HENRY ROYCE INSTITUTE

MATERIALS FOR BIOELECTRONICS IN HEALTHCARE

Strategy & Action Plan

MID-TERM REPORT

ROYCE

MATERIALS FOR BIOELECTRONICS IN HEALTHCARE STRATEGY AND ACTION PLAN

MID-TERM REPORT

Summary

The Henry Royce Institute are undertaking an ambitious strategy development activity relating to materials for bioelectronics in healthcare. They have appointed a partnership between Urban Foresight, ScotChem and CPI to define and explore actions that will meet the growing demand for advanced materials for bioelectronics.

This is an emerging high technology sector with significant potential to create research and industry activity in the UK, where universities and businesses large and small are already active in the sector. Notable capabilities in research, regulations and standards, and IPR management place the UK in a good position to lead in the development of materials for bioelectronics.

However, the emergent nature of the sector poses a challenge to effectively capturing all current activity and future potential.

The strategy's development so far has involved an in-depth scoping exercise, mapping of current academic and industrial activity, and progress towards a stakeholder intelligence map.

A draft scope has been developed to guide the landscape mapping and upcoming stakeholder engagement activities. It places boundaries on the definition of bioelectronics materials in healthcare – which can be interpreted as a broad spectrum of any electronic device interfacing with humans, from consumer wearable technologies to long-term implantable prosthetics.

The landscape mapping has identified activity relevant to this scope in a literature review and patent search, and a company and funding search is currently underway.

This mid-term report provides an overview of the strategy development's initial findings. It demonstrates the scale of the sector under study and provides a summary of the methodologies used so far to define it.

Scope of the study

A proposed scope statement for the study has been produced, and is given below. It is based on:

- Initial research into how other groups have defined “Bioelectronics”
- The descriptions used in relevant scientific conferences and meetings
- Research interests of academic and industry stakeholders identified by Royce
- The interests of UK companies developing products related to Bioelectronics
- Advice from the Royce project steering group

“Bioelectronics is the electronic monitoring and control of biological systems for applications in medicine, agriculture, industry, and the environment. It brings together biology, engineering, and materials science.

This project will focus on materials for Bioelectronics in healthcare. These are 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, monitoring, diagnosis, and treatment of disease, for patient rehabilitation, and for improving health in general.”

Included within this project scope, for example, are materials with healthcare applications that involve making electrical connections at the cell-material interface or electronic interfaces targeting sensing or modulation of biological processes.

Example of topics which will be considered out of scope for this strategy are:

- 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

However, as the strategy development activities turn towards exploring future opportunities and trends for the sector, these areas may be considered because their development will influence the regulation and markets for the areas currently in scope.

The nature of this strategy development approach means that the scope statement will change as stakeholders are engaged and the future of the sector is explored. Key contacts from Royce have already been approached to comment on this scope and their valuable feedback will be reflected in development activities.

Landscape mapping findings

A mapping activity of current sector activity is underway. This is key to understanding areas of growth and interest in the sector to ensure that in the immediate- to mid-term, the UK's materials ecosystem is effectively fostering the sector.

Once complete, stakeholder engagement will build on this foundational understanding to highlight how this landscape will evolve into the future and what strategic actions are needed to support it.

The mapping activities have included:

- Literature review
- Patent search
- Company search
- Funding search

Literature review

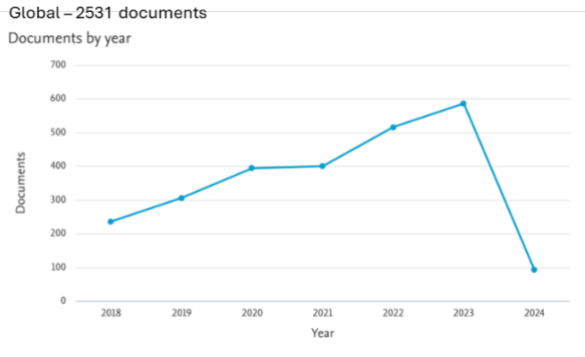
Databases of research papers were searched for relevant activity. The terms used in this search were "bioelectronic" and "bioelectronics".

