IHI Call Days | Call 9

Next generation materials for implanted bioelectronic medical devices (NEXT-BIO)

Contact person name: Steven Bagshaw

Organisation : CPI

E-mail: steven.bagshaw@uk-cpi.com

Link to the IHI brokerage platform:

- https://tinyurl.com/4mwwefp3
- https://tinyurl.com/yy2y4ef9

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Challenges and objectives

- Development of new **implantable Bioelectronic devices** is being held back by lack of availability of new conducting materials and suitable supply chains to get them into medical devices beyond academic labs
- Improvements to the **longevity** of implanted devices is needed because they are being implanted into younger people and to keep them cost effective for use
- Implanted medical devices are subject to the **highest level** of regulation

- Addresses objective **SO2**

- Bioelectronics seeks to provide treatments for conditions where **no treatment options exist**, or which **are not well addressed by drug treatment**
  - Examples – chronic pain, migraine, rheumatoid arthritis, sleep apnea, essential tremor

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Your approach to solve the problem

- Technical work
  - Develop **new electrically conducting materials** with better biocompatibility and mechanical properties like tissue
  - Develop **sensors** for use in-vivo which **resist biofouling** (enabling closed loop operation)
  - Develop **new materials** which can **withstand implantation** in the body for many years
  - Develop new methods for materials computational modelling and predictive testing
- Supply chain building
  - Establish facilites to manufacture production quantities of key materials to **medical grade** and to build them into implantable devices for evaluation
- Regulatory work
  - Improving access to, and knowledge of, key materials' **long term biocompatibility data**

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Is your project suitable for IHI?

- Implantable bioelectric devices can deliver new or improved patient treatments but not if they are **expensive** to implant, require frequent **revisions** or significant extra patient **follow-ups** later down the line. So, the **care pathways** and **health economic** benefits of the whole system need to be accounted for
- Materials manufacturers lack commercial incentives to develop new materials for the implantables market as volumes are relatively small, regulation barriers are high, and return on investment times are long
- **Medical device companies** developing new bioelectronic devices **need materials** with better performance but are having to fall back to a small sub-set of materials that are already well qualified for long term use in the body
- **Materials manufacturers** need the right demand signaling to know what new materials are required

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Outcomes and Impact

- Results/outcomes and impact
  - A **new generation** of conducting materials optimised for bioelectronics and long-term implantation
  - A **medical grade supply chain** for new bioelectronic materials
  - **Improved facilities** for development of bioelectronic devices meeting quality standards
  - Improved access to, and knowledge of, **biocompatible materials** through data standards, networking and advisory services
  - **Better understanding** of how materials behave in the body over long periods of time

- How to ensure translation?
  - Promote the challenges and **needs of clinicians** to those researching bioelectronic solutions
  - **Build proper supply chain** for materials into these devices

- Strengthening competitiveness?
  - The European implantable devices market is the **second largest globally after the USA** and there is a **growing demand** due to the aging population and increasing chronic conditions

- How does your project proposal contribute to the expected benefits for patients?
  - Bioelectronic devices often provide **targeted treatments** with **fewer side effects** than medication. Many are also **adjustable and reversible**

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Expertise and resources

- We have:
  - Facilities and capability to scale up the manufacture of new conducting polymer materials to GMP standard
  - Developed non-enzymatic biosensors intended for implantation for closed loop control of implanted bioelectronic devices
  - Clean room facilities for prototyping of bioelectronic devices
  - Helped to produce a roadmap for the UK in the development of materials for Bioelectronics (for the Royce Institute, University of Manchester)

- We are looking for:
  - Medical device companies developing implantable bioelectronic devices
  - Materials manufacturers/developers lacking
  - Academic groups active in development of new materials for bioelectronics
  - Individuals or organizations involved in the regulation of implanted medical devices
  - Organizations involved in the testing and validation of implantable medical devices
  - CPI is not brining any in-kind contributions

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