grand Challenges should be progressed in a Materials for Bioelectronics Challenge Programme.

This would support coherent research, development and innovation along these material requirements and others identified in the materials for bioelectronics roadmap. The new national centre for bioelectronics could play a pivotal role in coordinating this challenge programme.

Many of the other challenges and complaints of stakeholders in the bioelectronics sector are common across innovation – particularly materials innovation – in the UK.

More general actions to create an environment for translating and scaling our excellent research solutions into impactful commercial options should be encouraged in policy, research, and funding. Royce is in the process of developing a national strategy for materials innovation, which will complement this strategy.

The methods used in this report for identifying the GVA and jobs generated by bioelectronics should be adopted to monitor the impact of actions to grow the sector.

The pacemaker, cochlear implants and a continuous glucose monitor are transformational solutions to managing common health conditions that are widely accepted and almost taken for granted in our healthcare system. Another bioelectronic solution like these could be invented imminently, drastically improving life chances and the quality of life of a large population of patients.

The materials components of these solutions will be key to their development, and the UK is in prime position to deliver these.

HENRY ROYCE INSTITUTE

The Henry Royce Institute was established to ensure the UK can exploit its world-leading expertise in advanced materials and accelerate innovation from discovery to application. With over £200 million of facilities in dedicated state-of-the art laboratories, Royce is ensuring that academics and industry in the UK's materials community have access to world-class research capabilities, infrastructure, expertise, and skills development.

ROYCE.AC.UK

ScotChem

ScotChem is the strategic alliance for the chemical sciences in Scotland. We connect industry, academic expertise, government, the third sector, and the public. We promote and support chemistry-related industries and broker strategic partnerships to address critical challenges. Our aim is to enhance research impact and translation, drive innovation and increase economic prosperity.

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cpi

CPI connects the dots within the innovation ecosystem to make great ideas and inventions a reality. We're a pioneering social enterprise that accelerates the development, scale-up and commercialisation of deep tech and sustainable manufacturing solutions. As a trusted partner of industry, academia, government, and the investment community, we're the catalyst that delivers sustainability and healthcare innovations to benefit people, places, and our planet.

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Urban Foresight

Urban Foresight is a multidisciplinary innovation practice dedicated to accelerating the next generation of technologies, services and policy frameworks for places. We work with ambitious organisations around the world on projects that improve lives, protect the environment and boost local economies.

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