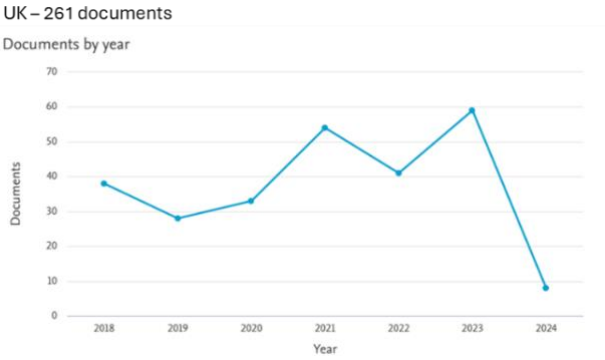
Searches using relevant terms beyond these two specific words produced many more results, however, the majority of them were judged to be "false positives". That is, research papers on adjacent sectors, including agriculture and computer science, that deviated from the specific materials challenges and opportunities that this strategy is aimed at.

This table summarises the search methods and sources used.

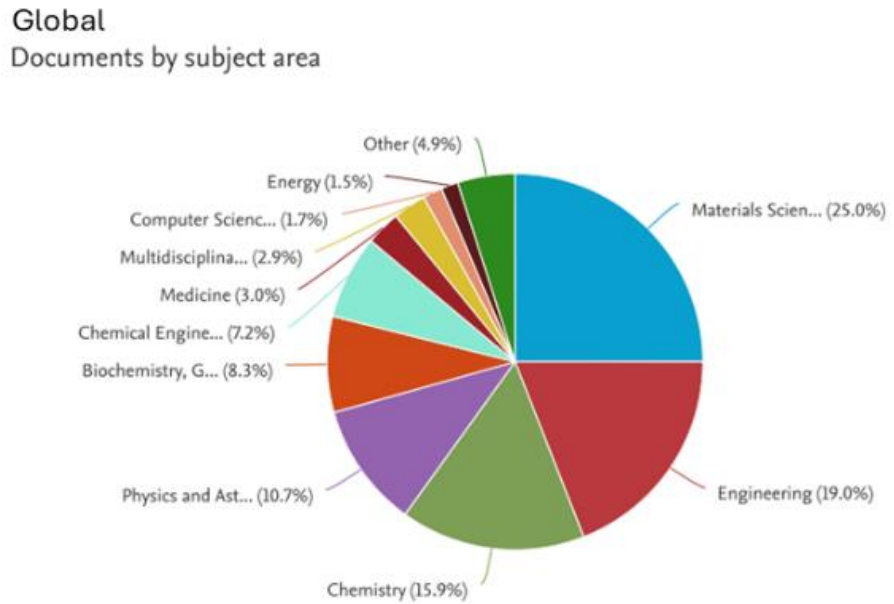
Search terms	• Bioelectronic • Bioelectronics
Search parameters	• Title • Abstract • Keyword • Topic
Search limits	• Articles • Journals
Databases	• Web of Science • Scopus • Scifinder

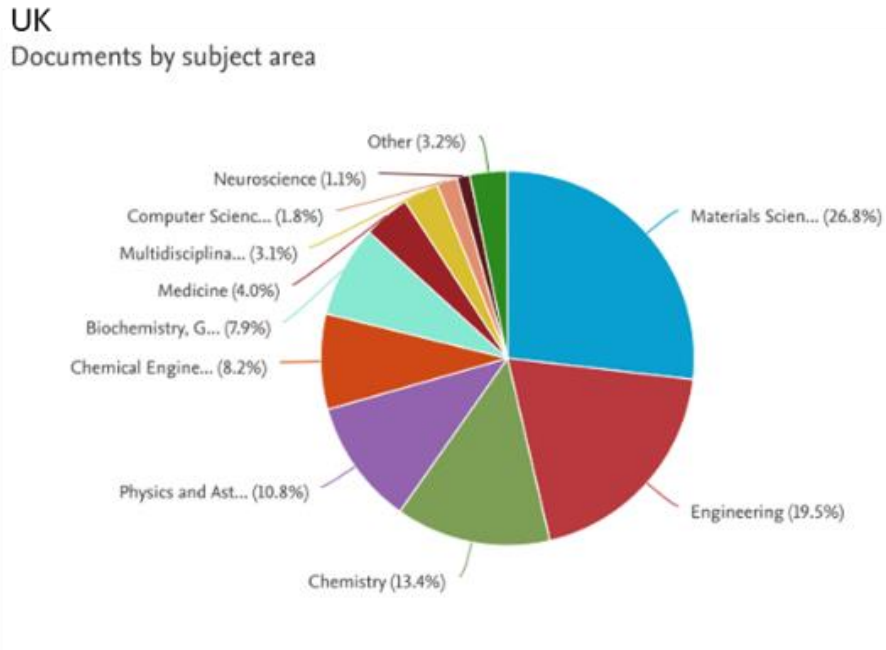
This search identified 2,531 publications globally, and 261 from the UK. The highest affiliations for the UK papers were from the University of Cambridge, Imperial College London, University of Oxford, University of London, and University College London.





The publication rate demonstrates a steady increase globally – depressed slightly by the Covid-19 pandemic.





By subject area, the UK reflects the global distribution – with around 1 in 4 papers published on materials science.

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

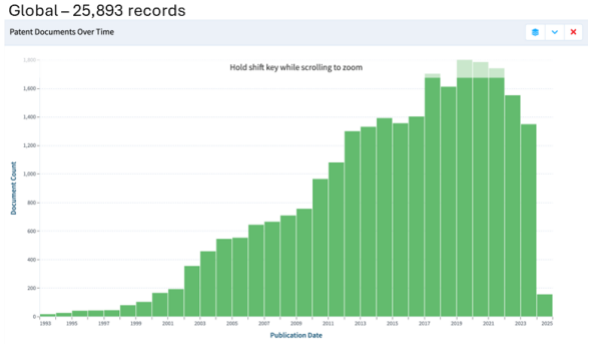
Patent search

The patent search also used the terms “bioelectronic” and “bioelectronics”. Again, when the search terms were broadened, using other terms opened up the search to too significant a proportion of false positives.

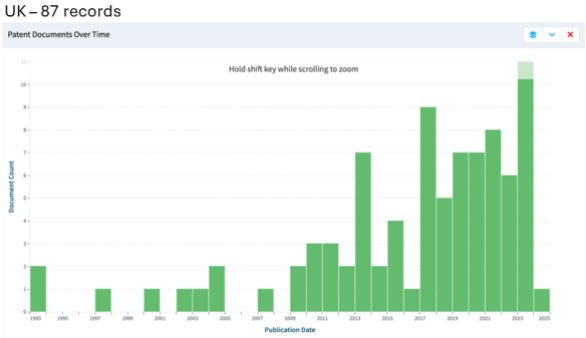
Country names were matched according to the International Organization for Standardization (ISO) codes from the priority numbers to find the locations where the patents are likely being developed.

The search used the lens.org patent database and identified over 25,800 global patents, being created at an increasing rate, reflecting the trend seen in the publication rate.

Global – 25,893 records



UK – 87 records



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

This indicates a trend of UK researchers not raising their patents in the UK, but elsewhere, and that UK researchers are not translating their research into IP. The potential root causes of this trend will be explored in the stakeholder engagement activity.

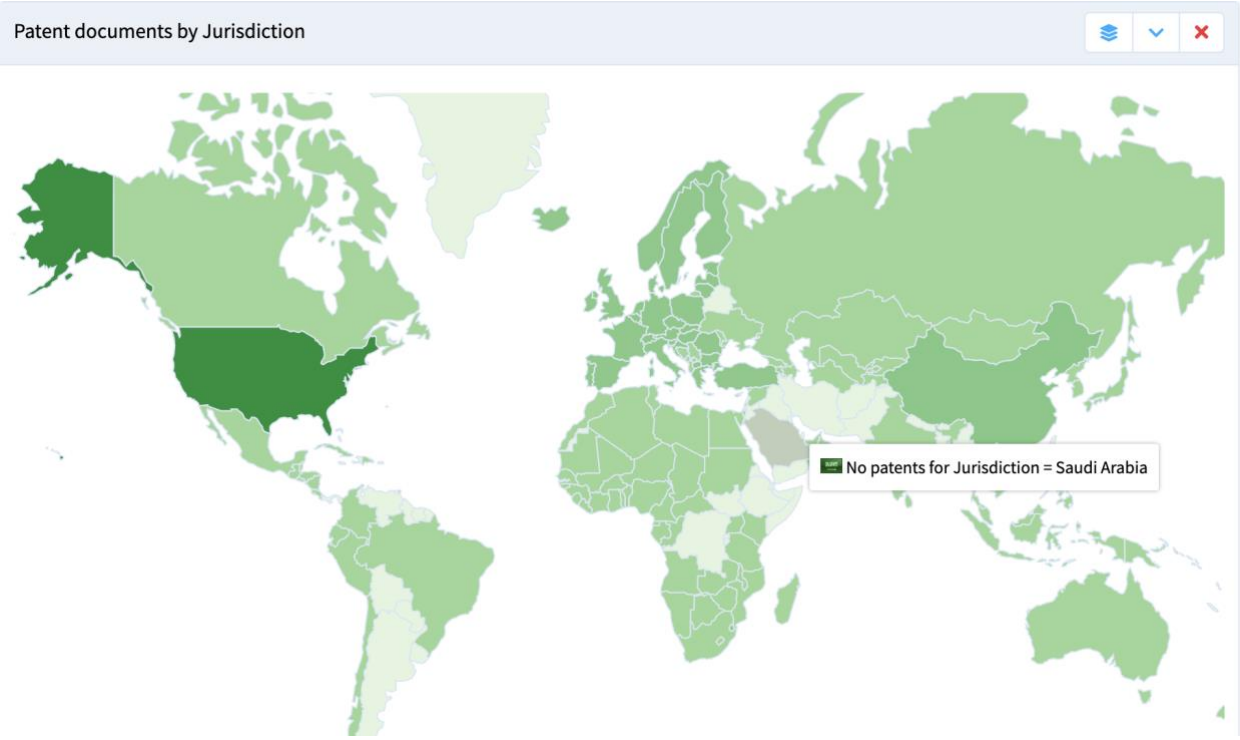
Patent activity is concentrated in the USA – with 65% of patents raised from there – with activity rising in China, the origin of 11% of global patents.

The number of patents in the USA being remarkably higher than the rest of the world is thought to be due to their 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.

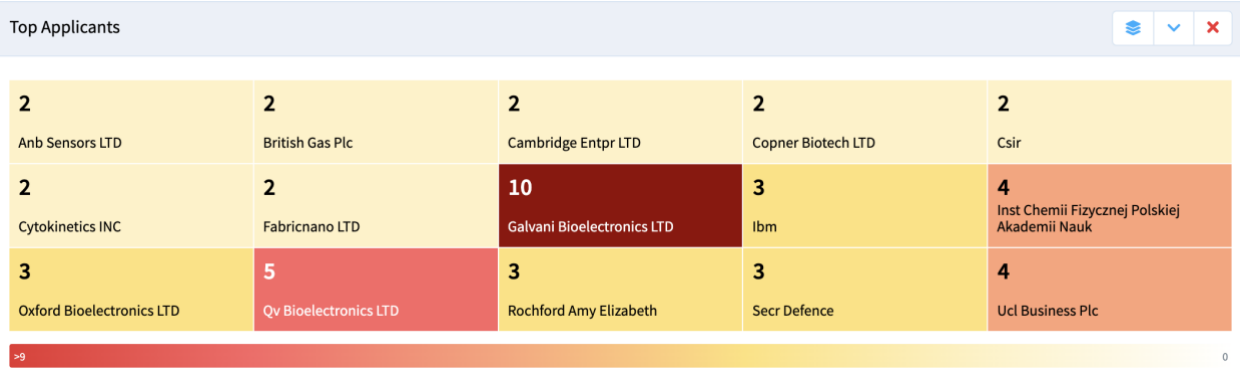
In the USA, a higher proportion of patents also do not progress further or become inactive. Patents in the USA are specific, which means that there is a large number of derivative patents filed to protect IPR. In addition, the 1980 Bayh-Doles Act encouraged extensive patenting of academic inventions, even if ultimately they were not commercialised. This is because federally-funded academic inventors could retain titles and therefore university spin-outs 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 their 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 Bioelectonics and Galvani Bioelectronics – two companies that are already engaged in this strategy development.

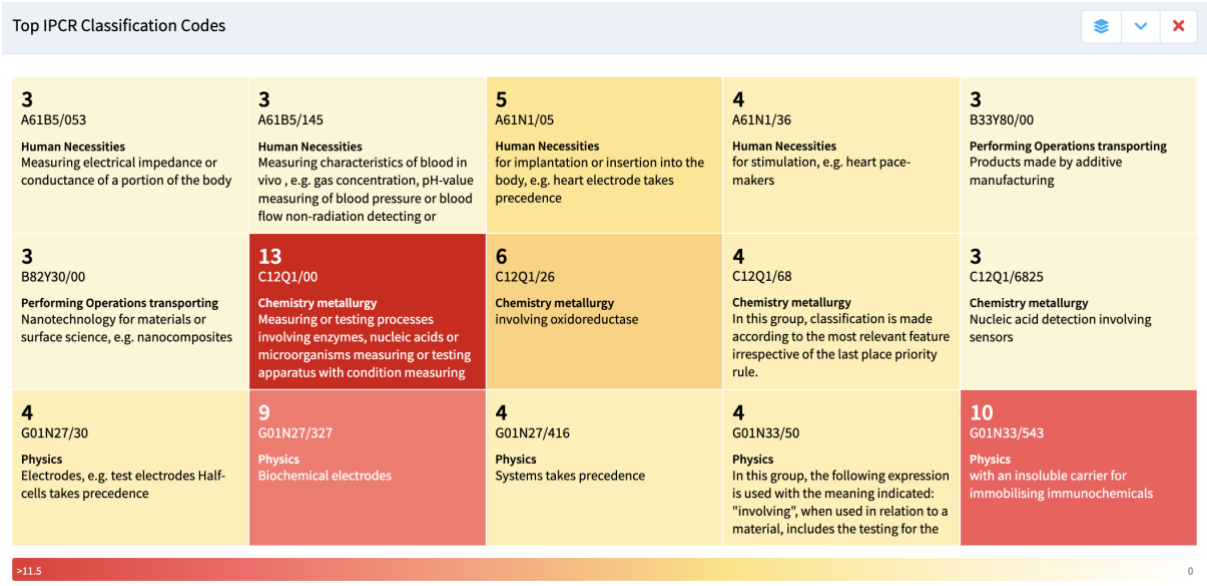


These businesses are relatively small. In general, the patent search has highlighted a lower than expected level of activity from large, multi-national organisations in this sector.

This finding will be explored in more detail through stakeholder engagement, but 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.

Company search

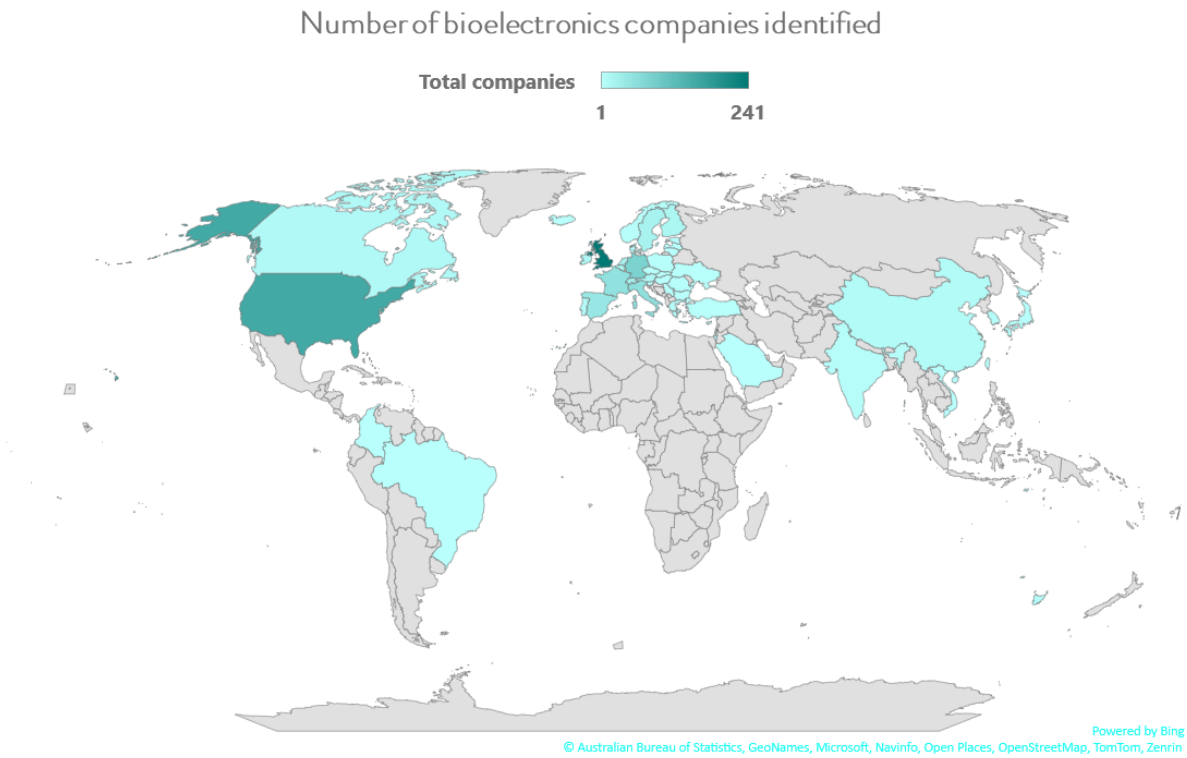
The patent search uncovered the Cooperative Patent Classification (CPC), International Patent Classification (IPCR) and Standard Industrial Classification (SIC) codes used by businesses active in the area. These were used in the company search.



SIC codes:

- 26400: Manufacture of consumer electronics
- 26600: Manufacture of irradiation, electromedical and electrotherapeutic equipment
- 33190: Repair of other equipment
- 62020: Information technology consultancy activities
- 72110: Research and experimental development on biotechnology
- 72190: Other research and experimental development on natural sciences and engineering
- 74909: Other professional, scientific and technical activities not elsewhere classified
- 86900: Other human health activities

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.



Overall, over 1,030 companies have been identified worldwide as having an interest in the materials for bioelectronics in healthcare sector. 241 of these companies are based in the UK.

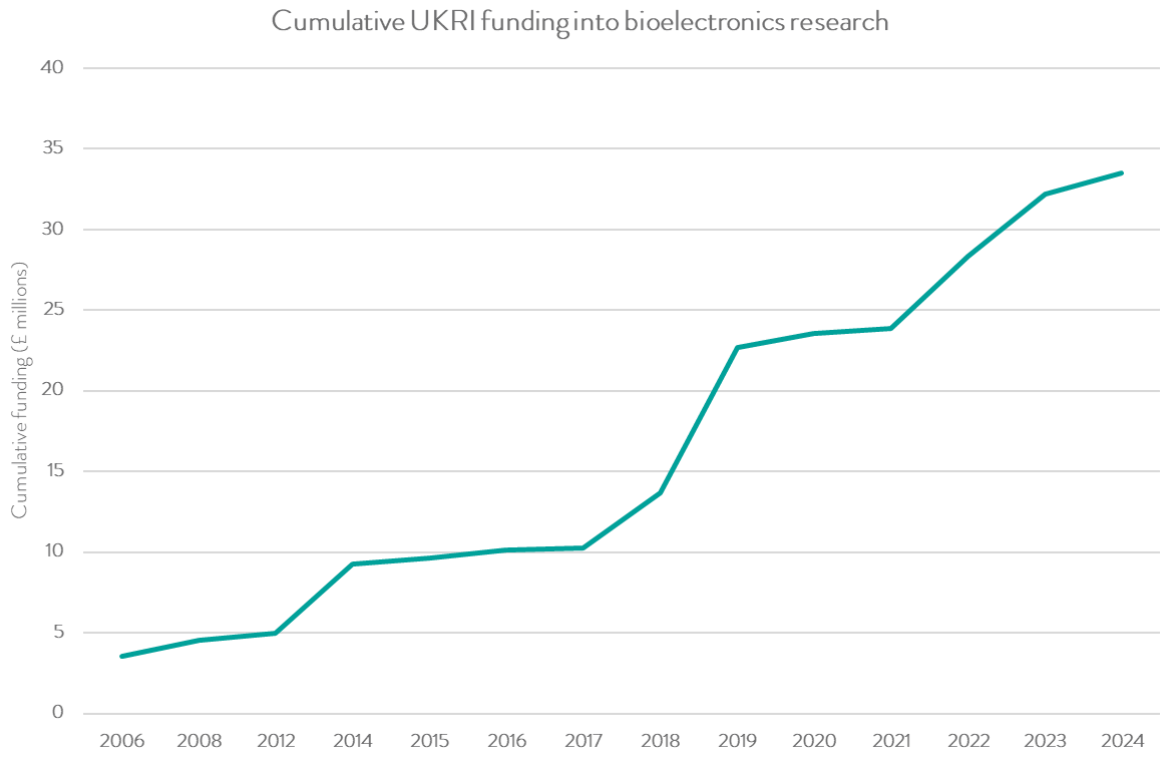
Funding search

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 funding
- National Science Foundation funding for US academic funding

Early insight into venture funding reflects the observation from the patent search of a pattern of larger businesses funding start-ups or small businesses to develop a particular application, rather than investing internally in the materials solutions for bioelectronics.

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.



The largest rise in funding was in 2022 with over a £5 million increase in funding into bioelectronics research. This is potentially due to funding periods overlapping in that year, but may well reflect an increased interest in, research activity in and investment for bioelectronics.

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 also increase 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 is 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.

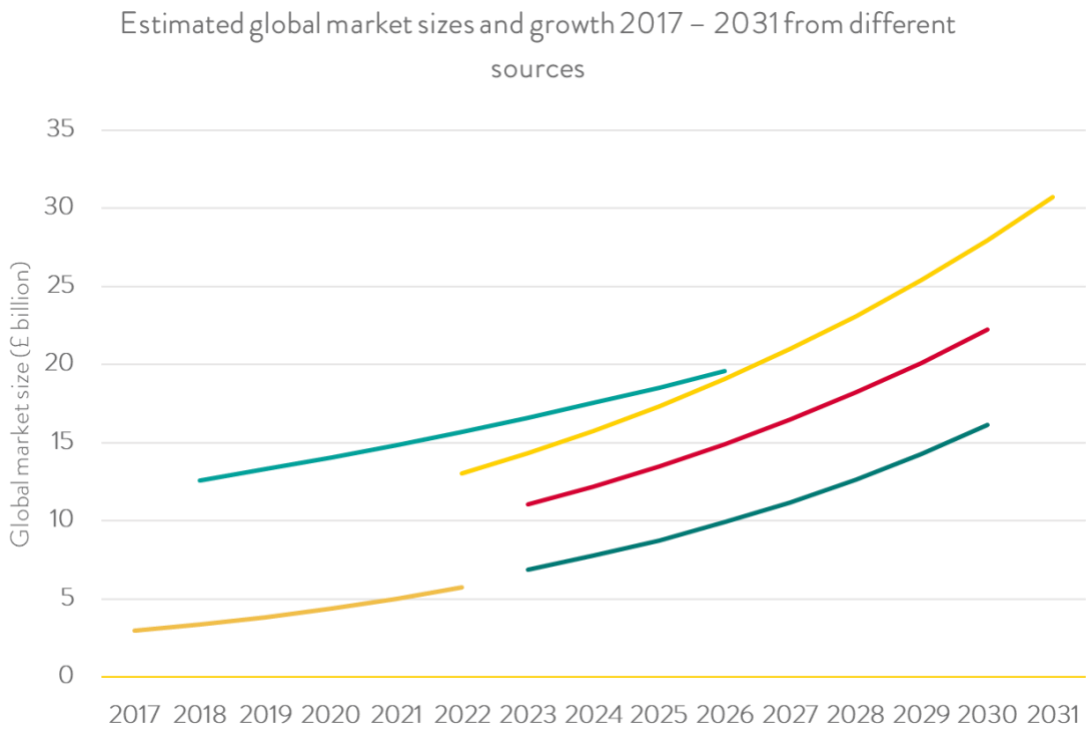
Global market size

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).

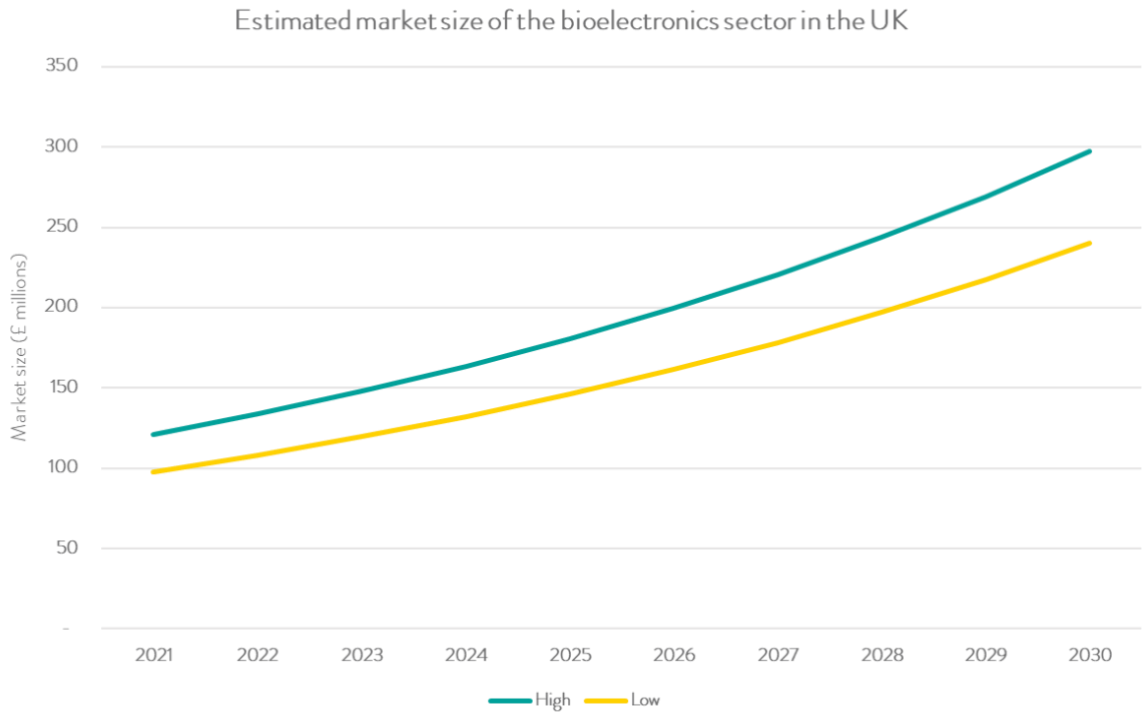
This model found that the estimated global market size for bioelectronics was between £6.0 billion and £15.7 billion in 2022. The global market size for bioelectronics could reach between £16.2 billion and £28.0 billion by 2030.



This growth range represents a range of compound annual growth rates (CAGRs) of 6% to 14%. This is 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. The projected market size for the bioelectronics sector in the UK by 2030 could be between £240 million and £298 million.



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

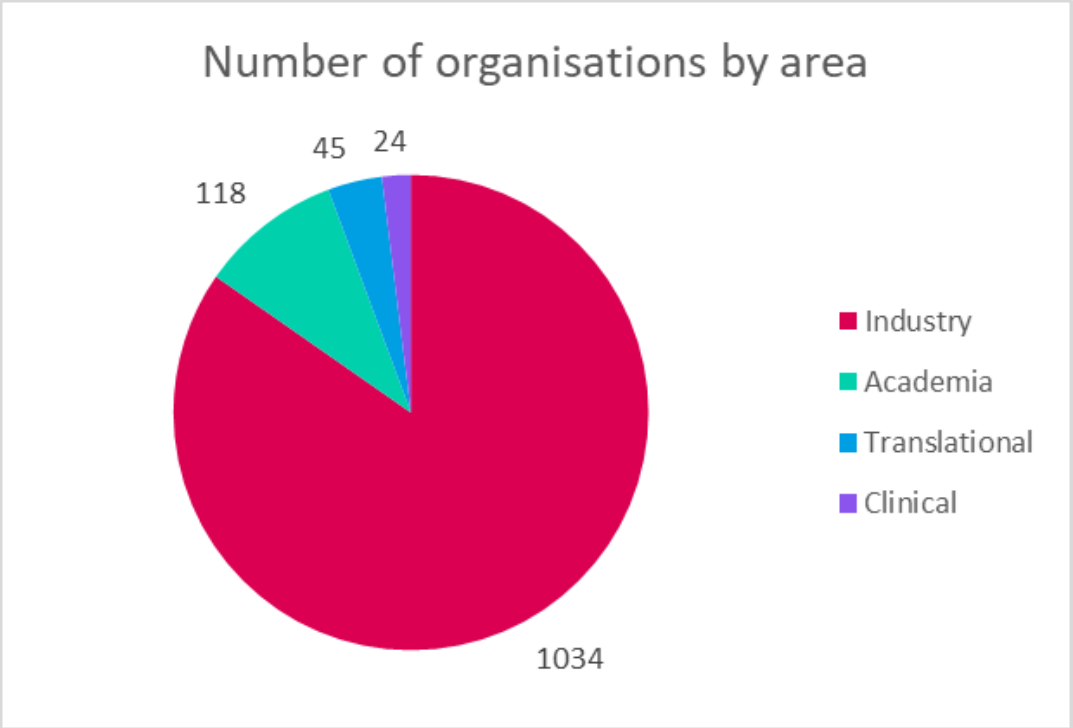
It was assumed that the large companies (those with over 250 employees) do not focus entirely on bioelectronics: the percentage of turnover attributed to bioelectronics is therefore limited to 10%, which is the average percentage of patent activity that large companies focus on bioelectronics out of 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 before) versus 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, it is assumed that the UK market will growth at the average compounded annual growth rate (CAGR) estimated across the global market reports of 10.5%.

Stakeholder mapping

A list of over 1,221 potential stakeholder organisations has been consolidated through this landscape mapping activity.



Nearly 200 email addresses for individuals at these organisations have been sourced.

In the next phase of the strategy's development, these stakeholders will be prioritised and engaged to gather their insight on:

- Current opportunities and challenges in advanced materials development and use in the sector.
- Future areas of growth, and related materials needs.

The engagement programme will be designed to contact stakeholders at scale. It is anticipated that online surveys will be used to gather structured insight data on these topics from a wide range of stakeholders. High priority stakeholders that are key to the UK's sector's development will be invited for one-to-one online interviews.

Project plan and next steps

This programme will deliver a strategy report with actionable pathways to building a materials innovation ecosystem that meets the demands of the growing bioelectronics sector in the UK and globally.

The below project plan summarises the project timeline.

The strategy and action plan will be completed in June, and will be heavily informed by stakeholder engagement. It will be presented and confirmed with attendees at the 2024 Cambridge Bioelectronics Symposium on 1st – 3rd July.

	Project month					
Project activity	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**
Activity 1: Current state research						
Definition of the sector						
Mapping of the landscape						
Activity 2: Future opportunities						
Stakeholder mapping and engagement design						
Engagement activities						
Activity 3: Strategy delivery						
Strategy writing						
Delivery						